UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

APPENDIX IN SUPPORT OF BRIEF FOR TIMELY PRODUCTION

NOW COMES, Plaintiff Public Health and Medical Professionals for Transparency and files this Appendix in Support of its Brief for Timely Production.

Dated: December 7, 2021

SIRI & GLIMSTAD LLP

Aaron Siri, NY Bar No. 4321790
Elizabeth A. Brehm, NY Bar No. 4660353
Gabrielle G. Palmer, CO Bar No. 48948
200 Park Avenue
New York, New York 10166
Tel: (212) 532-1091
Fax: (646) 417-5967
aaron@sirillp.com
ebrehm@sirillp.com
gpalmer@sirillp.com

HOWIE LAW, PC
John Howie
Texas Bar Number: 24027239
2608 Hibernia Street
Dallas, Texas 75204
Tel: (214) 622-6340
jhowie@howielaw.net

Attorneys for Plaintiff

Exhibit A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

DECLARATION OF PETER MCCULLOUGH, MD, MPH, PRESIDENT OF PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY (PHMPT)

I, Peter McCullough, declare as follows:

1. I make this statement based upon my own personal knowledge and am prepared to testify to the facts and matters set forth herein.

2. I am the President of Public Health and Medical Professionals for Transparency ("**PHMPT**"), a not-for-profit organization with an office located at 1090 Texan Trail, Suite 534, Grapevine, Texas, 76051.

3. PHMPT is made up of public health professionals, medical professionals, scientists and journalists. It currently has more than 75 members, including at least 23 professors at major universities, 28 medical doctors, and three are journalists. PHMPT maintains a website at www.phmpt.org and its current list of members can be found on this website.

4. Many of PHMPT's members, including all its members who are journalists, are primarily engaged in disseminating information to the public and do so across various platforms, including through interviews, articles, blogs, essays and podcasts.

5. PHMPT exists solely to obtain and disseminate the data relied upon by the FDA to license COVID-19 vaccines. PHMPT takes no position on the data other than it should be made publicly available to allow independent experts to conduct their own review and analyses.

6. In furtherance of its mission, and in an effort to ensure that the Food and Drug Administration is transparent, PHMPT seeks to obtain the data and information relied upon by the FDA to license Pfizer's COVID-19 vaccine.

7. PHMPT intends to make any records it obtains, including from its FOIA request, immediately available to the public through both its website and its individual members' platforms.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge this 5th day of December 2021, at Dallas, Texas.

Peter McCullough, MD, MPH.

Exhibit B

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv -01058-P

DECLARATION OF HARVEY RISCH, MD, PhD

I, Harvey A. Risch, M.D., Ph.D., declare as follows:

1. I make this statement based upon my own personal knowledge, education, and experience.

2. I am prepared to testify to the facts and matters set forth herein. A true and accurate copy of my *curriculum vitae* is attached hereto as **Exhibit A**.

Experience & Credentials

3. I am a full professor of epidemiology at Yale School of Public Health and Yale School of Medicine, and a practicing academic epidemiologist with more than 40 years of experience in epidemiologic methods, both in research and teaching. Over this career, I have taught introductory, intermediate and advanced epidemiologic research methods to Master of Public Health students, PhD students, postdoctoral fellows, hospital residents and junior faculty members.

4. My 40 years of scientific research has primarily concerned the etiology of cancer according to various types of exposures including infectious, genetic, hormonal, pharmacologic, occupational, behavioral, dietary and other factors. I have been a member of the Society for Epidemiologic Research since 1982, the American Society of Preventive Oncology since 1984, and elected Fellow of the American College of Epidemiology since 1991. I received the Bachelor of Science degree in mathematics and biology from the California Institute of Technology in 1972 and completed medical training at UC San Diego School of Medicine in 1976. I then completed a PhD in biomathematics in 1980 at the University of Chicago, where my dissertation work involved mathematical solutions for the general stochastic epidemic model, on which I have published in the peer-reviewed scientific literature. During 1980-1983, I held a postdoctoral fellowship in the Department of Epidemiology at the University of Washington School of Public Health. In 1983, I moved to the University of Toronto, where I was Assistant and then Associate Professor, before moving in 1991 to Yale School of Public Health, becoming Professor of Epidemiology in 2001.

5. I have published more than 350 peer-reviewed original research papers in very well-regarded scientific journals and have an h-index of 96, with more than 43,000 publication citations to my work to-date. I have served as grant reviewer or chair on some two dozen grant review panels including many at the National Institutes of Health (NIH), as well as peer reviewer for more than 50 scientific and medical journals. I have been Associate Editor of the Journal of the National Cancer Institute since 2000, Member of the Board of Editors of the American Journal of Epidemiology from 2014-2020, and Editor of the International Journal of Cancer since 2008.

6. In 2018, I received two prestigious awards for my research: the "Best of the AACR Journals" award for "Aspirin Use and Reduced Risk of Pancreatic Cancer," one of the most highly

cited Cancer Epidemiology, Biomarkers & Prevention articles published in 2016 (April 2018) (http://aacrjournals.org/h-a-risch-bio), and the international Ruth Leff Siegel Award for Excellence in Pancreatic Cancer Research, (http://columbiasurgery.org/pancreas/ruth-leff-siegel-award), $50,000 cash stipend prize.

7. I am an elected member of the Connecticut Academy of Science and Engineering, and based on my strong epidemiologic methods experience and PhD work in infectious epidemic models, was selected to be a member of the Academy committee that was organized in 2020 to formulate plans for the reopening of the state of Connecticut after its lockdown ended. Since early in the COVID-19 pandemic, I have been active in researching early treatment options for this disease. In May of 2020, I published a seminal article in the American Journal of Epidemiology, entitled *Early Outpatient Treatment of Symptomatic, High-Risk COVID-19 Patients That Should Be Ramped Up Immediately*[1] which was distinguished as garnering the highest attention to a paper ever published in this journal. Since then, I have gone on to write several other articles on the importance of early treatment for COVID-19 patients.[2] Additionally, I have participated in peer-

---

[1] Risch HA. "Early Outpatient Treatment of Symptomatic, High-Risk COVID-19 Patients That Should Be Ramped Up Immediately" https://academic.oup.com/aje/article/189/11/1218/5847586.

[2] **Risch HA**. THE AUTHOR REPLIES. Am J Epidemiol 2020;189(11):1444-1449. doi: 10.1093/aje/kwaa152. PMCID: PMC7454297 (letter); https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7454297/pdf/kwaa152.pdf; **Risch HA**. Risch Responds to "How to Consider Low Reported Death Rates in COVID-19". Am J Epidemiol 2020;189(11):1230-1231. doi: 10.1093/aje/kwaa156. PMCID: PMC7454272 (letter); https://academic.oup.com/aje/article/189/11/1230/5873642;

Risch HA. Response to: "Overcoming the therapeutic nihilism of out-of-hospital management of COVID-19 patients". Am J Epidemio. 2020 Dec 16:kwaa275. doi: 10.1093/aje/kwaa275. Online ahead of print. PMCID: PMC7799246 (letter) ; https://academic.oup.com/aje/article-abstract/190/7/1435/6038970?redirectedFrom=fulltext;

Risch HA. Connecticut Academy of Science and Engineering, Inc. (May 29, 2020). An Adaptive Risk-Based Strategy for Connecticut's Ongoing COVID-19 Response [White Paper]. Retrieved from https://cyberlab.engr.uconn.edu/wp-content/uploads/sites/2576/2020/06/CASE_AnAdaptiveRisk-BasedStrategyforConnecticutsOngoingCOVID-19 Response_FINAL_FINAL.pdf;

Alexander, P. E., Armstrong, R., Fareed, G., Lotus, J., Oskoui, R., Prodromos, C., **Risch, H. A.,** Tenenbaum, H. C., Wax, C. M., Dara, P., McCullough, P. A. and Gill, K. K. (2021) 'Early multidrug treatment of SARS-CoV-2 infection (COVID-19) and reduced mortality among nursing home (or outpatient/ambulatory) residents', Medical Hypotheses. Elsevier BV. 153, p. 110622. doi: 10.1016/j.mehy.2021.110622;

reviewed research studies over the course of 2020 and 2021 on this topic.[3]

8. In November of 2020 I testified before the United States Senate as an expert in the early treatment of COVID-19.[4]

9. My *curriculum vitae* further demonstrates my academic and scientific achievements and provides a list of other publications authored by me since 1977.

Pfizer COVID-19 Vaccination Data

10. Independent scientists and epidemiologists need access to the complete body of data underlying the FDA's approval of Pfizer's COVID-19 vaccine as soon as possible. The review of those data by independent professionals is akin to the peer review process, which is the foundation of good science. Absent an independent review, the nation is dependent on one body's review – a body under tremendous political pressure which shortened the typical review process, making it impossible to carry out all analyses that are typically performed. The data the FDA relied on, including the complete body of data that the FDA received from Pfizer in making its licensing decision, has not been released to the public.

---

[3] McCullough PA, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP, Safder T, Tecson KM, Wang DD, McKinnon JE, O'Neill WW, Zervos M, **Risch HA**. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. 2021;134(1):16-22. doi: 10.1016/j.amjmed.2020.07.003. PMCID: PMC7410805. https://pubmed.ncbi.nlm.nih.gov/32771461/;

McCullough PA, Alexander PE, Armstrong R, Arvinte C, Bain AF, Bartlett RP, Berkowitz RL, Berry AC, Borody TJ, Brewer JH, Brufsky AM, Clarke T, Derwand R, Eck A, Eck J, Eisner RA, Fareed GC, Farella A, Fonseca SNS, Geyer CE Jr, Gonnering RS, Graves KE, Gross KBV, Hazan S, Held KS, Hight HT, Immanuel S, Jacobs MM, Ladapo JA, Lee LH, Littell J, Lozano I, Mangat HS, Marble B, McKinnon JE, Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, **Risch HA**, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Rev Cardiovasc Med. 2020;21(4):517-530. doi: 10.31083/j.rcm.2020.04.264. https://pubmed.ncbi.nlm.nih.gov/33387997/ *Not a result of NIH funding.

[4] https://www.hsgac.senate.gov/imo/media/doc/Testimony-Risch-2020-11-19.pdf.

11. Unless or until all the documents and data underlying licensure of Pfizer's COVID-19 vaccine are received, a proper and independent analysis cannot be completed. Attempting to recreate analyses on efficacy or safety without all the relevant data – data already limited by the short time period of the trials – would prove useless.

Pfizer Data Must Be Reviewed and Analyses Confirmed by Independent Parties

A. FDA is Subject to Political Pressure

12. There are myriad reasons why the FDA's analyses of the data should be confirmed by independent researchers. Professionals working in the scientific and healthcare professions all seek second opinions. Scientists use peer review because everyone should have someone independent looking over their work. Making the data Pfizer submitted to the FDA available to independent scientists and healthcare professionals is akin to a peer review process and is critical to ensure the accuracy of the conclusions reached, especially given the political and time pressure put upon the FDA while reaching those conclusions.

13. It is unfortunate but realistic to note that the FDA has succumbed to political pressure over the years, on both sides of the aisle. One need only review the history of FDA whistleblowers to evidence decisions biased by external pressures and not built on scientific considerations. Here, the political pressure on the FDA to get a vaccine into the arms of Americans was enormous, likely more than ever seen, including the President making it a centerpiece of his administration.

B. The Vaccine was Developed and Reviewed in an Unprecedented, Short Period of Time Following an Inadequate Clinical Trial

14. The FDA did not hold the Pfizer vaccine to the same standard as other vaccines. While shortening the regulation process for the COVID-19 vaccines was not necessarily inappropriate, due to the exigency of the pandemic, that shortening casts doubt that enough

information was actually obtained to make wise and proper decisions. There has never been a vaccine approved in such a short time period, there has never been any human mRNA vaccine approved until this year, and overlapping phases of studies and manufacturing does not account for all of the shortened time (i.e., the overlapping does not get you from 7+ years, which is more typical, to 1 year, which is what happened here). The most critical reason these data need independent verification is because of this drastically shorted regulatory process. Combining the history of an agency having historically succumbed to external pressures and the shortening of the typical timeframe for assessment of data can foster certain issues to be overlooked and not considered. It is nearly impossible that the FDA could have done everything it typically does in its review of a vaccine in the short period within which Pfizer's vaccine was reviewed and approved.

15. In addition to the other concerns, the FDA allowed Pfizer from the start to conduct an inadequate clinical trial which casts doubt on the adequacy of its review of the data submitted by Pfizer. In a randomized trial, if the primary outcome is relatively infrequent, 40 thousand people is not a "large" or adequately powered trial and for this reason the Pfizer trial had a randomization issue. For randomization to work well enough to remove possible confounding by unmeasured variables, both the numbers of participants in each arm of the trial, and the numbers of primary outcome events in those participants in each arm must be large, at least a few hundred outcomes in each arm.[5] All outcomes need to have been randomized to ensure that their study subjects are balanced in their other variables. The magnitude of balance is what matters – the small numbers of primary outcome events as seen in Pfizer's trial does not demonstrate that the

[5] Deaton A, Cartwright N. Understanding and misunderstanding randomized controlled trials. Soc Sci Med 2018;210:2-21. doi: 10.1016/j.socscimed.2017.12.005. PMCID: PMC6019115. https://doi.org/10.1016/j.socscimed.2017.12.005.

outcome events were randomized enough to remove confounding and biases sufficiently. This is the whole point of randomization, that it balances unmeasured confounding variables, variables that cannot be accounted for precisely because they are unmeasured. The FDA failed to account for this issue and it is but one reason that the complete body of data submitted by Pfizer to the FDA needs to be independently reviewed.

C. Pfizer's Data Can Help Determine Best Route Forward During an Ongoing Pandemic

16. Independent scientists and epidemiologists like myself need these data sooner rather than later. We do not know – no one knows – what will happen with this vaccine or the pandemic a year from now. We are still in a pandemic, the vaccines are failing, children are starting to be vaccinated, we are moving to boosters for all eligible Americans and so we need to have as complete an understanding of these vaccines and their efficacy, or lack thereof, as soon as possible so that we can learn how to properly manage things moving forward. Management is continuing to be a big issue and is affecting all aspects of society; it is affecting the economy, creating job loss, lost homes, failing businesses, endings of careers, and more. Time is of the essence. Collective efforts of all scientists in the United States will produce more insights at a quicker pace than if the FDA hoards data, prohibiting others from getting involved. The FDA promised to be transparent when it seemed to understand the importance behind transparency – but it seems to have now lost that understanding.

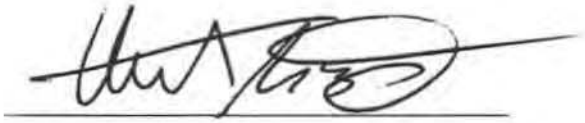
17. Finally, every person infected with SARS-CoV-2 makes thousands of variants of SARS-CoV-2 every day. For a person who has never been infected with this virus and has not been vaccinated, the strain of SARS-CoV-2 infecting that individual will vastly outnumber any variants arising in that individual. In other words, the strain infecting such a person will have a replication advantage over any variant thereby dramatically outnumbering the variant. In contrast,

in a person receiving a "leaky" vaccine -- such as the Pfizer vaccine -- that creates only partially successful immune suppression of the virus, the vaccine immunity will suppress the replication of the strain of SARS-SoV-2 with which that person is infected which will give a replication advantage to a variant that is less affected by the vaccine that occurs in the vaccinated person. This replication advantage provides the variant an enhanced ability to find a new host and become the primary strain in that host, especially if that host has the same vaccine immunity that let the variant replicate in the first place. For example, the omicron variant has already evaded immunity from existing vaccines and is beginning to spread.

18. Moreover, the SARS-CoV-2 vaccines have begun to show evidence of small incremental reductions in general immunity with each vaccine dose.[6] If you incrementally and repetitively lower natural immunity over time with more vaccine doses, then virus strains that would have previously been well fought may become more difficult to fight and lead to more severe infections that are more difficult to treat.

19. We need all of the Pfizer data to understand and solve, among others, the problems identified above as soon as possible.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct this 5th day of December 2021, at Fairfield, Connecticut.



Harvey A. Risch, M.D., Ph.D

[6] UK Health Security Agency. COVID-19 vaccine surveillance report - week 42. October 21, 2021. GOV-10227. Page 23. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1027511/Vaccine-surveillance-report-week-42.pdf.

Curriculum Vitae of Harvey A. Risch, M.D., Ph.D.

(Exhibit A to Risch Declaration)

Curriculum Vitae for: HARVEY A. RISCH, M.D., PH.D.

Professor of Epidemiology
Yale School of Public Health, Yale School of Medicine

Business Address: Yale School of Public Health
60 College Street, LEPH 413
P.O. Box 208034, New Haven, CT 06520-8034
Phone: (203) 785-2848; Fax: (203) 785-4497
E-mail: harvey.risch@yale.edu

Education:

Date	*School*	*Degree, Major*
9/80-12/82	University of Washington	Postdoctoral Fellow, Epidemiology
9/76-8/80	University of Chicago	Ph.D., Biomathematics
9/72-6/76	UC San Diego School of Medicine	M.D., Medicine
9/67-6/72	California Institute of Technology	B.S. (Honors), Biology; Mathematics

Professional Appointments:

7/01-	Professor of Epidemiology, Department of Chronic Disease Epidemiology, Yale School of Public Health, Yale School of Medicine, New Haven, CT.
1/12-	Director, Molecular Cancer Epidemiology Laboratory and Shared Resource, Yale Comprehensive Cancer Center and Yale School of Public Health
9/06-8/07	Lady Davis Visiting Professor, Department of Community Medicine and Epidemiology, Faculty of Medicine, Technion-Israel Institute of Technology, Haifa, Israel
1/91-6/01	Associate Professor of Epidemiology, Department of Epidemiology and Public Health, Yale University School of Medicine.
1/83-12/90	Epidemiologist-Biostatistician, Epidemiology Unit, National Cancer Institute of Canada, Toronto, Ontario.
7/90-12/90	Associate Professor, Department of Preventive Medicine and Biostatistics, University of Toronto, Toronto, Ontario (Concurrent Appointment).
1/83-6/90	Assistant Professor, Department of Preventive Medicine and Biostatistics, University of Toronto, Toronto, Ontario (Concurrent Appointment).
9/80-12/82	Postdoctoral Fellow, Department of Epidemiology, School of Public Health and Community Medicine, University of Washington, Seattle, Washington.
7/79-8/80	Postdoctoral Fellow, Department of Pathology, University of Chicago, Chicago, Illinois.

h-Index: 95. Publication citations: more than 44,000 research citations as of June 22, 2021.

Awards, Memberships, etc.:

NSF Undergraduate Research Fellowship, Department of Mathematics, California Institute of Technology, Pasadena (6/70-9/70)
General Medicine Stipended Externship, UC San Diego School of Medicine, La Jolla (6-9/73)
Theoretical Biology Predoctoral Traineeship, University of Chicago (9/76-6/79)
Pathobiology Postdoctoral Traineeship (GM 7190), University of Chicago (7/79-8/80)
Cancer Epidemiology Postdoctoral Traineeship (CA 9168), University of Washington (9/80-12/82)
Member, Society for Epidemiologic Research (1982-)
Member, American Society of Preventive Oncology (1984-)
Full Member, Sigma Xi (1986-)
Fellow, American College of Epidemiology (1991-); Member (1984-91)
Member, Yale Cancer Center (1992-), Sections: Cancer Prevention and Control; Gynecologic Oncology; Cancer Genetics
"Best of the AACR Journals" for "Aspirin Use and Reduced Risk of Pancreatic Cancer," one of the most highly cited *Cancer Epidemiology, Biomarkers & Prevention (CEBP)* articles published in 2016 (April 2018) (http://aacrjournals.org/h-a-risch-bio)
The Ruth Leff Siegel Award for Excellence in Pancreatic Cancer Research (2018), $50,000 (http://columbiasurgery.org/pancreas/ruth-leff-siegel-award)
Member, Connecticut Academy of Science and Engineering (2019-)
Highest attention paper ever published in the American Journal of Epidemiology (2020) (https://oxfordjournals.altmetric.com/details/82900954)

Consortia:

BEACON: Barrett's Esophagus and Esophageal Adenocarcinoma Consortium (2005-)
OCAC: Ovarian Cancer Association Consortium (International Consortium of Case-Control Studies of Ovarian Cancer) (2005-)
PanC4: Pancreatic Cancer Case-Control Consortium (2006-); Elected Steering Committee Member (2008-2013, 2014-2017, 2018-2021)
Panscan: Pancreas Cancer Genome-wide Association Study Consortium (2008-)
CIMBA: Consortium of Investigators of Modifiers of BRCA1/2 (2017-)

Research Interests:

Cancer epidemiology and etiology—Pancreas, Ovary, Lung, Breast, Stomach, Bladder, etc.
Cancer genetic epidemiology: polymorphisms, major genes; Hormonal factors and cancer; Occupational/environmental exposures and cancer; Diet and cancer; *Helicobacter pylori* and cancer
Epidemiologic methods; Causal inference; Cancer registration, control and prevention

Teaching Experience:

Advanced Epidemiologic Research Methods (Yale University CDE 619a) (Course developer)
Fundamentals of Epidemiology (Yale University CDE/EMD 508) (Course developer)
Principles of Epidemiology II (Yale University CDE 516) (Course developer)
Research Methods in Epidemiology I (University of Toronto CHL 4102f) (Course co-developer)
Research Methods in Epidemiology II (University of Toronto CHL 4105s) (Course developer)
Cancer Epidemiology (University of Toronto CHL 4103f; Yale University CDE 532b)

Trainees

PhD: Advisor to five students; dissertation committee member for 11 students.
MPH or MSc: Advisor to 36 students.
Postdoctoral Fellows: Advisor to 16 fellows.

Visiting Faculty: Host to four visiting professors.

Service Activity:

Grant Review Panels:

Health Canada, National Health Research and Development Program: Epidemiology, Occupational Health and Chronic Disease Panel (1987-91)
NIH External Site Reviewer (1995)
NIH Study Section Regular Member: Epidemiology and Disease Control (EDC2) (1997)
US Army MRMC Ovarian Cancer Research Program Integration Panel Member (1997-2002)
American Cancer Society Extramural Grant Reviewer (1998)
Chair, Epidemiology Grant Review Panel, National Cancer Institute of Canada (2000-2)
Dutch Cancer Society Extramural Research Grant Reviewer (2000, 2001, 2008)
Cancer Council Australia Extramural Research Grant Reviewer (2004)
Pancreatic Cancer Action Network-AACR Career Development Awards Scientific Review Committee (2016-8)
NIH Study Section Member: Epidemiology and Disease Control (EDC2) (2000)
NIH Study Section Member: Epidemiology Special Emphasis Panel (ZRG4, 1998; ZRG1, 2001-3)
NIH Study Section Member: Pancreas SPORE Panel (ZCA1 GRB-V, 2002-3)
NIH Study Section Member: Small Grants Program for Cancer Epidemiology Panel (ZCA1 SRRB-Q, 2003)
NIH Study Section Member: Cancer Genetics Panel (CG) (2004, 2006)
NIH Study Section Member: Cancer Epidemiology, Prevention and Control (NCI-E X1) (2005)
NIH Study Section Member: Breast and Ovarian Cancer Genetics (ZRG1 ONC-U 03M) (2005)
NIH Study Section Member: Gene-Environment Interactions (ZHL1 CSR-D S1 R) (2007)
NIH Study Section Member: Epidemiology of Cancer Member Conflicts (ZRG1 HOP-Q, 2009; ZRG1 PSE-B, 2010)
NIH Study Section Member: Barrett's Esophagus Translational Research Network (ZCA1 SRLB-1 (O1) R, 2011)
NIH Study Section Member: Core Infrastructure and Methodological Research for Cancer Epidemiology Cohorts (ZCA1 SRLB-9 (M2) B, 2013; ZCA1 TCRB-9 (J2) R, 2014; ZCA1 SRBJ (O2) S, 2015)
NIH Study Section Member: Cancer Management, Epidemiology, and Health Behavior (ZCA1 SRLB-B (J1) S, 2013)
NIH Study Section Member: Population Science (U01) (ZCA1 RTRB-Z M1 R, 2016)
Medical Research Council UK External Reviewer (2019)

Journal Editor:

Associate Editor, *American Journal of Epidemiology* (1997-2014)
Editor pro tem, *American Journal of Epidemiology* (2002-2014)
Member, Board of Editors, *American Journal of Epidemiology* (2014-2020)
Associate Editor, *Journal of the National Cancer Institute* (2000-)
Editor, *International Journal of Cancer* (2008-)

Journal Referee:

Alimentary Pharmacology & Therapeutics (2015-)
American Journal of Epidemiology (1986-)
American Journal of Medical Genetics (2004-)
American Journal of Obstetrics and Gynecology (2015-)
American Journal of Preventive Medicine (1988-)

Annals of Epidemiology (1992-)
Annals of Oncology (2001-)
Annals of Surgical Oncology (2011-)
Biodemography and Social Biology (2018-)
Biometrics (1990-)
Blood Transfusion (2015-)
BMC Cancer (2007-)
BMC Public Health (2007-)
British Journal of Cancer (2003-)
Canadian Journal of Public Health (1987-)
Canadian Medical Association Journal (1983-)
Cancer (1996-)
Cancer Causes and Control (1992-)
Cancer Detection and Prevention (2003-2009)
Cancer Epidemiology (2009-)
Cancer Epidemiology, Biomarkers and Prevention (1995-)
Cancer Genetics (2012-)
Cancer Research (1988-)
Carcinogenesis (2008-)
Clinical Cancer Research (2015-)
Clinical Gastroenterology and Hepatology (2007-)
Current Pharmacogenomics (2007-)
DNA and Cell Biology (2019-)
Environmental Pollution (2018-)
Epidemiology (1989-)
European Journal of Cancer (2001-)
European Journal of Epidemiology (1995-)
European Journal of Human Genetics (2008-)
Gastroenterology (2007-)
Gynecologic Oncology (1997-)
International Journal of Cancer (1995-)
International Journal of Epidemiology (1995-)
JAMA (1990-)
Journal for Nurse Practitioners (2018-)
Journal of Clinical Epidemiology (2006-)
Journal of Clinical Gastroenterology (2010-)
Journal of Clinical Medicine (2019-)
Journal of Epidemiology (2016-)
Journal of Infectious Diseases (2002-)
Journal of the National Cancer Institute (1992-)
Menopause (2011-)
Molecular Carcinogenesis (2009-)
Nature Clinical Practice Oncology (2005-)
Nature Scientific Reports (2016-)
New England Journal of Medicine (2017-)
Oncology Research (2001-)
Oncotarget (2017-)
Preventive Medicine (1994-)

Reproductive Sciences (2008-)
Science (2004-)
Treatments in Endocrinology (2003-)
Tumor Biology (2015-)
World Journal of Gastroenterology (2013-)

Other Review and Service:

Society for Epidemiologic Research Student Prize Paper Review Committee (1987, 1994)
American Society for Clinical Oncology Cancer Prevention Curriculum (2006)
External Advisory Board Member, Multiple Myeloma Prevention Program Project, Washington University (2014-2015)
Mayo Clinic SPORE in Pancreatic Cancer External Advisory Committee (2018-2023)
Connecticut Academy of Science and Engineering (CASE) Advisory Committee on Covid-19 for Reopening Connecticut (2020)

Academic and Professional Standing Committees:

Yale School of Public Health:
Doctoral (Admissions and Progress; 1991-1999)
MPH (Academic Progress; 1991-1995)
Computer (1999-2001)
Medical Studies (2000-2005)
Chair, Genetics and Public Health Interest Group (2003-2006)
Chair, C.E.A. Winslow Medal Committee (2007-2010)
Chair, Hildreth Memorial Fund Committee (2007-2012)
The Honorable Tina Brozman Foundation Small Grant Proposal Review Committee (2010)
Chair, MPH Thesis Dean's Prize Committee (2010-)
Chair, Department of Chronic Disease Epidemiology, Epidemiology Competencies Committee (2015-)
Committee for Academic and Professional Integrity (2018-2021)
Education Committee (2019-)

Yale School of Medicine:
Program in Investigative Medicine Doctoral Committee (1999-2007)
Mentored Clinical Research Scholar Program Advisory Board (2003-2008)

Yale Cancer Center:
Rapid Case Ascertainment System Shared Resource (1995-)
American Cancer Society Institutional Research Award Review Committee (1996-2001)

American College of Epidemiology:
Education Committee (1996-2002)
Policy Committee (1997-2003)

Peer-Reviewed Research Publications:

Accepted for Publication or In-Press

Cartmel B, Hughes M, Ercolano EA, Gottlieb L, Li F, Zhou Y, Harrigan M, Ligibel JA, von Gruenigen VE, Gogoi R, Schwartz PE, **Risch HA**, Lu L, Irwin ML. Randomized trial of exercise on depressive symptomatology and brain derived neurotrophic factor (BDNF) in ovarian cancer survivors: The Women's Activity and Lifestyle Study in Connecticut (WALC).

Gynecol Oncol 2021:S0090-8258(21)00195-5. doi: 10.1016/j.ygyno.2021.02.036. PMCID: PMC Journal in Process. In Press.

Zhang H, Greenwood DC, **Risch HA**, Bunce D, Hardie LJ, Cade JE. Meat consumption and risk of incident dementia: cohort study of 493,888 UK Biobank participants. Am J Clin Nutr 2021:nqab028. doi: 10.1093/ajcn/nqab028. PMCID: PMC Journal in Process. In Press.

Mocci E, Kundu P, Wheeler W, Arslan AA, Beane Freeman LE, Bracci PM, Brennan P, Canzian F, Du M, Gallinger S, Giles GG, Goodman PJ, Kooperberg C, Le Marchand L, Neale RE, Shu XO, Visvanathan K, White E, Zheng W, Albanes D, Andreotti G, Babic A, Bamlet WR, Berndt SI, Blackford AL, Bueno-de-Mesquita B, Buring JE, Campa D, Chanock SJ, Childs EJ, Duell EJ, Fuchs CS, Gaziano JM, Giovannucci EL, Goggins MG, Hartge P, Hassan MM, Holly EA, Hoover RN, Hung RJ, Kurtz RC, Lee IM, Malats N, Milne RL, Ng K, Oberg AL, Panico S, Peters U, Porta M, Rabe KG, Riboli E, Rothman N, Scelo G, Sesso HD, Silverman DT, Stevens VL, Strobel O, Thompson IM, Tjonneland A, Trichopoulou A, Van Den Eeden SK, Wactawski-Wende J, Wentzensen N, Wilkens LR, Yu H, Yuan F, Zeleniuch-Jacquotte A, Amundadottir LT, Li D, Jacobs EJ, Petersen GM, Wolpin BM, **Risch HA**, Kraft P, Chatterjee N, Klein AP, Stolzenberg-Solomon RZ. Smoking modifies pancreatic cancer risk loci on 2q21.3. Cancer Res 2021:canres.3267.2020. doi: 10.1158/0008-5472.CAN-20-3267. PMCID: PMC Journal in Process. In Press.

Corlin L, Ruan M, Tsilidis KK, Bouras E, Yu Y-H, Stolzenberg-Solomon R, Klein AP, **Risch HA**, Amos CI, Sakoda LC, Vodi ka P, Rish PK, Beck J, Platz EA, Michaud DS. Two-Sample Mendelian Randomization Analysis of Associations Between Periodontal Disease and Risk of Cancer. Accepted for Publication, JNCI Cancer Spectrum. PMCID: PMC Journal in Process.

Lakeman IMM, van den Broek AJ, Vos J, Barnes DR, Adlard J, Andrulis IL, Arason A, Arnold N, Arun BK, Balmaña J, Barrowdale D, Benitez J, Borg A, Caldés T, Caligo MA, Chung WK, Claes KBM, GEMO Study Collaborators-, EMBRACE Collaborators, Collée JM, Couch FJ, Daly MB, Dennis J, Dhawan M, Domchek SM, Eeles R, Engel C, Evans DG, Feliubadaló L, Foretova L, Friedman E, Frost D, Ganz PA, Garber J, Gayther SA, Gerdes A-M, Godwin AK, Goldgar DE, Hahnen E, Hake CR, Hamann U, Hogervorst FBL, Hooning MJ, Hopper JL, Hulick PJ, Imyanitov EN, OCGN Investigators, HEBON Investigators, kConFab Investigators, Isaacs C, Izatt L, Jakubowska A, James PA, Janavicius R, Jensen UB, Jiao Y, John EM, Joseph V, Karlan BY, Kets CM, Konstantopoulou I, Kwong A, Legrand C, Leslie G, Lesueur F, Loud JT, Lubiński J, Manoukian S, McGuffog L, Miller A, Gomes DM, Montagna M, Mouret-Fourme E, Nathanson KL, Neuhausen SL, Nevanlinna H, Yie JNY, Olah E, Olopade OI, Park SK, Parsons MT, Peterlongo P, Piedmonte M, Radice P, Rantala J, Rennert G, **Risch HA**, Schmutzler RK, Sharma P, Simard J, Singer CF, Stadler Z, Stoppa-Lyonnet D, Sutter C, Tan YY, Teixeira MR, Teo SH, Teulé A, Thomassen M, Thull DL, Tischkowitz M, Toland AE, Tung N, van Rensburg EJ, Vega A, Wappenschmidt B, Devilee P, van Asperen CJ, Bernstein JL, Offit K, Easton DF, Rookus MA, Chenevix-Trench G, Antoniou AC, Robson M, Schmidt MK, Consortium of Investigators of Modifiers of BRCA1 and BRCA2. The predictive ability of the 313-variant-based polygenic risk score for contralateral breast cancer risk prediction in women of European ancestry with a heterozygote BRCA1 or BRCA2 pathogenic variant. Accepted for publication, Genet Med. PMCID: PMC Journal in Process.

2021

McCullough PA, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP,

Safder T, Tecson KM, Wang DD, McKinnon JE, O'Neill WW, Zervos M, **Risch HA**. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. 2021;134(1):16-22. doi: 10.1016/j.amjmed.2020.07.003. PMCID: PMC7410805

Kho PF, Amant F, Annibali D, Ashton K, Attia J, Auer PL, Beckmann MW, Black A, Brinton L, Buchanan DD, Chanock SJ, Chen C, Chen MM, Cheng THT, Cook LS, Crous-Bous M, Czene K, De Vivo I, Dennis J, Dörk T, Dowdy SC, Dunning AM, Dürst M, Easton DF, Ekici AB, Fasching PA, Fridley BL, Friedenreich CM, García-Closas M, Gaudet MM, Giles GG, Goode EL, Gorman M, Haiman CA, Hall P, Hankinson SE, Hein A, Hillemanns P, Hodgson S, Hoivik EA, Holliday EG, Hunter DJ, Jones A, Kraft P, Krakstad C, Lambrechts D, Le Marchand L, Liang X, Lindblom A, Lissowska J, Long J, Lu L, Magliocco AM, Martin L, McEvoy M, Milne RL, Mints M, Nassir R, Otton G, Palles C, Pooler L, Proietto T, Rebbeck TR, Renner SP, **Risch HA**, Rübner M, Runnebaum I, Sacerdote C, Sarto GE, Schumacher F, Scott RJ, Setiawan VW, Shah M, Sheng X, Shu XO, Southey MC, Tham E, Tomlinson I, Trovik J, Turman C, Tyrer JP, Van Den Berg D, Wang Z, Wentzensen N, Xia L, Xiang YB, Yang HP, Yu H, Zheng W, Webb PM, Thompson DJ, Spurdle AB, Glubb DM, O'Mara TA. Mendelian randomization analyses suggest a role for cholesterol in the development of endometrial cancer. Int J Cancer 2021;148(2):307-319. doi: 10.1002/ijc.33206. PMCID: PMC7757859

Glubb DM, Thompson DJ, Aben KKH, Alsulimani A, Amant F, Annibali D, Attia J, Barricarte A, Beckmann MW, Berchuck A, Bermisheva M, Bernardini MQ, Bischof K, Bjorge L, Bodelon C, Brand AH, Brenton JD, Brinton LA, Bruinsma F, Buchanan DD, Burghaus S, Butzow R, Cai H, Carney ME, Chanock SJ, Chen C, Chen XQ, Chen Z, Cook LS, Cunningham JM, De Vivo I, deFazio A, Doherty JA, Dörk T, du Bois A, Dunning AM, Dürst M, Edwards T, Edwards RP, Ekici AB, Ewing A, Fasching PA, Ferguson S, Flanagan JM, Fostira F, Fountzilas G, Friedenreich CM, Gao B, Gaudet MM, Gawełko J, Gentry-Maharaj A, Giles GG, Glasspool R, Goodman MT, Gronwald J, Harris HR, Harter P, Hein A, Heitz F, Hildebrandt MAT, Hillemanns P, Høgdall E, Høgdall CK, Holliday EG, Huntsman DG, Huzarski T, Jakubowska A, Jensen A, Jones ME, Karlan BY, Karnezis A, Kelley JL, Khusnutdinova E, Killeen JL, Kjaer SK, Klapdor R, Köbel M, Konopka B, Konstantopoulou I, Kopperud RK, Koti M, Kraft P, Kupryjanczyk J, Lambrechts D, Larson MC, Le Marchand L, Lele S, Lester J, Li AJ, Liang D, Liebrich C, Lipworth L, Lissowska J, Lu L, Lu KH, Macciotta A, Mattiello A, May T, McAlpine JN, McGuire V, McNeish IA, Menon U, Modugno F, Moysich KB, Nevanlinna H, Odunsi K, Olsson H, Orsulic S, Osorio A, Palli D, Park-Simon TW, Pearce CL, Pejovic T, Permuth JB, Podgorska A, Ramus SJ, Rebbeck TR, Riggan MJ, **Risch HA**, Rothstein JH, Runnebaum IB, Scott RJ, Sellers TA, Senz J, Setiawan VW, Siddiqui N, Sieh W, Spiewankiewicz B, Sutphen R, Swerdlow AJ, Szafron LM, Teo SH, Thompson PJ, Thomsen LCV, Titus L, Tone A, Tumino R, Turman C, Vanderstichele A, Edwards DV, Vergote I, Vierkant RA, Wang Z, Wang-Gohrke S, Webb PM; OPAL Study Group; AOCS Group, White E, Whittemore AS, Winham SJ, Wu X, Wu AH, Yannoukakos D, Spurdle AB, O'Mara TA. Cross-Cancer Genome-Wide Association Study of Endometrial Cancer and Epithelial Ovarian Cancer Identifies Genetic Risk Regions Associated with Risk of Both Cancers. Cancer Epidemiol Biomarkers Prev 2021;30(1):217-228. doi: 10.1158/1055-9965.EPI-20-0739. PMCID: PMC Journal in Process.

Streicher SA, Klein AP, Olson SH, Kurtz RC, Amundadottir LT, DeWan AT, Zhao H, **Risch HA**. A pooled genome-wide association study identifies pancreatic cancer susceptibility loci on chromosome 19p12 and 19p13.3 in the full-Jewish population. Hum Genet 2021;140(2):309-319. doi: 10.1007/s00439-020-02205-8. PMCID: PMC Journal in Process.

Jordan SJ, Na R, Weiderpass E, Adami HO, Anderson KE, van den Brandt PA, Brinton LA, Chen C, Cook LS, Doherty JA, Du M, Friedenreich CM, Gierach GL, Goodman MT, Krogh V, Levi F, Lu L, Miller AB, McCann SE, Moysich KB, Negri E, Olson SH, Petruzella S, Palmer JR, Parazzini F, Pike MC, Prizment AE, Rebbeck TR, Reynolds P, Ricceri F, **Risch HA**, Rohan TE, Sacerdote C, Schouten LJ, Serraino D, Setiawan VW, Shu XO, Sponholtz TR, Spurdle AB, Stolzenberg-Solomon RZ, Trabert B, Wentzensen N, Wilkens LR, Wise LA, Yu H, La Vecchia C, De Vivo I, Xu W, Zeleniuch-Jacquotte A, Webb PM. Pregnancy outcomes and risk of endometrial cancer: A pooled analysis of individual participant data in the Epidemiology of Endometrial Cancer Consortium. Int J Cancer 2021;148(9):2068-2078. doi: 10.1002/ijc.33360. PMCID: PMC7969437

Lee AW, Rosenzweig S, Wiensch A; Australian Ovarian Cancer Study Group, Ramus SJ, Menon U, Gentry-Maharaj A, Ziogas A, Anton-Culver H, Whittemore AS, Sieh W, Rothstein JH, McGuire V, Wentzensen N, Bandera EV, Qin B, Terry KL, Cramer DW, Titus L, Schildkraut JM, Berchuck A, Goode EL, Kjaer SK, Jensen A, Jordan SJ, Ness RB, Modugno F, Moysich K, Thompson PJ, Goodman MT, Carney ME, Chang-Claude J, Rossing MA, Harris HR, Doherty JA, **Risch HA**, Khoja L, Alimujiang A, Phung MT, Brieger K, Mukherjee B, Pharoah PDP, Wu AH, Pike MC, Webb PM, Pearce CL. Expanding Our Understanding of Ovarian Cancer Risk: The Role of Incomplete Pregnancies. J Natl Cancer Inst 2021;113(3):301-308. doi: 10.1093/jnci/djaa099. PMCID: PMC Journal in Process.

Dighe SG, Chen J, Yan L, He Q, Gharahkhani P, Onstad L, Levine DM, Palles C, Ye W, Gammon MD, Iyer PG, Anderson LA, Liu G, Wu AH, Dai JY, Chow WH, **Risch HA**, Lagergren J, Shaheen NJ, Bernstein L, Corley DA, Prenen H, deCaestecker J, MacDonald D, Moayyedi P, Barr H, Love SB, Chegwidden L, Attwood S, Watson P, Harrison R, Ott K, Moebus S, Venerito M, Lang H, Mayershofer R, Knapp M, Veits L, Gerges C, Weismüller J, Gockel I, Vashist Y, Nöthen MM, Izbicki JR, Manner H, Neuhaus H, Rösch T, Böhmer AC, Hölscher AH, Anders M, Pech O, Schumacher B, Schmidt C, Schmidt T, Noder T, Lorenz D, Vieth M, May A, Hess T, Kreuser N, Becker J, Ell C, Ambrosone CB, Moysich KB, MacGregor S, Tomlinson I, Whiteman DC, Jankowski J, Schumacher J, Vaughan TL, Madeleine MM, Hardie LJ, Buas MF. Germline variation in the insulin-like growth factor pathway and risk of Barrett's esophagus and esophageal adenocarcinoma. Carcinogenesis 2021;42(3):369-377. doi: 10.1093/carcin/bgaa132. PMCID: PMC8052954

López de Maturana E, Rodríguez JA, Alonso L, Lao O, Molina-Montes E, Martín-Antoniano IA, Gómez-Rubio P, Lawlor R, Carrato A, Hidalgo M, Iglesias M, Molero X, Löhr M, Michalski C, Perea J, O'Rorke M, Barberà VM, Tardón A, Farré A, Muñoz-Bellvís L, Crnogorac-Jurcevic T, Domínguez-Muñoz E, Gress T, Greenhalf W, Sharp L, Arnes L, Cecchini L, Balsells J, Costello E, Ilzarbe L, Kleeff J, Kong B, Márquez M, Mora J, O'Driscoll D, Scarpa A, Ye W, Yu J; PanGenEU Investigators, García-Closas M, Kogevinas M, Rothman N, Silverman DT; SBC/EPICURO Investigators, Albanes D, Arslan AA, Beane-Freeman L, Bracci PM, Brennan P, Bueno-de-Mesquita B, Buring J, Canzian F, Du M, Gallinger S, Gaziano JM, Goodman PJ, Gunter M, LeMarchand L, Li D, Neale RE, Peters U, Petersen GM, **Risch HA**, Sánchez MJ, Shu XO, Thornquist MD, Visvanathan K, Zheng W, Chanock SJ, Easton D, Wolpin BM, Stolzenberg-Solomon RZ, Klein AP, Amundadottir LT, Marti-Renom MA, Real FX, Malats N. A multilayered post-GWAS assessment on genetic susceptibility to pancreatic cancer. Genome Med 2021;13(1):15. doi: 10.1186/s13073-020-00816-4. PMCID: PMC7849104

2020

McCullough PA, Alexander PE, Armstrong R, Arvinte C, Bain AF, Bartlett RP, Berkowitz RL, Berry AC, Borody TJ, Brewer JH, Brufsky AM, Clarke T, Derwand R, Eck A, Eck J, Eisner

RA, Fareed GC, Farella A, Fonseca SNS, Geyer CE Jr, Gonnering RS, Graves KE, Gross KBV, Hazan S, Held KS, Hight HT, Immanuel S, Jacobs MM, Ladapo JA, Lee LH, Littell J, Lozano I, Mangat HS, Marble B, McKinnon JE, Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, **Risch HA**, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Rev Cardiovasc Med. 2020;21(4):517-530. doi: 10.31083/j.rcm.2020.04.264. *Not a result of NIH funding.

Risch HA. Early Outpatient Treatment of Symptomatic, High-Risk COVID-19 Patients That Should Be Ramped Up Immediately as Key to the Pandemic Crisis. Am J Epidemiol 2020;189(11):1218-1226. doi: 10.1093/aje/kwaa093. PMCID: PMC7546206

Zhang H, Ahearn TU, Lecarpentier J, Barnes D, Beesley J, Qi G, Jiang X, O'Mara TA, Zhao N, Bolla MK, Dunning AM, Dennis J, Wang Q, Ful ZA, Aittomäki K, Andrulis IL, Anton-Culver H, Arndt V, Aronson KJ, Arun BK, Auer PL, Azzollini J, Barrowdale D, Becher H, Beckmann MW, Behrens S, Benitez J, Bermisheva M, Bialkowska K, Blanco A, Blomqvist C, Bogdanova NV, Bojesen SE, Bonanni B, Bondavalli D, Borg A, Brauch H, Brenner H, Briceno I, Broeks A, Brucker SY, Brüning T, Burwinkel B, Buys SS, Byers H, Caldés T, Caligo MA, Calvello M, Campa D, Castelao JE, Chang-Claude J, Chanock SJ, Christiaens M, Christiansen H, Chung WK, Claes KBM, Clarke CL, Cornelissen S, Couch FJ, Cox A, Cross SS, Czene K, Daly MB, Devilee P, Diez O, Domchek SM, Dörk T, Dwek M, Eccles DM, Ekici AB, Evans DG, Fasching PA, Figueroa J, Foretova L, Fostira F, Friedman E, Frost D, Gago-Dominguez M, Gapstur SM, Garber J, García-Sáenz JA, Gaudet MM, Gayther SA, Giles GG, Godwin AK, Goldberg MS, Goldgar DE, González-Neira A, Greene MH, Gronwald J, Guénel P, Häberle L, Hahnen E, Haiman CA, Hake CR, Hall P, Hamann U, Harkness EF, Heemskerk-Gerritsen BAM, Hillemanns P, Hogervorst FBL, Holleczek B, Hollestelle A, Hooning MJ, Hoover RN, Hopper JL, Howell A, Huebner H, Hulick PJ, Imyanitov EN; kConFab Investigators; ABCTB Investigators, Isaacs C, Izatt L, Jager A, Jakimovska M, Jakubowska A, James P, Janavicius R, Janni W, John EM, Jones ME, Jung A, Kaaks R, Kapoor PM, Karlan BY, Keeman R, Khan S, Khusnutdinova E, Kitahara CM, Ko YD, Konstantopoulou I, Koppert LB, Koutros S, Kristensen VN, Laenkholm AV, Lambrechts D, Larsson SC, Laurent-Puig P, Lazaro C, Lazarova E, Lejbkowicz F, Leslie G, Lesueur F, Lindblom A, Lissowska J, Lo WY, Loud JT, Lubinski J, Lukomska A, MacInnis RJ, Mannermaa A, Manoochehri M, Manoukian S, Margolin S, Martinez ME, Matricardi L, McGuffog L, McLean C, Mebirouk N, Meindl A, Menon U, Miller A, Mingazheva E, Montagna M, Mulligan AM, Mulot C, Muranen TA, Nathanson KL, Neuhausen SL, Nevanlinna H, Neven P, Newman WG, Nielsen FC, Nikitina-Zake L, Nodora J, Offit K, Olah E, Olopade OI, Olsson H, Orr N, Papi L, Papp J, Park-Simon TW, Parsons MT, Peissel B, Peixoto A, Peshkin B, Peterlongo P, Peto J, Phillips KA, Piedmonte M, Plaseska-Karanfilska D, Prajzendanc K, Prentice R, Prokofyeva D, Rack B, Radice P, Ramus SJ, Rantala J, Rashid MU, Rennert G, Rennert HS, **Risch HA**, Romero A, Rookus MA, Rübner M, Rüdiger T, Saloustros E, Sampson S, Sandler DP, Sawyer EJ, Scheuner MT, Schmutzler RK, Schneeweiss A, Schoemaker MJ, Schöttker B, Schürmann P, Senter L, Sharma P, Sherman ME, Shu XO, Singer CF, Smichkoska S, Soucy P, Southey MC, Spinelli JJ, Stone J, Stoppa-Lyonnet D; EMBRACE Study; GEMO Study Collaborators, Swerdlow AJ, Szabo CI, Tamimi RM, Tapper WJ, Taylor JA, Teixeira MR, Terry M, Thomassen M, Thull DL, Tischkowitz M, Toland AE, Tollenaar RAEM, Tomlinson I, Torres D, Troester MA, Truong T, Tung N, Untch M, Vachon CM, van den Ouweland AMW, van der Kolk LE, van Veen EM, vanRensburg EJ, Vega A, Wappenschmidt B, Weinberg CR, Weitzel

JN, Wildiers H, Winqvist R, Wolk A, Yang XR, Yannoukakos D, Zheng W, Zorn KK, Milne RL, Kraft P, Simard J, Pharoah PDP, Michailidou K, Antoniou AC, Schmidt MK, Chenevix-Trench G, Easton DF, Chatterjee N, García-Closas M. Genome-wide association study identifies 32 novel breast cancer susceptibility loci from overall and subtype-specific analyses. Nat Genet 2020;52(6):572-581. doi: 10.1038/s41588-020-0609-2. PMCID: PMC7808397

Babic A, Sasamoto N, Rosner BA, Tworoger SS, Jordan SJ, **Risch HA**, Harris HR, Rossing MA, Doherty JA, Fortner RT, Chang-Claude J, Goodman MT, Thompson PJ, Moysich KB, Ness RB, Kjaer SK, Jensen A, Schildkraut JM, Titus LJ, Cramer DW, Bandera EV, Qin B, Sieh W, McGuire V, Sutphen R, Pearce CL, Wu AH, Pike M, Webb PM, Modugno F, Terry KL. Association Between Breastfeeding and Ovarian Cancer Risk. JAMA Oncol 2020;6(6):e200421. doi: 10.1001/jamaoncol.2020.0421. PMCID: PMC7118668

Fachal L, Aschard H, Beesley J, Barnes DR, Allen J, Kar S, Pooley KA, Dennis J, Michailidou K, Turman C, Soucy P, Lemaçon A, Lush M, Tyrer JP, Ghoussaini M, Moradi Marjaneh M, Jiang X, Agata S, Aittomäki K, Alonso MR, Andrulis IL, Anton-Culver H, Antonenkova NN, Arason A, Arndt V, Aronson KJ, Arun BK, Auber B, Auer PL, Azzollini J, Balmaña J, Barkardottir RB, Barrowdale D, Beeghly-Fadiel A, Benitez J, Bermisheva M, Białkowska K, Blanco AM, Blomqvist C, Blot W, Bogdanova NV, Bojesen SE, Bolla MK, Bonanni B, Borg A, Bosse K, Brauch H, Brenner H, Briceno I, Brock IW, Brooks-Wilson A, Brüning T, Burwinkel B, Buys SS, Cai Q, Caldés T, Caligo MA, Camp NJ, Campbell I, Canzian F, Carroll JS, Carter BD, Castelao JE, Chiquette J, Christiansen H, Chung WK, Claes KBM, Clarke CL; GEMO Study Collaborators; EMBRACE Collaborators, Collée JM, Cornelissen S, Couch FJ, Cox A, Cross SS, Cybulski C, Czene K, Daly MB, de la Hoya M, Devilee P, Diez O, Ding YC, Dite GS, Domchek SM, Dörk T, Dos-Santos-Silva I, Droit A, Dubois S, Dumont M, Duran M, Durcan L, Dwek M, Eccles DM, Engel C, Eriksson M, Evans DG, Fasching PA, Fletcher O, Floris G, Flyger H, Foretova L, Foulkes WD, Friedman E, Fritschi L, Frost D, Gabrielson M, Gago-Dominguez M, Gambino G, Ganz PA, Gapstur SM, Garber J, García-Sáenz JA, Gaudet MM, Georgoulias V, Giles GG, Glendon G, Godwin AK, Goldberg MS, Goldgar DE, González-Neira A, Tibiletti MG, Greene MH, Grip M, Gronwald J, Grundy A, Guénel P, Hahnen E, Haiman CA, Håkansson N, Hall P, Hamann U, Harrington PA, Hartikainen JM, Hartman M, He W, Healey CS, Heemskerk-Gerritsen BAM, Heyworth J, Hillemanns P, Hogervorst FBL, Hollestelle A, Hooning MJ, Hopper JL, Howell A, Huang G, Hulick PJ, Imyanitov EN; KConFab Investigators; HEBON Investigators; ABCTB Investigators, Isaacs C, Iwasaki M, Jager A, Jakimovska M, Jakubowska A, James PA, Janavicius R, Jankowitz RC, John EM, Johnson N, Jones ME, Jukkola-Vuorinen A, Jung A, Kaaks R, Kang D, Kapoor PM, Karlan BY, Keeman R, Kerin MJ, Khusnutdinova E, Kiiski JI, Kirk J, Kitahara CM, Ko YD, Konstantopoulou I, Kosma VM, Koutros S, Kubelka-Sabit K, Kwong A, Kyriacou K, Laitman Y, Lambrechts D, Lee E, Leslie G, Lester J, Lesueur F, Lindblom A, Lo WY, Long J, Lophatananon A, Loud JT, Lubiński J, MacInnis RJ, Maishman T, Makalic E, Mannermaa A, Manoochehri M, Manoukian S, Margolin S, Martinez ME, Matsuo K, Maurer T, Mavroudis D, Mayes R, McGuffog L, McLean C, Mebirouk N, Meindl A, Miller A, Miller N, Montagna M, Moreno F, Muir K, Mulligan AM, Muñoz-Garzon VM, Muranen TA, Narod SA, Nassir R, Nathanson KL, Neuhausen SL, Nevanlinna H, Neven P, Nielsen FC, Nikitina-Zake L, Norman A, Offit K, Olah E, Olopade OI, Olsson H, Orr N, Osorio A, Pankratz VS, Papp J, Park SK, Park-Simon TW, Parsons MT, Paul J, Pedersen IS, Peissel B, Peshkin B, Peterlongo P, Peto J, Plaseska-Karanfilska D, Prajzendanc K, Prentice R, Presneau N, Prokofyeva D, Pujana MA, Pylkäs K, Radice P, Ramus SJ, Rantala J, Rau-Murthy R, Rennert G, **Risch HA**, Robson M, Romero A, Rossing M, Saloustros E, Sánchez-Herrero E, Sandler DP, Santamariña M,

Saunders C, Sawyer EJ, Scheuner MT, Schmidt DF, Schmutzler RK, Schneeweiss A, Schoemaker MJ, Schöttker B, Schürmann P, Scott C, Scott RJ, Senter L, Seynaeve CM, Shah M, Sharma P, Shen CY, Shu XO, Singer CF, Slavin TP, Smichkoska S, Southey MC, Spinelli JJ, Spurdle AB, Stone J, Stoppa-Lyonnet D, Sutter C, Swerdlow AJ, Tamimi RM, Tan YY, Tapper WJ, Taylor JA, Teixeira MR, Tengström M, Teo SH, Terry MB, Teulé A, Thomassen M, Thull DL, Tischkowitz M, Toland AE, Tollenaar RAEM, Tomlinson I, Torres D, Torres-Mejía G, Troester MA, Truong T, Tung N, Tzardi M, Ulmer HU, Vachon CM, van Asperen CJ, van der Kolk LE, van Rensburg EJ, Vega A, Viel A, Vijai J, Vogel MJ, Wang Q, Wappenschmidt B, Weinberg CR, Weitzel JN, Wendt C, Wildiers H, Winqvist R, Wolk A, Wu AH, Yannoukakos D, Zhang Y, Zheng W, Hunter D, Pharoah PDP, Chang-Claude J, García-Closas M, Schmidt MK, Milne RL, Kristensen VN, French JD, Edwards SL, Antoniou AC, Chenevix-Trench G, Simard J, Easton DF, Kraft P, Dunning AM. Fine-mapping of 150 breast cancer risk regions identifies 191 likely target genes. Nat Genet 2020;52(1):56-73. doi: 10.1038/s41588-019-0537-1. PMCID: PMC6974400

Feng H, Gusev A, Pasaniuc B, Wu L, Long J, Abu-Full Z, Aittomäki K, Andrulis IL, Anton-Culver H, Antoniou AC, Arason A, Arndt V, Aronson KJ, Arun BK, Asseryanis E, Auer PL, Azzollini J, Balmaña J, Barkardottir RB, Barnes DR, Barrowdale D, Beckmann MW, Behrens S, Benitez J, Bermisheva M, Białkowska K, Blanco A, Blomqvist C, Boeckx B, Bogdanova NV, Bojesen SE, Bolla MK, Bonanni B, Borg A, Brauch H, Brenner H, Briceno I, Broeks A, Brüning T, Burwinkel B, Cai Q, Caldés T, Caligo MA, Campbell I, Canisius S, Campa D, Carter BD, Carter J, Castelao JE, Chang-Claude J, Chanock SJ, Christiansen H, Chung WK, Claes KBM, Clarke CL; GEMO Study Collaborators; EMBRACE Collaborators; GC-HBOC study Collaborators, Couch FJ, Cox A, Cross SS, Cybulski C, Czene K, Daly MB, de la Hoya M, De Leeneer K, Dennis J, Devilee P, Diez O, Domchek SM, Dörk T, Dos-Santos-Silva I, Dunning AM, Dwek M, Eccles DM, Ejlertsen B, Ellberg C, Engel C, Eriksson M, Fasching PA, Fletcher O, Flyger H, Fostira F, Friedman E, Fritschi L, Frost D, Gabrielson M, Ganz PA, Gapstur SM, Garber J, García-Closas M, García-Sáenz JA, Gaudet MM, Giles GG, Glendon G, Godwin AK, Goldberg MS, Goldgar DE, González-Neira A, Greene MH, Gronwald J, Guénel P, Haiman CA, Hall P, Hamann U, Hake C, He W, Heyworth J, Hogervorst FBL, Hollestelle A, Hooning MJ, Hoover RN, Hopper JL, Huang G, Hulick PJ, Humphreys K, Imyanitov EN; ABCTB Investigators; HEBON Investigators; BCFR Investigators; OCGN Investigators, Isaacs C, Jakimovska M, Jakubowska A, James P, Janavicius R, Jankowitz RC, John EM, Johnson N, Joseph V, Jung A, Karlan BY, Khusnutdinova E, Kiiski JI, Konstantopoulou I, Kristensen VN, Laitman Y, Lambrechts D, Lazaro C, Leroux D, Leslie G, Lester J, Lesueur F, Lindor N, Lindström S, Lo WY, Loud JT, Lubiński J, Makalic E, Mannermaa A, Manoochehri M, Manoukian S, Margolin S, Martens JWM, Martinez ME, Matricardi L, Maurer T, Mavroudis D, McGuffog L, Meindl A, Menon U, Michailidou K, Kapoor PM, Miller A, Montagna M, Moreno F, Moserle L, Mulligan AM, Muranen TA, Nathanson KL, Neuhausen SL, Nevanlinna H, Nevelsteen I, Nielsen FC, Nikitina-Zake L, Offit K, Olah E, Olopade OI, Olsson H, Osorio A, Papp J, Park-Simon TW, Parsons MT, Pedersen IS, Peixoto A, Peterlongo P, Peto J, Pharoah PDP, Phillips KA, Plaseska-Karanfilska D, Poppe B, Pradhan N, Prajzendanc K, Presneau N, Punie K, Pylkäs K, Radice P, Rantala J, Rashid MU, Rennert G, **Risch HA**, Robson M, Romero A, Saloustros E, Sandler DP, Santos C, Sawyer EJ, Schmidt MK, Schmidt DF, Schmutzler RK, Schoemaker MJ, Scott RJ, Sharma P, Shu XO, Simard J, Singer CF, Skytte AB, Soucy P, Southey MC, Spinelli JJ, Spurdle AB, Stone J, Swerdlow AJ, Tapper WJ, Taylor JA, Teixeira MR, Terry MB, Teulé A, Thomassen M, Thöne K, Thull DL, Tischkowitz M, Toland AE, Tollenaar RAEM, Torres D, Truong T, Tung N, Vachon CM, van Asperen CJ, van den

Ouweland AMW, van Rensburg EJ, Vega A, Viel A, Vieiro-Balo P, Wang Q, Wappenschmidt B, Weinberg CR, Weitzel JN, Wendt C, Winqvist R, Yang XR, Yannoukakos D, Ziogas A, Milne RL, Easton DF, Chenevix-Trench G, Zheng W, Kraft P, Jiang X. Transcriptome-wide association study of breast cancer risk by estrogen-receptor status. Genet Epidemiol 2020;44(5):442-468. doi: 10.1002/gepi.22288. PMCID: PMC7987299

Zhong J, Jermusyk A, Wu L, Hoskins JW, Collins I, Mocci E, Zhang M, Song L, Chung CC, Zhang T, Xiao W, Albanes D, Andreotti G, Arslan AA, Babic A, Bamlet WR, Beane-Freeman L, Berndt S, Borgida A, Bracci PM, Brais L, Brennan P, Bueno-de-Mesquita B, Buring J, Canzian F, Childs EJ, Cotterchio M, Du M, Duell EJ, Fuchs C, Gallinger S, Gaziano JM, Giles GG, Giovannucci E, Goggins M, Goodman GE, Goodman PJ, Haiman C, Hartge P, Hasan M, Helzlsouer KJ, Holly EA, Klein EA, Kogevinas M, Kurtz RJ, LeMarchand L, Malats N, Männistö S, Milne R, Neale RE, Ng K, Obazee O, Oberg AL, Orlow I, Patel AV, Peters U, Porta M, Rothman N, Scelo G, Sesso HD, Severi G, Sieri S, Silverman D, Sund M, Tjønneland A, Thornquist MD, Tobias GS, Trichopoulou A, Van Den Eeden SK, Visvanathan K, Wactawski-Wende J, Wentzensen N, White E, Yu H, Yuan C, Zeleniuch-Jacquotte A, Hoover R, Brown K, Kooperberg C, **Risch HA**, Jacobs EJ, Li D, Yu K, Shu XO, Chanock SJ, Wolpin BM, Stolzenberg-Solomon RZ, Chatterjee N, Klein AP, Smith JP, Kraft P, Shi J, Petersen GM, Zheng W, Amundadottir LT. A Transcriptome-Wide Association Study Identifies Novel Candidate Susceptibility Genes for Pancreatic Cancer. J Natl Cancer Inst 2020;112(10):1003-1012. doi: 10.1093/jnci/djz246. PMCID: PMC7566474

Barnes DR, Rookus MA, McGuffog L, Leslie G, Mooij TM, Dennis J, Mavaddat N, Adlard J, Ahmed M, Aittomäki K, Andrieu N, Andrulis IL, Arnold N, Arun BK, Azzollini J, Balmaña J, Barkardottir RB, Barrowdale D, Benitez J, Berthet P, Białkowska K, Blanco AM, Blok MJ, Bonanni B, Boonen SE, Borg Å, Bozsik A, Bradbury AR, Brennan P, Brewer C, Brunet J, Buys SS, Caldés T, Caligo MA, Campbell I, Christensen LL, Chung WK, Claes KBM, Colas C; GEMO Study Collaborators; EMBRACE Collaborators, Collonge-Rame MA, Cook J, Daly MB, Davidson R, de la Hoya M, de Putter R, Delnatte C, Devilee P, Diez O, Ding YC, Domchek SM, Dorfling CM, Dumont M, Eeles R, Ejlertsen B, Engel C, Evans DG, Faivre L, Foretova L, Fostira F, Friedlander M, Friedman E, Frost D, Ganz PA, Garber J, Gehrig A, Gerdes AM, Gesta P, Giraud S, Glendon G, Godwin AK, Goldgar DE, González-Neira A, Greene MH, Gschwantler-Kaulich D, Hahnen E, Hamann U, Hanson H, Hentschel J, Hogervorst FBL, Hooning MJ, Horvath J, Hu C, Hulick PJ, Imyanitov EN; kConFab Investigators; HEBON Investigators; GENEPSO Investigators, Isaacs C, Izatt L, Izquierdo A, Jakubowska A, James PA, Janavicius R, John EM, Joseph V, Karlan BY, Kast K, Koudijs M, Kruse TA, Kwong A, Laitman Y, Lasset C, Lazaro C, Lester J, Lesueur F, Liljegren A, Loud JT, Lubiński J, Mai PL, Manoukian S, Mari V, Mebirouk N, Meijers-Heijboer HEJ, Meindl A, Mensenkamp AR, Miller A, Montagna M, Mouret-Fourme E, Mukherjee S, Mulligan AM, Nathanson KL, Neuhausen SL, Nevanlinna H, Niederacher D, Nielsen FC, Nikitina-Zake L, Noguès C, Olah E, Olopade OI, Ong KR, O'Shaughnessy-Kirwan A, Osorio A, Ott CE, Papi L, Park SK, Parsons MT, Pedersen IS, Peissel B, Peixoto A, Peterlongo P, Pfeiler G, Phillips KA, Prajzendanc K, Pujana MA, Radice P, Ramser J, Ramus SJ, Rantala J, Rennert G, **Risch HA**, Robson M, Rønlund K, Salani R, Schuster H, Senter L, Shah PD, Sharma P, Side LE, Singer CF, Slavin TP, Soucy P, Southey MC, Spurdle AB, Steinemann D, Steinsnyder Z, Stoppa-Lyonnet D, Sutter C, Tan YY, Teixeira MR, Teo SH, Thull DL, Tischkowitz M, Tognazzo S, Toland AE, Trainer AH, Tung N, van Engelen K, van Rensburg EJ, Vega A, Vierstraete J, Wagner G, Walker L, Wang-Gohrke S, Wappenschmidt B, Weitzel JN, Yadav S, Yang X, Yannoukakos D, Zimbalatti D, Offit K, Thomassen M, Couch FJ, Schmutzler RK, Simard J,

Easton DF, Chenevix-Trench G, Antoniou AC; Consortium of Investigators of Modifiers of BRCA and BRCA2. Polygenic risk scores and breast and epithelial ovarian cancer risks for carriers of BRCA1 and BRCA2 pathogenic variants. Genet Med 2020 Oct;22(10):1653-1666. doi: 10.1038/s41436-020-0862-x. PMCID: PMC7521995

Szente Fonseca SN, de Queiroz Sousa A, Wolkoff AG, Moreira MS, Pinto BC, Valente Takeda CF, Rebouças E, Vasconcellos Abdon AP, Nascimento ALA, **Risch HA**. Risk of hospitalization for Covid-19 outpatients treated with various drug regimens in Brazil: Comparative analysis. Travel Med Infect Dis 2020;38:101906. doi: 10.1016/j.tmaid.2020.101906. PMCID: PMC7604153

Xie SH, Fang R, Huang M, Dai J, Thrift AP, Anderson LA, Chow WH, Bernstein L, Gammon MD, **Risch HA**, Shaheen NJ, Reid BJ, Wu AH, Iyer PG, Liu G, Corley DA, Whiteman DC, Caldas C, Pharoah PD, Hardie LJ, Fitzgerald RC, Shen H, Vaughan TL, Lagergren J. Association Between Levels of Sex Hormones and Risk of Esophageal Adenocarcinoma and Barrett's Esophagus. Clin Gastroenterol Hepatol 2020;18(12):2701-2709.e3. doi: 10.1016/j.cgh.2019.11.030. PMCID: PMC7580878

Lin Y, Nakatochi M, Hosono Y, Ito H, Kamatani Y, Inoko A, Sakamoto H, Kinoshita F, Kobayashi Y, Ishii H, Ozaka M, Sasaki T, Matsuyama M, Sasahira N, Morimoto M, Kobayashi S, Fukushima T, Ueno M, Ohkawa S, Egawa N, Kuruma S, Mori M, Nakao H, Adachi Y, Okuda M, Osaki T, Kamiya S, Wang C, Hara K, Shimizu Y, Miyamoto T, Hayashi Y, Ebi H, Kohmoto T, Imoto I, Kasugai Y, Murakami Y, Akiyama M, Ishigaki K, Matsuda K, Hirata M, Shimada K, Okusaka T, Kawaguchi T, Takahashi M, Watanabe Y, Kuriki K, Kadota A, Okada R, Mikami H, Takezaki T, Suzuki S, Yamaji T, Iwasaki M, Sawada N, Goto A, Kinoshita K, Fuse N, Katsuoka F, Shimizu A, Nishizuka SS, Tanno K, Suzuki K, Okada Y, Horikoshi M, Yamauchi T, Kadowaki T, Yu H, Zhong J, Amundadottir LT, Doki Y, Ishii H, Eguchi H, Bogumil D, Haiman CA, Le Marchand L, Mori M, **Risch H**, Setiawan VW, Tsugane S, Wakai K, Yoshida T, Matsuda F, Kubo M, Kikuchi S, Matsuo K. Genome-wide association meta-analysis identifies GP2 gene risk variants for pancreatic cancer. Nat Commun 2020;11(1):3175. doi: 10.1038/s41467-020-16711-w. PMCID: PMC7314803

Dong J, Maj C, Tsavachidis S, Ostrom QT, Gharahkhani P, Anderson LA, Wu AH, Ye W, Bernstein L, Borisov O, Schröder J, Chow WH, Gammon MD, Liu G, Caldas C, Pharoah PD, **Risch HA**, May A, Gerges C, Anders M, Venerito M, Schmidt T, Izbicki JR, Hölscher AH, Schumacher B, Vashist Y, Neuhaus H, Rösch T, Knapp M, Krawitz P, Böhmer A, Iyer PG, Reid BJ, Lagergren J, Shaheen NJ, Corley DA, Gockel I, Fitzgerald RC; Stomach and Oesophageal Cancer Study (SOCS) consortium, Cook MB, Whiteman DC, Vaughan TL, Schumacher J, Thrift AP. Sex-Specific Genetic Associations for Barrett's Esophagus and Esophageal Adenocarcinoma. Gastroenterology 2020;159(6):2065-2076.e1. doi: 10.1053/j.gastro.2020.08.052. PMCID: PMC Journal in Process.

Zhang YD, Hurson AN, Zhang H, Choudhury PP, Easton DF, Milne RL, Simard J, Hall P, Michailidou K, Dennis J, Schmidt MK, Chang-Claude J, Gharahkhani P, Whiteman D, Campbell PT, Hoffmeister M, Jenkins M, Peters U, Hsu L, Gruber SB, Casey G, Schmit SL, O'Mara TA, Spurdle AB, Thompson DJ, Tomlinson I, De Vivo I, Landi MT, Law MH, Iles MM, Demenais F, Kumar R, MacGregor S, Bishop DT, Ward SV, Bondy ML, Houlston R, Wiencke JK, Melin B, Barnholtz-Sloan J, Kinnersley B, Wrensch MR, Amos CI, Hung RJ, Brennan P, McKay J, Caporaso NE, Berndt SI, Birmann BM, Camp NJ, Kraft P, Rothman N, Slager SL, Berchuck A, Pharoah PDP, Sellers TA, Gayther SA, Pearce CL, Goode EL, Schildkraut JM, Moysich KB, Amundadottir LT, Jacobs EJ, Klein AP, Petersen GM, **Risch**

HA, Stolzenberg-Solomon RZ, Wolpin BM, Li D, Eeles RA, Haiman CA, Kote-Jarai Z, Schumacher FR, Al Olama AA, Purdue MP, Scelo G, Dalgaard MD, Greene MH, Grotmol T, Kanetsky PA, McGlynn KA, Nathanson KL, Turnbull C, Wiklund F; Breast Cancer Association Consortium (BCAC); Barrett's and Esophageal Adenocarcinoma Consortium (BEACON); Colon Cancer Family Registry (CCFR); Transdisciplinary Studies of Genetic Variation in Colorectal Cancer (CORECT); Endometrial Cancer Association Consortium (ECAC); Genetics and Epidemiology of Colorectal Cancer Consortium (GECCO); Melanoma Genetics Consortium (GenoMEL); Glioma International Case-Control Study (GICC); International Lung Cancer Consortium (ILCCO); Integrative Analysis of Lung Cancer Etiology and Risk (INTEGRAL) Consortium; International Consortium of Investigators Working on Non-Hodgkin's Lymphoma Epidemiologic Studies (InterLymph); Ovarian Cancer Association Consortium (OCAC); Oral Cancer GWAS; Pancreatic Cancer Case-Control Consortium (PanC4); Pancreatic Cancer Cohort Consortium (PanScan); Prostate Cancer Association Group to Investigate Cancer Associated Alterations in the Genome (PRACTICAL); Renal Cancer GWAS; Testicular Cancer Consortium (TECAC), Chanock SJ, Chatterjee N, Garcia-Closas M. Assessment of polygenic architecture and risk prediction based on common variants across fourteen cancers. Nat Commun 2020;11(1):3353. doi: 10.1038/s41467-020-16483-3. PMCID: PMC7335068

Yuan F, Hung RJ, Walsh N, Zhang H, Platz EA, Wheeler W, Song L, Arslan AA, Beane Freeman LE, Bracci P, Canzian F, Du M, Gallinger S, Giles GG, Goodman PJ, Kooperberg C, Le Marchand L, Neale RE, Rosendahl J, Scelo G, Shu XO, Visvanathan K, White E, Zheng W, Albanes D, Amiano P, Andreotti G, Babic A, Bamlet WR, Berndt SI, Brennan P, Bueno-de-Mesquita B, Buring JE, Campbell PT, Chanock SJ, Fuchs CS, Gaziano JM, Goggins MG, Hackert T, Hartge P, Hassan MM, Holly EA, Hoover RN, Katzke V, Kirsten H, Kurtz RC, Lee IM, Malats N, Milne RL, Murphy N, Ng K, Oberg AL, Porta M, Rabe KG, Real FX, Rothman N, Sesso HD, Silverman DT, Thompson IM, Wactawski-Wende J, Wang X, Wentzensen N, Wilkens LR, Yu H, Zeleniuch-Jacquotte A, Shi J, Duell EJ, Amundadottir LT, Li D, Petersen GM, Wolpin BM, **Risch HA**, Yu K, Klein AP, Stolzenberg-Solomon R. Genome-Wide Association Study Data Reveal Genetic Susceptibility to Chronic Inflammatory Intestinal Diseases and Pancreatic Ductal Adenocarcinoma Risk. Cancer Res 2020;80(18):4004-4013. doi: 10.1158/0008-5472.CAN-20-0447. PMCID: PMC7861352

Cristiano S, McKean D, Carey J, Bracci P, Brennan P, Chou M, Du M, Gallinger S, Goggins MG, Hassan MM, Hung RJ, Kurtz RC, Li D, Lu L, Neale R, Olson S, Petersen G, Rabe KG, Fu J, **Risch H**, Rosner GL, Ruczinski I, Klein AP, Scharpf RB. Bayesian copy number detection and association in large-scale studies. BMC Cancer 2020;20(1):856. doi: 10.1186/s12885-020-07304-3. PMCID: PMC7487704

Tang H, Jiang L, Stolzenberg-Solomon RZ, Arslan AA, Beane Freeman LE, Bracci PM, Brennan P, Canzian F, Du M, Gallinger S, Giles GG, Goodman PJ, Kooperberg C, Le Marchand L, Neale RE, Shu XO, Visvanathan K, White E, Zheng W, Albanes D, Andreotti G, Babic A, Bamlet WR, Berndt SI, Blackford A, Bueno-de-Mesquita B, Buring JE, Campa D, Chanock SJ, Childs E, Duell EJ, Fuchs C, Gaziano JM, Goggins M, Hartge P, Hassam MH, Holly EA, Hoover RN, Hung RJ, Kurtz RC, Lee IM, Malats N, Milne RL, Ng K, Oberg AL, Orlow I, Peters U, Porta M, Rabe KG, Rothman N, Scelo G, Sesso HD, Silverman DT, Thompson IM Jr, Tjønneland A, Trichopoulou A, Wactawski-Wende J, Wentzensen N, Wilkens LR, Yu H, Zeleniuch-Jacquotte A, Amundadottir LT, Jacobs EJ, Petersen GM, Wolpin BM, **Risch HA**, Chatterjee N, Klein AP, Li D, Kraft P, Wei P. Genome-Wide Gene-Diabetes and Gene-Obesity Interaction Scan in 8,255 Cases and 11,900 Controls from PanScan and PanC4 Consortia.

Cancer Epidemiol Biomarkers Prev 2020;29(9):1784-1791. doi: 10.1158/1055-9965.EPI-20-0275. PMCID: PMC7483330

Zhu J, Shu X, Guo X, Liu D, Bao J, Milne RL, Giles GG, Wu C, Du M, White E, **Risch HA**, Malats N, Duell EJ, Goodman PJ, Li D, Bracci P, Katzke V, Neale RE, Gallinger S, Van Den Eeden SK, Arslan AA, Canzian F, Kooperberg C, Beane Freeman LE, Scelo G, Visvanathan K, Haiman CA, Le Marchand L, Yu H, Petersen GM, Stolzenberg-Solomon R, Klein AP, Cai Q, Long J, Shu XO, Zheng W, Wu L. Associations between Genetically Predicted Blood Protein Biomarkers and Pancreatic Cancer Risk. Cancer Epidemiol Biomarkers Prev 2020;29(7):1501-1508. doi: 10.1158/1055-9965.EPI-20-0091. PMCID: PMC7334065

Shen Y, **Risch H**, Lu L, Ma X, Irwin ML, Lim JK, Taddei T, Pawlish K, Stroup A, Brown R, Wang Z, Jia W, Wong L, Mayne ST, Yu H. Risk factors for hepatocellular carcinoma (HCC) in the northeast of the United States: results of a case-control study. Cancer Causes Control 2020;31(4):321-332. doi: 10.1007/s10552-020-01277-1. PMCID: PMC7136513

Thi-Hai Pham Y, Utuama O, Thomas CE, Park JA, La Vecchia C, **Risch HA**, Tran CT, Le TV, Boffetta P, Raskin L, Luu HN. High mobility group A protein-2 as a tumor cancer diagnostic and prognostic marker: a systematic review and meta-analysis. Eur J Cancer Prev 2020;29(6):565-581. doi: 10.1097/CEJ.0000000000000602. *Not a result of NIH funding.

Brieger KK, Peterson S, Lee AW, Mukherjee B, Bakulski KM, Alimujiang A, Anton-Culver H, Anglesio MS, Bandera EV, Berchuck A, Bowtell DDL, Chenevix-Trench G, Cho KR, Cramer DW, DeFazio A, Doherty JA, Fortner RT, Garsed DW, Gayther SA, Gentry-Maharaj A, Goode EL, Goodman MT, Harris HR, Høgdall E, Huntsman DG, Shen H, Jensen A, Johnatty SE, Jordan SJ, Kjaer SK, Kupryjanczyk J, Lambrechts D, McLean K, Menon U, Modugno F, Moysich K, Ness R, Ramus SJ, Richardson J, **Risch H**, Rossing MA, Trabert B, Wentzensen N, Ziogas A, Terry KL, Wu AH, Hanley GE, Pharoah P, Webb PM, Pike MC, Pearce CL; Ovarian Cancer Association Consortium. Menopausal hormone therapy prior to the diagnosis of ovarian cancer is associated with improved survival. Gynecol Oncol 2020;158(3):702-709. doi: 10.1016/j.ygyno.2020.06.481. PMCID: PMC7487048

Modugno F, Fu Z, Jordan SJ, Group A, Chang-Claude J, Fortner RT, Goodman MT, Moysich KB, Schildkraut JM, Berchuck A, Bandera EV, Qin B, Sutphen R, McLaughlin JR, Menon U, Ramus SJ, Gayther SA, Gentry-Maharaj A, Karpinskyj C, Pearce CL, Wu AH, **Risch HA**, Webb PM. Offspring sex and risk of epithelial ovarian cancer: a multinational pooled analysis of 12 case-control studies. Eur J Epidemiol 2020;35(11):1025-1042. doi: 10.1007/s10654-020-00682-9. PMCID: PMC7981786

Ghoneim DH, Zhu J, Zheng W, Long J, Murff HJ, Ye F, Setiawan VW, Wilkens LR, Khankari NK, Haycock P, Antwi SO, Yang Y, Arslan AA, Beane Freeman LE, Bracci PM, Canzian F, Du M, Gallinger S, Giles GG, Goodman PJ, Kooperberg C, Le Marchand L, Neale RE, Scelo G, Visvanathan K, White E, Albanes D, Amiano P, Andreotti G, Babic A, Bamlet WR, Berndt SI, Brais LK, Brennan P, Bueno-de-Mesquita B, Buring JE, Campbell PT, Rabe KG, Chanock SJ, Duggal P, Fuchs CS, Gaziano JM, Goggins MG, Hackert T, Hassan MM, Helzlsouer KJ, Holly EA, Hoover RN, Katske V, Kurtz RC, Lee IM, Malats N, Milne RL, Murphy N, Oberg AL, Porta M, Rothman N, Sesso HD, Silverman DT, Thompson IM Jr, Wactawski-Wende J, Wang X, Wentzensen N, Yu H, Zeleniuch-Jacquotte A, Yu K, Wolpin BM, Jacobs EJ, Duell EJ, **Risch HA**, Petersen GM, Amundadottir LT, Kraft P, Klein AP, Stolzenberg-Solomon RZ, Shu XO, Wu L. Mendelian Randomization Analysis of n-6 Polyunsaturated Fatty Acid Levels and Pancreatic Cancer Risk. Cancer Epidemiol Biomarkers Prev 2020;29(12):2735-2739. doi: 10.1158/1055-9965.EPI-20-0651. PMCID: PMC7710600

Yang T, Tang H, **Risch HA**, Olson SH, Peterson G, Bracci PM, Gallinger S, Hung RJ, Neale RE, Scelo G, Duell EJ, Kurtz RC, Khaw KT, Severi G, Sund M, Wareham N, Amos CI, Li D, Wei P. Incorporating multiple sets of eQTL weights into gene-by-environment interaction analysis identifies novel susceptibility loci for pancreatic cancer. Genet Epidemiol 2020;44(8):880-892. doi: 10.1002/gepi.22348. PMCID: PMC7657998

Xiao Y, He L, Chang W, Zhang S, Wang R, Chen X, Li X, Wang Z, **Risch HA**. Self-harm behaviors, suicidal ideation, and associated factors among rural left-behind children in west China. Ann Epidemiol 2020;42:42-49. doi: 10.1016/j.annepidem.2019.12.014. *Not a result of NIH funding.

Shuch B, Li S, **Risch H**, Bindra RS, McGillivray PD, Gerstein M. Estimation of the carrier frequency of fumarate hydratase alterations and implications for kidney cancer risk in hereditary leiomyomatosis and renal cancer. Cancer 2020;126(16):3657-3666. doi: 10.1002/cncr.32914. *Not a result of NIH funding.

2019

Lor GCY, **Risch HA**, Fung JW, Yeung SLA, Wong IOL, Zheng W, Pang H. Reporting and guidelines for Mendelian randomization analysis: A systematic review of oncological studies. Cancer Epidemiol 2019;62:101577. doi: 10.1016/j.canep.2019.101577. *Not a result of NIH funding.

Ferreira MA, Gamazon ER, Aittomäki K, Andrulis IL, Anton-Culver H, Arndt V, Aronson KJ, Arun BK, Asseryanis E, Auer PL, Azzollini J, Balmaña J, Barkardottir RB, Barnes DR, Barrowdale D, Beckmann MW, Behrens S, Benitez J, Bermisheva M, Blomqvist C, Bogdanova NV, Bojesen SE, Bolla MK, Borg A, Brauch H, Brenner H, Broeks A, Burwinkel B, Caldés T, Caligo MA, Campbell I, Canzian F, Carter J, Carter BD, Castelao JE, Chang-Claude J, Chanock SJ, Christiansen H, Chung WK, Claes KBM, Clarke CL, Couch FJ, Cox A, Cross SS, Czene K, Daly MB, de la Hoya M, Dennis J, Devilee P, Diez O, Dörk T, Dunning AM, Dwek M, Eccles DM, Ejlertsen B, Ellberg C, Engel C, Eriksson M, Fasching PA, Fletcher O, Flyger H, Friedman E, Frost D, Gabrielson M, Gago-Dominguez M, Ganz PA, Gapstur SM, Garber J, García-Closas M, García-Sáenz JA, Gaudet MM, Giles GG, Glendon G, Godwin AK, Goldberg MS, Goldgar DE, González-Neira A, Greene MH, Gronwald J, Guénel P, Haiman CA, Hall P, Hamann U, He W, Heyworth J, Hogervorst FBL, Hollestelle A, Hoover RN, Hopper JL, Huang G, Hulick PJ, Humphreys K, Imyanitov EN, Isaacs C, Jakimovska M, Jakubowska A, James P, Janavicius R, Jankowitz RC, John EM, Johnson N, Jones ME, Joseph V, Kaczmarek K, Kar S, Karlan BY, Keuhl T, Khusnutdinova E, Kiiski JI, Ko Y-D, Konstantopoulou I, Kristensen VN, Laitman Y, Lambrechts D, Lazaro C, Leslie G, Lester J, Lesueur F, Lindor N, Lindström S, Long J, Loud JT, Lubiński J, Makalic E, Mannermaa A, Margolin S, Mavroudis D, McGuffog L, Meindl A, Menon U, Michailidou K, Miller A, Montagna M, Moreno F, Moserle L, Mulligan AM, Nathanson KL, Neuhausen SL, Nevanlinna H, Nevelsteen I, Nielsen FC, Nikitina-Zake L, Nussbaum RL, Offit K, Olah E, Olopade OI, Olsson H, Osorio A, Papp J, Park-Simon T-W, Parsons MT, Pedersen IS, Peixoto A, Peterlongo P, Pharoah PDP, Plaseska-Karanfilska D, Poppe B, Prentice R, Presneau N, Radice P, Rantala J, Rennert G, **Risch HA**, Saloustros E, Sanden K, Sandler DP, Sawyer EJ, Schmidt MK, Schmutzler RK, Sharma P, Shu X-O, Simard J, Singer CF, Soucy P, Southey MC, Spinelli JJ, Spurdle AB, Stone J, Swerdlow AJ, Tapper WJ, Taylor JA, Teixeira MR, Terry MB, Teulé A, Thomassen M, Thöne K, Thull DL, Tischkowitz M, Toland AE, Torres D, Truong T, Tung N, Vachon C, van Asperen CJ, van den Ouweland AMW, van Rensburg EJ, Vega A, Viel A, Wang Q, Wappenschmidt B, Weinberg CR, Weitzel JN, Wendt C, Winqvist R, Yang XR, Yannoukakos D, Ziogas A, GC-HBOC study collaborators, OCGN, HEBON Investigators, GEMO Study Collaborators,

EMBRACE, BCFR Investigators, kConFab Investigators, ABCTB Investigators, Antoniou AC, Kraft P, Easton DF, Zheng W, Milne RL, Beesley J, Chenevix-Trench G. Genome-wide association and transcriptome studies identify novel putative target genes and risk loci for breast cancer. Nat Commun 2019;10(1):1741. doi: 10.1038/s41467-018-08053-5. PMCID: PMC6465407

Dong J, Gharahkhani P, Chow W-H, Gammon MD, Liu G, Caldas C, Wu AH, Ye W, Onstad L, Anderson LA, Bernstein L, Pharoah PD, **Risch HA**, Corley DA, Fitzgerald RC, Stomach and Esophageal Cancer Study (SOCS) Consortium, Iyer PG, Reid BJ, Lagergren J, Shaheen NJ, Vaughan TL, MacGregor S, Love S, Palles C, Tomlinson I, Gockel I, May A, Gerges C, Anders M, Böhmer AC, Becker J, Kreuser N, Thieme R, Noder T, Venerito M, Veits L, Schmidt T, Schmidt C, Izbicki JR, Hölscher AH, Lang H, Lorenz D, Schumacher B, Mayershofer R, Vashist Y, Ott K, Vieth M, Weismüller J, Nöthen MM, Moebus S, Knapp M, Peters WHM, Neuhaus H, Rösch T, Ell C, Jankowski J, Schumacher J, Neale RE, Whiteman DC, Thrift AP. Vitamin D status and the risks of Barrett's esophagus and esophageal adenocarcinoma: a Mendelian randomization study. Clin Gastroenterol Hepatol. 2019: S1542-3565(19)30088-6. doi: 10.1016/j.cgh.2019.01.041. PMCID: PMC Journal in Process.

Xiao Y, Yang H, Lu J, Li D, Xu C, **Risch HA**. Serum gamma-glutamyltransferase and the overall survival of metastatic pancreatic cancer. BMC Cancer 2019;19:1020. doi: 10.1186/s12885-019-6250-8. *Not a result of NIH funding.

Xiao Y, Wang Y, Chang W, Chen Y, Yu Z, **Risch H**. Factors associated with psychological resilience in left-behind children in southwest China. Asian J Psychiatr 2019;46:1-5. doi: 10.1016/j.ajp.2019.09.014. *Not a result of NIH funding.

Baecker A, Kim S, **Risch HA**, Nuckols TK, Wu BU, Hendifar AE, Pandol SJ, Pisegna JR, Jeon CY. Do changes in health reveal the possibility of undiagnosed pancreatic cancer? Development of a risk-prediction model based on healthcare claims data. PLoS One 2019;14(6):e0218580. doi: 10.1371/journal.pone.0218580. PMCID: PMC6592596.

Chen FC, Childs EJ, Mocci E, Bracci PM, Gallinger S, Li D, Neale R, Olson SH, Scelo G, Bamlet WR, Blackford A, Borges M, Brennan P, Chaffee KG, Duggal P, Hassan M, Holly EA, Hung RJ, Goggins M, Kurtz RC, Oberg AL, Orlow I, Yu H, Petersen GM, **Risch HA**, Klein AP. Analysis of heritability and genetic architecture of pancreatic cancer: a PanC4 study. Cancer Epidemiol Biomarkers Prev 2019;28(7):1238-45. doi: 10.1158/1055-9965.EPI-18-1235. PMCID: PMC6606380.

Reid BM, Permuth JB, Chen YA, Fridley BL, Iversen E, Chen Z, Jim HS, Vierkant RA, Cunningham JM, Barnholtz Sloan J, Narod S, **Risch H**, Schildkraut JM, Goode EL, Monteiro ANA, Sellers TA. Genome wide analysis of common copy number variation and epithelial ovarian cancer risk. Cancer Epidemiol Biomarkers Prev 2019;28(7):1117-26. PMCID: PMC Journal in Process.

Buckley MA, Woods NT, Tyrer J, Mendoza-Fandino G, Lawrenson K, Hazelett DJ, Najafabadi HS, Gjyshi A, Carvalho RS, Lyra PC Jr, Coetzee SG, Shen HC, Karevan R, Yang A, Earp M, Chen YA, Yoder SJ, **Risch HA**, Aben KKH, Anton Culver H, Antonenkova N, Bruinsma F, Bandera EV, Bean YT, Beckmann MW, Bisogna M, Bjorge L, Bogdanova N, Brinton LA, Brooks-Wilson A, Bunker CH, Butzow R, Campbell IG, Carty K, Chang-Claude J, Cook LS, Cramer DW, Cunningham JM, Cybulski C, Dansonka-Mieszkowska A, du Bois A, Dicks E, Doherty JA, Dörk T, Dürst M, Easton DF, Eccles DM, Edwards RP, Ekici AB, Fasching PA, Fridley BL, Gao Y-T, Gentry-Maharaj A, Giles GG, Glasspool R, Goodman MT, Gronwald J, Harter P, Hasmad HN, Hein A, Heitz F, Hildebrandt MAT, Hillemanns P, Hogdall CK, Hogdall

E, Hosono S, Iversen ES, Jakubowska A, Jensen A, Ji B-T, Karlan BY, Kellar M, Kelley JL, Kiemeney LA, Krakstad C, Kjaer SK, Kupryjanczyk J, Lambrechts D, Lambrechts S, Le ND, Lee AW, Lele S, Leminen A, Lester J, Levine DA, Liang D, Lim BK, Lissowska J, Lu K, Lubinski J, Lundvall L, Massuger LFAG, Matsuo K, McGuire V, McLaughlin JR, McNeish I, Menon U, Milne RL, Modugno F, Moysich KB, Ness RB, Nevanlinna H, Eilber U, Odunsi K, Olson SH, Orlow I, Orsulic S, Weber RP, Paul J, Pearce CL, Pejovic T, Pelttari LM, Permuth-Wey J, Pike MC, Poole EM, Rosen B, Rossing MA, Rothstein JH, Rudolph A, Runnebaum IB, Rzepecka IK, Salvesen HB, Schwaab I, Shu, X-O, Shvetsov YB, Siddiqui N, Sieh W, Song H, Southey MC, Spiewankiewicz B, Sucheston-Campbell L, Teo S-H, Terry KL, Thompson PJ, Thomsen L, Tangen IL, Tsai Y, Tworoger SS, van Altena AM, Van Nieuwenhuysen E, Vergote I, Walsh CS, Wang-Gohrke S, Wentzensen N, Whittemore AS, Wicklund KG, Wilkens LR, Wu AH, Wu X, Woo Y-L, Yang H, Zheng W, Ziogas A, Berchuck A, Chenevix-Trench G, AOCS management group, Schildkraut JM, Ramus SJ, Kelemen LE, Freedman ML, Phelan CM, Coetzee GA, Noushmehr H, Hughes TR, Sellers TA, Goode EL, Pharoah PD, Gayther SA, Monteiro ANA. Functional analysis and fine mapping of the 9p22.2 ovarian cancer susceptibility locus. Cancer Res 2019;79(3):467-81. doi: 10.1158/0008-5472.CAN-17-3864. PMCID: PMC Journal in Process.

Chhoda A, Lu L, Clerkin BM, **Risch H**, Farrell J. Pancreatic cancer screening: current approaches. Am J Pathol 2019;189(1):22-35. doi: 10.1016/j.ajpath.2018.09.013. *Not a result of NIH funding.

Webb PM, Na R, Weiderpass E, Adami HO, Anderson KE, Bertrand KA, Botteri E, Brasky TM, Brinton LA, Chen C, Doherty JA, Lu L, McCann SE, Moysich KB, Olson S, Petruzella S, Palmer JR, Prizment AE, Schairer C, Setiawan VW, Spurdle AB, Trabert B, Wentzensen N, Wilkens L, Yang HP, Yu H, **Risch HA**, Jordan SJ. Use of aspirin, other nonsteroidal anti-inflammatory drugs and acetaminophen and risk of endometrial cancer: The Epidemiology of Endometrial Cancer Consortium. Ann Oncol 2019;30(2):310-316. doi: 10.1093/annonc/mdy541. PMCID: PMC Journal in Process.

Jiang X, Finucane HK, Schumacher FR, Schmit SL, Tyrer JP, Han Y, Michailidou K, Lesseur C, Kuchenbaecker KB, Dennis J, Conti DV, Casey G, Gaudet MM, Huyghe JR, Albanes D, Aldrich MC, Andrew AS, Andrulis IL, Anton-Culver H, Antoniou AC, Antonenkova NN, Arnold SM, Aronson KJ, Arun BK, Bandera EV, Barkardottir RB, Barnes DR, Batra J, Beckmann MW, Benitez J, Benlloch S, Berchuck A, Berndt SI, Bickeböller H, Bien SA, Blomqvist C, Boccia S, Bogdanova NV, Bojesen SE, Bolla MK, Brauch H, Brenner H, Brenton JD, Brook MN, Brunet J, Brunnström H, Buchanan DD, Burwinkel B, Butzow R, Cadoni G, Caldés T, Caligo MA, Campbell I, Campbell PT, Cancel-Tassin G, Cannon-Albright L, Campa D, Caporaso N, Carvalho AL, Chan AT, Chang-Claude J, Chanock SJ, Chen C, Christiani DC, Claes KBM, Claessens F, Clements J, Collée JM, Cruz Correa M, Couch FJ, Cox A, Cunningham JM, Cybulski C, Czene K, Daly MB, deFazio A, Devilee P, Diez O, Gago-Dominguez M, Donovan JL, Dörk T, Duell EJ, Dunning AM, Dwek M, Eccles DM, Edlund CK, Velez Edwards DR, Ellberg C, Evans DG, Fasching PA, Ferris RL, Liloglou T, Figueiredo JC, Fletcher O, Fortner RT, Fostira F, Franceschi S, Friedman E, Gallinger SJ, Ganz PA, Garber J, García-Sáenz JA, Gayther SA, Giles GG, Godwin AK, Goldberg MS, Goldgar DE, Goode EL, Goodman MT, Goodman G, Grankvist K, Greene MH, Gronberg H, Gronwald J, Guénel P, Håkansson N, Hall P, Hamann U, Hamdy FC, Hamilton RJ, Hampe J, Haugen A, Heitz F, Herrero R, Hillemanns P, Hoffmeister M, Høgdall E, Hong Y-C, Hopper JL, Houlston R, Hulick PJ, Hunter DJ, Huntsman DG, Idos G, Imyanitov EN, Ingles SA, Isaacs C, Jakubowska A, James P, Jenkins MA, Johansson M, Johansson M, John EM, Joshi AD, Kaneva

R, Karlan BY, Kelemen LE, Kühl T, Khaw K-T, Khusnutdinova E, Kibel AS, Kiemeney LA, Kim J, Kjaer SK, Knight JA, Kogevinas M, Kote-Jarai Z, Koutros S, Kristensen VN, Kupryjanczyk J, Lacko M, Lam S, Lambrechts D, Landi MT, Lazarus P, Le ND, Lee E, Lejbkowicz F, Lenz H-J, Leslie G, Lessel D, Lester J, Levine DA, Li L, Li CI, Lindblom A, Lindor NM, Liu G, Loupakis F, Lubiński J, Maehle L, Maier C, Mannermaa A, Le Marchand L, Margolin S, May T, McGuffog L, Meindl A, Middha P, Miller A, Milne RL, MacInnis RJ, Modugno F, Montagna M, Moreno V, Moysich KB, Mucci L, Muir K, Mulligan AM, Nathanson KL, Neal DE, Ness AR, Neuhausen SL, Nevanlinna H, Newcomb PA, Newcomb LF, Nielsen FC, Nikitina-Zake L, Nordestgaard BG, Nussbaum RL, Offit K, Olah E, Al Olama AA, Olopade OI, Olshan AF, Olsson H, Osorio A, Pandha H, Park JY, Pashayan N, Parsons MT, Pejovic T, Penney KL, Peters WHM, Phelan CM, Phipps AI, Plaseska-Karanfilska D, Pring M, Prokofyeva D, Radice P, Stefansson K, Ramus SJ, Raskin L, Rennert G, Rennert HS, van Rensburg EJ, Riggan MJ, **Risch HA**, Risch A, Roobol MJ, Rosenstein BS, Rossing MA, De Ruyck K, Saloustros E, Sandler DP, Sawyer EJ, Schabath MB, Schleutker J, Schmidt MK, Setiawan VW, Shen H, Siegel EM, Sieh W, Singer CF, Slattery ML, Sorensen KD, Southey MC, Spurdle AB, Stanford JL, Stevens VL, Stintzing S, Stone J, Sundfeldt K, Sutphen R, Swerdlow AJ, Tajara EH, Tangen CM, Tardon A, Taylor JA, Teare MD, Teixeira MR, Terry MB, Terry KL, Thibodeau SN, Thomassen M, Bjørge L, Tischkowitz M, Toland AE, Torres D, Townsend PA, Travis RC, Tung N, Tworoger SS, Ulrich CM, Usmani N, Vachon CM, Van Nieuwenhuysen E, Vega A, Aguado-Barrera ME, Wang Q, Webb PM, Weinberg CR, Weinstein S, Weissler MC, Weitzel JN, West CML, White E, Whittemore AS, Wichmann H-E, Wiklund F, Winqvist R, Wolk A, Woll P, Woods M, Wu AH, Wu X, Yannoukakos D, Zheng W, Zienolddiny S, Ziogas A, Zorn KK, Lane JM, Saxena R, Thomas D, Hung RJ, Diergaarde B, McKay J, Peters U, Hsu L, García Closas M, Eeles RA, Chenevix-Trench G, Brennan PJ, Haiman CA, Simard J, Easton DF, Gruber SB, Pharoah PDP, Price AL, Pasaniuc B, Amos CI, Kraft P, Lindström S. Shared heritability and functional enrichment across six solid cancers. Nat Commun 2019;10(1):431. doi: 10.1038/s41467-018-08054-4. PMCID: PMC Journal in Process.

2018

Liu G, Mukherjee B, Lee S, Lee AW, Wu AH, Bandera EV, Jensen A, Rossing MA, Moysich KB, Chang-Claude J, Doherty J, Gentry-Maharaj A, Kiemeney L, Gayther SA, Modugno F, Massuger L, Goode EL, Fridley B, Terry KL, Cramer DW, Ramus SJ, Anton- Culver H, Ziogas A, Tyrer JP, Schildkraut JM, Kjaer SK, Webb PM, Ness RB, Menon U, Berchuck A, Pharoah PD, **Risch H**, Pearce CL, Ovarian Cancer Association Consortium. Robust tests for additive gene-environment interaction in case-control studies using gene-environment independence. Am J Epidemiol 2018;187(2):366-77. doi: 10.1093/aje/kwx243. PMCID: PMC Journal in Process.

Harris HR, Babic A, Webb PM, Nagle CM, Jordan SJ, Australian Ovarian Cancer Study Group, **Risch HA**, Rossing MA, Doherty JA, Goodman MT, Modugno F, Ness RB, Moysich KB, Kjær SK, Høgdall E, Jensen A, Schildkraut JM, Berchuck A, Cramer DW, Bandera EV, Wentzensen N, Kotsopoulos J, Narod SA, Phelan CM, McLaughlin JR, Anton-Culver H, Ziogas A, Pearce CL, Wu AH, Terry KL, Ovarian Cancer Association Consortium. Polycystic ovary syndrome, oligomenorrhea, and risk of ovarian cancer histotypes: Evidence from the Ovarian Cancer Association Consortium. Cancer Epidemiol Biomarkers Prev 2018;27(2):174-82. doi: 10.1158/1055-9965.EPI-17-0655. PMCID: PMC Journal in Process.

Dong J, Buas MF, Gharahkhani P, Kendall BJ, Onstad L, Zhao S, Anderson LA, Wu AH, Ye W, Bird NC, Bernstein L, Chow W-H, Gammon MD, Liu G, Caldas C, Pharoah PD, **Risch HA**,

Iyer PG, Reid BJ, Hardie LJ, Lagergren J, Shaheen NJ, Corley DA, Fitzgerald RC, Stomach and Oesophageal Cancer Study (SOCS) Consortium, Whiteman DC, Vaughan TL, Thrift AP. Determining risk of Barrett's Esophagus and esophageal adenocarcinoma based on epidemiologic factors and genetic variants. Gastroenterology 2018;154(5):1273-81.e3. doi: 10.1053/j.gastro.2017.12.003. PMCID: PMC Journal in Process.

Dong J, Levine DM, Buas MF, Zhang R, Onstad L, Fitzgerald RC, Stomach and Oesophageal Cancer Study (SOCS) Consortium, Corley DA, Shaheen NJ, Lagergren J, Hardie LJ, Reid BJ, Iyer PG, **Risch HA**, Caldas C, Caldas I, Pharoah PDP, Liu G, Gammon MD, Chow W-H, Bernstein L, Bird NC, Ye W, Wu AH, Anderson LA, MacGregor S, Whiteman DC, Vaughan TL, Thrift AP. Interactions between genetic variants and environmental factors affect risk of esophageal adenocarcinoma and Barrett's Esophagus. Clin Gastroenterol Hepatol 2018;16(10):1598-606.e4. doi: 10.1016/j.cgh.2018.03.007. PMCID: PMC Journal in Process.

Dixon-Suen SC, Nagle CM, Thrift AP, Pharoah PDP, Pirie A, Pearce CL, Zheng W, Australian Ovarian Cancer Study Group, Chenevix-Trench G, Fasching PA, Beckmann MW, Lambrechts D, Vergote I, Lambrechts S, Van Nieuwenhuysen E, Rossing MA, Doherty JA, Wicklund KG, Chang-Claude J, Jung AY, Moysich KB, Odunsi K, Goodman MT, Wilkens LR, Thompson PJ, Shvetsov YB, Dörk T, Park-Simon T-W, Hillemanns P, Bogdanova N, Butzow R, Nevanlinna H, Pelttari LM, Leminen A, Modugno F, Ness RB, Edwards RP, Kelley JL, Heitz F, du Bois A, Harter P, Schwaab I, Karlan BY, Lester J, Orsulic S, Rimel BJ, Kjær SK, Høgdall E, Jensen A, Goode EL, Fridley BL, Cunningham JM, Winham SJ, Giles GG, Bruinsma F, Milne RL, Southey MC, Hildebrandt MAT, Wu X, Lu KH, Liang D, Levine DA, Bisogna M, Schildkraut JM, Berchuck A, Cramer DW, Terry KL, Bandera EV, Olson SH, Salvesen HB, Vestrheim Thomsen LC, Kopperud RK, Bjorge L, Kiemeney LA, Massuger LFAG, Pejovic T, Bruegl A, Cook LS, Le ND, Swenerton KD, Brooks-Wilson A, Kelemen LE, Lubiński J, Huzarski T, Gronwald J, Menkiszak J, Wentzensen N, Brinton L, Yang H, Lissowska J, Høgdall CK, Lundvall L, Song H, Tyrer JP, Campbell I, Eccles D, Paul J, Glasspool R, Siddiqui N, Whittemore AS, Sieh W, McGuire V, Rothstein JH, Narod SA, Phelan C, **Risch HA**, McLaughlin JR, Anton-Culver H, Ziogas A, Menon U, Gayther SA, Ramus SJ, Gentry-Maharaj A, Wu AH, Pike MC, Tseng C-C, Kupryjanczyk J, Dansonka-Mieszkowska A, Budzilowska A, Rzepecka IK, Webb PM, Ovarian Cancer Association Consortium. Adult height is associated with increased risk of ovarian cancer: a Mendelian randomisation study. Br J Cancer 2018;118(8):1123-9. doi: 10.1038/s41416-018-0011-3. PMCID: PMC Journal in Process.

Antwi SO, Bamlet WR, Pedersen KS, Chaffee KG, **Risch HA**, Shivappa N, Steck SE, Anderson KE, Bracci PM, Polesel J, Serraino D, La Vecchia C, Bosetti C, Li D, Oberg AL, Arslan AA, Albanes D, Duell EJ, Huybrechts I, Amundadottir LT, Hoover R, Mannisto S, Chanock S, Zheng W, Shu X-O, Stepien M, Canzian F, Bueno-de-Mesquita B, Quirós JR, Zeleniuch-Jacquotte A, Bruinsma F, Milne RL, Giles GG, Hébert JR, Stolzenberg-Solomon RZ, Petersen GM. Pancreatic cancer risk is modulated by inflammatory potential of diet and ABO genotype: A consortia-based evaluation and replication study. Carcinogenesis. 2018:bgy072. doi: 10.1093/carcin/bgy072. PMCID: PMC Journal in Process.

Earp M, Tyrer JP, Winham SJ, Lin H-Y, Chornokur G, Dennis J, Aben KKH, Anton Culver H, Antonenkova N, Bandera EV, Bean YT, Beckmann MW, Bjorge L, Bogdanova N, Brinton LA, Brooks-Wilson A, Bruinsma F, Bunker CH, Butzow R, Campbell- IG, Carty K, Chang-Claude J, Cook LS, Cramer DW, Cunningham JM, Cybulski C, Dansonka-Mieszkowska A, Despierre E, Doherty JA, Dörk T, du Bois A, Dürst M, Easton DF, Eccles DM, Edwards RP, Ekici AB, Fasching PA, Fridley BL, Gentry-Maharaj A, Giles GG, Glasspool R, Goodman MT, Gronwald J, Harter P, Hein A, Heitz F, Hildebrandt MAT, Hillemanns P, Hogdall CK, Høgdall E, Hosono

S, Iversen ES, Jakubowska A, Jensen A, Ji B-T, Jung AY, Karlan BY, Kellar M, Kiemeney LA, Lim BK, Kjaer SK, Krakstad C, Kupryjanczyk J, Lambrechts D, Lambrechts S, Le ND, Lele S, Lester J, Levine DA, Li Z, Liang D, Lissowska J, Lu K, Lubinski J, Lundvall L, Massuger LFAG, Matsuo K, McGuire V, McLaughlin JR, McNeish I, Menon U, Milne RL, Modugno F, Moysich KB, Ness RB, Nevanlinna H, Odunsi K, Olson SH, Orlow I, Orsulic S, Paul J, Pejovic T, Pelttari LM, Permuth JB, Pike MC, Poole EM, Rosen B, Rossing MA, Rothstein JH, Runnebaum IB, Rzepecka IK, Schernhammer E, Schwaab I, Shu X-O, Shvetsov YB, Siddiqui N, Sieh W, Song H, Southey MC, Spiewankiewicz B, Sucheston-Campbell L, Tangen IL, Teo S-H, Terry KL, Thompson PJ, Thomsen L, Tworoger SS, van Altena AM, Vergote I, Vestrheim Thomsen LC, Vierkant RA, Walsh CS, Wang-Gohrke S, Wentzensen N, Whittemore AS, Wicklund KG, Wilkens LR, Woo Y-L, Wu AH, Wu X, Xiang Y-B, Yang H, Zheng W, Ziogas A, Lee AW, Pearce CL, Berchuck A, Schildkraut JM, Ramus SJ, Monteiro ANA, Narod SA, Sellers TA, Gayther SA, Kelemen LE, Chenevix-Trench G, **Risch HA**, Pharoah PDP, Goode EL, Phelan CM. Variants in genes encoding small GTPases and association with epithelial ovarian cancer susceptibility. PLoS One 2018;13(7):e0197561. doi: 10.1371/journal.pone.0197561. PMCID: PMC Journal in Process.

Mukhtar F, Boffetta P, Dabo B, Park JY, Tran TV, Tran HT-T, Whitney M, **Risch HA**, Le LC, Zheng W, Shu X-O, Luu HN. Disparities by race, age, and sex in the improvement of survival for lymphoma. PLoS One 2018;13(7):e0199745. doi: 10.1371/journal.pone.0199745. *Not a result of NIH funding.

Lu Y, Beeghly-Fadiel A, Wu L, Guo X, Li B, Moysich KB, Im HK, Andrulis IL, Anton-Culver H, Arun BK, Bandera EV, Barkardottir RB, Barnes DR, Barnes D, Benitez J, Bjorge L, Brenton J, Butzow R, Caldes T, Caligo MA, Campbell I, Chang-Claude J, Claes KBM, Couch FJ, Cramer DW, Daly MB, deFazio A, Dennis J, Diez O, Domchek SM, Dörk T, Easton DF, Eccles DM, Fasching PA, Fortner RT, Fountzilas G, Friedman E, Ganz PA, Garber J, Giles GG, Godwin AK, Goldgar DE, Goodman MT, Greene MH, Gronwald J, Hamann U, Heitz F, Hildebrandt MAT, Høgdall CK, Hollestelle A, Hulick PJ, Huntsman DG, Imyanitov EN, Isaacs C, Jakubowska A, James P, Karlan BY, Kelemen LE, Kiemeney LA, Kjaer SK, Kupryjanczyk J, Kwong A, Lambrechts D, Le ND, Leslie G, Lesueur F, Levine DA, May T, McGuffog L, McNeish I, Modugno F, Montagna M, Neuhausen SL, Nevanlinna H, Nielsen FC, Nikitina-Zake L, Nussbaum RL, Offit K, Olah E, Olopade OI, Olson SH, Olsson H, Osorio A, Park SK, Parsons M, Peeters PHM, Pejovic T, Peterlongo P, Phelan CM, Pujana MA, Ramus SJ, Rennert G, Riboli E, **Risch H**, Rodriguez GC, Rodríguez-Antona C, Romieu I, Rookus MA, Rossing MA, Sandler DP, Schmutzler RK, Setiawan VW, Sharma P, Sieh W, Simard J, Singer CF, Song H, Southey MC, Spurdle AB, Sutphen R, Swerdlow AJ, Teixeira MR, Teo SH, Thomassen M, Tischkowitz M, Toland AE, Tung N, Tworoger SS, van Rensburg EJ, Vega A, Edwards DV, Webb PM, Weitzel JN, Wentzensen N, White E, Wolk A, Wu AH, Yannoukakos D, Zorn KK, BCFR, EMBRACE, GEMO Study Collaborators, HEBON, KConFab Investigators, SWE-BRCA, Mod SQuaD study collaborators, GC-HBOC study collaborators, CONSIT study collaborators, Gayther SA, Antoniou AC, Berchuck A, Goode EL, Chenevix-Trench G, Sellers TA, Pharoah PDP, Zheng W, Long J. A transcriptome-wide association study among 97,898 women to identify candidate susceptibility genes for epithelial ovarian cancer risk. Cancer Res 2018;78(18):5419-30. doi: 10.1158/0008-5472.CAN-18-0951. PMCID: PMC Journal in Process.

O'Mara TA, Glubb DM, Amant F, Annibali D, Ashton K, Attia J, Auer PL, Beckmann MW, Black A, Bolla MK, Brauch H, Brenner H, Brinton L, Buchanan DD, Burwinkel B, Chang-Claude J, Chanock SJ, Chen C, Chen MM, Cheng THT, Clarke CL, Clendenning M, Cook LS, Couch FJ,

Cox A, Crous-Bous M, Czene K, Day F, Dennis J, Depreeuw J, Doherty JA, Dörk T, Dowdy SC, Dürst M, Ekici AB, Fasching PA, Fridley BL, Friedenreich CM, Fritschi L, Fung J, García-Closas M, Gaudet MM, Giles GG, Goode EL, Gorman M, Haiman CA, Hall P, Hankinson S, Healey CS, Hein A, Hillemanns P, Hodgson S, Hoivik E, Holliday EG, Hopper JL, Hunter DJ, Jones A, Krakstad C, Kristensen VN, Lambrechts D, Le Marchand L, Liang X, Lindblom A, Lissowska J, Long J, Lu L, Magliocco AM, Martin L, McEvoy M, Meindl A, Michailidou K, Milne RL, Mints M, Montgomery GW, Nassir R, Olsson H, Orlow I, Otton G, Palles C, Perry JRB, Peto J, Pooler L, Prescott J, Proietto T, Rebbeck TR, **Risch HA**, Rogers PAW, Rübner M, Runnebaum I, Sacerdote C, Sarto GE, Schumacher F, Scott RJ, Setiawan VW, Shah M, Sheng X, Shu X-O, Southey MC, Swerdlow AJ, Tham E, Trovik J, Turman C, Tyrer JP, Vachon C, VanDen Berg D, Vanderstichele A, Wang Z, Webb PM, Wentzensen N, Werner HMJ, Winham SJ, Wolk A, Xia L, Xiang Y-B, Yang HP, Yu H, Zheng W, National Study of Endometrial Cancer Genetics Group (NSECG), RENDOCAS, The Australian National Endometrial Cancer Study Group (ANECS), CHIBCHA Consortium, Pharoah PDP, Dunning AM, Kraft P, De Vivo I, Tomlinson I, Easton DF, Spurdle AB, Thompson DJ. Identification of nine new susceptibility loci for endometrial cancer. Nat Commun 2018;9(1):3166. doi: 10.1038/s41467-018-05427-7. PMCID: PMC Journal in Process.

Kelemen LE, Earp M, Fridley BL, Chenevix-Trench G, Australian Ovarian Cancer Study Group, Fasching PA, Beckmann MW, Ekici AB, Hein A, Lambrechts D, Lambrechts S, Van Nieuwenhuysen E, Vergote I, Rossing MA, Doherty JA, Chang-Claude J, Behrens S, Moysich KB, Cannioto R, Lele S, Odunsi K, Goodman MT, Shvetsov YB, Thompson PJ, Wilkens LR, Dörk T, Antonenkova N, Bogdanova N, Hillemanns P, Runnebaum IB, du Bois A, Harter P, Heitz F, Schwaab I, Butzow R, Pelttari LM, Nevanlinna H, Modugno F, Edwards RP, Kelley JL, Ness RB, Karlan BY, Lester J, Orsulic S, Walsh C, Kjaer SK, Jensen A, Cunningham JM, Vierkant RA, Giles GG, Bruinsma F, Southey MC, Hildebrandt MAT, Liang D, Lu K, Wu X, Sellers TA, Levine DA, Schildkraut JM, Iversen ES, Terry KL, Cramer DW, Tworoger SS, Poole EM, Bandera EV, Olson SH, Orlow I, Vestrheim LC, Bjorge L, Krakstad C, Tangen IL, Kiemeney LA, Aben KKH, Massuger LFAG, van Altena AM, Pejovic T, Bean Y, Kellar M, Cook LS, Le ND, Brooks-Wilson A, Gronwald J, Cybulski C, Jakubowska A, Lubiński J, Wentzensen N, Brinton LA, Lissowska J, Hogdall E, Engelholm SA, Hogdall C, Lundvall L, Nedergaard L, Pharoah PDP, Dicks E, Song H, Tyrer JP, McNeish I, Siddiqui N, Carty K, Glasspool R, Paul J, Campbell IG, Eccles D, Whittemore AS, McGuire V, Rothstein JH, Sieh W, Narod SA, Phelan CM, McLaughlin JR, **Risch HA**, Anton-Culver H, Ziogas A, Menon U, Gayther SA, Gentry-Maharaj A, Ramus SJ, Wu AH, Pearce CL, Lee AW, Pike MC, Kupryjanczyk J, Podgorska A, Plisiecka-Halasa J, Sawicki W, Goode EL, Berchuck A, Ovarian Cancer Association Consortium. rs495139 in the TYMS-ENOSF1 region and risk of ovarian carcinoma of mucinous histology. Int J Mol Sci 2018;19(9). pii: E2473. doi: 10.3390/ijms19092473. PMCID: PMC Journal in Process.

Visvanathan K, Shaw P, May B, Bahadirli-Talbot A, Kaushiva A, **Risch H**, Narod S, Wang T-L, Parkash V, Vang R, Levine D, Soslow R, Kurman R, Shih I-M. Fallopian tube lesions in women at high risk for ovarian cancer: A multicenter study. Accepted for publication, Cancer Prev Res (Phila) 2018;11(11):697-706. doi: 10.1158/1940-6207.CAPR-18-0009. PMCID: PMC Journal in Process.

Walsh N, Zhang H, Hyland P, Yang Q, Mocci E, Zhang M, Childs EJ, Collins I, Wang Z, Arslan AA, Beane-Freeman L, Bracci PM, Canzian F, Duell EJ, Gallinger S, Giles GG, Goodman GE, Goodman PJ, Kooperberg C, LeMarchand L, Neale RE, Olson SH, Scelo G, Shu XO, Van Den Eeden SK, Visvanathan K, White E, Zheng W, Albanes D, Andreotti G, Babic A, Bamlet WR,

Berndt SI, Borgida A, Boutron-Ruault MC, Brais L, Brennan P, Bueno de-Mesquita B, Buring J, Chaffee KG, Chanock S, Cleary S, Cotterchio M, Foretova L, Fuchs C, Gaziano JMM, Giovannucci E, Goggins M, Hackert T, Haiman C, Hartge P, Hasan M, Helzlsouer KJ, Herman J, Holcatova I, Holly EA, Hoover R, Hung RJ, Janout V, Klein EA, Kurtz RC, Laheru D, Lee I-M, Lu L, Malats N, Mannisto S, Milne RL, Oberg AL, Orlow I, Patel AV, Peters U, Porta M, Real FX, Rothman N, Sesso HD, Severi G, Silverman D, Strobel O, Sund M, Thornquist MD, Tobias GS, Wactawski-Wende J, Wareham N, Weiderpass E, Wentzensen N, Wheeler W, Yu H, Zeleniuch-Jacquotte A, Kraft P, Li D, Jacobs EJ, Petersen GM, Wolpin BM, **Risch HA**, Amundadottir LT, Yu K, Klein AP, Stolzenberg-Solomon RZ. Agnostic pathway/gene set analysis of genome-wide association data identifies associations for pancreatic cancer. J Natl Cancer Inst 2018:djy155. doi: 10.1093/jnci/djy155. PMCID: PMC Journal in Process.

Klein AP,* Wolpin BM,* **Risch HA,*** Stolzenberg-Solomon RZ,* Mocci E, Zhang M, Obazee O, Childs EJ, Hoskins JW, Jermusyk A, Zhong J, Chen F, Albanes D, Andreotti G, Arslan AA, Babic A, Bamlet WR, Beane-Freeman L, Berndt SI, Blackford A, Borges M, Borgida A, Bracci PM, Brais L, Brennan P, Brenner H, Bueno-de-Mesquita B, Buring J, Campa D, Capurso G, Cavestro GM, Chaffee KG, Chung C, Cleary S, Cotterchio M, Dijk F, Duell EJ, Foretova L, Fuchs C, Funel N, Gallinger S, Gaziano JMM, Gazouli M, Giles GG, Giovannucci E, Goggins M, Goodman GE, Goodman PJ, Hackert T, Haiman C, Hartge P, Hasan M, Hegyi P, Helzlsouer KJ, Herman J, Holcatova I, Holly EA, Hoover R, Hung RJ, Jacobs EJ, Jamroziak K, Janout V, Kaaks R, Khaw K-T, Klein EA, Kogevinas M, Kooperberg C, Kulke MH, Kupcinskas J, Kurtz RJ, Laheru D, Landi S, Lawlor RT, Lee I-M, LeMarchand L, Lu L, Malats N, Mambrini A, Mannisto S, Milne RL, Mohelníková-DuchoHová B, Neale RE, Neoptolemos JP, Oberg AL, Olson SH, Orlow I, Pasquali C, Patel AV, Peters U, Pezzilli R, Porta M, Real FX, Rothman N, Scelo G, Sesso HD, Severi G, Shu X-O, Silverman D, Smith JP, Soucek P, Sund M, Talar-Wojnarowska R, Tavano F, Thornquist MD, Tobias GS, Van Den Eeden SK, Vashist Y, Visvanathan K, Vodicka P, Wactawski-Wende J, Wang Z, Wentzensen N, White E, Yu H, Yu K, Zeleniuch-Jacquotte A, Zheng W, Kraft P, Li D, Chanock S, Canzian F, Petersen GM, Amundadottir LT. Genome-wide meta-analysis identifies five new susceptibility loci for pancreatic cancer. Nat Commun 2018;9:556. PMCID: PMC Journal in Process.

Peres LC, **Risch H**, Terry KL, Webb PM, Goodman MT, Wu AH, Alberg AJ, Bandera EV, Barnholtz-Sloan J, Bondy ML, Cote ML, Funkhouser E, Moorman PG, Peters ES, Schwartz AG, Terry PD, Manichaikul A, Abbott SE, Camacho F, Jordan SJ, Nagle CM, Australian Ovarian Cancer Study Group, Rossing MA, Doherty JA, Modugno F, Moysich K, Ness R, Berchuck A, Cook L, Le N, Brooks-Wilson A, Sieh W, Whittemore A, McGuire V, Rothstein J, Anton-Culver H, Ziogas A, Pearce CL, Tseng C, Pike M, Schildkraut JM, African American Cancer Epidemiology Study, Ovarian Cancer Association Consortium. Racial/ethnic differences in the epidemiology of ovarian cancer: A pooled analysis of 12 case-control studies. Int J Epidemiol 2018;47(2):460-72. PMCID: PMC Journal in Process.

Babic A, Harris HR, Vitonis AV, Titus LJ, Jordan SJ, Webb PM, Australian Ovarian Cancer Study Group, **Risch HA**, Rossing MA, Doherty JA, Wicklund K, Goodman MT, Modugno F, Moysich KB, Ness R, Kjaer SK, Schildkraut J, Berchuck A, Pierce CL, Wu AH, Cramer DW, Terry KL. Menstrual pain and risk of epithelial ovarian cancer: results from the Ovarian Cancer Association Consortium. Int J Cancer 2018;142(3):460-9. PMCID: PMC Journal in Process.

2017

Zhou Y, Cartmel B, Gottlieb L, Ercolano EA, Li F, Harrigan M, McCorkle R, Ligibel JA, von Gruenigen VE, Gogoi R, Schwartz PE, **Risch HA**, Irwin ML. Randomized trial of exercise on

quality of life in women with ovarian cancer: Women's Activity and Lifestyle Study in Connecticut (WALC). J Natl Cancer Inst 2017;109(12):djx072. doi: 10.1093/jnci/djx072. PMCID: PMC Journal in Process.

Streicher SA, Klein AP, Olson SH, Amundadottir LT, DeWan AT, Zhao H, **Risch HA**. Impact of sixteen established pancreatic cancer susceptibility loci in American Jews. Cancer Epidemiol Biomarkers Prev 2017;26(10):1540-8. PMCID: PMC Journal in Process.

Risch HA, Lu L, Streicher SA, Wang J, Zhang W, Ni Q, Kidd MS, Yu H, Gao Y-T. Aspirin use and reduced risk of pancreatic cancer. Cancer Epidemiol Biomarkers Prev 2017;26(1):68-74. PMCID: PMC5225096.

Li N, Petrick JL, Steck SE, Bradshaw PT, McClain KM, Niehoff NM, Engel LS, Shaheen NJ, **Risch HA**, Vaughan TL, Wu AH, Gammon MD. A pooled analysis of dietary sugar/carbohydrate intake and esophageal and gastric cardia adenocarcinoma incidence and survival in the United States (US). Int J Epidemiol 2017;46(6):1836-46. PMCID: PMC Journal in Process.

McGee J, Gianneakas V, Karlan B, Lubinski J, Gronwald J, Rosen B, McLaughlin J, **Risch H**, Sun P, Foulkes WD, Neuhausen S, Kotsopoulos J, Narod SA, Hereditary Ovarian Cancer Clinical Study Group. Risk of breast cancer after a diagnosis of ovarian carcinoma cancer in *BRCA* mutation carriers: is preventive mastectomy warranted? Gynecol Oncol 2017;145(2):346-51. *NIH funding pre-dates mandate.

Mukhtar F, Boffetta P, **Risch HA**, Bubu OM, Womack L, Tran TV, Zgibor JC, Luu HN. Survival predictors of Burtkitt's Lymphoma in children, adults and elderly in the United States during 2000-2013. Int J Cancer 2017;140(7):1494-502. *Not a result of NIH funding.

Rasmussen CB, Kjaer SK, Albieri V, Bandera EV, Doherty JA, Høgdall E, Webb PM, Jordan SJ, AOCS Study Group, Rossing MA, Wicklund KG, Goodman MT, Modugno F, Moysich KB, Ness RB, Edwards RP, Schildkraut JM, Berchuck A, Olson SH, Kiemeney LA, Massuger LFAG, Narod SA, Phelan C, Anton-Culver H, Ziogas A, Wu AH, Pearce CL, **Risch HA**, Jensen A, on behalf of the Ovarian Cancer Association Consortium. Pelvic inflammatory disease and risk of ovarian cancer and borderline ovarian tumors: a pooled analysis of 13 case-control studies. Am J Epidemiol 2017;185(1):8-20. PMCID: PMC Journal in Process.

Buas MF, He Q, Johnson LG, Onstad L, Levine DM, Thrift AP, Gharahkhani P, Palles C, Lagergren J, Fitzgerald RC, Ye W, Caldas C, Bird NC, Shaheen NJ, Bernstein L, Gammon MD, Wu AH, Hardie LJ, Pharoah PD, Liu G, Iyer P, Corley DA, **Risch HA**, Chow WH, Prenen H, Chegwidden L, Love S, Attwood S, Moayyedi P, MacDonald D, Harrison R, Watson P, Barr H, deCaestecker J, Tomlinson I, Jankowski J, Whiteman DC, MacGregor S, Vaughan TL, Madeleine MM. Germline variation in inflammation-related pathways and risk of Barrett's oesophagus and oesophageal adenocarcinoma. Gut 2017;66(10):1739-47. PMCID: PMC Journal in Process.

Akbari MR, Zhang S, Cragun D, Lee JH, Coppola D, McLaughlin J, **Risch HA**, Rosen B, Shaw P, Sellers TA, Schildkraut J, Narod SA, Pal T. Correlation between germline mutations in MMR genes and microsatellite instability in ovarian cancer specimens. Fam Cancer 2017;16(3):351-5. PMCID: PMC Journal in Process.

Kotsopoulos J, Sopik V, Rosen B, Fan I, McLaughlin JR, **Risch H**, Sun P, Narod SA, Akbari MR. Frequency of germline PALB2 mutations among women with epithelial ovarian cancer. Fam Cancer 2017;16(1):29-34. PMCID: PMC Journal in Process.

Kim SJ, Rosen B, Fan I, Ivanova A, McLaughlin JR, **Risch H**, Narod SA, Kotsopoulos J.

Epidemiologic factors that predict long-term survival following a diagnosis of epithelial ovarian cancer. Br J Cancer 2017;116(7):964-71. PMCID: PMC Journal in Process.

Præstegaard C, Jensen A, Jensen SM, Nielsen TSS, Webb PM, Nagle CM, DeFazio A, Australian Ovarian Cancer Study Group, Høgdall E, Rossing MA, Doherty JA, Wicklund KG, Goodman MT, Modugno F, Moysich K, Ness RB, Edwards R, Matsuo K, Hosono S, Goode EL, Winham SJ, Fridley BL, Cramer DW, Terry KL, Schildkraut JM, Berchuck A, Bandera EV, Paddock LE, Massuger LFAG, Wentzensen N, Pharoah P, Song H, Whittemore A, McGuire V, Sieh W, Rothstein J, Anton-Culver H, Ziogas A, Menon U, Gayther SA, Ramus SJ, Gentry-Maharaj A, Wu AH, Pearce CL, Pike M, Lee AW, Sutphen R, Chang-Claude J, **Risch HA**, Kjaer SK, Ovarian Cancer Association Consortium. Cigarette smoking is associated with adverse survival among women with ovarian cancer: results from a pooled analysis of 19 studies. Int J Cancer 2017;140(11):2422-35. PMCID: PMC Journal in Process.

Kar SP, Adler E, Tyrer J, Hazelett D, Anton-Culver H, Bandera EV, Beckmann MW, Berchuck A, Bogdanova N, Brinton L, Butzow R, Campbell I, Carty K, Chang-Claude J, Cook LS, Cramer DW, Cunningham JM, Dansonka-Mieszkowska A, Anne Doherty JA, Dörk T, Dürst M, Eccles D, Fasching PA, Flanagan J, Gentry-Maharaj A, Glasspool R, Goode EL, Goodman MT, Gronwald J, Heitz F, Hildebrandt MAT, Høgdall E, Høgdall CK, Huntsman DG, Jensen A, Karlan BY, Kelemen LE, Kiemeney LA, Kjaer SK, Kupryjanczyk J, Lambrechts D, Levine DA, Li Q, Lissowska J, Lu KH, Lubiński J, Massuger LFAG, McGuire V, McNeish I, Menon U, Modugno F, Monteiro AN, Moysich KB, Ness RB, Nevanlinna H, Paul J, Pearce CL, Pejovic T, Permuth JB, Phelan C, Pike MC, Poole EM, Ramus SJ, **Risch HA**, Rossing MA, Salvesen HB, Schildkraut JM, Sellers TA, Sherman M, Siddiqui N, Sieh W, Song H, Southey M, Terry KL, Tworoger SS, Walsh C, Wentzensen N, Whittemore AS, Wu AH, Yang H, Zheng W, Ziogas A, Freedman ML, Gayther SA, Pharoah PDP, Lawrenson K. Enrichment of putative PAX8 target genes at serous epithelial ovarian cancer susceptibility loci. Br J Cancer 2017;116(4):524-35. PMCID: PMC Journal in Process.

Lindström S, Finucane H, Bulik-Sullivan B, Schumacher F, Amos C, Hung R, Rand K, Gruber SB, Conti D, Permuth-Wey J, Lin H-Y, Sellers TA, Amundadottir L, Stolzenberg-Solomon R, Klein A, Petersen G, **Risch H**, Wolpin B, Peters U, GECCO Consortium, Eeles R, Easton D, Haiman CA, Hunter DJ, Neale B, Price A, Kraft P, PanScan, GECCO Consortium, CORECT Consortium, DRIVE Consortium, ELLIPSE Consortium, FOCI Consortium, TRICL Consortium. Quantifying the genetic correlation between multiple cancer types. Cancer Epidemiol Biomarkers Prev 2017;26(9):1427-35. PMCID: PMC Journal in Process.

Jordan SJ, Na R, Johnatty SE, Wise LA, Adami HO, Brinton LA, Chen C, Cook, LS, Dal Maso L, De Vivo I, Freudenheim JL, Friedenreich CM, La Vecchia C, McCann SE, Moysich KB, Lu L, Olson SH, Palmer JR, Petruzella S, Pike MC, Rebbeck TR, Ricceri F, **Risch HA**, Sacerdote C, Setiawan VW, Sponholtz TR, Shu XO, Spurdle AB, Weiderpass E, Wentzensen N, Yang HP, Yu H, Webb PM. Breastfeeding and endometrial cancer risk: an analysis from the Epidemiology of Endometrial Cancer Consortium. Obstet Gynecol 2017;129(6):1059-67. PMCID: PMC Journal in Process.

Telomeres Mendelian Randomization Collaboration, Haycock PC, Burgess S, Nounu A, Zheng J, Okoli GN, Bowden J, Wade KH, Timpson NJ, Evans DM, Willeit P, Aviv A, Gaunt TR, Hemani G, Mangino M, Ellis HP, Kurian KM, Pooley KA, Eeles RA, Lee JE, Fang S, Chen WV, Law MH, Bowdler LM, Iles MM, Yang Q, Worrall BB, Markus HS, Hung RJ, Amos CI, Spurdle AB, Thompson DJ, O'Mara TA, Wolpin B, Amundadottir L, Stolzenberg-Solomon R, Trichopoulou A, Onland-Moret NC, Lund E, Duell EJ, Canzian F, Severi G, Overvad K, Gunter

MJ, Tumino R, Svenson U, van Rij A, Baas AF, Bown MJ, Samani NJ, van t'Hof FNG, Tromp G, Jones GT, Kuivaniemi H, Elmore JR, Johansson M, Mckay J, Scelo G, Carreras-Torres R, Gaborieau V, Brennan P, Bracci PM, Neale RE, Olson SH, Gallinger S, Li D, Petersen GM, **Risch HA**, Klein AP, Han J, Abnet CC, Freedman ND, Taylor PR, Maris JM, Aben KK, Kiemeney LA, Vermeulen SH, Wiencke JK, Walsh KM, Wrensch M, Rice T, Turnbull C, Litchfield K, Paternoster L, Standl M, Abecasis GR, SanGiovanni JP, Li Y, Mijatovic V, Sapkota Y, Low SK, Zondervan KT, Montgomery GW, Nyholt DR, van Heel DA, Hunt K, Arking DE, Ashar FN, Sotoodehnia N, Woo D, Rosand J, Comeau ME, Brown WM, Silverman EK, Hokanson JE, Cho MH, Hui J, Ferreira MA, Thompson PJ, Morrison AC, Felix JF, Smith NL, Christiano AM, Petukhova L, Betz RC, Fan X, Zhang X, Zhu C, Langefeld CD, Thompson SD, Wang F, Lin X, Schwartz DA, Fingerlin T, Rotter JI, Cotch MF, Jensen RA, Munz M, Dommisch H, Schaefer AS, Han F, Ollila HM, Hillary RP, Albagha O, Ralston SH, Zeng C, Zheng W, Shu XO, Reis A, Uebe S, Hüffmeier U, Kawamura Y, Otowa T, Sasaki T, Hibberd ML, Davila S, Xie G, Siminovitch K, Bei JX, Zeng YX, Försti A, Chen B, Landi S, Franke A, Fischer A, Ellinghaus D, Flores C, Noth I, Ma SF, Foo JN, Liu J, Kim JW, Cox DG, Delattre O, Mirabeau O, Skibola CF, Tang CS, Garcia-Barcelo M, Chang KP, Su WH, Chang YS, Martin NG, Gordon S, Wade TD, Lee C, Kubo M, Cha PC, Nakamura Y, Levy D, Kimura M, Hwang SJ, Hunt S, Spector T, Soranzo N, Manichaikul AW, Barr RG, Kahali B, Speliotes E, Yerges-Armstrong LM, Cheng CY, Jonas JB, Wong TY, Fogh I, Lin K, Powell JF, Rice K, Relton CL, Martin RM, Davey Smith G. Association between telomere length and risk of cancer and non-neoplastic diseases: a mendelian randomization study. JAMA Oncol 2017;3(5):636-51. PMCID: PMC Journal in Process.

Minlikeeva AN, Freudenheim JL, Cannioto RA, Szender JB, Eng KH, Modugno F, Ness RB, LaMonte MJ, Friel G, Segal BH, Odunsi K, Mayor P, Zsiros E, Schmalfeldt B, Klapdor R, Dçrk T, Hillemanns P, Kelemen LE, Kçbel M, Steed H, de Fazio A; Australian Ovarian Cancer Study Group, Jordan SJ, Nagle CM, **Risch HA**, Rossing MA, Doherty JA, Goodman MT, Edwards R, Matsuo K, Mizuno M, Karlan BY, Kjær SK, Høgdall E, Jensen A, Schildkraut JM, Terry KL, Cramer DW, Bandera EV, Paddock LE, Kiemeney LA, Massuger LF, Kupryjanczyk J, Berchuck A, Chang-Claude J, Diergaarde B, Webb PM, Moysich KB; Ovarian Cancer Association Consortium. History of hypertension, heart disease, and diabetes and ovarian cancer patient survival: evidence from the ovarian cancer association consortium. Cancer Causes Control 2017;28(5):469-86. PMCID: PMC Journal in Process.

Dixon SC, Nagle CM, Wentzensen N, Trabert B, Beeghly-Fadiel A, Schildkraut JM, Moysich KB, deFazio A; Australian Ovarian Cancer Study Group, **Risch HA**, Rossing MA, Doherty JA, Wicklund KG, Goodman MT, Modugno F, Ness RB, Edwards RP, Jensen A, Kjær SK, Høgdall E, Berchuck A, Cramer DW, Terry KL, Poole EM, Bandera EV, Paddock LE, Anton-Culver H, Ziogas A, Menon U, Gayther SA, Ramus SJ, Gentry-Maharaj A, Pearce CL, Wu AH, Pike MC, Webb PM. Use of common analgesic medications and ovarian cancer survival: results from a pooled analysis in the Ovarian Cancer Association Consortium. Br J Cancer 2017;116(9):1223-8. PMCID: PMC Journal in Process.

Phelan CM, Kuchenbaecker KB, Tyrer JP, Kar SP, Lawrenson K, Winham SJ, Dennis J, Pirie A, Riggan M, Chornokur G, Earp MA, Lyra PC Jr, Lee JM, Coetzee S, Beesley J, McGuffog L, Soucy P, Dicks E, Lee A, Barrowdale D, Lecarpentier J, Leslie G, Aalfs CM, Aben KKH, Adams M, Adlard J, Andrulis IL, Anton-Culver H, Antonenkova N, AOCS study group, Aravantinos G, Arnold N, Arun BK, Arver B, Azzollini J, Balmaña J, Banerjee SN, Barjhoux L, Barkardottir RB, Bean Y, Beckmann MW, Beeghly-Fadiel A, Benitez J, Bermisheva M, Bernardini M, Birrer MJ, Bisogna M, Bjorge L, Black A, Blankstein K, Blok MJ, Bodelon C,

Bogdanova N, Bojesen A, Bonanni B, Borg Å, Bradbury AR, Brenton JD, Brewer C, Brinton L, Broberg P, Brooks-Wilson A, Bruinsma F, Brunet J, Buecher B, Butzow R, Buys SS, Caldes T, Caligo MA, Campbell I, Cannioto R, Carney ME, Cescon T, Chan SB, Chang-Claude J, Chanock S, Chen XQ, Chiew Y-E, Chiquette J, Chung WK, Claes KBM, Conner T, Cook LS, Cook J, Cramer DW, Cunningham JM, D'Aloisio AA, Daly MB, Damiola F, Damirovna SD, Dansonka-Mieszkowska A, Dao F, Davidson R, DeFazio A, Delnatte C, Doheny KF, Diez O, Ding YC, Doherty JA, Domchek SM, Dorfling CM, Dörk T, Dossus L, Duran M, Dürst M, Dworniczak B, Eccles D, Edwards T, Eeles R, Eilber U, Ejlertsen B, Ekici AB, Ellis S, Elvira M, EMBRACE Study, Eng KH, Engel C, Evans DG, Fasching PA, Ferguson S, Ferrer SF, Flanagan JM, Fogarty ZC, Fortner RT, Fostira F, Foulkes WD, Fountzilas G, Fridley BL, Friebel TM, Friedman E, Frost D, Ganz PA, Garber J, García MJ, Garcia-Barberan V, Gehrig A, GEMO Study Collaborators, Gentry-Maharaj A, Gerdes A-M, Giles GG, Glasspool R, Glendon G, Godwin AK, Goldgar DE, Goranova T, Gore M, Greene MH, Gronwald J, Gruber S, Hahnen E, Haiman CA, Håkansson N, Hamann U, Hansen TVO, Harrington PA, Harris HR, Hauke J, HEBON Study, Hein A, Henderson A, Hildebrandt MAT, Hillemanns P, Hodgson S, Høgdall CK, Høgdall E, Hogervorst FBL, Holland H, Hooning MJ, Hosking K, Huang R-Y, Hulick PJ, Hung J, Hunter DJ, Huntsman DG, Huzarski T, Imyanitov EN, Isaacs C, Iversen ES, Izatt L, Izquierdo A, Jakubowska A, James P, Janavicius R, Jernetz M, Jensen A, Jensen UB, John EM, Johnatty S, Jones ME, Kannisto P, Karlan BY, Karzenis A, Kast K, KConFab Investigators, Kennedy CJ, Khusnutdinova E, Kiemeney LA, Kiiski JI, Kim S-W, Kjaer SK, Köbel M, Kopperud RK, Kruse TA, Kupryjanczyk J, Kwong A, Laitman Y, Lambrechts D, Larrañaga N, Larson MC, Lazaro C, Le ND, Marchand LL, Lee JW, Lele SB, Leminen A, Leroux D, Lester J, Lesueur F, Levine DA, Liang D, Liebrich C, Lilyquist J, Lipworth L, Lissowska J, Lu KH, Lubiński J, Luccarini C, Lundvall L, Mai PL, Mendoza-Fandiño G, Manoukian S, Massuger LFAG, May T, Mazoyer S, McAlpine J, McGuire V, McLaughlin JR, McNeish I, Meijers-Heijboer HEJ, Meindl A, Menon U, Mensenkamp AR, Merritt M, Milne RL, Mitchell G, Modugno F, Moes-Sosnowska J, Moffitt M, Montagna M, Moysich KB, Mulligan AM, Musinsky J, Nathanson KL, Nedergaard L, Ness RB, Neuhausen SL, Nevanlinna H, Niederacher D, Nussbaum RL, Odunsi K, Olah E, Olopade OI, Olsson H, Olswold C, O'Malley DM, Ong K-r, Onland-Moret NC, OPAL study group, Orr N, Orsulic S, Osorio A, Palli D, Papi L, Park-Simon T-W, Paul J, Pearce CL, Pedersen IS, Peeters PHM, Peissel B, Peixoto A, Pejovic T, Pelttari LM, Permuth JB, Peterlongo P, Pezzani L, Pfeiler G, Phillips K-A, Piedmonte M, Pike MC, Piskorz AM, Poblete SR, Pocza T, Poole EM, Poppe B, Porteous ME, Prieur F, Prokofyeva D, Pugh E, Pujana MA, Pujol P, Radice P, Rantala J, Rappaport-Fuerhauser C, Rennert G, Rhiem K, Rice P, Richardson A, Robson M, Rodriguez GC, Rodríguez-Antona C, Romm J, Rookus MA, Rossing MA, Rothstein JH, Rudolph A, Runnebaum IB, Salvesen HB, Sandler DP, Schoemaker MJ, Senter L, Setiawan VW, Severi G, Sharma P, Shelford T, Siddiqui N, Side LE, Sieh W, Singer CF, Sobol H, Song H, Southey MC, Spurdle AB, Stadler Z, Steinemann D, Stoppa-Lyonnet D, Sucheston-Campbell LE, Sukiennicki G, Sutphen R, Sutter C, Swerdlow AJ, Szabo CI, Szafron L, Tan YY, Taylor JA, Tea M-K, Teixeira MR, Teo S-H, Terry KL, Thompson PJ, Thomsen LCV, Thull DL, Tihomirova L, Tinker AV, Tischkowitz M, Tognazzo S, Toland AE, Tone A, Trabert B, Travis R, Trichopoulou A, Tung N, Tworoger SS, van Altena AM, Van Den Berg D, van der Hout AH, van der Luijt RB, Van Heetvelde M, Van Nieuwenhuysen E, van Rensburg EJ, Vanderstichele A, Varon-Mateeva R, Vega A, Edwards DV, Vergote I, Vierkant RA, Vijai J, Vratimos A, Walker L, Walsh C, Wand D, Wang-Gohrke S, Wappenschmidt B, Webb PM, Weinberg CR, Weitzel JN, Wentzensen N, Whittemore AS, Wijnen JT, Wilkens LR, Wolk A, Woo M, Wu X, Wu AH, Yang H, Yannoukakos D, Ziogas A, Zorn KK, Narod SA, Easton DF,

Amos CI, Schildkraut JM, Ramus SJ, Ottini L, Goodman MT, Park SK, Kelemen LE, **Risch HA**, Thomassen M, Offit K, Simard J, Schmutzler RK, Hazelett D, Monteiro AN, Couch FJ, Berchuck A, Chenevix-Trench G, Goode EL, Sellers TA, Gayther SA, Antoniou AC, Pharoah PDP. Identification of 12 new susceptibility loci for different histotypes of epithelial ovarian cancer. Nat Genet 2017;49(5):680-91. PMCID: PMC Journal in Process.

Minlikeeva AN, Freudenheim JL, Eng KH, Cannioto RA, Friel G, Szender JB, Segal B, Odunsi K, Mayor P, Diergaarde B, Zsiros E, Kelemen L, Köbel M, Steed H, de Fazio A, Australian Ovarian Cancer Study Group, Jordan S, Fasching PA, Beckmann MW, **Risch HA**, Rossing MA, Doherty JA, Chang-Claude J, Goodman MT, Dçrk T, Edwards R, Modugno F, Ness RB, Matsuo K, Mizuno M, Karlan BY, Goode EL, Kjær SK, Høgdall E, Schildkraut JM, Terry KL, Cramer DW, Bandera EV, Paddock L, KiemeneyLA, Massuger LF, Sutphen R, Anton-Culver H, Ziogas A, Menon U, Gayther S, Ramus S, Gentry-Maharaj A, Pearce CL, Kupryjanczyk J, Jensen A, Webb PM, Moysich KB, Ovarian Cancer Association Consortium. History of comorbidities and survival of ovarian cancer patients, results from the Ovarian Cancer Association Consortium. Cancer Epidemiol Biomarkers Prev 2017;26(9):1470-3. PMCID: PMC Journal in Process.

2016

Chen MM, O'Mara TA, Thompson DJ, Painter JN, Australian National Endometrial Cancer Study Group (ANECS), Attia J, Black A, Brinton L, Chanock S, Chen C, Chen C, Cheng THT, Cook LS, Crous-Bou M, Doherty J, Friedenreich CM, Garcia-Closas M, Gaudet MM, Gorman M, Haiman C, Hankison SE, Hartge P, Henderson BE, Hodgson S, Holliday EG, Horn-Ross PL, Hunter DJ, Le Marchand L, Liang X, Lissowska J, Long J, Lu L, Magliocco AM, Martin L, McEvoy M, National Study of Endometrial Cancer Genetics Group (NSECG), Olson SH, Orlow I, Pooler L, Prescott J, Rastogi R, Rebbeck TR, **Risch H**, Sacerdote C, Schumacher F, Setiawan VW, Scott RJ, Sheng X, Shu X-O, VanDen Berg D, Weiss NS, Wentzensen N, Xia L, Xiang Y-B, Yang HP, Yu H, Zhang W, Pharoah PDP, Dunning AM, Tomlinson I, Easton DF, Kraft P, Spurdle AB, De Vivo I. GWAS meta-analysis of 16,852 women identifies new susceptibility locus for endometrial cancer. Hum Mol Genet 2016;25(12):2612-20. PMCID: PMC5868213.

Fu Y, Biglia N, Wang Z, Shen Y, **Risch HA**, Lu L, Canuto EM, Jia W, Katsaros D, Yu H. Long non-coding RNAs, *ASAP1-IT1*, *FAM215A*, and *LINC00472*, in epithelial ovarian cancer. Gyn Oncol 2016;143(3):642-9. *Not a result of NIH funding.

Schulte A, Pandeya N, Fawcett J, Fritschi L, Klein K, **Risch HA**, Webb PM, Whiteman DC, Neale RE. Association between family cancer history and risk of pancreatic cancer. Cancer Epidemiol 2016;45:145-50. *Not a result of NIH funding.

Lu L, **Risch, HA**. Exosomes: potential for early detection in pancreatic cancer. Future Oncol 2016;12(8):1081-90. *Not a result of NIH funding.

Lu L, Katsaros D, Canuto EM, Biglia N, **Risch HA**, Yu H. LIN-28B/let-7a/IGF-II axis molecular subtypes are associated with epithelial ovarian cancer prognosis. Gynecol Oncol 2016;141(1):121-7. *Not a result of NIH funding.

Wei R, De Vivo I, Huang S, **Risch H**, Moore JH, Yu H, Garmire LX. Meta-dimensional data integration identifies critical pathways for susceptibility, tumorigenesis and progression of endometrial cancer. Oncotarget 2016;7(34):55249-63. PMCID: PMC5342415.

Clyde MA, Palmieri Weber RP, Iversen ES, Poole EM, Doherty JA, Goodman MT, Ness RB, **Risch HA**, Rossing MA, Terry KL, Wentzensen N, Whittemore AS, Anton-Culver H, Bandera

EV, Berchuck A, Carney ME, Cramer DW, Cunningham JM, Cushing-Haugen KL, Edwards RP, Fridley BL, Goode EL, Lurie G, McGuire V, Modugno F, Moysich KB, Olson SH, Pearce CL, Pike MC, Rothstein JH, Sellers TA, Sieh W, Stram D, Thompson PJ, Vierkant RA, Wicklund KG, Wu AH, Ziogas A, Tworoger SS, Schildkraut JM, Ovarian Cancer Association Consortium. Risk prediction for epithelial ovarian cancer in eleven United States-based case-control studies: incorporation of epidemiologic risk factors and 17 confirmed genetic loci. Am J Epidemiol 2016;184(8):579-89. PMCID: PMC5065620.

Karami S, Han Y, Pande M, Cheng I, Rudd J, Pierce BL, Nutter EL, Schumacher FR, Kote-Jarai Z, Lindstrom S, Witte JS, Fang S, Han J, Kraft P, Hunter D, Song F, Hung RJ, McKay J, Gruber SB, Chanock SJ, Risch A, Shen H, Haiman CA, Boardman L, Ulrich CM, Casey G, Peters U, Al Olama AA, Berchuck A, Berndt SI, Bezieau S, Brennan P, Brenner H, Brinton L, Caporaso N, Chan AT, Chang-Claude J, Christiani DC, Cunningham JM, Easton D, Eeles RA, Eisen T, Gala M, Gallinger SJ, Gayther SA, Goode EL, Grönberg H, Henderson BE, Houlston R, Joshi AD, Küry S, Landi MT, Le Marchand L, Muir K, Newcomb PA, Permuth-Wey J, Pharoah P, Phelan C, Potter JD, Ramus SJ, **Risch H**, Schildkraut J, Slattery ML, Song H, Wentzensen N, White E, Wiklund F, Zanke BW, Sellers TA, Zheng W, Chatterjee N, Amos CI, Doherty JA, GECCO and the GAME-ON Network: CORECT, DRIVE, ELLIPSE, FOCI, and TRICL. Telomere structure and maintenance gene variants and risk of five cancer types. Int J Cancer 2016;139(12):2655-70. PMCID: PMC5198774.

Machiela MJ, Zhou W, Karlins E, Sampson JN, Freedman ND, Yang Q, Hicks B, Dagnall C, Hautman C, Jacobs KB, Abnet CC, Aldrich MC, Amos C, Amundadottir LT, Berndt SI, Black A, Blot WJ, Bock CH, Bracci PM, Brinton LA, Burdett L, Buring JE, Butler MA, Carreón T, Chang I-S, Chatterjee N, Chen C, Chen C, Chen K, Chung CC, Cook LS, Bou MC, Cullen M, Davis FG, De Vivo I, Ding T, Doherty J, Duell EJ, Epstein CG, Fan J-H, Figueroa JD, Fraumeni JF Jr, Friedenreich CM, Fuchs CS, Gao Y-T, Gapstur SM, Garcia-Closas M, Gaudet MM, Gaziano JM, Giles GG, Gillanders EM, Giovannucci EL, Goldin L, Goldstein AM, Haiman CA, Hallmans G, Hankinson SE, Harris CC, Henriksson R, Holly EA, Hong Y-C, Hoover RN, Hsiung CA, Hu N, Hu W, Hunter DJ, Hutchinson A, Jenab M, Johansen C, Khaw K-T, Kim HN, Kim YH, Kim YT, Klein R, Koh W-P, Kolonel LN, Kooperberg C, Kraft P, Krogh V, Kurtz RC, LaCroix A, Lan Q, Landgren A, Landi MT, Le Marchand L, Li D, Liang X, Liao LM, Lin D, Liu J, Lissowska J, Lu L, Magliocco AM, Malats N, Matsuo K, McNeill LH, McWilliams RR, Melin BS, Mirabello L, Moore L, Olson SH, Orlow I, Park JY, Patiño-Garcia A, Peplonska B, Peters U, Petersen GM, Pooler L, Prescott J, Prokunina-Olsson L, Purdue M, Qiao Y-L, Rabe KG, Rajaraman P, Real FX, Riboli E, **Risch HA**, Rodriguez-Santiago B, Ruder AM, Savage SA, Schumacher F, Schwartz AG, Schwartz KL, Seow A, Sesso HD, Setiawan VW, Severi G, Shen H, Sheng X, Shin M-H, Shu X-O, Silverman DT, Spitz MR, Stevens VL, Stolzenberg-Solomon R, Stram D, Tang Z-Z, Taylor PR, Teras LR, Tobias GS, VanDen Berg D, Viswanathan K, Wacholder S, Wang J-C, Wang Z, Wentzensen N, Wheeler W, White E, Wiencke JK, Wolpin BM, Wong MP, Wu C, Wu T, Wu X, Wu Y-L, Wunder JS, Xia L, Yang HP, Yang P-C, Yu K, Zanetti KA, Zeleniuch-Jacquotte A, Zheng W, Zhou B, Ziegler RG, Perez-Jurado LA, Caporaso NE, Rothman N, Tucker M, Dean MC, Yeager M, Chanock SJ. Female chromosome X mosaicism is age-related and preferentially affects the inactivated X chromosome. Nat Commun 2016;7:11843. PMCID: PMC4909985.

Lawrenson K, Kar S, McCue K, Kuchenbaeker K, Michailidou K, Tyrer J, Beesley J, Ramus SJ, Li Q, Delgado MK, Lee J, Aittomäki K, Andrulis IL, Anton-Culver H, Arndt V, Arun BK, Arver B, Bandera EV, Barile M, Barkardottir RB, Barrowdale D, Beckmann MW, Benitez J, Berchuck A, Bisogna M, Bjorge L, Blomqvist C, Blot W, Bogdanova N, Bojesen A, Bojesen

SE, Bolla MK, Bonanni B, Borresen-Dale A-L, Brauch H, Brennan P, Brenner H, Bruinsma F, Brunet J, Buhari SA, Burwinkel B, Butzow R, Buys SS, Cai Q, Caldes T, Campbell I, Canniotto R, Chang-Claude J, Chiquette J, Choi J-Y, Claes KBM, GEMO Study Collaborators, Cook LS, Cox A, Cramer DW, Cross SS, Cybulski C, Czene K, Daly MB, Damiola F, Dansonka-Mieszkowska A, Darabi H, Dennis J, Devilee P, Diez O, Doherty JA, Domchek SM, Dorfling CM, Dörk T, Dumont M, Ehrencrona H, Ejlertsen B, Ellis S, EMBRACE, Engel C, Eunjung L, Evans DG, Fasching PA, Feliubadalo L, Figueroa J, Flesch-Janys D, Fletcher O, Flyger H, Foretova L, Fostira F, Foulkes WD, Fridley BL, Friedman E, Frost D, Gambino G, Ganz PA, Garber J, García-Closas M, Gentry-Maharaj A, Ghoussaini M, Giles GG, Glasspool R, Godwin AK, Goldberg MS, Goldgar DE, González-Neira A, Goode EL, Goodman MT, Greene MH, Gronwald J, Guénel P, Haiman CA, Hall P, Hallberg E, Hamann U, Hansen TVO, Harrington PA, Hartman M, Hassan N, Healey S, HEBON, Heitz F, Herzog J, Høgdall E, Høgdall CK, Hogervorst FBL, Hollestelle A, Hopper JL, Hulick PJ, Huzarski T, Imyanitov EN, KConFab Investigators, Australian Ovarian Cancer Study Group, Isaacs C, Ito H, Jakubowska A, Janavicius R, Jensen A, John EM, Johnson N, Kabisch M, Kang D, Kapuscinski M, Karlan BY, Khan S, Kiemeney LA, Kjaer SK, Knight JA, Konstantopoulou I, Kosma V-M, Kristensen V, Kupryjanczyk J, Kwong A, de la Hoya M, Laitman Y, Lambrechts D, Le N, De Leeneer K, Lester J, Levine DA, Li J, Lindblom A, Long J, Lophatananon A, Loud JT, Lu K, Lubinski J, Mannermaa A, Manoukian S, Le Marchand L, Margolin S, Marme F, Massuger LFAG, Matsuo K, Mazoyer S, McGuffog L, McLean C, McNeish I, Meindl A, Menon U, Mensenkamp AR, Milne RL, Montagna M, Moysich KB, Muir K, Mulligan AM, Nathanson KL, Ness RB, Neuhausen SL, Nevanlinna H, Nord S, Nussbaum RL, Odunsi K, Offit K, Olah E, Olopade OI, Olson JE, Olswold C, O'Malley D, Orlow I, Orr N, Osorio A, Park SK, Pearce CL, Pejovic T, Peterlongo P, Pfeiler G, Phelan CM, Poole EM, Pylkäs K, Radice P, Rantala J, Rashid MU, Rennert G, Rhenius V, Rhiem K, **Risch HA**, Rodriguez G, Rossing MA, Rudolph A, Salvesen HB, Sangrajrang S, Sawyer EJ, Schildkraut JM, Schmidt MK, Schmutzler RK, Sellers TA, Seynaeve C, Shah M, Shen C-Y, Shu X-O, Sieh W, Singer CF, Sinilnikova OM, Slager S, Song H, Soucy P, Southey MC, Stenmark-Askmalm M, Stoppa-Lyonnet D, Sutter C, Swerdlow A, Tchatchou S, Teixeira MR, Teo SH, Terry KL, Terry MB, Thomassen M, Tibiletti MG, Tihomirova L, Tognazzo S, Toland AE, Tomlinson I, Torres D, Truong T, Tseng C-C, Tung N, Tworoger SS, Vachon C, van den Ouweland AMW, van Doorn HC, van Rensburg EJ, Van't Veer LJ, Vanderstichele A, Vergote I, Vijai J, Wang Q, Wang-Gohrke S, Weitzel JN, Wentzensen N, Whittemore AS, Wildiers H, Winqvist R, Wu AH, Yannoukakos D, Yoon S-Y, Yu J-C, Zheng W, Zheng Y, Khanna KK, Simard J, Monteiro AN, French JD, Couch FJ, Freedman ML, Easton DF, Dunning AM, Pharoah PDP, Edwards SL, Chenevix-Trench G, Antoniou AC, Gayther SA. Functional mechanisms underlying pleiotropic risk alleles at the 19p13.1 breast-ovarian cancer susceptibility locus. Nat Commun 2016;7:12675. PMCID: PMC5023955.

Dixon SC, Nagle CM, Thrift AP, Pharoah PDP, Pearce CL, Zheng W, Painter JN, AOCS Group, Australian Cancer Study (Ovarian Cancer), Chenevix-Trench G, Fasching PA, Beckmann MW, Lambrechts D, Vergote I, Lambrechts S, Van Nieuwenhuysen E, Rossing MA, Doherty JA, Wicklund KG, Chang-Claude J, Rudolph A, Moysich KB, Odunsi K, Goodman MT, Wilkens LR, Thompson PJ, Shvetsov YB, Dörk T, Park-Simon T-W, Hillemanns P, Bogdanova N, Butzow R, Nevanlinna H, Pelttari LM, Leminen A, Modugno F, Ness RB, Edwards RP, Kelley JL, Heitz F, Karlan BY, Kjær SK, Høgdall E, Jensen A, Goode EL, Fridley BL, Cunningham JM, Winham SJ, Giles GG, Bruinsma F, Milne RL, Southey MC, Hildebrandt MAT, Wu X, Lu KH, Liang D, Levine DA, Bisogna M, Schildkraut JM, Berchuck A, Cramer DW, Terry KL,

Bandera EV, Olson SH, Salvesen HB, Thomsen LC, Kopperud RK, Bjorge L, Kiemeney LA, Massuger LFAG, Pejovic T, Cook LS, Le ND, Swenerton KD, Brooks-Wilson A, Kelemen LE, Lubiński J, Huzarski T, Gronwald J, Menkiszak J, Wentzensen N, Brinton L, Yang H, Lissowska J, Høgdall CK, Lundvall L, Song H, Tyrer JP, Campbell I, Eccles D, Paul J, Glasspool R, Siddiqui N, Whittemore AS, Sieh W, McGuire V, Rothstein JH, Narod SA, Phelan C, **Risch HA**, McLaughlin JR, Anton-Culver H, Ziogas A, Menon U, Gayther SA, Ramus SJ, Gentry-Maharaj A, Wu AH, Pike MC, Tseng C-C, Kupryjanczyk J, Dansonka-Mieszkowska A, Budzilowska A, Spiewankiewicz B, Webb PM, Ovarian Cancer Association Consortium. Adult body mass index and risk of ovarian cancer by subtype: a Mendelian randomization study. Int J Epidemiol 2016;45(3): 884-95. PMCID: PMC5644573.

Permuth JB, Reid B, Earp M, Chen YA, Monteiro ANA, Chen Z, AOCS Study Group, Chenevix-Trench G, Fasching PA, Beckmann MW, Lambrechts D, Vanderstichele A, Van Niewenhuyse E, Vergote I, Rossing MA, Doherty JA, Chang-Claude J, Moysich K, Odunsi K, Goodman MT, Shvetsov YB, Wilkens LR, Thompson PJ, Dörk T, Bogdanova N, Butzow R, Nevanlinna H, Pelttari L, Leminen A, Modugno F, Edwards RP, Ness RB, Kelley J, Heitz F, Karlan B, Lester J, Kjaer SK, Jensen A, Giles G, Neumann S, Hildebrandt M, Liang D, Lu KH, Wu X, Levine DA, Bisogna M, Berchuck A, Cramer DW, Terry KL, Tworoger SS, Poole EM, Bandera EV, Fridley B, Cunningham J, Winham SJ, Olson SH, Orlow I, Bjorge L, Kiemeney LA, Massuger L, Pejovic T, Moffitt M, Le N, Cook LS, Brooks-Wilson A, Kelemen LE, Gronwald J, Lubinski J, Wentzensen N, Brinton LA, Lissowska J, Yang H, Hogdall E, Hogdall C, Lundvall L, Pharoah PDP, Song H, Campbell I, Eccles D, McNeish I, Whittemore A, McGuire V, Sieh W, Rothstein J, Phelan CM, **Risch H**, Narod S, McLaughlin J, Anton-Culver H, Ziogas A, Menon U, Gayther S, Ramus SJ, Gentry-Maharaj A, Pearce CL, Wu AH, Kupryjanczyk J, Dansonka-Mieszkowska A, Schildkraut JM, Cheng JQ, Goode EL, Sellers TA, Ovarian Cancer Association Consortium. Inherited variants affecting RNA editing may contribute to ovarian cancer susceptibility: results from a large-scale collaboration. Oncotarget 2016;7(45): 72381-94. PMCID: PMC5340123.

Hampras SS, Sucheston-Campbell LE, Cannioto R, Chang-Claude J, Modugno F, Dörk T, Hillemanns P, Preus L, Knutson KL, K.Wallace P, Hong C-C, Friel G, Davis W, Nesline M, Pearce CL, Kelemen LE, Goodman MT, Bandera EV, Terry KL, Schoof N, Eng KH, Clay A, Singh PK, Joseph JM, Aben KKH, Anton-Culver H, Antonenkova N, Baker H, Bean Y, Beckmann MW, Bisogna M, Bjorge L, Bogdanova N, Brinton LA, Brooks-Wilson A, Bruinsma F, Butzow R, Campbell IG, Carty K, Cook LS, Cramer DW, Cybulski C, Dansonka-Mieszkowska A, Dennis J, Despierre E, Dicks E, Doherty JA, du Bois A, Dürst M, Easton D, Eccles D, Edwards RP, Ekici AB, Fasching PA, Fridley BL, Gao Y-T, Gentry-Maharaj A, Giles GG, Glasspool R, Gronwald J, Harrington P, Harter P, Hasmad HN, Hein A, Heitz F, Hildebrandt MAT, Hogdall C, Hogdall E, Hosono S, Iversen ES, Jakubowska A, Jensen A, Ji B-T, Karlan BY, Kellar M, Kelley JL, Kiemeney LA, Klapdor R, Kolomeyevskaya N, Krakstad C, Kjaer SK, Kruszka B, Kupryjanczyk J, Lambrechts D, Lambrechts S, Le ND, Lee AW, Lele S, Leminen A, Lester J, Levine DA, Liang D, Lissowska J, Liu S, Lu K, Lubinski J, Lundvall L, Massuger LFAG, Matsuo K, McGuire V, McLaughlin JR, McNeish I, Menon U, Moes-Sosnowska J, Narod SA, Nedergaard L, Nevanlinna H, Nickels S, Olson SH, Orlow I, Weber RP, Paul J, Pejovic T, Pelttari LM, Perkins B, Permuth-Wey J, Pike MC, Plisiecka-Halasa J, Poole EM, **Risch HA**, Rossing MA, Rothstein JH, Rudolph A, Runnebaum IB, Rzepecka IK, Salvesen HB, Schernhammer E, Schmitt K, Schwaab I, Shu X-O, Shvetsov YB, Siddiqui N, Sieh W, Song H, Southey MC, Tangen IL, Teo S-H, Thompson PJ, Timorek A, Tsai Y-Y, Tworoger SS, Tyrer J, van Altena AM, Vergote I, Vierkant RA, Walsh C, Wang-Gohrke S,

Wentzensen N, Whittemore AS, Wicklund KG, Wilkens LR, Wu AH, Wu X, Woo Y-L, Yang H, Zheng W, Ziogas A, Gayther SA, Ramus SJ, Sellers TA, Schildkraut JM, Phelan CM, Berchuck A, Chenevix-Trench on behalf of the Australian Ovarian Cancer Study Group G, Cunningham JM, Pharoah PDP, Ness RB, Odunsi K, Goode EL, Moysich KB. Assessment of variation in immunosuppressive pathway genes reveals TGFBR2 to be associated with risk of clear cell ovarian cancer. Oncotarget 2016;7(43):69097-110. PMCID: PMC5340115.

Zhang M, Wang Z, Obazee O, Jia J, Childs E, Hoskins J, Figlioli G, Mocci E, Collins I, Chung CC, Hautman C, Arslan AA, Beane-Freeman L, Bracci PM, Buring J, Duell EJ, Gallinger S, Giles GG, Goodman GE, Goodman PJ, Kamineni A, Kolonel LN, Kulke MH, Malats N, Olson SH, Sesso HD, Visvanathan K, White E, Zheng W, Abnet CC, Albanes D, Andreotti G, Austin MA, Bueno-de-Mesquita HB, Basso D, Berndt SI, Boutron-Ruault M-C, Bijlsma M, Brenner H, Burdette L, Campa D, Caporaso NE, Capurso G, Cavestro GM, Cotterchio M, Costello E, Elena J, Boggi U, Gaziano JM, Gazouli M, Giovannucci EL, Goggins M, Gorman MJ, Gross M, Haiman CA, Hassan M, Helzlsouer KJ, Hu N, Hunter DJ, Iskierka-Jazdzewska E, Jenab M, Kaaks R, Key TJ, Khaw K-T, Klein EA, Kogevinas M, Krogh V, Kupcinskas J, Kurtz RC, Landi MT, Landi S, Le Marchand L, Mambrini A, Mannisto S, Milne RL, Neale R, Oberg AL, Panico S, Patel AV, Peeters PHM, Peters U, Pezzilli R, Tavano F, Porta M, Purdue M, Quiros JR, Riboli E, Rothman N, Scarpa A, Scelo G, Shu X-O, Silverman DT, Soucek P, Strobel O, Sund M, Małecka-Panas E, Taylor PR, Travis RC, Thornquist M, Tjønneland A, Tobias GS, Trichopoulos D, Vashist Y, Vodicka P, Wactawski-Wende J, Wentzensen N, Yu H, Yu K, Zeleniuch-Jacquotte A, Kooperberg C, **Risch HA**, Jacobs EJ, Li D, Fuchs C, Hoover R, Hartge P, Chanock SJ, Petersen GM, Stolzenberg-Solomon RS, Wolpin BM, Kraft P, Klein AP, Canzian F, Amundadottir LT. Three new pancreatic cancer susceptibility signals identified on chromosomes 1q32.1, 5p15.33 and 8q24.21. Oncotarget 2016;7(41):66328-43. PMCID: PMC5340084.

Cannioto R, LaMonte MJ, **Risch HA**, Hong C-C, Sucheston-Campbell LE, Eng KH, Szender JB, Chang-Claude J, Schmalfeldt B, Klapdor R, Gower E, Minlikeeva AN, Zirpoli G, Bandera EV, Berchuck A, Cramer D, DohertyJA, Edwards RP, Fridley BL, Goode EL, Goodman MT, Hogdall E, Hosono S, Jensen A, Jordan S on behalf of The Australian Ovarian Cancer Study Group, Kjaer SK, Matsuo K, Ness RB, Olsen CM, Olson SH, Pearce CL, Pike MC, Rossing MA, Szamreta EA, Thompson PJ, Tseng C-C, Vierkant RA, Webb PM, Wentzensen N, Wicklund KG, Winham SJ, Wu AH, Modugno F, Schildkraut JM, Terry KL, Kelemen LE, Moysich KB. Chronic recreational physical inactivity and epithelial ovarian cancer risk: Evidence from the Ovarian Cancer Association Consortium. Cancer Epidemiol Biomarkers Prev 2016;25(7): 1114-24. PMCID: PMC4930728.

Cannioto RA, LaMonte MJ, Kelemen LE, **Risch HA**, Eng KH, Minlikeeva AN, Hong C-C, Szender JB, Sucheston-Campbell L, Joseph JM, Berchuck A, Chang-Claude J, Cramer DW, DeFazio A on behalf of The Australian Ovarian Cancer Study Group, Diergaarde B, Dörk T, Doherty JA, Edwards RP, Fridley BL, Friel G, Goode EL, Goodman MT, Hillemanns P, Hogdall E, Hosono S, Kelley JL, Kjaer SK, Klapdor R, Matsuo K, Odunsi K, Nagle CM, Olsen CM, Paddock LE, Pearce CL, Pike MC, Rossing MA, Schmalfeldt B, Segal B, Szamreta EA, Thompson PJ, Tseng C-C, Vierkant R, Schildkraut JM, Wentzensen N, Wicklund KG, Winham SJ, Wu AH, Modugno F, Ness RB, Jensen A, Webb PM, Terry K, Bandera EV, Moysich KB. Recreational physical inactivity and mortality in women with invasive epithelial ovarian cancer: Evidence from the Ovarian Cancer Association Consortium. Br J Cancer 2016;115(1): 95-101. PMCID: PMC4931371.

Ong J-S, Cuellar-Partida G, Lu Y, Australian Ovarian Cancer Study, Fasching PA, Hein A,

Burghaus S, Beckmann MW, Lambrechts D, Van Nieuwenhuysen E, Vergote I, Vanderstichele A, Doherty JA, Rossing MA, Chang-Claude J, Eilber U, Rudolph A, Wang-Gohrke S, Goodman MT, Bogdanova N, Dörk T, Dürst M, Hillemanns P, Runnebaum IB, Antonenkova N, Butzow R, Leminen A, Nevanlinna H, Pelttari LM, Edwards RP, Kelley JL, Modugno- F, Moysich KB, Ness RB, Cannioto R, Høgdall E, Høgdall CK, Jensen A, Giles- GG, Bruinsma F, Kjaer SK, Hildebrandt MAT, Liang D, Lu KH, Wu X, Bisogna M, Dao F, Levine DA, Cramer DW, Terry KL, Tworoger SS, Stampfer M, Missmer S, Bjorge L, Salvesen HB, Kopperud RK, Bischof K, Aben KKH, Kiemeney LA, Massuger LFAG, Brooks-Wilson A, Olson SH, McGuire V, Rothstein JH, Sieh W, Whittemore AS, Cook LS, Le ND, Gilks CB, Gronwald J, Jakubowska A, Lubiński J, Kluz T, Song H, Tyrer JP, Wentzensen N, Brinton L, Trabert B, Lissowska J, McLaughlin JR, Narod SA, Phelan C, Anton-Culver H, Ziogas A, Eccles D, Campbell I, Gayther SA, Gentry-Maharaj A, Menon U, Ramus SJ, Wu AH, Dansonka-Mieszkowska A, Kupryjanczyk J, Timorek A, Szafron L, Cunningham JM, Fridley BL, Winham SJ, Bandera EV, Poole EM, Morgan TK, **Risch HA**, Goode EL, Schildkraut JM, Pearce CL, Berchuck A, Pharoah PDP, Chenevix-Trench G, Gharahkhani P, Neale RE, Webb PM, MacGregor S. Association of vitamin D levels and risk of ovarian cancer: a Mendelian randomization study. Int J Epidemiol 2016;45(5):1619-30. PMCID: PMC5100621.

Hollestelle A, van der Baan FH, Berchuck A, Johnatty SE, Aben KK, Agnarsson BA, Aittomäki K, Alducci E, Andrulis IL, Anton-Culver H, Antonenkova NN, Antoniou AC, Apicella C, Arndt V, Arnold N, Arun BK, Arver B, Ashworth A, Australian Ovarian Cancer Study Group, Baglietto L, Balleine R, Bandera EV, Barrowdale D, Bean YT, Beckmann L, Beckmann MW, Benitez J, Berger A, Berger R, Beuselinck B, Bisogna M, Bjorge L, Blomqvist C, Bogdanova NV, Bojesen A, Bojesen SE, Bolla MK, Bonanni B, Brand JS, Brauch H, Breast Cancer Family Register, Brenner H, Brinton L, Brooks-Wilson A, Bruinsma F, Brunet J, Brüning T, Budzilowska A, Bunker CH, Burwinkel B, Butzow R, Buys SS, Caligo MA, Campbell I, Carter J, Chang-Claude J, Chanock SJ, Claes KBM, Collée JM, Cook LS, Couch FJ, Cox A, Cramer D, Cross SS, Cunningham JM, Cybulski C, Czene K, Damiola F, Dansonka-Mieszkowska A, Darabi H, de la Hoya M, de Fazio A, Dennis J, Devilee P, Dicks EM, Diez O, Doherty JA, Domchek SM, Dorfling CM, Dörk T, Dos Santos Silva I, du Bois A, Dumont M, Dunning AM, Duran M, Easton DF, Eccles D, Edwards RP, Ehrencrona H, Ejlertsen B, Ekici AB, Ellis SD, EMBRACE, Engel C, Eriksson M, Fasching PA, Feliubadalo L, Figueroa J, Flesch-Janys D, Fletcher O, Fontaine A, Fortuzzi S, Fostira F, Fridley BL, Friebel T, Friedman E, Friel G, Frost D, Garber J, García-Closas M, Gayther SA, GEMO Study Collaborators, GENICA Network, Gentry-Maharaj A, Gerdes A-M, Giles GG, Glasspool R, Glendon G, Godwin AK, Goodman MT, Gore M, Greene MH, Grip M, Gronwald J, Gschwantler Kaulich D, Guénel P, Guzman SR, Haeberle L, Haiman CA, Hall P, Halverson SL, Hamann U, Hansen TVO, Harter P, Hartikainen JM, Healey S, HEBON, Hein A, Heitz F, Henderson BE, Herzog J, Hildebrandt MAT, Høgdall CK, Høgdall E, Hogervorst FBL, Hopper JL, Humphreys K, Huzarski T, Imyanitov EN, Isaacs C, Jakubowska A, Janavicius R, Jaworska K, Jensen A, Jensen UB, Johnson N, Jukkola-Vuorinen A, Kabisch M, Karlan BY, Kataja V, Kauff N, KConFab Investigators, Kelemen LE, Kerin MJ, Kiemeney LA, Kjaer SK, Knight JA, Knol-Bout JP, Konstantopoulou I, Kosma V-M, Krakstad C, Kristensen V, Kuchenbaecker KB, Kupryjanczyk J, Laitman Y, Lambrechts D, Lambrechts S, Larson MC, Lasa A, Laurent-Puig P, Lazaro C, Le ND, Le Marchand L, Leminen A, Lester J, Levine DA, Li J, Liang D, Lindblom A, Lindor N, Lissowska J, Long J, Lu KH, Lubinski J, Lundvall L, Lurie G, Mai PL, Mannermaa A, Margolin S, Mariette F, Marme F, Martens JWM, Massuger LFAG, Maugard C, Mazoyer S, McGuffog L, McGuire V, McLean C, McNeish I, Meindl A, Menegaux F, Menéndez P,

Menkiszak J, Menon U, Mensenkamp AR, Miller N, Milne RL, Modugno F, Montagna M, Moysich KB, Müller H, Mulligan AM, Muranen TA, Narod SA, Nathanson KL, Ness RB, Neuhausen SL, Nevanlinna H, Neven P, Nielsen FC, Nielsen SF, Nordestgaard BG, Nussbaum RL, Odunsi K, Offit K, Olah E, Olopade OI, Olson JE, Olson SH, Oosterwijk JC, Orlow I, Orr N, Orsulic S, Osorio A, Ottini L, Paul J, Pearce CL, Pedersen IS, Peissel B, Pejovic T, Pelttari LM, Perkins J, Permuth-Wey J, Peterlongo P, Peto J, Phelan CM, Phillips K-A, Piedmonte M, Pike MC, Platte R, Plisiecka-Halasa J, Poole EM, Poppe B, Pylkäs K, Radice P, Ramus SJ, Rebbeck TR, Reed MWR, Rennert G, **Risch HA**, Robson M, Rodriguez GC, Romero A, Rossing MA, Rothstein JH, Rudolph A, Runnebaum I, Salani R, Salvesen HB, Sawyer EJ, Schildkraut JM, Schmidt MK, Schmutzler RK, Schneeweiss A, Schoemaker MJ, Schrauder MG, Schumacher F, Schwaab I, Scuvera G, Sellers TA, Severi G, Seynaeve CM, Shah M, Shrubsole M, Siddiqui N, Sieh W, Simard J, Singer CF, Sinilnikova OM, Smeets D, Sohn C, Soller M, Song H, Soucy P, Southey MC, Stegmaier C, Stoppa-Lyonnet D, Sucheston L, SWE-BRCA, Swerdlow A, Tangen IL, Tea M-K, Teixeira MR, Terry KL, Terry MB, Thomassen M, Thompson PJ, Tihomirova L, Tischkowitz M, Toland AE, Tollenaar RAEM, Tomlinson I, Torres D, Truong T, Tsimiklis H, Tung N, Tworoger SS, Tyrer JP, Vachon CM, Van 't Veer LJ, van Altena AM, Van Asperen CJ, van den Berg D, van den Ouweland AMW, van Doorn HC, Van Nieuwenhuysen E, van Rensburg EJ, Vergote I, Verhoef S, Vierkant RA, Vijai J, Vitonis AF, Wachenfeldt Av, Walsh C, Wang Q, Wang-Gohrke S, Wappenschmidt B, Weischer M, Weitzel JN, Weltens C, Wentzensen N, Whittemore AS, Wilkens LR, Winqvist R, Wu AH, Wu X, Yang HP, Zaffaroni D, Zamora MP, Zheng W, Ziogas A, Chenevix-Trench G, Pharoah PDP, Rookus MA, Hooning MJ, Goode EL. No clinical utility of *KRAS* variant rs61764370 for ovarian or breast cancer. Gynecol Oncol 2016;141(2):386-401. PMCID: PMC4630206.

Kar SP, Beesley J, Al Olama AA, Michailidou K, Tyrer J, Kote-Jarai ZS, Lawrenson K, Lindstrom S, Ramus SJ, Thompson DJ, ABCTB Investigators, Kibel AS, Dansonka-Mieszkowska A, Michael A, Dieffenbach AK, Gentry-Maharaj A, Whittemore AS, Wolk A, Monteiro A, Peixoto A, Kierzek A, Cox A, Rudolph A, Gonzalez-Neira A, Wu AH, Lindblom A, Swerdlow A, AOCS Study Group, Australian Cancer Study (Ovarian Cancer), APCB BioResource, Ziogas A, Ekici AB, Burwinkel B, Karlan BY, Nordestgaard BG, Blomqvist C, Phelan C, McLean C, Pearce CL, Vachon C, Cybulski C, Slavov C, Stegmaier C, Maier C, Ambrosone CB, Høgdall CK, Teerlink CC, Kang D, Tessier DC, Schaid DJ, Stram DO, Cramer DW, Neal DE, Eccles D, Flesch-Janys D, Edwards DRV, Wokozorczyk D, Levine DA, Yannoukakos D, Sawyer EJ, Bandera EV, Poole EM, Goode EL, Khusnutdinova E, Høgdall E, Song F, Bruinsma F, Heitz F, Modugno F, Hamdy FC, Wiklund F, Giles GG, Olsson H, Wildiers H, Ulmer H-U, Pandha H, **Risch HA**, Darabi H, Salvesen HB, Nevanlinna H, Gronberg H, Brenner H, Brauch H, Anton-Culver H, Song H, Lim H-Y, McNeish I, Campbell I, Vergote I, Gronwald J, Lubiński J, Stanford JL, Benítez J, Doherty JA, Permuth JB, Chang-Claude J, Donovan JL, Dennis J, Schildkraut JM, Schleutker J, Hopper JL, Kupryjanczyk J, Park JY, Figueroa J, Clements JA, Knight JA, Peto J, Cunningham JM, Pow-Sang J, Batra J, Czene K, Lu KH, Herkommer K, Khaw K-T, kConFab Investigators, Matsuo K, Muir K, Offitt K, Chen K, Moysich KB, Aittomäki K, Odunsi K, Kiemeney LA, Massuger LFAG, Fitzgerald LM, Cook LS, Cannon-Albright L, Hooning MJ, Pike MC, Bolla MK, Luedeke M, Teixeira MR, Goodman MT, Schmidt MK, Riggan M, Aly M, Rossing MA, Beckmann MW, Moisse M, Sanderson M, Southey MC, Jones M, Lush M, Hildebrandt MAT, Hou M-F, Schoemaker MJ, Garcia-Closas M, Bogdanova N, Rahman N, NBCS Investigators, Le ND, Orr N, Wentzensen N, Pashayan N, Peterlongo P, Guénel P, Brennan P, Paulo P, Webb PM, Broberg P, Fasching PA, Devilee P, Wang Q, Cai Q, Li Q, Kaneva R, Butzow R, Kopperud RK, Schmutzler RK,

Stephenson RA, MacInnis RJ, Hoover RN, Winqvist R, Ness R, Milne RL, Travis RC, Benlloch S, Olson SH, McDonnell SK, Tworoger SS, Maia S, Berndt S, Lee SC, Teo S-H, Thibodeau SN, Bojesen SE, Gapstur SM, Kjær SK, Pejovic T, Tammela TL, GENICA Network, PRACTICAL consortium, Dörk T, Brüning T, Wahlfors T, Key TJ, Edwards TL, Menon U, Hamann U, Mitev V, Kosma V-M, Setiawan VW, Kristensen V, Arndt V, Vogel W, Zheng W, Sieh W, Blot WJ, Kluzniak W, Shu X-O, Gao Y-T, Schumacher F, Freedman ML, Berchuck A, Dunning AM, Simard J, Haiman CA, Spurdle A, Sellers TA, Hunter DJ, Henderson BE, Kraft P, Chanock SJ, Couch FJ, Hall P, Gayther SA, Easton DF, Chenevix-Trench G, Eeles R, Pharoah PDP, Lambrechts D. Genome-wide meta-analyses of breast, ovarian and prostate cancer association studies identify multiple new susceptibility loci shared by at least two cancer types. Cancer Discov 2016;6(9):1052-67. PMCID: PMC5010513.

Gharahkhani P, Fitzgerald RC, Vaughan TL, Tomlinson I, Gockel I, Palles C, Buas MF, May A, Gerges C, Anders M, Becker J, Kreuser N, Noder T, Venerito M, Veits L, Schmidt T, Manner H, Schmidt C, Hess T, Böhmer AC, Izbicki JR, Hölscher AH, Lang H, Lorenz D, Schumacher B, Hackelsberger A, Mayershofer R, Pech O, Vashist Y, Ott K, Vieth M, Weismüller J, Nöthen MM, Barrett's and Esophageal Adenocarcinoma Consortium (BEACON), Wellcome Trust Case-Control Consortium (WTCCC), Attwood S, Barr H, Chegwidden L, deCaestecker J, Harrison R, Love SB, MacDonald D, Moayyedi P, Prenen H, Watson RGP, Iyer PG, Anderson LA, Bernstein L, Chow W-H, Hardie LJ, Lagergren J, Liu G, **Risch HA**, Wu AH, Ye W, Bird NC, Shaheen NJ, Gammon MD, Corley DA, Caldas C, Moebus S, Knapp M, Peters WHM, Neuhaus H, Rösch T, Ell C, MacGregor S, Pharoah P, Whiteman DC, Jankowski J, Schumacher J. Genome-wide association studies in oesophageal adenocarcinoma and Barrett's oesophagus: a large-scale meta-analysis. Lancet Oncol 2016;17(10):1363-73. PMCID: PMC5052458.

Dai J, Tapsoba J de D, Bernstein L, Chow W-H, Shaheen NJ, Anderson L, Liu G, Iyer P, Reid BJ, Wu AH, Corley DA, Gammon MD, Hardie LJ, **Risch HA**, Bird NC, Lagergren J, Ye W, Whiteman DC, Vaughan TL. Constrained score statistics identify novel genetic variants interacting with multiple risk factors in Barrett's Esophagus. Am J Hum Genet 2016;99(2):352-65. PMCID: PMC4974090.

Lujan-Barroso L, Zhang W, Olson SH, Gao Y-T, Yu H, Baghurst PA, Bracci PM, Bueno-de-Mesquita HB, Foretová L, Gallinger S, Holcatova I, Janout V, Ji B-T, Kurtz RC, La Vecchia C, Lagiou P, Li D, Miller AB, Serraino D, Zatonski W, **Risch HA**, Duell EJ. Menstrual and reproductive factors, hormone use and risk of pancreatic cancer: analysis from the International Pancreatic Cancer Case-Control Consortium (PanC4). Pancreas 2016;45(10):1401-10. PMCID: PMC5065728.

Kho PF, Fawcett J, Fritschi L, **Risch H**, Webb PM, Whiteman DC, Neale RE. Nonsteroidal anti-inflammatory drugs, statins and pancreatic cancer risk: a population-based case-control study. Cancer Causes Control 2016;27(12):1457-64. *Not a result of NIH funding.

Drahos J, Xiao Q, **Risch HA**, Freedman ND, Abnet CC, Anderson LA, Bernstein L, Brown L, Chow W-H, Gammon MD, Kamangar F, Liao LM, Murray LJ, Ward MH, Ye W, Wu AH, Vaughan TL, Whiteman DC, Cook MB. Age-specific risk factor profiles of adenocarcinomas of the esophagus: a pooled analysis from the International BEACON Consortium. Int J Cancer 2016;138(1):55-64. PMCID: PMC4607633.

Shi J, Park J-H, Duan J, Berndt S, Moy W, Yu K, Song L, Wheeler W, Hua X, Silverman D, Garcia-Closas M, Hsiung CA, Figueroa JD, Cortessis VK, Malats N, Karagas MR, Vineis P, Chang I-S, Lin D, Zhou B, Seow A, Matsuo K, Hong Y-C, Caporaso NE, Wolpin B, Jacobs E, Petersen G, Klein AP, Li D, **Risch H**, Sanders AR, Hsu L, Schoen RE, Brenner H, MGS

(Molecular Genetics of Schizophrenia) GWAS Consortium, GECCO (The Genetics and Epidemiology of Colorectal Cancer Consortium), The GAME-ON/TRICL (Transdisciplinary Research in Cancer of the Lung) GWAS Consortium, PRACTICAL (PRostate cancer AssoCiation group To Investigate Cancer Associated aLterations) Consortium, PanScan and PanC4 Consortium, The GAMEON/ ELLIPSE Consortium, Stolzenberg-Solomon R, Gejman P, Lan Q, Rothman N, Amundadottir LT, Landi MT, Levinson DF, Chanock SJ, Chatterjee N. Winner's curse correction and variable thresholding improve performance of polygenic risk modeling based on genome-wide association study summary-level data. PLoS Genet 2016;12(12):e1006493. PMCID: PMC5201242.

McWilliams RR, Maisonneuve P, Bamlet WR, Petersen GM, Li D, **Risch HA**, Yu H, Fontham ET, Luckett B, Bosetti C, Negri E, La Vecchia C, Talamini R, Bueno de Mesquita HB, Bracci P, Gallinger S, Neale RE, Lowenfels AB. Risk factors for early-onset and very-early-onset pancreatic adenocarcinoma: a Pancreatic Cancer Case-Control Consortium (PanC4) analysis. Pancreas 2016;45(2):311-6. PMCID: PMC4710562.

Kotsopoulos J, Rosen B, Fan I, Moody J, McLaughlin JR, **Risch H**, May T, Sun P, Narod SA. Ten-year survival after epithelial ovarian cancer is not associated with *BRCA* mutation status. Gynecol Oncol 2016;140(1):42-7. *NIH funding pre-dates mandate.

Ek WE, Lagergren K, Cook M, Wu AH, Abnet CC, Levine D, Chow W-H, Bernstein L, **Risch HA**, Shaheen NJ, Bird NC, Corley DA, Hardie LJ, Fitzgerald RC, Gammon M, Romero Y, Liu G, Ye W, Vaughan TL, MacGregor S, Whiteman DC, Westberg L, Lagergren J. Polymorphisms in genes in the androgen pathway and risk of Barrett's Esophagus and esophageal adenocarcinoma. Int J Cancer 2016;138(5):1146-52. PMCID: PMC4715576.

Lu L, Katsaros D, **Risch HA**, Canuto EM, Biglia N, Yu H. MicroRNA let-7a modifies the effect of self-renewal gene *HIWI* on patient survival of epithelial ovarian cancer. Mol Carcinog 2016;55(4):357-65. *Not a result of NIH funding.

Præstegaard C, Kjaer, SK, Nielsen TSS, Jensen SM, Webb PM, Australian Ovarian Cancer Study Group, Nagle CM, Høgdall E, **Risch HA**, Rossing MA, Doherty JA, Wicklund KG, Goodman MT, Modugno F, Moysich K, Ness RB, Edwards RP, Goode EL, Winham SJ, Fridley BL, Cramer DW, Terry KL, Schildkraut JM, Berchuck A, Bandera EV, Paddock L, Kiemeney LA, Massuger LF, Wentzensen N, Pharoah P, Song H, Whittemore AS, McGuire V, Sieh W, Rothstein J, Anton-Culver H, Ziogas A, Menon U, Gayther SA, Ramus SJ, Gentry-Maharaj A, Wu AH, Pearce CL, Pike MC, Lee AW, Chang-Claude J, Jensen A, Ovarian Cancer Association Consortium. The association between socioeconomic status and tumour stage at diagnosis of ovarian cancer: a pooled analysis of 18 case-control studies. Cancer Epidemiol 2016;41:71-9. PMCID: PMC4993452.

Cuellar-Partida G, Lu Y, Dixon SC, Australian Ovarian Cancer Study, Fasching PA, Hein A, Burghaus S, Beckmann MW, Lambrechts D, Van Nieuwenhuysen E, Vergote I, Vanderstichele A, Doherty JA, Rossing MA, Chang-Claude J, Rudolph A, Wang-Gohrke S, Goodman MT, Bogdanova N, Dörk T, Dürst M, Hillemanns P, Runnebaum IB, Antonenkova N, Butzow R, Leminen A, Nevanlinna H, Pelttari LM, Edwards RP, Kelley JL, Modugno F, Moysich KB, Ness RB, Cannioto R, Høgdall E, Høgdall C, Jensen A, Giles GG, Bruinsma F, Kjaer SK, Hildebrandt MAT, Liang D, Lu KH, Wu X, Bisogna M, Dao F, Levine DA, Cramer DW, Terry KL, Tworoger SS, Stampfer M, Missmer S, Bjorge L, Salvesen HB, Kopperud RK, Bischof K, Aben KKH, Kiemeney LA, Massuger LFAG, Brooks-Wilson A, Olson SH, McGuire V, Rothstein JH, Sieh W, Whittemore AS, Cook LS, Le ND, Gilks CB, Gronwald J, Jakubowska A, Lubiński J, Kluz T, Song H, Tyrer JP, Wentzensen N, Brinton L, Trabert B, Lissowska J,

McLaughlin JR, Narod SA, Phelan C, Anton-Culver H, Ziogas A, Eccles D, Campbell I, Gayther SA, Gentry-Maharaj A, Menon U, Ramus SJ, Wu AH, Dansonka-Mieszkowska A, Kupryjanczyk J, Timorek A, Szafron L, Cunningham JM, Fridley BL, Winham SJ, Bandera EV, Poole EM, Morgan TK, Goode EL, Schildkraut JM, Pearce CL, Berchuck A, Pharoah PDP, Webb PM, Chenevix-Trench G, **Risch HA**, MacGregor S. Assessing the genetic architecture of epithelial ovarian cancer histological subtypes. Hum Genet 2016;135(7): 741-56. PMCID: PMC4976079.

Meeks HD, Song H, Michailidou K, Bolla MK, Dennis J, Wang Q, Barrowdale D, Frost D, EMBRACE, McGuffog L, Ellis S, Feng B, Buys SS, Hopper JL, Southey MC, Tesoriero A, kConFab Investigators, James PA, Bruinsma F, Campbell IG, Australia Ovarian Cancer Study Group, Broeks A, Schmidt MK, Hogervorst FBL, HEBON, Beckman MW, Fasching PA, Fletcher O, Johnson N, Sawyer EJ, Riboli E, Banerjee S, Menon U, Tomlinson I, Burwinkel B, Hamann U, Marme F, Rudolph A, Janavicius R, Tihomirova L, Tung N, Garber J, Cramer D, Terry KL, Poole EM, Tworoger SS, Dorfling CM, van Rensburg EJ, Godwin AK, Guénel P, Truong T, GEMO Study Collaborators, Stoppa-Lyonnet D, Damiola F, Mazoyer S, Sinilnikova OM, Isaacs C, Maugard C, Bojesen SE, Flyger H, Gerdes A-M, Hansen TVO, Jensen A, Kjaer SK, Hogdall C, Hogdall E, Pedersen IS, Thomassen M, Benitez J, González-Neira A, Osorio A, de la Hoya M, Perez Segura P, Diez O, Lazaro C, Brunet J, Anton-Culver H, Eunjung L, John EM, Neuhausen SL, Ding YC, Castillo D, Weitzel JN, Ganz PA, Nussbaum RL, Chan SB, Karlan BY, Lester J, Wu A, Gayther S, Ramus SJ, Sieh W, Whittermore AS, Monteiro ANA, Phelan CM, Terry MB, Piedmonte M, Offit K, Robson M, Levine D, Moysich KB, Cannioto R, Olson SH, Daly MB, Nathanson KL, Domchek SM, Lu KH, Liang D, Hildebrant MAT, Ness R, Modugno F, Pearce L, Goodman MT, Thompson PJ, Brenner H, Butterbach K, Meindl A, Hahnen E, Wappenschmidt B, Brauch H, Brüning T, Blomqvist C, Khan S, Nevanlinna H, Pelttari LM, Aittomäki K, Butzow R, Bogdanova NV, Dörk T, Lindblom A, Margolin S, Rantala J, Kosma V-M, Mannermaa A, Lambrechts D, Neven P, Claes KBM, Van Maerken T, Chang-Claude J, Flesch-Janys D, Heitz F, Varon-Mateeva R, Peterlongo P, Radice P, Viel A, Barile M, Peissel B, Manoukian S, Montagna M, Oliani C, Peixoto A, Teixeira MR, Collavoli A, Hallberg E, Olson JE, Goode EL, Hart S, Shimelis H, Cunningham JM, Giles GG, Milne RL, Healey S, Tucker K, Haiman CA, Henderson BE, Goldberg MS, Tischkowitz M, Simard J, Soucy P, Eccles DM, Le N, Borresen-Dale A-L, Kristensen V, Salvesen HB, Bjorge L, Bandera EV, **Risch H**, Zheng W, Beeghly-Fadiel A, Cai H, Pylkäs K, Tollenaar RAEM, van der Ouweland AMW, Andrulis IL, Knight JA, OCGN, Narod S, Devilee P, Winqvist R, Figueroa J, Greene MH, Mai PL, Loud JT, García-Closas M, Schoemaker MJ, Czene K, Darabi H, McNeish I, Siddiquil N, Glasspool R, Kwong A, Park SK, Teo SH, Yoon S-Y, Matsuo K, Hosono S, Woo YL, Gao Y-T, Foretova L, Singer CF, Feurhauser CR, Friedman E, Laitman Y, Rennert G, Imyanitov EN, Hulick PJ, Olopade OI, Senter L, Olah E, Doherty JA, Schildkraut J, Hollestelle A, Koppert LB, Kiemeney LA, Massuger LFAG, Cook LS, Pejovic T, Li J, Borg A, Öfverholm A, Rossing MA, Wentzensen N, Henriksson K, Cox A, Cross SS, Perkins BJ, Shah M, Kabisch M, Torres D, Jakubowska A, Lubinski J, Gronwald J, Agnarsson BA, Kupryjanczyk J, Moes-Sosnowska J, Fostira F, Konstantopoulou I, Slager S, Jones M, Prostate Cancer Association Group to Investigate Cancer Associated Alterations in the Genome, Antoniou AC, Berchuck A, Swerdlow A, Chenevix-Trench G, Dunning AM, Pharoah PDP, Hall P, Easton DF, Couch FJ, Spurdle AB, Goldgar DE. BRCA2 polymorphic stop codon K3326X and the risk of breast, prostate and ovarian cancers. J Natl Cancer Inst 2016;108(2):djv315. PMCID: PMC4907358.

2015

Risch HA, Yu H, Lu L, Kidd MS. Detectable symptomatology preceding the diagnosis of pancreatic cancer and absolute risk of pancreatic cancer diagnosis. Am J Epidemiol 2015;182(1):26-34. PMCID: PMC4479115.

Schulte A, Pandeya N, Fawcett J, Fritschi L, **Risch HA**, Webb PM, Whiteman DC, Neale RE. Association between *Helicobacter pylori* and pancreatic cancer risk: a meta-analysis. Cancer Causes Control 2015;26(7):1027-35. *Not a result of NIH funding.

Ivanova A, Loo A, Tworoger S, Crum CP, Fan I, McLaughlin JR, Rosen B, **Risch H**, Narod SA, Kotsopoulos J. Ovarian cancer survival by tumor dominance, a surrogate for site of origin. Cancer Causes Control 2015;26(4):601-8. *NIH funding pre-dates mandate.

Wang Z, Katsaros D, Shen Y, Fu Y, Canuto EM, Benedetto C, Lu L, Chu W-M, **Risch HA**, Yu H. Biological and clinical significance of *MAD2L1* and *BUB1*, genes frequently appearing in expression signatures for breast-cancer prognosis. PLoS One 2015;10(8):e0136246. PMCID: PMC4546117.

Waterhouse M, **Risch HA**, Bosetti C, Anderson KE, Petersen GM, Bamlet WR, Cotterchio M, Cleary SP, Ibiebele T, La Vecchia C, Skinner H, Strayer L, Bracci PM, Maisonneuve P, Bueno-de-Mesquita HB, Zatoński W, Lu L, Yu H, Janik-Koncewicz K, Polesel J, Serraino D, Neale RE, for the Pancreatic Cancer Case-Control Consortium (PanC4). Vitamin D and pancreatic cancer: a pooled analysis from the Pancreatic Cancer Case-Control Consortium. Ann Oncol 2015;26(8):1776-83. PMCID: PMC4511221.

Amankwah EK, Lin H-Y, Tyrer JP, Lawrenson K, Dennis J, Chornokur G, Aben KKH, Anton-Culver H, Antonenkova N, Bruinsma F, Bandera EV, Bean YT, Beckmann MW, Bisogna M, Bjorge L, Bogdanova N, Brinton LA, Brooks-Wilson A, Bunker CH, Butzow R, Campbell IG, Carty K, Chen Z, Chen YA, Chang-Claude J, Cook LS, Cramer DW, Cunningham JM, Cybulski C, Dansonka-Mieszkowska A, du Bois A, Despierre E, Dicks E, Doherty JA, Dörk T, Dürst M, Easton DF, Eccles DM, Edwards RP, Ekici AB, Fasching PA, Fridley BL, Gao Y-T, Gentry-Maharaj A, Giles GG, Glasspool R, Goodman MT, Gronwald J, Harrington P, Harter P, Hasmad HN, Hein A, Heitz F, Hildebrandt MAT, Hillemanns P, Hogdall CK, Hogdall E, Hosono S, Iversen ES, Jakubowska A, Jensen A, Ji B-T, Karlan BY, Jim H, Kellar M, Kiemeney LA, Krakstad C, Kjaer SK, Kupryjanczyk J, Lambrechts D, Lambrechts S, Le ND, Lee AW, Lele S, Leminen A, Lester J, Levine DA, Liang D, Lim BK, Lissowska J, Lu K, Lubinski J, Lundvall L, Massuger L FAG, Matsuo K, McGuire V, McLaughlin JR, McNeish I, Menon U, Milne RL, Modugno F, Moysich KB, Ness RB, Nevanlinna H, Eilber U, Odunsi K, Olson SH, Orlow I, Orsulic S, Weber RP, Paul J, Pearce CL, Pejovic T, Pelttari LM, Permuth-Wey J, Pike MC, Poole EM, **Risch HA**, Rosen B, Rossing MA, Rothstein JH, Rudolph A, Runnebaum IB, Rzepecka IK, Salvesen HB, Schernhammer E, Schwaab I, Shu X-O, Shvetsov YB, Siddiqui N, Sieh W, Song H, Southey MC, Spiewankiewicz B, Sucheston-Campbell L, Teo S-H, Terry KL, Thompson PJ, Thomsen L, Tangen IL, Tworoger SS, van Altena AM, Vierkant RA, Vergote I, Walsh CS, Wang-Gohrke S, Wentzensen N, Whittemore AS, Wicklund KG, Wilkens LR, Wu AH, Wu X, Woo Y-L, Yang H, Zheng W, Ziogas A, Kelemen LE, Berchuck A, Chenevix-Trench G on behalf of the AOCS management group, Schildkraut JM, Ramus SJ, Goode EL, Monteiro ANA, Gayther SA, Narod SA, Pharoah PDP, Sellers TA, Phelan CM. Epithelial-mesenchymal transition (EMT) gene variants and epithelial ovarian cancer (EOC) risk. Genet Epidemiol 2015;39(8):689-97. PMCID: PMC4721602.

Collaborative Group on Epidemiological Studies of Ovarian Cancer. Menopausal hormone use and ovarian cancer risk: Individual participant meta-analysis of 52 epidemiological studies. Lancet 2015;385:1835-42. *Not a result of NIH funding.

Wang Z, **Risch H**, Lu L, Irwin M, Mayne S, Schwartz P, Rutherford T, De Vivo I, Yu H. Joint effect of genotypic and phenotypic features of reproductive factors on endometrial cancer risk. Sci Rep 2015;5:15582. PMCID: PMC Journal in Process.

Machiela MJ, Zhou W, Sampson JN, Dean MC, Jacobs KB, Black A, Brinton LA, Chang I-S, Chen C, Chen C, Chen K, Cook LS, Crous Bou M, De Vivo I, Doherty J, Friedenreich CM, Gaudet MM, Haiman CA, Hankinson SE, Hartge P, Henderson BE, Hong Y-C, Hosgood III HD, Hsiung CA, Hu W, Hunter DJ, Jessop L, Kim HN, Kim YH, Kim YT, Klein R, Kraft P, Lan Q, Lin D, Liu J, Le Marchand L, Liang X, Lissowska J, Lu L, Magliocco AM, Matsuo K, Olson SH, Orlow I, Park JY, Pooler L, Prescott J, Rastogi R, **Risch HA**, Schumacher F, Seow A, Setiawan VW, Shen H, Sheng X, Shin M-H, Shu X-O, VanDen Berg D, Wang J-C, Wentzensen N, Wong MP, Wu C, Wu T, Wu Y-L, Xia L, Yang HP, Yang P-C, Zheng W, Zhou B, Abnet CC, Albanes D, Aldrich MC, Amos C, Amundadottir LT, Berndt SI, Blot WJ, Bock CH, Bracci PM, Burdett L, Buring JE, Butler MA, Carreón T, Chatterjee N, Chung CC, Cook MB, Cullen M, Davis FG, Ding T, Duell EJ, Epstein CG, Fan J-H, Figueroa JD, Fraumeni Jr. JF, Freedman ND, Fuchs CS, Gao Y-T, Gapstur SM, Patiño-Garcia A, Garcia-Closas M, Gaziano JM, Giles GG, Gillanders EM, Giovannucci EL, Goldin L, Goldstein AM, Greene MH, Hallmans G, Harris CC, Henriksson R, Holly EA, Hoover RN, Hu N, Hutchinson A, Jenab M, Johansen C, Khaw K-T, Koh W-P, Kolonel LN, Kooperberg C, Krogh V, Kurtz RC, LaCroix A, Landgren A, Landi MT, Li D, Liao LM, Malats N, McGlynn KA, McNeill LH, McWilliams RR, Melin BS, Mirabello L, Peplonska B, Peters U, Petersen GM, Prokunina-Olsson L, Purdue M, Qiao Y-L, Rabe KG, Rajaraman P, Real FX, Riboli E, Rodriguez-Santiago B, Rothman N, Ruder AM, Savage SA, Schwartz AG, Schwartz KL, Sesso HD, Severi G, Silverman DT, Spitz MR, Stevens VL, Stolzenberg-Solomon R, Stram D, Tang Z-Z, Taylor PR, Teras LR, Tobias GS, Viswanathan K, Wacholder S, Wang Z, Weinstein SJ, Wheeler W, White E, Wiencke JK, Wolpin BM, Wu X, Wunder JS, Yu K, Zanetti KA, Zeleniuch-Jacquotte A, Ziegler RG, de Andrade M, Barnes KC, Beaty TH, Bierut LJ, Desch KC, Doheny KF, Feenstra B, Ginsburg D, Heit JA, Kang JH, Laurie CA, Li JZ, Lowe WL, Marazita ML, Melbye M, Mirel DB, Murray J, Nelson SC, Pasquale LR, Rice K, Wiggs JL, Wise A, Tucker M, Perez-Jurado LA, Laurie CC, Caporaso NE, Yeager M, Chanock SJ. Characterization of large structural genetic mosaicism in human autosomes. Am J Hum Genet 2015;96(3):487-97. PMCID: PMC Journal in Process.

Fritschi L, Benke G, **Risch HA**, Schulte A, Webb PM, Whiteman DC, Fawcett J, Neale RE. Occupational exposure to *N*-nitrosamines and pesticides and risk of pancreatic cancer. Occup Environ Med 2015;72(9):678-83. *Not a result of NIH funding.

Salmena L, Shaw P, Fan I, McLaughlin JR, Rosen B, **Risch H**, Mitchell C, Sun P, Narod SA, Kotsopoulos J. Prognostic value of INPP4B protein immunohistochemistry in ovarian cancer. Eur J Gynaecol Oncol 2015;36(3):260-7. PMCID: PMC Journal in Process.

Lee E, Stram DO, Ek W, Onstad LE, MacGregor S, Buas M, Gharahkhani P, Ye W, Lagergren J, Bird NC, Romero Y, Shaheen NJ, Murray LJ, Hardie LJ, Gammon MD, Chow W-H, **Risch HA**, Corley DA, Reid BJ, Levine DM, Abnet C, Whiteman DC, Bernstein L, Vaughan TL, Wu AH. Pleiotropic analysis of cancer risk loci on esophageal adenocarcinoma risk. Cencer Epidemiol Biomarkers Prev 2015;24(11):1801-3. PMCID: PMC Journal in Process.

Prescott J, Setiawan VW, Wentzensen N, Schumacher F, Yu H, Delahanty R, Bernstein L, Chanock SJ, Chen C, Cook LS, Friedenreich C, Garcia-Closas M, Haiman CA, Le Marchand L, Liang X, Lissowska J, Lu L, Magliocco AM, Olson SH, **Risch HA**, Shu X-O, Ursin G, Yang HP, Kraft P, De Vivo I. Body mass index genetic risk score and endometrial cancer risk. PLoS One

2015;10(11):e0143256. PMCID: PMC Journal in Process.

Petrick JL, Steck SE, Bradshaw PT, Chow W-H, Engel LS, He K, **Risch HA**, Vaughan TL, Gammon MD. Dietary flavonoid intake and Barrett's Esophagus in western Washington State. Ann Epidemiol 2015;25(10):730-5.e2. PMCID: PMC Journal in Process.

Dai JY, Tapsoba Jde D, Buas MF, Onstad LE, DM, **Risch HA**, Chow W-H, Bernstein L, Ye W, Lagergren J, Bird NC, Corley DA, Shaheen NJ, Wu AH, Reid BJ, Hardie LJ, Whiteman DC, Vaughan TL. A newly identified susceptibility locus near *FOXP1* modifies the association of gastroesophageal reflux with Barrett's Esophagus. Cancer Epidemiol Biomarkers Prev 2015;24(11):1739-47. PMCID: PMC Journal in Process.

Shen Y, Wang Z, Loo LWM, Ni Y, Jia W, Fei P, **Risch HA**, Katsaros D, Yu H. *LINC00472* expression is regulated by promoter methylation and associated with disease-free survival in patients with grade 2 breast cancer. Breast Cancer Res Treat 2015;154(3):473-82. *Not a result of NIH funding.

Lagergren K, Ek WE, Levine D, Chow W-H, Bernstein L, Casson AG, **Risch HA**, Shaheen NJ, Bird NC, Reid BJ, Corley DA, Hardie LJ, Wu AH, Fitzgerald RC, Pharoah P, Caldas C, Romero Y, Vaughan TL, MacGregor S, Whiteman D, Westberg L, Nyren O, Lagergren J. Polymorphisms in genes of relevance for oestrogen and oxytocin pathways and risk of Barrett's Oesophagus and oesophageal adenocarcinoma: a pooled analysis from the BEACON Consortium. PLoS ONE 2015;10(9):e0138738. PMCID: PMC Journal in Process.

Kar SP, Tyrer JP, Li Q, Lawrenson K, Aben KKH, Anton-Culver H, Antonenkova N, Chenevix-Trench G, Australian Cancer Study, Australian Ovarian Cancer Study Group, Baker H, Bandera EV, Bean YT, Beckmann MW, Berchuck A, Bisogna M, Bjørge L, Bogdanova N, Brinton L, Brooks-Wilson A, Butzow R, Campbell I, Carty K, Chang-Claude J, Chen YA, Chen Z, Cook LS, Cramer D, Cunningham JM, Cybulski C, Dansonka-Mieszkowska A, Dennis J, Dicks E, Doherty JA, Dörk T, du Bois A, Dürst M, Eccles D, Easton DF, Edwards RP, Ekici AB, Fasching PA, Fridley BL, Gao Y-T, Gentry-Maharaj A, Giles GG, Glasspool R, Goode EL, Goodman MT, Grownwald J, Harrington P, Harter P, Hein A, Heitz F, Hildebrandt MAT, Hillemanns P, Hogdall E, Hogdall CK, Hosono S, Iversen ES, Jakubowska A, James P, Jensen A, Ji B-T, Karlan BY, Kjaer SK, Kelemen LE, Kellar M, Kelley J, Kiemeney LA, Krakstad C, Kupryjanczyk J, Lambrechts D, Lambrechts S, Le ND, Lee AW, Lele S, Leminen A, Lester J, Levine DA, Liang D, Lissowska J, Lu K, Lubinski J, Lundvall L, Massuger L, Matsuo K, McGuire V, McLaughlin JR, McNeish IA, Menon U, Modugno F, Moysich KB, Narod SA, Nedergaard L, Ness RB, Nevanlinna H, Odunsi K, Olson SH, Orlow I, Orsulic S, Weber RP, Pearce CL, Pejovic T, Pelttari LM, Permuth-Wey J, Phelan CM, Pike MC, Poole EM, Ramus SJ, **Risch HA**, Rosen B, Rossing MA, Rothstein JH, Rudolph A, Runnebaum IB, Rzepecka IK, Salvesen HB, Schildkraut JM, Schwaab I, Shu X-O, Shvetsov YB, Siddiqui N, Sieh W, Song H, Southey MC, Sucheston-Campbell LE, Tangen IL, Teo S-H, Terry KL, Thompson PJ, Timorek A, Tsai Y-Y, Tworoger SS, van Altena AM, Van Nieuwenhuysen E, Vergote I, Vierkant RA, Wang-Gohrke S, Walsh C, Wentzensen N, Whittemore AS, Wicklund KG, Wilkens LR, Woo Y-L, Wu X, Wu A, Yang H, Zheng W, Ziogas A, Sellers TA, Monteiro ANA, Freedman ML, Gayther SA, Pharoah PDP. Network-based integration of GWAS and gene expression identifies a HOX-centric network associated with serous ovarian cancer risk. Cancer Epidemiol Biomarkers Prev 2015;24(10):1574-84. PMCID: PMC Journal in Process.

Felix AS, Gaudet MM, La Vecchia C, Nagle CM, Shu X-O, Weiderpass E, Adami HO, Beresford S, Bernstein L, Chen C, Cook LS, De Vivo I, Doherty JA, Friedenreich CM, Gapstur SM, Hill D, Horn-Ross PL, Lacey JV, Levi F, Liang X, Lu L, Magliocco A, McCann SE, Negri E, Olson

SH, Palmer JR, Patel AV, Petruzella S, Prescott J, **Risch HA**, Rosenberg L, Sherman ME, Spurdle AB, Webb PM, Wise LA, Xiang Y-B, Xu W, Yang HP, Yu H, Zeleniuch-Jacquotte A, Brinton LA. Intrauterine devices and endometrial cancer risk: a pooled analysis of the Epidemiology of Endometrial Cancer Consortium. Int J Cancer 2015;136(5):E410-22. PMCID: PMC Journal in Process.

Lee AW, Tyrer JP, Doherty JA, Stram DA, Kupryjanczyk J, Dansonka-Mieszkowska A, Plisiecka-Halasa J, Spiewankiewicz B, Myers EJ, Australian Cancer Study (Ovarian Cancer), Australian Ovarian Cancer Study Group, Chenevix-Trench G, Fasching PA, Beckmann MW, Ekici AB, Hein A, Vergote I, Nieuwenhuysen EV, Lambrechts D, Wicklund KG, Eilber U, Wang-Gohrke S, Chang-Claude J, Rudolph A, Sucheston L, Odunsi K, Moysich KB, Shvetsov YB, Thompson PJ, Goodman MT, Wilkens LR, Dörk T, Hillemanns P, Dürst M, Runnebaum IB, Bogdanova N, Pelttari LM, Nevanlinna H, Leminen A, Edwards RP, Kelley JL, Harter P, Schwaab I, Heitz F, du Bois A, Orsulic S, Lester J, Walsh C, Karlan BY, Hogdall E, Kjaer SK, Jensen A, Vierkant RA, Cunningham JM, Goode EL, Fridley BL, Southey MC, Giles GG, Bruinsma F, Wu X, Hildebrandt MAT, Lu K, Liang D, Bisogna M, Levine DA, Weber RP, Schildkraut JM, Iversen ES, Berchuck A, Terry KL, Cramer DW, Tworoger SS, Poole EM, Olson SH, Orlow I, Bandera EV, Bjorge L, Tangen IL, Salvesen HB, Krakstad C, Massuger LFAG, Kiemeney LA, Aben KKH, van Altena AM, Bean Y, Pejovic T, Kellar M, Le ND, Cook LS, Kelemen LE, Brooks-Wilson A, Lubinski J, Gronwald J, Cybulski C, Jakubowska A, Wentzensen N, Brinton LA, Lissowska J, Yang H, Nedergaard L, Lundvall L, Hogdall C, Song H, Campbell IG, Eccles D, Glasspool R, Siddiqui N, Carty K, Paul J, McNeish I, Sieh W, McGuire V, Rothstein JH, Whittemore AS, McLaughlin JR, **Risch HA**, Phelan CM, Anton-Culver H, Ziogas A, Menon U, Ramus SJ, Gentry-Maharaj A, Harrington P, Pike MC, Modugno F, Rossing MA, Ness RB, Pharoah PDP, Stram DO, Wu AH, Pearce CL. Evaluating the ovarian cancer gonadotropin hypothesis: a candidate gene study. Gyn Oncol 2015;136(3):542-8. PMCID: PMC Journal in Process.

Campa D, Rizzato C, Stolzenberg-Solomon R, Pacetti P, Vodicka P, Cleary SP, Capurso G, Bueno-de-Mesquita HB, Werner J, Gazouli M, Butterbach K, Ivanauskas A, Giese N, Petersen GM, Fogar P, Wang Z, Bassi C, Ryska M, Theodoropoulos GE, Kooperberg C, Hassan M, Greenhalf W, Pasquali C, Hackert T, Fuchs CS, Mohelnikova-Duchonova B, Sperti C, Funel N, Dieffenbach AK, Wareham NJ, Buring J, Holcátová I, Costello E, Zambon C-F, Kupcinskas J, **Risch HA**, Kraft P, Bracci PM, Pezzilli R, Olson SH, Sesso HD, Hartge P, Strobel O, Małecka-Panas E, Visvanathan K, Arslan AA, Pedrazzoli S, Sou ek P, Gioffreda D, Key TJ, Talar-Wojnarowska R, Scarpa A, Mambrini A, Jacobs EJ, Jamroziak K, Klein A, Tavano F, Bambi F, Landi S, Austin MA, Vodickova L, Brenner H, Chanock SJ, Delle Fave G, Piepoli A, Cantore M, Zheng W, Wolpin BM, Amundadottir LT, Canzian F. The *TERT* gene harbors multiple variants associated with pancreatic cancer susceptibility. Int J Cancer 2015;137(9):2175-83. PMCID: PMC Journal in Process.

Lu Y, Cuellar G, Painter JN, Nyholt D, Australian Ovarian Cancer Study, The International Endogene Consortium, Morris AP, Fasching PA, Hein A, Burghaus S, Beckmann MW, Lambrechts; D, Van Nieuwenhuysen E, Vergote I, Vanderstichele A, Doherty JA, Rossing MA, Wicklund KG, Chang-Claude J, Eilber U, Rudolph A, Wang-Gohrke S, Goodman MT, Bogdanova N, Dörk T, Dürst M, Hillemanns P, Runnebaum IB, Antonenkova N, Butzow R, Leminen A, Nevanlinna H, Pelttari LM, Edwards RP, Kelley JL, Modugno F, Moysich KB, Ness RB, Cannioto R, Høgdall E, Jensen A, Giles GG, Bruinsma F, Kjaer SK, Hildebrandt MAT, Liang D, Lu KH, Wu X, Bisogna M, Dao F, Levine DA, Cramer DW, Terry KL, Tworoger SS, Missmer S, Bjorge L, Salvesen HB, Kopperud RK, Bischof K, Aben KKH,

Kiemeney LA, Massuger LFAG, Brooks-Wilson A, Olson SH, McGuire V, Rothstein JH, Sieh W, Whittemore AS, Cook LS, Le ND, Gilks CB, Gronwald J, Jakubowska A, Lubiński J, Gawełko J, Song H, Tyrer JP, Wentzensen N, Brinton L, Trabert B, Lissowska J, McLaughlin JR, Narod SA, Phelan C, Anton-Culver H, Ziogas A, Eccles D, Gayther SA, Gentry-Maharaj A, Menon U, Ramus SJ, Wu AH, Dansonka-Mieszkowska A, Kupryjanczyk J, Timorek A, Szafron L, Cunningham JM, Fridley BL, Winham SJ, Bandera EV, Poole EM, Morgan TK, **Risch HA**, Goode EL, Schildkraut JM, Webb PM, Pearce CL, Berchuck A, Pharoah PDP, Montgomery GW, Zondervan KT, Chenevix-Trench G, Macgregor S. Shared genetics underlying epidemiological association between endometriosis and ovarian cancer. Hum Mol Genet 2015;24(20):5955-64. PMCID: PMC Journal in Process.

Nagle CM, Dixon SC, Jensen A, Kjaer SK, Modugno F, deFazio A, Fereday S, Hung J, Johnatty SE, Australian Ovarian Cancer Study Group, Fasching PA, Beckmann MW, Lambrechts D, Vergote I, Van Nieuwenhuysen E, Lambrechts S, **Risch HA**, Rossing MA, Doherty JA, Wicklund KG, Chang-Claude J, Goodman MT, Ness RB, Moysich K, Heitz F, du Bois A, Harter P, Schwaab I, Matsuo K, Hosono S, Goode EL, Vierkant RA, Larson MC, Fridley BL, Høgdall C, Schildkraut JM, Weber RP, Cramer DW, Terry KL, Bandera EV, Paddock L, Rodriguez-Rodriguez L, Wentzensen N, Yang HP, Brinton LA, Lissowska J, Høgdall E, Lundvall L, Whittemore A, McGuire V, Sieh W, Rothstein J, Sutphen R, Anton-Culver H, Ziogas A, Pearce CL, Wu AH, Webb PM, Ovarian Cancer Association Consortium. Obesity and survival among women with ovarian cancer: results from the Ovarian Cancer Association Consortium. Br J Cancer 2015;113(5):817-26. PMCID: PMC Journal in Process.

Childs EJ, Mocci E, Campa D, Bracci PM, Gallinger S, Goggins M, Li D, Neale R, Olson SH, Scelo G, Amundadottir LT, Bamlet WR, Bijlsma MF, Blackford A, Borges M, Brennan P, Brenner H, Bueno-de-Mesquita HB, Canzian F, Capurso G, Cavestro GM, Chaffee KG, Chanock SJ, Cleary SP, Cotterchio M, Foretova L, Fuchs C, Funel N, Gazouli M, Hassan M, Herman JM, Holcatova I, Holly EA, Hoover RN, Hung RJ, Janout V, Key TJ, Kupcinskas J, Kurtz RC, Landi S, Lu L, Malecka-Panas E, Mambrini A, Mohelnikova-Duchonova B, Neoptolemos JP, Oberg AL, Orlow I, Pasquali C, Pezzilli R, Rizzato C, Saldia A, Scarpa A, Stolzenberg-Solomon RZ, Strobel O, Tavano F, Vashist YK, Vodicka P, Wolpin BM, Yu H, Petersen GM, **Risch HA**, Klein AP. Common variation at 2p13.3, 3q29, 7p13 and 17q25.1 associated with susceptibility to pancreatic cancer. Nat Genet 2015;47(8)911-6. PMCID: PMC4520746.

Lawrenson K, Li Q, Kar S, Seo J-H, Tyrer J, Spindler TJ, Lee J, Chen Y, Karst A, Drapkin R, Aben KKH, Anton-Culver H, Antonenkova N, Australian Ovarian Cancer Study Group, Baker H, Bandera EV, Bean Y, Beckmann MW, Berchuck A, Bisogna M, Bjorge L, Bogdanova N, Brinton LA, Brooks-Wilson A, Bruinsma F, Butzow R, Campbell IG, Carty K, Chang-Claude J, Chenevix-Trench G, Chen A, Chen Z, Cook LS, Cramer DW, Cunningham JM, Cybulski C, Dansonka-Mieszkowska A, Dennis J, Dicks E, Doherty JA, Dörk T, du Bois A, Dürst M, Eccles D, Easton DT, Edwards RP, Eilber U, Ekici AB, Fasching PA, Fridley BL, Gao Y-T, Gentry-Maharaj A, Giles GG, Glasspool R, Goode EL, Goodman MT, Grownwald J, Harrington P, Harter P, Hasmad HN, Hein A, Heitz F, Hildebrandt MAT, Hillemanns P, Hogdall E, Hogdall C, Hosono S, Iversen ES, Jakubowska A, James P, Jensen A, Ji B-T, Karlan BY, Kjaer SK, Kelemen LE, Kellar M, Kelley JL, Kiemeney LA, Krakstad C, Kupryjanczyk J, Lambrechts D, Lambrechts S, Le ND, Lee AW, Lele S, Leminen A, Lester J, Levine DA, Liang D, Lissowska J, Lu K, Lubinski J, Lundvall L, Massuger LFAG, Matsuo K, McGuire V, McLaughlin JR, Nevanlinna H, McNeish I, Menon U, Modugno F, Moysich KB, Narod SA, Nedergaard L, Ness RB, Noor Azmi MA, Odunsi K, Olson SH, Orlow I, Orsulic S, Weber RP,

Pearce CL, Pejovic T, Pelttari LM, Permuth-Wey J, Phelan CM, Pike MC, Poole EM, Ramus SJ, **Risch HA**, Rosen B, Rossing MA, Rothstein JH, Rudolph A, Runnebaum IB, Rzepecka IK, Salvesen HB, Schildkraut JM, Schwaab I, Sellers TA, Shu X-O, Shvetsov YB, Siddiqui N, Sieh W, Song H, Southey MC, Sucheston L, Tangen IL, Teo S-H, Terry KL, Thompson PJ, Timorek A, Tsai Y-Y, Tworoger SS, van Altena AM, Van Nieuwenhuysen E, Vergote I, Vierkant RA, Wang-Gohrke S, Walsh C, Wentzensen N, Whittemore AS, Wicklund KG, Wilkens LR, Woo Y-L, Wu X, Wu AH, Yang H, Zheng W, Ziogas A, Monteiro A, Pharoah PD, Gayther SA, Freedman ML. *Cis*-eQTL analysis and functional validation of candidate susceptibility genes for high-grade serous ovarian cancer. Nat Commun 2015;6:8234. PMCID: PMC4580986.

Kelemen LE, Lawrenson K, Tyrer J, Li Q, Lee JM, Seo J-H, Phelan CM, Beesley J, Chen X, Spindler TJ, Aben KKH, Anton-Culver H, Antonenkova N, Australian Ovarian Cancer Study Group, Baker H, Bandera EV, Bean Y, Beckmann MW, Bisogna M, Bjorge L, Bogdanova N, Brinton LA, Brooks-Wilson A, Bruinsma F, Butzow R, Campbell IG, Carty K, Chang-Claude J, Chen YA, Chen Z, Cook LS, Cramer DW, Cunningham JM, Cybulski C, Dansonka-Mieszkowska A, Dennis J, Dicks E, Doherty JA, Dörk T, du Bois A, Eccles D, Easton DT, Edwards RP, Eilber U, Ekici AB, Engelholm SA, Fasching PA, Fridley BL, Gao Y-T, Gentry-Maharaj A, Giles GG, Glasspool R, Goode EL, Goodman MT, Grownwald J, Harrington P, Harter P, Hasmad HN, Hein A, Heitz F, Hildebrandt MAT, Hillemanns P, Hogdall E, Hogdall C, Hosono S, Iversen ES, Jakubowska A, Jensen A, Ji B-T, Karlan BY, Kellar M, Kelley JL, Kiemeney LA, Krakstad C, Kjaer SK, Kupryjanczyk J, Lambrechts D, Lambrechts S, Le ND, Lee AW, Lele S, Leminen A, Lester J, Levine DA, Liang D, Lissowska J, Lu K, Lubinski J, Lundvall L, Massuger LFAG, Matsuo K, McGuire V, McLaughlin JR, McNeish I, Menon U, Modugno F, Moes-Sosnowska J, Moysich KB, Narod SA, Nedergaard L, Ness RB, Nevanlinna H, Noor Azmi MA, Odunsi K, Olson SH, Orlow I, Orsulic S, Weber RP, Paul J, Pearce CL, Pejovic T, Pelttari LM, Permuth-Wey J, Pike MC, Poole EM, Ramus SJ, **Risch HA**, Rosen B, Rossing MA, Rothstein JH, Rudolph A, Runnebaum IB, Rzepecka IK, Salvesen HB, Schildkraut JM, Schwaab I, Shu X-O, Shvetsov YB, Siddiqui N, Sieh W, Song H, Southey MC, Sucheston L, Tangen IL, Teo S-H, Terry KL, Thompson PJ, Tworoger SS, van Altena AM, Van Nieuwenhuysen E, Vergote I, Vierkant RA, Wang-Gohrke S, Walsh C, Wentzensen N, Whittemore AS, Wicklund KG, Wilkens LR, Wlodzimierz S, Woo Y-L, Wu X, Wu AH, Yang H, Zheng W, Ziogas A, Sellers TA, Freedman ML, Chenevix-Trench G, Pharoah PD, Gayther SA, Berchuck A, Ovarian Cancer Association Consortium. Genome-wide significant risk associations for mucinous ovarian carcinoma. Nat Genet 2015;47(8):888-97. PMCID: PMC4520768.

Petrick JL, Steck SE, Bradshaw PT, Trivers KF, Abrahamson PE, Engel LS, He K, Chow W-H, Mayne ST, **Risch HA**, Vaughan TL, Gammon MD. Dietary intake of flavonoids and oesophageal and gastric cancer: incidence and survival in the United States of America (USA). Br J Cancer 2015;112():1291-300. PMCID: PMC Journal in Process.

Yang HP, Cook LS, Weiderpass E, Adami H-O, Anderson KE, Cai H, Cerhan JR, Clendenen TV, Felix AS, Friedenreich CM, Garcia-Closas M, Goodman MT, Liang X, Lissowska J, Lu L, Magliocco AM, McCann SE, Moysich KB, Olson SH, Petruzella S, Pike MC, Polidoro S, Ricceri F, **Risch HA**, Sacerdote C, Setiawan VW, Shu XO, Spurdle AB, Trabert B, Webb PM, Wentzensen N, Xiang Y-B, Xu Y, Yu H, Zeleniuch-Jacquotte A, Brinton LA. Infertility and incident endometrial cancer risk: a pooled analysis from the epidemiology of endometrial cancer consortium (E2C2). Br J Cancer 2015;112(7):925-33. PMCID: PMC4453954.

Kuchenbaecker KB, Ramus SJ, Tyrer J, Lee A, Shen H, Beesley J, Lawrenson K, McGuffog L, Healey S, Lee JM, Spindler TJ, Lin YG, Pejovic T, Bean Y, Li Q, Coetzee S, Hazelett D, Miron

A, Southey M, Terry MB, Goldgar DE, Buys SS, Janavicius R, Dorfling CM, van Rensburg EJ, Neuhausen SL, Ding YC, Hansen TVO, Jønson L, Gerdes A-M, Ejlertsen B, Barrowdale D, Dennis J, Benitez J, Osorio A, Garcia MJ, Komenaka I, Weitzel JN, Ganschow P, Peterlongo P, Bernard L, Viel A, Bonanni B, Peissel B, Manoukian S, Radice P, Papi L, Ottini L, Fostira F, Konstantopoulou I, Garber J, Frost D, Perkins J, Platte R, Ellis S, EMBRACE, Godwin AK, Schmutzler RK, Meindl A, Engel C, Sutter C, Sinilnikova OM, GEMO Study Collaborators, Damiola F, Mazoyer S, Stoppa-Lyonnet D, Claes K, Leeneer KD, Kirk J, Rodriguez GC, Piedmonte M, O'Malley DM, de la Hoya M, Caldes T, Aittomäki K, Nevanlinna H, Collée JM, Rookus MA, Oosterwijk JC, Breast Cancer Family Registry, Tihomirova L, Tung N, Hamann U, Isaccs C, Tischkowitz M, Imyanitov EN, Caligo MA, Campbell I, Hogervorst FBL, HEBON, Olah E, Diez O, Blanco I, Brunet J, Lazaro C, Pujana MA, Jakubowska A, Gronwald J, Lubinski J, Sukiennicki G, Barkardottir RB, Plante M, Simard J, Soucy P, Montagna M, Tognazzo S, Teixeira MR, KConFab Investigators, Pankratz VS, Wang X, Lindor N, Szabo CI, Kauff N, Vijai J, Aghajanian CA, Pfeiler G, Berger A, Singer CF, Tea M-K, Phelan CM, Greene MH, Mai PL, Rennert G, Mulligan AM, Tchatchou S, Andrulis IL, Glendon G, Toland AE, Jensen UB, Kruse TA, Thomassen M, Bojesen A, Zidan J, Friedman E, Laitman Y, Soller M, Liljegren A, Arver B, Einbeigi Z, Stenmark-Askmalm M, Olopade OI, Nussbaum RL, Rebbeck TR, Nathanson KL, Domchek SM, Lu KH, Karlan BY, Walsh C, Lester J, Australian Cancer Study (Ovarian Cancer), Australian Ovarian Cancer Study Group, Hein A, Ekici AB, Beckmann MW, Fasching PA, Lambrechts D, Van Nieuwenhuysen E, Vergote I, Lambrechts S, Dicks E, Doherty JA, Wicklund KG, Rossing MA, Rudolph A, Chang-Claude J, Wang-Gohrke S, Eilber U, Moysich KB, Odunsi K, Sucheston L, Lele S, Wilkens LR, Goodman MT, Thompson PJ, Shvetsov YB, Runnebaum IB, Dürst M, Hillemanns P, Dörk T, Antonenkova N, Bogdanova N, Leminen A, Pelttari LM, Butzow R, Modugno F, Kelley JL, Edwards RP, Ness RB, du Bois A, Heitz F, Schwaab I, Harter P, Matsuo K, Hosono S, Orsulic S, Jensen A, Kruger Kjaer S, Hogdall E, Hasmad HN, Noor Azmi MA, Teo S-H, Woo Y-L, Fridley BL, Goode EL, Cunningham JM, Vierkant RA, Bruinsma F, Giles GG, Liang D, Hildebrandt MAT, Wu X, Levine DA, Bisogna M, Berchuck A, Iversen ES, Schildkraut JM, Concannon P, Weber RP, Cramer DW, Terry KL, Poole EM, Tworoger SS, Bandera EV, Orlow I, Olson SH, Krakstad C, Salvesen HB, Tangen IL, Bjorge L, van Altena AM, Aben KKH, Kiemeney LA, G. LFA, Kellar M, Brooks-Wilson A, Kelemen LE, Cook LS, Le ND, Cybulski C, Yang H, Lissowska J, Brinton LA, Wentzensen N, Hogdall C, Lundvall L, Nedergaard L, Baker H, Song H, Eccles D, McNeish I, Paul J, Carty K, Siddiqui N, Glasspool R, Whittemore AS, Rothstein JH, McGuire V, Sieh W, Ji B-T, Zheng W, Shu X-O, Gao Y-T, Rosen B, **Risch HA**, McLaughlin JR, Narod SA, Monteiro AN, Chen A, Lin H-Y, Permuth-Wey J, Sellers TA, Tsai Y-Y, Chen Z, Ziogas A, Anton-Culver H, Gentry-Maharaj A, Menon U, Harrington P, Lee AW, Wu AH, Pearce CL, Coetzee G, Pike MC, Dansonka-Mieszkowska A, Timorek A, Rzepecka IK, Kupryjanczyk J, Freedman M, Noushmehr H, Easton DF, Offit K, Couch FJ, Gayther S, Pharoah PDP, Antoniou AC, Chenevix-Trench G on behalf of the Consortium of Investigators of Modifiers of BRCA1 and BRCA2. Identification of six new susceptibility loci for invasive epithelial ovarian cancer. Nat Genet 2015;47(2):164-71. PMCID: PMC Journal in Process.

Xie G, Lu L, Qiu Y, Ni Q, Zhang W, Gao Y-T, **Risch HA**, Yu H, Jia W. Plasma metabolite markers for the detection of pancreatic cancer. J Proteome Res. 2015;14(2):1195-202. PMCID: PMC4324440.

Segev Y, Zhang S, Akbari MR, Sun P, Sellers TA, McLaughlin J, **Risch HA**, Rosen B, Shaw P, Schildkraut J, Narod SA, Pal T. Survival in women with ovarian cancer with and without microsatellite instability. Eur J Gynaecol Oncol 2015;36(6):681-4. *Not a result of NIH

funding.

Lu L, Katsaros D, Risch E, Deng Q, Biglia N, Picardo E, Mitidieri M, **Risch HA**, Yu H. Associations of LIN-28B/let-7a/IGF-II axis haplotypes with disease survival in epithelial ovarian cancer. Am J Clin Exp Obstet Gynecol 2015;2(3)102-15. *Not a result of NIH funding.

Chornokur G, Lin H-Y, Tyrer JP, Jim HSL, Lawrenson K, Amankwah EK, Qu X, Denis J, Tsai Y-Y, Chen Z, Chen AY, Permuth-Wey J, Aben K, Anton-Culver H, Antonenkova N, Australian Cancer Study, Australian Ovarian Cancer Study, Bruinsma F, Baker H, Bandera E, Bean Y, Beckmann M, Bisogna M, Bjorge L, Bogdanova N, Brinton L, Brooks-Wilson A, Bunker C, Butzow R, Campbell I, Carty K, Chang-Claude J, Concannon P, Cook LS, Cramer DW, Cunnigham JM, Cybulski C, Dansonka-Mieszkowska A, du Bois A, Despierre E, Dicks E, Doherty JA, Dork T, Durst M, Easton D, Eccles D, Edwards RP, Ekici AB, Fasching PA, Fridley BL, Gao Y-T, Gentry-Maharaj A, Giles GG, Glasspool R, Goodman MT, Gronwald J, Harrington P, Harter P, Hein A, Heitz F, Hildebrandt MAT, Hillemanns P, Hogdall C, Hogdall E, Hosono S, Jakubowska A, Jensen A, Ji B-T, Karlan BY, Kelemen LE, Kellar M, Kiemeney L, Krakstad C, Kruger Kjaer S, Kupryjanczyk J, Lambrechts D, Lambrechts S, Le ND, Lee A, Lele S, Leminen A, Lester J, Levine DA, Liang D, Lim BK, Lissowska J, Lu K, Lubinski J, Lundvall L, Massuger LFAG, Matsuo K, Milne RL, McGuire V, McLaughlin JR, McNeish I, Menon U, Modugno F, Moysich KB, Nedergaard L, Ness RB, Nevanlinna H, Nickels S, Odunsi K, Olson SH, Orlow I, Orsulic S, Palmieri-Weber R, Paul J, Pearce CL, Pejovic T, Pelttari LM, Pike MC, Poole EM, **Risch HA**, Rosen B, Rossing MA, Rothstein JH, Rudolph A, Runnebaum I, Rzepecka I, Salvensen HB, Schernhammer E, Schwaab I, Shu X-O, Shvetsov YB, Siddiqui N, Sieh W, Song H, Southey MC, Sucheston L, Teo S-H, Terry KL, Thompson PJ, Thorbjornsen I, Timorek A, Tworoger SS, van Altena AM, Vierkant RA, Vergote I, Walsh C, Wang-Gohrke S, Webb P, Wentzensen N, Whittemore AS, Wicklund KG, Wilkens LR, Wu AH, Wu X, Wu Y-L, Yang H, Zheng W, Ziogas A, Zulkifli F, Berchuck A, Chenevix-Trench G, Iversen E, Schildkraut JM, Ramus SJ, Goode EL, Monteiro ANA, Gayther SA, Narod SA, Sellers TA, Pharoah PDP, Phelan CM. Common genetic variation in cellular transport genes and epithelial ovarian cancer (EOC) risk. PLoS One 2015;10(6):e0128106. PMCID: PMC4474865.

Zhao J, Wang J, Du J, Xu H, Zhang W, Ni Q-X, Yu H, **Risch HA**, Gao Y-T, Gao Y. Urinary prostaglandin E_2 metabolite and pancreatic cancer risk: case-control study in urban Shanghai. PLoS One 2015;10(2):e0118004. PMCID: PMC4332509.

Arem H, Yu K, Xiong X, Moy K, Freedman ND, Mayne ST, Albanes D, Amundadottir LT, Arslan AA, Austin M, Bamlet WR, Beane-Freeman L, Bracci P, Canzian F, Chanock SJ, Cotterchio M, Duell EJ, Gallinger S, Giles GG, Goggins M, Goodman PJ, Hartge P, Hassan M, Helzlsouer K, Henderson B, Holly EA, Hoover R, Jacobs EJ, Kamineni A, Klein A, Klein E, Kolonel LN, Li D, Malats N, Männistö S, McCullough ML, Olson SH, Orlow I, Peters U, Petersen GM, Porta M, Severi G, Shu X-O, Van Den Eeden S, Visvanathan K, White E, Yu H, Zeleniuch-Jacquotte A, Zheng W, Tobias GS, Maeder D, Brotzman M, **Risch H**, Sampson JN, Stolzenberg-Solomon RZ. Vitamin D metabolic pathway genes and pancreatic cancer risk. PLoS One 2015;10(3):e0117574. PMCID: PMC4370655.

Buas MF, Onstad L, Levine DM, **Risch HA**, Chow W-H, Liu G, Fitzgerald RC, Bernstein L, Ye W, Bird NC, Romero Y, Casson AG, Corley DA, Shaheen NJ, Wu AH, Gammon MD, Reid BJ, Hardie LJ, Peters U, Whiteman DC, Vaughan TL. MiRNA-related SNPs and risk of esophageal adenocarcinoma and Barrett's Esophagus: Post genome-wide association analysis in

the BEACON consortium. PLoS One 2015;10(6):e0128617. PMCID: PMC4454432.

Shen Y, Katsaros D, Loo L, Hernandez BY, Chong C, Canuto EM, Biglia N, Lu L, **Risch H**, Chu W-M, Yu H. Prognostic and predictive values of long non-coding RNA LINC00472 in breast cancer. Oncotarget 2015;6(11):8579-92. *Not a result of NIH funding.

Sampson J, Wheeler WA, Yeager M, Panagiotou O, Wang Z, Berndt SI, Lan Q, Abnet CC, Amundadottir LT, Figueroa JD, Landi MT, Mirabello L, Savage SA, Taylor PR, De Vivo I, McGlynn KA, Purdue MP, Rajaraman P, Adami H-O, Ahlbom A, Albanes D, Amary MF, An S-J, Andersson U, Andriole G Jr, Andrulis IL, Angelucci E, Ansell SM, Arici C, Armstrong BK, Arslan AA, Austin MA, Baris D, Barkauskas DA, Bassig BA, Becker N, Benavente Y, Benhamou S, Berg C, Van Den Berg D, Bertrand KA, Birmann BM, Black A, Boeing H, Boffetta P, Boutron-Ruault M-C, Bracci PM, Brinton L, Brooks-Wilson AR, Bueno-de-Mesquita HB, Burdett L, Buring J, Cai Q, Cancel-Tassin G, Canzian F, Carrato A, Carreon T, Carta A, Chan JKC, Chang ET, Chang G-C, Chang I-S, Chang J, Chang-Claude J, Chen C-J, Chen C-Y, Chen C, Chen C-H, Chen C, Chen H, Chen K, Chen K-Y, Chen K-C, Chen Y, Chen Y-H, Chen Y-S, Chen Y-M, Chien L-H, Chirlaque M-D, Choi JE, Choi YY, Chow W-H, Chung CC, Clavel J, Clavel-Chapelon F, Cocco P, Colt JS, Comperat E, Conde L, Connors JM, Conti D, Cortessis VK, Cotterchio M, Cozen W, Crouch S, Crous-Bou M, Cussenot O, Davis FG, Dawsey SM, Ding T, Diver WR, Dorronsoro M, Dossus L, Duell EJ, Ennas MG, Erickson RL, Feychting M, Flanagan AM, Foretova L, Fraumeni JF Jr, Freedman ND, Freeman LEB, Fuchs C, Gago-Dominguez M, Gallinger S, Gao Y-T, Gapstur SM, Garcia-Closas M, García-Closas R, Gascoyne RD, Gastier-Foster J, Gaudet MM, Gaziano JM, Giffen C, Giles GG, Giovannucci E, Glimelius B, Goggins M, Gokgoz N, Goldstein AM, Gorlick R, Gross M, Grubb R III, Gu J, Guan P, Gunter M, Guo H, Habermann TM, Haiman CA, Halai D, Hallmans G, Hassan M, Hattinger C, He Q, He X, Helzlsouer K, Henderson B, Henriksson R, Hjalgrim H, Hoffman-Bolton J, Hohensee C, Holford TR, Holly EA, Hong Y-C, Hoover RN, Horn-Ross PL, Hosain GM, Hosgood HD III, Hsiao C-F, Hu N, Hu W, Hu Z, Huang M-S, Huerta J-M, Hung J-Y, Hutchinson A, Inskip PD, Jackson RD, Jacobs EJ, Jenab M, Jeon H-S, Ji B-T, Jin G, Jin L, Johansen C, Johnson A, Jung YJ, Kaaks R, Kamineni A, Kane E, Kang CH, Karagas MR, Kelly RS, Khaw K-T, Kim C, Kim HN, Kim JH, Kim JS, Kim YH, Kim YT, Kim Y-C, Kitahara CM, Klein AP, Klein RJ, Kogevinas M, Kohno T, Kolonel LN, Kooperberg C, Kricker A, Krogh V, Kunitoh H, Kurtz RC, Kweon S-S, LaCroix A, Lawrence C, Lecanda F, Lee VHF, Li D, Li H, Li J, Li Y-J, Li Y, Liao LM, Liebow M, Lightfoot T, Lim W-Y, Lin C-C, Lin D, Lindstrom S, Linet MS, Link BK, Liu C, Liu J, Liu L, Ljungberg B, Lloreta J, Lollo SD, Lu D, Lund E, Malats N, Mannisto S, Le Marchand L, Marina N, Masala G, Mastrangelo G, Matsuo K, Maynadie M, McKay J, McKean-Cowdin R, Melbye M, Melin BS, Michaud DS, Mitsudomi T, Monnereau A, Montalvan R, Moore LE, Mortensen LM, Nieters A, North KE, Novak AJ, Oberg AL, Offit K, Oh I-J, Olson SH, Palli D, Pao W, Park IK, Park JY, Park KH, Patel AV, Patiño-Garcia A, Pavanello S, Peeters PHM, Perng R-P, Peters U, Petersen GM, Picci P, Pike MC, Porru S, Prescott J, Prokunina-Olsson L, Qian B, Qiao Y-L, Rais M, Riboli E, Riby J, **Risch HA**, Rizzato C, Rodabough R, Roman E, De Roos AJ, Roupret M, Ruder AM, De Sanjose S, Scelo G, Schned A, Schumacher F, Schwartz K, Schwenn M, Seow A, Serra C, Serra M, Sesso HD, Setiawan VW, Severi G, Severson RK, Shanafelt TD, Shen H, Shen W, Shin M-H, Shiraishi K, Shu X-O, Siddiq A, Sierrasesúmaga L, Sihoe ADL, Skibola CF, Smith A, Smith MT, Southey MC, Spinelli JJ, Staines A, Stampfer M, Stern MC, Stevens VL, Stolzenberg-Solomon RS, Su J, Su W-C, Sund M, Sung JS, Sung SW, Tan W, Tang W, Tardón A, Thomas D, Thompson CA, Thun MJ, Tinker LF, Tirabosco R, Tjønneland A, Travis RC, Trichopoulos D, Tsai F-Y, Tsai Y-H, Tucker M, Turner J, Vajdic CM, Vermeulen RCH,

Villano DJ, Vineis P, Virtamo J, Visvanathan K, Wactawski-Wende J, Wang C, Wang C-L, Wang J-C, Wang J, Wei F, Weiderpass E, Weiner GJ, Weinstein S, Wentzensen N, White E, Witzig TE, Wolpin BM, Wong MP, Wu C, Wu G, Wu J, Wu T, Wu W, Wu X, Wu Y-L, Wunder J, Xiang Y-B, Xu J, Xu P, Yang P-C, Yang T-Y, Ye Y, Yin Z, Yokota J, Yoon H-I, Yu C-J, Yu H, Yu K, Yuan J-M, Zelenetz A, Zeleniuch-Jacquotte A, Zhang X-C, Zhang Y, Zhao X, Zhao Z, Zheng H, Zheng T, Zheng W, Zhou B, Zhu M, Zucca M, Boca SM, Cerhan JR, Ferri GM, Hartge P, Hsiung CA, Magnani C, Miligi L, Morton LM, Smedby KE, Teras LR, Vijai J, Wang SS, Brennan P, Caporaso NE, Hunter DJ, Kraft P, Rothman N, Silverman DT, Slager SL, Chanock SJ, Chatterjee N. Analysis of heritability and shared heritability based on genome-wide association studies for thirteen cancer types. J Natl Cancer Inst 2015;107(12):djv279. PMCID: PMC Journal in Process.

Palles C, Chegwidden L, Li X, Findlay JM, Farnham G, Giner FC, Peppelenbosch MP, Kovac M, Adams CL, Prenen H, Briggs S, Harrison R, Sanders S, MacDonald D, Haigh C, Tucker A, Love S, Nanji M, deCaestecker J, Ferry D, Rathbone B, Hapeshi J, Barr H, Zietek B, Maroo N, Gay L, Underwood T, Boulter L, McMurtry H, Monk D, Patel P, Ragunath K, Al Dulaimi D, Murray I, Koss K, Veitch A, Trudgill N, Nwokolo C, Rembacken B, Atherfold P, Green E, Ang Y, Kuipers EJ, Chow W, Paterson S, Kadri S, Beales I, Grimley C, Mullins P, Beckett C, Farrant M, Dixon A, Kelly S, Johnson M, Wajed S, Dhar A, Sawyer E, Roylance R, Onstad L, Gammon MD, Corley DA, Shaheen NJ, Bird NC, Hardie LJ, Reid BJ, Ye W, Liu G, Romero Y, Bernstein L, Wu AH, Casson AG, Fitzgerald R, Whiteman DC, **Risch HA**, Levine DM, Vaughan TL, Verhaar AP, van den Brande J, Toxopeus EL, Spaander MC, Wijnhoven BPL, van der Laan LJ, Krishnadath K, Wijmenga C, Trynka G, McManus R, Reynolds JV, O'Sullivan J, MacMathuna P, McGarrigle SA, Kelleher D, Vermeire S, Cleynen I, Bisschops R, Tomlinson I, Jankowski J. Polymorphisms near *TBX5* and *GDF7* are associated with increased risk for Barrett's Esophagus. Gastroenterology 2015;148(2):367-78. PMCID: PMC4315134.

2014

Lu Y, Ek WE, Whiteman D, Vaughan TL, Spurdle AB, Easton DF, Pharoah PD, Thompson DJ, Dunning AM, Hayward NK, Chenevix-Trench G, Q-MEGA and AMFS Investigators, ANECS-SEARCH, UKOPS-SEARCH, BEACON Consortium, Macgregor S. Most common 'sporadic' cancers have a significant germline genetic component. Hum Molec Genet 2014;23(22):6112-8. PMCID: PMC4271103.

Thrift AP, **Risch HA**, Onstad L, Shaheen NJ, Casson AG, Bernstein L, Corley DA, Levine DM, Chow W-H, Reid BJ, Romero Y, Hardie LJ, Liu G, Wu AH, Bird NC, Gammon MD, Ye W, Whiteman DC, Vaughan TL. Risk of esophageal adenocarcinoma decreases with height, based on consortium analysis and confirmed by Mendelian randomization. Clin Gastroenterol Hepatol 2014;12(10):1667-76. PMCID: PMC4130803.

Neale RE, Clark P, Fawcett J, Fritschi L, Nagler BN, **Risch H**, Walters RJ, Crawford WJ, Webb PM, Whiteman DC, Buchanan DD. Association between hypermethylation of DNA repetitive elements in white blood cell DNA and pancreatic cancer. Cancer Epidemiol 2014;38(5):576-82. *Not a result of NIH funding.

Segev Y, Pal T, Rosen B, McLaughlin JR, Sellers TA, **Risch HA**, Zhang S, Sun P, Narod SA, Schildkraut J. Risk factors for ovarian cancers with and without microsatellite instability. Int J Gynecol Cancer 2014;24(4):664-9. PMCID: PMC Journal in Process.

Wolpin BM, Rizzato C, Kraft P, Kooperberg C, Petersen GM, Wang Z, Arslan AA, Beane-Freeman L, Bracci PM, Buring J, Canzian F, Duell EJ, Gallinger S, Giles GG, Goodman GE, Goodman PJ, Jacobs EJ, Kamineni A, Klein AP, Kolonel LN, Kulke MH, Li D, Malats N,

Olson SH, **Risch HA**, Sesso HD, Visvanathan K, White E, Zheng W, Abnet CC, Albanes D, Andriotti G, Austin MA, Barfield R, Basso D, Berndt SI, Boutron-Ruault M-C, Brotzman M, Büchler MW, Bueno-de-Mesquita HB, Bugert P, Burdette L, Campa D, Caporaso NE, Capurso G, Chung C, Cotterchio M, Costello E, Elena J, Funel N, Gaziano JM, Giese N, Giovannucci EL, Goggins M, Gorman MJ, Gross M, Haiman CA, Hassan M, Helzlsouer K, Henderson BE, Holly EA, Hu N, Hunter DJ, Innocenti F, Jenab M, Kaaks R, Key TJ, Khaw K-T, Klein EA, Kogevinas M, Kupcinskas J, Kurtz RC, LaCroix A, Landi MT, Landi S, Le Marchand L, Mambrini A, Mannisto S, Milne RL, Nakamura Y, Oberg AL, Owzar K, Panico S, Patel AV, Peeters PHM, Peters U, Piepoli A, Porta M, Real FX, Riboli E, Rothman N, Scarpa A, Shu X-O, Silverman DT, Soucek P, Sund M, Talar-Wojnarowska R, Taylor PR, Theodoropoulos GE, Thornquist M, Tjønneland A, Tobias GS, Trichopoulos D, Vodicka P, Wactawski-Wende J, Wentzensen N, Wu C, Yu H, Yu K, Zeleniuch-Jacquotte A, Hoover R, Hartge P, Fuchs C, Chanock S, Stolzenberg-Solomon RS, Amundadottir L. Genome-wide association study identifies multiple susceptibility loci for pancreatic cancer. Nat Genet 2014;46(9):994-1000. PMCID: PMC4191666.

Finch A, Bacopoulos S, Rosen B, Fan I, Bradley L, **Risch H**, McLaughlin JR, Lerner-Ellis J, Narod SA. Preventing ovarian cancer through genetic testing: a population-based study. Clin Genet 2014;86(5):496-9. *NIH funding pre-dates mandate.

Kelemen LE, Terry KL, Goodman MT, Webb PM, Bandera EV, McGuire V, Rossing MA, Wang Q, Dicks E, Tyrer JP, Song H, Kupryjanczyk J, Dansonka-Mieszkowska A, Plisiecka-Halasa J, Timorek A, Menon U, Gentry-Maharaj A, Gayther SA, Ramus SJ, Narod SA, **Risch HA**, McLaughlin JR, Siddiqui N, Glasspool R, Paul J, Carty K, Gronwald J, Lubiński J, Jakubowska A, Cybulski C, Kiemeney LA, Massuger LFAG, van Altena AM, Aben KKH, Olson SH, Orlow I, Cramer DW, Levine DA, Bisogna M, Giles GG, Southey MC, Bruinsma F, Krüger Kjær S, Høgdall E, Jensen A, Høgdall CK, Lundvall L, Engelholm S-A, Heitz F, du Bois A, Harter P, Schwaab I, Butzow R, Nevanlinna H, Pelttari LM, Leminen A, Thompson PJ, Lurie G, Wilkens LR, Lambrechts D, Van Nieuwenhuysen E, Lambrechts S, Vergote I, Beesley J, AOCS Study Group/ACS Investigators, Fasching PA, Beckmann MW, Hein A, Ekici AB, Doherty JA, Wu AH, Pearce CL, Pike MC, Stram D, Chang-Claude J, Rudolph A, Dörk T, Dürst M, Hillemanns P, Runnebaum IB, Bogdanova N, Antonenkova N, Odunsi K, Edwards RP, Modugno F, Ness RB, Karlan BY, Walsh C, Lester J, Orsulic S, Fridley BL, Vierkant RA, Cunningham JM, Wu X, Lu K, Liang D, Hildebrandt MAT, Weber RP, Iversen ES, Tworoger SS, Poole EM, Salvesen HB, Krakstad C, Bjorge L, Tangen IL, Pejovic T, Bean Y, Kellar M, Wentzensen N, Brinton LA, Lissowska J, Garcia-Closas M, Campbell IG, Eccles D, Whittemore AS, Sieh W, Rothstein JH, Anton-Culver H, Ziogas A, Phelan CM, Moysich KB, Goode EL, Schildkraut JM, Berchuck A, Pharoah PDP, Sellers TA, Brooks-Wilson A, Cook LS, Le ND, on behalf of the Ovarian Cancer Association Consortium. Consortium analysis of gene and gene-folate interactions in purine and pyrimidine metabolism pathways with ovarian carcinoma risk. Mol Nutr Food Res 2014;58(10):2023-5. PMCID: PMC4197821.

Setiawan VW, Schumacher F, Prescott J, Haessler J, Malinowski J, Wentzensen N, Yang H, Chanock S, Brinton L, Hartge P, Lissowska J, Park SL, Cheng I, Bush WS, Crawford DC, Ursin G, Horn-Ross P, Bernstein L, Lu L, **Risch H**, Yu H, Sakoda LC, Doherty J, Chen C, Jackson R, Yasmeen S, Cote M, Kocarnik JM, Peters U, Kraft P, De Vivo I, Haiman CA, Kooperberg C, Le Marchand L. Cross-cancer pleiotropic analysis of endometrial cancer: PAGE and E2C2 Consortia. Carcinogenesis 2014;35(9):2068-73. PMCID:4146418.

Lawrenson K, Iversen ES, Tyrer J, Weber RP, Concannon P, Hazelett DJ, Li Q, Marks JR, Berchuck A, Lee JM, Aben KKH, Anton-Culver H, Antonenkova N, Australian Cancer Study

(Ovarian Cancer), Australian Ovarian Cancer Study Group, Bandera EV, Bean Y, Beckmann MW, Bisogna M, Bjorge L, Bogdanova N, Brinton LA, Brooks-Wilson A, Bruinsma F, Butzow R, Campbell IG, Carty K, Chang-Claude J, Chenevix-Trench G, Chen YA, Chen Z, Cook LS, Cramer DW, Cunningham JM, Cybulski C, Plisiecka-Halasa J, Dennis J, Dicks E, Doherty JA, Dörk T, du Bois A, Eccles D, Easton DT, Edwards RP, Eilber U, Ekici AB, Fasching PA, Fridley BL, Gao Y-T, Gentry-Maharaj A, Giles GG, Glasspool R, Goode EL, Goodman MT, Grownwald J, Harter P, Hasmad HN, Hein A, Heitz F, Hildebrandt MAT, Hillemanns P, Hogdall E, Hogdall C, Hosono S, Jakubowska A, Paul J, Jensen A, Karlan BY, Kruger Kjaer S, Kelemen LE, Kellar M, Kelley JL, Kiemeney LA, Krakstad C, Lambrechts D, Lambrechts S, Le ND, Lee AW, Cannioto R, Leminen A, Lester J, Levine DA, Liang D, Lissowska J, Lu K, Lubinski J, Lundvall L, Massuger LFAG, Matsuo K, McGuire V, McLaughlin JR, Nevanlinna H, McNeish I, Menon U, Modugno F, Moysich KB, Narod SA, Nedergaard L, Ness RB, Noor Azmi MA, Odunsi K, Olson SH, Orlow I, Orsulic S, Pearce CL, Pejovic T, Pelttari LM, Permuth-Wey J, Phelan CM, Pike MC, Poole EM, Ramus SJ, **Risch HA**, Rosen B, Rossing MA, Rothstein JH, Rudolph A, Runnebaum IB, Rzepecka IK, Salvesen HB, Budzilowska A, Sellers TA, Shu X-O, Shvetsov YB, Siddiqui N, Sieh W, Song H, Southey MC, Sucheston L, Tangen IL, Teo S-H, Terry KL, Thompson PJ, Timorek A, Tworoger SS, Van Nieuwenhuysen E, Vergote I, Vierkant RA, Wang-Gohrke S, Walsh C, Wentzensen N, Whittemore AS, Wicklund KG, Wilkens LR, Woo Y-L, Wu X, Wu AH, Yang H, Zheng W, Ziogas A, Coetzee GA, Freedman ML, Monteiro ANA, Moes-Sosnowska J, Kupryjanczyk J, Pharoah PDP, Gayther SA, Schildkraut JM. Common variants at the CHEK2 gene locus and risk of epithelial ovarian cancer. Carcinogenesis 2015;36(11):1341-53. PMCID: PMC Journal in Process.

Wang Z, Zhu B, Zhang M, Parikh H, Jia J, Chung CC, Sampson JN, Hoskins JW, Hutchinson A, Burdette L, Ibrahim A, Hautman C, Raj PS, Abnet CC, Adjei AA, Ahlbom A, Albanes D, Allen NE, Ambrosone CB, Aldrich M, Amiano P, Amos C, Andersson U, Andriole G Jr, Andrulis IL, Arici C, Arslan AA, Austin MA, Baris D, Barkauskas DA, Bassig BA, Beane Freeman LE, Berg CD, Berndt SI, Bertazzi PA, Biritwum RB, Black A, Blot W, Boeing H, Boffetta P, Bolton K, Boutron-Ruault M-C, Bracci PM, Brennan P, Brinton LA, Brotzman M, Bueno-de-Mesquita HB, Buring JE, Butler MA, Cai Q, Cancel-Tassin G, Canzian F, Cao G, Caporaso NE, Carrato A, Carreon T, Carta A, Chang G-C, Chang I-S, Chang-Claude J, Che X, Chen C-J, Chen C-Y, Chen C-H, Chen C, Chen K-Y, Chen Y-M, Chokkalingam AP, Chu LW, Clavel-Chapelon F, Colditz GA, Colt JS, Conti D, Cook MB, Cortessis VK, Crawford ED, Cussenot O, Davis FG, De Vivo I, Deng X, Ding T, Dinney CP, Di Stefano AL, Diver WR, Duell EJ, Elena JW, Fan J-H, Feigelson HS, Feychting M, Figueroa JD, Flanagan AM, Fraumeni JF Jr, Freedman ND, Fridley BL, Fuchs CS, Gago-Dominguez M, Gallinger S, Gao Y-T, Gapstur SM, Garcia-Closas M, Garcia-Closas R, Gastier-Foster JM, Gaziano JM, Gerhard DS, Giffen CA, Giles GG, Gillanders EM, Giovannucci EL, Goggins M, Gokgoz N, Goldstein AM, Gonzalez C, Gorlick R, Greene MH, Gross M, Grossman HB, Grubb R III, Gu J, Guan P, Haiman CA, Hallmans G, Hankinson SE, Harris CC, Hartge P, Hattinger C, Hayes RB, He Q, Helman L, Henderson BE, Henriksson R, Hoffman-Bolton J, Hohensee C, Holly EA, Hong Y-C, Hoover RN, Hosgood HD III, Hsiao C-F, Hsing AW, Hsiung CA, Hu N, Hu W, Hu Z, Huang M-S, Hunter DJ, Inskip PD, Ito H, Jacobs EJ, Jacobs KB, Jenab M, Ji B-T, Johansen C, Johansson M, Johnson A, Kaaks R, Kamat AM, Kamineni A, Karagas M, Khanna C, Khaw K-T, Kim C, Kim I-S, Kim YH, Kim Y-C, Kim YT, Kang CH, Jung YJ, Kitahara CM, Klein AP, Klein R, Kogevinas M, Koh W-P, Kohno T, Kolonel LN, Kooperberg C, Kratz CP, Krogh V, Kunitoh H, Kurtz RC, Kurucu N, Lan Q, Lathrop M, Lau CC, Lecanda F, Lee K-M, Lee MP, Le Marchand L, Lerner SP, Li D, Liao LM, Lim W-Y, Lin D, Lin J, Lindstrom S, Linet MS,

Lissowska J, Liu J, Ljungberg B, Lloreta J, Lu D, Ma J, Malats N, Mannisto S, Marina N, Mastrangelo G, Matsuo K, McGlynn KA, McKean-Cowdin R, McNeill LH, McWilliams RR, Melin BS, Meltzer PS, Mensah JE, Miao X, Michaud DS, Mondul AM, Moore LE, Muir K, Niwa S, Olson SH, Orr N, Panico S, Park JY, Patel AV, Patino-Garcia A, Pavanello S, Peeters PHM, Peplonska B, Peters U, Petersen GM, Picci P, Pike MC, Porru S, Prescott J, Pu X, Purdue MP, Qiao Y-L, Rajaraman P, Riboli E, **Risch HA**, Rodabough RJ, Rothman N, Ruder AM, Ryu J-S, Sanson M, Schned A, Schumacher FR, Schwartz AG, Schwartz KL, Schwenn M, Scotlandi K, Seow A, Serra C, Serra M, Sesso HD, Severi G, Shen H, Shen M, Shete S, Shiraishi K, Shu X-O, Siddiq A, Sierrasesumaga L, Sierri S, Sihoe ADL, Silverman DT, Simon M, Southey MC, Spector L, Spitz M, Stampfer M, Stattin P, Stern MC, Stevens VL, Stolzenberg-Solomon RZ, Stram DO, Strom SS, Su W-C, Sund M, Sung SW, Swerdlow A, Tan W, Tanaka H, Tang W, Tang Z-Z, Tardon A, Tay E, Taylor PR, Tettey Y, Thomas DM, Tirabosco R, Tjonneland A, Tobias GS, Toro JR, Travis RC, Trichopoulos D, Troisi R, Truelove A, Tsai Y-H, Tucker MA, Tumino R, Van Den Berg D, Van Den Eeden SK, Vermeulen R, Vineis P, Visvanathan K, Vogel U, Wang C, Wang C, Wang J, Wang SS, Weiderpass E, Weinstein SJ, Wentzensen N, Wheeler W, White E, Wiencke JK, Wolk A, Wolpin BM, Wong MP, Wrensch M, Wu C, Wu T, Wu X, Wu Y-L, Wunder JS, Xiang Y-B, Xu J, Yang HP, Yang P-C, Yatabe Y, Ye Y, Yeboah ED, Yin Z, Ying C, Yu C-J, Yu K, Yuan J-M, Zanetti KA, Zeleniuch-Jacquotte A, Zheng W, Zhou B, Mirabello L, Savage SA, Kraft P, Chanock SJ, Yeager M, Landi MT, Shi J, Chatterjee N, Amundadottir LT. Imputation and subset based association analysis across different cancer types identifies multiple independent risk loci in the *TERT-CLPTM1L* region on chromosome 5p15.33. Hum Molec Genet 2014;23(24):6616-33. PMCID: PMC Journal in Process.

Cook MB, Corley DA, Murray LJ, Liao LM, Kamangar F, Ye W, Gammon MD, **Risch HA**, Casson AG, Freedman ND, Chow W-H, Wu AH, Bernstein L, Nyrén O, Pandeya N, Whiteman DC, Vaughan TL. Gastroesophageal reflux in relation to adenocarcinomas of the esophagus: A pooled analysis from the Barrett's and Esophageal Adenocarcinoma Consortium (BEACON). PLoS One 2014;9(7):e103508. PMCID: PMC4116205.

Chen MM, Crous-Bou M, Setiawan VW, Prescott J, Olson SH, Wentzensen N, Black A, Brinton L, Chen C, Chen C, Cook LS, Doherty J, Friedenreich CM, Gaudet MM, Hankinson SE, Hartge P, Henderson BE, Horn-Ross PL, Hunter DJ, Le Marchand L, Liang X, Lissowska J, Lu L, Orlow I, Petruzella S, Pooler L, Rebbeck TR, **Risch H**, Sacerdote C, Schumacher F, Sheng X, Shu X-O, Weiss NS, Xia L, Van Den Berg D, Yang HP, Yu H, Chanock S, Haiman C, Kraft P, De Vivo I. Exome-wide association study of endometrial cancer in a multiethnic population. PLoS One 2014;9(5):e97045. PMCID: PMC4014590.

Tang H, Wei P, Duell EJ, **Risch HA**, Olson SH, Bueno-de-Mesquita HB, Gallinger S, Holly EA, Petersen G, Bracci PM, McWilliams RR, Jenab M, Riboli E, Tjønneland A, Boutron-Ruault MC, Kaaks R, Trichopoulos D, Panico S, Sund M, Peeters PHM, Khaw K-T, Amos CI, Li D. Axonal guidance signaling pathway interacting with smoking in modifying the risk of pancreatic cancer: A gene and pathway-based interaction analysis of GWAS data. Carcinogenesis 2014;35(5):1039-45. PMCID: PMC4004205.

Huang H, Ma X, Waagepetersen R, Holford T, Wang R, **Risch H**, Mueller L, Guan Y. A new estimation approach for combining epidemiological data from multiple sources. J Am Stat Assoc 2014;109(505):11-23. PMCID: PMC3964681.

Trabert B, Ness R, Lo-Ciganic W-H, Murphy M, Goode E, Poole E, Brinton L, Webb P, Nagle C, Jordan S, **Risch H**, Rossing MA, Doherty J, Goodman M, Lurie G, Krüger Kjær S, Høgdall E, Jensen A, Cramer D, Terry K, Vitonis A, Bandera E, Olson S, King M, Chandran U, Anton-

Culver H, Ziogas A, Menon U, Gayther S, Ramus S, Gentry-Maharaj A, Wu A, Pearce C, Pike M, Berchuck A, Schildkraut J, Wentzensen N, on behalf of the Ovarian Cancer Association Consortium. Aspirin, non-aspirin nonsteroidal anti-inflammatory drug, and acetaminophen use and risk of invasive epithelial ovarian cancer: a pooled analysis in the Ovarian Cancer Association Consortium. J Natl Cancer Inst 2014;106(2):djt431. PMCID: PMC3898362.

Xu H-L, Cheng J-R, Zhang W, Wang J, Yu H, Ni Q-X, **Risch HA**, Gao Y-T. Re-evaluation of ABO gene polymorphisms detected in a genome-wide association study and risk of pancreatic ductal adenocarcinoma in a Chinese population. Chin J Cancer 2014;33(2):68-73. PMCID: PMC3884064.

Charbonneau B, Block MS, Bamlet WR, Vierkant RA, Kalli KR, Fogarty Z, Rider DN, Sellers TA, Tworoger SS, Poole E, **Risch HA**, Salvesen HB, Kiemeny LA, Baglietto L, Giles GG, Severi G, Trabert B, Wentzensen N, Chenevix-Trench G for AOCS/ACS group, Whittemore AS, Sieh W, Chang-Claude J, Bandera EV, Orlow I, Terry K, Goodman MT, Thompson PJ, Cook LS, Rossing M, Ness RB, Narod SA, Kupryjanczyk J, Lu K, Bützow R, Dork T, Pejovic T, Campbell I, Le ND, Bunker CH, Bogdanova N, Runnebaum IB, Eccles DM, Paul J, Wu AH, Gayther SA, Hogdall E, Heitz F, Kaye SB, Karlan BY, Anton-Culver H, Gronwald J, Hogdall CK, Lambrechts D, Fasching PA, Menon U, Schildkraut J, Pearce CL, Levine DA, Kruger Kjær S, Cramer D, Flanagan JM, Phelan CM, Brown R, Massuger LFAG, Song H, Doherty JA, Krakstad C, Liang D, Odunsi K, Berchuck A, Jensen A, Lubiński J, Nevanlinna H, Bean YT, Lurie G, Ziogas A, Walsh C, Despierre E, Brinton L, Hein A, Rudolph A, Dansonka-Mieszkowska A, Olson SH, Harter P, Tyrer J, Vitonis AF, Brooks-Wilson A, Aben KK, Pike MC, Ramus SJ, Wik E, Cybulski C, Lin J, Sucheston L, Edwards R, McGuire V, Lester J, du Bois A, Lundvall L, Wang-Gohrke S, Szafron LM, Lambrechts S, Yang HP, Beckmann MW, Pelttari LM, van Altena AM, van den Berg D, Halle M, Gentry-Maharaj A, Schwaab I, Chandran U, Menkiszak J, Ekici AB, Wilkens LR, Leminen A, Modugno F, Friel G, Rothstein JH, Vergote I, Garcia-Closas M, Hildebrandt MAT, Sobiczewski P, Kelemen LE, Pharoah PDP, Moysich K, Knutson KL, Cunningham JM, Fridley BL, Goode EL. Risk of ovarian cancer and the NF-κB pathway: Genetic association with *IL1A* and *TNFSF10*. Cancer Res 2014;74(3):852-61. PMCID: PMC3946482.

Earp MA, Kelemen LE, Magliocco AM, Swenerton KD, Chenevix-Trench G, Australian Cancer Study, Australian Ovarian Cancer Study Group, Lu Y, Hein A, Ekici AB, Beckmann MW, Fasching PA, Lambrechts D, Despierre E, Vergote I, Lambrechts S, Doherty JA, Rossing MA, Chang-Claude J, Rudolph A, Friel G, Moysich KB, Odunsi K, Sucheston L, Lurie G, Goodman MT, Carney ME, Thompson PJ, Runnebaum I, Dürst M, Hillemanns P, Dörk T, Antonenkova N, Bogdanova N, Leminen A, Nevanlinna H, Pelttari LM, Butzow R, Bunker CH, Modugno F, Edwards RP, Ness RB, du Bois A, Heitz F, Schwaab I, Harter P, Karlan BY, Walsh C, Lester J, Jensen A, Kjær SK, Høgdall CK, Høgdall E, Lundvall L, Sellers TA, Fridley BL, Goode EL, Cunningham JM, Vierkant RA, Giles GG, Baglietto L, Severi G, Southey MC, Liang D, Wu X, Lu K, Hildebrandt MA, Levine DA, Bisogna M, Schildkraut JM, Iversen ES, Palmieri Weber R, Berchuck A, Cramer DW, Terry KL, Poole EM, Tworoger SS, Bandera EV, Chandran U, Orlow I, Olson SH, Wik E, Salvesen HB, Bjorge L, Halle MK, van Altena AM, Aben KK, Kiemeney LA, Massuger LFAG, Pejovic T, Bean YT, Cybulski C, Gronwald J, Lubinski J, Wentzensen N, Brinton LA, Lissowska J, Garcia-Closas M, Dicks E, Dennis J, Easton DF, Song H, Tyrer JP, Pharoah PDP, Eccles D, Campbell IG, Whittemore AS, McGuire V, Sieh W, Rothstein JH, Flanagan JM, Paul J, Brown R, Phelan CM, **Risch HA**, McLaughlin JR, Narod SA, Ziogas A, Anton-Culver H, Gentry-Maharaj A, Menon U, Gayther SA, Ramus SJ, Wu AH, Pearce CL, Pike MC, Dansonka-Mieszkowska A, Rzepecka IK, Szafron LM, Kupryjanczyk J,

Cook LS, Le ND, Brooks-Wilson A, on behalf of the Ovarian Cancer Association Consortium. Genome-wide association study of subtype-specific epithelial ovarian cancer risk alleles using pooled DNA. Hum Genet 2014;133(5):481-97. PMCID: PMC4063682.

Tang H, Wei P, Duell EJ, **Risch HA**, Olson SH, Bueno-de-Mesquita HB, Gallinger S, Holly EA, Petersen GM, Bracci PM, McWilliams RR, Jenab M, Riboli E, Tjønneland A, Boutron-Ruault MC, Kaaks R, Trichopoulos D, Panico S, Sund M, Peeters PHM, Khaw K-T, Amos CI, Li D. Genes-environment interactions in obesity- and diabetes-associated pancreatic cancer: A GWAS data analysis. Cancer Epidemiol Biomarkers Prev 2014;23(1):98-106. PMCID: PMC3947145.

De Vivo I, Prescott J, Setiawan VW, Olson SH, Wentzensen N, Australian National Endometrial Cancer Study Group, Attia J, Black A, Brinton L, Chen C, Chen C, Cook LS, Crous-Bou M, Doherty J, Dunning AM, Easton DF, Friedenreich CM, Garcia-Closas M, Gaudet MM, Haiman C, Hankinson SE, Hartge P, Henderson BE, Holliday E, Horn-Ross PL, Hunter DJ, Le Marchand L, Liang X, Lissowska J, Long J, Lu L, Magliocco AM, McEvoy M, O'Mara TA, Orlow I, Painter JN, Pooler L, Rastogi R, Rebbeck TR, **Risch H**, Sacerdote C, Schumacher F, Scott RJ, Sheng X, Shu X-O, Spurdle AB, Thompson D, VanDen Berg D, Weiss NS, Xia L, Xiang Y-B, Yang HP, Yu H, Zheng W, Chanock S, Kraft P. Genome.wide association study of endometrial cancer in E2C2. Hum Genet 2014;133(2):211-24. PMCID: PMC3898362.

Buas MF, Levine DM, Makar KW, Utsugi H, Onstad L, Li X, Galipeau PC, Shaheen NJ, Hardie LJ, Romero Y, Bernstein L, Gammon MD, Casson AG, Bird NC, **Risch HA**, Ye W, Liu G, Corley DA, Blount PL, Fitzgerald RC, Whiteman DC, Wu AH, Reid BJ, Vaughan TL. Integrative post-genome-wide association analysis of *CDKN2A* and *TP53* SNPs and risk of esophageal adenocarcinoma. Carcinogenesis 2014; 35(12):2740-7. PMCID: PMC Journal in Process.

Thrift AP, Shaheen NJ, Gammon MD, Bernstein L, Reid BJ, Onstad L, **Risch HA**, Liu G, Bird NC, Wu AH, Corley DA, Romero Y, Chanock S, Chow W-H, Casson AG, Levine DM, Zhang R, Ek WE, MacGregor S, Ye W, Hardie LJ, Vaughan TL, Whiteman DC. Obesity and risk of esophageal adenocarcinoma and Barrett's Esophagus: a Mendelian randomization study. J Natl Cancer Institute 2014;106(11):dju252. doi: 10.1093/jnci/dju252. PMCID: PMC4200028.

Streicher SA, Yu H, Lu L, Kidd MS, **Risch HA**. Case-control study of aspirin use and risk of pancreatic cancer. Cancer Epidemiol Biomarkers Prev 2014;23(7):1254-63. PMCID: PMC4091763.

Risch HA, Lu L, Kidd MS, Wang J, Zhang W, Ni Q, Gao Y-T, Yu H. *Helicobacter pylori* seropositivities and risk of pancreatic carcinoma. Cancer Epidemiol Biomarkers Prev 2014;23(1):172-8. PMCID: PMC3947155.

Schulte A, Pandeya N, Tran B, Fawcett J, Fritschi L, **Risch HA**, Webb PM, Whiteman DC, Neale RE, Queensland Pancreatic Cancer Study Group. Cigarette smoking and pancreatic cancer risk: more to the story than just pack-years. Eur J Cancer 2014;50(5):997-1003. . *Not a result of NIH funding.

Kotsopoulos J, Prescott J, De Vivo I, Fan I, McLaughlin J, Rosen B, **Risch H**, Sun P, Narod SA. Telomere length and mortality following a diagnosis of ovarian cancer. Cancer Epidemiol Biomarkers Prev 2014;23(11):2603-6. PMCID: PMC4221534.

Navarro Silvera SA, Mayne ST, Gammon MD, Vaughan TL, Chow W-H, Dubin JA, Dubrow R, Stanford JL, West AB, Rotterdam H, Blot WJ, **Risch HA**. Diet and lifestyle factors and risk of subtypes of esophageal and gastric cancer: classification tree analysis. Ann Epidemiol

2014;24(1):50-7. PMCID: PMC4006990.

2013

Pearce CL, Rossing MA, Lee AW, Ness R, Webb PM for Australian Cancer Study (Ovarian Cancer) and Australian Ovarian Cancer Study Group, Chenevix-Trench G, Jordan SM, Stram DA, Chang-Claude J, Hein R, Nickels S, Lurie G, Thompson PJ, Carney ME, Goodman MT, Moysich K, Hogdall E, Jensen A, Goode EL, Fridley BL, Cunningham JM, Vierkant RA, Weber RP, Ziogas A, Anton-Culver H, Gayther SA, Gentry-Maharaj A, Menon U, Ramus SJ, Brinton L, Wentzensen N, Lissowska J, Garcia-Closas M, Massuger LFAG, Kiemeney LALM, van Altena AM, Aben KKH, Berchuck A, Doherty JA, Iversen E, McGuire V, Moorman PG, Pharoah P, Pike MC, **Risch H**, Sieh W, Stram DO, Terry KL, Whittemore A, Wu AH, Schildkraut JM, Kjaer SK for the Ovarian Cancer Association Consortium. Combined and interactive effects of environmental and GWAS-identified risk factors in ovarian cancer. Cancer Epidemiol Biomarkers Prev 2013;22(5):880-90. PMCID: PMC3963289.

Leenders M, Bhattacharjee S, Vineis P, Stevens V, Bueno-de-Mesquita HB, Shu XO, Amundadottir L, Gross M, Tobias GS, Wactawski-Wende J, Arslan AA, Duell EJ, Fuchs CS, Gallinger S, Hartge P, Hoover RN, Holly EA, Jacobs EJ, Klein AP, Kooperberg C, Lacroix A, Li D, Mandelson MT, Olson SH, Petersen G, **Risch HA**, Yu K, Wolpin BM, Zheng W, Agalliu I, Albanes D, Boutron-Ruault MC, Bracci PM, Buring JE, Canzian F, Chang K, Chanock SJ, Cotterchio M, Gaziano JM, Giovanucci EL, Goggins M, Hallmans G, Hankinson SE, Hoffman-Bolton JA, Hunter DJ, Hutchinson A, Jacobs KB, Jenab M, Khaw KT, Kraft P, Krogh V, Kurtz RC, McWilliams RR, Mendelsohn JB, Patel AV, Rabe KG, Riboli E, Tjønneland A, Trichopoulos D, Virtamo J, Visvanathan K, Elena JW, Yu H, Zeleniuch-Jacquotte A, Stolzenberg-Solomon RZ. Polymorphisms in genes related to one-carbon metabolism are not related to pancreatic cancer in PanScan and PanC4. Cancer Causes Control 2013;24(3):595-602. PMCID: PMC4127987.

Ek WE, Levine DM, D'Amato M, Pedersen NL, Magnusson PKE, Bresso F, Onstad LE, Schmidt PT, Törnblom H, Nordenstedt H, Romero Y, Chow W-H, Murray LJ, Gammon MD, Liu G, Bernstein L, Casson AG, **Risch HA**, Shaheen NJ, Bird NC, Reid BJ, Corley DA, Hardie LJ, Ye W, Wu AH, Zucchelli M, Spector TD, Hysi P, Vaughan TL, Whiteman DC, MacGregor S. Germline genetic contributions to risk for esophageal adenocarcinoma, Barrett's Esophagus and gastroesophageal reflux. J Natl Cancer Inst 2013;105(22):1711-8. PMCID: PMC3833931.

Arem H, Reedy J, Sampson J, Jiao L, Hollenbeck AR, **Risch H**, Mayne ST, Stolzenberg-Solomon RZ. The Healthy Eating Index-2005 and risk of pancreatic cancer in the NIH-AARP Study. J Natl Cancer Inst 2013;105(17):1298-305. PMCID: PMC3760780.

Arem H, Mayne ST, Sampson J, **Risch H**, Stolzenberg-Solomon RZ. Dietary fat intake and risk of pancreatic cancer in the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial. Ann Epidemiol 2013;23(9):571-5. PMCID: PMC3752990.

Terry KL, Karageorgi S, Shvetsov YB, Merritt MA, Lurie G, Thompson PJ, Carney ME, Weber RP, Akushevich L, Lo-Ciganic W-H, Cushing-Haugen K, Sieh W, Moysich K, Doherty JA, Nagle CM, Australian Cancer Study (Ovarian Cancer), Australian Ovarian Cancer Study Group, Berchuck A, Pearce CL, Pike M, Ness RB, Webb PM, Rossing MA, Schildkraut J, **Risch H**, Goodman MT, The Ovarian Cancer Association Consortium. Genital powder use and risk of ovarian cancer: a pooled analysis of 8,525 cases and 9,859 controls. Cancer Prev Res 2013;6(8):811-21. PMCID: PMC3766843.

Setiawan VW, Yang HP, Pike MC, McCann S, Yu H, Xiang Y-B, Wolk A, Wentzensen N, Weiss N, Webb P, van den Brandt PA, van de Vijver K, Thompson PJ, Strom B, Spurdle AB, Soslow

R, Shu X-O, Schairer C, Sacerdote C, Rohan T, Robien K, **Risch HA**, Ricceri F, Rebbeck T, Rastogi R, Prescott J, Polidoro S, Park Y, Olson SH, Moysich K, Miller AB, McCullough M, Matsuno R, Magliocco AM, Lurie G, Lu L, Lissowska J, Liang X, Lacey JV, Kolonel L, Henderson B, Hankinson S, Hakansson N, Goodman M, Gaudet MM, Garcia-Closas M, Friedenreich C, Freudenheim J, Doherty J, de Vivo I, Courneya KS, Cook L, Chen C, Cerhan JR, Cai H, Brinton L, Bernstein L, Anderson K, Anton-Culver H, Schouten L, Horn-Ross P. Type I and II endometrial cancers: have they different risk factors? J Clin Oncol 2013;31(20):2607-18. PMCID: PMC3699726.

Olsen CM, Nagle CM, Whiteman DC, Ness R, Pearce CL, Pike MC, Rossing MA, Terry KL, Wu AH, Australian Cancer Study (Ovarian Cancer), Australian Ovarian Cancer Study Group, **Risch HA**, Yu H, Doherty JA, Chang-Claude J, Hein R, Nickels S, Wang-Gohrke S, Goodman MT, Carney ME, Matsuno RK, Lurie G, Moysich K, Kjaer SK, Jensen A, Hogdall E, Goode EL, Fridley BL, Vierkant RA, Larson MC, Schildkraut J, Hoyo C, Moorman P, Weber RP, Cramer DW, Vitonis AF, Bandera EV, Olson SH, Rodriguez-Rodriguez L, King M, Brinton LA, Yang H, Garcia-Closas M, Lissowska J, Anton-Culver H, Ziogas A, Gayther SA, Ramus SJ, Menon U, Gentry-Maharaj A, Webb PM, Ovarian Cancer Association Consortium. Obesity and risk of ovarian cancer subtypes: evidence from the Ovarian Cancer Association Consortium. Endocr Relat Cancer 2013;20(2);251-62. PMCID: PMC3857135.

Arem H, Bobe G, Sampson J, Subar AF, Park Y, **Risch H**, Hollenbeck A, Mayne ST, Stolzenberg-Solomon RZ. Flavonoid intake and risk of pancreatic cancer in the National Institutes of Health-AARP Diet and Health Study Cohort. Br J Cancer 2013;108(5):1168-72. PMCID: PMC3619057.

Faber MT, Kjær SK, Dehlendorff C, Chang-Claude J, Andersen KK, Høgdall E, Webb PM, Jordan SM, The Australian Cancer Study (Ovarian Cancer), Australian Ovarian Cancer Study Group, Rossing MA, Doherty JA, Goodman MT, Ness R, Goode EL, Schildkraut J, Cramer DW, Terry KL, Bandera EV, Olson SH, Kiemeney LA, Massuger L, Moysich K, Odunsi K, Song H, Pharaoh P, Whittemore A, McGuire V, Sieh W, Sutphen R, Narod SA, Menon U, Gayther SA, Ramus SJ, Gentry-Maharaj A, Pearce CL, **Risch HA**, Jensen A, Ovarian Cancer Association Consortium. Cigarette smoking and risk of ovarian cancer—a pooled analysis of 21 case-control studies. Cancer Causes Control 2013;24(5):989-1004. PMCID: PMC3818570.

Permuth-Wey J, Lawrenson K, Shen HC, Velkova A, Tyrer JP, Chen Z, Lin H-Y, Chen YA, Tsai Y-Y, Qu X, Ramus SJ, Karevan R, Lee J, Lee N, Larson MC, Aben KK, Anton-Culver H, Antonenkova N, Antoniou A, Armasu SM, Australian Cancer Study, Australian Ovarian Cancer Study, Bacot F, Baglietto L, Bandera EV, Barnholtz-Sloan J, Beckmann MW, Birrer MJ, Bloom G, Bogdanova N, Brinton LA, Brooks-Wilson A, Brown R, Butzow R, Cai Q, Campbell I, Chang-Claude J, Chanock S, Chenevix-Trench G, Cheng JQ, Cicek MS, Coetzee GA, Consortium of Investigators of Modifiers of BRCA1/2, Cook LS, Couch FJ, Cramer DW, Cunningham JM, Dansonka-Mieszkowska A, Despierre E, Doherty JA, Dörk T, du Bois A, Dürst M, Easton DF, Eccles D, Edwards R, Ekici AB, Fasching PA, Fenstermacher DA, Flanagan JM, Garcia-Closas M, Gentry-Maharaj A, Giles GG, Glasspool RM, Gonzalez-Bosquet J, Goodman MT, Gore M, Górski B, Gronwald J, Hall P, Halle MK, Harter P, Heitz F, Hillemanns P, Hoatlin M, Høgdall CK, Høgdall E, Hosono S, Jakubowska A, Jensen A, Jim H, Kalli KR, Karlan BY, Kaye SB, Kelemen LE, Kiemeney LA, Kikkawa F, Konecny GE, Krakstad C, Krüger Kjaer S, Kupryjanczyk J, Lambrechts D, Lambrechts S, Lancaster JM, Le ND, Leminen A, Levine DA, Liang D, Lim BK, Lin J, Lissowska J, Lu KH, Lubiński J, Lurie G, Massuger LF, Matsuo K, McGuire V, McLaughlin JR, Menon U, Modugno F, Moysich KB, Nakanishi T, Narod SA, Nedergaard L, Ness RB, Nevanlinna H, Nickels S, Noushmehr H,

Odunsi K, Olson SH, Orlow I, Paul J, Pearce CL, Pejovic T, Pelttari LM, Pike MC, Poole EM, Raska P, Renner SP, **Risch HA**, Rodriguez-Rodriguez L, Rossing MA, Rudolph A, Runnebaum IB, Rzepecka IK, Salvesen HB, Schwaab I, Severi G, Shridhar V, Shu X-O, Shvetsov YB, Sieh W, Song H, Southey MC, Spiewankiewicz B, Stram D, Sutphen R, Teo S-H, Terry KL, Tessier DC, Thompson PJ, Tworoger SS, van Altena AM, Vergote I, Vierkant RA, Vincent D, Vitonis AF, Wang-Gohrke S, Weber RP, Wentzensen N, Whittemore AS, Wik E, Wilkens LR, Winterhoff B, Woo YL, Wu AH, Xiang Y-B, Yang HP, Zheng W, Ziogas A, Zulkifli F, Phelan CM, Iversen E, Schildkraut JM, Berchuck A, Fridley BL, Goode EL, Pharoah PDP, Monteiro ANA, Sellers TA, Gayther SA. Identification and molecular characterization of a new ovarian cancer susceptibility locus at 17q21.31. Nat Commun 2013;4:1627. PMCID: PMC3709460.

Levine DM, Ek WE, Zhang R, Liu X, Onstad L, Sather C, Lao-Sirieix P, Gammon MD, Corley DA, Shaheen NJ, Bird NC, Hardie LJ, Murray LJ, Reid BJ, Chow W-H, **Risch HA**, Nyrén O, Ye W, Liu G, Romero Y, Bernstein L, Wu AH, Casson AG, Chanock S, Harrington P, Caldas I, Debiram-Beecham I, Caldas C, Hayward NK, Pharoah P, Fitzgerald R, MacGregor S, Whiteman DC, Vaughan TL. A genome-wide association study identifies new susceptibility loci for esophageal adenocarcinoma and Barrett's Esophagus. Nat Genet 2013; 45(12):1487-93. PMCID: PMC3840115.

Klein AP, Lindström S, Mendelsohn JB, Steplowski E, Arslan AA, Bueno-de-Mesquita HB, Fuchs CS, Gallinger S, Gross M, Helzlsouer K, Holly EA, Jacobs EJ, LaCroix A, Li D, Mandelson MT, Olson SH, Petersen GM, **Risch HA**, Stolzenberg-Solomon RZ, Zheng W, Amundadottir L, Albanes D, Allen NE, Bamlet WR, Boutron-Ruault M-C, Buring JE, Bracci PM, Canzian F, Clipp S, Cotterchio M, Duell EJ, Elena J, Gaziano JM, Giovannucci EL, Goggins M, Hallmans G, Hassan M, Hutchinson A, Hunter DJ, Kooperberg C, Kurtz RC, Liu S, Overvad K, Palli D, Patel AV, Rabe KG, Shu X-O, Slimani N, Tobias GS, Trichopoulos D, Van Den Eeden SK, Vineis P, Virtamo J, Wactawski-Wende J, Wolpin BM, Yu H, Yu K, Zeleniuch-Jacquotte A, Chanock SJ, Hoover RN, Hartge P, Kraft P. An absolute risk model to identify individuals at elevated risk for pancreatic cancer in the general population. PLoS One 2013;8(9):e72311. PMCID: PMC3772857.

Bosetti C, Lucenteforte E, Bracci PM, Ji B-T, Negri E, Neale RE, **Risch HA**, Olson SH, Gallinger S, Miller AB, Bueno-de-Mesquita HB, Talamini R, Polesel J, Ghadirian P, Baghurst PA, Zatonski W, Fontham E, Holly EA, Gao Y-T, Yu H, Kurtz RC, Cotterchio M, Maisonneuve P, Zeegers MP, Duell EJ, Boffetta P, La Vecchia C. Ulcer, gastric surgery and pancreatic cancer risk: an analysis from the International Pancreatic Cancer Case-control Consortium (PanC4). Ann Oncol 2013;24(11):2903-10. PMCID: PMC3811904.

Sieh W, Salvador S, McGuire V, Weber RP, Terry KL, Rossing MA, **Risch H**, Wu AH, Webb PM, Moysich K, Doherty JA, Felberg A, Miller D, Jordan SJ, Australian Cancer Study (Ovarian Cancer), Australian Ovarian Cancer Study Group, Goodman MT, Lurie G, Chang-Claude J, Rudolph A, Krüger Kjær S, Jensen A, Høgdall E, Bandera EV, Olson SH, King MG, Rodriguez-Rodriguez L, Kiemeney LA, Marees T, Massuger LF, van Altena AM, Ness RB, Cramer DW, Pike MC, Pearce CL, Berchuck A, Schildkraut JM, Whittemore, AS, on behalf of the Ovarian Cancer Association Consortium. Tubal ligation and risk of ovarian cancer subtypes: a pooled analysis of case-control studies. Int J Epidemiol 2013;42(2):579-89. PMCID: PMC3619957.

Arem H, Neuhouser ML, Irwin ML, Cartmel B, Lu L, **Risch H**, Mayne ST, Yu H. Omega-3 and omega-6 fatty acid intakes and endometrial cancer risk in a population-based case-control study. Eur J Nutr 2013;52(3):1251-60. PMCID: PMC3548981.

Tran B, Whiteman DC, Webb PM, Fritschi L, Fawcett J, **Risch HA**, Lucas R, Pandeya N, Schulte A, Neale RE, for the Queensland Pancreatic Cancer Study Group. Association between ultraviolet radiation, skin sun sensitivity and risk of pancreatic cancer. Cancer Epidemiology 2013;37(6):886-92. *Not a result of NIH funding.

Wang J, Zhang W, Sun L, Yu H, **Risch HA**, Ni Q-X, Gao Y-T. Dietary energy density is positively associated with risk of pancreatic cancer in urban Shanghai Chinese. J Nutr 2013;143(10):1626-9. PMCID: PMC3771813.

Shen H, Fridley BL, Song H, Lawrenson K, Cunningham JM, Ramus SJ, Cicek MS, Tyrer J, Stram D, Larson MC, Köbel M, PRACTICAL Consortium, Ziogas A, Zheng W, Yang HP, Wu AH, Wozniak EL, Woo YL, Winterhoff B, Wik E, Whittemore AS, Wentzensen N, Weber RP, Vitonis AF, Vincent D, Vierkant RA, Vergote I, Van Den Berg D, Van Altena AM, Tworoger SS, Thompson PJ, Tessier DC, Terry KL, Teo S-H, Templeman C, Stram DO, Southey MC, Sieh W, Siddiqui N, Shvetsov YB, Shu X-O, Shridhar V, Wang-Gohrke S, Severi G, Schwaab I, Salvesen HB, Rzepecka IK, Runnebaum I, Rossing MA, Rodriguez-Rodriguez L, **Risch HA**, Renner SP, Poole EM, Pike MC, Phelan CM, Pelttari LM, Pejovic T, Paul J, Orlow I, Omar SZ, Olson SH, Odunsi K, Nickels S, Nevanlinna H, Ness RB, Narod SA, Nakanishi T, Moysich KB, Monteiro ANA, Moes-Sosnowska J, Modugno F, Menon U, McLaughlin JR, McGuire V, Matsuo K, Mat Adenan NA, Massuger LFG, Lurie G, Lundvall L, Lubiński J, Lissowska J, Levine DA, Leminen A, Lee AW, Le ND, Lambrechts S, Lambrechts D, Kupryjanczyk J, Krakstad C, Konecny GE, Krüger Kjaer S, Kiemeney LA, Kelemen LE, Keeney GL, Karlan BY, Karevan R, Kalli KR, Kajiyama H, Ji B-T, Jensen A, Jakubowska A, Iversen E, Hosono S, Høgdall CK, Høgdall E, Hoatlin M, Hillemanns P, Heitz F, Hein R, Harter P, Halle MK, Hall P, Gronwald J, Gore M, Goodman MT, Giles GG, Gentry-Maharaj A, Garcia-Closas M, Flanagan JM, Fasching PA, Ekici AB, Edwards R, Eccles D, Easton DF, Dürst M, du Bois A, Dörk T, Doherty JA, Despierre E, Dansonka-Mieszkowska A, Cybulski C, Cramer DW, Cook LS, Chen X, Charbonneau B, Chang-Claude J, Campbell I, Butzow R, Bunker CH, Brueggmann D, Brown R, Brooks-Wilson A, Brinton LA, Bogdanova N, Block MS, Benjamin E, Beesley J, Beckmann MW, Bandera EV, Baglietto L, Bacot F, Armasu SM, Antonenkova N, Anton-Culver H, Aben KK, Australian Ovarian Cancer Study Group, Australian Cancer Study, Schildkraut JM, Sellers TA, Huntsman D, Berchuck A, Chenevix-Trench G, Gayther SA, Pharoah PDP, Laird PW, Goode EL, Pearce CL. Epigenetic analysis leads to identification of HNF1B as a subtype-specific susceptibility gene for ovarian cancer. Nat Commun 2013;4(1628):1-10. PMCID: PMC3848248.

Bojesen SE, Pooley KA, Johnatty SE, Beesley J, Michailidou K, Tyrer JP, Edwards SL, Pickett HA, Shen HC, Smart CE, Hillman KM, Mai PL, Lawrenson K, Stutz MD, Lu Y, Karevan R, Woods N, Johnston RL, French JD, Chen X, Wesicher M, Nielsen SF, Maranian MJ, Ghoussaini M, Ahmed S, Baynes C, Humphreys MK, Wang J, Dennis J, McGuffog L, Barrowdale D, Lee A, Healey S, Lush M, Tessier DC, Vincent D, Bacot F, Australian Cancer Study, Australian Ovarian Cancer Study Group, Vergote I, Lambrechts S, Despierre E, **Risch HA**, González-Neira A, Rossing MA, Pita G, Doherty JA, Álvarez N, Larson MC, Fridley BL, Schoof N, Chang-Claude J, Cicek MS, Peto J, Kalli KR, Broeks A, Armasu SM, Schmidt MK, Braaf LM, Winterhoff B, Nevanlinna H, Konecny GE, Lambrechts D, Rogmann L, Guénel P, Teoman A, Milne RL, Garcia JJ, Cox A, Shridhar V, Burwinkel B, Marme F, Hein R, Sawyer EJ, Haiman CA, Wang-Gohrke S, Andrulis IL, Moysich KB, Hopper JL, Odunsi K, Lindblom A, Giles GG, Brenner H, Simard J, Lurie G, Fasching PA, Carney ME, Radice P, Wilkens LR, Swerdlow A, Goodman MT, Brauch H, García-Closas M, Hillemanns P, Winqvist R, Dürst M, Devilee P, Runnebaum I, Jakubowska A, Lubinski J, Mannermaa A, Butzow R, Bogdanova

NV, Dörk T, Pelttari L, Zheng W, Leminen A, Anton-Culver H, Bunker CH, Kristensen V, Ness RB, Muir K, Edwards R, Meindl A, Heitz F, Matsuo K, du Bois A, Wu AH, Harter P, Teo S-H, Schwaab I, Shu X-O, Blot W, Hosono S, Kang D, Nakanishi T, Hartman M, Yatabe Y, Hamann U, Karlan BY, Sangrajrang S, Krüger Kjaer S, Gaborieau V, Jensen A, Eccles D, Høgdall E, Shen C-Y, Brown J, Woo YL, Shah M, Noor Azmi MA, Luben R, Omar SZ, Czene K, Vierkant RA, Nordestgaard BG, Flyger H, Vachon C, Olson JE, Wang X, Levine DA, Rudolph A, Palmieri Weber R, Flesch-Janys D, Iversen E, Nickels S, Schildkraut JM, Dos Santos Silva I, Cramer DW, Gibson L, Terry KL, Fletcher O, Vitonis AF, van der Schoot CE, Poole EM, Hogervorst FBL, Tworoger SS, Liu J, Bandera EV, Li J, Olson SH, Humphreys K, Orlow I, Blomqvist C, Rodriguez-Rodriguez L, Aittomäki K, Salvesen HB, Muranen TA, Wik E, Brouwers B, Krakstad C, Wauters E, Halle MK, Wildiers H, Kiemeney LA, Mulot C, Aben KK, Laurent-Puig P, van Altena AM, Truong T, Massuger LF, Benitez J, Pejovic T, Arias Perez JI, Hoatlin M, Zamora MP, Cook LS, Balasubramanian SP, Kelemen LE, Schneeweiss A, Le ND, Sohn C, Brooks-Wilson A, Tomlinson I, Kerin MJ, Miller N, Cybulski C, kConFab Investigators, Henderson BE, Menkiszak J, Schumacher F, Wentzensen N, Marchand LL, Yang HP, Mulligan AM, Glendon G, Engelholm SA, Knight JA, Høgdall CK, Apicella C, Gore M, Tsimiklis H, Song H, Southey MC, Jager A, van den Ouweland AM, Brown R, Martens JW, Flanagan JM, Kriege M, Paul J, Margolin S, Siddiqui N, Severi G, Whittemore AS, Baglietto L, McGuire V, Stegmaier C, Sieh W, Müller H, Arndt V, Labrèche F, Gao Y-T, Goldberg MS, Yang G, Dumont M, McLaughlin JR, Hartmann A, Ekici AB, Beckmann MW, Phelan CM, Lux MP, Permuth-Wey J, Peissel B, Sellers TA, Ficarazzi F, Barile M, Ziogas A, Ashworth A, Gentry-Maharaj A, Jones M, Ramus SJ, Orr N, Menon U, The Genica Network, Pearce CL, Brüning T, Pike MC, Ko Y-D, Lissowska J, Figueroa J, Kupryjanczyk J, Chanock SJ, Dansonka-Mieszkowska A, Jukkola-Vuorinen A, Rzepecka IK, Pylkäs K, Bidzinski M, Kauppila S, Hollestelle A, Seynaeve C, Monteiro ANA, Tollenaar RAM, Durda K, Jaworska K, Hartikainen JM, Kosma V-M, Kataja V, Antonenkova NN, Long J, Shrubsole M, Deming-Halverson S, Lophatananon A, Siriwanarangsan P, Stewart-Brown S, Ditsch N, Lichtner P, Schmutzler RK, Ito H, Iwata H, Tajima K, Tseng C-C, Stram DO, van den Berg D, Yip CH, Ikram MK, Teh Y-C, Cai H, Lu W, Signorello LB, Cai Q, Noh D-Y, Yoo K-Y, Miao H, Iau PT, Teo YY, McKay J, Shapiro C, Ademuyiwa F, Fountzilas G, Hsiung C-N, Yu J-C, Hou M-F, Healey CS, Luccarini C, Wang Q, Peock S, Stoppa-Lyonnet D, Peterlongo P, SWE-BRCA, Rebbeck TR, Piedmonte M, Singer CF, Friedman E, Thomassen M, Offit K, Hansen TVO, Neuhausen SL, Szabo CI, Blanco I, Garber J, Narod SA, Weitzel JN, Montagna M, Olah E, Godwin AK, Yannoukakos D, Goldgar DE, Caldes T, Imyanitov EN, Tihomirova L, Arun BK, Campbell I, Mensenkamp AR, van Asperen CJ, van Roozendaal K, Meijers-Heijboer HEJ, HEBON, Collée JM, Oosterwijk JC, Hooning MJ, Rookus MA, van der Luijt RB, van Os TAM, Evans DG, Frost D, Fineberg E, Embrace, Barwell J, Walker L, Kennedy MJ, Platte R, Davidson R, Ellis SD, Cole T, De Paillerets BB, Buecher B, Damiola F, Gemo Study Collaborators, Faivre L, Frenay M, Sinilnikova OM, Caron O, Giraud S, Mazoyer S, Bonadona V, Caux-Moncoutier V, Toloczko-Grabarek A, Gronwald J, Byrski T, Spurdle AB, Bonanni B, Zaffaroni D, Giannini G, Bernard L, Dolcetti R, Manoukian S, Norbert A, Engel C, Deissler H, Rhiem K, Meindl A, Niederacher D, Plendl H, Sutter C, Wappenschmidt B, Borg A, Melin B, Rantala J, Soller M, Nathanson KL, Domchek SM, Rodriguez GC, Salani R, Geschwantler Kaulich D, Tea M-K, Paluch SS, Laitman Y, Skytte A-B, Kruse TA, Jensen UB, Robson M, Gerdes A-M, Ejlertsen B, Foretova L, Savage SA, Lester J, Soucy P, Kuchenbaecker KB, Olswold C, Cunningham JM, Slager S, Pankratz VS, Dicks E, Lakhani SR, Couch FJ, Hall P, Gayther SA, Pharoah PDP, Reddel RR, Goode EL, Greene MH, Easton DF, Berchuck A, Antoniou AC, Chenevix-Trench G, Dunning AM. Multiple independent TERT variants

associated with telomere length and risks of breast and ovarian cancer. Nat Genet 2013;45(4):371-86. PMCID: PMC3670748.

Pharoah PDP, Tsai Y-Y, Ramus SJ, Phelan CM, Goode EL, Lawrenson K, Buckley M, Fridley BL, Tyrer JP, Shen H, Weber R, Karevan R, Larson MC, Song H, Tessier DC, Bacot F, Vincent D, Cunningham JM, Dennis J, Dicks E, Australian Cancer Study, Australian Ovarian Cancer Study Group, Aben KK, Anton-Culver H, Antonenkova N, Armasu SM, Baglietto L, Bandera EV, Beckmann MW, Bloom G, Bogdanova N, Brenton J, Brinton LA, Brooks-Wilson A, Brown R, Butzow R, Campbell I, Carney ME, Carvalho RS, Chang-Claude J, Chen A, Chen Z, Chow W-H, Cicek MS, Coetzee G, Cook LS, Cramer DW, Cybulski C, Dansonka-Mieszkowska A, Despierre E, Doherty JA, Dörk T, du Bois A, Dürst M, Eccles D, Edwards R, Ekici AB, Fasching PA, Fenstermacher D, Flanagan J, Gao Y-T, Garcia-Closas M, Gentry-Maharaj A, Giles G, Gjyshi A, Gore M, Gronwald J, Guo Q, Halle MK, Harter P, Hein A, Heitz F, Hillemanns P, Hoatlin M, Høgdall E, Høgdall CK, Hosono S, Jakubowska A, Jensen A, Kalli KR, Karlan BY, Kelemen L, Kiemeney LA, Krüger Kjaer S, Konecny GE, Krakstad C, Kupryjanczyk J, Lambrechts D, Lambrechts S, Le ND, Lee N, Lee J, Leminen A, Lim BK, Lissowska J, Lubiński J, Lundvall L, Lurie G, Massuger LFAG, Matsuo K, McGuire V, McLaughlin JR, Menon U, Modugno F, Moysich KB, Nakanishi T, Narod SA, Ness RB, Nevanlinna H, Nickels S, Noushmehr H, Odunsi K, Olson SH, Orlow I, Paul J, Pejovic T, Pelttari LM, Permuth-Wey J, Pike MC, Poole EM, Qu X, **Risch HA**, Rodriguez-Rodriguez L, Rossing MA, Rudolph A, Runnebaum I, Rzepecka IK, Salvesen HB, Schwaab I, Severi G, Shen H, Shridhar V, Shu X-O, Sieh W, Southey MC, Spellman P, Tajima K, Teo S-H, Thompson PJ, Timorek A, Tworoger SS, van Altena AM, Van Den Berg D, Vergote I, Vierkant RA, Vitonis AF, Wang-Gohrke S, Wentzensen N, Whittemore AS, Wik E, Winterhoff B, Woo YL, Wu AH, Yang HP, Zheng W, Ziogas A, Zulkifli F, Goodman MT, Hall P, Easton DF, Pearce CL, Berchuck A, Chenevix-Trench G, Iversen E, Monteiro AN, Gayther SA, Schildkraut JM, Sellers TA. GWAS meta analysis and replication identifies three new susceptibility loci for ovarian cancer. Nat Genet 2013;45(4):362-72. PMCID: PMC3693183.

Delahanty RJ, Xiang Y-B, Spurdle A, Beeghly-Fadiel A, Long J, Thompson D, Tomlinson I, Yu H, Lambrechts D, Dörk T, Goodman MT, Zheng Y, Salvesen HB, Bao P-P, Amant F, Beckmann MW, Coenegrachts L, Coosemans A, Dubrowinskaja N, Dunning A, Runnebaum I, Easton D, Ekici AB, Fasching PA, Halle MK, Hein A, Howarth K, Gorman M, Kaydarova D, Krakstad C, Lose F, Lu L, Lurie G, O'Mara T, Matsuno RK, Pharoah P, **Risch H**, Schwake A, Trovik J, Turmanov N, Wen W, Lu W, Cai Q, Zheng W, Shu X-O. Polymorphisms in inflammation pathway genes and endometrial cancer risk. Cancer Epidemiol Biomarkers Prev 2013;22(2):216-23. PMCID: PMC3677562.

Narod SA, Moody JRK, Rosen B, Fan I, **Risch [H]A**, Sun P, McLaughlin JR. Estimating survival rates after ovarian cancer among women tested for BRCA1 and BRCA2 mutations. Clin Genet 2013;83(3):232-7. *NIH funding pre-dates mandate.

McLaughlin JR, Rosen B, Moody J, Pal T, Fan I, Shaw P, **Risch HA**, Sellers TA, Sun P, Narod SA. Long-term ovarian cancer survival associated with mutation in BRCA1 or BRCA2. J Natl Cancer Inst 2013;105(2):141-8. *NIH funding pre-dates mandate.

Kelemen LE, Bandera EV, Terry KL, Rossing MA, Brinton LA, Doherty JA, Ness RB, Krüger Kjær S, Chang-Claude J, Köbel M, Lurie G, Thomson PJ, Carney ME, Moysich K, Edwards RP, Bunker CH, Jensen A, Høgdall E, Cramer DW, Vitonis AF, Olson SH, King M, Chandran U, Lissowska J, Garcia-Closas M, Yang H, Webb PM, Schildkraut JM, Goodman MT, **Risch HA**. Recent alcohol consumption and risk of incident ovarian carcinoma: a pooled analysis of

5,342 cases and 10,358 controls from the Ovarian Cancer Association Consortium. BMC Cancer 2013;13:28. PMCID: PMC3568733.

Risch HA, Lu L, Wang J, Zhang W, Ni Q-X, Gao Y-T, Yu H. ABO blood group and risk of pancreatic cancer: a study in Shanghai and meta-analysis. Am J Epidemiol 2013;177(12):1326-37. PMCID: PMC3732019.

Parikh H, Jia J, Zhang X, Chung C, Jacobs KB, Yeager M, Boland J, Hutchinson A, Burdett L, **Risch HA**, Jacobs EJ, Stolzenberg-Solomon RZ, Chanock SJ, Wolpin BM, Petersen GM, Fuchs CS, Hartge P, Amundadottir L. A re-sequence analysis of genomic loci on chromosomes 1q32.1, 5p15.33 and 13q22.1 associated with pancreatic cancer risk. Pancreas 2013;42(2):209-215. PMCID: PMC3618611.

2012

Hoyo C, Cook MB, Kamangar F, Freedman ND, Whiteman DC, Bernstein L, Brown LM, **Risch HA**, Ye W, Sharp L, Wu AH, Ward MH, Casson AG, Murray LJ, Corley DA, Nyren O, Pandeya N, Vaughan TL, Chow W-H, Gammon MD. Body mass index in relation to oesophageal and oesophagogastric junction adenocarcinomas: a pooled analysis from the international BEACON consortium. Int J Epidemiol 2012;41(6):1706-18. PMCID: PMC3535758.

Bosetti C, Lucenteforte E, Silverman DT, Petersen G, Bracci PM, Ji BT, Negri E, Li D, **Risch HA**, Olson SH, Gallinger S, Miller AB, Bueno-de-Mesquita HB, Talamini R, Polesel J, Ghadirian P, Baghurst PA, Zatonski W, Fontham E, Bamlet WR, Holly EA, Bertuccio P, Gao YT, Hassan M, Yu H, Kurtz RC, Cotterchio M, Su J, Maisonneuve P, Duell EJ, Boffetta P, La Vecchia C. Cigarette smoking and pancreatic cancer: an analysis from the International Pancreatic Cancer Case-Control Consortium (PanC4). Ann Oncol 2012;23(7):1880-88. PMCID: PMC3387822.

Lu L, Zhu G, Zhang C, Deng Q, Katsaros D, Mayne ST, **Risch HA**, Mu L, Canuto EM, Gregori G, Benedetto C, Yu H. Association of large noncoding RNA HOTAIR expression and its downstream intergenic CpG island methylation with survival in breast cancer. Breast Cancer Res Treat 2012;136(3)875-83. *Not a result of NIH funding.

Wang J, Zhang W, Sun L, Yu H, Ni Q-X, **Risch H**, Gao Y-T. Green tea drinking and risk of pancreatic cancer: a large-scale, population-based case-control study in urban Shanghai. Cancer Epidemiol 2012;36(6):e354-8. PMCID: PMC3490023.

Raska P, Iversen E, Chen A, Chen Z, Fridley BL, Permuth-Wey J, Tsai Y-Y, Vierkant RA, Goode EL, **Risch H**, Schildkraut JM, Sellers TA, Barnholtz-Sloan J. European American stratification in ovarian cancer case control data: the utility of genome-wide data for inferring ancestry. PLoS One 2012;7(5): e35235. doi:10.1371/journal.pone.0035235. PMCID: PMC3348917.

Su Z, Gay LJ, Strange A, Palles C, Band G, Whiteman DC, Lescai F, Langford C, Nanji M, Edkins S, van der Winkel A, Levine D, Sasieni P, Bellenguez C, Howarth K, Freeman C, Trudgill N, Tucker AT, Pirinen M, Peppelenbosch MP, van de rLaan LJW, Kuipers EJ, Drenth JPH, Peters WH, Reynolds JV, Kelleher DP, McManus R, Grabsch H, Prenen H, Bisschops R, Krishnadath K, Siersema PD, van Baal JW, Middleton M, Petty R, Gillies R, Burch N, Bhandari P, Paterson S, Edwards C, Penman I, Vaidya K, Ang Y, Murray I, Patel P, Ye W, Mullins P, Wu AH, Bird NC, Dallal H, Shaheen NJ, Murray LJ, Koss K, Bernstein L, Romero Y, Hardie LJ, Zhang R, Winter H, Corley DA, Panter S, **Risch HA**, Reid BJ, Sargeant I, Gammon MD, Smart H, Dhar A, McMurtry H, Ali H, Liu G, Casson AG, Chow W-H, Rutter M, Tawil A, Morris D, Nwokolo C, Isaacs P, Rodgers C, Ragunath K, MacDonald C, Haigh C, Monk D, Davies G,

Wajed S, Johnston D, Gibbons M, Cullen S, Church N, Langley R, Griffin M, Alderson D, Deloukas P, Hunt SE, Gray E, Dronov S, Potter SC, Tashakkori-Ghanbaria A, Anderson M, Brooks C, Blackwell JM, Bramon E, Brown MA, Casas JP, Corvin A, Duncanson A, Markus HS, Mathew CG, Palmer CNA, Plomin R, Rautanen A, Sawcer SJ, Trembath RC, Viswanathan AC, Wood N, Trynka G, Wijmenga C, Cazier J-B, Atherfold P, Nicholson AM, Gellatly NL, Glancy D, Cooper SC, Cunningham D, Lind T, Hapeshi J, Ferry D, Rathbone B, Brown J, Love S, Attwood S, MacGregor S, Watson P, Sanders S, Ek W, Harrison RF, Moayyedi P, de Caestecker J, Barr H, Stupka E, Vaughan TL, Peltonen L, Spencer CCA, Tomlinson I, Donnelly P, Jankowski JAZ. Common variants at the MHC locus and at chromosome 16q24.1 predispose to Barrett's Esophagus. Nat Genet 2012;44(10):1131-6. PMCID: PMC3459818.

Ji Y, Shen M-C, Jin X-L, Zhu M-H, Wang H, Ni Q-X, Zhang W, Wang J, Sun L, Yu H, **Risch H**, Gao Y-T. Pathologic characteristics of pancreatic cancer in Shanghai urban area: preliminary analysis of 350 cases. Zhong Liu [Tumor] 2012;32(3):199-202. (Publication in Chinese).

Pal T, Akbari MR, Sun P, Lee J-H, Fulp J, Thompson Z, Coppola D, Nicosia S, Sellers TA, McLaughlin J, **Risch HA**, Rosen B, Shaw P, Schildkraut J, Narod SA. Frequency of mutations in mismatch repair genes in a population-based study of women with ovarian cancer. Br J Cancer 2012;107(10):1783-90. PMCID: PMC3493867.

Collaborative Group on Epidemiological Studies of Ovarian Cancer. Ovarian cancer and smoking: individual participant meta-analysis including 28,114 women with ovarian cancer from 51 epidemiological studies. Lancet Oncol 2012;13(9):946-56. *Not a result of NIH funding.

Lu L, Katsaros D, Mayne ST, **Risch HA**, Benedetto C, Canuto EM, Yu H. Functional study of risk loci of stem cell-associated gene lin-28B and associations with disease survival outcomes in epithelial ovarian cancer. Carcinogenesis 2012;33(11):2119-25. *Not a result of NIH funding.

Fridley BL, Chalise P, Tsai Y-Y, Sun Z, Vierkant RA, Larson MC, Cunningham JM, Iversen ES, Fenstermacher D, Barnholtz-Sloan J, Asmann Y, **Risch HA**, Schildkraut JM, Phelan CM, Sutphen R, Sellers TA, Goode EL. Germline copy number variation and ovarian cancer survival. Front Genet 2012;3:142. PMCID: PMC3413872.

Kotsopoulos J, Moody JRK, Fan I, Rosen B, **Risch HA**, McLaughlin JR, Sun P, Narod SA. Height, weight, BMI and ovarian cancer survival. Gyn Oncol 2012;127(1):83-7. *NIH funding pre-dates mandate.

Li D, Duell EJ, Yu K, **Risch HA**, Olson SH, Kooperberg C, Wolpin BM, Jiao L, Dong X, Wheeler B, Arslan AA, Bueno-de-Mesquita HB, Fuchs CS, Gallinger S, Gross M, Hartge P, Hoover RN, Holly EA, Jacobs EJ, Klein AP, LaCroix A, Mandelson MT, Petersen G, Zheng W, Agalliu I, Albanes D, Boutron-Ruault M-C, Bracci PM, Buring JE, Canzian F, Chang K, Chanock SJ, Cotterchio M, Gaziano JM, Giovannucci EL, Goggins M, Hallmans G, Hankinson SE, Hoffman Bolton JA, Hunter DJ, Hutchinson A, Jacobs KB, Jenab M, Khaw K-T, Kraft P, Krogh V, Kurtz RC, McWilliams RR, Mendelsohn JB, Patel AV, Rabe KG, Riboli E, Shu X-O, Tjønneland A, Tobias GS, Trichopoulos D, Virtamo J, Visvanathan K, Watters J, Yu H, Zeleniuch-Jacquotte A, Amundadottir L, Stolzenberg-Solomon RZ. Pathway analysis of genome-wide association study data highlights pancreatic development genes as susceptibility factors for pancreatic cancer. Carcinogenesis 2012;33(7):1384-90. PMCID: PMC3405651.

Duell EJ, Lucenteforte E, Olson SH, Bracci PM, Li D, **Risch HA**, Silverman DT, Ji B-T, Gallinger S, Holly EA, Fontham EH, Maisonneuve P, Bueno-de-Mesquita HB, Ghadirian P, Kurtz RC, Ludwig E, Yu H, Lowenfels AB, Seminara D, Petersen GM, LaVecchia C, Boffetta P.

Pancreatitis and pancreas cancer risk: a pooled analysis in the International Pancreatic Cancer Case-Control Consortium (PanC4). Ann Oncol 2012;23(11):2964-70. PMCID: PMC3477881.

Palmer AJ, Lochhead P, Hold GL, Rabkin CS, Chow WH, Lissowska J, Vaughan TL, Berry S, Gammon M, **Risch H**, El-Omar EM. Genetic variation in C20orf54, PLCE1 and MUC1 and the risk of upper gastrointestinal cancers in Caucasian populations. Eur J Cancer Prev 2012;21(6):541-4. PMCID: PMC3460062.

Jacobs KB, Yeager M, Zhou W, Wacholder S, Wang Z, Rodriguez-Santiago B, Hutchinson A, Deng X, Liu C, Horner M-J, Cullen M, Epstein CG, Burdett L, Dean MC, Chatterjee N, Sampson J, Chung CC, Kovaks J, Gapstur SM, Stevens VL, Teras LT, Gaudet MM, Albanes D, Weinstein SJ, Virtamo J, Taylor PR, Freedman ND, Abnet CC, Goldstein AM, Hu N, Yu K, Yuan J-M, Liao L, Ding T, Qiao Y-L, Gao Y-T, Koh W-P, Xiang Y-B, Tang Z-Z, Fan J-H, Aldrich MC, Amos C, Blot WJ, Bock CH, Gillanders EM, Harris CC, Haiman CA, Henderson BE, Kolonel LN, Marchand LL, McNeill LH, Rybicki BA, Schwartz AG, Signorello LB, Spitz MR, Wiencke JK, Wrensch M, Wu X, Zanetti KA, Ziegler RG, Figueroa JD, Garcia-Closas M, Malats N, Marenne G, Prokunina-Olsson L, Baris D, Schwenn M, Johnson A, Landi MT, Goldin L, Consonni D, Bertazzi PA, Rotunno M, Rajaraman P, Andersson U, Freeman LEB, Berg CD, Buring JE, Butler MA, Carreon T, Feychting M, Ahlbom A, Gaziano JM, Giles GG, Hallmans G, Hankinson SE, Hartge P, Henriksson R, Inskip PD, Johansen C, Landgren A, McKean-Cowdin R, Michaud DS, Melin BS, Peters U, Ruder AM, Sesso HD, Severi G, Shu X-O, Visvanathan K, White E, Wolk A, Zeleniuch-Jacquotte A, Zheng W, Silverman DT, Kogevinas M, Gonzalez JR, Villa O, Li D, Duell EJ, **Risch HA**, Olson SH, Kooperberg C, Wolpin BM, Jiao L, Hassan M, Wheeler W, Arslan AA, Bueno-de-Mesquita HB, Fuchs CS, Gallinger S, Gross MD, Holly EA, Klein AP, LaCroix A, Mandelson MT, Petersen G, Boutron-Ruault M-C, Bracci PM, Canzian F, Chang K, Cotterchio M, Giovannucci EL, Goggins M, Bolton JAH, Jenab M, Khaw K-T, Krogh V, Kurtz RC, McWilliams RR, Mendelsohn JB, Rabe KG, Riboli E, Tjønneland A, Tobias GS, Trichopoulos D, Elena JW, Yu H, Amundadottir L, Stolzenberg-Solomon RZ, Kraft P, Schumacher F, Stram D, Savage SA, Mirabello L, Andrulis I, Wunder J, García AP, Sierrasesúmaga L, Barkauskas DA, Gorlick RG, Purdue M, Chow W-H, Moore LE, Schwartz KL, Davis FG, Hsing AW, Berndt SI, Black A, Wentzensen N, Brinton LA, Lissowska J, Peplonska B, McGlynn KA, Cook MB, Graubard BI, Kratz CP, Greene MH, Erickson RL, Hunter DJ, Thomas G, Hoover RN, Real FX, Fraumeni JF, Caporaso NE, Tucker M, Rothman N, Pérez-Jurado LA, Chanock SJ. Detectable clonal mosaicism and its relationship to aging and cancer. Nat Genet 2012;44(6):651-8. PMCID: PMC3372921.

Lubin JH, Cook MB, Pandeya N, Vaughan TL, Abnet CC, Giffen C, Webb PM, Murray LJ, Casson AG, **Risch HA**, Ye W, Kamangar F, Bernstein L, Sharp L, Nyrén O, Gammon MD, Corley DA, Wu AH, Brown LM, Chow W-H, Ward MH, Freedman ND, Whiteman DC. The importance of exposure rate on odds ratios by cigarette smoking and alcohol consumption for esophageal adenocarcinoma and squamous cell carcinoma in the Barrett's Esophagus and Esophageal Adenocarcinoma Consortium. Cancer Epidemiology 2012;36(3):306-16. PMCID: PMC3489030

Long J, Zheng W, Xiang Y-B, Lose F, Thompson D, Tomlinson I, Yu H, Wentzensen N, Lambrechts D, Dörk T, Dubrowinskaja N, Goodman MT, Salvesen HB, Fasching PA, Scott RJ, Delahanty R, Zheng Y, O'Mara T, Healey CS, Hodgson S, **Risch H**, Yang HP, Amant F, Turmanov N, Schwake A, Lurie G, Trovik J, Beckmann MW, Ashton K, Ji B-T, Bao P-P, Howarth K, Lu L, Lissowska J, Coenegrachts L, Kaidarova D, Dürst M, Thompson PJ, Krakstad C, Ekici AB, Otton G, Shi J, Zhang B, Gorman M, Brinton L, Coosemans A, Matsuno RK, Halle MK, Hein A, Proietto A, Cai H, Lu W, Dunning A, Easton D, Gao Y-T, Cai Q,

Spurdle AB, Shu X-O. Genome-wide association study identifies a possible susceptibility locus for endometrial cancer. Cancer Epidemiol Biomarkers Prev 2012;21(6):980-7. PMCID: PMC3372671

Setiawan VW, Pike MC, Karageorgi S, Deming SL, Anderson K, Bernstein L, Brinton LA, Cai H, Cerhan JR, Cozen W, Chen C, Doherty J, Freudenheim JL, Goodman MT, Hankinson SE, Lacey JV Jr, Liang X, Lissowska J, Lu L, Lurie G, Mack T, Matsuno RK, McCann S, Moysich KB, Olson SH, Rastogi R, Rebbeck TR, **Risch H**, Robien K, Schairer C, Shu X-O, Spurdle AB, Strom BL, Australian National Endometrial Cancer Study Group, Thompson PJ, Ursin G, Webb PM, Weiss N, Wentzensen N, Xiang Y-B, Yang HP, Yu H, Horn-Ross PL, De Vivo I. Age at last birth in relation to risk of endometrial cancer: pooled analysis in the Epidemiology of Endometrial Cancer Consortium. Am J Epidemiol 2012;176(4):269-78. PMCID: PMC3491967

Pearce CL, Templeman C, Rossing MA, Lee A, Near A, Australian Cancer Study (Ovarian Cancer), Australian Ovarian Cancer Study Group, Doherty JA, Cushing-Haugen KL, Wicklund KG, Chang-Claude J, Hein R, Wang-Gohrke S, Lurie G, Wilkens LR, Carney ME, Goodman MT, Moysich10, Kjaer SK, Hogdall E, Jensen A, Goode EL, Fridley BL, Larson MC, Schildkraut JM, Palmieri RT, Cramer DW, Terry KL, Vitonis AF, Titus-Ernstoff L, Ziogas A, Brewster W, Anton-Culver H, Gentry Maharaj A, Ramus SJ, Anderson AR, Brueggmann D, Fasching PA, Gayther SA, Huntsman D, Menon U, Nagle CM, Ness R, Pike MC, **Risch H**, Webb PM, Wu AH, Berchuck A, Ovarian Cancer Association Consortium. Association between endometriosis and risk of histological subtypes of ovarian cancer: a pooled analysis of case–control studies. Lancet Oncol 2012;13(4):385-94. PMCID: PMC3664011.

Zeng H, Irwin ML, Lu L, **Risch H**, Mayne S, Mu L, Deng Q, Scarampi L, Mitidieri M, Katsaros D, Yu H.. Physical activity and breast cancer survival—an epigenetic link through reduced methylation of a tumor suppressor gene L3MBTL1. Breast Cancer Res Treat 2012;133(1):127-35. *Not a result of NIH funding.

Liao LM, Vaughan TL, Corley DA, Cook MB, Casson AG, Kamangar F, Abnet CC, **Risch HA**, Giffen C, Freedman ND, Chow W-H, Sadeghi S, Pandeya N, Whiteman DC, Murray LJ, Bernstein L, Gammon MD, Wu AH. Nonsteroidal anti-inflammatory drug use reduces risk of adenocarcinomas of the esophagus and esophagogastric junction in a pooled analysis. Gastroenterology 2012;142(3):442-52. PMCID: PMC3488768.

Collaborative Group on Epidemiological Studies of Ovarian Cancer. Beral V, Hermon C, Peto R, Reeves G, Brinton L, Green AC, Marchbanks P, Negri E, Ness R, Peeters P, Vessey M, Calle EE, Rodriguez C, Dal Maso L, Talamini T, Cramer D, Hankinson SE, Tworoger SS, Chetrit A, Hirsh-Yechezkel G, Lubin F, Sadetzki S, Appleby P, Banks E, Berrington de Gonzalez A, Bull D, Crossley B, Goodill A, Green I, Green J, Key T, Collins R, Doll R, Agudo A, Gonzalez CA, Lee N, Ory HW, Peterson HB, Wingo PA, Martin N, Pardthaisong T, Silpisornkosol S, Theetranont C, Boosiri B, Chutivongse S, Jimakorn P, Virutamasen P, Wongsrichanalai C, Titus-Ernstoff L, Byers T, Rohan T, Mosgaard BJ, Yeates D, Marshall JR, Chang-Claude J, Anderson KE, Folsom AR, Rossing MA, Thomas D, Weiss N, Franceschi S, La Vecchia C, Adami HO, Magnusson C, Riman T, Weiderpass E, Wolk A, Freedman DM, Hartge P, Lacey JM, Hoover R, Schouten LJ, van den Brandt PA, Chantarakul N, Koetsawang S, Rachawat D, Graff-Iversen G, Selmer R, Bain CJ, Purdie DM, Siskind V, Webb PM, McCann SE, Hannaford P, Kay C, Binns CW, Lee AH, Zhang M, Nasca P, Coogan PF, Rosenberg L, Kelsey J, Paffenbarger R, Whittemore A, Katsouyanni K, Trichopoulou A, Trichopoulos D, Tzonou A, Dabancens A, Martinez L, Molina R, Salas O, Goodman MT, Laurie G, Carney ME, Wilkens

LR, Bladstrom A, Olsson H, Grisso JA, Morgan M, Wheeler JE, Casagrande J, Pike MC, RK Ross RK, Wu AH, Kumle M, Lund E, McGowan L, Shu XO, Zheng W, Farley TMM, Holck S, Meirik O, **Risch HA**. Ovarian cancer and body size: Individual participant meta-analysis including 25,157 women with ovarian cancer from 47 epidemiological studies. PLoS Med 2012;9(4):e1001200. doi:10.1371/journal.pmed.1001200. *Not a result of NIH funding.

2011

Permuth-Wey J, Chen Z, Tsai Y-Y, Lin H-Y, Chen YA, Barnholtz-Sloan J, Birrer MJ, Chanock SJ, Cramer DW, Cunningham JM, Fenstermacher D, Fridley BL, Garcia-Closas M, Gayther SA, Gentry-Maharaj A, Gonzalez-Bosquet J, Iversen E, Jim H, McLaughlin J, Menon U, Narod SA, Phelan CM, Ramus SJ, **Risch H**, Song H, Sutphen R, Terry KL, Tyrer J, Vierkant RA, Wentzensen N, Lancaster JM, Cheng JQ, Berchuck A, Pharoah PDP, Schildkraut JM, Goode EL, Sellers TA on behalf of the Ovarian Cancer Association Consortium (OCAC). MicroRNA processing and binding site polymorphisms are not replicated in the Ovarian Cancer Association Consortium. Cancer Epidemiol Biomarkers Prev 2011;20:1793-7. PMCID: PMC3153581.

Permuth-Wey J, Kim D, Tsai Y-Y, Lin H-Y, Chen YA, Barnholtz-Sloan J, Birrer MJ, Gregory Bloom G, Chanock SJ, Chen Z, Cramer DW, Cunningham JM, Dagne G, Ebbert-Syfrett J, Fenstermacher D, Fridley BL, Garcia-Closas M, Gayther SA, Ge W, Gentry-Maharaj A, Gonzalez-Bosquet J, Goode EL, Iversen E, Jim H, Kong W, McLaughlin J, Menon U, Monteiro ANA, Narod SA, Pharoah PDP, Phelan CM, Qu X, Ramus SJ, **Risch H**, Schildkraut JM, Song H, Stockwell H, Sutphen R, Terry KL, Tyrer J, Vierkant RA, Wentzensen N, Lancaster JM, Cheng JQ, Sellers TA on behalf of the Ovarian Cancer Association Consortium (OCAC). *LIN28B* polymorphisms influence susceptibility to epithelial ovarian cancer. Cancer Res 2011;71:3896-903. PMCID: PMC3107389.

Lu L, **Risch H**, Irwin ML, Mayne ST, Cartmel B, Schwartz P, Rutherford T, Yu H. Long-term overweight and weight gain in early adulthood in association with risk of endometrial cancer. Int J Cancer 2011;129:1237-43. PMCID: PMC3125463.

Zhang S, Royer R, Li S, McLaughlin JR, Rosen B, **Risch HA**, Fan I, Bradley L, Shaw PA, Narod SA. Frequencies of BRCA1 and BRCA2 mutations among 1,342 unselected patients with invasive ovarian cancer. Gyn Oncol 2011;121:353-7. PMID:21324516. *NIH funding pre-dates mandate.

Freedman ND, Murray LJ, Kamangar F, Abnet CC, Cook MB, Nyrén O, Ye W, Wu AH, Bernstein L, Brown LM, Ward MH, Pandeya N, Green A, Casson AG, Giffen C, **Risch HA**, Gammon MD, Chow W-H, Vaughan TL, Corley DA, Whiteman DC. Alcohol intake and risk of esophageal adenocarcinoma: a pooled analysis from the BEACON Consortium. Gut 2011;60:1029-37. PMCID: PMC3439838.

Lu L, Zhang C, Zhu G, Irwin M, **Risch H**, Menato G, Mitidieri M, Katsaros D, Yu H. Telomerase expression and telomere length in breast cancer and their associations with adjuvant treatment and disease outcome. Breast Cancer Res 2011;13:R56:1-8. http://breast-cancer-research.com/content/13/3/R56. *Not a result of NIH funding.

Lu L, Katsaros D, Zhu Y, Hoffman A, Luca S, Marion CE, Mu L, **Risch H**, Yu H. Let-7A regulation of insulin-like growth factors in breast cancer. Breast Cancer Res Treat 2010, Published online: DOI 10.1007/s10549-010-1168-5. *Not a result of NIH funding.

Permuth-Wey J, Chen YA, Tsai Y-Y, Chen Z, Qu X, Lancaster JM, Stockwell H, Dagne G, Iversen E, **Risch H**, Barnholtz-Sloan J, Cunningham JM, Vierkant RA, Fridley BL, Sutphen

R, McLaughlin J, Narod SA, Goode EL, Schildkraut JM, Fenstermacher D, Phelan CM, Sellers TA. Inherited variants in mitochondrial biogenesis genes may influence epithelial ovarian cancer risk. Cancer Epidemiol Biomarkers Prev 2011;20:1131-45. PMCID: PMC3111851.

Pharoah PDP, Palmieri RT, Ramus SJ, Gayther SA, Andrulis IL, Anton-Culver H, Antonenkova N, Antoniou AC, Goldgar D for the BCFR Investigators, Beattie MS, Beckmann MW, Birrer MJ, Bogdanova N, Bolton KL, Brewster W, Brooks-Wilson A, Brown R, Butzow R, Caldes T, Caligo MA, Campbell I, Chang-Claude J, Chen YA, Cook LS, Couch FJ, Cramer DW, Cunningham JM, Despierre E, Doherty JA, Dörk T, Dürst M, Eccles DM, Ekici AB, Easton D for the EMBRACE Investigators, Fasching PA, de Fazio A, Fenstermacher DA, Flanagan JM, Fridley BL, Friedman E, Gao B, Sinilnikova O for the GEMO Study Collaborators, Gentry-Maharaj A, Godwin AK, Goode EL, Goodman MT, Gross J, Hansen TVO, Harnett P, Rookus M for the HEBON Investigators, Heikkinen T, Hein R, Høgdall C, Høgdall E, Iversen ES, Jakubowska A, Johnatty SE, Karlan BY, Kauff ND, Kaye SB, Chenevix-Trench G for the kConFab Investigators and the Consortium of Investigators of Modifiers of BRCA1/2, Kelemen LE, Kiemeney LA, Krüger Kjaer S, Lambrechts D, LaPolla JP, Lázaro C, Le ND, Leminen A, Leunen K, Levine DA, Lu Y, Lundvall L, Macgregor S, Marees T, Massuger LF, McLaughlin JR, Menon U, Montagna M, Moysich KB, Narod SA, Nathanson KL, Nedergaard L, Ness RB, Nevanlinna H, Nickels S, Osorio A, Paul J, Pearce CL, Phelan CM, Pike MC, Radice P, Rossing MA, Schildkraut JM, Sellers TA, Singer CF, Song H, Stram DO, Sutphen R, Lindblom A for the SWE-BRCA Investigators, Terry KL, Tsai Y-Y, van Altena AM, Vergote I, Vierkant RA, Vitonis AF, Walsh C, Wang-Gohrke S, Wappenschmidt B, Wu AH, Ziogas A, Berchuck A and **Risch HA** for the Ovarian Cancer Association Consortium. The role of *KRAS* rs61764370 in invasive epithelial ovarian cancer: implications for clinical testing. Clin Cancer Res 2011;17:3742-50. PMCID: PMC3107901.

Zeng H, Yu H, Lu L, Jain D, Kidd MS, Saif MW, Chanock SJ and Hartge P for the PanScan Consortium, **Risch HA**. Genetic effects and modifiers of radiotherapy and chemotherapy on survival in pancreatic cancer. Pancreas 2011;40:657-63. PMCID: PMC3116071.

Navarro Silvera SA, Mayne ST, **Risch HA**, Gammon MD, Vaughan T, Chow W-H, Dubin JA, Dubrow R, Schoenberg J, Stanford JL, West AB, Rotterdam H, Blot WJ. Principal component analysis of dietary and lifestyle patterns in relation to risk of subtypes of esophageal and gastric cancer. Ann Epidemiol 2011;21:543-50. PMCID: PMC3109225.

Lochhead P, Frank B, Hold GL, Rabkin CS, Ng MTH, Vaughan TL, **Risch HA**, Gammon MD, Lissowska J, Weck MN, Raum E, Müller H, Illig T, Klopp N, Dawson A, McColl KE, Brenner H, Chow WH, El-Omar EM. Genetic variation in the prostate stem cell antigen gene and upper gastrointestinal cancer in white individuals. Gastroenterology 2011;140:435-41. PMCID: PMC3031760.

Lochhead P, Ng MT, Hold GL, Rabkin CS, Vaughan TL, Gammon MD, **Risch HA**, Lissowska J, Mukhopadhya I, Chow W-H, El-Omar EM. Possible association between a genetic polymorphism at 8q24 and risk of upper gastrointestinal cancer. Eur J Cancer Prev 2011;20:54-7. PMCID: PMC3020097.

Zhou Y, Irwin ML, **Risch HA**. Pre- and post-diagnosis body mass index, weight change and ovarian cancer mortality. Gynecol Oncol 2011;140:435-41. PMCID: PMC3034401.

Bertuccio P, La Vecchia C, Silverman D, Petersen G, Bracci PM, Negri E, Li D, **Risch HA**, Olson SH, Gallinger S, Miller AB, Bueno-de-Mesquita HB, Talamini R, Polesel J, Ghadirian P, Baghurst PA, Zatonski W, Fontham E, Bamlet WR, Holly EA, Lucenteforte E, Hassan M, Yu

H, Kurtz RC, Cotterchio M, Su J, Maisonneuve P, Duell EJ, Bosetti C, Boffetta P. Cigar and pipe smoking, smokeless tobacco use and pancreatic cancer: an analysis from the International Pancreatic Cancer Case-Control Consortium (PanC4). Ann Oncol 2011;22:1420-6. PMID: 21245160. PMCID: PMC3139985.

Arem H, Irwin ML, Zhou Y, Lu L, **Risch H**, Yu H. Physical activity and endometrial cancer in a population-based case-control study. Cancer Causes Control 2011;22:219-26. PMCID: PMC3075067.

Soskolne CL, Jhangri GS, Scott HM, Brenner DR, Siemiatycki J, Lakhani R, Gérin M, Dewar R, Miller AB, **Risch HA**. A population-based case-control study of occupational exposure to acids and the risk of lung cancer: Evidence for specificity of association. Int J Occup Environ Health 2011;17:1-8. *Not a result of NIH funding.

2010

Goode EL, Chenevix-Trench G, Song H, Ramus SJ, Notaridou M, Lawrenson K, Widschwendter M, Vierkant RA, Larson MC, Kjaer SK, Birrer MJ, Berchuck A, Schildkraut J, Tomlinson I, Kiemeney LA, Cook LS, Gronwald J, Garcia-Closas M, Gore ME, Campbell I, Whittemore AS, Sutphen R, Phelan C, Anton- Culver H, Pearce CL, Lambrechts D, Rossing MA, Chang-Claude J, Moysich KB, Goodman MT, Dörk T, Nevanlinna H, Ness RB, Rafnar T, Hogdall C, Hogdall E, Fridley BL, Cunningham JM, Sieh W, McGuire V, Godwin AK, Cramer DW, Hernandez D, Levine D, Lu K, Iversen ES, Palmieri RT, Houlston R, van Altena AM, Aben KKH, Massuger LFAG, Brooks-Wilson A, Kelemen LE, Le ND, Jakubowska A, Lubinski J, Medrek K, Stafford A, Easton DF, Tyrer J, Bolton KL, Harrington P, Eccles D, Chen A, Molina AN, Davila BN, Arango H, Tsai Y-Y, Chen Z, **Risch HA**, McLaughlin J, Narod SA, Ziogas A, Brewster W, Gentry-Maharaj A, Menon U, Wu AH, Stram DO, Pike MC, The Wellcome Trust Case-Control Consortium, Beesley J, Webb PM, The Australian Cancer Study (Ovarian Cancer), The Australian Ovarian Cancer Study Group, Chen X, Ekici AB, Thiel FC, Beckmann MW, Yang H, Wentzensen N, Lissowska J, Fasching PA, Despierre E, Amant F, Vergote I, Doherty J, Hein R, Wang-Gohrke S, Lurie G, Carney ME, Thompson PJ, Runnebaum I, Hillemanns P, Dürst M, Antonenkova N, Bogdanova N, Leminen A, Butzow R, Heikkinen T, Stefansson K, Sulem P, Besenbacher S, Sellers TA, Gayther SA, Pharoah PDP, The Ovarian Cancer Association Consortium (OCAC). A genome-wide association study identifies susceptibility loci for ovarian cancer at 2q31 and 8q24. Nat Genet 2010;42:874-9. PMCID: PMC3020231.

Ratner E, Lu L, Boeke M, Barnett R, Nallur S, Chin LJ, Pelletier C, Blitzblau R, Tassi R, Paranjape T, Hui P, Godwin AK, Yu H, **Risch H**, Rutherford T, Schwartz P, Santin A, Matloff E, Zelterman D, Slack FJ, Weidhaas JB. A KRAS-variant in ovarian cancer acts as a genetic marker of cancer risk. Cancer Res 2010;70:6509-15. PMCID: PMC2923587.

Cook MB, Kamangar F, Whiteman DC, Freedman ND, Gammon MD, Bernstein L, Brown LM, **Risch HA**, Ye W, Sharp L, Wu AH, Ward MH, Giffen C, Casson AG, Abnet CC, Murray LJ, Corley DA, Nyrén O, Vaughan TL, Chow W-H. Cigarette smoking and adenocarcinomas of the esophagus and esophagogastric junction: a pooled analysis from the International BEACON Consortium. J Natl Cancer Inst 2010;102:1344-53. PMCID: PMC2935475.

Risch HA, Yu H, Lu L, Kidd MS. ABO blood group, *Helicobacter pylori* seropositivity, and risk of pancreatic cancer: a case-control study. J Natl Cancer Inst 2010;102(7):502-5. PMCID: PMC2902822.

Johnatty SE, Beesley J, Chen X, Macgregor S, Duffy DL, Spurdle AB, deFazio A, Gava N, Webb PM, Rossing MA, Doherty JA, Goodman MT, Lurie G, Thompson PJ, Wilkens LR, Ness RB,

Moysich KB, Chang-Claude J, Wang-Gohrke S, Cramer DW, Terry KL, Hankinson SE, Tworoger SS, Garcia-Closas M, Yang H, Lissowska J, Chanock SJ, Pharoah PD, Song H, Whitemore AS, Pearce CL, Stram DO, Wu AH, Pike MC, Gayther SA, Ramus SJ, Menon U, Gentry-Maharaj A, Anton-Culver H, Ziogas A, Hogdall E, Kjaer SK, Hogdall C, Berchuck A, Schildkraut JM, Iversen ES, Moorman PG, Phelan CM, Sellers TA, Cunningham JM, Vierkant RA, Rider DN, Goode EL, Haviv I, Chenevix-Trench G; Ovarian Cancer Association Consortium; Australian Ovarian Cancer Study Group; Australian Cancer Study (Ovarian Cancer). Evaluation of candidate stromal epithelial cross-talk genes identifies association between risk of serous ovarian cancer and TERT, a cancer susceptibility "hot-spot". PLoS Genet 2010;6:e1001016. PMCID: PMC2900295.

Elliott KS, Zeggini E, McCarthy MI, Gudmundsson J, Sulem P, Stacey SN, Thorlacius S, Amundadottir L, Grönberg H, Xu J, Gaborieau V, Eeles RA, Neal DE, Donovan JL, Hamdy FC, Muir K, Hwang SJ, Spitz MR, Zanke B, Carvajal-Carmona L, Brown KM; Australian Melanoma Family Study Investigators, Hayward NK, Macgregor S, Tomlinson IP, Lemire M, Amos CI, Murabito JM, Isaacs WB, Easton DF, Brennan P, PanScan Consortium, Barkardottir RB, Gudbjartsson DF, Rafnar T, Hunter DJ, Chanock SJ, Stefansson K, Ioannidis JP. Evaluation of association of *HNF1B* variants with diverse cancers: collaborative analysis of data from 19 genome-wide association studies. PLoS One 2010;5:e10858. PMCID: PMC2878330.

Petersen GM, Amundadottir L, Fuchs CS, Kraft P, Stolzenberg-Solomon RZ, Jacobs KB, Arslan AA, Bueno-de-Mesquita HB, Gallinger S, Gross M, Helzlsouer K, Holly EA, Jacobs EJ, Klein AP, LaCroix A, Li D, Mandelson MT, Olson SH, **Risch HA**, Zheng W, Albanes D, Bamlet WR, Berg CD, Boutron-Ruault M-C, Buring JE, Bracci PM, Canzian F, Clipp S, Cotterchio M, de Andrade M, Duell EJ, Gaziano JM, Giovannucci EL, Goggins M, Hallmans G, Hankinson SE, Hassan M, Howard B, Hunter DJ, Hutchinson A, Jenab M, Kaaks R, Kooperberg C, Krogh V, Kurtz RC, Lynch SM, McWilliams RR, Mendelsohn JB, Michaud DS, Parikh H, Patel AV, Peeters PHM, Rajkovic A, Riboli E, Rodriguez L, Seminara D, Shu X-O, Thomas G, Tjønneland A, Tobias GS, Trichopoulos D, Van Den Eeden SK, Virtamo J, Wactawski-Wende J, Wang Z, Wolpin B, Yu H, Yu K, Zeleniuch-Jacquotte A, Fraumeni JF Jr, Hoover RN, Hartge P, Chanock SJ. A genome-wide association study identifies pancreatic cancer susceptibility loci on chromosomes 13q22.1, 1q32.1 and 5p15.33. Nat Genet 2010;42(3):224-8. PMCID: PMC28533179.

2009

Song H, Ramus SJ, Tyrer J, Bolton K, Gentry-Maharaj A, Wozniak E, Anton-Culver H, Chang-Claude J, Cramer DW, DiCioccio R, Dörk T, Goode EL, Goodman MT, Schildkraut JM, Sellers T, Beckmann MW, Beesley J, Blaakaer J, Carney ME, Chanock S, Chen Z, Cunningham JM, Dicks E, Doherty JA, Duerst M, Ekici AB, Fenstermacher D, Fridley BL, Gore ME, Hankinson SE, Hogdall C, Hogdall E, Iversen ES, Jacobs IJ, Jakubowska A, Lissowska J, Lubiński J, Lurie G, McGuire V, McLaughlin J, M drek K, Moorman PG, Moysich K, Narod S, Phelan C, **Risch H**, Stram DO, Strick R, Terry KL, Tsai Y-Y, Tworoger SS, Van Den Berg DJ, Vierkant RA, Wang-Gohrke S, Webb PM, Wilkens LR, Wu AH, Yang H, Ziogas A, Australian Cancer (Ovarian) Study, The Australian Ovarian Cancer Study Group, The Hannover-Jena Ovarian Cancer Study Group, The Ovarian Cancer Association Consortium, Whittemore AS, Rossing MA, Ponder BAJ, Pearce CL, Ness RB, Menon U, Krüger Kjær S, Gronwald J, Garcia-Closas M, Fasching P, Easton DF, Chenevix-Trench G, Berchuck A, Pharoah PDP, Gayther SA. A genome-wide association study identifies a novel ovarian cancer susceptibility locus on 9p22.2. Nat Genet 2009;41:996-1000. PMCID:

PMC2844110.

Amundadottir L, Kraft P, Stolzenberg-Solomon RZ, Fuchs CS, Petersen GM, Arslan AA, Bueno-de-Mesquita HB, Gross M, Helzlsouer K, Jacobs EJ, LaCroix A, Zheng W, Albanes D, Bamlet W, Berg CD, Berrino F, Bingham S, Buring JE, Bracci PM, Canzian F, Clavel-Chapelon F, Clipp S, Cotterchio M, de Andrade M, Duell EJ, Fox JW Jr, Gallinger S, Gaziano JM, Giovannucci E, Goggins M, González C, Hallmans G, Hankinson SE, Hassan M, Holly EA, Hunter DJ, Hutchinson A, Jackson R, Jacobs K, Jenab M, Kaaks R, Klein AP, Kooperberg C, Kurtz RC, Li D, Lynch SM, Mandelson M, McWilliams RR, Mendelsohn JB, Michaud DS, Olson SH, Overvad K, Patel AV, Peeters PHM, Rajkovic A, Riboli E, **Risch HA**, Shu X-O, Thomas G, Tobias GS, Trichopoulos D, Van Den Eeden SK, Virtamo J, Wactawski-Wende J, Wolpin BM, Yu H, Yu K, Zeleniuch-Jacquotte A, Chanock SJ, Hartge P, Hoover RN. Genome-wide association study identifies ABO blood group susceptibility variants for pancreatic cancer. Nat Genet 2009;41:986-90. PMCID: PMC2839871.

Hoyo C, Schildkraut JM, Murphy SK, Chow W-H, Vaughan TL, **Risch H**, Marks JR, Jirtle RL, Calingeart B, Mayne S, Fraumeni J Jr, Gammon MD. IGF2R polymorphisms and risk of esophageal and gastric adenocarcinoma. Int J Cancer 2009;125:2673-8. PMCID: PMC3008656.

Concato J, Jain D, Uchio E, **Risch H**, Li WW, Wells CK. Molecular markers and death from prostate cancer. Ann Intern Med 2009;150:595-603. *Not a result of NIH funding.

Bentov Y, Brown TJ, Akbari MR, Royer R, **Risch H**, Rosen B, McLaughlin J, Sun P, Zhang S, Narod SA, Casper RF. Polymorphic variation of genes in the fibrinolytic system and the risk of ovarian cancer. PLoS ONE 2009;4:e5918. PMCID: PMC2691597.

Figueroa JD, Terry MB, Gammon MD, Vaughan TL, **Risch HA**, Zhang F-F, Kleiner DE, Bennett WP, Howe CL, Dubrow R, Mayne ST, Fraumeni JF Jr, Chow W-H. Cigarette smoking, body mass index, gastro-esophageal reflux disease, and non-steroidal anti-inflammatory drug use and risk of subtypes of esophageal and gastric cancers by P53 overexpression. Cancer Causes Control 2009;20:361-8. PMCID: PMC2726999.

Hold GL, Rabkin CS, Gammon MD, Berry SH, Smith MG, Lissowska J, **Risch HA**, Chow W-H, Mowat NAG, Vaughan TL, El-Omar EM. CD14-159C/T and TLR9-1237T/C polymorphisms are not associated with gastric cancer risk in Caucasian populations. Eur J Cancer Prev 2009;18:117-9. PMCID: PMC2679029.

Metcalfe KA, Fan I, McLaughlin J, **Risch HA**, Rosen B, Murphy J, Bradley L, Armel S, Sun P, Narod SA. Uptake of clinical genetic testing for ovarian cancer in Ontario: a population-based study. Gynecol Oncol 2009;112:68-72. PMCID: PMC3074978.

2008

Antoniou AC, Cunningham AP, Peto J, Evans DG, Lalloo F, Narod SA, **Risch HA**, Eyfjord JE, Hopper JL, Southey MC, Olsson H, Johannsson O, Borg A, Pasini B, Radice P, Manoukian S, Eccles DM, Tang N, Olah E, Anton-Culver H, Warner E, Lubinski J, Gronwald J, Gorski B, Tryggvadottir L, Syrjakoski K, Kallioniemi O-P, Eerola H, Nevanlinna H, Pharoah PDP, Easton DF. The BOADICEA model of genetic susceptibility to breast and ovarian cancers: updates and extensions. Br J Cancer 2008;98:1457-66. PMCID: PMC2361716.

Navarro Silvera SA, Mayne ST, **Risch H**, Gammon MD, Vaughan TL, Chow W-H, Dubrow R, Schoenberg JB, Stanford JL, West AB, Rotterdam H, Blot WJ, Fraumeni JF Jr. Food group intake and risk of subtypes of esophageal and gastric cancer. Int J Cancer 2008;123:852-60. PMCID: PMC3008621.

Vaninetti NM, Geldenhuys L, Porter GA, **Risch H**, Hainaut P, Guernsey DL, Casson AG. Inducible nitric oxide synthase, nitrotyrosine and p53 mutations in the molecular pathogenesis of Barrett's Esophagus and esophageal adenocarcinoma. Mol Carcinog 2008;47:275-85. *Not a result of NIH funding.

Pearce CL, Wu AH, Gayther SA, Bale AE, Australian Cancer Study (Ovarian Cancer) and Australian Ovarian Cancer Study Group, Beck PA, Beesley J, Chanock S, Cramer DW, DiCioccio R, Edwards R, Fredericksen ZS, Garcia-Closas M, Goode EL, Green AC, Hartmann LC, Hogdall E, Kruger Kjaer S, Lissowska J, McGuire V, Modugno F, Moysich K, Ness RB, Ramus SJ, **Risch HA**, Sellers TA, Song H, Stram DO, Terry KL, Webb PM, Whiteman DC, Whittemore AS, Zheng W, Pharoah PDP, Chenevix-Trench G, Pike MC, Schildkraut J, Berchuck A, on behalf of the Ovarian Cancer Association Consortium (OCAC). Progesterone receptor variation and risk of ovarian cancer is limited to the invasive endometrioid subtype: results from the ovarian cancer association consortium pooled analysis. Br J Cancer 2008;98:282-8. PMCID: PMC2361465.

Collaborative Group on Epidemiological Studies of Ovarian Cancer. Beral V, Doll R, Hermon C, Peto R, Reeves G. Ovarian cancer and oral contraceptives: collaborative reanalysis of data from 45 epidemiological studies including 23257 women with ovarian cancer and 87303 controls. Lancet 2008;371:303-14. *Not a result of NIH funding.

Harley I, Rosen B, **Risch HA**, Siminovitch K, Beiner ME, McLaughlin J, Sun P, Narod SA. Ovarian cancer risk is associated with a common variant in the promoter sequence of the mismatch repair gene MLH1. Gynecol Oncol 2008;109:384-7. PMCID: PMC3060029.

2007

Terry MB, Gammon MD, Zhang FF, Vaughan TL, Chow W-H, **Risch HA**, Schoenberg JB, Mayne ST, Stanford JL, West AB, Rotterdam H, Blot WJ, Fraumeni JF Jr, Santella RM. *Alcohol dehydrogenase* 3 and risk of esophageal and gastric adenocarcinomas. Cancer Causes Control 2007;18:1039-46.

Concato J, Jain D, Li WW, **Risch HA**, Uchio EM, Wells CK. Molecular markers and mortality in prostate cancer. BJU Intl 2007;100:1259-63.

Hold GL, Rabkin CS, Chow W-H, Smith MG, Gammon MD, **Risch HA**, Vaughan TL, McColl KEL, Lissowska J, Zatonski W, Schoenberg JB, Blot WJ, Mowat NAG, Fraumeni JF Jr, El-Omar EM. A functional polymorphism of Toll-like receptor 4 gene increases risk of gastric carcinoma and its precursors. Gastroenterology 2007;132:905-12.

Wideroff L, Vaughan TL, Farin FM, Gammon MD, **Risch H**, Stanford JL, Chow W-H. GST, NAT1, CYP1A1 polymorphisms and risk of esophageal and gastric adenocarcinomas. Cancer Detect Prev 2007;31:233-6.

Brokaw J, Katsaros D, Wiley A, Lu L, Su D, Sochirca O, de la Longrais IAR, Mayne S, **Risch H**, Yu H. IGF-I in epithelial ovarian cancer and its role in disease progression. Growth Factors 2007;25:346-54.

McLaughlin JR, **Risch HA**, Lubinski J, Moller P, Ghadirian P, Lynch H, Karlan B, Fishman D, Rosen B, Neuhausen SL, Offit K, Kauff N, Domchek S, Tung N, Friedman E, Foulkes W, Sun P, Narod SA, Hereditary Ovarian Cancer Clinical Study Group. Reproductive risk factors for ovarian cancer in carriers of BRCA1 or BRCA2 mutations: a case-control study. Lancet Oncol 2007;8:26-34.

Koutros S, Holford TR, Hahn T, Lantos PM, McCarthy PL Jr, **Risch HA**, Swede H. Excess diagnosis of non-Hodgkin's lymphoma during spring in the USA. Leuk Lymphoma

2007;48:357-66.

2006

Risch HA, McLaughlin JR, Cole DEC, Rosen B, Bradley L, Fan I, Tang J, Li S, Zhang S, Shaw PA, Narod SA. Population BRCA1 and BRCA2 mutation frequencies and cancer penetrances: a kin-cohort study in Ontario, Canada. J Natl Cancer Inst 2006;98(23):1694-706.

Risch HA, Bale AE, Beck PA, Zheng W. *PGR* +331A/G and increased risk of epithelial ovarian cancer. Cancer Epidemiol Biomarkers Prev 2006;15:1738-41.

Lu L, Katsaros D, Wiley A, Rigault de la Longrais IA, **Risch HA**, Puopolo M, Yu H. The relationship of insulin-like growth factor-II, insulin-like growth factor binding protein-3, and estrogen receptor-alpha expression to disease progression in epithelial ovarian cancer. Clin Cancer Res 2006;12:1208-14.

Mayne ST, **Risch HA**, Dubrow R, Chow W-H, Gammon MD, Vaughan TL, Borchardt L, Schoenberg JB, Stanford JB, West AB, Rotterdam H, Blot WJ, Fraumeni JF Jr. Carbonated soft drink consumption and risk of esophageal adenocarcinoma. J Natl Cancer Inst 2006;98:72-5.

Beeghly A, Katsaros D, Chen H, Fracchioli S, Zhang Y, Massobrio M, **Risch H**, Jones B, Yu H. Glutathione S-transferase polymorphisms and ovarian cancer treatment and survival. Gynecol Oncol 2006;100:330-7.

2005

Trivers KF, De Roos AJ, Gammon MD, Vaughan TL, **Risch HA**, Olshan AF, Schoenberg JB, Mayne ST, Dubrow R, Stanford JL, Abrahamson P, Rotterdam H, West AB, Fraumeni JF Jr, Chow W-H. Demographic and lifestyle predictors of survival in patients with esophageal or gastric cancers. Clin Gastroenterol Hepatol 2005;3:225-30.

Antoniou AC, Pharoah PDP, Narod S, **Risch HA**, Eyfjord JE, Hopper JL, Olsson H, Johannsson O, Borg Å, Pasini B, Radice P, Manoukian S, Eccles DM, Tang N, Olah E, Anton-Culver H, Warner E, Lubinski J, Gronwald J, Gorski B, Tulinius H, Thorlacius S, Eerola H, Nevanlinna H, Syrjäkoski K, Kallioniemi O-P, Thompson D, Evans C, Peto J, Lalloo F, Evans DG, Easton DF. Breast and ovarian cancer risks to carriers of the BRCA1 5382insC and 185delAG and BRCA2 6174delT mutations: a combined analysis of 22 population based studies. J Med Genet 2005;42:602-3.

2004

Gammon MD, Terry MB, Arber N, Chow W-H, **Risch HA**, Vaughan TL, Schoenberg JB, Mayne ST, Stanford JL, Dubrow R, Rotterdam H, West AB, Fraumeni JF Jr, Weinstein IB, Hibshoosh, H. Nonsteroidal anti-inflammatory drug use associated with reduced incidence of adenocarcinomas of the esophagus and gastric cardia that overexpress Cyclin D1: a population-based study. Cancer Epidemiol Biomarkers Prev 2004;13:34-9.

2003

Engel LS, Chow W-H, Vaughan TL, Gammon MD, **Risch HA**, Stanford JL, Schoenberg JB, Mayne ST, Dubrow R, Rotterdam H, West AB, Blaser M, Blot WJ, Gail M, Fraumeni JF Jr. Population attributable risks of esophageal and gastric cancers. J Natl Cancer Inst 2003;95:1404-13.

Risch HA. Etiology of pancreatic cancer, with a hypothesis concerning the role of *N*-nitroso compounds and excess gastric acidity. J Natl Cancer Inst 2003;95(13):948-60.

Fung WLA, **Risch H**, McLaughlin J, Rosen B, Cole D, Vesprini D, Narod SA. The *N314D*

polymorphism of *galactose-1-phosphate uridyl transferase* does not modify the risk of ovarian cancer. Cancer Epidemiol Biomarkers Prev 2003;12:678-80.

Modugno F, Moslehi R, Ness RB, Nelson DB, Belle S, Kant JA, Wheeler JE, Wonderlick A, Fishman D, Karlan B, **Risch H**, Cramer DW, Dube M-P, Narod SA. Reproductive factors and ovarian cancer risk in Jewish *BRCA1* and *BRCA2* mutation carriers (United States). Cancer Causes Control 2003;14:439-46.

Modugno F, Ovarian Cancer and High-Risk Women Symposium Presenters. Ovarian cancer and high-risk women: Implications for prevention, screening, and early detection. Gynecol Oncol 2003;91:15-31.

El-Omar EM, Rabkin CS, Gammon MD, Vaughan TL, **Risch HA**, Schoenberg JB, Stanford JL, Mayne ST, Goedert J, Blot WJ, Fraumeni JF Jr, Chow W-H. Increased risk of noncardia gastric cancer associated with proinflammatory cytokine gene polymorphisms. Gastroenterology 2003;124:1193-201.

Antoniou A, Pharoah PDP, Narod S, **Risch HA**, Eyfjord JE, Hopper J, Loman N, Olsson H, Johannsson O, Borg Å, Pasini B, Radice P, Manoukian S, Eccles D, Tang N, Olah E, Anton-Culver H, Warner E, Lubinski J, Gronwald J, Gorski B, Tulinius H, Thorlacius S, Eerola H, Nevanlinna H, Syrjäkoski K, Kallionemi O-P, Thompson D, Evans C, Peto J, Lalloo F, Evans DG, Easton DF. Average risks of breast and ovarian cancer associated with *BRCA1* or *BRCA2* mutations detected in case series unselected for family history: a combined analysis of 22 studies. Am J Human Genet 2003;72:1117-30.

2002

Shaw PA, McLaughlin JR, Zweemer RP, Narod SA, **Risch H**, Verheijen RHM, Ryan A, Menko FH, Kenemans P, Jacobs IJ. Histopathologic features of genetically determined ovarian cancer. Int J Gynecol Pathol 2002;21:407-11.

Engel LS, Vaughan TL, Gammon MD, Chow W-H, **Risch HA**, Dubrow R, Mayne ST, Rotterdam H, Schoenberg JB, Stanford JL, West AB, Blot WJ, Fraumeni JF Jr. Occupation and risk of esophageal and gastric cardia adenocarcinoma. Am J Ind Med 2002;42:11-22.

Ness RB, Cramer DW, Goodman MT, Kjaer SK, Mallin K, Mosgaard BJ, Purdie DM, **Risch HA**, Vergona R, Wu A. Infertility, fertility drugs and ovarian cancer: a pooled analysis of case-control studies. Am J Epidemiol 2002;155:217-24.

2001

Dhillon PK, Farrow DC, Vaughan TL, Chow W-H, **Risch HA**, Gammon MD, Mayne ST, Stanford JL, Schoenberg JB, Ahsan H, Dubrow R, West AB, Rotterdam H, Blot WJ, Fraumeni JF Jr. Family history of cancer and risk of esophageal and gastric cancers in the United States. Int J Cancer 2001;93:148-52.

Mayne ST, **Risch HA**, Dubrow R, Chow W-H, Gammon MD, Vaughan TL, Farrow DC, Schoenberg JB, Stanford JB, Ahsan H, West AB, Rotterdam H, Blot WJ, Fraumeni JF Jr. Nutrient intake and risk of subtypes of esophageal and gastric cancer. Cancer Epidemiol Biomarkers Prev 2001;10:1055-62.

Runnebaum IB, Wang-Gohrke S, Vesprini D, Kreienberg R, Lynch H, Moslehi R, Ghadirian P, Weber B, Godwin AK, **Risch H**, Garber G, Lerman C, Olipade OI, Foulkes WD, Karlan B, Warner E, Rosen B, Rebbeck T, Tonin P, Dubé M-P, Kieback DG, Narod SA. Progesterone receptor variant increases ovarian cancer risk in *BRCA1* and *BRCA2* mutation carriers who were never exposed to oral contraceptives. Pharmacogenetics 2001;11:1-4.

Risch HA, McLaughlin JR, Cole DEC, Rosen B, Bradley L, Kwan E, Jack E, Vesprini DJ, Kuperstein G, Abrahamson JLA, Fan I, Wong B, Narod SA. Prevalence and penetrance of germline *BRCA1* and *BRCA2* mutations in a population series of 649 women with ovarian cancer. Am J Human Genet 2001;68(3):700-10.

2000

Whiteman DC, Murphy MFG, Cook LS, Cramer DW, Hartge P, Marchbanks PA, Nasca PC, Ness RB, Purdie DM, **Risch HA**. Multiple births and risk of epithelial ovarian cancer. J Natl Cancer Inst 2000;92:1172-7.

Moslehi R, Chu W, Karlan B, Fishman D, **Risch H**, Fields A, Smotkin D, Ben-David Y, Rosenblatt J, Russo D, Schwartz P, Tung N, Warner E, Rosen B, Friedman J, Brunet J-S, Narod SA. *BRCA1* and *BRCA2* mutation analysis of 208 Ashkenazi Jewish women with ovarian cancer. Am J Human Genet 2000;66:1259-72.

Shin HR, Kim JY, Ohno T, Cao K, Mizokami M, **Risch H**, Kim SR. Prevalence and risk factors of hepatitis C virus infection among Koreans in a rural area of Korea. Hepatol Res 2000;17:185-96.

Eras JL, Saftlas AF, Triche E, Hsu C-D, **Risch HA**, Bracken MB. Abortion and its effect on risk of preeclampsia and transient hypertension. Epidemiology 2000;11:36-43.

Farrow DC, Vaughan TL, Sweeney C, Gammon MD, Chow W-H, **Risch HA**, Stanford JL, Hansten PD, Mayne ST, Schoenberg JB, Rotterdam H, Ahsan H, West AB, Dubrow R, Fraumeni JF Jr, Blot WJ. Gastroesophageal reflux disease, use of H2 receptor antagonists, and risk of esophageal and gastric cancer. Cancer Causes Control 2000;11:231-8.

1999

Wang-Gohrke S, Weikel W, **Risch H**, Vesprini D, Abrahamson J, Lerman C, Godwin A, Moslehi R, Olipade O, Brunet J-S, Stickeler E, Kieback DG, Kreienberg R, Weber B, Narod SA, Runnebaum IB. Intron variants of the p53 gene are associated with increased risk for ovarian cancer but not in carriers of BRCA1 or BRCA2 germline mutations. Br J Cancer 1999;81:179-83.

Zweemer RP, Shaw PA, Verheijen RHM, Ryan A, Berchuk A, Ponder BAJ, **Risch H**, McLaughlin JR, Narod SA, Menko FH, Kenemans P, Jacobs IJ. Accumulation of p53 protein is frequent in ovarian cancers associated with BRCA1 and BRCA2 germline mutations. J Clin Pathol 1999;52:372-5.

1998

Risch HA. Hormonal etiology of epithelial ovarian cancer, with a hypothesis concerning the role of androgens and progesterone. J Natl Cancer Inst 1998;90(23):1774-86.

Narod SA, **Risch H**, Moslehi R, Dørum A, Neuhausen S, Olsson H, Provencher D, Radice P, Evans G, Bishop S, Brunet J-S, Ponder BAJ, Klijn JGM. Oral contraceptives and the risk of hereditary ovarian cancer. The Hereditary Ovarian Cancer Clinical Study Group. N Engl J Med 1998;339(7):424-8.

Vaughan TL, Farrow DC, Hansten PD, Chow W-H, Gammon MD, **Risch HA**, Stanford JL, Schoenberg JB, Mayne ST, Rotterdam H, Dubrow R, Ahsan H, West AB, Blot WJ, Fraumeni JF Jr. Risk of esophageal and gastric adenocarcinomas in relation to use of calcium channel blockers, asthma drugs, and other medications that promote gastroesophageal reflux. Cancer Epidemiol Biomarkers Prev 1998;7:749-56.

Chow W-H, Blaser MJ, Blot WJ, Gammon MD, Vaughan TL, **Risch HA**, Perez-Perez GI,

Schoenberg JB, Stanford JL, Rotterdam H, West AB, Fraumeni JF Jr. An inverse relation between *cagA*+ strains of *Helicobacter pylori* infection and risk of esophageal and gastric cardia adenocarcinoma. Cancer Res 1998;58:588-90.

Farrow DC, Vaughan TL, Hansten PD, Stanford JL, **Risch HA**, Gammon MD, Chow W-H, Dubrow R, Ahsan H, Mayne ST, Schoenberg JB, West AB, Rotterdam H, Fraumeni JF Jr, Blot WJ. Use of aspirin and other non-steroidal anti-inflammatory drugs and risk of esophageal and gastric cancer. Cancer Epidemiol Biomarkers Prev 1998;7:97-102.

Chow WH, Blot WJ, Vaughan TL, **Risch HA**, Gammon MD, Stanford JL, Dubrow R, Schoenberg JB, Mayne ST, Farrow DC, Ahsan H, West AB, Rotterdam H, Niwa S, Fraumeni JF Jr. Body mass index and risk of adenocarcinomas of the esophagus and gastric cardia. J Natl Cancer Inst 1998;90:150-5.

1997

Gammon MD, Schoenberg JB, Ahsan H, **Risch HA**, Vaughan TL, Chow W-H, Rotterdam H, West AB, Dubrow R, Stanford JL, Mayne ST, Farrow DC, Niwa S, Blot WJ, Fraumeni JF Jr. Tobacco, alcohol, and socioeconomic status and adenocarcinomas of the esophagus and gastric cardia. J Natl Cancer Inst 1997;89:1277-84.

Chang S, **Risch HA**. Perineal talc exposure and risk of ovarian carcinoma. Cancer 1997;79:2396-401.

Yoo K-Y, Tajima K, Miura S, Takeuchi T, Hirose K, **Risch H**, Dubrow R. Breast cancer risk factors according to combined estrogen and progesterone receptor status: a case-control analysis. Am J Epidemiol 1997;146:307-14.

1996

Risch HA. Estrogen replacement therapy and risk of epithelial ovarian cancer. Gynecol Oncol 1996;63:254-7.

Risch HA, Marrett LD, Jain M, Howe GR. Differences in risk factors for epithelial ovarian cancer by histologic type: results of a case-control study. Am J Epidemiol 1996;144(4):363-72.

1995

Risch HA, Howe GR. Pelvic inflammatory disease and the risk of epithelial ovarian cancer. Cancer Epidemiol Biomarkers Prev 1995;4:447-51.

Risch HA, Howe GR. Menopausal hormone use and colorectal cancer in Saskatchewan: A record linkage cohort study. Cancer Epidemiol Biomarkers Prev 1995;4:21-8.

1994

Risch HA, Jain M, Marrett LD, Howe GR. Dietary fat intake and risk of epithelial ovarian cancer. J Natl Cancer Inst 1994;86:1409-15.

Risch HA, Marrett LD, Howe GR. Parity, contraception, infertility and the risk of epithelial ovarian cancer. Am J Epidemiol 1994;140(7):585-97.

Risch HA, Jain M, Marrett LD, Howe GR. Dietary lactose intake, lactose intolerance, and the risk of epithelial ovarian cancer in southern Ontario (Canada). Cancer Causes Control 1994;5:540-8.

Narod SA, Madlensky L, Bradley L, Cole D, Tonin P, Rosen B, **Risch HA**. Hereditary and familial ovarian cancer in Southern Ontario. Cancer 1994;74:2341-6.

Risch HA, Howe GR. Menopausal hormone usage and breast cancer in Saskatchewan: A record-linkage cohort study. Am J Epidemiol 1994;139:670-83.

1993

Risch HA, Howe GR, Jain MJ, Burch JD, Holowaty EJ, Miller AB. Are female smokers at higher risk for lung cancer than male smokers? A case-control analysis by histologic type. Am J Epidemiol 1993;138(5):281-93.

Holowaty PH, Miller AB, Baines CJ, **Risch HA**. Canadian National Breast Screening Study: First screen results as predictors of future breast cancer risk. Cancer Epidemiol Biomarkers Prev 1993;2:11-9.

Yoo K-Y, Tajima K, Miura S, Yoshida M, Murai H, Kuroishi T, Lee Y, **Risch HA**, Dubrow R. A hospital-based case-control study of breast-cancer risk factors by estrogen and progesterone receptor status. Cancer Causes Control 1993;4:39-44.

1991

Holowaty EJ, **Risch HA**, Burch JD, Miller AB. Lung cancer in women in the Niagara region, Ontario: A case-control study. Can J Publ Health 1991;82:304-9.

1990

Jain M, Burch JD, Howe GR, **Risch HA**, Miller AB. Dietary factors and risk of lung cancer: Results from a case-control study, Toronto, 1981-1985. Int J Cancer 1990;45:287-93.

1989

Miller AB, Howe GR, Sherman GJ, Lindsay JP, Yaffe MJ, Dinner PJ, **Risch HA**, Preston DL. Mortality from breast cancer after irradiation during fluoroscopic examinations in patients being treated for tuberculosis. N Engl J Med 1989;321:1285-9.

Burch JD, Rohan TE, Howe GR, **Risch HA**, Hill GB, Steele R, Miller, AB. Risk of bladder cancer by source and type of tobacco exposure: a case-control study. Int J Cancer 1989;44:622-8.

Howe GR, Burch JD, Chiarelli AM, **Risch HA**, Choi BCK. An exploratory case-control study of brain tumors in children. Cancer Res 1989;49:4349-52.

1988

Risch HA, Burch JD, Miller AB, Hill GB, Steele R, Howe GR. Dietary factors and the incidence of cancer of the urinary bladder. Am J Epidemiol 1988;127(6):1179-91.

Risch HA, Burch JD, Miller AB, Hill GB, Steele R, Howe GR. Occupational factors and the incidence of cancer of the bladder in Canada. Br J Ind Med 1988;45(6):361-7.

Narod SA, Neri L, **Risch HA**, Raman S. Lymphocyte micronuclei and sister-chromatid exchanges among Canadian federal laboratory employees. Am J Ind Med 1988;14:449-456.

Risch HA, Weiss NS, Clarke EA, Miller AB. Risk factors for spontaneous abortion and its recurrence. Am J Epidemiol 1988;128:420-30.

Robles SC, Marrett LD, Clarke EA, **Risch HA**. An application of capture-recapture methods to the estimation of completeness of cancer registration. J Clin Epidemiol 1988;41:495-501.

1987

Burch JD, Craib KJP, Choi BCK, Miller AB, **Risch HA**, Howe GR. An exploratory case-control study of brain tumors in adults. J Natl Cancer Inst 1987;78:601-9.

1986

Baines CJ, Wall C, **Risch HA**, Kuin JK, Fan IJ. Changes in breast self-examination behaviour in a cohort of 8214 women in the Canadian National Breast Screening Study. Cancer 1986;57:1209-16.

Sclabassi RJ, Kroin JS, Hinman CL, **Risch HA**. The effect of cortical ablation on afferent activity in the cat somatosensory system. Electroenceph Clin Neurophysiol 1986;64:31-40.

1985

Risch HA, Jain M, Choi NW, Fodor JG, Pfeiffer CJ, Howe GR, Harrison LW, Craib KJP, Miller AB. Dietary factors and the incidence of cancer of the stomach. Am J Epidemiol 1985;122:947-59.

Sclabassi RJ, Hinman CL, Kroin JS, **Risch HA**. A non-linear analysis of afferent modulatory activity in the cat somatosensory system. Electroenceph Clin Neurophysiol 1985;60:444-54.

1983

Risch HA, Weiss NS, Lyon JL, Daling JR, Liff JM. Events of reproductive life and the incidence of epithelial ovarian cancer. Am J Epidemiol 1983;117(2):128-39.

Risch HA. An approximate solution for the standard deterministic epidemic model. Math Biosciences 1983;63:1-8.

1979

Risch HA. The correlation between relatives under assortative mating for an X-linked and autosomal trait. Ann Hum Genet 1979;43:151-65.

1977

Sclabassi RJ, **Risch HA**, Hinman CL, Kroin JS, Enns NF, Namerow NS. Complex pattern evoked somatosensory responses in the study of multiple sclerosis. Proc IEEE 1977;65:626-33.

Chapters in Books:

Holick CN, **Risch HA**. Smoking and Ovarian Cancer. In: *Tobacco: Science, Policy and Public Health, second edition*, Boyle P, Gray N, Henningfield J, Seffrin J, Zatonski W, eds. New York: Oxford University Press, pp. 503-11, 2010.

Holick CN, **Risch HA**. Smoking and Ovarian Cancer. In: *Tobacco and Public Health: Science and Policy*, Boyle P, Gray N, Henningfield J, Seffrin J, Zatonski W, eds. New York: Oxford University Press, pp. 511-21, 2004.

Risch HA. Hormones and Epithelial Ovarian Cancer. In: *Proceedings of the Second International Symposium of the Portuguese Menopause Society*, Neves-e-Castro M, Wren BG, eds. London, UK: Parthenon Publishing Group, pp. 129-40, 2002.

Risch HA. Etiologic Mechanisms in Epithelial Ovarian Cancer. In: *Proceedings of the Third International Symposium on Hormonal Carcinogenesis*, Li JJ, Daling JR, Li SA, eds. New York: Springer Verlag, pp. 307-19, 2000.

Howe GR, Burch JD, **Risch HA**. Artificial sweeteners, caloric intake and cancer: the epidemiologic evidence. In: *Sweeteners: Health Effects*, Williams G, ed. Princeton: Princeton Scientific Publishers, 1988.

Choi NW, Miller AB, Fodor JG, Jain M, Howe GR, **Risch HA**, Ruder AM. Consumption of precursors of *N*-nitroso compounds and human gastric cancer. In: *The Relevance of N-Nitroso compounds to Human Cancer Exposures and Mechanisms*, Bartsch H, O'Neill I, Schulte-

Hermann R, eds. Lyon: IARC Scientific Publications No. 84, 1987.

Editorials and Other Invited Papers:

Risch HA. Diabetes and pancreatic cancer: both cause and effect. JNCI J Natl Cancer Inst 2019;111(1):djy093. doi: 10.1093/jnci/djy093

Risch HA. Pancreatic cancer: *Helicobacter pylori* colonization, *N*-nitrosamine exposures, and ABO blood group. Mol Carcinog 2012;51(1):109-18.

Risch HA. It's time to accept that intake of dairy foods is not related to risk of ovarian cancer. Nat Clin Pract Oncol 2006;3:472-3.

Risch H. Involvement of dietary factors, *Helicobacter pylori*, and host inflammatory cytokine genetic polymorphisms in the etiology of pancreatic carcinoma. Zhong Liu [Tumor] 2003;23:445-7.

Risch HA. Postmenopausal estrogen-only, but not estrogen + progestin, was associated with an increased risk of ovarian cancer. Evid-Based Obstet Gynecol 2003;5:53-4.

Risch HA. Hormone replacement therapy and the risk of ovarian cancer. Gyn Oncol 2002; 86:115-7.

Other Papers:

Risch HA. THE AUTHOR REPLIES. Am J Epidemiol 2020;189(11):1444-1449. doi: 10.1093/aje/kwaa152. PMCID: PMC7454297 (letter)

Risch HA. Risch Responds to "How to Consider Low Reported Death Rates in COVID-19". Am J Epidemiol 2020;189(11):1230-1231. doi: 10.1093/aje/kwaa156. PMCID: PMC7454272 (letter)

Risch HA. Response to: "Overcoming the therapeutic nihilism of out-of-hospital management of COVID-19 patients". Am J Epidemio. 2020 Dec 16:kwaa275. doi: 10.1093/aje/kwaa275. Online ahead of print. PMCID: PMC7799246 (letter)

Connecticut Academy of Science and Engineering, Inc. (May 29, 2020). An Adaptive Risk-Based Strategy for Connecticut's Ongoing COVID-19 Response [White Paper]. Retrieved from https://www.ctcase.org/reports/Adaptive%RiskBased%Approach.pdf

Risch HA. Re: NSAID use and pancreatic cancer risk. Gastroenterology 2018;155:931 (letter).

Risch HA. Low-dose aspirin and pancreatic cancer risk—Reply. Cancer Epidemiol Biomarkers Prev 2017;26(7):1155-6 (letter).

Risch HA. Aspirin and pancreatic cancer—Response. Cancer Epidemiol Biomarkers Prev 2017;26(6):979 (letter).

Risch HA, Yu H, Lu L, Kidd MS. Risch et al. respond to "Clinical utility of prediction models for rare outcomes: The example of pancreatic cancer." Am J Epidemiol 2015;182(1):39-40. (response to invited commentary).

Risch HA, Berchuck A, Pharoah PDP for the Ovarian Cancer Association Consortium. *KRAS* rs61764370 in epithelial ovarian cancer—Response. Clin Cancer Res 2011;17:6601 (letter).

Bertuccio P, La Vecchia C, Silverman DT, Petersen GM, Bracci PM, Negri E, Li D, **Risch HA**, Olson SH, Gallinger S, Miller AB, Bueno-de-Mesquita HB, Talamini R, Polesel J, Ghadirian P, Baghurst PA, Zatonski W, Fontham E, Bamlet WR, Holly EA, Lucenteforte E, Hassan M, Yu H, Kurtz RC, Cotterchio M, Su J, Maisonneuve P, Duell EJ, Bosetti C, Boffetta P. Reply to: Are

cohort data on smokeless tobacco use and pancreatic cancer confounded by alcohol use? Ann Oncol 2011;22:1931-2. (letter).

Risch HA. Cyclin E Overexpression Relates to Ovarian Cancer Histology but Not to Risk Factors. Cancer Epidemiol Biomarkers Prev 2008;17:1841 (letter).

Zhang Y, Zhu Y, **Risch HA**. Changing incidence of thyroid cancer. JAMA 2006;296:1350 (letter).

Mayne ST, **Risch HA**, Dubrow R, Chow W-H, Gammon MD, Vaughan TL, Fraumeni JF Jr. Re: "Carbonated Soft Drink Consumption and Risk of Esophageal Adenocarcinoma." Response. J Natl Cancer Inst 2006;98:646-7 (letter).

Risch HA, Miller AB. Re: "Are Women More Susceptible to Lung Cancer?" J Natl Cancer Inst 2004;96(20):1560 (letter).

Risch HA. Re: "Etiology of pancreatic cancer, with a hypothesis concerning the role of *N*-nitroso compounds and excess gastric acidity." Response. J Natl Cancer Inst 2004;96:75-6 (letter).

Risch HA, Narod SA. Re: "Cancer risks in BRCA1 carriers: Time for the next generation of studies." J Natl Cancer Inst 2003;95:758 (letter).

Risch HA, Narod SA. Re: "On the use of familial aggregation in population-based case probands for calculating penetrance." J Natl Cancer Inst 2003;95:73-4 (letter).

Risch HA, Miller AB. Re: "Sex, smoking and cancer: a reappraisal." J Natl Cancer Inst 2002;94:308 (letter).

Narod SA, Sun P, **Risch HA**, for the Hereditary Ovarian Cancer Clinical Study Group. Ovarian cancer, oral contraceptives, and *BRCA* mutations. N Engl J Med 2001;345:1706-7 (letter).

Whiteman DC, Murphy MFG, Cook LS, Cramer DW, Hartge P, Marchbanks PA, Nasca PC, Ness RB, Purdie DM, **Risch HA**. Re: "Multiple births and risk of epithelial ovarian cancer--Response." J Natl Cancer Inst 2001;93:319-20 (letter).

Risch HA. Oral contraceptive use, anovulatory action and risk of epithelial ovarian cancer. Epidemiology 2000;11:614 (letter).

Risch HA. Re: "Hormonal etiology of epithelial ovarian cancer, with a hypothesis concerning the role of androgens and progesterone." Response. J Natl Cancer Inst 1999;91:650-1 (letter).

Risch HA. Re: "Relationship between lifetime ovulatory cycles and overexpression of mutant p53 in epithelial ovarian cancer." J Natl Cancer Inst 1997;89:1726-7 (letter).

Risch HA, Howe GR, Jain MJ, Burch JD, Holowaty EJ, Miller AB. Re: "Are female smokers at higher risk for lung cancer than male smokers? A case-control analysis by histologic type"—The authors reply. Am J Epidemiol 1994;140:187-8 (letter).

Risch HA, Howe GR, Jain MJ, Burch JD, Holowaty EJ, Miller AB. Lung cancer risk for female smokers. Science 1994;263(5151):1206-8 (letter).

Risch HA. Re: "Likelihood-based Confidence Limits." Ann Epidemiol 1992;2:767-9 (letter).

Risch HA. Re: "A simple method to calculate the confidence interval of a standardized mortality ratio (SMR)." Am J Epidemiol 1991;133:212 (letter).

Risch HA. Re: "Risk factors for spontaneous abortion and its recurrence"—The first author replies. Am J Epidemiol 1990;131:571-3 (letter).

Miller AB, **Risch HA**. Diet and lung cancer. Chest--The Cardiopulmonary Journal 1989 (Suppl);96:8s-9s.

Risch HA, Weiss NS, Daling JR, Lyon JL, Liff JM. Re: "Events of reproductive life and the

incidence of epithelial ovarian cancer"—The authors reply. Am J Epidemiol 1989;129:862-3 (letter).

Risch HA, Tibshirani RJ. Likelihood-based conditional logistic regression methods for comparing different classes of controls under individual matching to a single case group. Am J Epidemiol 1988;128:446-8 (letter).

Risch HA. Book Review: Peter Taylor, *The Smoke Ring: Tobacco, Money and Multinational Politics*. J Public Health Policy 1985;6:137-139.

Risch HA. On approximate solutions for the general stochastic epidemic. Ph.D. dissertation, University of Chicago, 1980.

Risch HA. Functional power series analysis of somatosensory evoked potentials. M.D. dissertation, University of California at San Diego, 1976.

Published Abstracts:

Cartmel B, Hughes M, Zhou Y, Gottlieb L, Ercolano E, **Risch H**, Harrigan M, McCorkle R, Irwin M. Randomized trial of exercise on depressive symptoms in women diagnosed with ovarian cancer: The women's activity and lifestyle study in Connecticut (WALC). Psychooncology 2018;27(Suppl 1):97. doi:http://dx.doi.org/10.1002/pon.4623

Streicher SA, Klein AP, Olson SH, Kurtz RC, DeWan AT, Zhao H, **Risch HA**. A pooled genome-wide association study of pancreatic cancer susceptibility loci in American Jews. Cancer Res 2017;77(13 Suppl): Abstract 1326. doi:10.1158/1538-7445.AM2017-1326.

Rasmussen CB, Kjaer SK, Albieri V, Webb PM, **Risch HA**, Rossing MA, Goodman MT, Moysich KB, Schildkraut JM, Bandera EV, Massuger LFAG, Phelan C, Anton-Culver H, Pearce CL, Wu AH, Jensen A. Pelvic inflammatory disease and risk of invasive ovarian cancer and borderline ovarian tumors: A pooled analysis of 13 case-control studies. Int J Gynecol Obstet 2015;131(Suppl 5):e421.

Prastegaard C, Jensen A, Svane TS, **Risch HA**, Rossing MA, Chang-Claude J, Goodman MT, Moysich K, Matsuo K, Goode EL, Terry KL, Schildkraut JM, Massuger LFAG, Bandera EV, Wentzensen N, Whittemore A, Sutphen R, Anton-Culver H, Menon U, Gentry-Maharaj A, Wu A, Pearce CL, Webb PM, Kruger Kjaer S. The impact of cigarette smoking on ovarian cancer survival: A pooled analysis of 20 case control studies from the ovarian cancer association consortium. Int J Gynecol Obstet 2015;131(Suppl 5):e172.

Zhou Y, Gottlieb L, Cartmel B, Li F, Ercolano EA, Harrigan M, McCorkle R, Ligibel JA, Von Gruenigen VE, Gogoi R, Schwartz PE, **Risch HA**, Irwin ML. Randomized trial of exercise on quality of life and fatigue in women diagnosed with ovarian cancer: The Women's Activity and Lifestyle study in Connecticut (WALC). J Clin Oncol 2015;33(15 Suppl):9505.

Yang HP, Cook LS, Weiderpass E, Adami H-O, Anderson KE, Cai H, Cerhan JR, Clendenen T, Felix AS, Friedenreich C, Garcia-Closas M, Goodman MT, Liang X, Lissowska J, Lu L, Magliocco AM, McCann SE, Moysich KB, Olson SH, Pike MC, Polidoro S, Ricceri F, **Risch H**, Sacerdote C, Setiawan VW, Shu XO, Spurdle AB, Trabert B, Webb PM, Wentzensen N, Xiang Y-B, Xu Y, Yu H, Zeleniuch-Jacquotte A, Brinton LA. Infertility and risk of incident endometrial carcinoma: a pooled analysis from the Epidemiology of Endometrial Cancer Consortium. Cancer Res 2014;74(19 Suppl);2167.

Tang H, Duell EJ, **Risch HA**, Olson SH, Bueno-de-Mesquita HB, Gallinger S, Holly EA, Petersen GM, Bracci PM, McWilliams RR, Jenab M, Riboli E, Tjønneland A, Boutron-Ruault MC,

Kaaks R, Trichopoulos D, Panico S, Sund M, Peeters PHM, Khaw K-T, Amos CI, Li D, Wei P. Genome-wide gene-diabetes and gene-obesity interaction scan in the pancreatic cancer case control consortium. Cancer Res 2014;74(19 Suppl);2214.

Irwin M, Gottlieb L, Cartmel B, Ercolano E, Rothbard M, Zhou Y, Schwartz PE, Ligibel JA, Von Gruenigen VE, **Risch H**. Trial of exercise in ovarian cancer survivors. J Clin Oncol 2012;30(suppl; abstr TPS1614).

Lu L, Katsaros D, **Risch H**, Yu H. Stem cell-associated gene Lin-28B genotype and phenotype in epithelial ovarian cancer and their associations with disease survival outcomes. Cancer Res 2012;72(8 Suppl);3655.

Risch HA. Why is pancreatic cancer less frequent in Asia than in the US, in spite of the higher prevalence of risk factors in Asia? Observations on the etiology of pancreatic cancer. J Epidemiol 2011;21(Suppl):43-6.

Berchuck A, Pharoah P, Ramus S, Gayther S, Palmieri R, Pearce C, Couch F, Antonio A, Goode E, Schildkraut J, Chenevix-Trench G, Sellers T, **Risch H**, for the Consortium of Investigators of Modifiers of BRCA1/2 and the Ovarian Cancer Association Consortium. Association of KRAS SNP rs61764370 with risk of invasive epithelial ovarian cancer: Implications for clinical testing. Gyn Oncol 2011;121:S2-3.

Tsai Y-Y, Chen YA, Chen Z, Permuth-Wey J, Iversen E, **Risch H**, Barnholtz-Sloan J, Cunningham JM, Vierkant RA, Fridley BL, Fenstermacher D, Sutphen R, Phelan CM, Narod SA, Schildkraut JM, Goode EL, Sellers TA. A novel region on 8q24.21 is associated with ovarian cancer susceptibility. Cancer Res 2011;70:4724. doi:10.1158/1538-7445.AM10-4724

Permuth-Wey J, Tsai Y-Y, Chen YA, Chen Z, Lancaster JM, Iverson E, **Risch H**, Barnholtz-Sloan J, Cunningham JM, Vierkant RA, Fridley BL, Fenstermacher D, Sutphen R, Narod SA, Goode EL, Schildkraut JM, Sellers TA, Phelan CM. Mitochondrial genetic variants influence ovarian cancer risk. Cancer Res 2011;70:2835. doi:10.1158/1538-7445.AM10-2835

Risch HA. Gene, environment, and risk factor interaction in pancreatic cancer. Cancer Prev Res 2010;3(12 Suppl):ED02-03. doi:10.1158/1940-6207.PREV-10-ED02-03

Ng MT, Rabkin CS, Lochhead P, Lissowska J, Vaughan TL, Gammon M, **Risch H**, Chow W-H, Hold GL, El-Omar E. Assessment of novel genetic polymorphisms and risk of upper gastrointestinal carcinoma. Gastroenterology 2010;138(5)(Suppl 1):S612.

Neale R, Whiteman D, Young J, Fritschi L, Fawcete J, Webb P, **Risch H**. The Queensland Pancreatic Cancer Study--Identifying risk factors for pancreatic cancer. Pancreas 2008;36:223.

Vaninetti N, Macdonald K, Geldenhuys L, **Risch H**, Porter G, Guernsey D, Casson AG. Nitric oxide in the molecular pathogenesis of Barrett Esophagus and esophageal adenocarcinoma. Gastroenterology 2007;132(Suppl 2):A635-6.

Engel LS, Vaughan TL, Gammon MD, Chow WH, **Risch HA**, Dubrow R, Mayne ST, Rotterdam H, Schoenberg JB, Stanford JL, West AB, Blot WJ, Fraumeni JF. Occupation and risk of esophageal and gastric cardia adenocarcinoma. Epidemiology 2002;13:S163.

Pharoah P, Antoniou A, **Risch H**, Narod S, Hopper J, Loman N, Olson H, Johansson O, Borg A, Pasini B, Radici P, Eccles D, Tang N, Olah E, Anton-Culver H, Eyfjord J, Evans DG, Evans C, Peto J, Easton D. Average risks of breast and ovarian cancer in women who carry a BRCA1 or BRCA2 mutation: a preliminary analysis of pooled family data from unselected case series. Am J Human Genet 2001;69 (Suppl 1):256.

Ness RB, Cramer DW, Goodman M, Kjaer SK, Mosgaard B, Purdie DM, **Risch H**, Vergona R, Wu A. Infertility and ovarian cancer: A pooled analysis. Am J Epidemiol 2001;153:S111.

McLaughlin J, Cole D, Narod S, Rosen B, **Risch H**. Reproductive and genetic risk factors for ovarian cancer. Am J Epidemiol 2001;153:S205.

Lew EA, **Risch HA**, Chow WH, Gammon MD, Vaughan TL, Schoenberg JB, Stanford JL, West AB, Rotterdam H, Blot WJ, Blaser MJ, Fraumeni JF. Helicobacter pylori, gastroesophageal reflux, their interrelationships, and the risk of esophageal adenocarcinoma. Gastroenterology 2001;120(Suppl 1):A31.

Lew EA, **Risch HA**, Chow WH, Gammon MD, Vaughan TL, Schoenberg JB, Stanford JL, Farrow D, West AB, Rotterdam H, Blot WJ, Fraumeni JF. Epidemiological study of risk factors for gastric carcinoids. Gastroenterology 2001;120(Suppl 1):A256.

El-Omar EM, Chow WH, Gammon MD, Vaughan TL, **Risch HA**, Fraumeni JF Jr. Pro-inflammatory genotypes of IL-1 beta, TNF-alpha and IL-10 increase risk of distal gastric cancer but not of cardia or oesophageal adenocarcinomas. Gastroenterology 2001;120(Suppl 1):A86.

Saftlas A, Wang W, **Risch H**, Woolson R, Hsu C, Bracken M. Prepregnancy body mass index and gestational weight gain as risk factors for preeclampsia and transient hypertension. Ann Epidemiol 2000;10:475.

Chu W, McLaughlin J, Phelan C, Cole D, **Risch H**, Narod S. The HRAS1 minisatellite locus increases the risk of ovarian cancer in BRCA1 carriers, but not in BRCA2 carriers or sporadic ovarian cancer. Am J Human Genet 2000;67:(Suppl 2):82.

Mayne ST, **Risch H**, Dubrow R, Chow W-H, Blot W, Gammon M, Vaughan T, Farrow DC, Schoenberg J, Stanford J, Ahsan H, Fraumeni JF Jr. Nutrient intake and risk of adenocarcinomas of the esophagus and gastric cardia. FASEB J 1999;13:A1021.

Hibshoosh H, Gammon MD, Rotterdam H, West AB, Terry MB, Vaughan TL, **Risch HA**, Chow WH, Fraumeni J, Arber N. Cyclin D1 overexpression in esophageal and gastric carcinoma: Correlation with histopathology. Lab Invest 1999;79:76A.

Shaw PA, Zweemer RP, McLaughlin J, Narod SA, **Risch H**, Jacobs IJ. Characteristics of genetically determined ovarian cancer. Lab Invest 1999;79:124A.

Farrow DC, Vaughan TL, Sweeney C, Gammon MD, Chow W-H, **Risch HA**, Stanford JL, Hansten PD, Mayne ST, Schoenberg JB, Rotterdam H, Ahsan H, West AB, Dubrow R, Fraumeni JF Jr, Blot WJ. Gastroesophageal reflux disease, use of H_2 receptor antagonists, and risk of esophageal and gastric cancer. Ann Epidemiol 1998;8:456.

Farrow DC, Vaughan TL, Hansten PD, Stanford JL, **Risch HA**, Gammon MD, Chow W-H, Dubrow R, Ahsan H, Mayne ST, Schoenberg JB, West AB, Rotterdam H, Fraumeni JF Jr, Blot WJ. Use of aspirin and other non-steroidal anti-inflammatory drugs and risk of esophageal and gastric cancer. Ann Epidemiol 1998;8:134.

Chow WH, Blot WJ, Vaughan TL, **Risch HA**, Gammon MD, Farrow DC, Mayne ST, Schoenberg JB, Fraumeni JF Jr. Body mass index and risk of adenocarcinomas of the esophagus and gastri cardia. Cancer Epidemiol Biomarkers Prev 1998;7:175.

Vaughan T, Farrow D, Chow W-H, Gammon M, **Risch H**, Hansten P, Schoenberg J, Mayne S, Fraumeni J Jr. Risk of esophageal and gastric adenocarcinoma and use of calcium antagonists and other medications that promote gastroesophageal reflux. Cancer Epidemiol Biomarkers Prev 1998;7:178.

Chow WH, Blaser MJ, Blot WJ, Gammon MD, Vaughan TL, **Risch HA**, Pérez-Pérez GI, Fraumeni JF Jr. H. pylori and CagA status in relation to risk of adenocarcinomas of esophagus and stomach by anatomic subsite. Gut 1997;41(Suppl):A33-4.

Abrahamson JLA, Vesprini DJ, Mclaughlin J, Cole D, Rosen B, Bradley L, Robb K, Jack E, Rehal P, Morris A, Patterson C, Fan I, Brunel JS, Narod SA, **Risch HA**. High proportion of germline BRCA1 and BRCA2 mutations in unselected ovarian cancer. Am J Human Genet 1997;61(Suppl):A59.

Risch HA. Estrogen replacement therapy and the risk of epithelial ovarian cancer. Am J Epidemiol 1996;143:S42.

Risch HA, Howe GR. Pelvic inflammatory disease and the risk of epithelial ovarian cancer. Am J Epidemiol 1995;141:S24.

Risch HA, Jain M, Marrett LD, Howe GR. Dietary fat intake and the risk of epithelial ovarian cancer. Am J Epidemiol 1994;139:S37.

Klaus D, Dubrow R, **Risch H**, Troncale F. Risk of colorectal adenomas and use of nonsteroidal antiinflammatory drugs (NSAIDS) and acetaminophen (APAP). Am J Epidemiol 1994;139:S78.

Risch HA, Malcolm E, Howe GR. Cohort study of menopausal hormone usage and breast cancer in Saskatchewan. Am J Epidemiol 1993;138:610.

Risch HA, Howe GR, Jain MJ, Burch JD, Holowaty EJ, Miller AB. Are female smokers at higher risk for lung cancer than male smokers? A case-control analysis by histologic type. Am J Epidemiol 1992;136:1015.

Risch HA. A unified framework for meta-analysis by maximum likelihood. Am J Epidemiol 1988;128:906.

Risch HA. Measuring tumor induction period in case-control studies of chronic exposures. Am J Epidemiol 1986;124:499.

Research Grants Held:

2020-2025 AP Klein (Principal Investigator), G Petersen, D Li, **HA Risch**, P Bracci, S Gallinger, R Hung, M Meng, E Jacobs, J Manjer, M Sund, V Katzke, A Arslan, L Le Marchand, R Milne, R Stolzenberg-Solomon, C Kooperberg, S van den Eeden, J Genkinger, A Schwartz, J Brody, S Lynch, A Tjønneland, X-O Shu, L Amundadottir, K Visvanathan, B Wolpin. *Multi-Ancestry Mapping of Pancreatic Cancer Susceptibility Loci.* (National Cancer Institute, $112,843 total direct costs to Yale subcontract over 60 months)

2018-2020 CY Jeon (Principal Investigator), S Freedland, S Kim, NY Kyeong, TK Nuckols, SJ Pandol, **HA Risch**, B Spiegel. *Predicting the Diagnosis of Pancreatic Cancer by Leveraging Big Data*. (National Cancer Institute, $235,000 total direct costs over 24 months)

2018-2018 ML Irwin (Principal Investigator), L Lu, **H Risch**. *Impact of exercise and diet-induced weight loss on immunosuppression in breast cancer survivors*. (Cynthia Barnett Breast Cancer Foundation, $25,000 total costs over 12 months)

2017-2018 **HA Risch** (Principal Investigator), L Lu. *Feasibility of circulating exosomal proteins in ovarian cancer diagnosis*. (Brozman Ovarian Cancer Foundation, $25,000 total

costs over 12 months)

2016-2021 AP Klein (Principal Investigator), P Bracci, S Cleary, S Gallinger, R Hung, D Li, R Neale, S Olson, G Petersen, **HA Risch,** G Scelo. *Validation and Fine-scale Mapping of Pancreatic Cancer Susceptibility Loci.* (National Cancer Institute, $220,000 total direct costs to Yale subcontract over 60 months)

2013-2017 Y Guan, X Ma (Principal Investigators), D Zimmerman, P Diggle, T Holford, **H Risch**, L Mueller, Y Zhang. *New Statistical Methods to Handle Spatial Uncertainty in Cancer Risk Estimation*. (National Cancer Institute, $1,100,000 total direct costs over 48 months)

2011-2016 R Kurman (Principal Investigator), H Berman, L Cope, T Diaz-Montes, M Gauthier, D Huso, D Levine, E Matloff, S Narod, V Parkash, **H Risch**, G Rosner, P Shaw, I-M Shih, R Soslow, R Vang, K Visvanathan, T-L Wang, et al. *Prevention of Ovarian High-Grade Serous Carcinoma by Elucidating Its Early Changes.* (Department of Defense USMRMC, $9,166,162 total direct costs, of which $199,000 total direct to Yale epidemiology subcontract, over 60 months).

2011-2015 AP Klein (Principal Investigator), P Bracci, P Brennan, E Duell, S Gallinger, D Li, R Neale, S Olson, G Petersen, **HA Risch**. *Validation and Fine-scale Mapping of Pancreatic Cancer Susceptibility Loci.* (National Cancer Institute, $197,000 total direct costs to Yale subcontract over 48 months)

2011-2013 AP Klein, **HA Risch** (Co-Principal Investigators). *Validation and Fine-Scale Mapping of Pancreatic Cancer Susceptibility Loci*. (National Human Genome Research Institute, covers costs of large-scale high-throughput genotyping of collaborative multi-center pancreatic cancer study (see previous grant) at the Center for Inherited Disease Research (CIDR)).

2010-2016 H Yu (Principal Investigator), M Irwin, X Ma, S Mayne, **H Risch**, H Zhao, J Lim. *Epidemiologic Study of Hepatocellular Carcinoma in the US*. (National Cancer Institute, $5,385,000 total direct costs over 60 months)

2010-2014 T Sellers (Principal Investigator), A Berchuck, G Bloom, M Clyde, D Fenstermacher, B Fridley, S Gayther, W Ge, E Goode, E Iversen, H-Y Lin, S Mears, A Monteiro, T Moorman, L Pearce, P Pharoah, C Phelan, **H Risch**, MA Rossing, J Schildkraut, G Trench, Y-Y Tsai. *Follow-up of Ovarian Cancer Genetic Association and Interaction Studies (FOCI)*. (National Cancer Institute, $108,926 total direct costs to Yale subcontract 2012-2014)

2010-2013 CL Pearce (Principal Investigator), JA Doherty, S Gayther, VM McGuire, **H Risch**, MA Rossing, J Schildkraut, TA Sellers, W Sieh, D Stram, G Trench, P Webb, A Whittemore, A Wu. *Identifying Ovarian Cancer Susceptibility Alleles Using Genome-Wide Scan Data*. (National Cancer Institute, $22,500 total direct costs to Yale subcontract)

2009-2014 M Irwin (Principal Investigator), J Dziura, R McCorkle, G Mor, **H Risch**, P Schwartz, H Yu. *Impact of Exercise on Ovarian Cancer Prognosis*. (National Cancer Institute, $2,045,493 total direct costs over 59 months)

2009-2012 T Vaughan, D Whiteman (Principal Investigators), L Bernstein, D Corley, MD Gammon, L Hardie, N Hayward, G Liu, L Murray, O Nyrén, U Peters, B Reid, **HA Risch**, Y Romero, N Shaheen, D Stram, D Van Den Berg, B Weir, A Wu. *Barrett's and Esophageal Adenocarcinoma Consortium Genetic Susceptibility Study*. (National

Cancer Institute, $3,750,000 total direct costs over 36 months)

2009-2010 M Goodman (Principal Investigator), A Berchuck, J Chang-Claude, D Cramer, CM Garcia, E Goode, S Krueger Kjaer, R Ness, P Pharoah, **HA Risch**, M Rossing, R Sutphen, K Terry, G Trench, A Whittemore. *Collaborative Genetic Study of Ovarian Cancer Risk*. (National Cancer Institute, $17,419 total direct costs over 12 months, to Yale subcontract)

2007-2014 **HA Risch** (Principal Investigator), Y-T Gao, MS Kidd, H Yu. *Case-Control Study of Pancreas Cancer in Shanghai, China*. (National Cancer Institute, $1,858,377 total direct costs over 75 months)

2007-2012 P Salovey (Principal Investigator), M Irwin, ST Mayne, **HA Risch**. *Promoting Cancer Prevention/Control with Message Framing: III. Extending Tailored Cancer Information Service-Delivered Messages Across the Cancer Continuum*. (National Cancer Institute: $1,525,215 total direct costs over 58 months)

2007-2012 R Neale (Principal Investigator), D Whiteman, J Young, L Fritschi, J Fawcett, P Webb, **H Risch**. *Case-Control Study of Genetic and Environmental Risk Factors for Pancreatic Carcinoma*. (National Health and Medical Research Council (Australia): AU$946,475 total nonacademic direct costs over 60 months)

2007-2011 T Sellers (Principal Investigator), D Ballinger, J Barnholtz-Sloan, ME Colter, Y Huang, E Iversen, J Lancaster, J McLaughlin, S Narod, VS Pankratz, **H Risch**, J Schildkraut, R Sutphen. *Haplotype-Based Genome Screen for Ovarian Cancer Loci*. (National Cancer Institute, $5,726,016 total direct costs over 60 months)

2006-2007 R Neale (Principal Investigator), D Whiteman, L Fritschi, J Young, J Fawcett, P Webb, **H Risch**. *A Case-Control Study of the Environmental and Genetic Causes of Pancreatic Carcinoma*. (Queensland Cancer Fund: AU$258,339 total nonacademic direct costs over 16 months)

2003-2012 **HA Risch** (Principal Investigator), FS Gorelick, D Jain, MS Kidd, ST Mayne, MD Topazian, H Yu. *Case-Control Study of Pancreas Cancer Etiologic Factors*. (National Cancer Institute: $2,578,672 total direct costs over 80 months, in NCE)

2003-2010 H Yu (Principal Investigator), **HA Risch**, ST Mayne, M Irwin, B Cartmel. *Role of Genetic and Lifestyle Interplay in Uterus Cancer*. (National Cancer Institute: $2,185,432 total direct costs over 60 months, in NCE)

2003-2006 SA Narod (Principal Investigator), B Rosen, JR McLaughlin, P Shaw, **HA Risch**. *The contribution of BRCA2 to ovarian cancer*. (National Cancer Institute of Canada: $375,000 total nonacademic direct costs over 36 months)

2002-2005 H Yu (Principal Investigator), **HA Risch**. *DNA Methylation, Aging, and Prostate Cancer Risk*. (National Cancer Institute: $600,000 total direct costs over 48 months)

2002-2006 JP Concato (Principal Investigator), W Li, P Peduzzi, **HA Risch**, D Jain. *Risk of Mortality in Prostate Cancer*. (USVA: $424,000 total direct costs over 48 months)

2001-2007 P Salovey (Principal Investigator), **HA Risch**, ST Mayne, M Morra. *Promoting Cancer Prevention/Control with Message Framing. II*. (National Cancer Institute: $1,324,481 total direct costs over 72 months)

1999-2005 **HA Risch** (Principal Investigator), AE Bale. *DNA Polymorphisms in Ovarian Cancer: Case-Control Study*. (National Cancer Institute: $325,168 total direct costs over 58 months)

1998-2002 JP Concato (Principal Investigator), W Li, P Peduzzi, S Flynn, C Howe, **HA Risch**, D Esrig. *Risk of Mortality in Prostate Cancer*. (USVA: $425,245 total direct costs over 48 months)

1997-2003 **HA Risch** (Principal Investigator), L DiPietro, AF Saftlas, A Duleba, ML Carcangiu. *Case-Control Study of Ovarian Cancer Hormonal Etiology*. (National Cancer Institute: $1,445,806 total direct costs over 70 months)

1997-2000 SA Narod (Principal Investigator), **HA Risch**. *Risk-Factor Analysis of BRCA1 and BRCA2 Carriers*. (National Cancer Institute: $1,228,000 total direct costs over 36 months)

1997-2001 P Salovey (Principal Investigator), **HA Risch**, M Morra. *Promoting Cancer Prevention/Control with Message Framing*. (National Cancer Institute: $498,295 total direct costs over 48 months)

1996-1999 P Salovey (Principal Investigator), **HA Risch**, M Morra. *Message Framing, Persuasion, and Cancer Prevention/Detection*. (American Cancer Society: $198,000 total direct costs over 24 months)

1994-2000 **HA Risch** (Principal Investigator), JR McLaughlin, SA Narod, NJ Risch, EJ Holowaty, BP Rosen, DEC Cole. *Genetic-Epidemiology Study of Epithelial Ovarian Tumors*. (National Cancer Institute: $799,551 total direct costs over 69 months)

1994-1997 SA Narod (Principal Investigator), HT Lynch, **HA Risch**, DE Goldgar. *The Prevention of Hereditary Breast and Ovarian Cancer*. (National Cancer Institute: $356,875 total direct costs over 34 months)

1992-1996 **HA Risch** (Principal Investigator), ST Mayne, R Dubrow, AB West. *Epidemiologic Study of Esophageal/Gastric Adenocarcinoma*. (National Cancer Institute: $536,163 total direct costs over 43 months)

1991-1992 **HA Risch** (Principal Investigator). *Latency-Temporality Analysis in Case-Control Studies of Chronic Exposures*. (National Institutes of Health (BSRG): $19,000 total direct costs over 12 months)

1990-1991 **HA Risch** (Principal Investigator), GR Howe, R West, LM Strand. *A Record-Linkage Cohort Study of Menopausal Hormone Usage and Endometrial Cancer in Saskatchewan*. (National Health Research and Development Program, Health and Welfare Canada: $50,476 total nonacademic direct costs over 8 months)

1990-1994 JAJ Stolwijk (Principal Investigator), **HA Risch**, ST Mayne, R Dubrow, T Holford. *Cancer Prevention Research Unit for Connecticut at Yale*. (National Cancer Institute: $3,865,000 total direct costs over 60 months)

1989-1993 **HA Risch** (Principal Investigator), LD Marrett, GR Howe, M Jain. *A Case-Control Study of Dietary Factors and Epithelial Ovarian Cancer*. (National Health Research and Development Program, Health and Welfare Canada: $343,766 total nonacademic direct costs over 41 months)

1986-1990 GR Howe (Principal Investigator), **HA Risch**, M Jain, JD Burch, C Wall. *Research Project Support of the NCIC Epidemiology Unit*. (National Cancer Institute of Canada: total nonacademic direct costs $228,093 in 1986-7; $440,454 in 1987-8; $205,617 in 1988-9, etc.)

Selected Scholarly Presentations and Workshops:

11/20 "Randomized Controlled Trials, Hydroxychloroquine and Risk of Hospitalization and Mortality in Patients with Covid-19." Testimony, US Senate Committee on Homeland Security & Governmental Affairs, Washington, DC.

5/19 "Pancreatic Cancer and Diet." Pancreatic Cancer Case-Control Consortium (PanC4) Annual Meeting, Baltimore, MD.

3/19 "Reducing Mortality of What Will Be the #3 Cause of Cancer Death Two Years from Now." Virus and Other Infection-associated Cancers Research Seminar, Yale School of Medicine, New Haven, CT.

5/18 "New Concepts in Causation." Keynote speaker, Pancreatic Cancer Case-Control Consortium (PanC4) Annual Meeting, Baltimore, MD.

2/18 "Risk Factors for Pancreatic Cancer." Yale Pancreas Symposium 2018: Multidisciplinary Management of Pancreatic Cancer. New Haven, CT.

4/17 "Reducing Mortality of what will be the #2 Cause of Cancer Death Four Years from Now." Gastroenterologic Oncology Service, Yale Cancer Center, New Haven, CT.

3/17 "Genomewide Association Study of Pancreatic Cancer in American Jews." Pancreatic Cancer Case-Control Consortium (PanC4) Annual Meeting, Baltimore, MD.

3/17 "New Markers and Approaches in Predicting Risk of Pancreatic Cancer." Pancreatic Cancer Case-Control Consortium (PanC4) Annual Meeting, Baltimore, MD.

12/16 "Genomewide Association Study of Pancreatic Cancer in American Jews." Pancreatic Cancer Case-Control Consortium (PanC4) GWAS Study Annual Meeting, Bethesda, MD.

10/16 "Reducing Mortality of Pancreatic Cancer in the International Context." Inaugural Global Oncology Seminar Series speaker, Yale Cancer Center, New Haven, CT.

6/16 "Prevention of Pancreatic Cancer." Pancreatic Cancer Case-Control Consortium (PanC4) Annual Meeting, Milan, Italy.

1/16 "Reducing Mortality of what will be the #2 Cause of Cancer Death Five Years from Now." Department of Therapeutic Radiation, Yale School of Medicine, New Haven, CT.

10/15 "Reducing Mortality of what will be the #2 Cause of Cancer Death Five Years from Now." Division of Cancer Epidemiology and Genetics, National Cancer Institute, NIH, Rockville, MD.

3/15 "Absolute Risk Models for Pancreatic Cancer." Pancreatic Cancer Case-Control Consortium (PanC4) Annual Meeting, Baltimore, MD.

12/12 Keynote Speaker, "From Cancer Registration to Cancer Etiology to Cancer Prevention." Cancer Registrars Association of New England Annual Meeting, Norwich, CT.

3/12 "Pancreatic Cancer Risk Models." Pancreatic Cancer Case-Control Consortium (PanC4) Annual Meeting, Baltimore, MD.

3/12 Cancer Center Grand Rounds: "*Helicobacter pylori*, ABO Blood Group and the Etiology of Pancreatic Cancer in China and the US." Yale University School of Medicine, New Haven, CT.

9/11 "Etiology of Pancreatic Cancer: Theory and Evidence." Seminar, Division of Chronic Disease Epidemiology, Yale University School of Public Health, New Haven, CT.

3/11 "Genetic Effects and Modifiers of Radiotherapy and Chemotherapy on Survival in Pancreatic Cancer," Pancreatic Cancer Case-Control Consortium (PanC4) Annual Meeting, New York, NY.

1/11 Keynote Speaker, "Why is Pancreatic Cancer Less Frequent in Asia than in the US, in Spite of the Higher Prevalence of Risk Factors in Asia? Observations on the Etiology of Pancreatic Cancer." Japan Epidemiology Association National Meetings, Sapporo, Japan.

1/11 Department Seminar: "*BRCA1* and *BRCA2* Mutations: Population Frequencies and Associations with a Variety of Cancers." Division of Epidemiology and Prevention, Aichi Cancer Center Research Institute, Nagoya, Japan.

1/11 Cancer Center Grand Rounds, "Why is Pancreatic Cancer Less Frequent in Asia than in the US, in Spite of the Higher Prevalence of Risk Factors in Asia? Observations on the Etiology of Pancreatic Cancer." Japan National Cancer Center, Tokyo, Japan.

11/10 Educational Session Seminar, "Gene, environment, and risk-factor interaction in pancreatic cancer." AACR Frontiers in Cancer Prevention Annual International Meeting, Philadelphia PA.

11/10 Workshop Presentation: "*KRAS* variation and risk of ovarian cancer." Biennial meeting of the Ovarian Cancer Association Consortium (OCAC), Bethesda, MD.

5/10 Cancer Center Retreat Seminar, "ABO blood group, *Helicobacter pylori* colonization and pancreatic cancer." Yale University School of Medicine, New Haven, CT.

3/10 "*Helicobacter pylori* colonization, ABO blood group and risk of pancreatic cancer," Pancreatic Cancer Case-Control Consortium (PanC4) Annual Meeting, Bethesda, MD.

7/09 Epidemiology Grand Rounds: "Pancreas Cancer and *Helicobacter pylori* in the U.S. and China." Department of Epidemiology, Shanghai Cancer Institute, Shanghai, China.

3/09 Cancer Center Grand Rounds: "Inconsistencies in Pancreas-Cancer Risk Factors and Disease Incidence Between the U.S. and China: Observations on the Etiology of Pancreas Cancer." Yale University School of Medicine, New Haven, CT.

11/08 Workshop Participant, Defining the Public Health Research Agenda for Ovarian Cancer, Centers for Disease Control, Atlanta, GA.

7/08 Workshop Presentation: "*Helicobacter pylori* and pancreas cancer." Biological and Clinical Risks and Potential Benefits of *Helicobacter pylori* Colonization, Division of Microbiology and Infectious Diseases, NIAID, NIH, Bethesda, MD.

1/08 Research Seminar: "Smoking and lung cancer in women—yet again." Program in Cancer Prevention and Control, Yale Cancer Center, New Haven, CT.

11/07 Workshop Presentation: "*BRCA1* and *BRCA2* Mutations: Frequencies in the General Population of North America and Associations with Breast, Ovary, Stomach, Pancreas and Other Cancers." Nanjing International Symposium of New Frontiers in Cancer Research and Advanced Training Workshop of Cancer Molecular Epidemiology, Nanjing Medical University, Nanjing, China.

10/07 Workshop Presentation: "Why have epidemiology data and outcomes of clinical trials

not correlated?" Third Haifa Cancer Prevention Workshop. CHS National Cancer Control Center, Faculty of Medicine, Technion Israel Institute of Technology, Haifa, Israel.

6/07 Workshop: "Advanced Statistical Methods for Epidemiologic Studies". Department of Community Medicine and Epidemiology, Technion Israel Institute of Technology Faculty of Medicine, Haifa, Israel.

3/07 Ruth and Bruce Rappaport Seminar: "Why Pancreas Cancer is Less Frequent in China than the US, in Spite of the Generally Higher Chinese Prevalence of Risk Factors: Insights on the Etiology of Pancreas Cancer." Faculty of Medicine, Technion Israel Institute of Technology, Haifa, Israel.

2/07 Seminar: "Smoking and lung cancer in women—yet again." Department of Community Medicine and Epidemiology, Technion Israel Institute of Technology Faculty of Medicine, Haifa, Israel.

1/07 Seminar: "Etiologic theories for epithelial ovarian cancer." Department of Community Medicine and Epidemiology, Technion Israel Institute of Technology Faculty of Medicine, Haifa, Israel.

11/06 Seminar: "*BRCA1* and *BRCA2* Mutations: Frequencies in the General Population and Associations with Breast, Ovary, Stomach, Pancreas and Other Cancers." New York University Cancer Center, New York, NY.

2/06 Cancer Center Grand Rounds: "*BRCA1* and *BRCA2* Mutations: Their Frequencies in the General Population and Their Associations with Breast, Ovary, Stomach, Pancreas and Other Cancers," Yale University School of Medicine, New Haven, CT.

11/05 Symposium: "Why Pancreas Cancer is Less Frequent in China than the US, in spite of the Generally Higher Chinese Prevalence of Risk Factors: Insights on the Etiology of Pancreas Cancer." Clinical Oncological Society of Australia annual scientific meeting, Brisbane, Australia (Sponsored by the Queensland Cancer Fund).

11/05 Symposium: "Risks and penetrances of germline *BRCA1* and *BRCA2* mutations for ovarian, breast, stomach, pancreas and other cancers: updated results from the Ontario (Canada) ovarian cancer kin-cohort study." Clinical Oncological Society of Australia annual scientific meeting, Brisbane, Australia (Sponsored by the Queensland Cancer Fund).

6/05 Seminar: "Why Pancreas Cancer is Less Frequent in China than the US, in spite of the Generally Higher Chinese Prevalence of Risk Factors: Insights on the Etiology of Pancreas Cancer." Tumor Registrars Association of Connecticut Quarterly Meeting, Yale-New Haven Hospital, New Haven, CT.

5/05 Seminar: "Why Pancreas Cancer is Less Frequent in China than the US, in spite of the Higher Prevalence of Risk Factors There: Insights on the Etiology of Pancreas Cancer." Sylvester Comprehensive Cancer Center, University of Miami, Miami, FL.

5/02 Symposium: "Genetic Epidemiology of Ovarian Cancer." Ovarian Cancer and High-Risk Women: Implications of Prevention, Screening and Early Detection. University of Pittsburgh, Pittsburgh, PA.

12/01 Seminar: "Prevalence and Penetrance of Germline *BRCA1* and *BRCA2* Mutations in Unselected Ovarian Cancer." Kaplan Cancer Center, NYU School of Medicine, New York, NY.

10/01 Research Seminar: "Prevalence and Penetrance of Germline *BRCA1* and *BRCA2* Mutations in Unselected Ovarian Cancer." Memorial Sloan Kettering Cancer Center, New York, NY.

6/01 Combined Monthly Research Seminar: "Prevalence and Penetrance of Germline *BRCA1* and *BRCA2* Mutations in Unselected Ovarian Cancer." Programs in Ovarian Cancer, Cancer Genetics and Cancer Prevention, Yale Cancer Center, New Haven, CT.

10/00 Departmental Seminar: "Etiology of Epithelial Ovarian Cancer." Department of Public Health Sciences, Fox Chase Cancer Center, Philadelphia, PA.

9/98 "Etiologic Mechanisms in Epithelial Ovarian Cancer," Third International Symposium on Hormonal Carcinogenesis, Seattle, WA.

5/98 Departmental Grand Rounds: "BRCA1 and BRCA2 Mutations in Unselected Ovarian Cancer," Department of Gynecologic Oncology, Yale University School of Medicine, New Haven, CT.

9/97 Departmental Seminar: "Etiologic Mechanisms in Epithelial Ovarian Cancer." Division of Epidemiology, Columbia University School of Public Health, New York, NY.

9/97 "Use of aspirin and other non-steroidal anti-inflammatory drugs and risk of esophageal and gastric cancer." American College of Epidemiology Annual Meetings, Cambridge, MA.

3/97 "Risk Factors for Familial and Hereditary Ovarian Cancer." American Cancer Society Science Writers Seminar, Reston, VA.

2/97 Departmental Grand Rounds: "Etiologic and Histologic Considerations in the Occurrence of Ovarian Cancer." Department of Pathology, Yale School of Medicine, New Haven, CT.

1/97 Departmental Seminar: "Ovarian Cancer Pathophysiology: Etiologic and Methodologic Issues." Department of Epidemiology, University of North Carolina School of Public Health, Chapel Hill, NC.

6/96 "Risk factors for BRCA1-associated ovarian cancer." NCI Extramural Genetic Epidemiology PIs Second Biennial Meetings, Frederick, MD.

6/96 "Estrogen replacement therapy and the risk of epithelial ovarian cancer." Society for Epidemiologic Research Annual Meetings, Boston, MA.

6/95 "Pelvic inflammatory disease and the risk of epithelial ovarian cancer." Society for Epidemiologic Research Annual Meetings, Snowbird, UT.

6/94 "Dietary fat intake and the risk of epithelial ovarian cancer." Society for Epidemiologic Research Annual Meetings, Miami, FL.

6/93 "A cohort study of menopausal hormone usage and breast cancer in Saskatchewan." Society for Epidemiologic Research Annual Meetings, Keystone, CO.

2/93 "A cohort study of menopausal hormone usage and breast cancer in the province of Saskatchewan, Canada." International Epidemiology Association Regional European Meeting, Jerusalem.

9/92 "A record-linkage cohort study of menopausal hormone usage and breast cancer in Saskatchewan." American College of Epidemiology Annual Meetings, Bethesda, MD.

9/92 "Record-linkage cohort study of menopausal hormone usage and breast cancer."

Yale/Dana Farber Conference on Cancer Prevention and Control, Department of Epidemiology and Public Health, Yale University, New Haven, CT.

6/92 "Are female smokers at higher risk for lung cancer than male smokers? A case-control analysis by histologic type." Society for Epidemiologic Research Annual Meetings, Minneapolis, MN.

12/91 Departmental Seminar: "Some interesting results on lung cancer in women." Department of Epidemiology and Public Health, Yale University, New Haven, CT.

11/89 Departmental Seminar: "Occupational and dietary associations with bladder-cancer incidence." Department of Epidemiology and Public Health, Yale University, New Haven, CT.

8/89 "A demonstration of the GLIMP computer program for epidemiologic analysis." Canadian Epidemiology Research Conference Meetings, Ottawa.

4/89 "Nonlinear dose-response models with standard logistic regression." Upstate New York and Southern Ontario Epidemiology Group Meetings, Toronto.

6/88 "A unified framework for meta-analysis by maximum likelihood." Society for Epidemiologic Research Annual Meetings, Vancouver.

4/88 Departmental Seminar: "Occupational and dietary factors in the study of cancer of the bladder." Division of Epidemiology and Biostatistics, Graduate School of Public Health, San Diego State University, San Diego, CA.

3/88 Seminar: "Diet and occupation in the causation of bladder cancer." School of Public Health, New York State Department of Health, SUNY, Albany, NY.

12/87 Departmental Seminar: "Dietary and occupation factors in a case-control study of bladder cancer." Department of Epidemiology, Harvard School of Public Health, Boston, MA.

12/87 Departmental Seminar: "Risk factors for spontaneous abortion and its recurrence, and habitual abortion." Department of Medical Genetics, Hospital for Sick Children, Toronto.

11/87 Departmental Seminar: "Occupational and dietary factors in the causation of bladder cancer." Department of Social and Preventive Medicine, SUNY School of Medicine, Buffalo, NY.

11/87 Departmental Seminar: "Dietary and occupational factors in the study of bladder cancer." Department of Epidemiology and Biostatistics, University of Western Ontario, London.

9/87 Departmental Seminar: "Dietary and occupational factors in a case-control study of bladder cancer." Department of Epidemiology and Community Medicine, University of Ottawa.

11/86 Departmental Seminar: "Application of linear structural hypotheses in observational epidemiologic studies." Department of Environmental and Occupational Medicine, Mount Sinai School of Medicine, New York, NY.

9/86 Departmental Seminar: "Application of linear structural equations in observational epidemiologic studies." Department of Epidemiology and Public Health, Yale University, New Haven, CT.

6/86 "Measuring tumor induction period in case-control studies of chronic exposures."

Society for Epidemiologic Research Annual Meetings, Pittsburgh, PA.

8/84 "Nitrate and ascorbate in a study of gastric cancer." International Epidemiology Association Meetings, Vancouver.

5/84 "An improved method for obtaining confidence intervals of the odds ratio in logistic regression." Epidemiologic Methods Workshop, Upstate New York and Southern Ontario Epidemiology Group Meetings, Toronto.

Exhibit C

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

DECLARATION OF TOM JEFFERSON, MD MRCGP FFPHM

I, Thomas Jefferson, declare as follows:

1. I make this statement based upon my own personal knowledge, education, and experience. I am prepared to testify to the facts and matters set forth herein. A true and accurate copy of my curriculum vitae is attached hereto as Exhibit A.

Relevant Credentials and Experience

2. I am a member of the World Health Organization (WHO) COVID-19 Infection Prevention and Control Research Working Group.

3. I received my Degree in Medicine and Surgery from Pisa University (1979). I then went on to continue my studies in the United Kingdom receiving a Diploma from the Royal College of Obstretrician & Gynaecologists (1982), Certificate of Vocational Training in General Practice (1984), Membership of the Royal College of General Practitioners (1985), Membership of the Chartered Institute of Linguists (1985), Diploma in Tropical Medicine & Hygiene (1987), Master of Science in Community Medicine (1988), and Membership of the Faculty of Public Health Medicine (MFPHM 1990). I hold accreditations in the UK in Public Health Medicine

(1990) and General Practice (1990). I earned my Certificate in Health Economics at the University of Aberdeen (1996) and a Fellowship of the Faculty of Public Health Medicine (FFPHM 1999).

4. I was part of a team in the Nordic Cochrane Centre where we compiled an evidence set to conduct a systemic review of HPV vaccine industry clinical study programs and non-industry funded studies.

5. Since 2015, I am a Fellow of the Centre for Evidence Based Medicine of the University of Oxford. I am now Senior Clinical Tutor on the Complex Reviews Module of the Master of Science in Evidence Based Health course. This involves reviews of regulatory data, economic studies, diagnostic studies, qualitative studies and IPI meta-analyses.

6. I collaborate with other Cochrane colleagues as co-investigators for the John and Laura Arnold Foundation for development of RIAT (Restoring Invisible and Abandoned Trials) Support Center. This Center will help accelerate the correction of the scientific record of clinical trials by making it more accurate and complete. I have worked with the Cochrane Central Editorial Unit where we stabilized our three long-standing influenza vaccine reviews.

7. I was a member of EMA's Clinical Trials Advisory Group 2.

8. I was on the editorial board of the BMJ Evidence Based Medicine from 2018 to 2021.

9. In the past, I have carried out research for the Ministry of Defence UK, NICE, Roche, EU, WHO, GlaxoSmithKline, Sanofi-Synhtelabo, Istituto Superiore di Sanita', ASSR (now Agenas), Netherlands Health Council, IMS Health, Piemonte Region of Northern Italy, and Agenzia di Sanita' Pubblica Lazio.

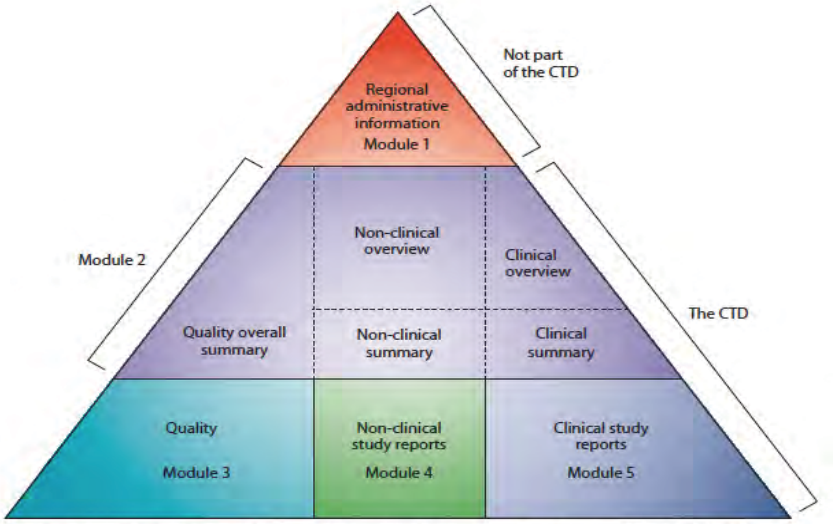
Opinion

A. For a Meaningful Review, All Data Must Be Released

10. Scientists seeking to conduct a proper analysis of Pfizer's COVID-19 vaccine data will need all of the documents submitted by Pfizer to the FDA because missing even a single dataset could corrupt any analysis.

11. Those data and documents in Pfizer's Biologic Licensing Application for its COVID-19 vaccine submitted to the FDA is likely to follow an international standard of structure for the content of such applications known as a Common Technical Document or CTD:

CTD Triangle



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

12. The CTD consists of five "modules" or parts and CTD content is closely connected. For example, Module 2 consists of summaries and overviews of both non-clinical (i.e., not in humans) and clinical (i.e., in humans) data and on the vaccine. Modules 3-5 explain in greater details the data from the summaries in Module 2. Module 3 reports details of the manufacturing process. Module 4 usually consists of pharmacokinetics toxicological (e.g., carcinogenesis)

studies carried out by the manufacturers, allowing an understanding of how the human body reacts to the vaccine and what happens to its components. Module 5 contains the Clinical Study Reports which are the very detailed reports of the randomized controlled trials and any other studies carried out to support the application.

13. Partial, incomplete, or batch release of parts of the CTD impede assessment of the application in a coherent way and may lead to errors in the interpretation of its content.

14. Covid-19 vaccines are global interventions rolled out to all age and risk groups. An estimated 9.5 billion doses have been administered thus far making it the largest medical intervention in the history of humankind with a novel medical product. Despite this, to date, publicly available information is limited to journal articles, press releases, and regulators' assessments of the vaccine's performance. All of these are subject to reporting bias. Such bias is often extremely difficult to identify unless the full documentation is available.

15. Cautious reviewers have pointed out the asymmetry of the global rollout of this product versus lack of transparency on data supporting its use which data is arguably the property of humankind (Tanveer S, Rowhani-Farid A, Hong K, et al. *Transparency of COVID-19 vaccine trials: decisions without data*. *BMJ Evidence-Based Medicine* Published Online First: 09 August 2021. doi: 10.1136/bmjebm-2021-111735).

B. Importance of Publicly Releasing the Data Immediately

16. It is important to publicly release these documents as soon as possible. Covid 19 vaccines are currently being used worldwide and, in many cases, are mandated. Pfizer's vaccine has been the subject of vigorous debate and the object of countless allegations of under reporting

of harms in the trials,[1] toxicity, lack of efficacy and conflicts of interest compromising various stages of their development, testing, trials, review and licensing. Including, direct allegations of data falsification and slack conduct[2] of the trial in two centers, reports of excess deaths linked to specific vaccine batches[3] and instability[4] of mRNA contained in the vaccine. Any delay in the data's release is likely to undermine the possibility of understanding the mechanism of action and benefits or limitations of this vaccine. Regardless of the merits of the arguments, only full and prompt access to the files will enable public scrutiny and sustain confidence in the integrity of the regulatory process.

17. The importance of independent review of data in science cannot be overstated. Science is never static. Our understanding evolves over time as a slow accumulation of knowledge allows general progress and occasional breakthroughs. Censorship and lack of transparency have always been the enemies of progress. In the case of Covid 19 vaccines, the importance of transparency in heightened by the mass administration to healthy populations and their unknown long-term effects.

18. In 2012, senior EMA regulators stated: "the potential benefits for public health of independent (re-) analysis of data are not disputed and in an open society trial sponsors and regulators do not have a monopoly on analysing and assessing drug trial results." (Eichler HG, Abadie E, Breckenridge A, Leufkens H, Rasi G. *Open clinical trial data for all? A view from regulators*. PLoS Med. 2012;9(4):e1001202. doi:10.1371/journal.pmed.1001202.)

---

[1] https://www.google.com/url?q=https://maryannedemasi.com/publications/f/are-adverse-events-in-covid-19-vaccine-trials-under-reported&sa=D&source=docs&ust=1638732374840000&usg=AOvVaw0n-eqwId8f6EX3rogE6aEc.

[2] https://www.bmj.com/content/375/bmj.n2635.full.

[3] https://dailyexpose.uk/2021/10/31/100-percent-of-covid-19-vaccine-deaths-caused-by-just-5-percent-of-the-batches-produced/.

[4] https://www.bmj.com/content/372/bmj.n627.

19. Given the insufficient and hurried testing and the culture of secrecy, it is arguable whether any informed consent is valid prior to making public all of the documents the FDA has in Pfizer's COVID-19 file.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct this sixth day of December 2021, at Rome, Italy.

Tom Jefferson, MD MRCGP FFPHM

Curriculum Vitae of Thomas Jefferson, MD MRCGP FFPHM

(Exhibit A to Jefferson Declaration)

CURRICULUM VITAE Thomas Oliver JEFFERSON
(17 November 2021)

Brief biographies appear in the series "Lifeline" on The Lancet 2003; 361:188. (11 January)
and in the Feature Pioneers of Transparency BMJ 2014;350:g7717

H-Index 65

Most cited papers:
Guidelines for authors and peer reviewers of economic submissions to the BMJ
MF Drummond, TO Jefferson. BMJ 313 (7052), 275-283 (1905 citations)

Vaccines for preventing influenza in healthy adults
V Demicheli, T Jefferson, E Ferroni, A Rivetti, C Di Pietrantonj. Cochrane database of systematic reviews (1889 citations)

Physical interventions to interrupt or reduce the spread of respiratory viruses
T Jefferson, CB Del Mar, L Dooley, E Ferroni, LA Al-Ansary, GA Bawazeer, ...
Cochrane database of systematic reviews (1219 citations)

Neuraminidase inhibitors for preventing and treating influenza in adults and children
T Jefferson, MA Jones, P Doshi, CB Del Mar, R Hama, MJ Thompson, Heneghan C.
Cochrane database of systematic reviews (934 citations)

Key words: Evidence synthesis, Epidemiology, Health Economics, Regulatory data, Respiratory viruses, Health Technology Assessment.

ADDRESS (Home)
Via Adige 28a
00061 Anguillara Sabazia
(Roma)
Italy
Mobile ++39 32 92025051
Email jefferson.tom@gmail.com

MEDALS & DECORATIONS

UNPROFOR Medal (1992)
OFFICER (BROTHER) Order of St John of Jerusalem (1994).
NATO Medal (Former Yugoslavia Clasp) 1996

RELEVANT ACADEMIC & PROFESSIONAL QUALIFICATIONS

Degree in Medicine and Surgery, Pisa University (1979).
Diploma of the Royal College of Obstetrician & Gynaecologists UK (DRCOG, 1982).
Certificate of Vocational Training in General Practice UK (1984).
Membership of the Royal College of General Practitioners UK (MRCGP 1985).
Membership of the Chartered Institute of Linguists UK (1985).
Diploma in Tropical Medicine & Hygiene UK (London School of Hygiene & Tropical Medicine 1987).
MSc Community Medicine UK (London School of Hygiene & Tropical Medicine 1988).
Membership of the Faculty of Public Health Medicine UK (MFPHM 1990).
Accreditation in Public Health Medicine UK (1990).
Accreditation in General Practice UK (1990).
Titolo di Scuola di Guerra (1991)
Certificate in Health Economics, University of Aberdeen UK (1996).
Fellowship of the Faculty of Public Health Medicine UK (FFPHM 1999).

RECENT and PRESENT ACTIVITIES

Unitl November 2019 I provided scientific supervision for the Agenas (Agenzia per i Servizi Sanitari Regionali) HTA programme for non-pharmaceuticals. Agenas is an agency of the Italian MoH. Part of my work entailed supervising a group of 10 researchers and taking responsibility for designing, devising and carrying out HTA and Horizon Scanning assessments. I was scientific lead for the European EUNeHTA Joint Action 2 (Workpackage 4 – devices and diagnostics) project (2012-2015, see below). The EUNeHTA Collaboration is a network of European public agencies producing structured HTA information for national use. In 2021 the Collaboration should become a permanent network funded by the

Commission. I was also scientific coordinator for Workpackage 4 which assessesed non pharmaceutical interventions, such as in vitro tests. This involved coordinating some 70 researchers from 28 agencies from 23 countries (from Estonia to Bulgaria, to Greece and Sweden). The project started in 2012 and was completed in 2015. I carried out the same role for the previous EUNeHTA project (Joint Action 1 or JA1 with the European Commission). Until November 2019 I was a member of two different workpackages and a reviewer for two projects in these workpackages as part of the EUNeHTA JA3.

I co-developed a methodology for synthetising evidence of effectiveness, efficiency, safety and resource utlisation using regulatory information and data from different sources, both regulatory and open source. This activity was initially funded by NIHR UK until mid-2015, then the Cochrane Methods Innovations Fund (MIF), NIHR again and since 2016 the Cochrane Nordic Centre. The MIF project was a collaboration to draft advice of when and how to include regulatory material in Cochrane reviews.
I am developing this work further by streamlining the use of regulatory data and its incorporation into user friendly, timely reviews.

As part of a team in the Nordic Cochrane Centre we carryied out a systematic review of HPV vaccines based on regulatory documents. The evidence set for the review was assembled by us from a variety of sources into an Index of the human papillomavirus (HPV) vaccine industry clinical study programmes and non-industry funded studies, shortly to be published. At present we are developing the same reviews further with the complete regulatory dataset released by Health Canada after a court case.

Since 2015 I am a Fellow of the Centre for Evidence Based Medicine of the **University of Oxford**, in the UK. I am now Senior Clinical Tutor on the Complex Reviews Module of the MSc in Evidence Based Health course.

I am visiting Professor Visiting Professor Institute of Health & Society at the Faculty of Medicine of Newcastle University (2019-2021).

With the 3 other Cochrane colleagues I am a co-investigator in a John and Laura Arnold Foundation grant for development of a RIAT support centre (2017-2020).

RIAT stands for Restoring Invisible and Abandoned Trials. In short, RIAT is a mechanism that enables researchers to address two long-standing problems in the medical literature: non-publication of trials and misreporting. Our concept was first outlined here: http://www.bmj.com/content/346/bmj.f2865

The RIAT Support Center will help accelerate the correction of the scientific record of clinical trials by making it more accurate and more complete.

Finally, with the help of the Cochrane Central Editorial Unit we stabilised of our three long-standing influenza vaccine reviews. These were released in January 2018.

My activity line of regulatory data started with updating of Cochrane review A159 (Neuraminidase Inhibitors for influenza). A159 is currently based exclusively on regulatory information (essentially clinical study reports - CSRs from EMA and comments by FDA and PMDA - about 150K pages in all).

The story is told in:

David Payne. Tamiflu: the battle for secret drug data. BMJ 2012;345:e7303 doi: 10.1136/bmj.e7303 (Published 29 October 2012).
http://www.bmj.com/content/345/bmj.e7303

http://www.nytimes.com/2013/06/30/business/breaking-the-seal-on-drug-research.html?pagewanted=1&_r=3&smid=tw-share

http://www.newsweek.com/2014/11/21/medical-science-has-data-problem-284066.html
The pioneers of transparency. BMJ 2015;350:g7717 (Published 02 Jan 2015)

I was a member of EMA's Clinical Trials Advisory Group 2 (CTAG2).

I was (2018-21) on the editorial board of BMJ Evidence Based Medicine (BMJ EBM).

I am an unpaid collaborator to the project *Beyond Transparency in Pharmaceutical Research and Regulation* led by Dalhousie University and funded by the Canadian Institutes of Health Research (2018-2022).

I currently teach on the Complex Reviews module of the MSc in Evidence Based Health Care at Oxford University and currently supervising to MSc students. This involves reviews of regulatory data, economic studies, diagnostic studies, qualitative studies and IPI meta-analyses.

I am a member of the WHO COVID-19 Infection Prevention and Control Research Working Group.

Since 2020, Tom has collaborated with the Centre for Evidence Medicine to clarify modes of transmission of SARS CoV-2: https://www.cebm.ox.ac.uk/research/transmission-of-sars-cov-2

PAST CONSULTANCIES AND OTHER ACTIVITIES

In the past I have carried out research for the **Ministry of Defence UK** (suite of Cochrane reviews on viral and arthropod borne fevers prevention), **NICE** (HTA of zanamivir for influenza), **Roche** (the economics of antivirals neuraminidase inhibitors), **EU** (systematic review of evidence of safety of MMR vaccines and of the economics of pneumococcal

vaccines), **WHO** (systematic review of evidence of safety of Hepatitis B vaccines), **Glaxo SmithKline** (systematic review of evidence of safety and effectiveness of DPT vaccines), **Sanofi- Synhtelabo** (Development of Pleconaril), **Istituto Superiore di Sanita'** and **ASSR** (now Agenas), (coordinator of the national clinical guidelines project) (see below), **Netherlands Health Council** (safety of Hepatitis B vaccine update review), **IMS Health** (Antidiabetic drugs) the **Piemonte Region** of Northern Italy (suite of Cochrane reviews on influenza vaccines), **Agenzia di Sanita' Pubblica Lazio** - Public Health Agency of Lazio Region (guidelines implementation trial project and coordination of a two cluster randomised trials of guidelines implementation, on behalf of the UK's Technology Assessment Programme I updated two reviews on the effects of editorial peer review. I have been involved in a 5 year update and rewrite of his Cochrane review on Neuraminidase Inhibitors exclusively based on regulatory information. (HTA – 10/80/01 Update and amalgamation of two Cochrane Reviews: neuraminidase inhibitors for preventing and treating influenza in healthy adults and children— *http://www.nets.nihr.ac.uk/projects/hta/108001*).

I am a member of the editorial base of the Cochrane Acute Respiratory Infections Group. Reviewer, Cochrane Infectious Diseases, Acute Respiratory Infections, Hepato-biliary, Airways and Colorectal Cancer Groups.

Director, Health Reviews Ltd, my own company.

Member, editorial, board of *Recenti Progressi in Medicina* and *BMC Health Services Research*.

Peer reviewer for BMJ, Lancet, JAMA, JAMA Internal Medicine, CMAJ, New England Journal of Medicine, Vaccine and Canadian Coordinating Office for Health Technology Assessment (CCOHTA) Emerging Technology bulletins.

I am an Academic Editor, PLOS ONE (2013-17) and have been a contributor to Last's Dictionary of Epidemiology (4th edition).

I do anonymous market access consultancy interviews for various pharmaceutical companies.

Between 1996 and 2009 I was the Co-ordinator of the Cochrane Vaccines Field and 1999 and 2012 I was honorary Research Fellow at the UK Cochrane Centre.

In 2011-13, I acted as an expert witness in a litigation case related to the antiviral oseltamivir, in two litigation cases on potential vaccine-related damage and in a labour case on influenza vaccines in healthcare workers in Canada. In 2016-17 I was a member of an independent data monitoring committee for a **Sanofi Pasteur** clinical trial on an influenza vaccine and a member of three advisory boards for **Boerhinger Ingelheim** (on bronchodilator drug), Takeda (cardiovascular drug) and Bayer (blood replacement).

As part of my HTA activity I have interviewed, collaborated and interacted with scores of clinicians in both primary and hospital care both in Italy and the rest of Europe. Over the past thirty years, I have worked in most therapeutic and prevention areas. Also as part of my Italian HTA and scientific activity I have interacted with patient organisations and have considerable knowledge of the regional Italian structure and its workings thanks to my role as consultant to Agenas.
The HTA report output is accessible at: https://www.agenas.gov.it/aree-tematiche/hta-health-technology-assessment/attivita-hta/report-hta
The Horizon scanning output is accessible at: https://www.agenas.gov.it/aree-tematiche/hta-health-technology-assessment/hs-horizon-scanning/report-hs

Since 2017 I am a member of the Italian MoH National Immunisation Technical Advisory Group (NITAG).

GENERAL PERSONAL & PROFESSIONAL BACKGROUND

I was born on 31 March 1954 in Viareggio (near Pisa), Italy. I was educated in Italy and went to UK in 1980 to do my hospital jobs prior to joining the Army. My professional career has spanned two specialties, General Practice (1980-1985) and Public Health (since 1986). I served in the British Army between 1981 and 1999.
My Army service took place in three continents and two conflicts (South Atlantic and Yugoslavia). I held the rank of Lieutenant Colonel. I am married with five children.

GENERAL PRACTICE CAREER

SHO Medicine, Arbroath Infirmary (1980 - 1981).
SHO Casualty, Croydon (1981).
Post Graduate Medical Officers' Course held Royal Military Academy, Sandhurst and the Royal Army Medical College, London (1981).
SHO O&G, British Military Hospital Hong Kong (1982).
Trainee GP and Regimental Medical Officer in several Gurkha units in Hong Kong and Nepal (1982 - 1984).
GP principal at Royal Military Academy Sandhurst, Armoured Regiment in Germany and Gurkha Battalion in UK and South Atlantic (1984 -1986).
Staff officer (various roles, 1987-1999)
Partner (part-time), North Lane Practice, Aldershot, Hampshire (1999-2001).

PUBLIC HEALTH CAREER

Registrar at the Department of Preventive Medicine at the Royal Army Medical College London (1987-1990).

Honorary Lecturer to the Department of Public Health at King's College Hospital, London (Professors Jim McEwen Norman Noah, 1989 - 1996).
Honorary Senior Lecturer to the Department of Public Health at King's College Hospital, London (1997 - current).
Detachment to the London School of Hygiene and Tropical Medicine on the Diploma in Tropical Medicine and Hygiene Course first and then on Master of Science in Community Medicine (1987- 1988).
Senior Registrar at the RAMC Training Centre near Aldershot (1988 - 1990). Student on the Higher Command and Staff Course at the Italian Army Staff College, Rome (1990 - 1991).
Second in Command of a Medical Battalion in Germany consisting of 250 personnel (1991 - 1992).

Assistant Force Medical Officer, United Nations Protection Force in Yugoslavia (UNPROFOR). I set up all medical facilities for the initial deployment in March 1992 and Director of Public Health for UNPROFOR. I was stationed in Sarajevo (Bosnia- Hercegovina), Belgrade (Serbia) and Zagreb (Croatia) for the duration of six months. Deputy Commander Medical (Preventive Medicine) British Army of the Rhine. I was responsible for all Preventive Medicine services for a population of 120.000 souls (1992-93).

Senior Technical Officer on the Health Services Market Test for British Forces Germany (1993-94). Responsible for developing the Statement of Requirement in preparation for the issuing of the Invitation To Tender and the developing of the purchasing function. Staff Officer, Ministry of Defence, Army Medical Directorate (1994-99). Responsible for health surveillance and health policy formulation for the British Army. My department carried out morbidity surveillance for the British Army and for the NATO SFOR mission in the Former Republic of Yugoslavia (FRY).

In February 1994 I was appointed Visiting Professor in Health Services Research at the University of Pavia, Northern Italy.

In June 1997 I was appointed Edmund Parkes Professor of Preventive Medicine at the Royal Defence Medical College. The chair is recognised by the Faculty of Public Health Medicine of the Royal College of Physicians of the United Kingdom. Additional responsibilities included the strategic management of the Army’s 90-strong Environmental Health cadre. This lapsed when I left the Army.

Principal in family medicine, Aldershot, UK, 1999-2001.
British Medical Association HC Roscoe Fellow for the study of the prevention and treatment of the common cold (2000-2002).

Adviser the Lazio Region Public Health Agency (IT) and the Istituto Superiore di Sanità (on the development of evidence-based clinical guidelines) 2001-2005

PRIZES

1982 Army Syntex Award for research into obstetric performance in different ethnic groups (see publication 5).

1984 University of Surrey Research Prize for work on haematological indices of pregnant Gurkha women (see publication 6).

1990 Parkes Memorial Prize for work on the selection and training of Army recruits (see publications 17 e 22).

2009 BMJ prize for best use of BMJ archival material (publication 232 on the “Spanish” influenza pandemic).

Past grants:

MOD(UK) - systematic reviews of interventions to prevent influenza in healthy adults

Roche UK Ltd - cost of illness study of the burden of influenza.

BMA Roscoe Fellowship - systematic review of the effects of antivirals for the common cold.

UK HTA programme - systematic review of the effects of zanamavir.

EU - systematic review of safety of MMR vaccines.

EU - systematic review of the economics of pneumococcal vaccines.

WHO - systematic review of evidence of safety of Hepatitis B vaccines.

WHO - systematic review of evidence of safety of aluminium in DTP vaccines.

Glaxo SmithKline Ltd - systematic review of evidence of safety and effectiveness of DPT vaccines.

NHS R&D programme - systematic review of the effects of peer review. An update was commissioned in May 2004.

Regione Piemonte, Italy – systematic reviews of the effects of influenza vaccines in children and elderly and quality studies and their publication on high impact factor journals.

Netherlands Health Council (safety of Hepatitis B vaccine update review)

DH (UK)/NIHR Cochrane review update incentive scheme (several awards)

Lazio Public Health Agency – systematic review of the epidemiology of *S.Pneumoniae*

DH (UK) National coordinating Centre for Methodology

WHO - Physical interventions to interrupt or reduce the spread of respiratory viruses: systematic review .

UK NIHR – Developing, updating and rewriting the Cochrane review on Neuraminidase Inhibitors exclusively based on regulatory information.

Cochrane - Methods Innovation Fund (MIF) 2014-17 to develop a methodology for summing up evidence of effectiveness, efficiency and safety using regulatory information and data from different sources, both regulatory and open source.

Arnold Foundation – RIAT centre

RECREATIONAL ACTIVITIES

Weight training, skiing.

MEMBERSHIP OF OTHER ORGANISATIONS (past and present)

Health Economics Study Group (HESG)
International Association of Health Economists (listed in the world directory of Health Economists).
Cochrane Airways Collaborative Review Group
LOCKNET (JAMA/BMJ peer-review network).
World Association of Medical Editors (WAME)
Health Technology Assessment International (international society for HTA)

PUBLICATIONS & REPORTS

1. CAROLI G, JEFFERSON T O. Wedding Party with S.Haifa. Annali Sclavo. 1978; 20: 959-962.

2. CAROLI G, JEFFERSON T O. Finding of E.Coli Phage in Urinary Tract Infections. Annali Sclavo. 1980; 22: 857-860.

3. JEFFERSON T O. Personal View. BMJ. 1982; 284: 1328.

4. JEFFERSON T O, COHEN C. Familial Siringomyelia with Mental Impairment. J R Army Med Corps. 1982; 128: 41-42.

5. JEFFERSON T O, REIDY A J. Incidence of Instrumental Deliveries in Primigravidae of 3 Different Ethnic Groups. J R Army Med Corps. 1983; 129: 46-47.

6. REIDY A J, JEFFERSON T O, KENNEDY P M D. Some Haematological Data on Pregnant Gurkha Women. J R Army Med Corps. 1984; 130: 20-21.

7. JEFFERSON T O. Physical Fitness and Smoking Patterns in a Gurkha Battalion. J R. Army Med Corps. 1986; 132: 168-172.

8. JEFFERSON T O, RASOR P A. Non Simulated Casualty Workload in 2 Field Hospital During Exercise "Bold Gannett". Giornale di Medicina Militare. 1985; 135: 265-268.

9. JEFFERSON T O, TAYLOR V M. Perinatal mortality in infants of two different ethnic groups. Family Practice 1985; 2:175-176.

10. JEFFERSON T O. (Anonymous) Mea culpa. Update. 1985; 31: 932.

11. JEFFERSON T O. Patterns of smoking in 2 infantry battalions. British Army Review. 1986; 82: 84.

12. JEFFERSON T O. A Camera in general practice (Ota's Naevus). Update. 1987; 35: 237.

13. KENNEDY P M D, JEFFERSON T O, REIDY A J. Growth in Gurkha Infants. Family Practice. 1986; 3: 54.

14. JEFFERSON T O. Buon Natale (Letter to the Editor). J Royal Coll Gen Pract.1986: 291.

15. OLLIER W, FENSTENSTEIN, JEFFERSON T O. HLA Antigens in Nepalese. Proceedings of the 3rd Asian Oceania Histocompatibility Conference, Sapporo 1986.

16. JEFFERSON T O. The Prevention of AIDS: Some Principles for the Inception and Assessment of a Health Education Campaign. Rivista Italiana d`Igiene 1988; 48: 3-11.

17. JEFFERSON T O. An Investigation of Medical Discharges from the British Army 1979-1986. J R Army Med Corps. 1989; 135: 115-123.

18. JEFFERSON T O, BRAND H, LEVRE` E, CAROLI G. The Personal Prevention of Malaria. Rivista Italiana d`Igiene 1989; 430: 443-450.

19. JEFFERSON T O, CAROLI G, MOLINARI G, PEIRONE A P. Public Health and Community Medicine in England. Rivista Italiana d`Igiene 1989; 49: 226-238.

20. BASNET I, HADYAPANIOTOU C, JEFFERSON T O, MILLS A. Abortion Services in Wandsworth (MSc Field Service Attachment). London School of Hygiene & Tropical Medicine, 1988.

21. TAYLOR L E, JEFFERSON T O, CAROLI G . Water Supply Engineering and Public Health in the United Kingdom. Rivista Italiana d`Igiene 1990; 50: 81-93.

22. JEFFERSON T O. An Investigation into Regular Recruit Wastage from the British Army, 1988. J R Army Med Corps 1990; 136: 138-145.

23. TAYLOR L E, JEFFERSON T O, CAROLI G. The Water Supply of London. Rivista Italiana d`Igiene. 1990; 3-4: 169-177.

24. DEMICHELI V, JEFFERSON T O, AMPOLA M, CAROLI G, PEIRONE A P. Il Lay Belief System. Nota 1: Lo Studio del Comportamento Sanitario. Rivista Italiana d`Igiene 1990; 3-4: 134-150.

25. JEFFERSON T O, DEMICHELI V, CAROLI G. Nesso tra Casi di Leucemia Infantile e Centrale Nucleare di Sellafield (U K): un Puzzle Epidemiologico. Rivista Italiana d`Igiene 1990 3-4: 178-191.

26. DEMICHELI V, JEFFERSON T O. Le Conseguenze Economiche della Salmonellosi. Antibioticoterapia per la pratica. 1991; 2: 73-81.

27. JEFFERSON T O. First Aid Training. An Appraisal. The Soldier's Longest Journey. J R Army Med Corps. 1991; 137: 27-30.

28. JEFFERSON T O. Procedures for the collection and bottling of mineral waters - Guidelines for handlers. Rivista Italiana d`Igiene 1990; 5-6: 496-8.

29. BISOGNI L, JEFFERSON T O, DEMICHELI V, LOMOLINO G, PACELLI G. Studio della prevalenza delle infezioni ospedaliere in un ospedale generale di zona. Rivista Italian di Antibioticoterapia per la pratica 1991; 4: 159-63.

30. DEMICHELI V, LOMOLINO G, JEFFERSON T O. Audit nei servizi di Igiene Pubblica: l`opinione dei cittadini sugli interventi per incovenienti igienici. Atti del IV Congresso Nazionale della Societa` Italiana di VRQ, Pavia 22-25 Settembre 1991, pagina 66. Editrice Periodici 1991.

31. DEMICHELI V, LOMOLINO G, JEFFERSON T O. La qualita` delle iniziative di formazione: l`aggiornamento del personale sul problema delle infezioni ospedaliere. Atti

del IV Congresso Nazionale della Societa` Italiana di VRQ, Pavia 22-25 Settembre 1991, pagina 81. Editrice Periodici 1991.

32. DEMICHELI V, LOMOLINO G, JEFFERSON T O. L`apporto della Economia Sanitaria alla qualita` delle decisioni. La determinazione del costo della sofferenza.Atti del IV Congresso Nazionale della Societa` Italiana di VRQ, Pavia 22-25 Settembre 1991, pagina 106. Editrice Periodici 1991.

33. DEMICHELI V, LOMOLINO G, JEFFERSON T O. Affermazioni di consenso e verifica della qualita`. Atti del IV Congresso Nazionale della Societa` Italiana di VRQ, Pavia 22-25 Settembre 1991, pagina 107. Editrice Periodici 1991.

34. DEMICHELI V, JEFFERSON T O. Cost-benefit analysis of the introduction of mass vaccination against Hepatitis B in Italy. Journal of Public Health Medicine 1992; 4: 367-375. (Paper presented to the third European Health Services Research Meeting - University College London, 13 - 14 December 1991).

35. DEMICHELI V, JEFFERSON T O. Manuale di Programmazione e organizzazione Sanitaria. Quaderni di Epidemiologia 17. La Goliardica Pavese, Pavia 1992.

36. DEMICHELI V, JEFFERSON T O. Criteri di valutazione del nesso causale e loro applicazione alla questione delle relazioni fra le radiazioni ionizzanti e la leucemia infantile. Tecnica Sanitaria 1993 (in press).

37. JEFFERSON T O, DEMICHELI V, LOMOLINO G. Problemi di Valutazione epidemiologica nelle piccole catastrofi ambientali. Il caso di Camelford in Cornovaglia. Tecnica Sanitaria 1993 (in press).

38. JEFFERSON T O. Public Health Aspects of the war in Yugoslavia. Public Health 1993; 107: 75-8.

39. JEFFERSON T O, DEMICHELI V, WRIGHT D A. An economic evaluation of the introduction of vaccination against Hepatitis A in a peace-keeping operation. The case of the United Nations Protection Force in Yugoslavia (UNPROFOR). International Journal of Technology Assessment in Health Care 1994; 10:490-97. Poster presented at the Fifth European Health Services Research Conference at Maastricht, (December 1993).

40. DEMICHELI V, LOMOLINO G, JEFFERSON T O. Audit of an environmental service in Italy. Proceedings of the Summer Conference of the Faculty of Public Health Medicine, 1992, Eastbourne, Sussex, Inghilterra.

41. JEFFERSON T O, DEMICHELI V. The costs of disease - a look at world literature. Presented at the "Meeting Internazionale sui costi delle malattie e della Salmonellosi", Pavia University (5-6 April 1993) (in press).

42. JEFFERSON T O, DEMICHELI V. Is vaccination against Hepatitis A and B cost-effective? A preliminary look at world literature. Presented at the "Meeting Internazionale sui costi delle malattie e della Salmonellosi", Pavia University (5-6 April 1993) (in press).

43. JEFFERSON T O, DEMICHELI V. Is vaccination against Hepatitis B efficient? A review of world literature. Health Economics 1994; 3:25-37. Paper presented at the Fifth European Health Services Research Conference at Maastricht, (December 1993).

44. JEFFERSON T O. Public Health and the war in Yugoslavia. In McKee M (ed): Health for all in a changing Europe. HFA 2000 News 1993; 25:4-5.

45. DEMICHELI V, JEFFERSON T O. Cost-benefit analysis of the introduction of mass vaccination against Hepatitis B in Italy (letter to the Editor). Journal of Public Health Medicine 1993; 14: 289-290.

46. JEFFERSON T O, MUGFORD M, GRAY A, DEMICHELI V.Puchasers and cost-effectiveness of interventions. Are secondary economic evaluations possible? Abstract presented at the Second Cochrane Colloqium, Hamilton, Ontario, October 1994.

47. JEFFERSON T O, BEHRENS R, DEMICHELI V. Should British soldiers be vaccinated against Hepatitis A? An economic analysis. Vaccine 1994; 12:1379-83.

48. JEFFERSON T O, PIERCE B, DEMICHELI V. Economic burden of an outbreak of a communicable disease of unknown aetiology in a military unit. Journal of Epidemiology and Community Health 1994; 48:423. (letter to the Editor).

49. AKEHURST R, GRAY A, BUXTON M, CHALMERS I, DONALDSON C, CHURNSIDE R, FENN P, FORBES J, GRIFFIN J, HOWARD S, JEFFERSON T, MC GUIRE A, MUGFORD M, O'BRIEN B, OXMAN A, TOWSE A. Assembling information in reviews of randomised controlled trials for subsequent cost-effectiveness analysis. Oxford: UK Cochrane Centre, Workshop Report, November 1993.

50. JEFFERSON T O, MACMILLAN A H M. Whither diplomatosis? Whither APHOM? J Royal Army Med Corps 1994 (letter to the editor).

51. JEFFERSON T O, MUGFORD M, DEMICHELI V. QALY league tables. Health Economics 1994; 3:205. (letter to the editor).

52. MUGFORD M, JEFFERSON T O, SOLL R. A Secondary Systematic Review to Assess whether and how results of randomised controlled trials of surfactant treatment for neonatal RDS can be used to inform questions of cost-effectiveness. Abstract presented at the Second Cochrane Colloqium, Hamilton, Ontario, October 1994.

53. MUGFORD M, McGUIRE A, JEFFERSON T O. Results of a survey of health

economists on generalising from economic evaluations.

54. JEFFERSON T O, MUGFORD M, GRAY A, DEMICHELI V. An exercise on the feasibility of carrying out secondary economic analyses. Abstract presented at the Second Cochrane Colloqium, Hamilton, Ontario, October 1994.

55. JEFFERSON T O. Environmental problems for workers abroad. In: Berhens R H, Riley W (editors). Caring for expatriates and workers abroad. Health issues and ethical dilemmas. Proceedings of an international meeting organised by the British Postgraduate Medical Federation the Hospital for Tropical Diseases and the London School of Hygiene and Tropical Medicine. British Postgraduate Medical Federation, London 1994.

56. JEFFERSON T O, DEMICHELI V. A panel priority rating exercise for the British Forces Germany Health Services Market Test. J Royal Army Med Corps 1995; 141:29-34.

57. DEMICHELI V, CASADIO G P, LANCIOTTI G, NOVACO F, JEFFERSON T O. The Emilia costing study: valutazione dell'impatto economico della salmonellosi umana. Mecosan 1995; 11:8-15.

58. WILLIAMS C, COYLE D, GRAY A, HUTTON J, JEFFERSON T O, KARLSSON G, KESTELOOT K, UYL-DE-GROOT, WAIT S. European School of Oncology advisory report to the Commission of the European Communities for "Europe Against Cancer Programme" - cost-effectiveness in cancer care. European Journal of Cancer 1995; 31:1410-24.

59. JEFFERSON T O. Book Review - A Literature Review of the Cost-Effectiveness of Nuclear Medicine by Jan Carter. King's Fund Centre. London: 1995. BMJ 1995.

60. JEFFERSON T O. Book Review - The Measures of Medicine: Benefits, Harms and Costs by Richard K Riegelman. Blackwell Science. London: 1995. BMJ 1995.

61. JEFFERSON T O. The Army and the Cochrane Collaboration (editorial). J Royal Army Med Corps 1995; 141:57-58.

62. JEFFERSON T O. Book Review - Outcomes into Clinical Practice by T Delamothe (editor). BMJ Publishing Group. London: 1994. J Royal Army Med Corps 1995; 141:57-58.

63. JEFFERSON T O, DEMICHELI V. Studi economici sulle riviste mediche: e' tempo di pensare a linee guida. Mecosan 1995; 13: 8-12.

64. JEFFERSON T O, DEMICHELI V, ENTWISTLE V. Assessing quality of economic submissions to the BMJ. BMJ 1995; 311:393-94 (letter to the editor).

65. JEFFERSON T O, DEMICHELI V. Are guidelines for peer-reviewing economic evaluations necessary? A survey of current editorial practice. Health Economics 1995; 4:383-88.

66. SASSI F, DEMICHELI V, JEFFERSON T O. Systematic Review and synthesis of economic studies. Paper presented at the Scientific Basis of Health Services conference. London 2-4 October 1995.

67. JEFFERSON T O, DEMICHELI V, MACMILLAN A H M. Epidemiological needs assessment in the British Army. Poster presented at the Scientific Basis of Health Services conference. London 2-4 October 1995.

68. DEMICHELI V, JEFFERSON T O. Le salmonellosi e lo studio dei costi delle malattie. In De Palma A, Novaco F, Orlandi L (editors). Le salmonellosi: epidemiologia, costo economico e strategie di intervento. Regione Emilia-Romagna, Assessorato alla Sanita', Bologna 1995; 6-12.

69. JEFFERSON T O, DEMICHELI V. The costs of disease - a look at world literature. In
De Palma A, Novaco F, Orlandi L (editors). Le salmonellosi: epidemiologia, costo economico e strategie di intervento. Regione Emilia-Romagna, Assessorato alla Sanita', Bologna 1995; pages 70-74.

70. DEMICHELI V, JEFFERSON T O. Presentazione dello studio sulla valutazione delle conseguenze economiche della salmonellosi umana in Emilia-Romagna. In De Palma A, Novaco F, Orlandi L (editors). Le salmonellosi: epidemiologia, costo economico e strategie di intervento. Regione Emilia-Romagna, Assessorato alla Sanita', Bologna 1995; 90-93.

71. SASSI F, DEMICHELI V, JEFFERSON T O. Pooling cost data from systematic reviews of economic studies. Poster presented at the Third Cochrane Colloquium, Oslo, Norway, 4-8 October 1995.

72. JEFFERSON T O. The quest for trials on the efficacy of human vaccines: results of the handsearch of the Vaccine journal. Poster presented at the Third Cochrane Colloquium, Oslo, Norway, 4-8 October 1995.

73. JEFFERSON T O. Book Review - Chalmers I, Altman DG. Systematic reviews BMJ Publishing Group. London: 1995. J Royal Army Med Corps 1995; 141:179

74. JEFFERSON T O, DEMICHELI V. Economic evaluation of Influenza vaccination and economic modelling. Can results be pooled? Pharmaeconomics 1996; 9 Suppl 3: 67-72.

75. JEFFERSON T O, DEMICHELI V, MACMILLAN A H M. Pilot study of the introduction of the J95 health data collection system. J Royal Army Med Corps 1996**;** **142**:25-29.

76. JEFFERSON T O, JEFFERSON V M. The quest for trials on the efficacy of human vaccines. Results of the handsearch of "*Vaccine*". Vaccine 1996; 14: 461-64.

77. DRUMMOND M F, JEFFERSON T O for the BMJ Working Party on guidelines for authors and peer-reviewers of economic submissions to the British Medical Journal. Buxton M Demicheli V, Donaldson C, Jönsson B, Mugford M, Rennie D, Rovira J, Rutten F, Schulman K, Smith R, Tonks A, Torrance G, Towse A). Guidelines for authors and peer-reviewers of economic submissions to the British Medical Journal. BMJ 1996; 313:275-83 (3 August).

78. JEFFERSON T O, MUGFORD M, GRAY A, DEMICHELI V. An exercise on the feasibility of carrying out secondary economic analyses. Health Economics 1996;5:155-165.

79. JEFFERSON T O, DEMICHELI V, MUGFORD M. Elementary Economic Evaluation in Health Care. London: BMJ Books 1996.

80. DEMICHELI V, JEFFERSON T O. Economic aspects of vaccination (Editorial). Vaccine 1996;

81. JEFFERSON T O. Economic evaluations as an aid to decisions on whether to carry out trials - Commentary. Lancet 1996; 348: 141 (20 July).

82. JEFFERSON TO, ROMANO G, DEMICHELI V. La valutazione dell'impatto economico di incidenti tossinfettivi alimentari: problemi metodologici e prospettive italiane. L'Igiene Moderna 1996; 105:993-1003.

83. DEMICHELI V, RIVETTI D, JEFFERSON TO. Economic aspects of a small epidemic of Hepatitis A in a religious community in Northern Italy. Journal of Infection 1996; 33:87-90

84. JEFFERSON TO (Book Review). Medical Informatics.....the essentials. By F T de Dombal. Butterworth Heinemann. Oxford: 1996. J Royal Med Corps 1997;143:64.

85. JEFFERSON T O. New and not so new vaccines- Editorial. BMJ 1996;313:768 (28 September 1996).

86. JEFFERSON TO, DEMICHELI V, PRATT M, DEEKS J, SASSI F, MACMILLAN A. The effectiveness of vaccines against Hepatitis B in healthcare workers. In Gluud C, J¢rgensen T, Morabito A, Pagliaro L, Poynard T, Sutton R (eds). Cochrane Database of Systematic Reviews; Issue 4. Update Software 2001.

87. DEMICHELI V, JEFFERSON TO, PRATT M, BEHRENS R, GRAVES P, BOTTASSO F, RIVETTI D, MACMILLAN A, MORRIS C. The effects of Anthrax vaccines. In Garner P, Gelband H, Oliaro P, Salinas R (eds). Cochrane Database of Systematic Reviews; Update Software 2001, Issue 4.

88. MILLER SAStJ, JEFFERSON TO. Military Health Surveillance. J Royal Med Corps 1997; 143:3 (editorial)

89. DEMICHELI V, JEFFERSON TO, PRATT M, BEHRENS R, GRAVES P, BOTTASSO F, RIVETTI D, MACMILLAN A, MORRIS C. The effects of Plague vaccines. In Garner P, Gelband H, Oliaro P, Salinas R (eds). Cochrane Database of Systematic Reviews; Issue 4. Update Software 2001.

90. DEMICHELI V, JEFFERSON TO, PRATT M, BEHRENS R, GRAVES P, BOTTASSO F, RIVETTI D, MACMILLAN A, MORRIS C. The effects of vaccines against Tick-Borne Encephalitis (TBE). In Garner P, Gelband H, Oliaro P, Salinas R (eds). Cochrane Database of Systematic Reviews; Update Software 2000, issue 4.

91. JEFFERSON TO, DEMICHELI V, PRATT M. Evidence-based vaccinology. The work of the Cochrane Vaccines Field. Journal of Epidemiology and Community Health 1998;52:207-208.

92. JEFFERSON TO, SMITH R, DRUMMOND MF, KALE R, YI Y, PRATT M. Evaluating the BMJ guidelines on economic submissions: prospective audit of economic submissions to the *BMJ* and *Lancet*. Paper presented at the Third International Congress on Peer Review in Biomedical Publication, Prague 18-20 September 1997.

93. JEFFERSON TO, DEMICHELI V, HUTTON J. The use of systematic reviews for peer reviewing. Poster presented at the Third International Congress on Peer Review in Biomedical Publication, Prague 18-20 September 1997.

94. JEFFERSON TO, DEMICHELI V. A systematic review of world literature on the economics of influenza. Information and News on Influenza. European Scientific Working Group on Influenza. 1997; 7:6.

95. JEFFERSON TO Redundant publication in biomedical sciences. Scientific misconduct or necessity? Science and Engineering Ethics 1998; 4:135-40. (See Corrigenda in Science and Engineering Ethics 1998; 4:392).

96. RIVETTI D. DEMICHELI V, DEEKS J, JEFFERSON TO, PRATT M. The effectiveness and safety of vaccines against human anthrax: a systematic review. Vaccine 1998; 16:880-84.

97. GRAVES PM, DEMICHELI V, JEFFERSON TO, DEEKS JJ, PRATT M. The effects of cholera vaccines. In Garner P, Gelband H, Oliaro P, Salinas R (eds). Cochrane Database of Systematic Reviews; Update Software 2000, Issue 4.

98. JEFFERSON TO. Vaccine trial data systematically assembled, pooled and disseminated by the Cochrane Collaboration. Vaccine 1998; 16:1487-95.

99. JEFFERSON TO, DEMICHELI V. No evidence that vaccines cause insulin dependent diabetes mellitus. Journal of Epidemiology and Community Health 1998; 52: 674-675.

100. DEMICHELI V, JEFFERSON T O. An exploratory review of the economics of recombinant vaccines against Hepatitis B (HB). In: Ronchi E (Editor) Biotechnology and Medical innovation: Socio-economic assessment of the technology, the potential and the products. OECD, Paris 1997 pages 105-123.

101. HUTTON J, JEFFERSON TO. Assessing the potential cost-effectiveness of pneumococcal vaccines: methodological issues and current evidence. Abstract 1998.

102. WRIGHT LA, DEMICHELI V, GILLESPIE WJ, JEFFERSON TO. Morbidity surveillance in the British Army - the first 12 months. J R Army Med Corps 1998; 144:11-17.

103. JEFFERSON TO. An introduction to Health Economics. Epidemiology Supercourse on the Web (editor R LaPorte, University of Pittsburgh) 1998. http://www.pitt.edu/~super1/hec02/.

104. JEFFERSON TO, DRUMMOND MF, SMITH R, YI Y, PRATT M, KALE R. Evaluating the *BMJ* guidelines on economic submissions - Prospective audit of economic submissions to the *BMJ* and *Lancet*. JAMA 1998; 280:275-77.

105. JEFFERSON TO. Vaccines and their adverse effects - real or perceived (editorial). *BMJ* 1998; 317:159-60.

106.JEFFERSON TO. Economic evaluation alongside the UK collaborative ECMO trial (commentary). *BMJ* 1998; 317:915-6.

107. JEFFERSON TO, DEMICHELI V. The socioeconomics of influenza. In Nicholson, Hay and Webster (editors): Textbook of Influenza. London: Blackwell 1998 pages 541-47.

108. JEFFERSON TO, DEMICHELI V. Relation between experimental and non-experimental study designs.HB vaccines: a case study. Journal of Epidemiology and Community Health 1999; 53:51-54.

109. DEMICHELI V, RIVETTI D, DEEKS JJ, JEFFERSON TO. Vaccines for preventing influenza in healthy adults (Cochrane Review). In: The Cochrane Library, Issue 1, 2003. Oxford: Update Software.

110. JEFFERSON TO, DEMICHELI V, DEEKS JJ, RIVETTI D. Neuraminidase inhibitors for influenza. Cochrane Database of Systematic Reviews (Acute Respiratory Infections Module); Oxford: Update Software 2003, Issue 1.

111. JEFFERSON TO, DEMICHELI V, DEEKS JJ, RIVETTI D. Amantadine & rimantadine for influenza. Cochrane Database of Systematic Reviews (Acute Respiratory Infections Module); Oxford: Update Software 2003, Issue 1.

112. JEFFERSON TO, DEMICHELI V. Methodological quality of economic modelling studies: a case study with hepatitis B vaccines. Pharmacoeconomics 1998; 14:251-7.

113. JEFFERSON TO, DEMICHELI V, DEEKS JJ, RIVETTI D. Cochrane reviews and systematic reviews of economic evaluations: the case of amantadine and rimantadine in the prevention and treatment of influenza. In: Snacken R, Szucs TD (editors). The socioeconomics of influenza and its control measures. Pharmacoeconomics 1999; 16: S85-S98.

114. JEFFERSON TO, DEMICHELI V. J95-EPINATO based planning parameters for medical support to operations other than war (OOTW). J R Army Med Corps 1998; 144:72-78.

115. HUTTON J, IGLESIAS C, JEFFERSON TO. Assessing the potential cost-effectiveness of pneumococcal vaccines: methodological issues and current evidence. Drugs and Aging 1999 15 Suppl 1:31-36.

116. JEFFERSON TO. What are the costs and benefits of editorials and non-systematic reviews? BMJ 1999; 318:135. (Personal View) (9 January).

117. JEFFERSON TO, DEMICHELI V, DEEKS JJ, RIVETTI D. Prevention and early treatment of influenza in healthy adults. Vaccine 2000; 18:957-1030.

118. JEFFERSON TO, MEIER CR, WEGMÜLLER Y. The impact of influenza on adults. Poster presented at the 21st International Congress of Chemotherapy, Birmingham, UK, 4-7 July 1999. Journal of Antimicrobial Chemotherapy 1999 4(Suppl): 43. Abstract P10. (Winner of the 21st International Congress of Chemotherapy Young Investigators Award)

119. JEFFERSON TO, WEGMÜLLER Y, BARKER C, WARD P. Influenza in the workplace: effect of Oseltamivir on ability to perform usual activities and attendance at work. Poster presented at the 21st International Congress of Chemotherapy, Birmingham, UK, 4-7 July 1999. Journal of Antimicrobial Chemotherapy 1999 4(Suppl): 46. Abstract P23.

120. JEFFERSON TO, RABINOVICH R, TUOMILEHTO J. Vaccines and their real or perceived adverse effects – authors' conclusions are at odds with investigators'. BMJ 1999; 318:1487 (letter to the editor).

121. JEFFERSON TO. Should the topics of Cochrane Reviews be Prioritised? Abstract presented at the seventh Cochrane Colloquium, Rome 4-7 October 1999.

122. JEFFERSON TO, DEMICHELI V. Should we Review Single Interventions or All Comparators in a Decision-Making Context? Abstract presented at the seventh Cochrane Colloquium, Rome 4-7 October 1999.

123. JEFFERSON TO, MILAN S. How are the topics of Cochrane Reviews decided? Abstract presented at the seventh Cochrane Colloquium, Rome 4-7 October 1999.

124. JEFFERSON TO. Do vaccines make best use of available resources? (In other words are they cost-effective?). In: Furminger I (editor): 4th European Conference on Vaccinology: the societal value of vaccination. Vaccine 1999; 17:S69-73.

125. GODLEE F, JEFFERSON TO (Editors). Peer Review in Health Sciences. London: BMJ Books 1999.

126. JEFFERSON TO. Real or perceived adverse effects of vaccines and the media – a tale of our times (Editorial). Journal of Epidemiology and Community Health 2000; 54:402-3.

127. JEFFERSON TO. Economic and non-economic factors in evaluating prevention versus treatment. Abstract of talk given at the AAAS Annual Meeting and Science Innovation Symposium (Abstract A 51). Washington DC 17-22 February 2000.

128. JEFFERSON TO, DEEKS JJ. The use of systematic reviews for peer reviewing. In: GODLEE F, JEFFERSON TO (Editors). Peer Review in Health Sciences. London: BMJ Books 1999.

129. COLORECTAL CANCER COLLABORATIVE GROUP. Palliative chemotherapy for advanced colorectal cancer: systematic review and meta-analysis. BMJ 2000; 321:531-5.

130. JEFFERSON TO, DEMICHELI V, DEEKS JJ, RIVETTI D. Prevention and early treatment of influenza in healthy adults. Vaccine 2000; 18:957-1030.

131. JEFFERSON T O, DEMICHELI V, MUGFORD M. Elementary Economic Evaluation in Health Care. Second Edition. London: BMJ Books 2000.

132. HEIJBEL H, JEFFERSON TO. Vaccine Safety – Improving monitoring. Vaccine

2001; 19:2457-60.

132. JEFFERSON TO. Comment: Efficacy and safety of the oral neuraminidase inhibitor Oseltamivir in treating acute influenza. A randomised controlled trial. Evidence-based healthcare 2000; 4:94.

133. MEIER CR, NAPALKOV PN, WEGMUELLER Y, JEFFERSON T, JICK H. Population-based study on incidence, risk factors, clinical complications and drug utilisation associated with influenza in the United Kingdom. European Journal of Clinical Microbiology and Infectious Diseases 2000;19(11):834-842.

133. JEFFERSON TO, HEIJBEL H. Demyelinating disease and Hepatitis B vaccination - Is there a link? Drug Safety 2001; 24(4):249-54.

134. JEFFERSON TO. Monitoring the safety of vaccines: methodological challenges. Paper presented at the 8th Annual meeting of the European Society of Pharmacoviglilance. Verona, Italy 21-23 September 2000. Abstract number 45.

135. JEFFERSON TO, DEMICHELI V. The quality of methods of economic evaluations in healthcare: time for action (editorial). BMJ 2002; 324:313-4. (9 February).

136. WAGER E, JEFFERSON TO. Shortcomings of peer review in biomedical journals. Learned Publishing 2001; 14:257-63.

137. JEFFERSON TO, DEMICHELI V, VALE L. The quality of systematic reviews of economic evaluations in healthcare and what they are telling us: it is time for action. JAMA 2002; 287:2809-2812.

138. BURLS A, CLARK W, STEWART T, PRESTON C, BRYAN S, JEFFERSON T, FRY-SMITH A. Zanamivir for the treatment of influenza in adults. NHS HTA Programme, London: 2002; Vol 6: No 9.

139. JEFFERSON TO, TYRRELL D. Antivirals for the Common Cold (Cochrane Review). In: The Cochrane Library, Issue 1, 2003. Oxford: Update Software.

140. JEFFERSON TO, ALDERSON P, DAVIDOFF F, WAGER E. Editorial peer review for improving the quality of reports of biomedical studies (Cochrane Methodology Review). In: The Cochrane Library, Issue 1, 2003. Oxford: Update Software.

141. JEFFERSON TO, TYRRELL D. Vaccines for the Common Cold (Protocol for a Cochrane Review). In: The Cochrane Library, Issue 1, 2003. Oxford: Update Software.

142. SPIER R, JEFFERSON TO, DEMICHELI V. An editorial policy statement. Submission of economic evaluations of vaccines. Vaccine 2002; 20:1693-1695.

143. JEFFERSON TO, ALDERSON P, DAVIDOFF F, WAGER E. Effects of editorial peer review: a systematic review. JAMA 2002; 287:2784-2786.

144. JEFFERSON TO, WAGER E, DAVIDOFF F. Measuring the quality of editorial peer review. JAMA 2002; 287:2786-2790.

145. WAGER E, GODLEE F, JEFFERSON TO. How to survive peer review. London, BMJ Books 2002.

146. JEFFERSON TO. Advances in the diagnosis and management of influenza. Current Infectious Diseases Reports 2002; 4: 206-10.

147 JEFFERSON TO, BIANCO E, DEMICHELI V. Influenza vaccines in adults. Occupational Medicine 2002; 52(5):255-58.

148. JEFFERSON TO, DEMICHELI V, VALE L. Methodological quality of economic evaluations of health care interventions – evidence from systematic reviews. In: Donalson C, Mugford M, Vale L (editors). Evidence-based Health economics: from effectiveness to efficiency in health care. London BMJ Books 2002. Pages 67-88.

149. DEMICHELI V, JEFFERSON TO, VALE L. Effectiveness estimates in economic evaluation. In: Donalson C, Mugford M, Vale L (editors). Evidence-based Health economics: from effectiveness to efficiency in health care. London BMJ Books 2002. Pages 89-98.

150. JEFFERSON TO, BIANCO E. Quanto protetti? Aretre' Roche 2002; 35:24-5.

151. JEFFERSON T, RUDIN M. 1st International Symposium on the Evaluation of Safety of Human Vaccines. Expert Opin Drug Saf 2002; 1(2):195-98.

152. JEFFERSON TO, TRAVERSA G. Hepatitis B vaccination: risk-benefit profile and role of systematic reviews in the assessment of causality of adverse events following immunisation. Journal of Medical Virology 2002; 67;451-53.

153. JEFFERSON TO, DEMICHELI V. Polysaccharide Pneumococcal Vaccines. Editorial . BMJ 2002 (in press).

154. JEFFERSON T, DEMICHELI V, VALE L. Educating authors and reviewers of economic evaluations of health care. JAMA 2002 Aug 28;288(8):959 (Letter to the Editor).

155. JEFFERSON TO, PRICE D, DEMICHELI V. Unintended Events following immunisation with MMR: a systematic review. Phamacoepidemiology and Drug Safety 2002; 11:S286 (abstract).

156. JEFFERSON TO, RUDIN M, DIPIETRANTONJ C. systematic review of the effects of DTP vaccines in children with or without inactivated polio vaccine (IPV). Phamacoepidemiology and Drug Safety 2002; 11:S285 (abstract).

157. MELE A, JEFFERSON T, FRANCO E, SALMASO S. Change from oral poliovirus vaccine to inactivated poliovirus vaccine. The Lancet 2002; 360:1178 (12 October).

156. BONHOEFFER J, KOHL K, CHEN R, DUCLOS P, HEIJBEL H, HEININGER U, JEFFERSON T, LOUPI E and The Brighton Collaboration. The Brighton Collaboration: addressing the need for standardized case definitions of adverse events following immunization (AEFI). Vaccine 2002; 21:298-302.

157. JEFFERSON TO, SHASHOK K. Journals: how to decide what's worth publishing. Nature 2003; 421:209-10.

158. DEMICHELI V, RIVETTI A, DI PIETRANTONJ C, CLEMENTS CJ, JEFFERSON T. Hepatitis B vaccination and multiple sclerosis - Evidence from a systematic review. Journal of Viral Hepatitis 2003; 5:343-4.

159. JEFFERSON TO, RUDIN M, DIPIETRANTONJ C. Systematic review of the effects of pertussis vaccines in children. Vaccine 2003 2003; 21(17-18):2012-2023.

160. JEFFERSON TO, DEMICHELI V. Economic Analysis on infleunza vaccination and treatment. Annals of Internal Medicine 2003; 138(7):607 (letter to the Editor).

161. MELE A, JEFFERSON TO. The use of Hepatitis A vaccine in Italy - evidence-based recommendations from an expert panel. Vaccine 2003; 21:2223 (editorial).

162. JEFFERSON TO, DEMICHELI V. Observational data on harm are already included in systematic reviews. BMJ 2003; 327:750.

163. JEFFERSON TO, PRICE D, DEMICHELI V, BIANCO E. Unintended Events following immunisation with MMR: a systematic review. Vaccine 2003; 21(25-26):3954-60.

164. JEFFERSON TO, SHASHOK K, WAGER E. Get Peered! BMJ 2003. (Christmas issue).

165. GODLEE F, JEFFERSON TO (Editors). Peer Review in Health Sciences. Second edition. London: BMJ Books 2003.

166. MATERIA E, BAGLIO G, CANONACO,D, JEFFERSON T, MELE A, MARCHISIO P, DI DOMENICANTONIO R, GUASTICCHI G. Promoting clinical and organizational appropriateness of tonsillectomy in Italy. European J Public Health 2003; 13: 86 (Supplement. Abstracts of the 11th Annual EUPHA Meeting Globalisation and health in

Europe: harmonising public health practices, Roma 20-22 November 2003.)

167. JEFFERSON TO, RUDIN M, DIPIETRANTONJ C. Adverse events following immunization with aluminium-containing DTP vaccines - systematic review of the evidence. Lancet Infect Dis 2004; 4: 84–90.

168. JEFFERSON T. Informed choice and balance are victims of the MMR-autism saga. *Lancet Infect Dis* 2004; 4**:** 135-36.

169. JEFFERSON T, PRICE D, DEMICHELI V, BIANCO E. Selective quotation of evidence in vaccines research. Lancet 2004; 363: 1738 (letter to the Editor).

170. JEFFERSON TO. The role of editorial peer review in the evaluation of vaccine safety. Vaccine 2004; 22: 2073-75.

171. JEFFERSON TO, Demicheli V. The first international symposium on vaccine safety. Vaccine 2004:22: 2042-43.

172. PERRIA C. For the IMPLEMEG Study Group (Pierluigi Bartoletti, Paolo Billi, Virgilio Calzini, Maurizio D'Amato, Alfonso Fiorillo, Gabriella Guasticchi, Carmelina Guerriera, Giuseppe Grasso, Tom Jefferson, Sergio Leotta, Donatella Mandolini, Walter Marrocco, Mazzieri Scheggi, Amina Pasquarella, Carla Perria, Concetta Suraci). **Strategies for the introduction and implementation of a guideline for the treatment of type 2 diabetics by general practitioners (GPs) of the Lazio region of Italy (IMPLEMEG study): Protocol for a cluster randomised controlled trial [ISRCTN80116232]**. BMC Health Services Research 2004, 4:13 (14 Jun 2004)
http://www.biomedcentral.com/1472-6963/4/13

173. JEFFERSON TO, RUDIN M, DIPIETRANTONJ C. Reply to the letter to the Editor Vaccine 2004; 22(21-22):2685.

174. JEFFERSON TO. Bioterrorism and compulsory vaccination. Better vaccines are needed if vaccination is to be made compulsory. (Editorial). BMJ 2004; 329: 524-25. (4 September)

174. JEFFERSON TO. What are we to do about influenza? (Editorial). BMJ 2004; 329: 633-4.

175. SMITH S, DEMICHELI V, JEFFERSON T, HARNDEN A, MATHESON N, DI PIETRANTONJ C. Vaccines for preventing influenza in healthy children (Protocol for a Cochrane Review). In: The Cochrane Library, Issue 3, 2004. Chichester, UK: John Wiley & Sons, Ltd.

176. RIVETTI D, DEMICHELI V, DI PIETRANTONJ C, JEFFERSON TO, THOMAS R. Vaccines for preventing influenza in the elderly (Protocol for a Cochrane Review). In: The Cochrane Library, Issue 3, 2004. Chichester, UK: John Wiley & Sons, Ltd.

177. JEFFERSON TO. How to deal with influenza: Author's reply. BMJ 2004;329:1238, doi:10.1136/bmj.329.7476.1238-b

178. BIANCO E, DE MASI S, MELE A, JEFFERSON T. Effectiveness of imune globulina in preventing infectious hepatitis and hepatitis A: a systematic review. Digestive and Liver Disease 2004; 36: 834-42

179. JEFFERSON TO, Demicheli V, Price D. Informed choice, balance and the MMR-autism saga (authors' reply). The Lancet Infectious Diseases 2005; 5(1):3-4..

180. JEFFERSON TO. Glossary of peer review. Journal of Epidemiology and Community Health 2004; 58:272.

181. JEFFERSON T, SMITH S, DEMICHELI V, HARNDEN A, RIVETTI A, DI PIETRANTONJ C. Assessment of the efficacy and effectiveness of influenza vaccines in healthy children: systematic review. Lancet 2005; 365:773-80 (26th of February).

182. JEFFERSON T. L'applicazione della medicina basata sulle prove alla tomoscintigrafia a emissione di positroni (PET). Decidere in Medicina 2005; 2:34-40.

183. JEFFERSON T, SMITH S, DEMICHELI V, HARNDEN A, RIVETTI A. Influenza vaccines in healthy children – authors' reply. The Lancet 2005; 385:2087.

184. JEFFERSON T. Peer review and publishing: it's time to move the agenda on. The Lancet 2005; 366:283-284. DOI:10.1016/S0140-6736(05)66968-1.

185. JEFFERSON T. Microbial challenge studies of volunteers—a challenge worth accepting. Lancet 2005 (in press) commentary.

186. JEFFERSON T, SMITH S, DEMICHELI V, HARNDEN A, RIVETTI A. Safety of influenza vaccines in children. Lancet 2005; 366:803-04.

187. JEFFERSON T, RIVETTI D, RIVETTI A, RUDIN M, DI PIETRANTONJ C, DEMICHELI V. Efficacy and effectiveness of influenza vaccines in the elderly: systematic review. Lancet 2005 ; 366:1165 -1174.

188. JEFFERSON T. Attenti alle bufale. Roma: Pensiero Scientifico Editore 2005.

189. Jefferson T, Demicheli V, Rivetti D, Jones M, Di Pietrantonj C, Rivetti A. Antivirals for influenza in healthy adults: systematic review. The Lancet 2006; 367: 303-13. Published Online January 19 2006; DOI: 10.1016/S0140-6736(06) 67970-1.

190. THOMAS RE, JEFFERSON TO, DEMICHELI V, RIVETTI D. Influenza vaccination for health care workers who work with the elderly: A systematic review. The Lancet Infectious Diseases 2006; 6:273-79.

191. JEFFERSON T. Alternative models of quality control for scientific research. Nature 2006 (http://www.nature.com/nature/peerreview/debate/index.html).

192. JEFFERSON T. Attenti alle bufale. Roma, Pensiero Scientifico Editore 2005

193. JEFFERSON T, FERRONI E, CURTALE F, GIORGI ROSSI P, BORGIA P. *S. pneumoniae* in Western Europe: serotype distribution and incidence in children less than 2 years old. The Lancet Infectious Diseases 2006; 6:405-10.

194. JEFFERSON T, FRATI D, GRASSO E. Aviaria: influenza dei polli? Roma: Pensiero Scientifico Editore 2006

195. JEFFERSON T, RUDIN M, BRODNEY FOLSE S, DAVIDOFF F. Editorial peer review for improving the quality of reports of biomedical studies. *The Cochrane Database of Methodology Reviews* 2006, Issue 1. Art. No.: MR000016.pub2. DOI: 10.1002/14651858.MR000016.pub2.

196. JEFFERSON T. The prevention of seasonal influenza – policy versus evidence. BMJ 2006; 333:912-15.

197. JEFFERSON T. Influenza. Clinical Evidence 2006.

196. D RIVETTI, T JEFFERSON, R THOMAS, M RUDIN, A RIVETTI, C DI PIETRANTONJ, V DEMICHELI. Vaccines for preventing influenza in the elderly. Cochrane Database of *Systematic Reviews* 2006, Issue 3. Art. No.: CD004876. DOI: 10.1002/14651858.CD004876.pub2.

197. Jefferson T. Look at all the evidence before stockpiling Amantadine. BMJ 2007; 334:439 (letter to the editor).

198. TO Jefferson, D Rivetti, C Di Pietrantonj, A Rivetti, V Demicheli. Vaccines for preventing influenza in healthy adults. *Cochrane Database of Systematic Reviews* 2007, Issue 2. Art. No.: CD001269. DOI: 10.1002/14651858.CD001269.pub3.

199. TOM JEFFERSON, LUCIA ZARRA, AND LIVIU STOICA. Attenti Alle Bufale ('Beware of Red Herrings'), or, How to Make Evidence-Based Medicine Work for You J. R. Soc. Med. 2006 99: 625-627.

200. TOM JEFFERSON AND LUCIA ZARRA. Bufala spotting, part one: assessing research paper**s** J. R. Soc. Med. 2007 100: 38-39.

201. TOM JEFFERSON AND LUCIA ZARRA. Bufale spotting, part two: assessing systematic reviews J. R. Soc. Med. 2007 100: 180-181.

202. TOM JEFFERSON AND LUCIA ZARRA. Bufale spotting, part three: assessing editorials. J. R. Soc. Med. 2007; 100(6): p. 267

203. CARLA PERRIA, DONATELLA MANDOLINI, CARMELINA GUERRERA, THOMAS JEFFERSON, PAOLO BILLI, VIRGILIO CALZINI, ALFONSO FIORILLO, GIUSEPPE GRASSO, SERGIO LEOTTA, WALTER MARROCCO, CONCETTA SURACI AND AMINA PASQUARELLA. Implementing a guideline for the treatment of type 2 diabetics: results of a Cluster- Randomized Controlled Trial (C-RCT) **[ISRCTN80116232]**. BMC Health Services Research 2007, 7:79 (04 Jun 2007). http://www.biomedcentral.com/1472-6963/7/79

204. TOM JEFFERSON AND LUCIA ZARRA. Bufale Spotting, part 5: Assessing a website. J. R. Soc. Med. 2007; 100(8): p. 367 http://www.jrsm.org/cgi/content/full/100/8/367?ct=ct

205. TO JEFFERSON, D RIVETTI, C DI PIETRANTONJ. Inactivated influenza vaccines in the elderly—are you sure? (Comment). The Lancet (Published Ondine Septmber 25, 2007, DOI:10.1016/S0140-6736(07)61389-0).

206. TOM JEFFERSON, RUTH FOXLEE, CHRIS DEL MAR, LIZ DOOLEY, ELIANA FERRONI, BILL HEWAK, ADI PRABHALA, SREE NAIR, AND ALEX RIVETTI. Physical interventions to interrupt or reduce the spread of respiratory viruses: systematic review. BMJ. 2008; 336(7635): p. 77-80

207. TOM JEFFERSON AND LUCIA ZARRA. Bufale Spotting, part 7: Assessing an advert. J. R. Soc. Med. 2007; 100(11): p. 502

208. T JEFFERSON. Cattive Acque. Il Pensiero Scientifico Editore. 2007

209. TOM JEFFERSON AND LUCIA ZARRA. Bufale Spotting, part 9: assessing an economic evaluation. J R Soc Med. 2008; 101(4): p. 175-176.

210. T JEFFERSON, A RIVETTI, A HARNDEN, C DI PIETRANTONJ, AND V DEMICHELI. Vaccines for preventing influenza in healthy children. Cochrane Database Syst Rev 1 Jan 2008: p. CD004879

211. C CATES, T JEFFERSON, AND B ROWE. Vaccines for preventing influenza in people with asthma. Cochrane Database Syst Rev 1 Jan 2008: p. CD000364. http://highwire.stanford.edu/cgi/medline/pmid;18425863

212. TOM JEFFERSON. More cases, doctor? Yes please! Cases J 16 Jul 2008 1(1): p. 38. http://highwire.stanford.edu/cgi/medline/pmid;18631383

213. TOM JEFFERSON. Darkness falls. BMJ. 2008; 337(nov12_1): p. a2501

214. FABIO BERNARDINI, MARINA CERBO, TOM JEFFERSON, ALESSANDRA LO SCALZO, MARCO RATTI - Wireless Capsule Endoscopy in the diagnosis of small bowel disease. Age.na.s. HTA Report. Rome, September 2008. *http://www.ministerosalute.it/dispositivi/paginainternasf.jsp?id=1202&menu=hta*

215. ANTONELLA CAVALLO, MARINA CERBO, DARIO FELLA, TOM JEFFERSON, ANTONIO MIGLIORE, MARIA ROSARIA PERRINI. - Prostheses for primary total hip replacement in Italy. Age.na.s. HTA Report, Rome, September 2008. *http://www.ministerosalute.it/dispositivi/paginainternasf.jsp?id=1202&menu=hta*

216. ANNA MARIA VINCENZA AMICOSANTE, MARINA CERBO, TOM JEFFERSON, SIMONA PAONE, LAURA VELARDI. Rapid (bed-side) tests for influenza. Age.na.s. HTA Report - Rome, September 2008.

217. T JEFFERSON, C DI PIETRANTONJ, M G DEBALINI, A RIVETTI, AND V DEMICHELI. Inactivated influenza vaccines: Methods, policies, and politics. J Clin Epidemiol 2008; 1-10. http://highwire.stanford.edu/cgi/medline/pmid;19124222 doi: 10.1016/j.jclinepi.2008.07.001.

218. T JEFFERSON, C DI PIETRANTONJ, MG DEBALINI, A RIVETTI, V DEMICHELI. Study quality, concordance, take home message, funding and impact. Their relationship in influenza vaccines studies. BMJ 2009 338(feb12_2): p. b354 http://www.bmj.com/cgi/content/abstract/338/feb12_2/b354?ct=ct.

221. T JEFFERSON. Ranking antidepressants. Lancet 23 May 2009 373(9677): p. 1759;

219. JEFFERSON T. Influenza. BMJ Clinical Evidence 2009.

223 A LO SCALZO, M RATTI, T JEFFERSON, F BERNARDINI, AND M CERBO. Wireless capsule for endoscopy in Italy: adding context-specific data to the review of the evidence from literature. Int J Technol Assess Health Care 1 Jul 2009 25(3): p. 297. http://highwire.stanford.edu/cgi/medline/pmid;19619348

224 JEFFERSON T. Pneumococcal vaccines: confronting the confounders. The Lancet 2009; 373: 2008-09.

225 TOM JEFFERSON. A brief history of shroud waving through the centuries. BMJ. 2009; 338(jun30_3): p. b2610 http://www.bmj.com/cgi/content/extract/338/jun30_3/b2610?ct=ct

226. JEFFERSON T, DEL MAR C, DOOLEY L, FERRONI E, AL-ANSARY LA, BAWAZEER GA, VAN DRIEL ML, FOXLEE R, RIVETTI A. Physical interventions to interrupt or reduce the spread of respiratory viruses: systematic review. BMJ. 2009 Sep 21;339:b3675. doi: 10.1136/bmj.b3675. Review.

227. HERXHEIMER A, CLARKE M, EDWARDS R, JEFFERSON T, LOKE Y. A/H1N1 flu. Time for case-control studies of NSAIDs and oseltamivir. BMJ. 2009 Jul 28;339:b3048. doi: 10.1136/bmj.b3048. No abstract available.

228. MIGLIORE A, RATTI M, CERBO M, JEFFERSON T. Health Technology Assessment: managing the introduction and use of medical devices in clinical practice in Italy. Expert Rev Med Devices. 2009 May;6(3):251-7. Review. PMID: 19419283 [PubMed - indexed for MEDLINE]

229. T JEFFERSON, M JONES, P DOSHI, AND C DEL MAR. Possible harms of oseltamivir--a call for urgent action. Lancet 17 Oct 2009 374(9698): p. 1312.

230. JEFFERSON, T. Guest Editorial: Mistaken identity: seasonal influenza versus influenza-like illness. Clinical Evidence 5 October, 2009.

231. TOM JEFFERSON, MARK JONES, PETER DOSHI, AND CHRIS DEL MAR. Neuraminidase inhibitors for preventing and treating influenza in healthy adults: systematic review and meta-analysis. BMJ. 2009; 339(dec07_2): p. b5106. http://www.bmj.com/cgi/content/abstract/339/dec07_2/b5106?ct=ct

232. TOM JEFFERSON AND ELIANA FERRONI. The Spanish influenza pandemic seen through the BMJ's eyes: observations and unanswered questions. BMJ. 2009; 339(dec16_3): p. b5313 http://www.bmj.com/cgi/content/extract/339/dec16_3/b5313?ct=ct

233. A MIGLIORE, MR PERRINI, E ROMANINI, D FELLA, A CAVALLO, M CERBO, AND T JEFFERSON. Comparison of the performance of hip implants with data from different arthroplasty registers. J Bone Joint Surg Br 1 Dec 2009 91(12): p. 1545. http://highwire.stanford.edu/cgi/medline/pmid;19949114

234. TOM JEFFERSON. Neuraminidase inhibitors produce a small reduction in duration of seasonal influenza in children and reduce transmission in affected households, but effects on serious complications unclear. Evid. Based Med. 2010; 15(1): p. 20-21 http://ebm.bmj.com/cgi/content/extract/15/1/20?ct=ct

235. FERRONI E, JEFFERSON T (2011). Angelo Celli and research on the prevention of malaria at the turn of the 20th century. JLL Bulletin: Commentaries on the history of treatment evaluation (www.jameslindlibrary.org)

236 THOMAS RE, JEFFERSON T, LASSERSON TJ. Influenza vaccination for health care workers who work with the elderly: a Cochrane review. *Health Technology Assessment*, *H1N1 and pandemic flu A special themed issue of HTA*, 2010;14(55):493-588.

237. MIGLIORE A, CORIO M, PAONE S, CERBO M AND JEFFERSON T. Accommodating intraocular lenses for patients with cataract: A review. Expert Review of Ophthalmology 2011 6:4 (431-436).

238. Cochrane Neuraminidase Inhibitors Review Team. Does Oseltamivir Really Reduce Complications of Influenza? Clinical Infectious Diseases. 2011 Dec 15;53(12):1302–3.

239. JEFFERSON T. Should journals sell reprints? BMJ 2011;343:d6448 doi: 10.1136/bmj.d6448

240. JEFFERSON T, JONES MA, DOSHI P, DEL MAR CB, HENEGHAN CJ, HAMA R, THOMPSON MJ. Neuraminidase inhibitors for preventing and treating influenza in healthy adults and children. *Cochrane Database of Systematic Reviews* 2012, Issue 1. Art. No.: CD008965. DOI: 10.1002/14651858.CD008965.pub3.

241. DOSHI P, JONES MA, JEFFERSON T. Rethinking credible evidence synthesis. *BMJ* 2012; 344:d7898 doi: 10.1136/bmj.d7898

242. Drug Data Shouldn't Be Secret. By PETER DOSHI AND TOM JEFFERSON. The New York Times, April 10, 2012
URL: http://www.nytimes.com/2012/04/11/opinion/drug-data-shouldnt-be-secret.html
Shortened URL: http://nyti.ms/Ivgh9c

243. DOSHI P, JEFFERSON T, DEL MAR C (2012) The Imperative to Share Clinical Study Reports: Recommendations from the Tamiflu Experience. PLoS Med 9(4): e1001201. doi:10.1371/journal.pmed.1001201
Short URL: http://bit.ly/HIbwqO PDF for printing: http://bit.ly/HFBYTV

244. JONES M, HAMA R, JEFFERSON T, DOSHI P. Neuropsychiatric Adverse Events and Oseltamivir for Prophylaxis Drug Saf 2012; 35 (12): 1187-1190.

245. DOSHI P, JEFFERSON T. The first 2 years of the European Medicines Agency's policy on access to documents: Secret no Longer. Arch Intern Med. Published online December 19, 2012. doi:
http://dx.doi.org/10.1001/jamainternmed.2013.3838
http://archinte.jamanetwork.com/article.aspx?articleid=1486542

246. DOSHI P, JEFFERSON T. Clinical study reports of randomised controlled trials: an exploratory review of previously confidential industry reports. BMJ Open. 2013 Feb 26;3(2):e002496.
http://bmjopen.bmj.com/content/3/2/e002496.full and
http://dx.doi.org/10.1136/bmjopen-2012-002496

247. DOSHI P, DICKERSIN K, HEALY D, VEDULA SS, JEFFERSON T. Restoring invisible and abandoned trials: a call for people to publish the findings *BMJ* 2013; 346 doi: http://dx.doi.org/10.1136/bmj.f2865 (Published 13 June 2013).

248. CHAN A-W, SONG F, VICKERS A, JEFFERSON T, DICKERSIN K, GØTZSCHE PC et al. Increasing value and reducing waste: addressing inaccessible research. The Lancet, Volume 383, Issue 9913, Pages 257 - 266, 18 January 2014. doi:10.1016/S0140-6736(13)62296-5. http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2813%2962296-5/fulltext.

249. JEFFERSON T, JONES MA, DOSHI P, DEL MAR CB, HAMA R, THOMPSON MJ, et al. Neuraminidase inhibitors for preventing and treating influenza in healthy adults and children. Cochrane Database of Systematic Reviews 2014, Issue 4. Art. No.: CD008965 DOI: 10.1002/14651858.CD008965.pub4

250. HENEGHAN CJ, ONAKPOYA I, THOMPSON M, SPENCER EA, JONES M, JEFFERSON T. Zanamivir for influenza in adults and children: systematic review of clinical study reports and summary of regulatory comments. BMJ 2014; 348. DO 10.1136/bmj.g2547. UL http://www.bmj.com/content/348/bmj.g2547

251. JEFFERSON T, DOSHI P. Multisystem failure: the story of anti-influenza drugs. BMJ 2014;348. DOi 10.1136/bmj.g2263
UL http://www.bmj.com/content/348/bmj.g2263

252. JEFFERSON T, DOSHI P. EMA's double U-turn on its Peeping Tom policy for data release. BMJ Blog 2014.

253. JEFFERSON T, DOSHI P, LEMMENS T. EMA's data sharing policy—towards peeping tom based medicine? BMJ Blog 2014. http://blogs.bmj.com/bmj/2014/05/22/tom-jefferson-et-al-emas-data-sharing-policy-towards-peeping-tom-based-medicine/

254. JEFFERSON T, JONES MA, DOSHI P, DEL MAR CB, HAMA R, THOMPSON MJ, ONAKPOYA I, HENEGHAN CJ. Risk of bias in industry-funded oseltamivir trials: comparison of core reports versus full clinical study reports. BMJ Open 2014;4:e005253-e005253
http://bmjopen.bmj.com/cgi/content/full/bmjopen-2014-005253?ijkey=AHfmbBvUum2MicR&keytype=ref

255. JEFFERSON T. EMA's release of regulatory data—trust but verify
BMJ Blogs

256. JEFFERSON T. EMA's Release of Regulatory Data: Possible Fall out for Journals and Research Synthesis.

257. TOM JEFFERSON AND PETER DOSHI: Thanksgiving special—menus needed at the EMA's restaurant

258. PETER DOSHI and TOM JEFFERSON. The Evidence Base for New Drugs (editorial). Published: 2 March 2015; BMJ 2015;350:h952. http://www.bmj.com/content/350/bmj.h952

259. TOM JEFFERSON. The EMA revolution gathers pace http://blogs.bmj.com/bmj/2015/06/30/tom-jefferson-the-ema-revolution-gathers-pace/

260. Are we ready for the EMA revolution? http://blogs.bmj.com/bmj/2015/06/30/tom-jefferson-are-we-ready-for-the-ema-revolution/

261. EMA confidential—the EMA continues consultation on its 0070 policy and concerns appear http://blogs.bmj.com/bmj/2015/07/09/tom-jefferson-ema-confidential/

262. KHALED EL EMAM, TOM JEFFERSON, PETER DOSHI http://blogs.bmj.com/bmj/2015/08/27/maximizing-the-value-of-clinical-study-reports/

263. KHALED EL EMAM, TOM JEFFERSON, PETER DOSHI. The release of regulatory documents under EMA policy 0070: Now you see them, now you don't.

264. DOSHI P, JEFFERSON T. Open data 5 years on: a case series of 12 freedom of information requests for regulatory data to the European Medicines Agency. Trials (2016) 17:78 DOI 10.1186/s13063-016-1194-7. http://trialsjournal.biomedcentral.com/articles/10.1186/s13063-016-1194-7

265. PETER DOSHI & TOM JEFFERSON. Access to clinical trial data from the European Medicines Agency.

266. JEFFERSON T, DEMICHELI V. Is the timing of recommended childhood vaccines evidence based? BMJ 2016; 352 doi: http://dx.doi.org/10.1136/bmj.i867 (Published 23 February 2016) Cite this as: BMJ 2016;352:i867. http://www.bmj.com/content/352/bmj.i867

267. CARL J HENEGHAN, IGHO ONAKPOYA, MARK A JONES, PETER DOSHI, CHRIS B DEL MAR, ROKURO HAMA, MATTHEW J THOMPSON, ELIZABETH A SPENCER, KAMAL R MAHTANI, DAVID NUNAN, JEREMY HOWICK, TOM JEFFERSON. Neuraminidase inhibitors for influenza: a systematic review and meta-analysis of regulatory and mortality data. Health Technology Assessment . 2016 (in press) http://www.journalslibrary.nihr.ac.uk/hta

268. JEFFERSON T. Facing the unreliability of clinical trials literature. Drug and Therapeutics Bulletin of Navarre, Spain. 2015;23(2).

http://www.navarra.es/home_en/Temas/Portal+de+la+Salud/Profesionales/Documentacion+y+publicaciones/Publicaciones+tematicas/Medicamento/BIT/

269. DAVIS C, LEXCHIN J, JEFFERSON T, GØTZSCHE P, MCKEE M. "Adaptive pathways" to drug authorisation: adapting to industry? BMJ 2016;354:i4437 doi: 10.1136/bmj.i4437 (Published 16 August 2016). Download free here

270. Tom Jefferson: The EMA's policy 0070 is live BMJ blogs

271. DOSHI P, HUR P, JONES M, ALBARMAWI H, JEFFERSON T, MORGAN DJ, SPEARS PA, POWERS JH. Informed consent to study purpose in randomized controlled trials of antibiotics, 1991-2011. JAMA Intern Med. Published online August 21, 2017. doi:10.1001/jamainternmed.2017.3820

272. TOM JEFFERSON. Sticking to principles and anticipating outcomes. Recenti Prog Med 2017; 108: 347-49. https://goo.gl/64jFkp

273 TOM JEFFERSON. The UK turns to Witty, Vallance, and Van Tam for leadership: revolving doors? BMJ blogs.

274. MAHTANI KR, JEFFERSON T, HENEGHAN C. What makes a systematic review "complex"? BMJ blogs.

275. DOSHI P, JEFFERSON T. Disclose Data Publicly, without Restriction. In Davis L, Miller JD, Sharfstein JM, Kesselheim AS. Blueprint for transparency at the US Food and Drug Administration. Winter 2017. Pages 42-45. DOI: 10.1177/1073110517750611.

276. JØRGENSEN L, GØTZSCHE PC, JEFFERSON T. Index of the human papillomavirus (HPV) vaccine industry clinical study programmes and non-industry funded studies: a necessary basis to address reporting bias in a systematic review. Systematic Reviews 2018 **7**:8. https://doi.org/10.1186/s13643-018-0675-z.

277. DEMICHELI V, JEFFERSON T, FERRONI E, RIVETTI A, DI PIETRANTONJ C. Vaccines for preventing influenza in healthy adults. Cochrane Database of Systematic Reviews 2018, Issue 2. Art. No.: CD001269. DOI: 10.1002/14651858.CD001269.pub6.

278. JEFFERSON T, RIVETTI A, DI PIETRANTONJ C, DEMICHELI V. Vaccines for preventing influenza in healthy children. Cochrane Database of Systematic Reviews 2018, Issue 2. Art. No.: CD004879. DOI: 10.1002/14651858.CD004879.pub5.

279. DEMICHELI V, JEFFERSON T, DI PIETRANTONJ C, FERRONI E, THORNING S, THOMAS RE, RIVETTI A. Vaccines for preventing influenza in the elderly. Cochrane Database of Systematic Reviews 2018, Issue 2. Art. No.: CD004876. DOI: 10.1002/14651858.CD004876.pub4.

280. JEFFERSON T, RIVETTI A DEMICHELI V. Why have three long-running Cochrane Reviews on influenza vaccines been stabilised? http://community.cochrane.org/news/why-have-three-long-running-cochrane-reviews-influenza-vaccines-been-stabilised

281. Tom Jefferson and Peter Doshi: RIP PubMed commons
BMJ Blogs

282. JEFFERSON T, JØRGENSEN L. Redefening the “E” in EBM. BMJ Evidence Based Medicine. 10.1136/bmjebm-2018-110918.

283. MAHTANI K, JEFFERSON T, HENEGHAN C, NUNAN D, AARONSON J. What is a ’complex systematic review'? Criteria, definition, and examples. 10.1136/bmjebm-2018-110965
http://dx.doi.org/10.1136/bmjebm-2018-110965.

284. JØRGENSEN L, GØTZSCHE PC, JEFFERSON T. The Cochrane HPV vaccine review was incomplete and ignored important evidence of bias. BMJ Evidence Based Medicine. Published Online First: 27 July 2018. doi: 10.1136/bmjebm-2018-111012.

285. JEFFERSON T, JØRGENSEN L. Human papillomavirus vaccines, complex regional pain syndrome, postural orthostatic tachycardia syndrome, and autonomic dysfunction - a review of the regulatory evidence from the European Medicines Agency. Indian J Med Ethics. Published online on October 17, 2016.

286. HODKINSON A, DIETZ KC, LEFEBVRE C, GOLDER S, JONES M, DOSHI P, HENEGHAN C, JEFFERSON T, BOUTRON I, STEWART L. The use of clinical study reports to enhance the quality of systematic reviews: a survey of systematic review authors. Systematic Reviews 2018. 7:117. https://doi.org/10.1186/s13643-018-0766-x

287. JEFFERSON T, DEMICHELI V, DI PIETRANTONJ C, RIVETTI D. Amantadine and rimantadine for influenza A in adults. Cochrane Database of Systematic Reviews 2006 , Issue 2 . Art. No.: CD001169. DOI: 10.1002/14651858.CD001169.pub3.

288. JØRGENSEN L, DOSHI P, GØTZSCHE P, JEFFERSON T. Challenges of independent assessment of potential harms of HPV vaccines BMJ 2018; 362 doi: https://doi.org/10.1136/bmj.k3694

289. PETER DOSHI, TOM JEFFERSON, MARK JONES, JOHN H. POWERS III. Baloxavir: Roche’s new oseltamivir? https://www.bmj.com/content/363/bmj.k4531/rr

290. Tom Jefferson. How Cochrane is doing pharma a good turn. https://blogs.bmj.com/bmj/2018/11/12/tom-jefferson-cochrane-pharma-good-turn/

291. DOSHI P, JEFFERSON T, JONES M ET AL. Call to action: RIAT restoration of a previously unpublished methodology in Gardasil vaccine trials. https://www.bmj.com/content/346/bmj.f2865/rr-7
Protocol available at: https://osf.io/234kw/. DOI 10.17605/OSF.IO/234KW

292. TOM JEFFERSON, FLORENCE BOURGEOIS, KYUNGWAN HONG, MARK JONES, HAEYOUNG LEE, VINAY PRASAD, O'MAREEN SPENCE, PETER DOSHI. Re-analysis of mortality in HPV vaccine trials: systematic review. PROSPERO 2019 CRD42019122348 Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42019122348

293. DOSHI P, JEFFERSON T, JONES M ET AL. Additional trials within scope: a follow-up to our "Call to action: RIAT restoration of a previously unpublished methodology in Gardasil vaccine trials". https://www.bmj.com/content/346/bmj.f2865/rr-9

294. CARL HENEGHAN, TOM JEFFERSON. Gender-affirming hormone in children and adolescents. https://blogs.bmj.com/bmjebmspotlight/ (Posted on 25th February 2019)

295. JEFFERSON T (2019). Sponsorship bias in clinical trials – growing menace or dawning realisation? JLL Bulletin: Commentaries on the history of treatment evaluation. (https://www.jameslindlibrary.org/articles/sponsorship-bias-in-clinical-trials-growing-menace-or-dawning-realisation/)

296. JEFFERSON T, FORMOSO G, VENTURELLI F, VICENTINI M, CHIAROLLA E, BALLINI L. Hadrontherapy for cancer. An overview of HTA reports and ongoing studies. Recenti Prog Med 2019; 110:566.

297. DOSHI ET AL. Adjuvant-containing control arms in pivotal quadrivalent human papillomavirus vaccine trials: restoration of previously unpublished methodology. BMJ Evidence-Based Medicine 2020. https://doi.org/10.1136/bmjebm-2019-111331

298. JØRGENSEN, L., GØTZSCHE, P.C. & JEFFERSON, T. Benefits and harms of the human papillomavirus (HPV) vaccines: systematic review with meta-analyses of trial data from clinical study reports. *Syst Rev* **9,** 43 (2020). https://doi.org/10.1186/s13643-019-0983-y

299. JØRGENSEN, L., GØTZSCHE, P.C. & JEFFERSON T. Benefits and harms of the human papillomavirus (HPV) vaccines: comparison of trial data from clinical study reports with corresponding trial register entries and journal publications. Syst Rev 9, 42 (2020). https://doi.org/10.1186/s13643-020-01300-1.

300. JEFFERSON T, DEMASI M, DOSHI P. Statins for primary prevention: what is the regulators role? Evid. Based Med. 2020 0: p. bmjebm-2019-111321v1-bmjebm-2019-111321. http://ebm.bmj.com/cgi/content/full/bmjebm-2019-111321.

301. JEFFERSON T. Covid 19—many questions, no clear answers. https://blogs.bmj.com/bmj/2020/03/02/tom-jefferson-covid-19-many-questions-no-clear-answers/

302. JEFFERSON T. Refining the “E” in EBM. BMJ Evidence Based Medicine.

Tom Jefferson: Covid 19—we live in surreal times
https://blogs.bmj.com/bmj/2020/03/05/tom-jefferson-covid-19-we-live-in-surreal-times/

Tom Jefferson: Covidair flight 19 from Rome to Oxford and back again.
https://blogs.bmj.com/bmj/2020/03/10/tom-jefferson-covidair-flight-19-from-rome-to-oxford-and-back-again/

303. DOSHI P, BOURGEOIS F, HONG K, ET AL. Adjuvant-containing control arms in pivotal quadrivalent human papillomavirus vaccine trials: restoration of previously unpublished methodology. BMJ Evidence-Based Medicine Published Online First: 17 March 2020. doi: 10.1136/bmjebm-2019-111331
https://doi.org/10.1136/bmjebm-2019-111331

JEFFERSON, T. (2020). Sponsorship bias in clinical trials: growing menace or dawning realisation? Journal of the Royal Society of Medicine, 113(4), 148–157.
https://doi.org/10.1177/0141076820914242
http://journals.sagepub.com/share/2F3RYZGUQTJTADJT3AJW?target=10.1177/0141076820914242

JEFFERSON, T. Refining the E in EBM. Evid. Based Med. 2020 0: p. bmjebm-2020-111348v1-bmjebm-2020-111348
http://ebm.bmjjournals.com/cgi/content/full/bmjebm-2020-111348v1?ctJEFFERSON T,

DEL MAR CB, DOOLEY L, FERRONI E, AL-ANSARY LA, BAWAZEER GA, ET AL. Physical interventions to interrupt or reduce the spread of respiratory viruses. *Cochrane Database of Systematic Reviews* 2020;(11):CD006207.
https://doi.org/10.1002/14651858.CD006207.pub5

DOSHI P, BOURGEOIS F, HONG K, ET AL
Adjuvant-containing control arms in pivotal quadrivalent human papillomavirus vaccine trials: restoration of previously unpublished methodology. BMJ Evidence-Based Medicine 2020;25:213-219.

DEMASI M, JEFFERSON T. Placebo—the Unknown Variable in a Controlled Trial. JAMA Intern Med. Published online February 22, 2021. doi:10.1001/jamainternmed.2020.8670
https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2776287?guestAccessKey=5a8bf8c3-e5f2-4a74-b9f5-

782b0f530895&utm_source=jps&utm_medium=email&utm_campaign=author_alert-jamanetwork&utm_content=author-author_engagement&utm_term=1m

TANVEER S, ROWHANI-FARID A, HONG K, ET AL. Transparency of COVID-19 vaccine trials: decisions without data BMJ Evidence-Based Medicine Published Online First: 09 August 2021. doi: 10.1136/bmjebm-2021-111735

CEBM BLOGS & MEDIA ARTICLES:

Tom Jefferson: Covid-19—supermarket wisdom
https://blogs.bmj.com/bmj/2020/03/20/tom-jefferson-covid-19-supermarket-wisdom/

COVID-19. Can Historical Antivirals Be of Use?
https://www.cebm.net/covid-19/covid-19-can-historical-antivirals-be-of-use/

COVID-19 – The Tipping Point
https://www.cebm.net/covid-19/covid-19-the-tipping-point/

COVID-19: What proportion are asymptomatic?
https://www.cebm.net/covid-19/covid-19-what-proportion-are-asymptomatic/

Problems in identifying the origins of an outbreak
https://www.cebm.net/covid-19/problems-in-identifying-the-origins-of-an-outbreak/

Covid 19 - Modelling the models
https://www.cebm.net/covid-19/modelling-the-models/

https://www.cebm.net/covid-19/sars-cov-2-viral-load-and-the-severity-of-covid-19/

Are COVID-19 patients in hospital or admitted to hospital?
https://www.cebm.net/covid-19/are-covid-19-patients-in-hospital-or-admitted-to-hospital/

COVID-19 – The great plague of Lombardy – a not so distant resonance chamber
https://www.cebm.net/covid-19/covid-19-the-great-plague-of-lombardy-a-not-so-distant-resonance-chamber/

Is Lombardy the widow of Hampstead?
https://www.cebm.net/covid-19/covid-19-is-lombardy-the-widow-of-hampstead/

What does RCGP surveillance tell us about COVID-19 in the community
https://www.cebm.net/covid-19/what-does-rcgp-surveillance-tell-us-about-covid-19-in-the-community/

COVID-19 – Tracking European Mortality

https://www.cebm.net/covid-19/covid-19-tracking-european-mortality/

COVID 19 – The Widow of Hampstead Revisited

Effect of Latitude on COVID-19

Six Countries: Three-quarters of the COVID Deaths

COVID-19 Global Charts of Deaths

Covid 19 Epidemic "Waves"
https://www.cebm.net/covid-19/covid-19-epidemic-waves/

COVID 19 – Nova et Vetera: Lazaretts of Venice
https://www.cebm.net/covid-19/covid-19-nova-et-vetera-lazaretts-of-venice/

COVID-19: Unravelling the Uncertainties
https://www.cebm.net/covid-19/covid-19-unravelling-the-uncertainties/

COVID-19: Re-establishing 'Fever Hospitals'
https://www.cebm.net/covid-19/covid-19-reestablishing-fever-hospitals/

COVID 19 - Understanding the Unknown in Acute Respiratory Infections
https://www.cebm.net/covid-19/covid-19-understanding-the-unknown-in-acute-respiratory-infections/

COVID-19: Have we forgotten our children in all this?
https://www.cebm.net/covid-19/covid-19-have-we-forgotten-our-children-in-all-this/

Let's bring back Britain's fever hospitals
https://www.spectator.co.uk/article/Lets-bring-back-Britains-fever-hospitals

Don't place too much faith in models predicting another coronavirus wave
https://www.telegraph.co.uk/politics/2020/05/16/dont-place-much-faith-models-predicting-another-coronavirus/

Could mass testing for Covid-19 do more harm than good?
https://www.spectator.co.uk/article/could-mass-testing-for-covid-19-do-more-harm-than-good-

TRANSMISSION OF SARS-COV-2 (work ongoing for complete synopsis, see https://www.cebm.ox.ac.uk/research/transmission-of-sars-cov-2)

TOM JEFFERSON, ELIZABETH SPENCER, JON BRASSEY, CARL HENEGHAN. Viral cultures for COVID-19 infectivity assessment. Systematic review. medRxiv 2020.08.04.20167932; doi: https://doi.org/10.1101/2020.08.04.20167932 https://www.medrxiv.org/content/10.1101/2020.08.04.20167932v2

T JEFFERSON, E A SPENCER, J BRASSEY, C HENEGHAN, Viral cultures for COVID-19 infectious potential assessment – a systematic review, Clinical Infectious Diseases, Dec 3, 2020. https://doi.org/10.1093/cid/ciaa1764

JEFFERSON, T.; HENEGHAN, C.; SPENCER, E.; BRASSEY, J.; PLUDDEMAN, A.; ONAKPOYA, I.; EVANS, D.; CONLY, J. A Hierarchical Framework for Assessing Transmission Causality of Respiratory Viruses . Preprints 2021, 2021040633 (doi: 10.20944/preprints202104.0633.v1).

ELENA CECILIA ROSCA, CARL HENEGHAN, ELIZABETH A SPENCER, JON BRASSEY, ANNETTEPLUDDEMANN, IGHO ONAKPOYA, DAVID H EVANS, JOHN M CONLY, TOM JEFFERSON. Transmission of SARS-CoV-2 associated with cruise ship travel: protocol for a systematic review (Version 1) medRxiv 2021.10.11.21264724; doi:https://doi.org/10.1101/2021.10.11.21264724

TOM JEFFERSON ELIZABETH SPENCER, JON BRASSEY, ANNETTE PLUDDEMANN, IGHO ONAKPOYA, DAVID H EVANS, JOHN M CONLY, CARL HENEGHAN. Transmission of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) from pre and asymptomatic infected individuals. A systematic review Clinical Microbiology and Infection 2021 (e pub ahead of print). https://www.clinicalmicrobiologyandinfection.com/article/S1198-743X(21)00616-9/fulltext

COLLATERAL GLOBAL REPORTS (with Carl Heneghan and Jon Brassey)

CG REPORT 1: The Impact of COVID-19 First Wave Restrictions on Cancer Care
1 June 2021

CG REPORT 2: The Impact of Interruptions in Childhood Vaccination
28 June 2021

CG REPORT 3: The Impact of Pandemic Restrictions on Childhood Mental Health
2 October 2021

CG REPORT 4: Effects of COVID-19 Restrictions on Air Pollution
2 November 2021

CG REPORT 5: The Impact of COVID-19 Restrictions on University Students' Mental Health
17 November 2021

Rome, 17 November October 2021

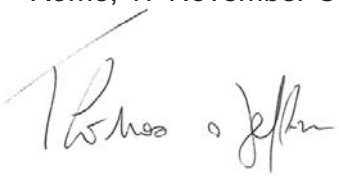


Exhibit D

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

DECLARATION OF PETER MCCULLOUGH, MD, MPH

I, Peter McCullough, MD, MPH, declare as follows:

1. I make this statement based upon my own personal knowledge, education, and experience. I am prepared to testify to the facts and matters set forth herein. A true and accurate copy of my *curriculum vitae* is attached hereto as **Exhibit A**.

Experience

2. I completed my medical degree as an Alpha Omega Alpha graduate from the University of Texas Southwestern Medical School in Dallas. I went on to complete my internal medicine residency at the University of Washington in Seattle, a cardiology fellowship including service as Chief Fellow at William Beaumont Hospital, and a master's degree in public health at the University of Michigan.

3. I am board certified in internal medicine and cardiovascular disease and hold an additional certification in clinical lipidology, and previously echocardiography. I practice internal medicine and clinical cardiology as well as teach, conduct research, and I am an active scholar in

medicine with roles as an author, editorialist, and reviewer at dozens of major medical journals and textbooks. I also participate in the maintenance of certification programs by the American Board of Internal Medicine for both Internal Medicine and Cardiovascular Diseases.

4. I have led clinical, education, research, and program operations at major academic centers (Henry Ford Hospital, Oakland University William Beaumont School of Medicine) as well as academically oriented community health systems. I spearheaded the clinical development of *in vitro* natriuretic peptide and neutrophil gelatinase associated lipocalin assays in diagnosis, prognosis, and management of heart and kidney disease now used worldwide. I also led the first clinical study demonstrating the relationship between severity of acute kidney injury and mortality after myocardial infarction. I have contributed to the understanding of the epidemiology of chronic heart and kidney disease through many manuscripts from the Kidney Early Evaluation Program Annual Data Report published in the American Journal of Kidney Disease and participated in clinical trial design and execution in cardiorenal applications of acute kidney injury, hypertension, acute coronary syndromes, heart failure, and chronic cardiorenal syndromes. I participated in event adjudication (involved attribution of cause of death) in trials of acute coronary syndromes, chronic kidney disease, heart failure, and data safety and monitoring of anti-diabetic agents, renal therapeutics, hematology products, and gastrointestinal treatments. I have served as the chairman or as a member of over 20 randomized trials of drugs, devices, and clinical strategies. Sponsors have included pharmaceutical manufacturers, biotechnology companies, and the National Institutes of Health.

5. I frequently lecture and advise on internal medicine, nephrology, and cardiology to leading institutions worldwide. I am recognized by my peers for my work on the role of chronic kidney disease as a cardiovascular risk state. I have over 1,000 related scientific publications,

including the "Interface between Renal Disease and Cardiovascular Illness" in Braunwald's Heart Disease Textbook. My works have appeared in the New England Journal of Medicine, Journal of the American Medical Association, and other top-tier journals worldwide. I am an associate editor of the American Journal of Cardiology and the American Journal of Kidney Diseases. I have testified before the U.S. Senate Committee on Homeland Security and Governmental Affairs, the U.S. Food and Drug Administration Cardiorenal Advisory Panel and its U.S. Congressional Oversight Committee, and, among other state health committees, the Texas Senate Committee on Health and Human Services.

6. I am a Fellow of the American College of Cardiology, the American Heart Association, the American College of Chest Physicians, the National Lipid Association, and the National Kidney Foundation. I am also a Diplomate of the American Board of Clinical Lipidology.

7. In 2013, I was honored with the International Vicenza Award for Critical Care Nephrology for my contribution and dedication to the emerging problem of cardiorenal syndromes. I am the President of the Cardiorenal Society of America, an organization dedicated to bringing together cardiologists and nephrologists and engage in research, improved quality of care, and community outreach to patients with both heart and kidney disease.[1]

8. I am the current President of the Cardiorenal Society of America, a professional organization dedicated to advancing research and clinical care for patients who have combined heart and kidney disease. I am the former Editor-in-Chief of *Cardiorenal Medicine*, a primary research journal listed by the National Library of Medicine which is the only publication with a primary focus on research concerning patients with combined heart and kidney disease. Finally, I am the current Editor-in-Chief of *Reviews in Cardiovascular Medicine*, a widely read journal that

[1] https://cardiorenalsociety.org/.

publishes reviews on contemporary topics in cardiology and is also listed by the National Library of Medicine.

9. My *curriculum vitae* further demonstrates my academic and scientific achievements and provides a list of publications authored by me in the past 30 years.

10. Since the outset of the pandemic, I have been a leader in the medical response to the COVID-19 disaster and have published "Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection," the first synthesis of sequenced multidrug treatment of ambulatory patients infected with SARS-CoV-2 in the *American Journal of Medicine* and updated in *Reviews in Cardiovascular Medicine*.[2] I have 51 peer-reviewed publications on the COVID-19 infection cited in the National Library of Medicine. Through a window to public policymakers, I have contributed extensively on issues surrounding the COVID-19 crisis. I testified on the SARS-CoV-2 outbreak in the U.S. Senate Committee on Homeland Security and Governmental Affairs on November 19, 2020. I testified on lessons learned from the pandemic response in the Texas Senate Committee on Health and Human Services on March 10, 2021, and on early treatment of COVID-19 the Colorado General Assembly on March 31, 2021. I testified in the New Hampshire Senate on legislation concerning the investigational COVID-19

[2] McCullough PA, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP, Safder T, Tecson KM, Wang DD, McKinnon JE, O'Neill WW, Zervos M, Risch HA. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. 2021 Jan;134(1):16-22. doi: 10.1016/j.amjmed.2020.07.003. Epub 2020 Aug 7. PMID: 32771461; PMCID: PMC7410805 available at https://pubmed.ncbi.nlm.nih.gov/32771461/; McCullough PA, Alexander PE, Armstrong R, Arvinte C, Bain AF, Bartlett RP, Berkowitz RL, Berry AC, Borody TJ, Brewer JH, Brufsky AM, Clarke T, Derwand R, Eck A, Eck J, Eisner RA, Fareed GC, Farella A, Fonseca SNS, Geyer CE Jr, Gonnering RS, Graves KE, Gross KBV, Hazan S, Held KS, Hight HT, Immanuel S, Jacobs MM, Ladapo JA, Lee LH, Littell J, Lozano I, Mangat HS, Marble B, McKinnon JE, Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, Risch HA, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Rev Cardiovasc Med. 2020 Dec 30;21(4):517-530. doi: 10.31083/j.rcm.2020.04.264. PMID: 33387997 available at https://pubmed.ncbi.nlm.nih.gov/33387997/.

vaccine on April 14, 2020. I have also testified in the South Carolina Senate Medical Advisory Committee on the treatment of COVID-19. My expertise on the SARS-CoV-2 infection and COVID-19 syndrome, like that of infectious disease specialists, is approximately 21 months old. I have formed my opinions based on my direct clinical experience with acute and convalescent COVID-19 cases as well has closely following the preprint and published literature on the outbreak. I have specifically reviewed all the key published rare cases and reports concerning possible recurrence of SARS-CoV-2.

11. I also add that, in addition to the education, experience, and credentials detailed above:

a. I diagnose and treat COVID-19 as a part of my practice.

b. I have a master's degree in public health in epidemiology from the University of Michigan.

c. I am an internist, cardiologist, and epidemiologist. I maintain American Board of Internal Medicine certification in internal medicine and cardiovascular diseases. I practice both internal medicine, including the management of common infectious diseases, as well as the cardiovascular complications of both the viral infection and the injuries developing after the COVID-19 vaccine.

d. I have 51 peer-reviewed publications regarding SARS-CoV-2 and COVID-19.

e. I have had more than 21 months dedicated to academic and clinical efforts in combating the SARS-CoV-2 virus and in doing so, have reviewed thousands of reports, participated in scientific congresses, group discussions, press releases, and have been considered among the world's experts on COVID-19.

f. My expertise on the SARS-CoV-2 infection and COVID-19 syndrome, like that of all infectious disease and other specialists, including Defendants' experts, is approximately 19 months old.

12. I also note that unlike medical specialists who support indiscriminate vaccination, I am not reliant upon any funding to perform research regarding infectious diseases, treat infectious diseases, or otherwise receive support from industry or government agencies as part of their work to develop, promote, sell, and/or market medical interventions for infectious diseases. Additionally, I am not under the duty to perform according to FAQ and other guidelines as a part of regulatory capture when federal funds flow to medical centers, groups, and other medical agencies as a part of "COVID-19 Relief" funding.

Opinion

A. The Pfizer COVID-19 Vaccine

13. The Pfizer COVID-19 vaccine is based on a gene therapy molecular platform. During the licensure process for this product, it skipped testing for genotoxicity, mutagenicity, teratogenicity, and oncogenicity. In is a truly novel medical product for which publicly available data regarding its safety and efficacy is limited.

14. Pfizer's COVID-19 vaccine has a potentially dangerous mechanism of action in that it causes the body to make an uncontrolled quantity of the pathogenic wild-type spike protein from the SARS-CoV-2 virus for at least two weeks, but probably a longer period based on the late emergence of vaccine injury reports. This is unlike all other vaccines where there is a set amount of antigen or live-attenuated virus. This means it is not predictable among patients who will produce more or less of the spike protein. The spike protein itself has been demonstrated to injure vital organs such as the brain, heart, lungs, as well as damage blood vessels and directly cause

blood clots. Additionally, because these vaccines infect cells within these organs, the generation of spike protein within heart and brain cells, causes the body's own immune system to attach to these organs. This is abundantly apparent with the burgeoning number of cases of myocarditis or heart inflammation among individuals below age 30 years.[3]

[3]*See* https://www.advisory.com/daily-briefing/2021/06/24/heart-inflammation; *See also* Rose, Jessica. A Report on the U.S. Vaccine Adverse Events Reporting System (VAERS) in association with COVID-19 Injectable Biological Products, *Current Problems in Cardiology* (2021), doi: https://doi.org/10/1016/j.cpcardiol.2021.101011; Rose, Jessica. A Report on the U.S. Vaccine Adverse Events Reporting System (VAERS) of the COVID-19 Messenger Ribonucleic Acid (mRNA) Biologicals. Science, Public Health Policy, and The Law: Volume 2:59-80 May 2021; Sinagra G, Merlo M, Pinamonti B, editors. Dilated Cardiomyopathy: From Genetics to Clinical Management [Internet]. Cham (CH): Springer; 2019; ESC Textbook of Cardiovascular Medicine, 3rd edition; Libby P, Swirski FK, Nahrendorf M. The Myocardium: More Than Myocytes. J Am Coll Cardiol. 2019 Dec24;74(25): 3136-3138.doi: 10.1016/j.jacc.2019.10.031. PMID: 31856970.; Banerjee I, Fuseler JW, Price RL, Borg TK, Baudino TA. Determination of cell types and numbers during cardiac development in the neonatal and adult rat and mouse. Am J Physiol Heart Circ Physiol. 2007 Sep;293(3):H1883-91. doi: 10.1152/ajpheart.00514.2007. Epub 2007 Jun 29. PMID: 17604329.; M.F. Wendt-Gallitelli, G. Isenberg. Electrophysiology and Microinjection.Methods in Neurosciences, 1991.; Harris KM, Mackey-Bojack S, Bennett M, Nwaudo D, Duncanson E, Maron BJ.Sudden Unexpected Death Due to Myocarditis in Young People, Including Athletes. Am J Cardiol. 2021 Mar 15; 143:131-134. doi: 10.1016/j.amjcard.2020.12.028. Epub 2020 Dec 19. PMID: 33347841.; https://www.mayoclinic.org/diseases-conditions/myocarditis/symptoms-causes/syc-20352539; Myocarditis Education Updates and How to Potentially Diagnose the Disease. Aug 4, 2020. Myocarditis Foundation; Myocarditis in children: incidence, clinical characteristics and outcomes. Jul 29, 2020. Myocarditis Foundation; https://www.cdc.gov/dhdsp/myocarditis.htm; https://www.cdc.gov/coronavirus/2019ncov/vaccines/safety/myocarditis.html; Siripanthong B, Nazarian S, Muser D, et al. Recognizing COVID-19-related myocarditis: The possible pathophysiology and proposed guideline for diagnosis and management. Heart Rhythm. 2020;17(9):1463-1471. doi: 10.1016/j.hrthm.2020.05.001; Mele D, Flamigni F, Rapezzi C, Ferrari R. Myocarditis in COVID-19 patients: current problems. Intern Emerg Med. 2021 Jan 23:1–7. doi: 10.1007/s11739-021-02635-w. Epub ahead of print. PMID: 33484452; PMCID: PMC7823176.; Castiello T, Georgiopoulos G, Finocchiaro G, et al. COVID-19 and myocarditis: a systematic review and overview of current challenges [published online ahead of print, 2021 Mar 24]. Heart Fail Rev. 2021;1-11. doi:10.1007/s10741-021-10087-9.; Albert E, Aurigemma G, Saucedo J, Gerson DS. Myocarditis following COVID-19 vaccination. Radiol Case Rep. 2021;16(8):2142-2145. doi: 10.1016/j.radcr.2021.05.033.; How Can COVID-19 Affect the Heart? Aug 18, 2020. Myocarditis Foundation; Montgomery J, Ryan M, Engler R, Hoffman D, McClenathan B, Collins L, Loran D, Hrncir D, Herring K, Platzer M, Adams N, Sanou A, Cooper LT Jr. Myocarditis Following Immunization With mRNA COVID-19 Vaccines in Members of the US Military. JAMA Cardiol. 2021 Jun 29. doi: 10.1001/jamacardio.2021.2833. Epub ahead of print.PMID: 34185045.; Martinez MW,Tucker AM, Bloom OJ, Green G, DiFiori JP, Solomon G, Phelan D, Kim JH, Meeuwisse W, Sills AK, Rowe D, Bogoch II, Smith PT, Baggish AL, Putukian M, Engel DJ. Prevalence of Inflammatory Heart Disease Among Professional Athletes with Prior COVID-19 Infection Who Received Systematic Return-to-Play Cardiac Screening. JAMA Cardiol. 2021 Jul 1;6(7):745-752. doi: 10.1001/jamacardio.2021.0565. PMID: 33662103; PMCID: PMC7934073.; Puntmann VO, Carerj ML, Wieters I,Fahim M, Arendt C, Hoffmann J, Shchendrygina A, Escher F, Vasa-Nicotera M, Zeiher AM, Vehreschild M, Nagel E. Outcomes of Cardiovascular Magnetic Resonance Imaging in Patients Recently Recovered From Coronavirus Disease 2019 (COVID-19). JAMA Cardiol. 2020 Nov 1;5(11):1265-1273. doi: 10.1001/jamacardio.2020.3557.Erratum in: JAMA Cardiol. 2020 Nov 1;5(11):1308. PMID: 32730619; PMCID: PMC7385689.; Gregorio Tersalvi,MD, Marco Vicenzi, MD, Davide Calabretta, MD, Luigi Biasco, MD, PhD, Giovanni Pedrazzini, MD, Dario Winterton, MD. Elevated Troponin in Patients with Coronavirus Disease 2019: Possible Mechanisms. Review article| Volume 26, ISSUE 6, P470-475, June 01, 2020. Published:April 18,2020DOI:https://doi.org/10.1016/j.cardfail.2020.04.009.; Nascimento JHP, Gomes BFO, Oliveira GMM. Cardiac Troponin as a Predictor of Myocardial Injury and Mortality from COVID-19. Arq Bras Cardiol. 2020 Oct;115(4):667-668. English, Portuguese. doi: 10.36660/abc.20200862. PMID: 33111867.; Ucar FM, Ozturk C, Yılmaztepe MA.

Evaluation of Tp-e interval, Tp-e/QT ratio and Tp-e/QTc ratio in patients with acute myocarditis. BMC Cardiovasc Disord. 2019 Oct 22;19(1):232. doi: 10.1186/s12872-019-1207-z. PMID: 31640548; PMCID: PMC6805629.; Fact Sheet for Vaccination Providers-Full EUA PI_Final_2.25.2021.pdf; Noa Dagan, M.D., et al. BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting. New England Journal of Medicine. February 24, 2021, DOI: 10.1056/NEJMoa2101765; Walsh EE, Frenck RW Jr, Falsey AR, Kitchin N, Absalon J, Gurtman A, Lockhart S, Neuzil K, Mulligan MJ, Bailey R, Swanson KA, Li P, Koury K, Kalina W, Cooper D, Fontes-Garfias C, Shi PY, Türeci Ö, Tompkins KR, Lyke KE, Raabe V, Dormitzer PR, Jansen KU, Şahin U, Gruber WC. Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates. N Engl J Med. 2020 Dec 17;383(25):2439-2450. doi: 10.1056/NEJMoa2027906. Epub 2020 Oct 14. PMID: 33053279; PMCID: PMC7583697.; Polack FP, et al. C4591001 Clinical Trial Group. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020 Dec 31;383(27):2603-2615. doi: 10.1056/NEJMoa2034577. Epub 2020 Dec 10. PMID: 33301246; PMCID: PMC7745181.; IPAK Report 2021-1. 2021. Post-vaccination Death Causality Likely Given Temporal Distribution of Deaths Following COVID19 Vaccinations. Interim results.; Tinari S. The EMA covid-19 data leak, and what it tells us about mRNA instability BMJ 2021; 372: n627 doi:10.1136/bmj.n627; Corbett, K.S., Edwards, D.K., Leist, S.R. et al. SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness. Nature 586, 567–571 (2020). https://doi.org/10.1038/s41586-020-2622-0.; Nalca A, Zumbrun EE. ACAM2000: the new smallpox vaccine for United States Strategic National Stockpile. Drug Des Devel Ther. 2010 SARSCoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE2. Circulation Research. April 30,2021.; RW Malone, PL Felgner, IM Verma. Cationic liposome-mediated RNA transfection. Proceedings of the National Academy of Sciences (PNAS) 86 (16), 6077-6081.; Gretchen Vogel, Jennifer Couzin-Frankel. Israel reports link between rare cases of heart inflammation and COVID-19 vaccination in young men. Jun. 1, 2021; Siripanthong B, Nazarian S, Muser D, et al. Recognizing COVID-19-related myocarditis: The possible pathophysiology and proposed guideline for diagnosis and management. Heart Rhythm. 2020;17(9): 1463-1471.doi: 10.1016/j.hrthm.2020.05.001; Mele D, Flamigni F, Rapezzi C, Ferrari R. Myocarditis in COVID-19 patients:current problems. Intern Emerg Med. 2021 Jan 23:1–7. doi: 10.1007/s11739-021-02635-w. Epub ahead of print. PMID: 33484452; PMCID: PMC7823176.; Toor SM, Saleh R, Sasidharan Nair V, Taha RZ, Elkord E. T-cell responses and therapies against SARS-CoV-2 infection. Immunology. 2021 Jan;162(1):30-43. doi: 10.1111/imm.13262. Epub 2020 Oct 27. PMID: 32935333; PMCID: PMC7730020.; Robbiani DF, et al. Convergent antibody responses to SARS-CoV-2 in convalescent individuals. Nature. 2020 Aug;584(7821):437-442. doi:10.1038/s41586-020-2456-9. Epub 2020 Jun 18. PMID: 32555388; PMCID: PMC7442695.; Le Bert N, et al. SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls. Nature. 2020 Aug;584(7821):457-462. doi: 10.1038/s41586-020-2550-z. Epub 2020 Jul 15. PMID: 32668444.; Mateus J, et al. Selective and cross-reactive SARS-CoV-2 T cell epitopes in unexposed humans. Science. 2020 Oct 2;370(6512):89-94. doi: 10.1126/science.abd3871. Epub 2020 Aug 4. PMID: 32753554; PMCID: PMC7574914.; Lipsitch M, Grad YH, Sette A, Crotty S. Cross-reactive memory T cells and herd immunity to SARS-CoV-2. Nat Rev Immunol. 2020 Nov;20(11):709-713. doi: 10.1038/s41577-020-00460-4. Epub 2020 Oct 6. PMID: 33024281; PMCID: PMC7537578.; Corbett, K.S., Edwards, D.K., Leist, S.R. et al. SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness. Nature 586, 567–571 (2020). https://doi.org/10.1038/s41586-020-2622-0.; Zimmermann P, Curtis N. Factors That Influence the Immune Response to Vaccination. Clin Microbiol Rev. 2019 Mar 13;32(2):e00084-18. doi: 10.1128/CMR.00084-18. PMID: 30867162; PMCID: PMC6431125.; Orenstein WA, Bernier RH, Dondero TJ, Hinman AR, Marks JS, Bart KJ, Sirotkin B. Field evaluation of vaccine efficacy. Bull World Health Organ. 1985;63(6):1055-68. PMID: 3879673; PMCID: PMC2536484.; Furman D, Davis MM. New approaches to understanding the immune response to vaccination and infection. Vaccine. 2015 Sep 29;33(40):5271-81. doi: 10.1016/j.vaccine.2015.06.117. Epub 2015 Jul 29. PMID: 26232539; PMCID: PMC4581990.; Ioannidis, J.P. (2021), Reconciling estimates of global spread and infection fatality rates of COVID-19: an overview of systematic evaluations. Eur J Clin Invest. Accepted Author Manuscript e13554. https://doi.org/10.1111/eci.13554; Noh J, Danuser G (2021) Estimation of the fraction of COVID-19 infected people in U.S. states and countriesworldwide. PLoS ONE 16(2): e0246772. https://doi.org/10.1371/journal.pone.0246772; Colson P, Rolain JM, Lagier JC, Brouqui P, Raoult D. Chloroquine and hydroxychloroquine as available weapons to fight COVID-19. Int J Antimicrob Agents. 2020 Apr;55(4):105932. doi: 10.1016/j.ijantimicag.2020.105932. Epub 2020 Mar 4. PMID:32145363; PMCID: PMC7135139.; Liang Chen, Xiangjie Li, Mingquan Chen, Yi Feng, Chenglong Xiong, The ACE2 expression in human heart indicates new potential mechanism of heart injury among patients infected with SARS-CoV-2, Cardiovascular Research, Volume 116, Issue 6, 1 May 2020, Pages 1097–1100, https://doi.org/10.1093/cvr/cvaa078.; Shant Der Sarkissian, Justin L. Grobe, Lihui Yuan, Dhruv R. Narielwala, Glenn A. Walter, Michael J. Katovich, Mohan K. Raizada. Cardiac Overexpression of Angiotensin Converting Enzyme 2 Protects the Heart From Ischemia-Induced Pathophysiology. Hypertension. 2008; 51:712-718.; Vaidyanathan R,

15. Vaccines for other coronaviruses have never been approved for humans, and data generated in the development of coronavirus vaccines designed to elicit neutralizing antibodies show that they may worsen COVID-19 disease via antibody dependent enhancement (ADE) and Th2 immunopathology, regardless of the vaccine platform and delivery method.

16. In March 2020, vaccine immunologists and coronavirus experts assessed SARS-CoV-2 vaccine risks based on SARS-CoV-2 vaccine trials in animal models. The expert group concluded that ADE and immunopathology were a real concern but stated that their risk was insufficient to delay clinical trials, although continued monitoring would be necessary.

B. Safety Concerns Regarding the Pfizer Vaccine

17. The lack of thorough testing in animals prior to clinical trials coupled with authorization based on safety data generated during trials that lasted less than 3.5 months raises questions regarding the safety of these vaccines. The recently identified role of SARS-CoV-2

O'Connell RP, Deo M, et al. The ionic bases of the action potential in isolated mouse cardiac Purkinje cell. Heart Rhythm. 2013;10(1):80-87. doi: 10.1016/j.hrthm.2012.10.002.; Peretto G, Sala S, Rizzo S, De Luca G, Campochiaro C, Sartorelli S, Benedetti G, Palmisano A, Esposito A, Tresoldi M, Thiene G, Basso C, Della Bella P. Arrhythmias in myocarditis: State of the art. Heart Rhythm. 2019 May;16(5):793-801. doi: 10.1016/j.hrthm.2018.11.024. Epub 2018 Nov 24. PMID: 30476544.; McCullough PA, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP, Safder T, Tecson KM, Wang DD, McKinnon JE, O'Neill WW, Zervos M, Risch HA. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. 2021 Jan;134(1):16-22. doi: 10.1016/j.amjmed.2020.07.003. Epub 2020 Aug 7. PMID:32771461; PMCID: PMC7410805.; McCullough PA, Alexander PE, Armstrong R, Arvinte C, Bain AF, Bartlett RP, Berkowitz RL, Berry AC, Borody TJ, Brewer JH, Brufsky AM, Clarke T, Derwand R, Eck A, Eck J, Eisner RA, Fareed GC, Farella A, Fonseca SNS, Geyer CE Jr, Gonnering RS, Graves KE, Gross KBV, Hazan S, Held KS, Hight HT, Immanuel S, Jacobs MM, Ladapo JA, Lee LH, Littell J, Lozano I, Mangat HS, Marble B, McKinnon JE, Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, Risch HA, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Rev Cardiovasc Med. 2020 Dec 30;21(4): 517-530.doi: 10.31083/j.rcm.2020.04.264. PMID: 33387997. McCullough PA, Vijay K. SARS-CoV-2 infection and the COVID-19 pandemic: a call to action for therapy and interventions to resolve the crisis of hospitalization, death, and handle the aftermath. Rev Cardiovasc Med. 2021 Mar 30;22(1): 9-10.doi: 10.31083/j.rcm.2021.01.301. PMID: 33

.

glycoprotein spike for inducing endothelial damage characteristic of COVID-19, even in absence of infection, is extremely relevant that most of the authorized vaccines induce the spike glycoproteins in the recipients.

18. In 1990, the Vaccine Adverse Event Reporting System (VAERS) was established as a national early warning system to detect possible safety problems in U.S. licensed vaccines. VAERS is a passive reporting system, meaning it relies on individuals to voluntarily send in reports of their experiences to the CDC and FDA. VAERS is useful in detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine.

19. The average number of total reports to VAERS for serious injuries from all vaccines per year between 1990 and 2019 was approximately 15,699, while the total safety reports in VAERS for serious injuries from just the COVID-19 Vaccine through November 19, 2021 is approximately 253,729. This includes 19,532 reports of death and 99,671 hospitalizations. By comparison, during the 20 years prior to introduction of the COVID-19 vaccine, VAERS received a total of 5,408 reports of deaths (an average of 270 deaths per year) and 51,034 reports of hospitalizations (an average of 2,551 hospitalizations per year) and that was *all* vaccines combined. Thus, the COVID-19 mass vaccination is associated with at least a 72-fold increase in annualized vaccine deaths reported to VAERS and 39-fold increase in annualized vaccine hospitalizations reported to VAERS.

20. Given the high rate of occurrence of adverse effects, and the wide range of types of adverse effects that have been reported to date, as well as the potential for vaccine-driven disease enhancement, Th2 immunopathology, autoimmunity and immune evasion, there is a need for a

better understanding of the benefits and risks of mass vaccination that can only come from a thorough review of the complete data submitted by Pfizer.

C. There is a Need for the Entire Universe of Data

21. Scientists and healthcare professionals need all of the documents submitted by Pfizer to conduct a proper analysis of the COVID-19 vaccines and the present and potential adverse events resulting from mass vaccination protocols. Missing even a single dataset could inaccurately skew any attempt at meaningful analysis. All scientific analyses rely on *complete* sets of information from the conception of hypothesis testing, protocol development and approval, initiation of implementation, baseline assessment and exclusions, administration of the test article, experimental and clinical observations, critical event collection and adjudication, data safety and clinical investigation integrity monitoring, data synthesis, statistical analysis, experimental and clinical inference, and generalizability. As a result of this process, all documents without exception, are required to perform a comprehensive evaluation of the vaccines, adverse events, and the overall benefit and risk posed in subpopulations, in different age-cohorts, and to public health in general.

22. The FDA provided an index listing of the documents within the product's licensure application, however the information provided about the documents is not detailed enough for one to be able to prioritize production and to ascertain what would be needed in order to complete an adequate and appropriate assessment.

D. The Need for the Data is Immediate

23. It is critical that these documents are publicly released as soon as possible. The combined failure of COVID-19 vaccine protection to last even six months and the catastrophic number of serious adverse events reported have created an urgent need for the scientific

community to study and the public to understand what has gone wrong in the United States and how we can remedy the public COVID-19 vaccine program currently being administered by the CDC/FDA.

24. Evidence on the safety of all SARS-CoV-2 vaccines is needed before exposing young children to this product and more people to the risk of repeated boosters, since failing to timely, properly, and independently study these implications could lead to an exacerbation of the current global crisis and a serious threat to American security, including intergenerationally. For example, risk-stratification of vaccine recipients is of critical importance but the data to properly analyze same is being withheld from the scientific community by the FDA.

25. Independent review is essential to scientific integrity and the protection of human subjects. An open scientific dialogue is urgent and indispensable to avoid erosion of public confidence in science and public health and to ensure that national health authorities protect the interests of humanity during the current pandemic. Returning public health policy to evidence-based medicine that relies on a careful evaluation of the relevant scientific research is imperative.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct this 5th day of December 2021, at Dallas, TX.

P. McCullough

Peter McCullough, MD, MPH

Curriculum Vitae of Peter McCullough, MD, MPH

(Exhibit A to McCullough Declaration)

Tuesday, October 6, 2021

CURRICULUM VITAE

PETER A. McCULLOUGH, MD, MPH, FACC, FCCP, FAHA, FNKF, FNLA, FCRSA

Business

HeartPlace
3409 Worth Street, #500
Dallas TX 75246
Desk: 214-841-2000
Cell: 248-444-6905
e-mail: PeterAMcCullough@gmail.com

Home 5231 Richard Avenue
Dallas, TX 75206

Birth date December 29, 1962
Birthplace Buffalo, NY, USA

EDUCATION

1) Certificate of Graduate Liberal Arts Studies: Southern Methodist University, December 17, 2016, principal faculty Dr. Anthony Picchioni, PhD, Adjunct Professor in Human Development, P.O. Box 750181, Dallas, TX 75275, 214-768-3417, www.smu.edu
   - Graduated with Honor

2) Master of Public Health: University of Michigan School of Public Health, August 19, 1994, Dean Noreen M. Clark, PhD, 109 Observatory Street, Ann Arbor, MI 48109-2029, phone 734-764-5454, www.sph.umich.edu
   - Major: General Epidemiology

3) Doctor of Medicine: University of Texas Southwestern Medical School, June 4, 1988, Dean Bryan M. Williams, MD, 5323 Harry Hines Boulevard, Dallas, TX 75235-9070, 214-648-3111, http://www.utsouthwestern.edu/education/medical-school/
   - Clinical year rank of 1 in 199, overall rank in class of 12 in 199
   - Alpha Omega Alpha Texas Gamma Chapter, installed March 17, 1988

4) Bachelor of Science: Baylor University, May 18, 1984, Chancellor Abner McCall, PhD, Office of the Registrar, Waco, TX 76798-7056, 254-710-1181, http://www.baylor.edu/
   - Double-major: Biology and Psychology
   - Graduated with Honor, degree rank of 29 in 131, university rank of 127 in 1,152

- Alpha Lambda Delta Freshman Honorary, installed March 19, 1981

POSTGRADUATE TRAINING

1) Cardiovascular Diseases Fellowship: William Beaumont Hospital (WBH) (presently Oakland University William Beaumont School of Medicine), Division of Cardiology, 3601 W. Thirteen Mile Rd, Royal Oak, MI 48073, 248-551-4198, 7-1-94 to 6-30-97, Chief Cardiovascular Fellow for 1996-97, William W. O'Neill, MD, Program Director and Division Chief

2) Internal Medicine Residency: University of Washington School of Medicine, Department of Internal Medicine, 1959 NE Pacific, Seattle, WA 98195, (206) 543-3239, 3-year traditional track, 7-1-88 to 6-30-91, James F. Wallace, MD, Program Director, Paul G. Ramsey, MD, Chairman of Medicine

PROFESSIONAL EXPERIENCE

HeartPlace , 3409 Worth Street, Suite 500, Dallas TX 75246, March 1, 2021.

Positions Held: 1) Attending Physician

Baylor Scott and White Health, Baylor Health Care System, Baylor University Medical Center (BUMC), Baylor Heart and Vascular Institute, Baylor Jack and Jane Hamilton Heart and Vascular Hospital, Dallas TX, Texas A & M University College of Medicine, Department of Medicine, Division of Cardiology, Baylor Heart and Vascular Institute, 621 N. Hall St., #H030, Dallas, TX 75226, February 3, 2014 to February 25, 2021. Cardiovascular Governance Council, Kevin Wheelan, MD, Cardiology Division Chief and Chief Medical Officer, Heart Institute Office (214) 820-7500

Positions Previously Held:

1) Professor in the Principal Faculty, Non-Tenure Track in the Department of Internal Medicine, Texas A & M University Health Sciences Center (2016-2021)
2) Chief of Cardiovascular Research (2014-2021)
3) Program Director, BUMC Cardiovascular Diseases Fellowship Program (2014-2021)
4) Vice Chief, BUMC Internal Medicine (2016-2021)

St. John Providence Health System, Providence Park Heart Institute, Department of Medicine, Cardiology Section, 47601 Grand River Avenue, Suite B-125, Novi, MI 48374, September 1, 2010 to July 19, 2013. Department of Medicine Chair, Anibal Drelichman, MD: 248-849-3152, Cardiology Section Chief: Shukri David, MD, 248-465-5955

Positions Previously Held:

1) Chief Academic and Scientific Officer (Academic Dean Equivalent), St. John Providence Health System, (2010 to 2013)
2) Medical Director, Clinical Lipidology, Department of Medicine, Cardiology Section (2010 to 2013)

William Beaumont Hospital, Department of Internal Medicine, Divisions of Nutrition and Preventive Medicine, Department of Cardiology, 3601 West Thirteen Mile Road, Royal Oak, MI 48073, October 1, 2002 to 2010. Department of Medicine Chair: Michael A. Maddens, M.D., 248-551-0622, Department of Cardiology Chair: David E. Haines, M.D., 248-858-0404

Oakland University William Beaumont School of Medicine, 472 O'Dowd Hall
2200 N. Squirrel, Rochester, MI 48309, Robert Folberg, MD, Medical School Dean, Kenneth Hightower, PhD, Dean of Allied Health Sciences, 248-370-3562. Clinical Professor of Health Sciences and Medicine (2007 to 2010)

Positions Previously Held:

1) Consultant Cardiologist and Chief, Division of Nutrition and Preventive Medicine (2002 to 2010), Department of Internal Medicine
2) Medical Director, Preventive Cardiology (2002 to 2010)
3) Medical Director, Lipid Apheresis Program (2007 to 2010)
4) Medical Director, Weight Control Center (2002-2005)

University of Missouri-Kansas City (UMKC) School of Medicine, Truman Medical Center, Department of Medicine, Cardiology Section, 2301 Holmes St., Kansas City, MO 64108. August 18, 2000-September 30, 2002. Department of Medicine Chair: George R. Reisz, M.D, 816-556-3450

Positions Previously Held:

1) Associate Professor of Medicine (Tenure Track) and Cardiology Section Chief (2000-2002)

Henry Ford Health System (HFHS), Henry Ford Heart and Vascular Institute, 2799 W. Grand Blvd., K-14, Detroit, MI 48202, July 1, 1997 to August 16, 2000. Cardiovascular Division Head: W. Douglas Weaver, M.D, 800-653-6568

Positions Previously Held:

1) Assistant Professor of Medicine (Tenure Track), Case Western Reserve University School of Medicine, and HFHVI Senior Staff Cardiologist
Medical Director, Preventive Cardiology, 1999-2000
2) Program Director, Cardiovascular Diseases Fellowship Training Program, 1999-2000
3) Director of Cardiovascular Informatics Section, 1997-2000
4) Associate Director of the Center for Clinical Effectiveness, 1997-99

5) Associate Director of the Cardiovascular Diseases Fellowship Program, 1998-99

Emergency Physicians Medical Group, PC, 2000 Green Road, Suite 300, Ann Arbor, MI 48105, 800-466-3764. Emergency medicine attending at Mission Health McPherson Hospital, Howell, 1991-1997; Oakwood Beyer Hospital Center, Ypsilanti 1991-1997, and Mercy Hospital, Grayling 1991-1992

Positions Previously Held:

1) Associate Member
2) Washtenaw County Human Services Deputy Medical Examiner, 1995-1996

Mercy Internal Medicine Associates, 308 Michigan Avenue, Grayling, MI 49738, Mercy Hospital-Grayling, 1100 Michigan Avenue, Grayling, MI 49738, 517-348-5461. Internal medicine attending at Mercy Hospital, Grayling, MI, 1991-1992

Positions Previously Held:

1) Coronary Care Unit Director
2) Physician Director of Cardiopulmonary Services

SPECIAL TRAINING

1) The Healthcare Forum Cardiovascular Health Fellowship, 1998-99
2) American Heart Association (AHA), 23rd 10-Day U.S. Seminar on the Epidemiology and Prevention of Cardiovascular Disease, July-August, 1997
3) University of Michigan Summer Session in Epidemiology, 1997-99
4) Stanford University Course on Medical Informatics, Palo Alto, CA, June, 1997
5) Current Practice of Vascular Ultrasound 3-Day Course, Chicago, IL, April, 1997
6) Advanced Pacemaker Concepts Course, CPI, Inc., Lansing, MI, 1995
7) Pacesetter Comprehensive Pacemaker 4-Day Course, Santa Fe, NM, 1997
8) Medtronic Bakken Education Tutorial and Medtronic Applied Physiological Research Laboratory Lead Implantation Training and Biventricular Implantation Training (2 sessions), Minneapolis, MN, 2001-2002
9) 2004 ASCeXAM Review Course, American Society of Echocardiography, San Francisco, CA, April 22-24, 2004
10) National Lipid Association Masters Course in Clinical Lipidology, Hilton Head, SC, August 21-23, 2008

CERTIFICATION AND LICENSURE

1) Licensed in the State of Washington 1988-1997 (#MD00027562), Michigan expires January 31, 2022 (#4301058147), and New York 1992 to present (#189283 inactive status), Missouri 2000-2002 (#2000165365 inactive status) and Texas expires May 31, 2022 (#P9222)

2) FLEX passed April 4, 1990, State of Washington, Department of Health, Board of Medical Examiners
3) Diplomate, American Board of Internal Medicine, Candidate #136084, September, 25, 1991, recertified May 1, 2001, recertified June 10, 2011, recertified April 6, 2021, valid through 2031, 510 Walnut Street, Suite 1700, Philadelphia, PA 19106-3699
4) Diplomate, American Board of Internal Medicine, Cardiovascular Diseases Subspecialty, Candidate #136084, November, 1997, valid through 2007, recertified October 1, 2007, valid through 2017, recertified September 28, 2017, valid through 2027, 510 Walnut Street, Suite 1700, Philadelphia, PA 19106-3699
5) Diplomate, American Board of Clinical Lipidology, September 27, 2008, 6816 Southpoint Parkway, Suite 1000, Jacksonville, FL 32216. Fellow, National Lipid Association
6) National Board of Echocardiography (NBE), Examination of Special Competence in Adult Echocardiography, 2004-2014 expired
7) Diplomate, American Board of Forensic Examiners, July 16, 1996, no expiration date

RECOGNITION

Teaching:

1. Henry Ford Hospital, 1999 Chief Medical Resident's Best Teacher Award

Research:

1. Chest Foundation Young Investigator Award 2001, Philadelphia, PA, November 7, 2001, President's International Awards Ceremony

2. National Kidney Foundation (NKF) of Michigan, Innovations in Health Care Award Finalist 2008, East Lansing, MI, April 17, 2008

3. American College of Cardiology (ACC) Simon Dack Award for Scholarly Excellence by the Journal of the American College of Cardiology, March 5, 2009

4. 11th International Vicenza Award in Critical Care Nephrology, International Renal Research Institute, Vicenza, Italy, June 11, 2013

Postgraduate:

1. Founding Fellow, Cardiorenal Society of America, March 2016
2. Fellow, National Lipid Association, January, 2013
3. Fellow, National Kidney Foundation, January, 2012
4. Fellow, American College of Chest Physicians, February, 2001
5. Fellow, American College of Physicians, January, 2001 to September, 2021
6. Fellow, American College of Cardiology, February, 1999

AFFILIATIONS

1) Alpha Omega Alpha, National Honor Medical Society, 1988 to present

2) American College of Emergency Physicians, Member, 1992-1994
3) American College of Forensic Examiners, Member 1996 to present
4) AHA, Council on Epidemiology and Prevention, 1995 to present
5) AHA, Grassroots Network, 1998-2000.
6) Central Society for Clinical Research, Member, 1999-2000
7) Council on Geriatric Cardiology, Member 1996-1997
8) Michigan Chapter of the ACC, Chair, Annual Cardiology Board Review, 1999-2000
9) Michigan State Medical Society, Member, 1997-2000, 2004 to 2009
10) The American Medical Informatics Association, 1997-2000
11) The Health Forum, Charter Cardiovascular Health Charter Alumni Representative, 1998 to 2002
12) Cardiorenal Society of America, Founding Executive Board Member, 2013 to present, Vice President 2014-2016, President 2016 to present
13) Dallas County Medical Society, 2014 to present
14) Texas Medical Association, 2014 to present
15) Baylor Alumni Association, 2015 to present
16) New York Academy of Sciences, 2016 to present
17) Truth for Health Foundation, Founding Executive Board Member, Chief Medical Advisor, 2021 to present

EDITORIAL RESPONSIBILITIES

1) *Advances in Chronic Kidney Disease,* Editorial Board Member, 2003-present. [referenced through Elsevier Bibliographic Database, EMBASE/Excerpta Medica, MEDLINE]
2) *American Journal of Cardiology,* Associate Editor, 2014 to present
3) *American Journal of Kidney Disease,* [referenced through Elsevier Bibliographic Database, EMBASE/Excerpta Medica, MEDLINE] Associate Editor, 2006 to 2019, Guest Editor, 2011, 2012
4) *Arquivos Brasileiros de Cardiologia*, International Editorial Board, 2006 to present
5) *Biocritique*, Editorial Board, 2001 to 2013, www.biocritique.com
6) *Blood Purification, Editorial Board 2018 to present*
7) *Cardiovascular Clinician,* Editorial Board, 2011 to 2013, internet site, CARDIOVASCULARClinician.com™
8) *Cardiovascular Diagnosis and Therapy (CDT),* Editorial Board *(*Print ISSN: 2223-3652; Online ISSN: 2223-3660, 2012 to present
9) *Cardiovascular Innovations and Applications (CVIA),* Editorial Board 2015 to present
10) *Cardiorenal Medicine,* Associate Editor, 2016-2017, Editor-in-Chief 2018 to 2021
11) *Circulation,* Editorial Board, 2016 to present
12) *Circulation Heart Failure,* Editorial Board, 2008 to present, Associate Editor, 2008 to 2016, Guest Editor 2010, 2011, 2012
13) *Clinical Exercise Physiology,* Clinical Consultant to the Editorial Board, 1998-2002.
14) *Cochrane Renal Group Module*, 2008, Editorial Contributor, Centre for Kidney Research, The Children's Hospital at Westmead, Westmead NSW, Australia

15) *Expert Review of Cardiovascular Therapy*, Editorial Advisory Panel, 2002 to present, www.future-drugs.com

16) *Journal of the American College of Cardiology,* Editorial Consultant, 2003-present. "Elite Reviewer" Recognition, 2004, 2005, 2006, 2007, 2008, 2011, 2014, 2016 (DeMaria AN. The elite reviewer. J Am Coll Cardiol 2003;41(1):157-8.)

17) *Journal of Geriatric Cardiology,* Editorial Board Member, 2003-present. The Institute of Geriatric Cardiology, Chinese PLA Hospital, Beijing. [Joint China-U.S.A. publication]

18) *Journal of Biorepository Science for Applied Medicine,* Honorary Editorial Board, 2012 to 2018

19) *Journal of Clinical & Experimental Cardiology*, OMICS Publishing Group, Open Access, CrossRef, PubMed, DOAJ, Index Copernicus, Scientific Commons, EBSCO, 2010 to 2017

20) *Journal of Diabetes & Metabolism,* OMICS Publishing Group, Open Access, 2010 to 2017

21) *Journal of Interventional Cardiology,* "News and Views", Section Editor, 2000-2003. Editorial Board Member, 2003 to present

22) Journal of Nephrology and Therapeutics, Editorial Board, OMICS Publishing Group, Editorial Board, 2010 to 2017

23) *Reviews in Cardiovascular Medicine, MedReviews, LLC,* www.medreviews.com "Cardiorenal Function," Section Editor, 2001-2002, Associate Editor, 2003-2009, Co-Editor, 2009 to present

24) The American College of Cardiology Foundation ACCEL Audio Journal, Editorial Board 2008 to present

25) The Open Atherosclerosis & Thrombosis Journal, [referenced through Bentham Open, PubMed, Google and Google Scholar] Editorial Board, 2008 to 2012

26) The Open Heart Failure Journal, [referenced through Bentham Open, PubMed, Google and Google Scholar] Editorial Board, 2008 to 2010

27) Therapy, [referenced through Elsevier Bibliographic Database, EMBASE/Excerpta Medica, MEDLINE], Editorial Board, 2008 to 2010

Manuscript Reviewer

1) *Advances in Chronic Kidney Disease,* 2004 to present (18)
2) *Advances in Medical Sciences*, 2012 to present (2)
3) *Advances in Therapy,* 2008 to present (1).
4) *American Family Physician,* 2004 to present (2)
5) *American Journal of Cardiovascular Drugs*, 2002 to present. (2)
6) *American Heart Journal (AHJ),* 1998 to present (22)
7) *American Journal of Cardiology (AJC),* 1999 to present (60)
8) *American Journal of Human Biology,* 2014 to present (1)
9) *American Journal of Hypertension,* 2011 to present (1)
10) *American Journal of Kidney Diseases (AJKD),* 2002 to present (30)
11) *American Journal of Medicine (AJM)*, 1997 to present (7)
12) *American Journal of the Medical Sciences (AJMS),* 2006 to present (3)
13) *American Journal of Nephrology,* 2004 to present (24)
14) *American Journal of Physiology: Renal Physiology,* 2006 to present (2)

15) *American Journal of Transplantation,* 2004 to present (1)
16) *Annals of Epidemiology,* 2004 to present (1)
17) *Annals of Internal Medicine,* 2008 to present (3)
18) *Annals of Noninvasive Electrocardiology,* 2009 to present (1)
19) *Antimicrobial Agents and Chemotherapy,* 2020 to present (1)
20) *Archives of Internal Medicine,* 2004 to present (2)
21) *Archives of Pathology and Laboratory Medicine,* 2007 to present (1)
22) *Arteriosclerosis, Thrombosis, and Vascular Biology,* 2010 to present (2)
23) *Autonomic Neuroscience: Basic and Clinical,* 2007 to present (1)
24) *BUMC Proceedings,* 2012 to present (3)
25) *Biochemia Medica,* 2012 to present (1)
26) *Biomed Central (BMC) Medical Imaging,* 2010 to present (1)
27) *Blood Purification,* 2010 to present (2)
28) *BMC Medicine,* 2007 to present (1)
29) *BMC Nephrology,* 2011 to present (1)
30) *BMJ Clinical Evidence,* 2008 to present (1)
31) *British Medical Journal (BMJ)*, 2009 to present (1)
32) *Canadian Medical Association Journal (CMAJ),* 2006 to present (3)
33) *Cardiac Failure Review,* 2015 to present (1)
34) *Cardiology,* 2007 to present (1)
35) *Cardiorenal Medicine;* 2013 to present (10)
36) *Cardiovascular Innovations and Applications,* 2016 to present (1)
37) *Cardiovascular Therapeutics,* 2010 to present (1)
38) *Catheterization and Cardiovascular Interventions*, 2000 to present (6)
39) *Chest,* 2000 to present (6)
40) *Circulation*, 1998 to present (100)
41) *Circulation Cardiovascular Interventions,* 2012 to present (1)
42) *Circulation Cardiovascular Quality and Outcomes,* 2010 to present (1)
43) *Circulation Heart Failure,* 2009 to present (4)
44) *Circulation Imaging,* 2012 to present (1)
45) *Cleveland Clinic Journal of Medicine,* 2008 to present (1)
46) *Clinica Chimica Acta,* 2013 (1)
47) *Clinical Cardiology,* 2001 (3)
48) *Clinical Chemistry and Laboratory Medicine,* 2010 to present (2)
49) *Clinical Exercise Physiology,* 2000-2002 (4)
50) *Clinical Journal of the American Society of Nephrology* 2008 to present (3)
51) *Clinical Kidney Journal*, 2012 to present (1)
52) *Clinical Medicine and Research,* 2008 to present (1)
53) *Clinical Nephrology,* 2008 to present (2)
54) *Clinical Physiology and Functional Imaging,* 2010 to present (1)
55) *Clinical Researcher*, 2002 to present (1)
56) *Clinics,* 2010 to present (1)
57) *Cochrane Collaboration,*2009 to present (2)
58) *Congestive Heart Failure,* 2005 to present (4)

59) *Coronary Artery Disease,* 2005 to present (1)
60) *Critical Care Medicine,* 2008 to present (2)
61) *Current Medical Research and Opinion,* 2005 to present (1)
62) *Diabetes Care,* 2011 to present (2)
63) *Diabetes and Vascular Disease Research*, 2011 to present (1)
64) *Diabetes, Obesity, and Metabolism,* 2019 to present (1)
65) *Diabetic Medicine,* 2008 to present (1)
66) *Drug Benefit Trends,* 1999 (1)
67) *Drugs,* 2000 (2)
68) *European Heart Journal*, 1995 (12)
69) *European Journal of Cardiovascular Prevention and Rehabilitation*, 2006 (1)
70) *European Journal of Heart Failure,* 2012 (4)
71) *Expert Opinion on Pharmacotherapy,* 2003 to present (3)
72) *Expert Opinion Therapeutic Patents,* 2004 to present (1)
73) *Expert Review of Cardiovascular Therapy,* 2008 to present (2)
74) *Global Heart*, 2012 (1)
75) *Heart,* 2004 (2)
76) *Heart and Vessels,* 2007 (2)
77) *Hemodialysis International* 2013 (2)
78) *Internal Medicine Journal (Australasia),* 2009 to present (1)

79) International Journal of Infectious Diseases 2020 to present (2)
80) *International Journal of Nephrology,* 2010 to present (2)
81) *Journal of Biomarkers,* 2013 (1)
82) *Journal of Geriatric Cardiology,* 2017 (1)
83) *International Journal of Infectious Diseases,* 2021 to present (3)
84) *Journal of Internal Medicine,* 2009 to present (1)
85) *Journal of Interventional Cardiology (JIC)*, 1996 to present (9)
86) *Journal of the American College of Cardiology (JACC)*, 1998 to present (228)
87) *Journal of the American College of Cardiology: Heart Failure (JACC Heart Fail)*, 2014 to present (12)
88) *Journal of the American College of Cardiology: Imaging (JACC Imag)*, 2014 to present (6)
89) *Journal of the American College of Cardiology: Interventions (JACC Interv)*, 2010 to present (10)
90) *Journal of the American Medical Association (JAMA),* 2002 to present (60)
91) *Journal of the American Medical Association Cardiology (JAMA Cardiology),* 2016 to present (20)
92) *Journal of the American Society of Echocardiography (JASE)*, 2009 to present (1)
93) *Journal of the American Society of Nephrology (JASN)* 2005 to present (14)
94) *Journal of Cardiac Failure,* 2003 to present (10)
95) *Journal of Clinical Outcomes Management*, 2011 to present (1)
96) *Journal of Critical Care,* 2011, to present (1)
97) *Journal of General Internal Medicine,* 2008 to present (1)
98) *Journal of Human Hypertension,* 2010 to present (1)

99) *Journal of Inherited Metabolic Disease,* 2014 to present (2)
100) *Journal of Lipid Research,* 2010 to present (1)
101) *Journal of Managed Care,* 2004 to present (1)
102) *Journal of Physiology and Pathophysiology*, 2009 to present (1)
103) *Kidney and High Blood Pressure Research,* 2008 to present (1)
104) *Kidney International,* 2004 to present (8)
105) *Medical Science Monitor,* 2008 to present (1)
106) *Medicine & Science in Sports and Exercise,* 2005 to present (3)
107) *Nature Clinical Practice Cardiovascular Medicine*, 2004 to present (4)
108) *Nature Clinical Practice Nephrology*, 2008 to present (1)
109) *Nature Reviews Nephrology,* 2009 to present (3)
110) *Nephron,* 2005 to present (1)
111) *Nephrology,* 2009 to present (1)
112) *Nephrology, Dialysis, and Transplantation,* 2005 to present (7)
113) *New England Journal of Medicine,* 2006 to present (8)
114) *Pharmacological Research (Italy),* 1999 (1)
115) *Pharmaceutical Sciences,* 2011 (1)
116) *PLoS Medicine,* 2005 (1)
117) *PLOS ONE,* 2013 (1)
118) *Prehospital Emergency Care*, 2015 (1)
119) *Preventive Medicine,* 2008 (1)
120) *Rejuvenation Research,* 2007 (1)
121) *Renal Failure*, 2011 (2)
122) *The Lancet,* 1999 to present (11)
123) *The Lancet Diabetes,* 2013 to present (5)
124) *The Lancet Global Health,* 2015 to present (2)

Major Meeting Abstract Grader

1) ACC Scientific Sessions 2001 to present (10)
2) ACC I2 Summit, 2006 to present (2)
3) American Diabetes Association, 2008 to present (13)
4) AHA Scientific Sessions, 1997 to present (8)
5) American Medical Informatics Association, Annual Symposium, 1998-2001 (3)
6) International Academy of Cardiology World Congress on Heart Disease, Academy of Cardiology Annual Scientific Sessions—Mechanisms and Management, 2002-present (3)
7) Transcatheter Therapeutics (TCT), 2004 (1)

Grant Reviewer

1. National Medical Research Council, Singapore, 2003-2004
2. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Special Emphasis Panel/Initial Review Group 2006/01 ZDK1 GRB-9, 2005

3. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Special Emphasis Review Group, 1 R01 DK070033-01A2, 2006
4. National Institutes of Health, National Heart Lung and Blood Institute, Study Section, ZHL1 CSR-H (M1), March 6-7, 2006, Heart Failure Network
5. Diabetes UK, The British Diabetic Association, Macleod House, 10 Parkway, London NW1 7AA. December 24, 2008
6. National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases, Special Review Panel, Chronic Renal Insufficiency Cohort Study (CRIC) and A Prospective Cohort Study of Kidney Disease in Children (CKiD) Study, February 23-25, 2012, March 6, 2013
7. National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases, Special Review Panel, ZDK1 GRB-7 (O3)S in response to PAR-DK-09-247: Ancillary Studies to Major Ongoing Clinical Research Studies to Advance Areas of Scientific Interest within the Mission of the NIDDK (R01), July 11, 2012
8. Alberta Innovates Health Solutions Collaborative Research & Innovation Opportunities (CRIO) Grant Review, September, 2012
9. Health Research Board of Ireland, Health Research Awards, 2013
10. National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases 2017/01 ZRG1 DKUS-R (55) Study Section 2016

Guidelines Reviewer

1. Kidney Disease Improving Global Outcome (KDIGO) Guidelines Review
    a. Prevention, Diagnosis, Evaluation and Treatment of Hepatitis C in Chronic Kidney Disease, Published April, 2008
    b. Diagnosis, Evaluation, Prevention and Treatment of Chronic Kidney Disease related Mineral and Bone Disorders (CKD-MBD), Published August, 2009
    c. Acute Kidney Injury (AKI), published March, 2012

CLINICAL TRIAL AND STUDY RESPONSIBILITIES

Overall Study Responsibilities: Steering and Executive Committees

1) Study Principal Investigator, Medicine vs Angiography for Thrombolytic Exclusion Patients (M.A.T.E.), 1994-1997, (multicenter, U.S., randomized controlled trial [RCT]). Status: closed.

2) Study Principal Investigator, The Resource Utilization Among Congestive Heart Failure Study (R.E.A.C.H.), 1998-2000, (single-center, prospective cohort study). Status: closed.

3) Study Principal Investigator, The Asthma, Beta-Agonists, and Congestive Heart Failure Study, (A.B.C.H.F.), 1998-1999, (single-center, case-control study). Status: closed.

4) Study Co-Principal Investigator, The Prevention of Radiocontrast Induced Nephropathy Clinical Evaluation (P.R.I.N.C.E.) Study, 1995-1998, (single-center, RCT). Status: closed.

5) Study Co-Principal Investigator, BNP Multinational Study, Principal Investigator, Alan Maisel, MD, Biosite Diagnostics, Inc., 2000-2006, (multicenter, international, prospective cohort study). Status: closed.

6) Study Co-Investigator, Prophylactic Oral Amiodarone Compared to Placebo for Prevention of Atrial Fibrillation Following Coronary Artery Bypass Graft Surgery (P.A.P.A.C.A.B.G.), 1996-1998, (single-center, RCT). Status: closed.

7) Study Co-Investigator, Rapid Early Bedside Markers of Myocardial Injury, 1998-1999, HFHS and Biosite Diagnostics, Inc. (prospective cohort study). Status: closed.

8) Member, Steering Committee, Clinical Study Protocol No. 2000-025: A Phase IIIb, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Safety, Efficacy, and Tolerability of Fenoldopam Mesylate in Subjects Undergoing Interventional Cardiology Procedures (CONTRAST), William W. O'Neill, MD and Gregg Stone, MD, Co-Principal Investigators, Abbott Laboratories, Inc., 2000-2003 (multicenter, US, RCT). Status: closed.

9) Chair, National Steering Committee, Kidney Early Evaluation Program (KEEP) NKF, Member 2000-2005, Co-Chair 2005-2010, Chair 2010-present (multicenter, U.S., prospective cohort study). Annual budget ~$1,325,198 (2009), ~$1,233,832 (2010), ~$1,614,953.00 (2011), ~$989,500 (2012), ~$1,217,000 (2013). Status: inactive.

10) Member, Steering Committee, Protocol No. 704.351 Evaluation of Synergy between Natrecor and Furosemide on Renal and Neurohormone Responses in Chronic Heart Failure: A Phase IV Study, Scios Inc., 2003-2005 (multicenter, U.S., randomized cross-over trial). Status: closed.

11) Member, Steering Committee, Protocol No. CCIB002FUS12. A Multicenter, Double-blind, Randomized, Parallel Group Study to Evaluate the Effects of Lotrel and Lotensin HCT on Microalbuminuria in Mild to Moderate Hypertensive Subjects with Type 2 Diabetes Mellitus, Novartis Pharmaceuticals, Inc., 2003-2006. Status: closed.

12) Rotating Executive Committee Principal Investigator Member, NIH HF-ACTION Trial (Exercise Training Program to Improve Clinical Outcomes in Individuals With Congestive Heart Failure), HL63747 01A2, 2006-2009. Principal Investigator, David Whellan, MD, status: closed.

13) Overall Study Principal Investigator, Neutrophil Gelatinase-Associated Lipocalin: A Novel Blood Marker for Risk of Developing Contrast Induced Nephropathy (ENCINO), multicenter, prospective, blinded cohort study, 2006-2009, status: closed.

14) Member, Steering Committee, VA NEPHRON-D: Diabetes iN Nephropathy Study, 2008 to 2013, trial stopped early for safety cardiovascular and acute kidney safety concerns in angiotensin converting enzyme inhibitor plus losartan arm, status: closed.

15) Member, External Expert Panel, National Institutes of Health, National Institute of Digestive and Diabetes and Kidney Diseases, Chronic Renal Insufficiency Cohort Study, status open, 2010 to present.

16) Member, Optimal Medical Management Subcommittee, National Institutes of Health, National Heart Lung and Blood Institute, International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA), status: open, 2011 to present.

17) Member, Steering Committee, National Institutes of Health, National Heart Lung and Blood Institute, International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) in patients with Chronic Kidney Disease (ISCHEMIA-CKD), status: open, 2012 to present.

18) Member, Steering Committee, Thrasos Innovation, Inc, A Phase II Multi-Center, Parallel-Group, Randomized, Double Blind, Proof-of-Concept, Adaptive Study Investigating the Safety and Efficacy of THR-184 Administered via Intravenous Infusion in Patients at Increased Risk of Developing Cardiac Surgery Associated-Acute Kidney Injury (CSA-AKI), status: closed, 2012 to 2015.

19) Overall Principal Investigator, AbbVie, Inc, Clinical Study Protocol M13-796, A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Trial of Multiple Dosing Regimens of ABT-719 for the Prevention of Acute Kidney Injury in Subjects Undergoing High Risk Cardiac Surgery, status: closed, 2013 to 2014.

20) Overall Principal Investigator, Bioporto, Inc, The NGAL Test™ As An Aid in the risk assessment for AKI stage II and III in an Intensive Care Population, status: open 2017 to present.

21) Member, Global Expert Panel, Novo Nordisk, Inc, A Research Study to See How Semaglutide Works Compared to Placebo in People With Type 2 Diabetes and Chronic Kidney Disease (FLOW), status: open.

Overall Study Responsibilities: Endpoint Committees

1) Member, Critical Endpoints Committee, Treat Angina with Aggrastat and Determine Cost of Therapy with an Invasive or Conservative Strategy, TACTICS-TIMI 18 (Protocol 019-00), 1998-2000, (multicenter, international, RCT). Status: closed

2) Member, Study Endpoints Committee, A Phase II, Escalation Trial of Vasoflux™ in Patients Undergoing Thrombolysis with Streptokinase for Acute Myocardial Infarction, Protocol CLN-P-V18-07001, Parexel International Corporation,1998, (multicenter, international, RCT). Status: closed

3) Member, Safety Endpoint Evaluation Committee, A Phase III, Single-Blind Controlled Study to Evaluate the Clinical Effects of a Hemoglobin-based Oxygen Carrier (HBOC-210) Given as a Transfusion Alternative in Patients Undergoing Orthopedic Surgery. (Protocol HEM-0115), Biopure Corporation with Quintiles, Inc., Clinical Event and Adjudication Services, 2000-2001. (multicenter, international, RCT). Status: closed

4) Member, Critical Endpoints Committee, Cerivastatin Heart Outcomes in Renal Disease: Understanding Survival (C.H.O.R.U.S.), Barry Brenner, MD and William F. Keane, MD, Co-Principal Investigators, Bayer Inc., 2000-2003 (multicenter, international, RCT). Status: study terminated early due to drug withdrawal from market

5) Member, Clinical Events Classification Committee, Correction of Hemoglobin and Outcomes in Renal Insufficiency (CHOIR), Ajay Singh, MD, Donal Reddan, MBBS, Principal Investigators, Ortho Biotech Inc., 2001-2004 (multicenter, international, RCT). Status: closed

6) Member, Critical Endpoint Committee, A Randomised, Double-blind, Parallel Group, Phase 3, Efficacy and Safety Study of AZD6140 (Ticagrelor) Compared with Clopidogrel for Prevention of Vascular Events in Patients with Non-ST or ST Elevation Acute Coronary Syndromes (ACS) [PLATO – A Study of PLATelet inhibition and Patient Outcomes.], AstraZeneca, Inc., Duke Clinical Research Institute, 2008, status: closed

7) Chair, Clinical Endpoints Committee, Alere San Diego, Inc, Alere Prospective Blinded Study of a Novel Troponin Assay (PEARL), status: closed 2015

8) Chair, Adjudication Committee, Myeloperoxidase In the Diagnosis of Acute coronary Syndromes (MIDAS) study, Alere, Inc., status: closed 2012

9) Independent Endpoint Adjudicator, BioPorto Diagnostics, The NGAL test as an aid for the Diagnosis of AKI in an Intensive Care Population, Code of the Study: KLIN 12-005, status closed, 2015

10) Independent Endpoint Adjudicator, Ischemix, Inc., Safety and Efficacy of CMX-2043 for Protection of the Heart and Kidneys in Subjects Undergoing Coronary Angiography (CARIN), status: closed 2016

11) Chair, Data Adjudication Committee, Estimating versus Measuring Plasma Volume and Kidney Function in Acute Decompensated Congestive Heart Failure, Eudra-CT Number 2018-002638-18, Sponsor: Charite-Unversitatsmedizin Berlin, FAST Biomedical, Inc, 2018-present

Overall Study Responsibilities: Data Safety Monitoring Committees

1) Member, External Advisory Committee/Data Safety Monitoring Board, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Polycystic Kidney Disease (PKD) Clinical Trials Network HALT-PKD Trial, Robert Schrier, MD, Principal Investigator, Committee Chair: William Henrich, MD, 2004-2008, Data Safety Monitoring Board, status: closed 2014

2) Chairman, Data Safety Monitoring Committee, Clinical Trials Program CS0011-A-U301, Daiichi Sankyo Pharma Development (DSPD) CS-011, Seven Core Trials of Rivoglitazone in Type 2 Diabetes: 1) A 26-week placebo-controlled trial of 1.0 and 1.5 mg rivoglitazone vs. 45 mg pioglitazone, as monotherapy in type 2 diabetics (CS0011-A-U301); 2) A 26-week placebo-controlled trial of 0.5, 1.0 and 1.5 mg rivoglitazone vs. 15, 30 and 45 mg pioglitazone, as monotherapy in type 2 diabetics (CS0011-A-U302); 3) A 26-week placebo-controlled trial of 1.0 and 1.5 mg rivoglitazone vs. 45 mg pioglitazone, in type 2 diabetics on metformin therapy, followed by a 26-week pioglitazone-controlled continuation period (CS0011-A-U303); 4) A 26-week placebo-controlled trial of 0.5 and 1.0 rivoglitazone vs. 30 mg pioglitazone, in type 2 diabetics on sulfonylureas therapy, followed by a 26-week pioglitazone-controlled continuation period (CS0011-A-U304); 5) A 26-week placebo-controlled trial of 0.5 and 1.0 mg rivoglitazone vs. 15 mg pioglitazone in type 2 diabetics on insulin therapy (CS0011-A-U305); 6) A long-term (12-24 months) randomized, general efficacy and safety study of rivoglitazone vs. pioglitazone, as monotherapy or add-on therapy, in type 2 diabetics (CS0011-A-U306); 7) A 26-week placebo-controlled trial of rivoglitazone and metformin, in type 2 diabetics (CS0011-A-U307), USFDA Special Protocol Assessment Agreement granted, status: closed, 2009 trials program terminated

3) Member, Data Safety Monitoring Committee, A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Cardiovascular Outcomes Following Treatment with Alogliptin in Addition to Standard of Care in Subjects with Type 2 Diabetes and Acute Coronary Syndrome SYR322_402, EXAMINE Trial Takeda Global Research and Development Center, Inc. (US) Takeda Global Research and Development Centre, Ltd. (Europe), status: 2009 trial stopped early for non-inferiority but futility on superiority outcome

4) Chair, Data Safety Monitoring Committee, Protocol D9120C00019, A randomised, double-blind, placebo controlled, multi-centre phase IIb dose finding study to assess the effect on GERD symptoms, safety and tolerability during four weeks treatment with AZD3355 in doses 60 mg, 120 mg, 180 mg and 240 mg bid as add-on treatment to a PPI in patients with GERD that are partial responders to PPI treatment, AstraZeneca, status: closed 2009, trials program terminated for safety

5) Member, Data Safety Monitoring Committee, Protocols: AMAG-FER-IDA-301, A Phase III, Randomized, Double-Blind, Placebo-Controlled Trial of Ferumoxytol for the Treatment of Iron Deficiency Anemia, Protocol: AMAG-FER-IDA-302, A Phase III, Randomized, Open-Label, Active Controlled Trial Comparing Ferumoxytol with Iron Sucrose for the Treatment of Iron Deficiency Anemia, Protocol: AMAG-FER-IDA-303, A Phase III, Open-Label Extension, Trial of the Safety and Efficacy of Ferumoxytol for the Episodic Treatment of Iron Deficiency Anemia, AMAG Pharmaceuticals, Inc., status: closed 2010, trial completed in 2013 without safety concerns

6) Chair, Independent Data Monitoring Committee, Protocol 402-C-0903 Bardoxolone Methyl Evaluation in Patients with Chronic Kidney Disease and Type 2 Diabetes: the Occurrence of Renal Events (BEACON), Reata Pharmaceuticals, Inc., status: trial stopped in 2012 early for cardiovascular and mortality safety concerns

7) Member, Independent Safety Council, Affymax Inc and Takeda Pharmaceutical Co., Omontys (peginesatide), status: closed, post-marketing surveillance led to voluntary drug withdrawal from market in 2013 for serious and fatal allergic reactions

8) Chair, Independent Data Monitoring Committee, AbbVie, Inc, Clinical Study Protocol M11-352 A Randomized, Multicountry, Multicenter, Double Blind, Parallel, Placebo-Controlled Study of the Effects of Atrasentan on Renal Outcomes in Subjects with Type 2 Diabetes and Nephropathy SONAR: Study Of Diabetic Nephropathy with Atrasentan, status closed 2018

9) Chair, Independent Data Monitoring Committee, AbbVie, Inc., Clinical Study Protocol M13-958 A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Trial of Multiple Dosing Regimens of ABT-719 for the Prevention of Acute Kidney Injury in Subjects Undergoing High Risk Major Surgery, status: closed 2015

10) Member, Data Monitoring Committee, Akebia Therapeutics, Inc., AKB-6548-CI-0007, Phase 2b Randomized, Double-Blind, Placebo-Controlled Study to Assess the Pharmacodynamic Response, Safety, and Tolerability to 20 Weeks of Oral Dosing of AKB-6548 in Subjects with Anemia Secondary to Chronic Kidney Disease (CKD), GFR Categories G3a-G5 (Stages 3, 4, and 5) (Pre-Dialysis), status: closed 2015

11) Member, Study Monitoring Team, Akebia Therapeutics, Inc., AKB-6548-CI-0011, Phase 2a Open-Label Study to Assess the Efficacy, Safety, and Tolerability of AKB-6548 in Subjects with Anemia Secondary to End Stage Renal Disease (ESRD), Undergoing Chronic Hemodialysis, status: closed 2016

12) Member, Data Monitoring Committee, Merck, Inc., Pfizer, Inc, Clinical Trials Program, Ertugliflozin (MK-8835/PF-04971729) Phase 2 and Phase 3 Development Program, status closed, 2012 to 2020

13) Member, Steering Committee, Medtronic, Inc., Monitoring in Dialysis, status: closed 2016

14) Member, Data Safety and Monitoring Board, St. Jude Medical, EnligHTN IV Multi-center, randomized, single-blind, sham controlled clinical investigation of renal denervation for uncontrolled hypertension, status: 2013 trial terminated before recruitment started

15) Chair, Data Safety Monitoring Board, Neumedicines, Inc., A Phase 2, Single-Dose, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of HemaMax™ (rHuIL-12) in Healthy Subjects, status: closed 2016

16) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., A Phase 2 Study of the Safety, Efficacy, and Pharmacodynamics of RTA 408 in the Treatment of Friedreich's Ataxia, 2014 to 2019, status: closed

17) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., A Phase 2 Study of the Safety, Efficacy, and Pharmacodynamics of RTA 408 in the Treatment of Mitochondrial Myopathy, 2015 to 2019, status: closed

18) Member, Patient Safety Review Committee, Reata Pharmaceuticals, Inc, A dose-ranging study of the efficacy and safety of Bardoxolone Methyl in patients with pulmonary arterial hypertension (402-C-1302), 2014 to 2018, status: closed

19) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., A Study of the Efficacy and Safety of Bardoxolone Methyl in Patients with Connective Tissue Disease-Associated Pulmonary Arterial Hypertension (CATALYST), 2016 to present, status: closed

20) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., A Phase 2/3 of Efficacy and Safety of Bardoxolone Methyl in Patients with Alport Syndrome (CARDINAL), 2017 to present, status: closed

21) Chair, Data Safety Monitoring Board, Sanfit, Inc., A double-blind, randomised, placebo-controlled study to assess the effect of SNF472 on progression of cardiovascular calcification on top of standard of care in end-stage-renal-disease (ESRD) patients on haemodialysis (HD) SNFCT2015-05, 2017 to 2019, status: closed

22) Chair, Data Monitoring Committee, Renew Research, KAI Research, A Randomized Pivotal Study of RenewTM NCP-5 for the Treatment of Mild Cognitive Impairment due to Alzheimer's Disease or Mild Dementia of the Alzheimer's Type, 2018 to present, status: closed

23) Chair, Data Safety Monitoring Committee, Sanofi, Inc, Multicenter, randomized, double-blind, placebo-controlled two stage study to characterize the efficacy, safety, tolerability and pharmacokinetics of GZ/SAR402671 in patients at risk of rapidly progressive Autosomal

Dominant Polycystic Kidney Disease (ADPKD) STUDY NUMBER: EFC15392 STUDY NAME: SAVE-PKD COMPOUND: GZ/SAR402671, 2018 to present, status: open

24) Chair, Data Safety Monitoring Board, National Institutes of Health, National Heart, Lung and Blood Institute R34 NHLBI Clinical Trial Pilot Studies (R34) Reducing Arrhythmia in Dialysis by Adjusting the Rx Electrolytes/Ultrafiltration (RADAR), David Charytan, MD, PI, 2019 to present, status: open

25) Chair, Data Safety Monitoring Board, GZ402671 EFC15392 Multicenter, randomized, double-blind, placebo-controlled two stage study to characterize the efficacy, safety, tolerability and pharmacokinetics of GZ/SAR402671 in patients at risk of rapidly progressive Autosomal Dominant Polycystic Kidney Disease (ADPKD), Sanofi, status: open

26) Chair, Data Safety Monitoring Board, MEDI3506, Trials Portfolio, D9182C00001 A Phase 2 Randomized, Double-blinded, Placebo-controlled Study to Evaluate the Efficacy and Safety of MEDI3506 in Adult Subjects with Moderate-to-severe Atopic Dermatitis; D9181C00001 A Phase II, Randomised, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of MEDI3506 in Adult Participants with Uncontrolled Moderate-to-severe Asthma; D9180C00002 A Phase II, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy, Safety and Tolerability of MEDI3506 in Participants with Moderate to Severe Chronic Obstructive Pulmonary Disease and Chronic Bronchitis (FRONTIER 4); D9183C00001 A Phase 2b Randomized, Double-blind, Placebo-controlled, Study to Evaluate the Efficacy and Safety of MEDI3506 in Subjects with Diabetic Kidney Disease, Axio Inc, A Cytel Company, status: open

GRANT AWARDS

Original Research Grants

G1) London JF (PI), Bis KG, Juni JE, Wilke N, DiCarli MF, Shetty AN, **McCullough PA**, Timmis GC. Magnetic Resonance vs. Positron Emission Tomography for the Detection of Myocardial Viability. Bracco Diagnostics Inc./SCA&I Grant, $25,000 (WBH RC-453), 1997-98. Additional WBH Research Institute Mini-grant, $5,000 (WBH Grant #RC-748). Level of involvement: author of the variable definitions, endpoints, and data analysis sections, 0% FTE. Status: closed 1998

G2) **McCullough PA** (PI), Shah S, Noor H, Marks KR, McCabe KB, Zong L, McCord J, Khoury N, Ulcickas-Yood M, Ward RE. Diagnostic Accuracy of an Emergency Department Clinical Decision Unit in the Evaluation of Chest Pain. HFHS Small Projects Fund $10,000 (HFHS Grant #A30785), 0% FTE. Status: closed 1997

G3) Keteyian SJ (Co-PI), **McCullough PA** (Co-PI), Brawner CA, Rosman HS, Stein P, Weaver WD. A Prospective Study of Case Identification and Triage of Patients Eligible for Cardiac

Rehabilitation. Merck & Co., U.S. Human Health, $30,000 (HFHS Grant #E18037), 3% FTE. Status: closed 1998

G4) **McCullough PA.** Novel Methods for Identifying High-Risk Patients for Subsequent Cardiovascular Events. Merck & Co., U.S. Human Health, $20,000 (HFHS Grant #M1060), 0% FTE. Status: closed 1998

G5) **McCullough PA.** Cardiovascular Informatics Development Award. Pfizer, Inc., $10,000 (HFHS Grant #E60022), 0% FTE. Status: closed 1998

G6) **McCullough PA,** Yee J, Soman S, Sallach J, Borzak S, Foreback C, Monaghan K, Tisdale JE, Bailey E, Bola P, Chase G, Marks KR, Weaver WD. A Prospective Dose-Ranging Trial of Folic Acid to Reduce Total Homocyst(e)ine Levels in Patients with End-Stage Renal Disease Undergoing Hemodialysis. HFHS Project Development Fund $10,000 (HFHS Grant #A20003), 0% FTE. Status: closed 1999

G7) **McCullough PA.** NuStep Recumbent Cross Trainer Product Development Pilot Study, NuStep, Inc., (single center, prospective pilot study), $12,500.00, (WBH Grant #RC- 08-94847). Status: closed 2005

G8) **McCullough PA,** Secondary Analyses from the PRINCE Trial, (single center data analysis), $20,000, PLC Medical, Inc., (WBH #RC 08-94851) Status: closed 2005

G9) **McCullough PA**, Sullivan RA. A Systematic Review of Vascular Calcification in Patients with Chronic Kidney Disease and End-Stage Renal Disease, 2002-2003, Braintree Labs, Inc., $40,000, 25% FTE (WBH Grant #RC 08-94833) Status: closed 2003

G10) Pasas SA, Davies MI, **McCullough PA.** Determination of Protein-bound Homocysteine in Human Plasma using Capillary Electrophoresis with Electrochemical Detection in Patients with Chronic Kidney Disease, 2003-2004, AHA Predoctoral Fellowship Program (Pasas), $38,000, 15% FTE (UMKC Grant #). Status: closed 2003

G11) Collins AC, Gladstone E, Robitscher JW, **McCullough PA**, Klag M, Narva A, Gilberston D for the NKF. Demonstration project: state-based screening for chronic kidney disease. Response to CDC-RFA-DP06-004, demonstration project for identifying individuals at high-risk for CKD in the US. Centers for Disease Control, $1,199,609, 12% FTE Status: closed 2007

G12) **McCullough PA**, Principal Investigator. Neutrophil Gelatinase-Associated Lipocalin (NGAL): A Novel Blood Marker for Risk of Developing Contrast-Induced Nephropathy (ENCINO). Biosite/Inovise, Inc., $229,000.00 (WBH #RC-94862), 0% FTE Status: closed 2009

G13) Agrawal V, Barnes M, **McCullough PA.** Evaluation of CKD awareness in medical residents. WBH intramural mini-grant R/C# 98662, $10,000.00, 0% FTE Status: closed 2008

G14) **McCullough PA,** overall Principal Investigator transferred to Zalesin K. FDA Investigational New Drug Exemption (INDE) #060672. A Prospective, Randomized, Placebo-Controlled, Parallel-Group, Pilot Trial of Paricalcitol in the Treatment of Hyperparathyroidism in Patients after Roux-en-Y Gastric Bypass Surgery with Chronic Kidney Disease, Abbott Laboratories, Inc., $496,600.00 (WBH #RC-90290), 0% FTE Status: closed 2009

G15) **McCullough PA**, overall Principal Investigator transferred to Miller WM, FDA INDE #107750. Investigator Initiated Study. A Prospective, Double-Blind, Randomized, Parallel Group, Placebo-Controlled Trial of Aliskiren versus Placebo in Non-Diabetic, Normotensive Obese Patients with Microalbuminuria, Novartis, Inc., $339,400.00 (WBH #RC-90345), Status: closed 2010

G16) **McCullough PA,** overall Principal Investigator. Investigator Initiated Study, FDA Investigational New Drug (IND) #74707. A Phase 2, randomized, double-blind, placebo-controlled trial, to assess the efficacy and safety of deferiprone in the reduction of markers of contrast-induced acute oxidative kidney injury. Cormedix, Inc, $857,745 (includes $101,442 for Beaumont Research Coordinating Center). Study centers included Providence Hospital and Medical Center Southfield, St. John Hospital and Medical Center, Detroit, Northern Michigan Hospitals, Petoskey, MI, St. Vincent's Hospital, Indianapolis, IN, Fairfield Cardiac Cath Labs, LLC, Fairfield, OH, Oklahoma Heart Hospital, Oklahoma City, OK, Ohio Health Research Institute, Columbus, OH, Mercy St. Vincent Hospital, Toledo, OH, Status: closed 2011

G17) **McCullough PA,** overall study Principal Investigator, A Prospective Randomized Parallel-Group Controlled Trial of Multiple Blood Biomarkers in the Personalized Management of Chronic Heart Failure, Baylor IRB 014-252, Baylor Foundation, 2014, $78,639.20, status: closed 2016.

G18) **McCullough PA**, overall study Principal Investigator, Baylor Hypertrophic Cardiomyopathy Program Development Project: Time-resolved, 3D phase contrast magnetic resonance imaging (MRI) (4D Flow) and Advanced Strain Rate Echocardiography in Patients with Hypertrophic Cardiomyopathy, Baylor IRB 014-175, Baylor Foundation, 2014, $100,000.00, status: open

G19) **McCullough PA,** overall study Principal Investigator, Preventive Cardiology Registry: Role of Proprotein Convertase Subtilisin/kexin type 9 (PCSK9) and Other Catabolic Determinants in Hypercholesterolemia in Patients with Suspected Heterozygous Familial Hypercholesterolemia Baylor IRB 014-122, Baylor Foundation, $3,100.00, status: closed 2014

G20) **McCullough PA,** overall study Principal Investigator and Study Chairman, Investigator Initiated Trial, "A Prospective, Double-blind, Placebo Controlled, Parallel Group,

Randomized Trial of Extended Release Exenatide versus Placebo in Diabetic Patients with Type 4 Cardiorenal Syndrome: EXTEND-CRS", D5551L00004/ISSEXEN0013, FDA IND 123200, Baylor IRB 014-149, AstraZeneca, 2014, $1,597,901.93, status: open

G21) **McCullough PA**, overall study Principal Investigator, Iso-osmolar Contrast and the Timing of Coronary Angiography in the Multivariate Risk for Cardiac Surgery Associated with Acute Kidney Injury and Major Adverse Renal and Cardiac Events (MARCE), Baylor IRB 014-096, GE Healthcare, Inc, 2015, $145,885.00, status open

G22) **McCullough PA**, overall study Principal Investigator, Timing of coronary angiography and multivariate risk for cardiac surgery associated acute kidney injury and major adverse renal and cardiac events (MARCE), Baylor IRB 014-096, Baylor Foundation, $8,100.00, status: closed 2016

G23) Mendez J, **McCullough PA**, et al, co-investigator, Assessment of Multiple Blood Biomarkers in Patients with Advanced Heart Failure Undergoing Evaluation for Cardiac Transplantation and Mechanical Circulatory Support, Baylor IRB 014-300, Critical Diagnostics, Inc, $10,400.00, status: closed 2016

G24) Bottiglieri, T, **McCullough PA**, et al, co-investigator, Urinary 11dhTxB2 response to acetylsalicylic acid (aspirin) in cardiovascular disease progression and adverse outcomes, Baylor IRB 008-230, Corgenix, Inc., $99,087.00, status: closed 2016

G25) Schussler JM, Vasudevan A, **McCullough PA**, co-investigator, Clinical outcomes and metabolomic and damage associated molecular patterns of acute kidney injury in patients undergoing percutaneous coronary intervention via the radial versus femoral artery approach, Baylor IRB 014-299, Baylor Health Care System Foundation, $61,416.00, status: closed 2018

G26) Tecson K, **McCullough PA**, coinvestigator, Contribution of Chronic Kidney Disease and Acute Kidney Injury to Heart Failure Outcomes, Baylor IRB 015-296, Baylor Health Care System Foundation, $43,424.60, status: open

G27) Vasudevan A, **McCullough PA**, coinvestigator, Burden of Cardiovascular Events Follow Percutaneous Coronary Intervention, Baylor IRB 015-297, Baylor Health Care System Foundation, $40,000.00, status: closed 2018

G28) Tecson, K, **McCullough PA**, Therapeutic Intensity of Lipid Lowering Therapy in Response to Recurrent Cardiovascular Events, Baylor IRB 017-106, Amgen, Inc., $249,990.00 status: open

G29) **McCullough PA**, Principal Investigator, A Case Finding Study of Familial Chylomicronemia, Akcea Pharmaceuticals, $10,000.00, status: closed 2017

G30) **McCullough PA**, Bottiglieri T, Tecson K. Baylor Foundation $49,923.80. Identifying metabolomic profiles among genetically confirmed familial hypercholesterolemia, dyslipidemia without familial hypercholesterolemia, and healthy controls, status start-up 2019

Site Principal Investigator Contracts

G1) Jafri S, **McCullough PA**, and the WATCH Investigators. Warfarin and Antiplatelet Therapy in Chronic Heart Failure, (W.A.T.C.H.) Field Center, Veterans Administration Cooperative Studies Program and Sanofi Pharmaceuticals, $36,000.00 (HFHS Grant #B51008) status: closed 2000

G2) Jafri S, **McCullough PA**, and the CHARM Investigators. Candesartan Cilexetil (Candesartan) in Heart Failure Assessment of Reduction in Mortality and Morbidity (C.H.A.R.M.) Field Center, 1999-2000, Astra Pharmaceuticals, $56,000.00 (HFHS Grant #E09045) status: closed 2000

G3) Schuger C, **McCullough PA**, and the MADIT Investigators. Multicenter Automatic Defibrillator Implantation Trial II (M.A.D.I.T.-II), Guidant Corporation/Cardiac Pacemakers (CPI), $96,000 (HFHS Grant #G10087) status: closed 2000

G4) Schuger C, **McCullough PA**, and the MIRACLE Investigators. Multicenter InSync Randomized Clinical Evaluation (M.I.R.A.C.L.E.), Medtronic Inc., $195,000, (HFHS Grant #G12006) status: closed 2000

G5) **McCullough PA,** Shetty A, Soman S and the CHORUS Investigators. Cerivastatin Heart Outcomes in Renal Disease: Understanding Survival (C.H.O.R.U.S.), Barry Brenner, MD and William F. Keane, MD, Co-Principal Investigators, Bayer Inc., 2000-2003 (RCT), Clinical Site Contract, Bayer Pharmaceuticals, $266,875.00 10% FTE (HFHS Grant #E05046) status: closed 2000

G6) **McCullough PA,** Manley HJ and the CHORUS Investigators. Cerivastatin Heart Outcomes in Renal Disease: Understanding Survival (C.H.O.R.U.S.), Barry Brenner, MD and William F. Keane, MD, Co-Principal Investigators, Bayer Inc., 2000-2003 (RCT), Clinical Site Contract, Bayer Pharmaceuticals, $279,000 10% FTE (UMKC Grant #E05046) status: closed 2001

G7) Nowak R, McCord J, **McCullough PA** and the BNP Investigators. Breathing Not Properly Study (B.N.P. Multinational Study), Alan Maisel, MD, and Peter A. McCullough, MD, MPH, Co-Principal Investigators, Biosite Diagnostics, Inc., (prospective cohort study) Field Center Contract, Biosite Diagnostics, Inc., $180,000.00 (HFHS Site), $500,000.00, 0% FTE (HFHS Grant #E03005) status: closed 2001

G8) Ehrman JK, **McCullough PA.** A Prospective Randomized Trial of a Personal Health Assistant in the Secondary Prevention of Heart Disease. Merck, Inc., $220,961.00, 7% FTE (HFHS Grant #E41010) status: closed 2002

G9) **McCullough PA** and the CORC Investigators. Kansas City Cardiomyopathy Questionnaire Interpretability Study, John A. Spertus, MD, MPH, Principal Investigator, Cardiovascular Outcomes Research Consortium (C.O.R.C.), 2001 (multicenter, U.S., prospective cohort study), $21,400.00, status: closed 2002

G10) **McCullough PA**, Rutherford BD, and the OAT Investigators. Occluded Artery Trial, Judith Hochman, MD, and Gervasio Lamas, MD, Co-Principal Investigators, National Institutes of Health, National Heart Lung and Blood Institute, $54,000.00. 0% FTE (UMKC Grant #K531122) status: closed 2002

G11) **McCullough PA** site Principal Investigator and National Executive Committee Member. Rapid Emergency Department Heart Failure Outpatient Trial, Biosite Diagnostics, $21,000. 0% FTE (UMKC Grant #K531130) status: closed 2002

G12) **McCullough PA** site Principal Investigator. African-American Heart Failure Trial (AHEFT). A Placebo-Controlled Trial of BiDil added to Standard Therapy in African American Patients with Heart Failure, NitroMed, Inc., $20,000.00 (UMKC Proposal #9722, TMC Grant #261231) status: closed 2002

G13) **McCullough PA** and the IMAGING Investigators for Cardiology Clinical Studies, LLC. Investigation of Myocardial Gated SPECT Imaging as Initial Strategy in Heart Failure: The IMAGING in Heart Failure Trial, Dupont Pharmaceuticals Inc., $20,000.00 (UMKC Proposal #9825, UMKC Grant #KG001278) status: closed 2002

G14) **McCullough PA**, site Principal Investigator, and Ad Hoc Executive Committee Member. Heart Failure and a Controlled Trial Investigating Outcomes of Exercise Training. National Institutes of Health, National Heart, Lung, and Blood Institute, subcontracted through the Duke Clinical Research Institute, $665,000, (NIH Grant #1 U01 HL63747 01A2, WBH Grant # RC 08-94837, Site #301) status: closed 2005

G15) **McCullough PA**, site Principal Investigator, and Executive Committee Member. Protocol No. 704.351 Evaluation of Synergy between Natrecor and Furosemide on Renal and Neurohormone Responses in Chronic Heart Failure: A Phase IV Study, Scios Inc., 2003 (multicenter, U.S., randomized cross-over trial), $105,447.50, (WBH Grant # RC 08-94836) status: closed 2005

G16) **McCullough PA,** site Principal Investigator and National Co-Principal Investigator. Protocol No. CCIB002FUS12. A Multicenter, Double-blind, Randomized, Parallel Group Study to Evaluate the Effects of Lotrel and Lotensin HCT on Microalbuminuria in Mild to

Moderate Hypertensive Subjects with Type 2 Diabetes Mellitus, Novartis Inc., (multicenter, U.S., randomized trial), $63,649.90, (WBH Grant #RC 08-94838) status: closed 2006

G17) **McCullough PA,** and the ACCOMPLISH Investigators. Protocol No. CCIB002.12301. Avoiding Cardiovascular Events through Combination Therapy in Patients Living with Systolic Hypertension, Novartis, Inc., 2003 (multicenter, multinational, randomized trial) $159,241.00, (WBH Grant #RC 08-94844) status: closed 2006

G18) **McCullough PA**, site Principal Investigator. Efficacy of Vasopressin Antagonism in Heart Failure: Outcome Study with Tolvaptan, Protocol #156-03-236, IND #50,533, Otsuka Maryland Research Institute, (multicenter, international, randomized trial), $210,750.00, (WBH Grant #RC 08-94842 changed to #RC 08-94849) status: closed 2005

G19) **McCullough PA,** site Principal Investigator. A Multicenter, Double-Blind, Randomized, Parallel Group, 6-week Study to Evaluate the Efficacy and Safety of Ezetimibe/Simvastatin Combination versus Atorvastatin in Patients with Hypercholesterolemia, Protocol #051/EZT544, Merck, Inc., (multicenter, U.S., randomized trial), $18,840.00, (WBH Grant #RC 08-94843) status: closed 2006

G20) **McCullough PA,** site Principal Investigator, A multicenter, double-bind randomized, parallel-group study to compare the effect of 24 weeks treatment with LAF237 (50 mg qd or bid) to placebo as add-on therapy in patients with type 2 diabetes inadequately controlled with metformin monotherapy. Novartis Pharmaceuticals, Inc., (multicenter, U.S., randomized trial), $30,700.00, (WBH Grant #RC 08-94845) status: closed 2007

G21) **McCullough PA,** site Principal Investigator. A multicenter, double-bind randomized, parallel-group study to compare the effect of 24 weeks treatment with LAF237 (50 mg qd or bid) to placebo as add-on therapy to pioglitazone 45 mg qd in patients with type 2 diabetes inadequately controlled with thiazolidinediones monotherapy. Novartis Pharmaceuticals, Inc., (multicenter, U.S., phase III randomized trial) $30,700.00, (WBH Grant #RC 08-94846) status: closed 2006

G22) **McCullough PA,** site Principal Investigator. An 8-week, randomized, double-blind, parallel group, multicenter placebo and active controlled disease escalation study to evaluate the safety and efficacy of aliskiren in patients with hypertension, $47,100.00 (WBH #RC 08- 94852) status: closed 2007

G23) **McCullough PA,** site Principal Investigator. A randomized, double-blind study to compare the durability of glucose lowering and preservation of pancreatic beta-cell function of rosiglitazone monotherapy compared to metformin or glyburide/glibenclamide in patients with drug naïve, recently diagnosed type 2 diabetes, $140,100.00, Novartis Pharmaceuticals (WBH #RC 08-94849) status: closed 2008

G24) **McCullough PA,** site Principal Investigator. A multicenter, randomized, double-blind factorial study of the co-administration of MK-0431 and metformin in patients with type 2 diabetes who have inadequate glycemic control, $36,735.00, Merck Research Laboratories (WBH #RC 08-94853) status: closed 2008

G25) **McCullough PA**, site Principal Investigator. Multicenter, Randomized, Double-Blind Study to Evaluate the Efficacy & Safety of Ezetimibe/Simvastatin and Niacin Co-Administered in Patients with type IIa or Type IIb Hyperlipidemia, $46,960.00, Merck Research Laboratories, MRK-091, (WBH #RC 08-94854) status: closed 2008

G26) **McCullough PA,** site Principal Investigator. A Multi-Center, Randomized, Double-Blind, factorial Design study to evaluate the lipid-altering efficacy & safety of MK-0524B Combination Tablet in Patients with Primary Hypercholesterolemia or Mixed Hyperlipidemia $40,849.00, Merck Research Laboratories, MRK-022. (WBH #RC 08-94855) status: closed 2007

G27) **McCullough PA,** site investigator. An 8-week, multicenter, randomized, double-blind, parallel-group study to evaluate the efficacy and safety of the combination of valsartan/HCTZ/amlodipine compared to valsartan/HCTZ, valsartan/amlodipine, and HCTZ/amlodipine in patients with moderate to severe hypertension, $43,500.00, Novartis Pharmaceuticals (WBH #RC 08-94857) status: closed 2007

G28) **McCullough PA,** site Principal Investigator. A multicenter randomized, double-blind parallel arm, 6-week study to evaluate the efficacy and safety of ezetimibe/simvastatin versus atorvastatin in patients with metabolic syndrome and hypercholesterolemia at high risk for coronary heart disease, $32,010.00. Merck Research Laboratories (WBH #RC 08-94861) status: closed 2008

G29) **McCullough PA,** site Principal Investigator. A multicenter, randomized, double-blind study to evaluate the safety and efficacy of the initial therapy with coadministration of sitagliptin and pioglitazone in patients with type 2 diabetes mellitus, $24,036.00, Merck Research Laboratories, MRK-064 (WBH #RC 08-94860) status: closed 2008

G30) Dixon, SD, site PI, **McCullough PA**, Multinational Executive Committee. RENAL GUARD Pilot Trial. PLC Medical Systems, $37,610.00 (WBH #RC- 90771) status: closed 2008

G31) **McCullough, PA**, site Principal Investigator, A multi-center, randomized, double-blind, placebo and active controlled, parallel group, dose range study to evaluate the efficacy and safety of LCZ696 comparatively to valsartan, and to evaluate AHU377 to placebo after 8-week treatment in patients with essential hypertension. Novartis, Inc., $31,965.28. (WBH #RC-94863) status: closed 2008

G32) **McCullough PA,** site Principal Investigator. Paricalcitol capsules benefits in renal failure induced cardiac morbidity in subjects with chronic kidney disease stage 3b/4,

(PRIMO Abbott Laboratories, ABT-M-10-030, $157,992.00, (WBH #RC-94864) status: closed 2008

G33) **McCullough PA,** site Principal Investigator. A randomized, double-blind, parallel group study to evaluate the effects of high-dose statin therapy on fluorodeoxyglucose (FDG) uptake in arteries of patients with atherosclerotic vascular disease. Merck Research Laboratories, MRK-081, $86,994.00 (WBH #RC 08-90223) status: closed 2008

G34) **McCullough PA,** site Principal Investigator. Patient registry for the Liposorber LA-15 system. Kaneka, Inc., $7,515.00, (WBH #RC-90877) status: closed 2009

G35) **McCullough PA,** site Principal Investigator. A 30-week multicenter, randomized, double-blind. Parallel-group study of the combination of ABT-335 and Rosuvastatin compared to rosuvastatin monotherapy in dyslipidemic subjects with stage 3 chronic kidney disease, Abbott M10-313, $128,544.00, (WBH #RC-90212) status: closed 2009

G36) **McCullough PA,** site Principal Investigator. A multicenter, randomized open label, active-comparator controlled study to assess the efficacy, safety, and tolerability of taspoglutide compared to exenatide in patients with type 2 diabetes mellitus inadequately controlled with metformin, thiazolidinedione, or a combination of both, Roche BC 21625, $72,012.50, (WBC #RC-90245) status: closed 2010

G37) **McCullough PA,** site Principal Investigator. A multicenter, randomized double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of taspoglutide compared to placebo in obese patients with type 2 diabetes mellitus inadequately controlled with metformin monotherapy, Roche BC 22092, $38,387.50, (WBH #RC-90258) status: closed 2009

G38) **McCullough PA,** site Principal Investigator. A safety and efficacy trial evaluating the use of apixaban for the extended treatment of deep vein thrombosis and pulmonary embolism, Bristol Myers Squibb-Pfizer CV185057, $173,750.00, (WBH #RC-90288) status: closed 2009

G39) **McCullough PA,** site Principal Investigator. A phase 3, active (warfarin) controlled, randomized, double-blind, parallel arm study to evaluate efficacy and safety of apixaban in preventing stroke and systemic embolism in subjects with nonvalvular atrial fibrillation, Bristol Myers Squibb-Pfizer CV1805030, $173,750.00, (WBH #RC-90275) status: 2009

G40) **McCullough PA,** site Principal Investigator. Treatment of Preserved Cardiac Function Heart Failure with an Aldosterone Antagonist Trial (TOPCAT), National Institutes of Health, National Heart, Lung, and Blood Institute, subcontracted through the New England Research Institutes, Inc., $86,250.00, (WBH #RC-90267) status: closed 2010

G41) **McCullough PA,** site Principal Investigator. An 8-week, randomized, double-blind, parallel group, multicenter, forced titration study to evaluate the efficacy and safety of aliskiren plus HCTZ verus aliskiren monotherapy in metabolic syndrome patients with stage 2 hypertension, Novartis, Inc., $107,362.44 (WBH #RC-90277) status: closed 2009

G42) **McCullough PA**, site Principal Investigator, Astute SAPPHIRE AST-111, Evaluation of Novel Biomarkers from Acutely Ill Patients at Risk for Acute Kidney Injury, Astute Medical, Inc, San Diego, CA, $23,195.50 status: closed 2012

G43) **McCullough PA**, site Principal Investigator, protocol number 156-10-292 titled "An Observational Prospective Registry to Identify Demographic and Clinical Characteristics of Patients Hospitalized with Euvolemic and Hypervolemic Hyponatremia and Assess the Comparative Effectiveness of Available Treatments and the Impact on Resource Utilization. Otsuka Inc., $21,262.60 status: initial contract fulfilled, reopened under extension and registry completed in 2013

G44) **McCullough PA**, site Principal Investigator, PROspective Multicenter Imaging Study for Evaluation of Chest Pain (PROMISE) Study, National Heart, Lung, and Blood Institute (NHLBI), Pamela Douglas, MD, Principal Investigator Clinical Coordinating Center, Duke Clinical Research Institute, $17,000.00 status: closed 2012

G45) **McCullough PA**, site Principal Investigator, ACZ885M/Canakinumab Clinical Trial Protocol CACZ885M2301 A randomized, double-blind, placebo-controlled, event-driven trial of quarterly subcutaneous canakinumab in the prevention of recurrent cardiovascular events among stable post-myocardial infarction patients with elevated hsCRP. Novartis, Inc., 2011 $279,223.00 status: closed 2015

G46) **McCullough PA**, site Principal Investigator, AN-CVD2233 Evaluation of the Safety and Efficacy of Short-term A-002 (Varespladib) Treatment in Subjects with Acute Coronary Syndromes (VISTA-16) Anthera Pharmaceuticals, Inc., 2011 $72,600.00 status: closed 2011

G47) **McCullough PA**, site Principal Investigator, BC22140A Cardiovascular outcomes study to evaluate the potential of aleglitazar to reduce cardiovascular risk in patients with a recent acute coronary syndrome (ACS) event and type 2 diabetes mellitus (T2D), F. Hoffmann-La Roche Ltd, $307,500.00 status: closed 2012

G48) **McCullough PA**, site Principal Investigator, A Double-blind, Randomized, Placebo-controlled, Multicenter Study (Phase 2) to Evaluate the Safety and Efficacy of IV Infusion Treatment with Omecamtiv Mecarbil in Subjects with Left Ventricular Systolic Dysfunction Hospitalized for Acute Heart Failure (Protocol 20100754), Amgen, Inc, 253,464.00 status: closed 2012

G49) **McCullough PA**, site Principal Investigator, MB102-073 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and

Efficacy of Dapagliflozin in Subjects with Type 2 Diabetes with Inadequately Controlled Hypertension on an Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB), Bristol-Myers Squibb Research and Development, 2011 $34,115.00 status: closed 2012

G50) **McCullough PA,** site Principal Investigator, MB102-077 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Dapagliflozin in Subjects with Type 2 Diabetes with inadequately controlled hypertension treated with an Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) and an additional Antihypertensive medication, Bristol-Myers Squibb Research and Development, $34,115.00 status: closed 2011

G51) **McCullough PA**, site Principal Investigator, ABT M11350 RADAR: Reducing Residual Albuminuria in Subjects with Diabetes and Nephropathy with AtRasentan – A Phase 2b, Prospective, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate Safety and Efficacy, Abbott Laboratories, $188,377.00 status: closed 2012

G52) **McCullough PA**, site Principal Investigator, PEGASUS TIMI 54 trial, A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Prevention of Thrombotic Events with Ticagrelor Compared to Placebo on a Background of Acetyl Salicylic Acid (ASA) Therapy in Patients with History of Myocardial Infarction, AstraZeneca, 2011 $98,530.00 status: transferred to PI Marcel Zughaib, MD

G53) **McCullough PA**, site Principal Investigator, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease AMG 145 Amgen Protocol Number 20110118 EudraCT number 2012-001398-97, Amgen, Inc., $1,732,062.80 status: closed 2016

G54) **McCullough PA,** site Principal Investigator, A single-blind, multi-site trial of the dietary supplement anatabine (RCP006) to determine the effects on peripheral markers of inflammation in patients with elevated levels of C-reactive protein (CRP). Roskamp Institute Protocol Number RI-11-01, $6700.00 status: closed 2012

G55) **McCullough PA**, site Principal Investigator, Long-term safety and tolerability of REGN727/SAR236553 in high cardiovascular risk patients with hypercholesterolemia not adequately controlled with their lipid modifying therapy: a randomized, double-blind, placebo-controlled study LTS11717 Sanofi Aventis, $252,000.00 status: closed 2013

G56) **McCullough PA**, site Principal Investigator, Assessment of Clinical Effects of Cholesteryl Ester Transfer Protein Inhibition with Evacetrapib in Patients at a High Risk for Vascular Outcomes – the ACCELERATE Study, protocol I1V-MC-EIAN, Eli Lilly, $421,202.00 status: closed 2014

G57) **McCullough PA,** site Principal Investigator, AEGR-733-025, LOWER: Lomitapide Observational Worldwide Evaluation Registry, Aegerion, Inc., 2014, $23,478.00 status: open

G58) **McCullough PA**, site Principal Investigator, The Evaluation Of PF-04950615 (RN316), In Reducing the Occurrence of Major Cardiovascular Events in High Risk Subjects (SPIRE-1), Pfizer, Inc., $145,343.90 status: closed 2016

G59) **McCullough PA**, site Principal Investigator, The Evaluation Of PF-04950615 (RN316) In Reducing the Occurrence of Major Cardiovascular Events in High Risk Subjects (SPIRE-2), Pfizer, Inc., $145,343.90 status: closed 2016

G60) **McCullough PA,** site Principal Investigator, Long Term Observational Study in Patients with Homozygous Familial Hypercholesterolemia Treated with Kynamaro™, Genzyme-Sanofi, Inc., $61,260.00 status: closed 2018

G61) **McCullough PA**, site Principal Investigator, CUP14366, Alirocumab (SAR236553) Expanded Access Program for the Treatment of Severe Hypercholesteremia Not Controlled with Maximal Tolerated Dose of Lipid Lowering Therapy Administered According to Standard of Care, Sanofi-Regeneron, Inc., 2015 $8,500.00 status: closed 2015

G62) **McCullough PA,** site Principal Investigator, Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE), Patient-Centered Outcomes Research Institute, 2015 $29,400.00 status: open

G63) **McCullough PA**, site Principal Investigator, Assessment of Heart Failure using Condition-Specific Impact Assessments (PROMIS), Patient-Centered Outcomes Research Institute, 2015 $81,840.00 status: 2017 status: closed

G64) **McCullough PA**, site Principal Investigator, A Randomized Parallel-Group, Placebo-Controlled, Double-Blind, Event-Driven, Multi-Center Pivotal Phase III Clinical Outcome Trial of Efficacy and Safety of the Oral sGC Stimulator Vericiguat in Subjects With Heart Failure With Reduced Ejection Fraction (HFrEF) - VerICiguaT Global Study in Subjects With Heart Failure With Reduced Ejection Fraction (VICTORIA), Merck, Inc, 2017 $878,163.90 status: closed

G65) **McCullough PA**, site Principal Investigator, A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with preserved Ejection Fraction (HFpEF), EMPEROR-PRESERVED, Boehringer-Ingleheim, 2017 $170,099.00, status: open

G66) **McCullough PA**, site Principal Investigator, A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in

patients with chronic Heart Failure with preserved Ejection Fraction (HFpEF), EMPEROR-REDUCED, Boehringer-Ingleheim, 2017 $170,099.00, status: open

G67) Schiffmann R, **McCullough PA** Sub-Investigator, 014-097 PB-102-F03 (Sponsor - Protalix - PRX-102 1mg/kg q 2 weeks) A Multi Center Extension Study of PRX-102 Administered by Intravenous Infusions Every 2 Weeks for 60 Months to Adult Fabry Patients, status: open

G68) Schiffmann R, **McCullough PA** Sub-Investigator, 014-288 AT1001-042 (Sponsor - Amicus - oral drug - chaperone) An Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Migalastat Hydrochloride Monotherapy in Subjects with Fabry Disease, status: closed.

G69) Schiffmann R, **McCullough PA** Sub-Investigator, 016-153 PB-102-F20 (Sponsor - Protalix - BLINDED - ERT PRX-102 or Fabrazyme 1mg/kg q 2 weeks) A Randomized, Double blind, Active Control Study of the Safety and Efficacy of PRX-102 compared to Agalsidase Beta on Renal Function in Patients with Fabry Disease Previously Treated with Agalsidase Beta – Study Number PB-102-F20, status: open

G70) Schiffmann R, **McCullough PA** Sub-Investigator, 017-189 PB-102-F50 (Sponsor - Protalix - PRX-102 infusion - 2mg/kg monthly) A Phase 3, Open Label, Switch Over Study to Assess the Safety, Efficacy and Pharmacokinetics of pengunigalsidase alfa (PRX-102) 2 mg/kg Administered by Intravenous Infusion Every 4 Weeks for 52 weeks in Patients with Fabry Disease Currently Treated with Enzyme Replacement Therapy: Fabrazyme® (agalsidase beta) or Replagal (agalsidase alfa), status: open

G71) Schiffmann R, **McCullough PA** 018-150 MODIFY (Sponsor - Idorsia - oral drug - substrate reduction) A multicenter, double-blind, randomized, placebo controlled, parallel-group study to determine the efficacy and safety of lucerastat oral monotherapy in adult subjects with Fabry disease, status: open

G72) **McCullough PA**, site Principal Investigator, A Randomized, Double-blind, Placebo-controlled, Parallel-group Multicenter Study to Evaluate the Effects of Sotagliflozin on Clinical Outcomes in Hemodynamically Stable Patients with Type 2 Diabetes Post Worsening Heart Failure (SAR 439954), Sanofi US Services, Inc, $214,600.00, 2019, status: open

G73) **McCullough PA**, site Sub-Investigator, A Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Safety and Efficacy of Alirocumab in Patients with Homozygous Familial Hypercholesterolemia (R727-CL-1628), Regeneron Pharmaceuticals, Inc, $143,503.00, 2019, status: closed

G74) **McCullough PA**, site Sub-Investigator, A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Evinacumab in

Patients with Homozygous Familial Hypercholesterolemia (R1500-CL-1629) Regeneron Pharmaceuticals, Inc, $143,503.00, 2019, status: closed

G75) **McCullough PA**, site Sub-Investigator, An Open-Label Study to Evaluate the Long-Term Efficacy and Safety of Evinacumab in Patients with Homozygous Familial Hypercholesterolemia (R1500-CL-1719) Regeneron Pharmaceuticals, Inc, $65,317.44, 2019, status: open

G76) Bottiglieri T, Tecson K, **McCullough PA**, Identifying metabolomic profiles among genetically confirmed familial hypercholesterolemia, dyslipidemia without familial hypercholesterolemia, and healthy controls, Baylor Health Care System Foundation, $49,293.80, 2020 status: open

G77) **McCullough PA**, Wheelan KE. BSWRI—Overall Principal Investigator, 001 A prospective clinical study of hydroxychloroquine in the prevention of SARS-COV-2 (COVID-19) infection in health care workers after high-risk exposures, FDA IND 149293, Baylor Health Care System Foundation, $506,506.00, 2020 status: open

G78) **McCullough PA**, Site Investigator, 4D-310-C001 entitled "An Open-label, Phase 1/2 Trial of Gene Therapy 4D-310 in Adult Males with Fabry Disease" 4D Molecular Therapeutics, Inc, $101,210.85, 2020 status: open

G79) **McCullough PA,** Site Investigator, TQJ230, Assessing the Impact of Lipoprotein (a) Lowering With TQJ230 on Major Cardiovascular Events in Patients With CVD (Lp(a)HORIZON) Novartis Pharmaceuticals Corporation, $3,475,000.00, 2020 status open

Published Abstracts

A1) **McCullough PA**, O'Neill WW, May M, Lichtenberg A, Strzelecki M, Grines CG, Safian RD. Predictors of Acute Complications after Percutaneous Coronary Revascularization with New Devices. J Am Coll Cardiol 1994; 122-123A [oral].

A2) **McCullough PA**, O'Neill WW, Hoffman M, Glazier S, Safian RD. The "Protective Effect" of Restenosis Lesions on Angiographic Complications with New Devices. Circulation 1995;92:I-346 [poster].

A3) **McCullough PA**, Wolyn R, Rocher LL, Levin RN, O'Neill, WW. Acute Contrast Nephropathy After Coronary Intervention: Prediction of Dialysis and Related Mortality in the Elderly. American Journal of Geriatric Cardiology 1996;5:52 [poster].

A4) **McCullough PA**, Wolyn R, Rocher LL, Levin RN, O'Neill WW. Acute Contrast Nephropathy After Coronary Intervention: Incidence, Risk Factors, and Relationship to Mortality. J Am Coll Cardiol 1996;304-305A [oral].

A5) **McCullough PA**, Ayad O, Goldstein JA. Cost-Effectiveness Analysis of Patients Admitted with Chest Pain and Normal or Near-Normal Electrocardiograms. Cathet Cardiovasc Diag 1996;38:118 [poster].

A6) Aliabadi D, **McCullough PA**, Kaplan B, Grines CL, Safian RD, Pica M, O'Neill WW, Goldstein JA. A Novel Mobile Fluoroscopic Imaging System for Rapid Bedside Coronary Angiography. Cathet Cardiovasc Diag 1996;38:111 [oral].

A7) Thompson RJ, **McCullough PA**, Kahn JK, O'Neill WW. Early Prediction of Death and Neurologic Outcome in Out-of-Hospital Sudden Death Survivors in the Emergency Department. Circulation 1996;94:I-356 [poster].

A8) **McCullough PA**, O'Neill WW, Graham M, David S, Stomel R, Rogers F, Grines CL. A Prospective Randomized Trial of Triage Angiography in Suspected Acute Myocardial Infarction Patients Who are Considered Ineligible for Reperfusion Therapy. Circulation 1996;94:I-570 [oral].

A9) Aliabadi D, **McCullough PA**, Grines CL, Safian RD, Pica MC, O'Neill WW, Goldstein JA. A Novel Mobile Fluoroscopic Imaging System for Rapid Bedside Coronary Angiography. J Am Coll Cardiol 1997;450A [poster].

A10) **McCullough PA**, O'Neill WW, Graham M, David S, Stomel R, Rogers F, Farhat A, Kazlauskaite R, Grines CL. Late Outcomes in the Medicine vs. Angiography for Thrombolytic Exclusion (MATE) Study. Circulation, 1997;96:I-595-596 [oral].

A11) Redle JD, West AJ, Khurana S, Marzan R, **McCullough PA**, Frumin HI. Prophylactic Oral Amiodarone with Beta Blockade has Favorable Effects on Atrial Fibrillation Post Coronary Bypass Surgery. Circulation, 1997;96:I-125 [poster].

A12) Sharma ND, Gandhi RS, Philbin EF, Weaver WD, **McCullough PA**. Which Patients with Left Ventricular Dysfunction Require Chronic Anticoagulation? A Prospective Analysis. J Am Coll Cardiol 1998;31:33A. [poster].

A13) **McCullough PA**, Tobin KJ, Kahn JK, O'Neill WW, Thompson RJ. Prediction of In-hospital Survival after Sudden Cardiac Death: Derivation and Validation of a Clinical Model. J Am Coll Cardiol 1998;31:485A [poster].

A14) Stevens M, **McCullough PA**, Tobin KJ, Speck JP, Westveer DC, Guido-Allen DA, Hartenburg DS, Puchrowicz-Ochocki SB, O'Neill WW. A Randomized Trial of Prevention Measures in Patients at High Risk for Contrast Nephropathy: Initial Results of the PRINCE Study. J Am Coll Cardiol 1998;31:469A [poster].

A15) Tobin KJ, **McCullough PA**, Speck JP, Westveer DC, Guido-Allen DA, Hartenburg DS, Puchrowicz-Ochocki SB, O'Neill WW, Stevens M. What Role Does Mannitol Play in Preventing Contrast Nephropathy? A Prospective Analysis. J Am Coll Cardiol 1998;31:469A [poster].

A16) **McCullough PA**, Al-Zagoum M, Graham M, David S, Stomel R, Rogers F, Farhat A, Kazlauskaite R, Grines CL, O'Neill WW. A Time to Treatment Analysis in the Medicine vs. Angiography for Thrombolytic Exclusion Trial. Cathet Cardiovasc Diag 1998;44:105 [oral].

A17) **McCullough PA**, Al-Zagoum M, O'Neill WW, Graham M, David S, Stomel R, Rogers F, Farhat A, Kazlauskaite R, Grines CL. A Program of Triage Angiography in Acute Coronary Syndromes Ineligible for Thrombolysis: An Efficacy Analysis. Cathet Cardiovasc Diag 1998;44:105[poster].

A18) Philbin EF, **McCullough PA**, Polanczyk CA, Jenkins PL, DiSalvo TG. Are Subjects in Heart Failure Trials Similar in Clinical Practice? Circulation, 1998;98:I-866 [moderated poster].

A19) **McCullough PA**, Smith S, Borzak S. Understanding the Risks Associated with Baseline Renal Function in the Coronary Care Unit. Circulation, 1998;98:I-413 [poster].

A20) Afzal A, Gunda M, Brawner CA, Havstad S, **McCullough PA**, Keteyian SJ. Race and the Rate of Referral to Cardiac Rehabilitation. Circulation, 1998;98:I-810-811 [poster].

A21) Borzak S, Every NR, Jankowski M, Havstad S, Chase GA, **McCullough PA**, Elston-Lafata J, Weaver WD. Elderly Patients with Unstable Angina Have Ongoing Risk for Future Events. Circulation, 1998;98:I-629 [oral].

A22) Borzak S, Every NR, Chase GA, Jankowski M, Havstad S, **McCullough PA**, Elston-Lafata J, Weaver WD. U.S. Regional Differences in Use of Revascularization for Unstable Angina Patients. Circulation, 1998;98:I-275 [oral].

A23) **McCullough PA,** Newman M, Kaiser Carlson L, Flower J, Tuchfield B. Accelerating the Improvement in Community Cardiovascular Health Using Web-Enhanced Project Development. J Am Coll Cardiol 1999;33:7A [info@ACC].

A24) Mehra P, Pasnoori V, Sengstock D, Obaidat O, Brawner CA, Keteyian SJ, Philbin EF, **McCullough PA.** The Effect of Reactive Airways Disease on Peak Oxygen Consumption in Congestive Heart Failure. J Am Coll Cardiol 1999;33:172A [poster].

A25) **McCullough PA,** Cingireddy U, Philbin EF, Weaver WD. Evidence for a Heart Failure Epidemic: Findings from the REACH Study. J Am Coll Cardiol 1999;33:179A [poster].

A26) **McCullough PA,** Cingireddy U, Philbin EF, Weaver WD. Secular Trends in the Management of Congestive Heart Failure by Primary Care Physicians and Cardiovascular Specialists. J Am Coll Cardiol 1999;33:247A [poster]

A27) Hassan SA, Borzak S, Philbin EF, Soman S, Shah S, Weaver WD, Yee J, Marks KR, **McCullough PA**. The Impact Chronic Renal Insufficiency on Heart Failure Mortality after Hospitalization. Journal of Cardiac Failure 1999;5 Suppl 1:70. [poster].

A28) Sengstock D, Obaidat O, Pasnoori V, Mehra P, **McCullough PA**. Asthma, Chronic Beta-Agonist Use, and the Development of Dilated Cardiomyopathy: Primary Results from the ABCHF Study. Journal of Cardiac Failure 1999;5 Suppl 1:64. [moderated poster].

A29) **McCullough PA,** Kuntz RE, Marks KR, Popma JJ. Should We Change from Aspirin and Ticlopidine to Aspirin and Clopidogrel after Routine Coronary Stenting? A Population-Based Decision Analysis. Circulation 1999;100:I-379.[oral].

A30) **McCullough PA,** Prakash R, Tobin KJ, O'Neill WW, Thompson RJ. Application of a Cardiac Arrest Score in Patients with Sudden Death and ST Segment Elevation for Triage Angiography and Intervention. Fighting Sudden Cardiac Death: A Worldwide Challenge, 1999;18:T-2.

A31) **McCullough PA,** Philbin EF, Czerska B, Spertus JA, Weaver WD. Population-based Medication Profiling in Heart Failure: Treatment Related Outcomes from the R.E.A.C.H. Study. J Am Coll Cardiol 2000; 35:542A [moderated poster].

A32) **McCullough PA,** Philbin EF, Czerska B, Spertus JA, Weaver WD. The Diagnostic Evaluation of Newly Discovered Heart Failure: Opportunities for Improvement from the R.E.A.C.H. Study. J Am Coll Cardiol 2000;35:327A [poster].

A33) Shah SS, Tokarski GF, McCord JK, Khoury NE, McCabe KB, Morlock RJ, Noor H, **McCullough PA**. Impact of an Emergency Department Cardiac Clinical Decision Unit on a Population of Patients with Episodic Chest Discomfort. J Am Coll Cardiol 2000;35:380A [poster].

A34) Kadakia RA, **McCullough PA**, Soman S, Jankowski M, Borzak S, Keeley EC. Does Percutaneous Revascularization Confer a Long-Term Survival Benefit in Patients with Acute Renal Failure? J Inv Cardiol 2000;12(11):P1.

A35) **McCullough PA**, Philbin EF, Spertus JA, Weaver WD. Gender Differences in the Diagnostic Evaluation of Heart Failure: Findings from the R.E.A.C.H. Study. J Inv Cardiol 2000;12(11):P23.

A36) Pampati V, Shenkman HJ, McKinnon JE, Khandelwal AK, Nori DM, **McCullough PA**. The Significance of QRS Prolongation in Heart Failure: Findings from the CONQUEST Study. Chest2000;118(4):133S.

A37) Hassan SA, Bhatt S, Borzak S, Pallekonda V, Soman SS, Yee J, Marks K, **McCullough PA**. Clinical and Echocardiographic Determinants of Congestive Heart Failure with Renal Dysfunction.Chest2000;118(4):134S.

A38) Soman SS, Vera E, Jaffery H, Singh S, Marks KR, Borzak S, **McCullough PA.** Impact of Age and Admission Hemoglobin on Coronary Care Unit Mortality. Chest 2000; 118(4):166S.

A39) Soman SS, Shah S, Marks KR, Yee J, Borzak S, **McCullough PA**. The Independent Association of Renal Dysfunction and Arrhythmias in the Intensive Care Unit Setting. Chest 2000;118(4):171172S.

A40) Sallach JA, Soman SS, Sallach SM, Yee J, Karriem V, Hoffman RM, **McCullough PA**. "Homocysteine Flux": An Opportunity to Modify Cardiovascular Risk in Hemodialysis Patients.Chest2000;118(4):218S.

A41) McKinnon JE, Khandelwal AK, Shenkman HJ, Pampati V, Nori DM, **McCullough PA**. Congestive Heart Failure and QRS Duration: Utilization in Establishing Prognosis in Systolic and Diastolic Dysfunction—Results of the CONQUEST Study. Chest 2000; 118(4):221S.

A42) Kadakia RA, Bonifacio DL, Mikhail B, Clark VL, **McCullough PA**. Survival Following Coronary Intervention in Patients with End Stage Renal Disease. Chest 2000; 118(4):226-227S.

A43) Hassan S, Nori D, Bhatt S, Borzak S, Philbin E, Weaver WD, Soman S, Shah S, **McCullough PA**. Impact of Bundle Branch Block (BBB) Pattern on EKG on Survival in Patients with Congestive Heart Failure (CHF), an Eight Year Follow-up Study. Journal of Heart Failure 2000;6(1):65 [A258].

A44) Soman SS, Sallach J, Sallach S, **McCullough PA**, Karriem V, Hoffman R, Yee J. Homocysteine (tHcy) Removal by Hemodialysis (HD) Modifies Cardiovascular Disease (CVD) Risk in ESRD. American Society of Nephrology 2000 [A0887].

A45) McCord JK, Nowak R, **McCullough PA**, Borzak S, Tokarski G, Tomlanovich M, Foreback C, Malki Q, Asfour A, Weaver WD. Very Rapid Rule-out: 90 Minute Exclusion of Acute Myocardial Infarction (AMI) with Troponin-I (cTnI) and Myoglobin (Myo). Circulation 2000;102(18): II497.

A46) Shenkman HJ, McKinnon JE, Khandelwal AK, Pampati V, Nori DM, **McCullough PA**. Determinants of QRS Prolongation in a Generalized Heart Failure Population: Findings from the Conquest Study. Circulation 2000;102(18): II617.

A47) Philbin EF, **McCullough PA**, Di Salvo TG, Dec W, Jenkins PL, Weaver WD. Socioeconomic Status is an Important Determinant of Use of Invasive Strategies after Myocardial Infarction in Hospitals with Cardiac Surgery. Circulation 2000;102(18): II840.

A48) **McCullough PA,** Sandberg KR, Borzak S, Hudson MP, Garg M, Manley HJ. Use of Aspirin and thrombolysis for myocardial infarction in patients with chronic renal disease: An opportunity for quality improvement, AHA Conference on Quality of Care and Outcomes P93, Circulation 2001.

A49) Ketterer MW, Goldberg AD, **McCullough PA**, Patel S, Farha AJ, Clark V, Keteyian S, Dennollet J, Chapp J, Thayer B, Deveshwar S. Psychosocial Correlates of Early Ischemic Heart Disease (IHD): Preliminary Results. Psychosomatic Medicine 2001;63:172-173.

A50) Fitzgerald FE, Thayer BL, Ehrman JK, Keteyian S, Jarvis R, **McCullough PA.** A Hospital Employee Cholesterol Challenge Using Spreads Containing Plant Sterol Esters to Help Reduce Total and LDL-Cholesterol. American Diabetes Association 2001 [p000].

A51) **McCullough PA,** Garg M, Bonifacio DL, Malineni K, Kadakia RR, Soman SS, Sandberg KR. Relationship between Lipid Levels and Advanced Coronary Calcification in End Stage Renal Disease. Central Society for Clinical Research Combined Annual Meeting, 2001 [P78] Journal of Investigative Medicine 2001;49:284A.

A52) **McCullough PA,** Hudson MP, Garg M, Borzak S. Benefits of Aspirin and Beta-Blockade after Myocardial Infarction in Patients with Advanced Renal Dysfunction. Central Society for Clinical Research Combined Annual Meeting, 2001 [P79] Journal of Investigative Medicine 2001;49:285A.

A53) Hannen MN, **McCullough PA,** Garg M, Quick AM. Tricuspid Valve Endocarditis in a Patient with Negative Blood Cultures and Right Atrial Mass. Central Society for Clinical Research Combined Annual Meeting, 2001 [P96] Journal of Investigative Medicine 2001;49:287A.

A54) **McCullough PA,** Garg M, Borzak S, Hudson MP. Outcomes after Myocardial Infarction in Patients with Advanced Renal Disease Treated with Aspirin and β-Blockade. CHEST 2001;120(4):145S.

A55) **McCullough PA,** Garg M, Borzak S, Hudson MP. Benefits of Aspirin and Beta-Blockade after Myocardial Infarction in Patients with Chronic Renal Disease. Circulation 2001;104 (17):II-234.

A56) Manhapra A, Jacobsen G, Havstad S, **McCullough P**, Hudson MP, Weaver WD, Borzak S. Improved Long Term Survival with Beta Blocker Therapy Among African Americans and Caucasians with Myocardial Infarction. Circulation 2001;104 (17):II-627.

A57) Manhapra A, Jacobsen G, Havstad S, **McCullough P**, Hudson MP, Weaver WD, Borzak S. Racial Differences in Long Term Survival following an Acute Myocardial Infarction. Circulation 2001;104 (17):II-778.

A58) Brown WW, Bakris GL, Collins A, Flack JM, Gannon M, Greene E, Grimm R, Keane WF, Klag M, **McCullough P**, Politoski G. Identification of Individuals at High Risk (HR) for Kidney Disease (KD) via Targeted Screening. International Society of Hypertension in Blacks 2001 Meeting, Las Vegas, July 8-12, 200, Plenary Presentation and Poster. Ethnicity & Disease 2001; 11 (2): 358.

A59) Brown WW, Bakris GL, Chen S, Collins A, Davis J, Flack JM, Gannon M, Greene E, Grimm R, Keane WF, Klag MJ, **McCullough PA**, Politoski G, Tran A. St. Louis VAMC/St. Louis University,

Rush Presbyterian, Minneapolis Medical Research Foundation, NKF, Wayne State University, Mayo Clinic, Hennepin County Medical Center, Johns Hopkins Medical Institutions, UMKC. Targeted Screenings Identify Persons at Risk for Kidney Disease (KD). Poster, ASN/ISN International Congress of Nephrology, San Francisco, October 13-17, 2001. J of the Am Soc of Nephrol 2201; 12: A1003.

A60) Maisel AS, Hlavin P, McCord J, Nowak RM, Hollander JE, Duc P, Steg G, Omland T, Westheim A, Abraham WT, Storrow AB, McKay CA, Wu AH, **McCullough PA**, for the BNP Multinational Study Investigators. B-Type Natriuretic Peptide in the Emergency Diagnosis of Diastolic Dysfunction Heart Failure. J Am Coll Cardiol 2002;39:140A.

A61) **McCullough PA**, Nowak RM, McCord J, Hollander JE, Steg G, Duc P, Westheim A, Omland T, Storrow AB, Abraham WT, Wu AH, Clopton P, Lenert L, Maisel AS, for the BNP Multinational Study Investigators. B-Type Natriuretic Peptide Adds to Clinical Judgment in the Diagnosis of Heart Failure: A Bayesian Analysis From the BNP Multinational Study. J Am Coll Cardiol 2002;39:140A.

A62) **McCullough PA**, Nowak RM, McCord J, Hollander JE, Loh E, Steg G, Duc P, Omland T, Westheim A, Abraham WT, Storrow AB, Wu AH, Hlavin P, Maisel AS, for the BNP Multinational Study Investigators. The Independent Contribution to Elevations in B-Type Natriuretic Peptide from Atrial Fibrillation. J Am Coll Cardiol 2002;39:90A.

A63) Maisel AS, Kazanegra R, McCord J, Nowak RM, Hollander JE, Duc P, Steg G, Omland T, Wold-Knudsen C, Westheim A, Abraham WT, Storrow AB, Wu AH, **McCullough PA**, for the BNP Multinational Study Investigators. The Effect of Diabetes on B-Type Natriuretic Peptide Levels in Patients with Acute Dyspnea. J Am Coll Cardiol 2002;39:182A.

A64) **McCullough PA**, Nowak RM, Foreback C, Borzak S, Tokarski G, Tomlanovich MC, Jacobsen G, Weaver WD, Sandberg KR, McCord J. Performance of Cardiac Troponin I in the Exclusion of Myocardial Infarction in Patients with Advanced Renal Disease. J Am Coll Cardiol 2002;39:326A.

A65) Khandelwal A, McKinnon JE, Shenkman HJ, Pampati V, Nori D, Kaatz S, Sandberg KR, **McCullough PA**. Epidemiology of Systolic and Diastolic Dysfunction Heart Failure in 3,471 Urban Patients. J Am Coll Cardiol 2002;39:192A.

A66) Maisel AS, Kazanegra R, McCord J, Nowak RM, Hollander JE, Duc P, Steg G, Omland T, Westheim A, Abraham WT, Storrow AB, Lamba S, Wu AH, **McCullough PA**, for the BNP Multinational Study Investigators. Primary Results of the BNP Multinational Study: B-Type Natriuretic Peptide in the Emergency Diagnosis of Heart Failure. J Am Coll Cardiol 2002;39:201A.

A67) **McCullough PA**, McCord J, Nowak RM, Hollander JE, Duc P, Omland T, Abraham WT, Wu AHB, Krishnaswamy P, Maisel AS. B-type Natriuretic Peptide Should be Part of the Diagnostic

Evaluation of Heart Failure: Implications from the Breathing Not Properly (BNP) Multinational Study. J Heart Failure 2002;7(1):44.

A68) Nowak RM, Maisel AS, McCord J, Kazanegra R, Hlavin P, Lenert LA, Clopton P, Hollander JE, Loh E, Duc P, Steg PG, Westheim A, Omland T, Abraham WT, Lamba S, Storrow AB, Wu AHB, McKay C, **McCullough PA.** B-type Natriuretic Peptide Complements Clinical Judgment in the Emergency Diagnosis of Heart Failure. Acad Emerg Med 2002 9: 359.

A69) Hollander JE, Maisel AS, Nowak RM, McCord J, Kazanegra R, Hlavin P, Lenert LA, Clopton P, Loh E, Duc P, Steg PG, Wertheimer A, Omland T, Abraham WT, Lamba S, Storrow AB, Wu AHB, McKay C, **McCullough PA**. Impact of Acute Myocardial Ischemia on Blood B-Type Natriuretic Peptide in the Emergency Diagnosis of Heart Failure. Acad Emerg Med 2002 9: 440.

A70) Knudsen CW, Omland T, Clopton P, Westheim A, Abraham WT, Storrow AB, McCord J, Nowak RM, Steg PG, Duc P, **McCullough PA**, Maisel AS. Diagnostic Value of Chest Radiographs in Patients Presenting with Acute Dyspnea: Comparison with B-type Natriuretic Peptide. Circulation 2002;106(19):II-683.

A71) Omland T, Knudsen CW, Westheim A, McCord J, Aumont MC, **McCullough PA**. The Effect of Hypertension on B-type Natriuretic Peptide Levels in Patients with Acute Dyspnea: An Analysis from the Breathing Not Properly Study. Circulation 2002;106(19):II-477.

A72) Sallach JA, McCord J, Sallach SM, Duc P, Omland T, Nowak RM, Hollander JE, Storrow AB, Abraham WT, Wu AHB, Clopton P, Krishnaswamy P, Maisel AS, **McCullough PA.** The Effect of Pre-Existing Ischemic Heart Disease on B-type Natriuretic Peptide Levels in Patients Presenting with Acute Dyspnea. Circulation 2002;106(19):II-565.

A73) Ehrman JK, Manhapra A, Jacobsen G, **McCullough PA.** Lower Socioeconomic Status is Associated with Poor Survival in Heart Failure Patients. Circulation 2002;106(19):II-762.

A74) **McCullough PA,** Omland T, Knudsen CW, Duc P, Nowak RM, McCord J, Hollander JE, Aumont MC, Steg PG, Westheim A, Storrow AB, Abraham WT, Lamba S, Wu AHB, Alan S. Maisel AS, BNP Multinational Study Investigators. Uncovering Heart Failure in Patients with Bronchospasm: Rationale for the Early Use of B-Type Natriuretic Peptide in the Emergency Department. J Am Coll Cardiol 2003;41:142A.

A75) Maisel AS, Kazanegra R, **McCullough PA,** McCord J, Nowak RM, Hollander JE, Wu AHB, Duc P, Omland T, Storrow AB, Krishnaswamy P, Abraham WT, Clopton P, Steg PG, Westheim A, Knudsen CW, Herrmann HC. Bedside B-Type Natriuretic Peptide in the Emergency Diagnosis of Systolic and Nonsystolic Heart Failure: Results From the Breathing Not Properly (BNP) Multinational Study. J Am Coll Cardiol 2003;41:143A.

A76) Steg PG, Duc P, Joubin L, McCord J, Abraham WT, Hollander JE, Omland T, Baron G, Aumont MC, Mentré F, **McCullough PA**, Maisel AS, BNP Multinational Study Investigators. A Comparison

of Bedside B-Type Natriuretic Peptide Versus Echocardiographic Determination of Ejection Fraction in the Diagnosis of Heart Failure. J Am Coll Cardiol 2003;41:337A.

A77) Mundy BJ, McCord J, Nowak RM, Hudson MP, Czerska B, Jacobsen G, Omland T, Wu AHB, Duc P, Hollander JE, **McCullough PA**, Maisel AS, BNP Multinational Study Investigators. B-Type Natriuretic Peptide Levels Are Inversely Related to Body Mass Index in Patients With Heart Failure. J Am Coll Cardiol 2003;41:158A.

A78) **McCullough PA**, Nowak RM, McCord J, Omland T, Knudsen CW, Duc P, Hollander JE, Steg PG, Aumont MC, Westheim A, Storrow AB, Abraham WT, Lamba S, Wu AHB, Maisel AS, BNP Multinational Study Investigators. What is in the Differential Diagnosis of a B-Type Natriuretic Peptide Level of 1,000 pg/ml? J Am Coll Cardiol 2003;41:159A.

A79) **McCullough PA,** Steg PG, Aumont MC, Duc P, Omland T, Knudsen CW, Nowak RM, McCord J, Hollander JE, Westheim A, Storrow AB, Abraham WT, Lamba S, Wu AHB, Maisel AS, BNP Multinational Study Investigators. What Causes Elevated B-Type Natriuretic Peptide in Patients Without Heart Failure? J Am Coll Cardiol 2003;41:278A.

A80) Gurudutt B. Kulkarni, John House, John A. Spertus, **Peter A. McCullough**. Chronic Kidney Disease: The Silent Killer After Coronary Angioplasty. J Am Coll Cardiol 2003;41:54A.

A81) Chew DP, Bhatt DL, Berger PB, Henry T, **McCullough PA**, Feit F, Bittl JA, Lincoff AM. Bivalirudin Provides Increasing Benefit With Declining Renal Function in Percutaneous Coronary Intervention: A Meta-Analysis of 5,035 Patients Enrolled in Three Randomized Trials. J Am Coll Cardiol 2003;41:83A.

A82) Stone GW, **McCullough PA,** Tumlin J, Madyoon H, Murray P, Wang A, Chu AA, Schaer G, Stevens M, Wilensky RL, O'Neill WW, Lepor N. A Prospective, Randomized Placebo-Controlled Multicenter Trial Evaluating Fenoldopam Mesylate for the Prevention of Contrast Induced Nephropathy: The CONTRAST Trial. J Am Coll Cardiol 2003;41:83A.

A83) **McCullough PA**, Duc P, Omland T, McCord J, Nowak RM, Hollander JE, Herrmann HC, Steg PG, Westheim A, Aumont MC, Knudsen CW, Storrow AB, Abraham WT, Lamba S, Wu AHB, Perez A, Clopton P, Krishnaswamy P, Kazanegra R, Maisel AS, BNP Multinational Study Investigators. B-Type Natriuretic Peptide and Renal Function in the Diagnosis of Heart Failure: An Analysis from the BNP Multinational Study. J Am Coll Cardiol 2003;41:222A.

A84) **McCullough PA,** Sandberg KR, Yanez J. Determinants of vascular calcification in patients with chronic kidney disease and end-stage renal disease: a systematic review. Am J Kidney Dis 2003;(42)227A.

A85) Kazanegra R, Clopton P, Krishnaswamy P, Nowak RM, McCord J, Hollander JE, Duc P, Omland T, Storrow AB, Abraham WT, Wu AH, Steg PG, Westheim A, Perez A, Herrmann HC, Knudsen CW, Aumont M-C, **McCullough PA,** Maisel AS. The impact of age, race and gender on the ability of B-

type natriuretic peptide to aid in the emergency diagnosis of heart failure: results from the breathing not properly (BNP) multinational study. J Cardiac Failure 2003; 9(5):S36.

A86) Aumont MC, Duc P, Baron G, McCord JA, Omland T, Storrow AB, **McCullough PA,** Maisel AS. High levels of brain natriuretic peptide without chronic heart failure: analysis of a multicentre study. Eur Heart J 2003;24(530): P2810.

A87) Havranek EP, Masoudi FA, Rumsfeld JS, Luther SA, **McCullough PA**, Jones PG, Rathore SS. Changes in BNP are not associated with outcomes in outpatients with heart failure. Circulation 2003;108(17):IV-692.

A88) Sandberg KR, Gallagher MJ, Krause KR, Franklin BA, **McCullough PA**. Caloric expenditure in the morbidly obese. Circulation 2003;108(17):IV-735.

A89) Gallagher MJ, Sandberg KR, de Jong A, Krause KR, **McCullough PA**, Franklin BA. Heart rate recovery after symptom limited exercise testing in obese patients. Circulation 2003;108(17):IV-735.

A90) Fishbane S, **McCullough PA,** Rudnick M. Systematic Review of the Role of N-acetylcysteine in the Prevention of Contrast Media-Induced Nephropathy. J Am Soc Nephrol Vol 14, 2003, 1553A.

A91) Stacul F, Bertrand ME, **McCullough PA**, Brinker J. Contrast-induced nephropathy (CIN) following iso-osmolar (IOCM) versus low-osmolar contrast media (LOCM) in patients undergoing angiography and predicting factors for CIN: a meta-analysis. European Congress of Radiology 2004, B-934.

A92) Maisel AS, Hollander J, Guss D, **McCullough PA,** Nowak R, Green G, Saltzberg M, Kazanegra R, Clopton P, Jesse R, for the REDHOT Investigators. Primary results of the Rapid Emergency Department Heart Failure Outpatient Trial (REDHOT): a multicenter trial examining B-type natriuretic peptide levels, emergency physician decision making and outcomes in patients with shortness of breath. J Am Coll Cardiol 2004; 43(5):6A.

A93) Knudsen CW, Omland T, Westheim A, Clopton P, Abraham WT, Storrow A, McCord JK, Nowak R, Duc P, **McCullough PA,** Maisel A. B-type natriuretic peptide and chest radiograph findings as indicators of systolic dysfunction in patients presenting with acute dyspnea. J Am Coll Cardiol 2004; 43(5):171A.

A94) Soman P, Lahiri A, Mieres J, Calnon D, Wolinsky D, Beller GA, Sias T, Burnham K, Conway L, **McCullough PA,** Daher E, Walsh MN, Wight J, Heller GV, Udelson JE. Investigation of Myocardial-Gated SPECT Imaging as an Initial Strategy in Heart Failure: The IMAGING in Heart Failure Study. J Am Coll Cardiol 2004;43(5):323A.

A95) Maisel AS, Bhalla MA, Gardetto N, McCord J, Nowak RM, Hollander JE, Wu AHB, Duc P, Omland T, Storrow AB, Krishnaswamy P, Abraham WT, Clopton P, Steg G, Aumont MC, Westheim A, Knudsen CW, Perez A, Kamin R, Kazanegra R, Herrmann HC, **McCullough PA,** for the BNP Multinational Study Investigators. Utility of B-type natriuretic peptide levels in predicting outcome of hospitalized patients with congestive heart failure: results of the Breathing Not Properly (BNP) Multinational Study. J Am Coll Cardiol 2004; 43(5):234A.

A96) Sandberg KR, Irving SD, Veri S, **McCullough PA.** Dietary and exercise habits in morbidly obese patients pre and post gastric bypass surgery. Presented at the 44th Annual Conference on Cardiovascular Disease Epidemiology and Prevention. Circulation 2004;109(6):P233.

A97) Sandberg KR, Gallagher MJ, Franklin BA, deJong AT, Krause KR, **McCullough PA.** The effects of bariatric surgery on exercise tolerance and cardiopulmonary fitness in the morbidly obese. American Society for Bariatric Surgery Annual Meeting 2004 [P7].

A98) Odom JS, Sandberg KR, **McCullough PA.** Psychological screening in bariatric surgery candidates. American Society for Bariatric Surgery Annual Meeting 2004 [P51].

A99) de Jong AT, Gallagher MJ, Sandberg KR, Krause KR, Ehrman JK, Keteyian SJ, Brawner CA, **McCullough PA**, Franklin BA. Ability to achieve maximal oxygen consumption during exercise testing in morbidly obese patients. Medicine & Science in Sports and Exercise 2004;36(4):S140 [999].

A100) Conklin A, de Jong AT, Franklin BA, **McCullough PA**. Evaluation of cardiorespiratory fitness in morbidly obese adults: a feasibility study. Medicine & Science in Sports and Exercise 2004;36(4):S140 [1000].

A101) Grayson D, De Jong AT, Ochoa A, Gallagher M, Franklin BA, **McCullough PA.** Oxygen consumption changes during EECP treatment in patients with and without coronary artery disease. Medicine & Science in Sports and Exercise 2004;36(4):S140 [1475].

A102) Jurkovitz C, Norris K, Li S, Shen SC, McGill JA, **McCullough PA**, Narva A, Bakris G, Collins A, Klag M, Brown W. Does Obesity Modify the Association between Hypertension and Race? An Analysis of the KEEP Population. Preventive Medicine 39(2004), S21.

A103) Strunk A, Bhalla V, Clopton P, Nowak RM, McCord J, Hollander JE, Duc, P, Storrow, AB, Abraham WT, Wu AHB, Steg G, Perez A, Kazanegra R, Herrmann HC, Aumont MC, **McCullough PA**, Maisel AS for the BNP Multinational Study Investigators*. Impact of the history of congestive heart failure on accuracy of BNP in the emergency diagnosis of heart failure: results from the breathing not properly (BNP) multinational study. J Card Failure 10(4):S50 #120, 8th Annual Scientific meeting of the Heart Failure Society of America, 2004.

A104) Jurkovitz C, Li S, Norris K, McGill J, Chen SC, Pergola P, Narva A, **McCullough PA**, Brown W, Klag M. Obesity is associated with risk factors for chronic kidney disease: Kidney Early Evaluation Program Results. J Am Soc Nephrol 2004;15:134A.

A105) Singh AK, McGill J, **McCullough PA**, Brown W, Collins A, Chen SC, Li S, Narva A, Herman WH, Bakris GL, Jurkovitz C, Norris K, Pergola P, Klag M. Advanced stages of chronic kidney disease (CKD) detected among screened individuals with diabetes mellitus, undiagnosed diabetes, and mildly elevated glucose values: Results from the NKF Kidney Early Evaluation Program (KEEP) Study. J Am Soc Nephrol 2004;15:322A.

A106) McGill J, **McCullough PA**, Brown W, Collins A, Chen SC, Li S, Narva A, Herman WH, Bakris GL, Norris K, Pergola P, Klag M, Jurkovitz C. Pre-menopausal and elderly women with chronic kidney disease (CKD) at highest risk of anemia: Results from the NKF Kidney Early Evaluation Program (KEEP) Study. J Am Soc Nephrol 2004;15:547A.

A107) Gallagher MJ, Franklin BA, deJong A, Sandberg KR, Krause KR, Ehrman JK, Keteyian SJ, Brawner CA, Mattichak SJ, Kahn JK, **McCullough PA**. Cardiorespiratory fitness levels in obesity approximate those of heart failure patients: implications for exercise prescription. Circulation 2004;110(17)822A.

A108) Knudsen CW, Clopton P, Klemsdal TO, Westheim A, Wu A, Abraham WT, Storrow AB, McCord JK, Nowak RM, **McCullough PA**, Omland T. Predictors of absence of heart failure in patients with elevated B-type natriuretic peptide levels. 2004;110(17)368A.

A109) Daniels LB, Clopton P, Hollander JE, Guss D, **McCullough P**, Nowak R, Green G, Saltzberg M, Ellison SR, Bhalia MA, Bhalia V, Jesse R, Maisel A. Effect of ethnicity on likelihood of admission for heart failure. J Am Coll Cardiol 2005;45(3)168A.

A110) **McCullough PA**, Brown WW, McGill JB, Collins AJ, Chen SC, Li S, Singh AK, Narva AS, Herman WH, Bakris GL, Jurkovitz CT, Norris KC, Pergola P, Klag MJ, for the KEEP Investigators. Independent components of chronic kidney disease as a cardiovascular risk factor; results from the Kidney Early Evaluation Program (KEEP). J Am Coll Cardiol 2005;45(3)424A.

A111) **McCullough PA**, Klag MJ, McGill JB, Collins AJ, Chen SC, Li S, Singh AK, Narva AS, Herman WH, Bakris GL, Jurkovitz CT, Norris KC, Pergola P, Brown WW, for the KEEP Investigators. Age over 30 becomes a cardiovascular risk factor in patients screened for chronic kidney disease, results from the Kidney Early Evaluation Program (KEEP). J Am Coll Cardiol 2005;45(3)434A.

A112) Daniels LB, Clopton P, Chiu A, McCord J, Hollander JE, Duc P, Omland T, Storrow AB, Wu AHB, Steg G, Westheim A, Knudsen CW, Hermann HC, **McCullough PA**, Maisel AS. Using B-type natriuretic peptide to diagnose heart failure in obese patients. J Am Coll Cardiol 2005;45(3)141A.

A113) Trivax JE, Gallagher MJ, Alexander DV, deJong AT, Kasturi G, Sandberg KR, Jafri SM, Krause KR, Chengelis DL Moy J, Franklin BA, **McCullough PA**. Poor aerobic fitness predicts complications associated with bariatric surgery. CHEST 2005;128(4)282S.

A114) Miller WM, Nori KE, Sandberg KR, Vial C, VanderLinden M, **McCullough PA**. Change in C-reactive protein levels with weight loss following gastric bypass surgery. Circulation 2005;111(14) P213.

A115) Moy J, Gallagher M de Jong A, Sandberg K, Trivax J, Alexander D, Kasturi G, Jafri S, Krause K, Chengelis D, Franklin B, **McCullough P**. Preoperative cardiopulmonary fitness predicts surgical complications after laparoscopic roux-en-Y gastric bypass surgery for morbid obesity. Obesity Research 2005;13, A14 (54-OR).

A116) Nori Janosz K, Koenig K, Leff C, Miller W, **McCullough P**. How much weight needs to be lost to resolve type 2 diabetes? Obesity Research 2005;13, A59 (229-P).

A117) Odom J, Ferrara M, **McCullough P**, Miller W. The effect of behavioral group attendance on weight loss while participating in an out-patient, hospital-based, meal replacement program. Obesity Research 2005;13, A144 (557-P).

A118) Miller W, Veri S, Odom J, Lillystone M, Gibbs D, **McCullough P**. Effects of a short-term multidisciplinary program for childhood obesity. Obesity Research 2005;13, A84 (328-P).

A119) Odom J, Ferrara M, **McCullough P**, Miller W. The effect of psychosocial factors on weight loss during an out-patient, hospital-based, meal replacement program. Obesity Research 2005;13, A69 (267-P).

A120) Vanhecke TE, Miller WM, Franklin BA, Weber JE, **McCullough PA**. Differences in health awareness knowledge, environmental tobacco smoke exposure (ETS), and body-shape perception among adolescents based upon body mass index. J Am Coll Cardiol 2006;47(4) 247A.

A121) Duru K, Jurkovitz C, Narva A, McGill J, Bakris G, Chen SC, Lu S, Pergola P, **McCullough P**, Singh A, Klag M, Collins A, Brown W, Norris K. Racial and gender differences in hypertension control and chronic kidney disease: results from the Kidney Early Evaluation Program (KEEP). NKF 2006 Spring Clinical Meetings; 245: P101.

A122) Conklin A, de Jong A, **McCullough PA**, Franklin B. Cardiorespiratory Fitness: Relation to Body Mass Index among the Morbidly Obese and Superobese. Med Sci Sports Exerc. 2006 May;38(5 Suppl):S84-5.

A123) Miller WM, Khazaal N, Nori-Janosz K, Franklin B, Vial C, Kaitner R, **McCullough P**. Advantages of group treatment and exercise promoting short-term weight loss in obese adults. Obesity 2006;14(Suppl):A157.

A124) **McCullough PA.** Which Types and Which Amount of Physical Activities to Achieve and Maintain a Healthy Body Weight? 4th Metabolic Syndrome, Type II Diabetes, and Atherosclerosis Congress (MSDA), 2007, AL-18, p 23.

A125) Vanhecke TE, **McCullough PA**, Trivax J, DeJong A, Franklin BA. Energy Expenditure, Epicardial Adipose Tissue and Cardiorespiratory Fitness in Morbidly Obese Adults: 2154: Board #67 June 1 8:00 AM - 9:30 AM. Med Sci Sports Exerc. 2007 May;39(5 Suppl):S385.

A126) Miller WM, Veri S, Odom J, Lillystone M, Washington T, **McCullough PA**, Franklin BA. Dietary behaviors and knowledge among urban pre-adolescents: 1581: board #71 may 30 3:30 PM - 5:00 PM. Med Sci Sports Exerc. 2007 May;39(5 Suppl):S247.

A127) DeJong AT, **McCullough P**, Franklin B. Use of VE/VCO2 slope Corrected for Peak VO2 as a Predictor of Post-Surgical Complications in Morbidly Obese Patients: 686: May 31 8:30 AM 8:45 AM. Med Sci Sports Exerc. 2007 May;39(5 Suppl):S40.

A128) Zalesin KC, Krause KR, Chengelis DL, **McCullough PA**. Determinants of the Resolution of Type 2 Diabetes after Bariatric Surgery. American Society of Bariatric Surgery. Surgery for Obesity and Related Disorders 3(3):314; 2007.

A129) Kadaj P, Vanhecke T, Barnes MA, Lazar MH, Gandhi M, **McCullough, PA**. Natriuretic peptide testing and APACHE II scores for the evaluation and prediction of outcome in acutely ill patients: a prospective cohort study. Chest 2007;132(4) 551S.

A130) Agrawal V, Khan I, Rai B, Krause KR, Chengelis DL, Zalesin KC, Rocher LL, **McCullough PA**. Weight loss after bariatric surgery reduces albuminuria in obese adults with diabetes. J Am Soc Nephrol, Oct 2007; 18: 574A.

A131) Agrawal V, Rai B, Khan I, Krause KR, Chengelis DL, Zalesin KC, Rocher LL, **McCullough PA**. Weight loss after bariatric surgery reduces albuminuria in obese adults. J Am Soc Nephrol, Oct 2007; 18: 767A.

A132) O'Donoghue M, Sabatine M, Boden WE, Braunwald E, Cannon CP, Clayton TC, de Winter RJ, Fox KA, Lagerqvist B, **McCullough PA**, Murphy SA, Spacek R, Swahn E, Wallentin L, Windhausen F. The benefit of early invasive strategy in women versus men with non-ST-elevation acute coronary syndromes: a collaborative meta-analysis of randomized trials. Circulation 2007:116(16);II-383.

A133) Boerrigter G, Costello-Boerrigter LC, Abraham WT, St. John Sutton, MG, Heublein D, Kruger KM, Hill MR, **McCullough PA**, Burnett JC. Cardiac resynchronization therapy with biventricular pacing improves renal function in heart failure patients with reduced glomerular filtration rate. Circulation 2007:116(16);II-405.

A134) Deliri H, Davis E, Hager CS, Welch CA, Malik FS, **McCullough PA**, Wagner GS, Carter WH. A prospective randomized trial of blood B-type natriuretic peptide levels informing management after elective coronary artery bypass surgery. Circulation 2007:116(16);II-683.

A135) **McCullough PA**, Li S, Collins AJ, Chen SC, Jurkovitz CT, Norris KC, McFarlane S, Johnson B, Shlipak M, Obialo C, Brown WW, Vassaloti J, Bakris GL, for the KEEP Investigators. Chronic kidney disease and risk for premature cardiovascular disease. Circulation 2007:116(16);II-852.

A136) **McCullough PA,** Leifer E, Ellis S, Rendall DS, Horwich T, Hill JA, Fonarow GC. Relationship between renal function and cardiopulmonary fitness in patients with systolic heart failure. J Am Coll Cardiol 2008;51(10)A52-53.

A137) O'Donoghue, Boden WE, Cannon CP, Clayton TC, de Winter RJ, Fox KA, Lagerqvist B, **McCullough PA**, Murphy SA, Spacek R, Swahn E, Wallentin L, Windhausen F, Sabatine MS. The benefit of an invasive strategy in diabetic versus non-diabetic subjects with non-ST segment elevation acute coronary syndromes; a collaborative meta-analysis of randomized trials. J Am Coll Cardiol 2008;51(10)A216.

A138) **McCullough PA**, Li S, Jurkovitz CT, Stevens LA, Wang C, Collins AJ, Chen SC, Norris KC, McFarlane S, Johnson B, Shlipak MG, Obialo CI, Brown WB, Vassalotti JA, Whaley-Connel AT, for the KEEP Investigators. Chronic kidney disease and cardiovascular disease in volunteer and randomly selected populations: KEEP and NHANES. Am J Kidney Dis 2008;51(4)B68.(Abstract #162)

A139) McFarlane SI, Chen SC, Whaley-Connell A, Sowers J, Vassalotti JA, Salifu MO, Li S, Wang C, Bakris G, **McCullough PA**, Collins AJ, Norris K for the KEEP Investigators. Racial and gender differences in prevalence and predictors of anemia of chronic kidney disease: KEEP and NHANES 1999-2004. Am J Kidney Dis 2008;51(4)B68. (Abstract #163)

A140) Pavey BS, Saab G, McFarlane SI, Sowers JR, Chen S, Li S, Vassalotti J, Collins AJ, Norris K, **McCullough PA**, Bakris G, Whaley-Connell A, for the KEEP Investigators. Prevalent components of cardiometabolic syndrome and cardiovascular disease from the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis 2008;51(4)B79. (Abstract #207)

A141) Agrawal V, Vanhecke TE, Franklin BA, Zalesin KC, Sangal RB, Hakmeh B, deJong AT, **McCullough PA**. Albuminuria in obese adults is associated with hypertension and sleep disturbance. Am J Kidney Dis 2008;51(4)B29. (Abstract #5)

A142) Vassalotti JA, Uribarri J, Chen SC, Li S, Wang C, Collins AJ, Calvo MS, Whaley-Connell A, Norris KC, **McCullough PA**, Andress DL, for the KEEP Investigators. Trends in mineral metabolism in the kidney early evaluation program (KEEP). Am J Kidney Dis 2008;51(4)B52. (Abstract #75)

A143) Agrawal V, Krause KR, Chengelis DL, Zalesin K, Rocher L, **McCullough PA**. Relation between degree of weight loss after bariatric surgery and reduction in high sensitivity C-reactive protein. Surgery for Obesity and Related Diseases 2008;3(4)324.(Abstract P33)

A144) Odom J, Washington TL, Zalesin K, **McCullough PA,** Hakmeh B. Psychosocial trends related to weight regain after bariatric surgery. Surgery for Obesity and Related Diseases 2008;3(4)324.(Abstract BH-04)

A145) **McCullough PA.** New insights on accelerated vascular calcification in patients with kidney disease. J Heart Dis 2008;(6):121 (Abstract 482).

A146) Agrawal V, Ghoshi AK, Barnes MA, **McCullough PA**. Perception of indications for nephrology referral among internal medicine residents. A national online survey. J Am Soc Neph 2008;19:812-13A (SA-PO3091).

A147) Agrawal V, Swami A, Al-Sabbagh M, Kosuri R, Samarapungavan D, **McCullough PA**. Contrast induced acute kidney injury in renal transplantation recipients undergoing cardiac catheterization. J Am Soc Neph 2008;19:986-87A (PUB766).

A148) Agrawal V, Agarwal M, Barnes MA, Ghosh AK, **McCullough PA**. Internal medicine resident's knowledge of chronic kidney disease complications and management: a national survey. NKF 2009 Spring Clinical Meetings; 43: I22.

A149) Li S, Chen SC, Vassaloti J, Norris K, **McCullough PA**, Bakris G, Collins A. Predictors of self-referred repeat CKD screening in the Kidney Early Evaluation Program (KEEP). NKF 2009 Spring Clinical Meetings; 48: I42.

A150) Whaley-Connell, Sowers JR, **McCullough PA**, Roberts T, McFarlane SI, Chen SC, Li S, Wang C, Collins AJ, Bakris GL, and the Kidney Early Evaluation Program Investigators. Diabetes mellitus and CKD awareness: the Kidney Early Evaluation Program and the National Health and Nutrition and Examination Survey. NKF 2009 Spring Clinical Meetings; 52: I60.

A151) Kalatizidis R, Li S, Wang C, Chen SC, **McCullough PA**, Bakris G. Hypertension in early-stage kidney disease: an update from the kidney early evaluation program. NKF 2009 Spring Clinical Meetings; 80: I170.

A152) Agrawal V, Agarwal M, Samarapungavan D, **McCullough PA**. Long term outcomes of contrast induced acute kidney injury in renal transplant recipients. NKF 2009 Spring Clinical Meetings; 83: I184.

A153) **McCullough PA**, Whaley-Connell A, Brown WW, Collins AJ, Chen SC, Li S, Norris KC, Johnson BC, Calhoun D, Jurkovitz C, McFarlane S, Obialo C, Shlipak M, Sowers J, Stevens L, Vassalotti JA, Bakris GL. Cardiovascular risk modification in chronic kidney disease patients with coronary

disease: results from the Kidney Early Evaluation Program (KEEP). J Am Coll Cardiol 2009;53(10):A224.

A154) Kosiborod M, **McCullough PA**, Rao S, Inzucchi SE, Maddox TM, Masoudi FA, Xiao L, Fiske S, Spertus JA. Hyperglycemia and risk of acute kidney injury after coronary angiography in patients hospitalized with acute myocardial infarction. J Am Coll Cardiol 2009;53(10):A382.

A155) Miller WM, Veri S, **McCullough PA**, Franklin BA. Children improve nutritional knowledge, increase physical activity and reduce body mass through a multidisciplinary school intervention. Poster: 2009 American College of Sports Medicine Annual Meeting; 2009 May 27; Seattle, WA. Medicine and Science in Sports and Exercise 2009;41(5):S1543.

A156) Zalesin, KC, Franklin BA, Lillystone M, Shamoun T, Krause K, Chengelis D, Mucci S, Shaheen KW, **McCullough PA**. Differential loss of fat and lean mass in the morbidly obese after bariatric surgery. Surgery for Obesity and Related Diseases 2009;5: S29 (poster) awarded Outstanding Poster Recognition

A157) Miller WM, Franklin BA, Veri S, Maaz Y, Jameel J, **McCullough PA**. Is degree of obesity associated with childhood obesity treatment outcomes? Poster: The Obesity Society's Annual Scientific Meeting; 2009 Oct 26; Washington, DC. Obesity 2009;17(2):S184

A158) Trivax JE, Franklin BA, Goldstein JA, Chinnaiyan KM, Gallagher MJ, deJong AT, Colar JM, Haines DE, **McCullough PA.** Acute cardiac effects of marathon running: evidence for right heart overload. Circulation 2009;120 (18): S513

A159) Amin AP, Riley K, Spertus JS, Venkitachalam L, Stolker JM, **McCullough PA**, Masoudi FA, Jones PG, Kosiborod M. Trends in the prevalence of acute kidney injury in patients with acute myocardial infarction. J Am Coll Cardiol 2010;55 (10): A102 (1046-282)

A160) Agrawal V, Garimella PS, Jaar BG, Plantinga L, Ye J, **McCullough PA.** Access to health care in adults evaluated for chronic kidney disease: findings from the Kidney Early Evaluation Program. NKF 2010 Spring Clinical Meetings, April 13-17, 2010, P35.

A161) Bomback AS, Kshirsagar AV, Whaley-Connell AT, Chen SC, Li S, Klemmer PJ, **McCullough PA,** Bakris GL. Racial differences in kidney function among individuals with obesity and metabolic syndrome: results from the Kidney Early Evaluation Program (KEEP). NKF 2010 Spring Clinical Meetings, April 13-17, 2010, P45.

A162) Saab G, Whaley-Connell A, Chen SC, Li S, Sowers JR, Norris K, Bakris G, **McCullough PA**. The association of serum phosphorus and pulse pressure in men and women with chronic kidney disease: data from the Kidney Early Evaluation Program. NKF 2010 Spring Clinical Meetings, April 13-17, 2010, P80.

A163) **McCullough PA**, Brown J, Weisbord S. The effects of iso-osmolar contrast media on contrast-induced acute kidney injury: a meta-analysis. Cath Cardiovasc Interv 2010;75(6):S78, B-034.

A164) **McCullough PA**, Capasso P. Patient discomfort associated with the use of intravascular iodinated contrast media: a meta-analysis of comparative randomized trials. Cath Cardiovasc Interv 2010;75(6):S80, B-037.

A165) Miller WM, Spring TJ, Zalesin KC, Kaeding K, deJong AT, **McCullough PA**, Franklin, BA. Resting metabolic rate is directly associated with cardiorespiratory fitness in the morbidly obese. Poster: AHA Annual Conference on Nutrition, Physical Activity and Metabolism; 2010 March 2; San Francisco, CA. *Circulation* 2010 March; Suppl. Page 114, Poster P75.

A166) Miller WM, So NC, Zalesin KC, Spring TJ, Kaeding K, Krause K, Chengelis D, deJong AT, Franklin BA, **McCullough PA**. Low resting metabolic rate is associated with low cardiorespiratory fitness, low vitamin D and hyperuricemia in bariatric surgery patients. Poster P-41: 27th Annual Meeting of the American Society for Metabolic and Bariatric Surgery; 2010 June 24; Las Vegas, NV. *Surgery for Obesity and Related Diseases* 2010;6:S41.

A167) Spring TJ, Franklin BA, **McCullough PA**, Miller W, Zalesin K, Kaeding K, deJong AT. Reduced resting oxygen consumption in the morbidly obese: Implications for exercise prescription. Poster: AHA Annual Conference on Nutrition, Physical Activity and Metabolism; 2010 March 2; San Francisco, CA. *Circulation* 2010 March; Suppl. Page 102, Poster P29.

A168) Vanhecke TE, Franklin BA, Soman P, Lahiri A, Mieres JH, Sias T, Calnon D, Wolinsky D, Beller G, Burnham K, Conway L, Wight J, Walsh M, Daher E, Heller G, Udelson JE, **McCullough PA**. Influence of Myocardial Ischemia on Outcomes in Patients with Systolic Versus Non-Systolic Heart Failure. Journal of the American College of Cardiology Volume 57, Issue 14, Supplement, 5 April 2011, Page E2015. Best Fellow-in-Training Poster.

A169) Babyev R, Whaley-Connell A, Kshirsaga AV, Navaneethan S, Chen SC, Li S, **McCullough PA**, Bakris GL, Bomback AS, for the KEEP Investigators. Race does not influence ESRD and mortality in obese patients with CKD stages 3-4: results from the Kidney Early Evaluation Program. NKF 2010 Spring Clinical Meetings, Las Vegas, NV, April 24-30, 2011, P55.

A170) Bose S, Mehta NN, Chen SC, **McCullough PA**, for the KEEP Investigators. Poor glycemic control but not dyslipidemia is associated with albuminuria in patients with CKD and type 2 diabetes mellitus: a Kidney Early Evaluation Program report. NKF 2011 Spring Clinical Meetings, Las Vegas, NV, April 24-30, 2011, P56.

A171) Whaley-Connell A, Saab G, Szpunar S, Stevens L, Shlipak M, Bomback A, Tamura MK, McFarlane S, Li S, Chen SC, Collins A, Norris K, Bakris G, **McCullough, PA,** for the KEEP Investigators. Disease state awareness, kidney disease, and relationship to ESRD and death. NKF 2011 Spring Clinical Meetings, Las Vegas, NV, April 24-30, 2011, P121.

A172) Shah A, Fried L, Chen SC, Qiu Y, Li S, Cavanaugh K, Norris KC, Whaley-Connell AT, **McCullough PA**, Mehrotra R. Associations between access to care and awareness of chronic kidney disease. NKF 2012 Spring Clinical Meetings, Washington, DC, May 9-13, 2012, P170.

A173) Akrawinthawong K, Shaw M, Kachner J, Apostolov E, Basnakian A. Shah S, Tilak J, **McCullough PA**. Urine catalytic iron and neutrophil gelatinase associated lipocalin as companion early markers of acute kidney injury after cardiac surgery: a prospective pilot study. NKF 2013 Spring Clinical Meetings, Orlando, FL, April 3-5, 2013, P02. Am J Kidney Disease 2013;61(4):A1.

A174) Mehrotra R, Chen SC, Kestenbaum B, Peralta C, Saab G, Sachs M, Shah A, Li S, Norris K, Whaley-Connell A. **McCullough PA**. Serum phosphorus and death or progression to end-stage renal disease in persons screened in the community for chronic kidney disease. NKF 2013 Spring Clinical Meetings, Orlando, FL, April 3-5, 2013, P149. Am J Kidney Disease 2013;61(4):A7.

A175) Amin A, Chen SC, Kosiborod M, Whaley-Connell A, Li S, **McCullough PA.** Synergistic relationship between eGFR and microalbuminuria in predicting long-term progression to ESRD or death in patients with piabetes: results from KEEP. NKF 2013 Spring Clinical Meetings, Orlando, FL, April 3-5, 2013, P176. Am J Kidney Disease 2013;61(4):A8.

A176) Jurkovitz C, Li S, Norris K, Saab G, Bomback A, Whaley-Connell A, **McCullough PA.** Association Between Lack of Health Insurance and Risk of Death and ESRD: Results from the Kidney Early Evaluation Program (KEEP). NKF 2013 Spring Clinical Meetings, Orlando, FL, April 3-5, 2013, P135. Am J Kidney Disease 2013;61(4):A6.

A177) Larsen TR, Singh G, Velocci V, **McCullough PA.** Bioimpedience and fluid overload in patients admitted to the intensive care unit for sepsis syndromes. Blood Purif 2013;35:241.

A178) Manatsathit W, Al-Hamid H, Gill B, Leelasinjaroen P, Hashmi U, Barawi M, **McCullough P.** Experience in the management of upper gastrointestinal bleeding and outcomes in patients taking dabigatran compared with warfarin: a retrospective, comparative study. Am J Gastroenterol 2013; 108:S464-S465.

A179) Fried LF, Emanuele N, Hongyuan Zhang J, Brophy M, Conner T, Duckworth W, Leehey DJ, **McCullough PA**, O'Connor TZ, Palevsky PM, Reilly RF, Seliger SL, Warren S, Watnick S, Peduzzi P, Guarino P. Combined Angiotensin Inhibition for Treatment of Diabetic Nephropathy: VA Nephron-D Trial. HI-OR03 J Am Soc Nephrol 24: 2013.

A180) Kumar N, **McCullough PA.** Epidemiology of Cardiovascular Mortality in Patients with Chronic Kidney Disease and End-Stage Renal Disease. SA-PO235 J Am Soc Nephrol 24: 2013.

A181) Khan S, **McCullough PA**, Chawla LS, Beaver TM, Bennett Guerrero E, Wang D, Houser MT. M13-796 Study Design – A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Safety and

Effi cacy Trial of Multiple Dosing Regimens of ABT-719 for Prevention of Acute Kidney Injury in Patients Undergoing High Risk Cardiac Surgeries. PUB013, J Am Soc Nephrol 24: 2013.

A182) Larsen T, Kinni V, Zaks J, David S, **McCullough P**. A Lethal Case of Influenza and Type 5 Cardiorenal Syndrome. Crit Care Med 2013;41(12 Suppl.):1296.

A183) Akrawinthawong K, Parker G, Stivers D, Cannon L, Dixon S, Ricci J, Kupfer K, Alexander P, David S, **McCullough PA.** Subclinical and clinical contrast-induced acute kidney injury: results from the ENCINO Study. Am J Kidney Dis 2014;63(5):A23

A184) Palazzuoli A, Pellegrini M, Ruocco G, Martini G, Franci B, Campagna MS, Gilleman M, Nuti N, **McCullough PA**, Ronco C. Continuous versus bolus intermittent loop diuretic infusion in acutely decompensated heart failure: a prospective randomized trial. European Heart Journal 2014; 35:386; Suppl 1; Meeting Abstract: 2226; European Society of Cardiology Congress, Barcelona, Spain, 2014

A185) Shin HJ, **McCullough PA**, Li S, Cho E, Rimm E, Rosner B, Manson JE, Hu FB. The Association Between Diet Quality After Diabetes Diagnosis and Major Cardiovascular Events in Women With Type 2 Diabetes Mellitus. Circulation. 2014;130:A17257

A186) Oudiz R, Meyer C, Chin M, Feldman J, Goldsberry A, McConnell J, **McCullough P**, O'Grady M, Tapson V, Torres F, Waxman A, White R. Initial Data Report from "LARIAT": A Phase 2 Study of Bardoxolone Methyl in PAH Patients on Stable Background Therapy. Chest 2015;148(4_MeetingAbstracts):639A. doi:10.1378/chest.2345856

A187) **McCullough PA**, Spinowitz B. Novel Agents for the Prevention and Management of Hyperkalemia. Journal of Managed Care and Speciality Pharmacy, Supplement 21 (10-a), October 2015: E23.

A188) Haase VH, Hartman CS, Maroni BJ, Farzaneh-Far R, **McCullough PA**. Vadadustat, a Novel Oral Treatment for Anemia of Chronic Kidney Disease, Maintains Stable Hemoglobin Levels in Dialysis Patients Converting from Erythropoiesis-Stimulating Agents. SA-PO1110 J Am Soc Nephrol 26: 2015.

A189) Palazzuoli A, Ruocco G, Pellegrini M, Franci B, Campagna MS, Nuti R, Ronco C, **McCullough PA.** Impact of loop diuretic infusion modalities on congestion signs and outcomes in patients with acute heart failure. European Heart Journal 2015; 36:672, Suppl 1 Meeting Abstract: P3791; European Society of Cardiology Congress, London, UK 2015.

A190) Haase V, Hartman C, Maroni B, Farzaneh-Far R, **McCullough P**. Vadadustat Maintains Stable Hemoglobin Levels in Dialysis Patients Converting from Erythropoiesis-Stimulating Agent (ESA). Poster 171. NKF Spring Clinical Meetings, 2016.

A191) Munkres AG, Vasudevan A, Shin HJ, Sarmast SA, **McCullough PA**. Abstract 212: Integration of Multiple Cardiac Biomarkers into a Disease-Specific Score: Relationship to Clinical Status and Therapeutic Intensity. Circulation: Cardiovascular Quality and Outcomes, March, 2016.

A192) Tecson K, Silver M, Brune S, Cauthen C, Kwan M, Schussler J, Vasudevan A, Watts J, **McCullough PA.** Impact of Enhanced External Counterpulsation on Heart Failure Rehospitalization Among Patients with Ischemic Cardiomyopathy. J Am Coll Cardiol. 2016;67(13_S):1545. doi:10.1016/S0735-1097(16)31546-7.

A193) Prasad A, Morales J, Williams K, Sohn A, Levin D, Khan A, **McCullough P**, Mehran R, Bailey S. Contemporary Practice Patterns Related to the Risk of Acute Kidney Injury in the Catherization Laboratory: Results from an International Survey of Society of Cardiovascular Angiography and Intervention (SCAI) Cardiologists. Journal of the American College of Cardiology Volume 67, Issue 13, Supplement, 5 April 2016, Page 322

A194) Mazimba S, **McCullough P**, Rosner M, Mejia-Lopez E, Bilchick K. Changes in Renal Perfusion Pressure During Hemodynamically Guided Therapy is Associated with Worsening Renal Function. Journal of the American College of Cardiology Volume 69, Issue 11, Supplement, 21 March 2017, Page 768

A195) Mazimba S, Welch T, **McCullough P**, Breathett K, Tallaj J, Bergin J, Kennedy J, Smith L, Abuannadi M, Bilchick B. Systemic Arterial Pulsatility Index (SAPI) Predicts Adverse Outcomes in Advanced Heart Failure Patients. Journal of the American College of Cardiology Volume 69, Issue 11, Supplement, 21 March 2017, Page 856

A196) Vasudevan A , **McCullough PA**, Sathyamoorthy M, Schussler JM, Velasco CE, Lopez LR, Swift C, Schiffmann R, Bottiglieri T. Abstract 104: Urinary 11-Dehydro-Thromboxane B2 and Mortality in Patients with Stable Coronary Artery Disease. Scientific Poster Abstracts Selected for the 2016 Congress on Atherosclerotic Cardiovascular Disease Prevention, Sept. 16-18, 2016, Boca Raton, Florida., Clin Cardiol. 2016 Sep;39 Suppl 1:4-18. doi: 10.1002/clc.22597.

A197) Tecson KM, Hamman BL, Choi JW, Garg P, Olugbode OA, Schussler JM, Stoler RC, Vasudevan A, Velasco CE, **McCullough PA**. Abstract 15609: The Effect of Contrast-Induced Acute Kidney Injury in High Risk Patients Undergoing Cardiac Surgery. Circulation. 2016;134(Suppl 1).

A198) Ballantyne CM, **McCullough PA**, Sanganalmath SK , Koren A, Letierce A, Davidson MH. Safety and Efficacy of Alirocumab in Patients With Atherosclerotic Cardiovascular Disease, Based on Statin Intensity: Pooled Analyses of 5 Placebo-controlled Phase 3 Trials. Circulation. 2016;134:A16873.

A199) Pergola PE, Spinowitz BS, **McCullough PA**, Singh B, Menoyo JA, Lavin PT, Rasmussen HS, Fishbane S. Effect of Sodium Zirconium Cyclosilicate Treatment for Hyperkalemia on Blood Pressure in a Long-Term Open-Label Phase 3 Study. J Am Soc Nephrol 27: 2016 (TH-PO478).

A200) Golestaneh L, Gaber AO, Kalim S, **McCullough PA**, Germain MJ. Neutrophil Gelatinase-Associated Lipocalin (NGAL) Correlates to AKI Stage in ICU Patients. J Am Soc Nephrol 27: 2016 (TH-PO643).

A201) Kalim S, Gaber AO, Golestaneh L, Germain MJ, **McCullough PA.** Multi Center ICU Study Finds NGAL Increases Rate of AKI Detection. J Am Soc Nephrol 27: 2016 (TH-PO667).

A202) Haase VH, Khawaja Z, Chan J, Zuraw Q, Farzaneh-Far R, Maroni BJ, **McCullough PA.** Vadadustat Maintains Hemoglobin (Hb) Levels in Dialysis-Dependent Chronic Kidney Disease (DD-CKD) Patients Independent of Systemic Inflammation or prior Dose of Erythropoiesis-Stimulating Agent (ESA). J Am Soc Nephrol 27: 2016 (TH-PO960).

A203) Bottiglieri T, Vasudevan A, Lopez LR, Swift C, Schiffmann R, **McCullough P**. Increased F2-Isoprostane Oxidative Stress in Coronary Artery Disease (CAD) Patients with Poor Aspirin-Induced Thromboxane A2 Inhibition. 84th European Atherosclerosis Society (EAS) Congress, Innsbruck, Austria, May 29-June 1, 2016.

A204) Winkelmayer W, Block G, Chertow G, Fishbane S, Komatsu Y, **McCullough P**, Pergola P, Rosenberger C, Williamson D, Yee J, Collins A, Khawaya Z, Sharma A, Zuraw Q, Maroni B. The INNO2VATE Phase 3 Program of Vadadustat for Treatment of Anemia in Dialysis-Dependent CKD: Rationale and Study Design. Poster 173. NKF Spring Clinical Meetings, 2017.

A205) Lopez LR, Vasudevan A, Sathyamoorthy M, Schussler JM, Velasco C, Swift C, Schiffmann R, Bottiglieri T, **McCullough, PA**. Relationship of platelet thromboxane inhibition by aspirin and all-cause mortality in patients with stable coronary artery disease. 85th European Atherosclerosis Society (EAS) Congress, SAG007, pg 90, Prague, Czech Republic, April 24-26, 2017

A206) Oudiz RJ, Meyer C, Chin M, Feldman J, Goldsberry A, McConnel JWl, **McCullough PA**, O'Grady M, Tapson VF, Torres F, Waxman A, White J. Results of Interim Analysis of the Efficacy and Safety of Bardoxolone Methyl in Patients with Pulmonary Arterial Hypertension Associated with Connective Tissue Disease (CTD) (The LARIAT Study) American Journal of Respiratory and Critical Care Medicine 2017;195:A6896 http://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2017.195.1_MeetingAbstracts.A6896

A207) **McCullough PA**, Weir MR, deGoma EM, Zuraw Q, Sharma A, Luo W, Middleton J. Vadadustat does not prolong corrected QT interval in a thorough QTC study in healthy subjects. MP418. 54th ERA-EDTA Congress, Madrid, Spain, June 3-6, 2017. www.era-edta2017.org

A208) Meyer C, Warnock D, Chin M, Goldsberry A, **McCullough P**, O'Grady M, Toto R, Ward K, Block G, Pergola P. MP142 A Phase 2/3 Study of the Efficacy and Safety of Bardoxolone Methyl in Patients with Alport Syndrome. Nephrology Dialysis Transplantation, Volume 32, Issue suppl_3, 1 May 2017, Pages iii480.

A209) **McCullough PA**, Uhlig K, Neylan JF, Fishbane S. Safety and Efficacy of Ferric Citrate in Patients with Nondialysis-Dependent Chronic Kidney Disease and Iron Deficiency Anemia: Post Hoc Analysis in Patients with or Without Heart Failure. Journal of Cardiac Failure, August 2017, Volume 23, Issue 8, Supplement, Pages S64–S65.

A210) **McCullough PA**, David G, Todoran T, Brilakis ES, Ryan MP, Gunnarsson C. Iso-Osmolar Contrast Media and Adverse Renal and Cardiac Events after Percutaneous Cardiovascular Intervention. Poster accepted for presentation at ISPOR 20th Annual European Congress, November 4-8, 2017, Glasgow, Scotland, *Value in Health*, 2017.

A211) Fried L, Emanuele N, Huang Y, Zhang JH, Palevsky PM, Johnson GR, Seliger SL, **McCullough PA**, Conner TA, Brophy M. ESRD and Mortality after VA NEPHRON-D. American Society of Nephrology Kidney Week 2017, November 1-5, 2017, New Orleans, LA, ABSTRACT: TH-PO717

A212) Block GA, Pergola PE, Inker L, **McCullough PA**, Chin M, Meyer CH, Rheault MN, Kashtan C, Warnock DG. Initial Data Report from "CARDINAL": A Phase 2/3 Study of Bardoxolone Methyl in Patients with Alport Syndrome. American Society of Nephrology Kidney Week 2017, November 1-5, 2017, New Orleans, LA, ABSTRACT: FR-PO1053

A213) Fishbane S, Adler SH, Singh B, Lavin PT, **McCullough PA**, Kosiborod M, Pergola PE, Packham DK, Roger SD, Lerma EV, Butler J, Von haehling S, Spinowitz BS, Block GA. Maintained Efficacy and Safety of Sodium Zirconium Cyclosilicate for Hyperkalemia: 12-Month, Open-Label, Phase 3 Study, American Society of Nephrology Kidney Week 2017, November 1-5, 2017, New Orleans, LA, ABSTRACT: TH-PO1112

A214) Packham DK, **McCullough PA**, Kosiborod M, Spinowitz BS, Fishbane S, Pergola PE, Lerma EV, Butler J, Von haehling S, Adler SH, Singh B, Lavin PT. Efficacy and Safety of Short-Term Treatment with Sodium Zirconium Cyclosilicate (ZS-9) for Hyperkalemia: Open-Label, Phase 3 Trial. American Society of Nephrology Kidney Week 2017, November 1-5, 2017, New Orleans, LA, ABSTRACT: FR-PO1074

A215) **McCullough PA**, Pergola P, Fishbane S, von Haehling S, Roger S, Adler S, Singh B, Lavin P, Butler J, Block G, Lerma E, Packham D, Kosiborod M. Efficacy and Safety of Sodium Zirconium Cyclosilicate to Treat Hyperkalemia Among Patients Taking Renin–Angiotensin–Aldosterone System Inhibitors in a 12-Month, Open-Label, Phase 3 Study: A Post Hoc Subgroup Analysis. Circulation. 2017;136:A16610

A216) Ambrosy AP, Mulder H, Coles A, Krauss WE, Lam CS, **McCullough PA**, Pina I, Tromp J, Whellan DJ, O'Connor C, Mentz RJ. Renal Function and Exercise Training in Ambulatory Heart Failure Patients With a Reduced Ejection Fraction - Findings From the HF-ACTION Randomized Controlled Trial. Circulation. 2017;136:A17039

A217) Tecson KM, Kluger AY, DiMario S, Harrison D, **McCullough PA**. Abstract 131: Recurrent acute cardiovascular events and statin use. Circ: Cardiovasc Qual Outcomes. 2018;11(Suppl 1):A131 LP – A131. http://circoutcomes.ahajournals.org/content/11/Suppl_1/A131.abstract.

A218) Roger S, Lavin P, Lerma E, **McCullough PA**, Butler J, Spinowitz B, von Haehling S, Kosiborod M, Adler S, Fishbane S, Packham D. Safety and Efficacy of Sodium Zirconium Cyclosilicate for Long-Term Treatment of Hyperkalaemia in Patients with Chronic Kidney Disease: Results From an Open-Label, Phase 3 Study. FP071, 55th ERA-EDTA Congress, Copenhagen, Denmark, May 24-27, 2018

A219) Rossing P, Block GA, Chertow GM, Chin M, Goldsberry A, **McCullough PA**, Meyer CJ, Packham D, Spinowitz B, Sprague SM, Warnock DG, Pergola PE. Effect of Bardoxolone Methyl Treatment on Urinary Albumin in Patients with Type 2 Diabetes and Chronic Kidney Disease – Post-Hoc Analysis from BEAM and BEACON. FP152, 55th ERA-EDTA Congress, Copenhagen, Denmark, May 24-27, 2018

A220) Meyer CJ, Chakinala MM, Chin MP, Coyne DW, Feldman J, Goldsberry A, **McCullough PA**, O'Grady M, Torres F, Oudiz RJ, Ward K, White RJ. Two-Year Durability of Improvements In eGFR with Bardoxolone Methyl in Patients with Pulmonary Arterial Hypertension: The LARIAT Study. FP804, 55th ERA-EDTA Congress, Copenhagen, Denmark, May 24-27, 2018

A221) Barker CM, Van Houten J, Mehta H, Cord D, Gunnarsson, Mollenkopf S, Verta P, **McCullough PA.** The Healthcare Burden of Disease Progession in Medicare Patients with Functional Mitral Regurgitation. J Am Coll Cardiol March 12, 2019, 73 (9 Supplement 1) 1051; DOI:10.1016/S0735-1097(19)31658-4

A222) Cork DP, Mehta H, Barker CM, Verta P, Gunnarsson C, Ryan MP, Baker ER, Mollenkopf S, Van Houten J, **McCullough PA**. The Economic Impact of Mitral Regurgitation, on Medically Managed Incident Heart Failure. J Am Coll Cardiol March 12, 2019, 73 (9 Supplement 1) 1130; DOI:10.1016/S0735-1097(19)31737-1

A223) Cork DP, Mehta H, Barker CM, Verta P, Ryan MP, Baker E, Gunnarrson C, Mollenkopf S, Van Houten J, **McCullough PA**. The Impact of Mitral Regurgitation on Mortality and Heart Failure Admissions in Newly Diagnosed Heart Failure. J Am Coll Cardiol March 12, 2019, 73 (9 Supplement 1) 1131; DOI:10.1016/S0735-1097(19)31738-3

A224) **McCullough PA**, Cork DP, Mehta HS, Barker CM, Gunnarrson C, Ryan M, Mollenkopf S. Van Houten J, Verta P. Abstract 151: Therapeutic Intensity in Medically Managed Incident Heart Failure Patients with and without Mitral Regurgitation: A Claims Based Analysis. 4 Apr 2019 https://doi.org/10.1161/hcq.12.suppl_1.151Circulation: Cardiovascular Quality and Outcomes. 2019;12:A151

A225) Van Houten J, Cork D, Mehta H, Barker C, Verta P, Gunnarsson C, Ryan MP, Baker ER, Mollenkopf S, **McCullough PA**. Therapeutic Intensity Algorithm is Associations with Annual

Expenditures in Medically Managed Incident Heart Failure Patients with and without Mitral Regurgitation. ISPOR (The Professional Society for Health Economics and Outcomes Research) New Orleans, LA May 21, 2019 (top 10% award winner).

A226) Barker C, Cork D, **McCullough P**, Mehta H, Van Houten J, Gunnarsson C, Mollenkopf S, Verta P. Survival in Clinically Significant Tricuspid Regurgitation Patients with and without Heart Failure: Evidence from Optum's Integrated Databases. J Am Coll Cardiol March 29, 2020, 71 (11 Supplement 1) 1319; DOI:10.1016/S0735-1097(20)31946-X, https://www.jacc.org/doi/10.1016/S0735-1097%2820%2931946-X

A227) Mehta H, **McCullough P**, Cork D, Barker C, Van Houten J, Gunnarsson C, Mollenkopf S, Verta P. Medical Therapy in Patients with Functional Mitral Regurgitation: Are Patients Optimized in the Real World? J Am Coll Cardiol March 29, 2020, 71 (11 Supplement 1) 1322; DOI:10.1016/S0735-1097(20)31949-5. https://www.jacc.org/doi/10.1016/S0735-1097%2820%2931949-5

A228) **McCullough PA**, Mehta H, Barker C, Van Houten J, Mollenkopf S, Gunnarsson C, Ryan M, Cork D. Mortality and Guideline Directed Medical Therapy in Heart Failure Patients with Reduced Ejection Fraction: Evidence from Real World Data. J Am Coll Cardiol May 15, 2021, 77 (18_Supplement_1) 670; DOI: 10.1016/S0735-1097(21)02029-https://www.jacc.org/doi/full/10.1016/S0735-1097%2821%2902029-5

A229) Tecson KM, Kluger AY, Cassidy-Bushrow AE, Liu B, Coleman CM, Jones LK, Jefferson CR, VanWormer JJ, Xiang P, Habib M, Mues KE, **McCullough PA**. Early Statin Use and Recurrent Major Adverse Cardiovascular Events: A Multicenter Study. Lipid Management Best Practices. 2020;14(4): 561. Doi: 10.1016/j.jacl.2020.05.030

A230) Bottiglieri T, Arning E, Tecson KM, **McCullough PA**. The Plasma Metabolome is Significantly Altered in Hypercholesterolemia. Circ Res. 2020;127(12): e272-e284. Doi: 10.1161/RES.0000000000000450

A231) Hamadeh A, Aldujeli A, Briedis K, Tecson KM, Sanchez JS, Al Dujeili M, Al-Obeidi A, Diez-Gil JL, Zaliunas R, Stoler R, **McCullough PA**. TCT CONNECT-213 Clinical Characteristics and Outcomes of Patients With COVID-19 and STEMI Treated With Fibrinolytic Therapy. J Am Coll Cardiol. 2020;76(17):B89–90. doi: 10.1016/j.jacc.2020.09.228.

A232) **McCullough PA.** (2021) Multifaceted Highly Targeted Sequential Multidrug Treatment of Early Ambulatory High-Risk SARS-CoV-2 Infection (COVID-19). J Infect Dis Res, 4(S1): 10.

Peer-Reviewed Published Manuscripts

M1) **McCullough PA**, O'Neill WW. Influence of Regional Cardiovascular Mortality on the Use of Angiography after Acute Myocardial Infarction. Am J Cardiol 1997;79:575-80. PMID: 97221465.

M2) Stewart RE, Miller DD, Bowers TR, **McCullough PA**, Ponto RA, Grines CL, O'Neill WW, Juni JE, Safian RD. PET Perfusion and Vasodilator Function after Angioplasty for Acute Myocardial Infarction. J Nuc Med 1997;38:770-777. PMID: 97314102.

M3) Aliabadi D, Pica MC, **McCullough PA**, Grines CL, Safian RD, O'Neill WW, Goldstein JA. Rapid Bedside Coronary Angiography with a Portable Fluoroscopic Imaging System. Cathet Cardiovasc Diagn 1997;41(4):449-455. PMID: 97403128.

M4) **McCullough PA**, Wolyn R, Rocher LL, Levin RN, O'Neill WW. Acute Renal Failure after Coronary Intervention: Incidence, Risk Factors, and Relationship to Mortality. Am J Med 1997;103:368-375. PMID: 98041552.

M5) Thompson RJ, **McCullough PA**, Kahn JK, O'Neill WW. Prediction of Death and Neurologic Outcome in the Emergency Department in Out-of-Hospital Cardiac Arrest Survivors. Am J Cardiol 1998;81:17-21. PMID: 98122431.

M6) **McCullough PA**, Ayad O, O'Neill WW, Goldstein JA. Costs and Outcomes of Patients Admitted with Chest Pain and Essentially Normal Electrocardiograms. Clin Cardiol 1998;21:22-26. PMID: 98134803.

M7) **McCullough PA**, Smith GS. Evaluation of Narrative Text for Case Finding: The Need for Accuracy Measurement. Am J Ind Med 1998;34:133-136. PMID: 98315422.

M8) **McCullough PA**, Thompson RJ, Tobin KJ, Kahn JK, O'Neill WW. Validation of a Decision Support Tool for the Evaluation of Cardiac Arrest Victims. Clin Cardiol 1998;21:195-200. PMID: 98202866

M9) **McCullough** PA, O'Neill WW, Graham M, Stomel RJ, Rogers F, David S, Farhat A, Kazlauskaite R, Al-Zagoum M, Grines CL. A Prospective Randomized Trial of Triage Angiography in Acute Coronary Syndromes Ineligible for Thrombolytic Therapy: Results of the Medicine versus Angiography in Thrombolytic Exclusion (MATE) Trial. J Am Coll Cardiol 1998;32:596-605. PMID: 98412530.

M10) Redle JD, Khurana S, Marzan R, **McCullough PA**, Stewart JR, Westveer DC, O'Neill WW, Bassett JS, Tepe NA, Frumin HI. Prophylactic Oral Amiodarone Compared to Placebo for Prevention of Atrial Fibrillation Following Coronary Artery Bypass Surgery. Am Heart J 1999;138:144-150. PMID: 10385778.

M11) Stevens MA, **McCullough PA**, Tobin KJ, Speck JP, Westveer DC, Guido-Allen DA, Timmis GC, O'Neill WW. A Prospective Randomized Trial of Prevention Measures in Patients at High Risk for Contrast Nephropathy: Results of the P.R.I.N.C.E. Study. J Am Coll Cardiol 1999;33:403-411. PMID: 99137305.

M12) **McCullough PA,** O'Neill WW. Unstable Angina: Early Use of Coronary Angiography and Intervention. Cardiol Clin 1999;17(2):373-386. PMID: 10384833.

M13) **McCullough PA,** Marks KR. Aspirin and Ticlopidine after Routine Coronary Stenting: The Gold Standard as of 1999. J Thromb Thrombolysis 1999;7:233-239. PMID: 10373716.

M14) Sharma ND, **McCullough PA**, Philbin EF, Weaver WD. Left Ventricular Thrombus and Subsequent Thromboembolism in Patients with Severe Systolic Dysfunction. Chest 1999;117:314-320. PMID: 10669669.

M15) **McCullough** PA, O'Neill WW, Graham M, Stomel RJ, Rogers F, David S, Farhat A, Kazlauskaite R, Al-Zagoum M, Grines CL. Impaired Culprit Vessel Flow in Acute Coronary Syndromes Ineligible for Thrombolysis. J Thromb Thrombolysis 2001;10(3):247-253. PMID: 11122545.

M16) **McCullough** PA, O'Neill WW, Graham M, Stomel RJ, Rogers F, David S, Farhat A, Kazlauskaite R, Al-Zagoum M, Grines CL. A Time to Treatment Analysis in the Medicine versus Angiography in Thrombolytic Exclusion (MATE) Trial. J Interven Cardiol 2001;14(4):415-422. PMID: 12053495.

M17) **McCullough PA**, Soman SS, Shah SS, Smith ST, Marks KR, Yee J, Steven Borzak S. Risks Associated with Renal Dysfunction in Coronary Care Unit Patients. J Am Coll Cardiol 2000;36(3):679-684. PMID: 10987584.

M18) Philbin EF, **McCullough PA**, Dec GW, DiSalvo TG. Length of Stay and Procedure Utilization are the Major Determinants of Hospital Charges for Heart Failure. Clin Cardiol 2001;24:56-62. PMID: 11195608.

M19) Philbin EF, **McCullough PA**, DiSalvo TG, Dec GW, Jenkins PL, Weaver WD. Socioeconomic Status is an Important Determinant of Utilization of Invasive Procedures after Acute Myocardial Infarction in New York State. Circulation 2000;102[suppl III]:III107-115. PMID: 11082372

M20) Stone GW, Tumlin JA, Madyoon H, Lepor NE, **McCullough PA**, Mathur VS, Murray PT, O'Neill WW. Design and Rationale of CONTRAST--A Prospective, Randomized, Placebo-Controlled Trial of Fenoldopam Mesylate for the Prevention of Radiocontrast Nephropathy. Rev Cardiovasc Med. 2001;2 Suppl 1:S31-6. PMID: 12439366.

M21) Philbin EF**, McCullough PA,** DiSalvo TG, Dec GW, Jenkins PL, Weaver WD. Underuse of invasive procedures among Medicaid patients with acute myocardial infarction. Am J Public Health. 2001 Jul;91(7):1082-8. PMID: 11441735

M22) Bonifacio D, Malineni K, Kadakia R, Soman S, Sandberg K, **McCullough PA**. Coronary Calcification and Interventional Outcomes in Dialysis Patients. J Cardiovasc Risk 2001;8(3):133-7. PMID 11455844

M23) Beattie JN, Soman SS, Sandberg KR, Yee J, Borzak S, **McCullough PA**. Determinants of Mortality after Myocardial Infarction in Patients with Advanced Renal Dysfunction. Am J Kid Disease 2001;37:1191-2000. PMID 11382688.

M24) Cannon CP, Weintraub WS, Demopoulos LA, Vicari R, Frey MJ, Lakkis N, Neumann FJ, Robertson DH, DeLucca PT, DiBattiste PM, Gibson CM, Braunwald E; TACTICS (Treat Angina with Aggrastat and Determine Cost of Therapy with an Invasive or Conservative Strategy)--Thrombolysis in Myocardial Infarction 18 Investigators (**McCullough PA**, Endpoints Committee). Comparison of early invasive and conservative strategies in patients with unstable coronary syndromes treated with the glycoprotein IIb/IIIa inhibitor tirofiban. N Engl J Med. 2001 Jun 21;344(25):1879-87. PMID: 11419424

M25) Shah SS, Noor H, Tokarski G, McCord J, Khoury N, McCabe KB, Marks KR, Morlock RJ, **McCullough PA**. Clinical Effectiveness Evaluation of an Emergency Department Clinical Decision Unit. British Journal of Clinical Governance 2001;6(1):40-45.

M26) Cheitlin MD, Gerstenblith G, Hazzard WR, Pasternak R, Fried LP, Rich MW, Krumholz HM, Peterson E, Reves JG, McKay C, Saksena S, Shen WK, Akhtar M, Brass LM, Biller J. (**McCullough PA**, Heart Failure Subcommittee). AHA Conference Proceedings: Do existing databases hold the answers to clinical questions in geriatric cardiovascular disease and stroke? Executive Summary. Database Conference, January 27-30, 2000. Circulation. 2001 Aug 14;104(7):E39. PMID: 11502721.

M27) McCord J, Nowak RM, **McCullough PA**, Foreback C, Borzak S, Tokarski G, Tomlanovich MC, Jacobsen G, Weaver WD. Ninety Minute Exclusion of Acute Myocardial Infarction Using Quantitative Point of Care Testing of Myoglobin and Troponin I. Circulation 2001; Sep 25;104(13):1483-8. PMID: 11571240.

M28) **McCullough PA**, Manley HJ. Prediction and Prevention of Contrast Nephropathy. J Interven Cardiol 2001;14(5):547-558. PMID: 12053647.

M29) **McCullough PA**, Philbin EF, Spertus JA, Kaatz S, Sandberg KR, Weaver WD. Confirmation of a Heart Failure Epidemic: Findings from the Resource Utilization Among Congestive Heart Failure (R.E.A.C.H.) Study. J Am Coll Cardiol 2002;39:60-69. PMID: 11755288.

M30) Riaz K, Forker AD, Garg M, **McCullough PA**. Atypical presentation of cocaine-induced Type A aortic dissection: a diagnosis made by transesophageal echocardiography. J Investig Med. 2002 Mar;50(2):140-2. PMID 11928942.

M31) Levin A, Stevens L, **McCullough PA**. Cardiovascular disease and the kidney. Tracking a killer in chronic kidney disease. Postgraduate Medicine 2002;11(4):53-60. PMID 11985133.

M32) Ketterer MW, Denollet J, Goldberg AD, **McCullough PA**, John S, Farha AJ, Clark V, Keteyian S, Chapp J, Thayer B, Deveshwar S. The Big Mush: Psychometric Measures are Confounded and

Nonindependent in Their Association with Age at Initial Diagnosis of Ischemic Coronary Heart Disease. J Cardiovasc Risk 2002:9;41-48. PMID 11984216.

M33) Abraham WT, Fisher WG, Smith AL, Delurgio DB, Leon AR, Loh E, Kocovic DZ, Packer M, Clavell AL, Hayes DL, Ellestad M, Trupp RJ, Underwood J, Pickering F, Truex C, McAtee P, Messenger J; MIRACLE Study Group. Multicenter InSync Randomized Clinical Evaluation (**McCullough PA**, Site Principal Investigator). Cardiac resynchronization in chronic heart failure. N Engl J Med. 2002 Jun 13;346(24):1845-53. PMID 12063368.

M34) **McCullough PA**. Outcomes studies and the biomedical research enterprise. J Interv Cardiol. 2002 Apr;15(2):167-70. PMID 12063813.

M35) Shenkman HJ, Pampati V, Khandelwal AK, McKinnon J, Nori D, Kaatz S, Sandberg KR, **McCullough PA**. Congestive Heart Failure and QRS Duration: Establishing Prognosis Study. Chest 2002 Aug;122(2):528-34. PMID 12171827.

M36) Soman SS, Sandberg KR, Borzak S, Hudson MP, Yee J, **McCullough PA**. The Independent Association of Renal Dysfunction and Arrhythmias in Critically Ill Patients. Chest 2002 Aug;122(2):669-77. PMID 12171849.

M37) Maisel AS, Krishnaswamy P, Nowak RM, McCord J, Hollander JE, Duc P, Omland T, Storrow AB, Abraham WT, Wu AHB, Clopton P, **McCullough PA,** for the BNP Multinational Study Investigators. Bedside B-type Natriuretic Peptide in the Emergency Diagnosis of Heart Failure: Primary Results from the Breathing Not Properly (BNP) Multinational Study. N Engl J Med, 2002:347(3);161-167. PMID 12124404.

M38) **McCullough PA,** Sullivan R. News and Views: Equipoise on Opening Chronic Total Occlusions. J Interven Cardiol 2002;15(3):243-247. PMID 12141153.

M39) **McCullough PA,** Sandberg KR, Borzak S, Hudson MP, Garg M, Manley HJ. Benefits of aspirin and beta-blockade after myocardial infarction in patients with chronic kidney disease. Am Heart J. 2002 Aug;144(2):226-32. PMID 12177638.

M40) **McCullough PA**, Nowak RM, McCord J, Hollander JE, Herrman HC, Steg PG, Duc P, Westheim A, Omland T, Wold Knudsen C, Storrow AB, Abraham WT, Lamba S, Wu AHB, Perez A, Clopton P, Krishnaswamy P, Kazanegra R, Maisel AS, for the BNP Multinational Study Investigators. B-type Natriuretic Peptide and Clinical Judgment in the Emergency Diagnosis of Heart Failure: An Analysis from the Breathing Not Properly (BNP) Multinational Study. Circulation 2002;106:416-422. PMID 12135939.

M41) **McCullough PA,** Nowak RM, Foreback C, Borzak S, Tokarski G, Tomlanovich MC, Weaver WD, Sandberg KR, McCord J. Emergency evaluation of chest pain in patients with advanced kidney disease. Arch Intern Med. 2002 Nov 25;162(21):2464-8. PMID 12437406.

M42) Guitterez N, Diaz A, Timmis GC, O'Neill WW, Stevens MA, **McCullough PA**. Determinants of serum creatinine trajectory in acute contrast nephropathy. J Interv Cardiol. 2002 Oct;15(5):349-54. PMID: 12440177.

M43) **McCullough PA,** Prakash R, Tobin KJ, O'Neill WW, Thompson RJ. Application of a cardiac arrest score in patients with sudden death and ST segment elevation for triage to angiography and intervention. J Interv Cardiol. 2002 Aug;15(4):257-61. PMID 12238419.

M44) Reddy HK, Koshy SK, Sturek M, Jayam VK, Bedi A, **McCullough PA.** Rationale and methods for assessment of coronary flow prior to coronary intervention: where are we headed? J Interv Cardiol. 2002 Aug;15(4):335-41. PMID 12238433.

M45) Sengstock D, Pasnoori V, Obaidat O, Mehra P, Marks KR, **McCullough PA**. Asthma, Beta-Agonists, and the Development of Congestive Heart Failure: Results of the A.B.C.H.F. Study. J Card Failure, 2002;8(4):232-238. PMID 12397571.

M46) Sullivan R, **McCullough PA**. Shifting statins from clinic to critical care. J Interv Cardiol. 2002 Oct;15(5):431-4. PMID 12440192.

M47) **McCullough PA.** Cardiorenal Risk: An Important Clinical Intersection. Rev Cardiovasc Med. 2002;3(2):71-76. PMID 12447150

M48) **McCullough PA**, Nowak RM, Foreback C, Borzak S, Tokarski G, Tomlanovich MC, Khoury NE, Weaver WD, Sandberg KR, McCord J. Performance of Multiple Cardiac Biomarkers Measured in the Emergency Department in Patients with Chronic Kidney Disease and Chest Pain. Acad Emerg Med. 2002 Dec;9(12):1389-1396. PMID 12460842

M49) **McCullough PA**. Scope of cardiovascular complications in patients with kidney disease. Ethn Dis. 2002 Fall;12(4):S3-44-8. PMID 12477154

M50) Safley DM, **McCullough PA**. Antiphospholipid syndrome with renal artery embolism: case report. Rev Cardiovasc Med. 2002 Fall;3(4):192-201. PMID: 12556753

M51) **McCullough PA,** Sandberg KR, Yee J, Hudson MP. Mortality benefit of angiotensin-converting enzyme inhibitors after cardiac events in patients with end-stage renal disease. J Renin Angiotensin Aldosterone Syst. 2002 Sep;3(3):188-91. PMID: 12563570

M52) **McCullough PA.** Beyond serum creatinine: defining the patient with renal insufficiency and why? Rev Cardiovasc Med 2003;4(Suppl 1):S2-S6. PMID 12556731

M53) Riaz K, Forker AD, Isley WL, Hamburg MS, **McCullough PA.** Hyperthyroidism: a curable cause of congestive heart failure-three case reports and a review of the literature. Congest Heart Fail. 2003 Jan-Feb;9(1):40-6. PMID 12556677

M54) **McCullough PA**, Philbin EF, Spertus JA, Sandberg KR, Sullivan RA, Kaatz S. Opportunities for improvement in the diagnosis and treatment of heart failure.
Clin Cardiol. 2003 May;26(5):231-7. PMID 12769251

M55) Maisel AS, DeMaria A, Krishnaswamy P, Nowak RM, McCord J, Hollander JE, Duc P, Omland T, Storrow AB, Abraham WT, Wu AHB, Clopton P, **McCullough PA,** for the BNP Multinational Study Investigators. Bedside B-Type natriuretic peptide in the emergency diagnosis of heart failure with reduced or preserved ejection fraction. Results from the Breathing Not Properly Multinational Study. J Am Coll Cardiol. 2003 Jun 4;41(11):2010-7.
PMID 12798574

M56) **McCullough PA,** Duc P, Omland T, McCord J, Nowak RM, Hollander JE, Herrmann HC, Steg PG, Westheim A, Knudsen CW, Storrow AB, Abraham WT, Lamba S, Wu AH, Perez A, Clopton P, Krishnaswamy P, Kazanegra R, Maisel AS; Breathing Not Properly Multinational Study Investigators. B-type natriuretic peptide and renal function in the diagnosis of heart failure: an analysis from the Breathing Not Properly Multinational Study.
Am J Kidney Dis. 2003 Mar;41(3):571-9. PMID 12612980

M57) **McCullough PA**, Hollander JE, Nowak RM, Storrow AB, Duc P, Omland T, McCord J, Hermann HC, Steg PG, Westheim A, Knudsen CW, Abraham WT, Lamba S, Wu AHB, Perez A, Clopton P, Krishnaswamy P, Kazanegra R, Maisel AS, for the BNP Multinational Study Investigators. Uncovering Heart Failure in Patients with a History of Pulmonary Disease: Rationale for the Early Use of B-type Natriuretic Peptide in the Emergency Department.
Acad Emerg Med. 2003 Mar;10(3):198-204. PMID 12615582

M58) **McCullough PA**. Why is chronic kidney disease the "spoiler" for cardiovascular outcomes? J Am Coll Cardiol. 2003 Mar 5;41(5):725-8. PMID 12628713

M59) Riaz K, **McCullough PA.** Fatal case of delayed repolarization due to cocaine abuse and global ischemia. Rev Cardiovasc Med. 2003 Winter;4(1):47-53. PMID 12684601

M60) Safley DM**, McCullough PA.** The Emerging Role of Brain Natriuretic Peptide in the Management of Acute and Chronic Heart Failure in Outpatients. Heart Fail Monit. 2003;4(1):13-20. PMID 12808480

M61) **McCullough PA**, Philbin EF, Spertus JA, Sandberg KR, Kaatz S. Angiotensin converting enzyme inhibitors and beta-blockers in African Americans with heart failure. Ethn Dis. 2003 Summer;13(3):331-6. PMID 12894957.

M62) **McCullough PA**. Acute coronary syndromes in patients with renal failure.
Curr Cardiol Rep. 2003 Jul;5(4):266-70. PMID 12801443

M63) **McCullough PA**. B-type natriuretic peptides. A diagnostic breakthrough in heart failure. Minerva Cardioangiol. 2003 Apr;51(2):121-9. PMID 12783068

M64) Keeley EC, Kadakia R, Soman S, Borzak S, **McCullough PA**. Analysis of long-term survival after revascularization in patients with chronic kidney disease presenting with acute coronary syndromes. Am J Cardiol. 2003 Sep 1;92(5):509-14. PMID 12943868.

M65) **McCullough PA**, Omland T, Maisel AS. B-type natriuretic peptides: a diagnostic breakthrough for clinicians. Rev Cardiovasc Med. 2003 Spring;4(2):72-80. PMID 12776016

M66) **McCullough PA**, Abraham WT. Does Quality of Life Evidence Assist in the Selection of Patients for Resynchronization Therapy? Card Electrophysiol Rev. 2003 Jan;7(1):71-76. PMID 12766523

M67) Chew DP, Bhatt DL, Kimball W, Henry TD, Berger P, **McCullough PA**, Feit F, Bittl JA, Lincoff AM. Bivalirudin provides increasing benefit with decreasing renal function: a meta-analysis of randomized trials. Am J Cardiol. 2003 Oct 15;92(8):919-23. PMID 14556866

M68) Maisel AS, **McCullough PA**. Cardiac natriuretic peptides: a proteomic window to cardiac function and clinical management. Rev Cardiovasc Med. 2003;4 Suppl 4:S3-S12. PMID 14564223

M69) **McCullough PA**, Sandberg KR. Sorting out the evidence on natriuretic peptides. Rev Cardiovasc Med. 2003;4 Suppl 4:S13-9. PMID 14564224

M70) **McCullough PA,** Sandberg KR. B-type natriuretic peptide and renal disease. Heart Fail Rev. 2003 Oct;8(4):355-8. PMID 14574057

M71) Keeley EC, **McCullough PA.** Coronary revascularization in patients with end-stage renal disease: risks, benefits, and optimal strategies. Rev Cardiovasc Med. 2003 Summer;4(3):125-30. PMID 12949440.

M72) McCord J, Nowak RM, Hudson MP, **McCullough PA**, Tomlanovich MC, Jacobsen G, Tokarski G, Khoury N, Weaver WD. The prognostic significance of serial myoglobin, troponin I, and creatine kinase-MB measurements in patients evaluated in the emergency department for acute coronary syndrome. Ann Emerg Med. 2003 Sep;42(3):343-50. PMID 12944886.

M73) Sarnak MJ, Levey AS, Schoolwerth AC, Coresh J, Culleton B, Hamm LL, **McCullough PA**, Kasiske BL, Kelepouris E, Klag MJ, Parfrey P, Pfeffer M, Raij L, Spinosa DJ, Wilson PW; AHA Councils on Kidney in Cardiovascular Disease, High Blood Pressure Research, Clinical Cardiology, and Epidemiology and Prevention. Kidney disease as a risk factor for development of cardiovascular disease: a statement from the AHA Councils on Kidney in Cardiovascular Disease, High Blood Pressure Research, Clinical Cardiology, and Epidemiology and Prevention. Circulation. 2003 Oct 28;108(17):2154-69. PMID 14581387.

M74) Sarnak MJ, Levey AS, Schoolwerth AC, Coresh J, Culleton B, Hamm LL, **McCullough PA**, Kasiske BL, Kelepouris E, Klag MJ, Parfrey P, Pfeffer M, Raij L, Spinosa DJ, Wilson PW; AHA Councils on Kidney in Cardiovascular Disease, High Blood Pressure Research, Clinical Cardiology, and Epidemiology and Prevention. Kidney disease as a risk factor for development of cardiovascular disease: a statement from the AHA Councils on Kidney in Cardiovascular Disease, High Blood Pressure Research, Clinical Cardiology, and Epidemiology and Prevention. Hypertension. 2003 Nov;42(5):1050-65. PMID 14604997.

M75) Stone GW, **McCullough PA**, Tumlin JA, Lepor NE, Madyoon H, Murray P, Wang A, Chu AA, Schaer GL, Stevens M, Wilensky RL, O'Neill WW; CONTRAST Investigators. Fenoldopam mesylate for the prevention of contrast-induced nephropathy: a randomized controlled trial. JAMA. 2003 Nov 5;290(17):2284-91. PMID 14600187.

M76) Steg PG, Duc P, Joubin L, McCord J, Abraham WT, Hollander JE, Omland T, Baron G, Aumont MC, Mentre F, **McCullough PA**, Maisel AS. A comparison of bedside B-type natriuretic peptide versus echocardiographic determination of ejection fraction in the diagnosis of heart failure. J Am Coll Cardiol. 2003 Mar 19;41(6 Suppl B):337. PMID 14637402

M77) Kernis SJ, Franklin BA, Sandberg KR, O'Neill WW, **McCullough PA**. Advantages of an early invasive approach in acute coronary syndromes. Am J Med. 2003 Dec 1;115(8):669-71. PMID 14656622

M78) **McCullough PA,** Sandberg KR. Epidemiology of contrast-induced nephropathy. Rev Cardiovasc Med. 2003;4 Suppl 5:S3-9. PMID 14668704

M79) Khanna A, **McCullough PA**. Malignant hypertension presenting as hemolysis, thrombocytopenia, and renal failure. Rev Cardiovasc Med. 2003 Fall;4(4):255-9. PMID 14674379

M80) **McCullough PA,** Fonarow GC. B-type natriuretic peptide and multimarker approaches in cardiovascular medicine. Rev Cardiovasc Med. 2003;4 Suppl 4:S1-2. PMID 14703686

M81) **McCullough PA,** Kuncheria J, Mathur VS. Diagnostic and therapeutic utility of B-type natriuretic peptide in patients with renal insufficiency and decompensated heart failure. Rev Cardiovasc Med. 2003;4 Suppl 7:S3-S12. PMID 14668695

M82) Franklin BA, **McCullough PA,** Gordon S. Winter Storm Warning: Snow Removal May Be Hazardous to Your (Patient's) Health. Curr Sports Med Rep. 2004 Apr;3(2):59-61. PMID 14980132

M83) Conaway DG, Sullivan RA, **McCullough PA.** Improved Symptoms, Physical Limitation, and Self-Efficacy After Resynchronization in a Patient with Heart Failure and a Prolonged QRS Duration. Rev Cardiovasc Med. 2004 Winter;5(1):53-7. PMID 15029112

M84) **McCullough PA,** Sandberg KR Chronic kidney disease and sudden death: strategies for prevention. Blood Purif. 2004;22(1):136-42. PMID 14732822

M85) Knudsen, CW, Omland, T, Clopton P, Westheim, A, Abraham, WT, Storrow AB, J McCord, Nowak, RM, Steg, PG, Duc, P, **McCullough, PA**, Maisel, AS, for the BNP Multinational Study Investigators. Diagnostic Value of B-type Natriuretic Peptide and Chest Radiograph Findings in Patients with Acute Dyspnea. Am J Med. 2004 Mar 15;116(6):363-8. PMID 15006584

M86) **McCullough PA,** Gibson CM, Dibattiste PM, Demopoulos LA, Murphy SA, Weintraub WS, Neumann FJ, Khanal S, Cannon CP; TACTICS-TIMI-18 INVESTIGATORS. Timing of Angiography and Revascularization in Acute Coronary Syndromes: J Interv Cardiol. 2004 Apr;17(2):81-86. PMID 15104769.

M87) **McCullough PA**. B-type natriuretic peptide and its clinical implications in heart failure. Am Heart Hosp J 2004;2:26-33.

M88) **McCullough PA**, Dorrell KA, Sandberg KR, Yerkey MW. Ximelagatran: a novel oral direct thrombin inhibitor for long-term anticoagulation. Rev Cardiovasc Med. 2004 Spring;5(2):99-103. PMID 15184843.

M89) Maisel AS, Clopton P, Krishnaswamy P, Nowak RM, McCord J, Hollander JE, Duc P, Omland T, Storrow AB, Abraham WT, Wu AH, Steg G, Westheim A, Knudsen CW, Perez A, Kazanegra R, Bhalla V, Herrmann HC, Aumont MC, **McCullough PA**; BNP Multinational Study Investigators. Impact of age, race, and sex on the ability of B-type natriuretic peptide to aid in the emergency diagnosis of heart failure: results from the Breathing Not Properly (BNP) multinational study. Am Heart J. 2004 Jun;147(6):1078-84. PMID 15199359.

M90) **McCullough PA**. Cardiovascular risk reduction and preservation of renal function in the early nephropathy patient. Adv Chronic Kidney Dis. 2004 Apr;11(2):184-91. PMID 15216489.

M91) Yerkey MW, Kernis SJ, Franklin BA, Sandberg KR, **McCullough PA**. Renal dysfunction and acceleration of coronary disease. Heart. 2004 Aug;90(8):961-6. PMID 15253986

M92) **McCullough PA,** Soman S. Cardiovascular calcification in patients with chronic renal failure: Are we on target with this risk factor? Kidney Int. 2004 Sep;66 Suppl 90:S18-24. PMID 15296503

M93) **McCullough PA,** Sandberg KR, Dumler F, Yanez JE. Determinants of coronary vascular calcification in patients with chronic kidney disease and end-stage renal disease: a systematic review. J Nephrol. 2004 Mar-Apr;17(2):205-15. PMID 15293519

M94) **McCullough PA.** Opportunities for improvement in the cardiovascular care of patients with end-stage renal disease. Adv Chronic Kidney Dis. 2004 Jul;11(3):294-303. PMID 15241743

M95) Dumler F, **McCullough PA**. Optimal dialysis for the end-stage renal disease patient with cardiovascular disease. Adv Chronic Kidney Dis. 2004 Jul;11(3):261-73. PMID 15241741

M96) Keeley EC, **McCullough PA.** Coronary revascularization in patients with coronary artery disease and chronic kidney disease. Adv Chronic Kidney Dis. 2004 Jul;11(3):254-60. PMID 15241740

M97) **McCullough PA.** Guest editorial: Cardiovascular care in end-stage renal disease. Adv Chronic Kidney Dis. 2004 Jul;11(3):245. PMID 15241738

M98) **McCullough PA**, Bakris GL, Owen WF Jr, Klassen PS, Califf RM. Slowing the progression of diabetic nephropathy and its cardiovascular consequences. Am Heart J. 2004 Aug;148(2):243-51. PMID 15308993

M99) Best PJ, Reddan DN, Berger PB, Szczech LA, **McCullough PA**, Califf RM. Cardiovascular disease and chronic kidney disease: insights and an update. Am Heart J. 2004 Aug;148(2):230-42. PMID 15308992

M100) Bakris GL, Toto RD, **McCullough PA**. Rationale and design of a study comparing two fixed-dose combination regimens to reduce albuminuria in patients with type II diabetes and hypertension. J Hum Hypertens. 2004 Sep 30 PMID 15457206.

M101) Wu AH, Omland T, Duc P, McCord J, Nowak RM, Hollander JE, Herrmann HC, Steg PG, Wold Knudsen C, Storrow AB, Abraham WT, Perez A, Kamin R, Clopton P, Maisel AS, **McCullough PA**. Breathing Not Properly Multinational Study Investigators. The effect of diabetes on B-type natriuretic peptide concentrations in patients with acute dyspnea: an analysis from the Breathing Not Properly Multinational Study. Diabetes Care. 2004 Oct;27(10):2398-404. PMID 15451907

M102) **McCullough PA**, Franklin BA. Conventional risk factors and cardiac events--debunking an old myth about prevalence. Rev Cardiovasc Med. 2004 Summer;5(3):185-6. PMID 15346104

M103) Maisel A, Hollander JE, Guss D, **McCullough P**, Nowak R, Green G, Saltzberg M, Ellison SR, Bhalla MA, Bhalla V, Clopton P, Jesse R; Rapid Emergency Department Heart Failure Outpatient Trial investigators. Primary results of the Rapid Emergency Department Heart Failure Outpatient Trial (REDHOT): a multicenter study of B-type natriuretic peptide levels, emergency department decision making, and outcomes in patients presenting with shortness of breath. J Am Coll Cardiol. 2004 Sep 15;44(6):1328-33. PMID 15364340

M104) **McCullough PA**. Cardiovascular disease in chronic kidney disease from a cardiologist's perspective. Curr Opin Nephrol Hypertens. 2004 Nov;13(6):591-600. PMID: 15483448

M105) McCord J, Mundy BJ, Hudson MP, Maisel AS, Hollander JE, Abraham WT, Steg PG, Omland T, Knudsen CW, Sandberg KR, **McCullough PA**. Relationship between obesity and B-type natriuretic Peptide levels. Arch Intern Med. 2004 Nov 8;164(20):2247-52. PMID: 15534162

M106) Wase A, Basit A, Nazir R, Jamal A, Shah S, Khan T, Mohiuddin I, White C, Saklayen M, **McCullough PA**. Impact of chronic kidney disease upon survival among implantable cardioverter-defibrillator recipients. J Interv Card Electrophysiol. 2004 Dec;11(3):199-204. PMID: 15548886

M107) **McCullough PA**. B-type natriuretic peptide and its clinical implications in heart failure. Am Heart Hosp J. 2004 Winter;2(1):26-33. PMID: 15604836

M108) Silver MA, Maisel A, Yancy CW, **McCullough PA**, Burnett JC Jr., Francis GS, Mehra MR, Peacock WF 4th, Fonarow G, Gibler WB, Morrow DA, Hollander J; BNP Consensus Panel. BNP Consensus Panel 2004: A clinical approach for the diagnostic, prognostic, screening, treatment monitoring, and therapeutic roles of natriuretic peptides in cardiovascular diseases. Congest Heart Fail. 2004 Sep-Oct;10(5 Suppl 3):1-30. PMID: 15604859

M109) **McCullough PA**. Preface. Ximelagatran and oral direct thrombin inhibition. Rev Cardiovasc Med. 2004;5 Suppl 5:S1. PMID: 15619609

M110) Prystowsky EN, **McCullough PA**. Introduction: the role of oral direct thrombin inhibitors in cardiovascular disease. Rev Cardiovasc Med. 2004;5 Suppl 5:S2-3. PMID: 15619611

M111) **McCullough PA**. Clinical applications of B-type natriuretic peptide levels in the care of cardiovascular patients. Minerva Cardioangiol. 2004 Dec;52(6):479-89. PMID: 15729209

M112) Safley DM, Awad A, Sullivan RA, Sandberg KR, Mourad I, Boulware M, Merhi W, **McCullough PA**. Changes in B-type natriuretic peptide levels in hemodialysis and the effect of depressed left ventricular function. Adv Chronic Kidney Dis. 2005 Jan;12(1):117-24. PMID: 15719344.

M113) **McCullough PA**, Khandelwal AK, McKinnon JE, Shenkman HJ, Pampati V, Nori D, Sullivan RA, Sandberg KR, Kaatz S. Outcomes and prognostic factors of systolic as compared with diastolic heart failure in urban America. Congest Heart Fail. 2005 Jan-Feb;11(1):6-11. PMID: 15722664.

M114) **McCullough PA**, Lepor NE. The deadly triangle of anemia, renal insufficiency, and cardiovascular disease: implications for prognosis and treatment. Rev Cardiovasc Med. 2005 Winter;6(1):1-10. PMID: 15741920

M115) El-Achkar TM, Ohmit SE, **McCullough PA**, Crook ED, Brown WW, Grimm R, Bakris GL, Keane WF, Flack JM. Higher prevalence of anemia with diabetes mellitus in moderate kidney insufficiency: The Kidney Early Evaluation Program. Kidney Int. 2005 Apr;67(4):1483-8. PMID: 15780101

M116) **McCullough PA**, Soman SS. Contrast-induced nephropathy. Crit Care Clin. 2005 Apr;21(2):261-80. PMID: 15781162

M117) **McCullough PA**. Evaluation and treatment of coronary artery disease in patients with end-stage renal disease. Kidney Int Suppl. 2005 Jun;(95):s51-8. PMID: 15882314

M118) Knudsen CW, Clopton P, Westheim A, Klemsdal TO, Wu AH, Duc P, McCord J, Nowak RM, Hollander JE, Storrow AB, Abraham WT, **McCullough PA**, Maisel AS, Omland T. Predictors of elevated B-type natriuretic peptide concentrations in dyspneic patients without heart failure: an analysis from the breathing not properly multinational study. Ann Emerg Med. 2005 Jun;45(6):573-80. PMID: 15940086

M119) Gallagher MJ, Franklin BA, Ehrman JK, Keteyian SJ, Brawner CA, deJong AT, **McCullough PA**. Comparative Impact of Morbid Obesity vs Heart Failure on Cardiorespiratory Fitness. Chest. 2005 Jun;127(6):2197-203. PMID: 15947337

M120) Mehta SR, Cannon CP, Fox KA, Wallentin L, Boden WE, Spacek R, Widimsky P, **McCullough PA**, Hunt D, Braunwald E, Yusuf S. Routine vs selective invasive strategies in patients with acute coronary syndromes: a collaborative meta-analysis of randomized trials. JAMA. 2005 Jun 15;293(23):2908-17. PMID: 15956636

M121) Merhi W, Dixon SR, O'Neill WW, Hanzel GS, **McCullough PA**. Percutaneous left ventricular assist device in acute myocardial infarction and cardiogenic shock. Rev Cardiovasc Med. 2005 Spring;6(2):118-23. PMID: 15976733

M122) Gallagher MJ, **McCullough PA.** The role of B-type natriuretic peptide in the diagnosis and treatment of decompensated heart failure. Int J Geriatric Cardiol 2004; September 1(1):21-28.

M123) **McCullough PA**, Hassan SA, Pallekonda V, Sandberg KR, Nori DB, Soman SS, Bhatt S, Hudson MP, Weaver WD. Bundle branch block patterns, age, renal dysfunction, and heart failure mortality. Int J Cardiol. 2005 Jul 10;102(2):303-8. PMID: 15982501

M124) Steg PG, Joubin L, McCord J, Abraham WT, Hollander JE, Omland T, Mentre F, **McCullough PA**, Maisel AS. B-type natriuretic Peptide and echocardiographic determination of ejection fraction in the diagnosis of congestive heart failure in patients with acute dyspnea. Chest. 2005 Jul;128(1):21-9. PMID 16002911

M125) Gallagher MJ, **McCullough PA**. The emerging role of natriuretic peptides in the diagnosis and treatment of decompensated heart failure. Curr Heart Fail Rep. 2004 Sep;1(3):129-35. PMID: 16036036

M126) **McCullough PA**, Sandberg KR, Miller WM, Odom JS, Sloan KC, de Jong AT, Nori KE, Irving SD, Krause KR, Franklin BA. Substantial weight gain during adulthood: the road to bariatric surgery. Prev Cardiol. 2005 Summer;8(3):155-9. PMID 16034218

M127) Miller WM, Nori Janosz KE, Yanez J, **McCullough PA**. Effects of weight loss and pharmacotherapy on inflammatory markers of cardiovascular disease. Expert Rev Cardiovasc Ther. 2005 Jul;3(4):743-59. PMID 16076283

M128) Nori Janosz KE, Miller WM, Odom J, Lillystone M, **McCullough PA**. Optimal diabetes management during medical weight loss for cardiovascular risk reduction. Expert Rev Cardiovasc Ther. 2005 Jul;3(4):761-75. PMID 16076284

M129) **McCullough PA**, Berman AD. Percutaneous coronary interventions in the high-risk renal patient: strategies for renal protection and vascular protection. Cardiol Clin. 2005 Aug;23(3):299-310. PMID 16084279

M130) Luther SA, **McCullough PA**, Havranek EP, Rumsfeld JS, Jones PG, Heidenreich PA, Peterson ED, Rathore SS, Krumholz HM, Weintraub WS, Spertus JA, Masoudi FA; for the Cardiovascular Outcomes Research Consortium. The Relationship Between B-type Natriuretic Peptide and Health Status in Patients With Heart Failure. J Card Fail. 2005 Aug;11(6):414-21. PMID 16105631

M131) Knudsen CW, Omland T, Clopton P, Westheim A, Wu AH, Duc P, McCord J, Nowak RM, Hollander JE, Storrow AB, Abraham WT, **McCullough PA**, Maisel A. Impact of atrial fibrillation on the diagnostic performance of B-type natriuretic Peptide concentration in dyspneic patients an analysis from the breathing not properly multinational study. J Am Coll Cardiol. 2005 Sep 6;46(5):838-44. PMID 16139134

M132) **McCullough PA**. Chronic angina: new medical options for treatment. Rev Cardiovasc Med. 2005 Summer;6(3):152-61. PMID 16195688

M133) Spertus J, Peterson E, Conard MW, Heidenreich PA, Krumholz HM, Jones P, **McCullough PA**, Pina I, Tooley J, Weintraub WS, Rumsfeld JS; Cardiovascular Outcomes Research Consortium. Monitoring clinical changes in patients with heart failure: a comparison of methods. Am Heart J. 2005 Oct;150(4):707-15. PMID 16209970

M134) **McCullough PA**. Effect of lipid modification on progression of coronary calcification. J Am Soc Nephrol. 2005 Nov;16 Suppl 2:S115-9. PMID 16251246

M135) Wu AH, Omland T, Wold Knudsen C, McCord J, Nowak RM, Hollander JE, Duc P, Storrow AB, Abraham WT, Clopton P, Maisel AS, **McCullough PA**. For The Breathing Not Properly Multinational Study Investigators. Relationship of B-type natriuretic peptide and anemia in patients with and without heart failure: A substudy from the Breathing Not Properly (BNP) Multinational Study. Am J Hematol. 2005 Oct 24;80(3):174-180. PMID 16247751

M136) Miller WM, Nori-Janosz KE, Lillystone M, Yanez J, **McCullough PA**. Obesity and lipids. Curr Cardiol Rep. 2005 Nov;7(6):465-70. PMID 16256017

M137) McCord J, Nowak RM, Jacobsen G, Sallach JA, Wu AH, Perez A, Omland T, Knudsen CW, Westheim A, Duc P, Steg PG, Hollander JE, Herrmann HC, Storrow AB, Abraham WT, Lamba S, **McCullough PA**, Maisel A. B-Type Natriuretic Peptide Levels in Patients in the Emergency Department with Possible Heart Failure and Previous Stable Angina Pectoris and/or Healed Myocardial Infarction. Am J Cardiol. 2005 Nov 15;96(10):1370-3. Epub 2005 Sep 23. PMID 16275180

M138) Chinnaiyan KM, Alexander D, **McCullough PA**. Role of Angiotensin II in the Evolution of Diastolic Heart Failure. J Clin Hypertens (Greenwich). 2005 Dec;7(12):740-7. PMID: 16330897

M139) **McCullough PA**. Symposium: cardiovascular diseases and renal insufficiency. Introduction. Int J Geriatric Cardiol 2005; September 2005 2(3):130.

M140) **McCullough PA**. Spectrum of cardiorenal disease. Int J Geriatric Cardiol 2005; September 2005 2(3):131-135.

M141) **McCullough PA**, Lepor NE. Anemia: A Modifiable Risk Factor for Heart Disease. Rev Cardiovasc Med. 2005;6 Suppl. 3:1-3. PMID: 16340932

M142) **McCullough PA**, Lepor NE. Piecing Together the Evidence on Anemia: The Link between Chronic Kidney Disease and Cardiovascular Disease. Rev Cardiovasc Med. 2005;6 Suppl. 3:4-12. PMID: 16340933

M143) **McCullough PA**, Silver MA, Kennard ED, Kelsey SF, Michaels AD; IEPR Investigators. Impact of body mass index on outcomes of enhanced external counterpulsation therapy. Am Heart J. 2006 Jan;151(1):139. PMID: 16368306

M144) Strunk A, Bhalla V, Clopton P, Nowak RM, McCord J, Hollander JE, Duc P, Storrow AB, Abraham WT, Wu AHB, Steg G, Perez A, Kazanegra R, Herrmann HC, Aumont MC, **McCullough PA**, Maisel A, for the BNP Multinational Study Investigators. Impact of the history of congestive heart failure on the utility of B-type natriuretic peptide in the emergency diagnosis of heart failure: Results from the Breathing Not Properly Multinational Study. Am J Med 119(1):69.e1-69.e11, 2006. PMID: 16431187

M145) **McCullough P.** Outcomes of contrast-induced nephropathy: Experience in patients undergoing cardiovascular intervention. Catheter Cardiovasc Interv. 2006 Mar;67(3):335-43. PMID: 16489569.

M146) **McCullough PA**, Mueller C, Yancy CW Jr. Overview of B-type natriuretic Peptide as a blood test. Congest Heart Fail. 2006 Mar-Apr;12(2):99-102. PMID: 16596044

M147) **McCullough PA.** Ranolazine: Focusing on angina pectoris. Drugs Today (Barc). 2006 Mar;42(3):177-83. PMID: 16628259

M148) Daniels LB, Clopton P, Bhalla V, Krishnaswamy P, Nowak RM, McCord J, Hollander JE, Duc P, Omland T, Storrow AB, Abraham WT, Wu AH, Steg PG, Westheim A, Knudsen CW, Perez A, Kazanegra R, Herrmann HC, **McCullough PA**, Maisel AS. How obesity affects the cut-points for B-type natriuretic peptide in the diagnosis of acute heart failure. Results from the Breathing Not Properly Multinational Study. Am Heart J. 2006 May;151(5):1006-12. PMID: 16644321

M149) Brenden CK, Hollander JE, Guss D, **McCullough PA**, Nowak R, Green G, Saltzberg M, Ellison SR, Bhalla MA, Bhalla V, Clopton P, Jesse R, Maisel AS; REDHOT Investigators. Gray zone BNP levels in heart failure patients in the emergency department: results from the Rapid Emergency Department Heart Failure Outpatient Trial (REDHOT) multicenter study. Am Heart J. 2006 May;151(5):1013-8. PMID: 16644322

M150) Daniels LB, Bhalla V, Clopton P, Hollander JE, Guss D, **McCullough PA**, Nowak R, Green G, Saltzberg M, Ellison SR, Bhalla MA, Jesse R, Maisel A. B-Type Natriuretic Peptide (BNP) Levels and Ethnic Disparities in Perceived Severity of Heart Failure Results From the Rapid Emergency Department Heart Failure Outpatient Trial (REDHOT) Multicenter Study of BNP Levels and Emergency Department Decision Making in Patients Presenting With Shortness of Breath. J Card Fail. 2006 May;12(4):281-5. PMID: 16679261

M151) Hanzel GS, Downes M, **McCullough PA**. Editorial: Renal function after renal artery stenting. J Geriatric Cardiol 2005;2(4):196-197.

M152) Foley RN, **McCullough PA.** Editorial: Anemia and left ventricular hypertrophy in non-dialysis chronic kidney disease. J Geriatric Cardiol 2005;2(4):195-196.

M153) **McCullough PA.** Chronic kidney disease: tipping the scale to the benefit of angiotensin-converting enzyme inhibitors in patients with coronary artery disease. Circulation. 2006 Jul 4;114(1):6-7. PMID: 16818827

M154) **McCullough PA**, Gallagher MJ, deJong AT, Sandberg KR, Trivax JE, Alexander D, Kasturi G, Jafri SM, Krause KR, Chengelis DL, Moy J, Franklin BA. Cardiorespiratory fitness and short-term complications after bariatric surgery. Chest. 2006 Aug;130(2):517-25. PMID: 16899853

M155) Ochoa AB, DeJong A, Grayson D, Franklin B, **McCullough P**. Effect of enhanced external counterpulsation on resting oxygen uptake in patients having previous coronary revascularization and in healthy volunteers. Am J Cardiol. 2006 Sep 1;98(5):613-5. Epub 2006 Jun 30. PMID: 16923446

M156) **McCullough PA**, Bertrand ME, Brinker JA, Stacul F. A meta-analysis of the renal safety of isosmolar iodixanol compared with low-osmolar contrast media. J Am Coll Cardiol. 2006 Aug 15;48(4):692-9. Epub 2006 Jul 24. PMID: 16904536

M157) **McCullough PA**, Wase A. Do implantable cardioverter-defibrillators improve survival in dialysis patients after cardiac arrest? Nat Clin Pract Nephrol. 2006 Feb;2(2):70-1. PMID: 16932394

M158) **McCullough PA**, Stacul F, Davidson C, Becker CR, Adam A, Lameire N, Tumlin J; CIN Consensus Working Panel. Overview. Am J Cardiol. 2006 Sep 18;98(6S1):2-4. Epub 2006 Feb 13. PMID: 16949374.

M159) **McCullough PA**, Adam A, Becker CR, Davidson C, Lameire N, Stacul F, Tumlin J; CIN Consensus Working Panel. Epidemiology and Prognostic Implications of Contrast-Induced Nephropathy. Am J Cardiol. 2006 Sep 18;98(6S1):5-13. Epub 2006 Feb 10. PMID: 16949375

M160) Tumlin J, Stacul F, Adam A, Becker CR, Davidson C, Lameire N, **McCullough PA**; CIN Consensus Working Panel. Pathophysiology of Contrast-Induced Nephropathy. Am J Cardiol. 2006 Sep 18;98(6S1):14-20. Epub 2006 Feb 17. PMID: 16949376

M161) Lameire N, Adam A, Becker CR, Davidson C, **McCullough PA**, Stacul F, Tumlin J; CIN Consensus Working Panel. Baseline Renal Function Screening. Am J Cardiol. 2006 Sep 18;98(6S1):21-26. Epub 2006 Feb 20. PMID: 16949377

M162) **McCullough PA**, Adam A, Becker CR, Davidson C, Lameire N, Stacul F, Tumlin J; CIN Consensus Working Panel. Risk Prediction of Contrast-Induced Nephropathy. Am J Cardiol. 2006 Sep 18;98(6S1):27-36. Epub 2006 Feb 23. PMID: 16949378

M163) Becker CR, Davidson C, Lameire N, **McCullough PA**, Stacul F, Tumlin J, Adam A; CIN Consensus Working Panel. High-Risk Situations and Procedures. Am J Cardiol. 2006 Sep 18;98(6S1):37-41. Epub 2006 Feb 20. PMID: 16949379

M164) Davidson C, Stacul F, **McCullough PA**, Tumlin J, Adam A, Lameire N, Becker CR; CIN Consensus Working Panel. Contrast Medium Use. Am J Cardiol. 2006 Sep 18;98(6S1):42-58. Epub 2006 Mar 2. PMID: 16949380

M165) Stacul F, Adam A, Becker CR, Davidson C, Lameire N, **McCullough PA**, Tumlin J; CIN Consensus Working Panel. Strategies to Reduce the Risk of Contrast-Induced Nephropathy. Am J Cardiol. 2006 Sep 18;98(6S1):59-77. Epub 2006 Mar 20. PMID: 16949381

M166) Vanhecke TE, Miller WM, Franklin BA, Weber JE, **McCullough PA**. Awareness, knowledge, and perception of heart disease among adolescents. Eur J Cardiovasc Prev Rehabil. 2006 Oct;13(5):718-23. PMID: 17001210

M167) Zalesin KC, **McCullough PA**. Bariatric surgery for morbid obesity: risks and benefits in chronic kidney disease patients. Adv Chronic Kidney Dis. 2006 Oct;13(4):403-17. PMID: 17045226

M168) Michaels AD, **McCullough PA**, Soran OZ, Lawson WE, Barsness GW, Henry TD, Linnemeier G, Ochoa A, Kelsey SF, Kennard ED, for the IEPR Investigators. Primer: practical approach to the selection of patients for and application of EECP. Nature Clinical Practice Cardiovascular Medicine 2006; 3: 623-632. PMID: 17063167

M169) **McCullough PA**. Failure of beta-blockers in the reduction of perioperative events: where did we go wrong? Am Heart J. 2006 Nov;152(5):815-8. PMID: 17070139

M170) **McCullough PA**. Renal safety of iodixanol. Expert Rev Cardiovasc Ther. 2006 Sep;4(5):655-61. PMID: 17081087

M171) Vanhecke TE, Franklin BA, Lillystone MA, Sandberg KR, DeJong AT, Krause KR, Chengelis DL, **McCullough PA**. Caloric Expenditure in the Morbidly Obese Using Dual Energy X-ray Absorptiometry. J Clin Densitom. 2006 Oct-Dec;9(4):438-44. Epub 2006 Sep 28. PMID: 17097530

M172) Conard MW, Haddock CK, Poston WS, Havranek E, **McCullough P**, Spertus J; Cardiovascular Outcomes Research Consortium. Impact of obesity on the health status of heart failure patients. J Card Fail. 2006 Dec;12(9):700-6. PMID: 17174231

M173) **McCullough PA**, Stacul F, Becker CR, Adam A, Lameire N, Tumlin JA, Davidson CJ. Contrast-Induced Nephropathy (CIN) Consensus Working Panel: Executive Summary. Rev Cardiovasc Med. 2006 Fall;7(4):177-97. PMID: 17224862

M174) Chinnaiyan KM, Alexander D, Maddens M, **McCullough PA.** Curriculum in cardiology: integrated diagnosis and management of diastolic heart failure. Am Heart J. 2007 Feb;153(2):189-200. PMID: 17239676

M175) Vogel JA, Franklin BA, Zalesin KC, Trivax JE, Krause KR, Chengelis DL, **McCullough PA.** Reduction in predicted coronary heart disease risk after substantial weight reduction after bariatric surgery. Am J Cardiol. 2007 Jan 15;99(2):222-6. Epub 2006 Nov 16. PMID: 17223422

M176) **McCullough PA,** Rocher LR. Statin therapy in renal disease: Harmful or protective. Curr Atheroscler Rep. 2007 Jan;9(1):18-24. PMID: 17169242

M177) **McCullough PA.** [Cardiorenal intersection: crossroads to the future.] Arq Bras Cardiol. 2007 Jan;88(1):117-26. Portuguese Translation. PMID: 17364130

M178) Mehta L, Devlin W, **McCullough PA**, O'Neill WW, Skelding KA, Stone GW, Boura JA, Grines CL. Impact of body mass index on outcomes after percutaneous coronary intervention in patients with acute myocardial infarction. Am J Cardiol. 2007 Apr 1;99(7):906-10. Epub 2007 Feb 12. PMID: 17398181

M179) **McCullough PA.** Kidney disease. Estimated glomerular filtration rate: why is it important? Rev Cardiovasc Med. 2007 Winter;8(1):46-9. PMID: 17401304

M180) Lawson WE, Hui JC, Kennard ED, Soran O, **McCullough PA**, Kelsey SF; for the IEPR Investigators. Effect of enhanced external counterpulsation on medically refractory angina patients with erectile dysfunction. Int J Clin Pract. 2007 May;61(5):757-62. PMID: 17493089

M181) **McCullough PA**, Jurkovitz CT, Pergola PE, McGill JB, Brown WW, Collins AJ, Chen SC, Li S, Singh A, Norris KC, Klag MJ, Bakris GL; for the KEEP Investigators. Independent Components of Chronic Kidney Disease as a Cardiovascular Risk State: Results From the Kidney Early Evaluation Program (KEEP). Arch Intern Med. 2007 Jun 11;167(11):1122-9. PMID: 17563019

M182) **McCullough PA.** Coronary artery disease. Clin J Am Soc Nephrol. 2007 May;2(3):611-6. Epub 2007 Mar 21. PMID: 17699471

M183) **McCullough PA**, Lepor NE. The rosiglitazone meta-analysis. Rev Cardiovasc Med. 2007 Spring;8(2):123-6. PMID: 17603430

M184) **McCullough PA**, Henry TD, Kennard ED, Kelsey SF, Michaels AD; for the IEPR Investigators. Residual high-grade angina after enhanced external counterpulsation therapy. Cardiovasc Revasc Med. 2007 Jul-Sep;8(3):161-5. PMID: 17765644

M185) Miller WM, Nori Janosz KE, Zalesin KC, **McCullough PA**. Nutraceutical meal replacements: more effective than all-food diets in the treatment of obesity. Therapy 2007, 4(5):623-639.

M186) Zalesin KC, Miller WM, Nori Janosz KE, Yanez J, Krause K, Chengelis DL, **McCullough PA**. Controversies in vitamin D: deficiency and supplementation after Roux-en-Y gastric bypass surgery. Therapy 2007, 4(5):561-574.

M187) Li S, Chen SC, Shlipak M, Bakris G, **McCullough PA**, Sowers J, Stevens L, Jurkovitz C, McFarlane S, Norris K, Vassalotti J, Klag MJ, Brown WW, Narva A, Calhoun D, Johnson B, Obialo C, Whaley-Connell A, Becker B, Collins AJ. Low birth weight is associated with chronic kidney disease only in men. Kidney Int. 2008 Mar;73(5):637-42. PMID: 18094674

M188) Duru OK, Li S, Jurkovitz C, Bakris G, Brown W, Chen SC, Collins A, Klag M, **McCullough PA,** McGill J, Narva A, Pergola P, Singh A, Norris K. Race and Sex Differences in Hypertension Control in CKD: Results From the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2008 Feb;51(2):192-8. PMID: 18215697

M189) **McCullough PA.** Multimodality prevention of contrast-induced acute kidney injury. Am J Kidney Dis. 2008 Feb;51(2):169-72. PMID: 18215694

M190) **McCullough PA**, Rocher LR. Statin therapy in renal disease: harmful or protective? Curr Diab Rep. 2007 Dec;7(6):467-73. PMID: 18255012

M191) Nori Janosz KE, Koenig Berris KA, Leff C, Miller WM, Yanez J, Myers S, Vial C, Vanderlinden M, Franklin BA, **McCullough PA**. Clinical resolution of type 2 diabetes with reduction in body mass index using meal replacement based weight loss. Vascular Disease Prevention vol.5, 17-23(2008).

M192) Bellomo R, Auriemma S, Fabbri A, D'Onofrio A, Katz N, **McCullough PA**, Ricci Z, Shaw A, Ronco C. The pathophysiology of cardiac surgery-associated acute kidney injury (CSA-AKI). Int J Artif Organs. 2008 Feb;31(2):166-78. PMID: 18311733

M193) Bakris GL, Toto RD, **McCullough PA**, Rocha R, Purkayastha D, Davis P; GUARD (Gauging Albuminuria Reduction With Lotrel in Diabetic Patients With Hypertension) Study Investigators. Effects of different ACE inhibitor combinations on albuminuria: results of the GUARD study. Kidney Int. 2008 Jun;73(11):1303-9. Epub 2008 Mar 19. PMID: 18354383

M194) **McCullough PA**, Li S, Jurkovitz CT, Stevens LA, Wang C, Collins AJ, Chen SC, Norris KC, McFarlane SI, Johnson B, Shlipak MG, Obialo CI, Brown WW, Vassalotti JA, Whaley-Connell AT; Kidney Early Evaluation Program Investigators. CKD and cardiovascular disease in screened high-risk volunteer and general populations: the Kidney Early Evaluation Program (KEEP) and National Health and Nutrition Examination Survey (NHANES) 1999-2004. Am J Kidney Dis. 2008 Apr;51(4 Suppl 2):S38-45. PMID: 18359407

M195) McFarlane SI, Chen SC, Whaley-Connell AT, Sowers JR, Vassalotti JA, Salifu MO, Li S, Wang C, Bakris G, **McCullough PA**, Collins AJ, Norris KC; Kidney Early Evaluation Program Investigators. Prevalence and associations of anemia of CKD: Kidney Early Evaluation Program (KEEP) and National Health and Nutrition Examination Survey (NHANES) 1999-2004. Am J Kidney Dis. 2008 Apr;51(4 Suppl 2):S46-55. PMID: 18359408

M196) Vassalotti JA, Uribarri J, Chen SC, Li S, Wang C, Collins AJ, Calvo MS, Whaley-Connell AT, **McCullough PA**, Norris KC; Kidney Early Evaluation Program Investigators. Trends in mineral metabolism: Kidney Early Evaluation Program (KEEP) and the National Health and Nutrition Examination Survey (NHANES) 1999-2004. Am J Kidney Dis. 2008 Apr;51(4 Suppl 2):S56-68. PMID: 18359409

M197) Whaley-Connell AT, Sowers JR, Stevens LA, McFarlane SI, Shlipak MG, Norris KC, Chen SC, Qiu Y, Wang C, Li S, Vassalotti JA, Collins AJ; **Kidney Early Evaluation Program Investigators**. CKD in the United States: Kidney Early Evaluation Program (KEEP) and National Health and Nutrition Examination Survey (NHANES) 1999-2004. Am J Kidney Dis. 2008 Apr;51(4 Suppl 2):S13-20. PMID: 18359403

M198) Whaley-Connell AT, Sowers JR, McFarlane SI, Norris KC, Chen SC, Li S, Qiu Y, Wang C, Stevens LA, Vassalotti JA, Collins AJ; **Kidney Early Evaluation Program Investigators**. Diabetes mellitus in CKD: Kidney Early Evaluation Program (KEEP) and National Health and Nutrition and Examination Survey (NHANES) 1999-2004. Am J Kidney Dis. 2008 Apr;51(4 Suppl 2):S21-9. PMID: 18359404

M199) **McCullough PA**. Acute kidney injury with iodinated contrast. Crit Care Med. 2008 Apr;36(4 Suppl):S204-11. PMID: 18382195

M200) deJong AT, Gallagher MJ, Sandberg KR, Lillystone MA, Spring T, Franklin BA, **McCullough PA**. Peak oxygen consumption and the minute ventilation/carbon dioxide production relation slope in morbidly obese men and women: influence of subject effort and body mass index. Prev Cardiol. 2008 Spring;11(2):100-5. PMID: 18401238

M201) **McCullough PA**. Contrast-induced acute kidney injury. J Am Coll Cardiol. 2008 Apr 15;51(15):1419-28. PMID: 18402894

M202) Vanhecke TE, Gandhi M, **McCullough PA**, Lazar MH, Ravikrishnan KP, Kadaj P, Begle RL. Outcomes of patients considered for, but not admitted to, the intensive care unit. Crit Care Med. 2008 Mar;36(3):812-7. PMID: 18431268

M203) Zalesin KC, Krause KR, Chengelis DL, **McCullough PA**. Determinants of resolution of type 2 diabetes after bariatric surgery. Vascular Disease Prevention 2008;5(2):75-80.

M204) Miller W, Odom J, Veri S, Korponic S, Lillystone M, **McCullough PA**. Impact of short-term educational and behavioral therapy on childhood obesity. Vascular Disease Prevention 2008; 5(2):129-134.

M205) Vanhecke TE, Franklin BA, Ajluni SC, Sangal RB, **McCullough PA**. Cardiorespiratory fitness and sleep-related breathing disorders. Expert Rev Cardiovasc Ther. 2008 Jun;6(5):745-58. PMID: 18510490

M206) Gebreegziabher Y, **McCullough PA**, Bubb C, Loney-Hutchinson L, Makaryus JN, Anand N, Divakaran V, Akhrass P, Alam A, Gizycki H, McFarlane SI. Admission hyperglycemia and length of hospital stay in patients with diabetes and heart failure: a prospective cohort study. Congest Heart Fail. 2008 May-Jun;14(3):117-20. PMID: 18550921

M207) O'Donoghue M, Boden WE, Braunwald E, Cannon CP, Clayton TC, de Winter RJ, Fox KA, Lagerqvist B, **McCullough PA**, Murphy SA, Spacek R, Swahn E, Wallentin L, Windhausen F, Sabatine MS. Early invasive vs conservative treatment strategies in women and men with unstable angina and non-ST-segment elevation myocardial infarction: a meta-analysis. JAMA. 2008 Jul 2;300(1):71-80. PMID: 18594042

M208) Franklin BA, **McCullough PA**. The "Null Effect" of Low-Density Lipoprotein Cholesterol Lowering on a Modest Baseline Intima-Media Thickness: Lessons Learned From the ENHANCE Trial. Prev Cardiol. 2008 Summer;11(3):177-8.

M209) Agrawal V, Kizilbash SH, **McCullough PA**. New therapeutic agents for diabetic kidney disease. Therapy. 2008 Jun;5(4):553-75.

M210) Vanhecke TE, Berman AD, **McCullough PA.** Body weight limitations of United States cardiac catheterization laboratories including restricted access for the morbidly obese. Am J Cardiol. 2008 Aug 1;102(3):285-6.

M211) Saab G, Whaley-Connell AT, **McCullough PA**, Bakris GL. CKD awareness in the United States: the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2008 Aug;52(2):382-3.

M212) **McCullough PA,** Li S, Jurkovitz CT, Stevens L, Collins AJ, Chen SC, Norris KC, McFarlane S, Johnson B, Shlipak MG, Obialo CI, Brown WW, Vassaloti J, Whaley-Connell AT, Brenner RM, Bakris GL; KEEP Investigators. Chronic kidney disease, prevalence of premature cardiovascular disease, and relationship to short-term mortality. Am Heart J. 2008 Aug;156(2):277-83. Epub 2008 Jun 4. PMID: 18657657

M213) **McCullough PA,** Lepor NE. Lipids, biomarkers, and noninvasive imaging of atherosclerotic disease activity in clinical trials. Rev Cardiovasc Med. 2008 Spring;9(2):142-9. PMID: 18660735

M214) **McCullough PA**, Agrawal V, Danielewicz E, Abela GS. Accelerated Atherosclerotic Calcification and Mönckeberg's Sclerosis: A Continuum of Advanced Vascular Pathology in Chronic Kidney Disease. Clin J Am Soc Nephrol. 2008 Nov;3(6):1585-98. PMID: 18667741

M215) Boerrigter G, Costello-Boerrigter LC, Abraham WT, Sutton MG, Heublein DM, Kruger KM, Hill MR, **McCullough PA**, Burnett JC Jr. Cardiac resynchronization therapy improves renal function in human heart failure with reduced glomerular filtration rate. J Card Fail. 2008 Sep;14(7):539-46. Epub 2008 May 27. PMID: 18722318

M216) Zalesin KC, Franklin BA, Miller WM, Peterson ED, **McCullough PA**. Impact of obesity on cardiovascular disease. Endocrinol Metab Clin North Am. 2008 Sep;37(3):663-84. PMID: 18775358

M217) Vanhecke TE, Franklin BA, Zalesin KC, Sangal RB, deJong AT, Agrawal V, **McCullough PA.** Cardiorespiratory fitness and obstructive sleep apnea syndrome in morbidly obese patients. Chest. 2008 Sep;134(3):539-45. PMID: 18779193

M218) Madala MC, Franklin BA, Chen AY, Berman AD, Roe MT, Peterson ED, Ohman EM, Smith SC Jr, Gibler WB, **McCullough PA**; CRUSADE Investigators. Obesity and Age of First Non-ST-Segment Elevation Myocardial Infarction. J Am Coll Cardiol. 2008 Sep 16;52(12):979-985. PMID: 18786477

M219) Agrawal V, Khan I, Rai B, Krause KR, Chengelis DL, Zalesin KC, Rocher LL, **McCullough PA.** The effect of weight loss after bariatric surgery on albuminuria. Clin Nephrol. 2008 Sep;70(3):194-202. PMID: 18793560

M220) Efstratiadis S, Kennard ED, Kelsey SF, Michaels AD; International EECP Patient Registry-2 Investigators.(**McCullough PA**, site Principal Investigator) Passive tobacco exposure may impair symptomatic improvement in patients with chronic angina undergoing enhanced external counterpulsation. BMC Cardiovasc Disord. 2008 Sep 17;8:23. PMID: 18798998

M221) **McCullough PA.** Radiocontrast-induced acute kidney injury. Nephron Physiol. 2008;109(4):p61-72. Epub 2008 Sep 18. PMID: 18802377

M222) **McCullough PA.** The impact of systemic calcified atherosclerosis in patients with chronic kidney disease. Adv Chronic Kidney Dis. 2008 Oct;15(4):335-7. PMID: 18805378

M223) **McCullough PA**, Chinnaiyan KM, Agrawal V, Danielewicz E, Abela GS. Amplification of atherosclerotic calcification and Mönckeberg's sclerosis: a spectrum of the same disease process. Adv Chronic Kidney Dis. 2008 Oct;15(4):396-412. PMID: 18805386

M224) Agrawal V, Krause KR, Chengelis DL, Zalesin KC, Rocher LL, **McCullough PA**. Relation between degree of weight loss after bariatric surgery and reduction in albuminuria and C-reactive protein. Surg Obes Relat Dis. 2009 Jan-Feb;5(1):20-6. Epub 2008 Aug 5. PMID: 18951068

M225) Agrawal V, Ghosh AK, Barnes MA, **McCullough PA.** Awareness and Knowledge of Clinical Practice Guidelines for CKD among Internal Medicine Residents: A National Online Survey. Am J Kidney Dis. 2008 Dec;52(6):1061-9. Epub 2008 Oct 30. PMID: 18976845

M226) Jamerson K, Weber MA, Bakris GL, Dahlöf B, Pitt B, Shi V, Hester A, Gupte J, Gatlin M, Velazquez EJ; ACCOMPLISH Trial Investigators. Benazepril plus amlodipine or hydrochlorothiazide for hypertension in high-risk patients. (**McCullough PA**, Site Principal Investigator) N Engl J Med. 2008 Dec 4;359(23):2417-28. PMID: 19052124

M227) Flemmer M, Rajab H, Mathena T, Paulson J, Perkins S, Whelan T, Chiu R, **McCullough PA**. Blood B-type natriuretic peptide and dialysis: present assessment and future analyses. South Med J. 2008 Nov;101(11):1094-100. PMID: 19088516

M228) Agrawal V, Ghosh AK, Barnes MA, **McCullough PA.** Perception of Indications for Nephrology Referral among Internal Medicine Residents: A National Online Survey Clin J Am Soc Nephrol. 2009 Feb;4(2):323-8. PMID: 19218472

M229) Fried LF, Duckworth W, Zhang JH, O'Connor T, Brophy M, Emanuele N, Huang GD, **McCullough PA**, Palevsky PM, Seliger S, Warren SR, Peduzzi P; for VA NEPHRON-D Investigators. Design of Combination Angiotensin Receptor Blocker and Angiotensin-Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy (VA NEPHRON-D). Clin J Am Soc Nephrol. 2009 Feb;4(2):361-8. Epub 2008 Dec 31. PMID: 19118120

M230) Chinnaiyan KM, **McCullough PA.** Optimizing Outcomes in Coronary CT Imaging. Rev Cardiovasc Med. 2008 Fall;9(4):215-24. PMID: 19122579

M231) Cardenas GA, Lavie CJ, Cardenas V, Milani RV, **McCullough PA.** The importance of recognizing and treating low levels of high-density lipoprotein cholesterol: a new era in atherosclerosis management. Rev Cardiovasc Med. 2008 Fall;9(4):239-58. PMID: 19122582

M232) Chinnaiyan KM, **McCullough PA**, Flohr TG, Wegner JH, Raff GL. Improved noninvasive coronary angiography in morbidly obese patients with dual-source computed tomography. J Cardiovasc Comput Tomogr. 2008 Dec 3. PMID: 19136325

M233) Soman P, Lahiri A, Mieres JH, Calnon DA, Wolinsky D, Beller GA, Sias T, Burnham K, Conway L, **McCullough PA**, Daher E, Walsh MN, Wight J, Heller GV, Udelson JE. Etiology and pathophysiology of new-onset heart failure: Evaluation by myocardial perfusion imaging. J Nucl Cardiol. 2009 Jan-Feb;16(1):82-91. Epub 2009 Jan 20. PMID: 19152132

M234) Goldfarb S, **McCullough PA**, McDermott J, Gay SB. Contrast-induced acute kidney injury: specialty-specific protocols for interventional radiology, diagnostic computed tomography radiology, and interventional cardiology. Mayo Clin Proc. 2009 Feb;84(2):170-9. PMID: 19181651

M235) **McCullough PA**. Treatment disparities in patients with acute coronary syndromes and kidney disease. Eur Heart J. 2009 Mar;30(5):526-7. PMID: 19201760

M236) Agrawal V, Ghosh AK, Barnes MA, **McCullough PA.** Perception of indications for nephrology referral among internal medicine residents: a national online survey. Clin J Am Soc Nephrol. 2009 Feb;4(2):323-8. PMID: 19218472

M237) **McCullough PA**, Chinnaiyan KM. Hazards of contrast-induced acute kidney injury in elderly women. Women's Health (Lond Engl). 2009 Mar;5(2):123-5. PMID: 19245350

M238) Vanhecke TE, Franklin BA, Miller WM, deJong AT, Coleman CJ, **McCullough PA**. Cardiorespiratory fitness and sedentary lifestyle in the morbidly obese. Clin Cardiol. 2009 Mar;32(3):121-4. PMID: 19301295

M239) Agrawal V, Marinescu V, Agarwal M, **McCullough PA**. Cardiovascular implications of proteinuria: an indicator of chronic kidney disease. Nat Rev Cardiol. 2009 Apr;6(4):301-11. PMID:19352334

M240) O'Connor CM, Whellan DJ, Lee KL, Keteyian SJ, Cooper LS, Ellis SJ, Leifer ES, Kraus WE, Kitzman DW, Blumenthal JA, Rendall DS, Miller NH, Fleg JL, Schulman KA, McKelvie RS, Zannad F, Piña IL; HF-ACTION Investigators.(**McCullough PA** Site Principal Investigator) Efficacy and safety of exercise training in patients with chronic heart failure: HF-ACTION randomized controlled trial. JAMA. 2009 Apr 8;301(14):1439-50. PMID: 19351941

M241) Vanhecke TE, Franklin BA, Maciejko J, Chinnaiyan K, **McCullough PA**. Lipoproteins, inflammatory biomarkers, and cardiovascular imaging in the assessment of atherosclerotic disease activity. Rev Cardiovasc Med. 2009 Winter;10(1):51-8. PMID:19367236

M242) Miller WM, Franklin BA, Nori Janosz KE, Vial C, Kaitner R, **McCullough PA**. Advantages of group treatment and structured exercise in promoting short-term weight loss and cardiovascular risk reduction in adults with central obesity. Metab Syndr Relat Disord 2009 May 18. PMID: 19450156

M243) Agrawal V, Swami A, Kosuri R, Alsabbagh M, Agarwal M, Samarapungavan D, Rocher LL, **McCullough PA.** Contrast-induced acute kidney injury in renal transplant recipients after cardiac catheterization. Clin Nephrol. 2009 Jun;71(6):687-96. PMID: 19473638

M244) Janosz KE, Zalesin KC, Miller WM, **McCullough PA**, Franklin BA. Impact of surgical and nonsurgical weight loss on diabetes resolution and cardiovascular risk reduction. Curr Diab Rep. 2009 Jun;9(3):223-8. PMID: 19490824

M245) **McCullough PA**, Neyou A. Comprehensive Review of the Relative Clinical Utility of B-Type Natriuretic Peptide and N-Terminal Pro-B-Type Natriuretic Peptide Assays in Cardiovascular Disease. Open Heart Failure Journal, 2009, 2, 6-17.

M246) Odom J, Zalesin KC, Washington TL, Miller WW, Hakmeh B, Zaremba DL, Altattan M, Balasubramaniam M, Gibbs DS, Krause KR, Chengelis DL, Franklin BA, **McCullough PA.** Behavioral Predictors of Weight Regain after Bariatric Surgery. Obes Surg. 2010 Mar;20(3):349-56 PMID: 19554382

M247) **McCullough PA,** Agarwal M, Agrawal V. Review article: Risks of coronary artery calcification in chronic kidney disease: do the same rules apply? Nephrology (Carlton). 2009 Jun;14(4):428-36. PMID: 19563385

M248) Agrawal V, Shah A, Rice C, Franklin BA, **McCullough PA**. Impact of treating the metabolic syndrome on chronic kidney disease. Nat Rev Nephrol. 2009 Sep;5(9):520-8. Epub 2009 Jul 28. Review. PMID: 19636332

M249) Moe SM, Drüeke TB, Block GA, Cannata-Andía JB, Elder G, Fukagawa M, Jorgetti V, Ketteler M, Langman CB, Levin A, MacLeod AM, McCann L, **McCullough PA**, Ott SM, Wang AY, Weisinger JR, Wheeler DC, Eckardt KU, Kasiske BL, Uhlig K, Moorthi R, Earley A, Persson R. Introduction and definition of CKD-MBD and the development of the guideline statements. Kidney Int Suppl. 2009 Aug;(113):S1-130. PMID: 19644521

M250) **McCullough PA**. Darapladib and atherosclerotic plaque: should lipoprotein-associated phospholipase A2 be a therapeutic target? Curr Atheroscler Rep. 2009 Sep;11(5):334-7. PMID: 19664375

M251) Agrawal V, Vanhecke TE, Rai B, Franklin BA, Sangal RB, **McCullough PA.** Albuminuria and Renal Function in Obese Adults Evaluated for Obstructive Sleep Apnea. Nephron Clin Pract. 2009 Aug 12;113(3):c140-c147. PMID: 19672111

M252) Agrawal V, Barnes MA, Ghosh AK, **McCullough PA.** Questionnaire instrument to assess knowledge of chronic kidney disease clinical practice guidelines among internal medicine residents. J Eval Clin Pract. 2009 Aug;15(4):733-8. PMID: 19674226

M253) Franklin BA, **McCullough PA**. Cardiorespiratory fitness: an independent and additive marker of risk stratification and health outcomes. Mayo Clin Proc. 2009 Sep;84(9):776-9. PMID: 19720774

M254) Lele S, Shah S, **McCullough PA**, Rajapurkar M. Serum catalytic iron as a novel biomarker of vascular injury in acute coronary syndromes. EuroIntervention. 2009 Aug;5(3):336-42. PMID: 19736158

M255) **McCullough PA**, Hanzel GS. B-type natriuretic peptide and echocardiography in the surveillance of severe mitral regurgitation prior to valve surgery. J Am Coll Cardiol. 2009 Sep 15;54(12):1107-9. PMID: 19744621

M256) Pahle AS, Sørli D, Omland T, Knudsen CW, Westheim A, Wu AH, Steg PG, McCord J, Nowak RM, Hollander JE, Storrow AB, Abraham WT, **McCullough PA**, Maisel A. Impact of systemic hypertension on the diagnostic performance of B-type natriuretic peptide in patients with acute dyspnea. Am J Cardiol. 2009 Oct 1;104(7):966-71. PMID: 19766765

M257) **McCullough PA.** Commentary: contrast-induced nephropathy and long-term adverse events: cause and effect? Nephrol Dial Transplant. 2009 Dec;24(12):3578-9. Epub 2009 Sep 25. PMID: 19783600

M258) Saab G, Whaley-Connell A, McFarlane SI, Li S, Chen SC, Sowers JR, **McCullough PA**, Bakris GL; Kidney Early Evaluation Program Investigators. Obesity is associated with increased parathyroid hormone levels independent of glomerular filtration rate in chronic kidney disease. Metabolism. 2009 Oct 1. PMID: 19800639

M259) McMurray MD, Trivax JE, **McCullough PA**. Serum cystatin C, renal filtration function, and left ventricular remodeling. Circ Heart Fail. 2009 Mar;2(2):86-9. PMID: 19808322

M260) Nori Janosz KE, Zalesin KC, Miller WM, **McCullough PA**. Treating type 2 diabetes: incretin mimetics and enhancers. Ther Adv Cardiovasc Dis. 2009 Oct;3(5):387-95. PMID: 19808944

M261) Thakkar BV, Hirsch AT, Satran D, Bart BA, Barsness G, **McCullough PA**, Kennard ED, Kelsey SF, Henry TD. The efficacy and safety of enhanced external counterpulsation in patients with

peripheral arterial disease. Vasc Med. 2010 Feb;15(1):15-20. Epub 2009 Oct 19. PMID: 19841026

M262) Keteyian SJ, Isaac D, Thadani U, Roy BA, Bensimhon DR, McKelvie R, Russell SD, Hellkamp AS, Kraus WE; HF-ACTION Investigators (**McCullough PA** Site Investigator). Safety of symptom-limited cardiopulmonary exercise testing in patients with chronic heart failure due to severe left ventricular systolic dysfunction. Am Heart J. 2009 Oct;158(4 Suppl):S72-7. PMID: 19782792

M263) Flynn KE, Lin L, Ellis SJ, Russell SD, Spertus JA, Whellan DJ, Piña IL, Fine LJ, Schulman KA, Weinfurt KP; HF-ACTION Investigators (**McCullough PA** Site Investigator). Outcomes, health policy, and managed care: relationships between patient-reported outcome measures and clinical measures in outpatients with heart failure. Am Heart J. 2009 Oct;158(4 Suppl):S64-71. PMID: 19782791

M264) Forman DE, Clare R, Kitzman DW, Ellis SJ, Fleg JL, Chiara T, Fletcher G, Kraus WE; HF-ACTION Investigators (**McCullough PA**). Relationship of age and exercise performance in patients with heart failure: the HF-ACTION study. Am Heart J. 2009 Oct;158(4 Suppl):S6-S15. PMID: 19782790

M265) Atchley AE, Kitzman DW, Whellan DJ, Iskandrian AE, Ellis SJ, Pagnanelli RA, Kao A, Abdul-Nour K, O'Connor CM, Ewald G, Kraus WE, Borges-Neto S; HF-ACTION Investigators (**McCullough PA**). Myocardial perfusion, function, and dyssynchrony in patients with heart failure: baseline results from the single-photon emission computed tomography imaging ancillary study of the Heart Failure and A Controlled Trial Investigating Outcomes of Exercise TraiNing (HF-ACTION) Trial. Am Heart J. 2009 Oct;158(4 Suppl):S53-63. PMID: 19782789

M266) Gardin JM, Leifer ES, Fleg JL, Whellan D, Kokkinos P, Leblanc MH, Wolfel E, Kitzman DW; HF-ACTION Investigators (**McCullough PA**). Relationship of Doppler-Echocardiographic left ventricular diastolic function to exercise performance in systolic heart failure: the HF-ACTION study. Am Heart J. 2009 Oct;158(4 Suppl):S45-52. PMID: 19782788

M267) Felker GM, Whellan D, Kraus WE, Clare R, Zannad F, Donahue M, Adams K, McKelvie R, Piña IL, O'Connor CM; HF-ACTION Investigators (**McCullough PA**). N-terminal pro-brain natriuretic peptide and exercise capacity in chronic heart failure: data from the Heart Failure and a Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION) study. Am Heart J. 2009 Oct;158(4 Suppl):S37-44. PMID: 19782787

M268) Horwich TB, Leifer ES, Brawner CA, Fitz-Gerald MB, Fonarow GC; HF-ACTION Investigators (**McCullough PA**). The relationship between body mass index and cardiopulmonary exercise testing in chronic systolic heart failure. Am Heart J. 2009 Oct;158(4 Suppl):S31-6. PMID: 19782786

M269) Russell SD, Saval MA, Robbins JL, Ellestad MH, Gottlieb SS, Handberg EM, Zhou Y, Chandler B; HF-ACTION Investigators (**McCullough PA**). New York Heart Association functional class predicts

exercise parameters in the current era. Am Heart J. 2009 Oct;158(4 Suppl):S24-30. PMID: 19782785

M270) Piña IL, Kokkinos P, Kao A, Bittner V, Saval M, Clare B, Goldberg L, Johnson M, Swank A, Ventura H, Moe G, Fitz-Gerald M, Ellis SJ, Vest M, Cooper L, Whellan D; HF-ACTION Investigators (**McCullough PA**). Baseline differences in the HF-ACTION trial by sex. Am Heart J. 2009 Oct;158(4 Suppl):S16-23. PMID: 19782784

M271) O'Connor CM, Whellan DJ; HF-ACTION Investigators (**McCullough PA**). Understanding heart failure through the HF-ACTION baseline characteristics. Am Heart J. 2009 Oct;158(4 Suppl):S1-5. PMID: 19782783

M272) **McCullough PA**, Tumlin JA. Prostaglandin-Based Renal Protection Against Contrast-Induced Acute Kidney Injury. Circulation. 2009 Nov 3;120(18):1749-51. PMID: 19841295

M273) **McCullough PA,** Khan M, James J. Serum cystatin C in the estimation of glomerular filtration on chronic Angiotensin-converting enzyme inhibitor therapy: an illustrative case report. J Clin Hypertens (Greenwich). 2009 Nov;11(11):651-5. PMID: 19878376

M274) Agrawal V, Agarwal M, Ghosh AK, Barnes MA, **McCullough PA**. Identification and Management of Chronic Kidney Disease Complications by Internal Medicine Residents: A National Survey. Am J Ther. 2009 Nov 14. PMID: 19918169

M275) Zalesin KC, Franklin BA, Lillystone MA, Shamoun T, Krause KR, Chengelis DL, Mucci SJ, Shaheen KW, **McCullough PA**. Differential Loss of Fat and Lean Mass in the Morbidly Obese after Bariatric Surgery. Metab Syndr Relat Disord. 2010 Feb;8(1):15-20. PMID: 19929598

M276) Lubanski MS, **McCullough PA.** Kidney's role in hypertension. Minerva Cardioangiol. 2009 Dec;57(6):743-59. PMID: 19942846

M277) Agrawal V, Rai B, Fellows J, **McCullough PA.** In-hospital outcomes with thrombolytic therapy in patients with renal dysfunction presenting with acute ischaemic stroke. Nephrol Dial Transplant. 2010 Apr;25(4):1150-7. Epub 2009 Nov 27. PMID: 19945951

M278) **McCullough PA**, Chinnaiyan KM. Annual progression of coronary calcification in trials of preventive therapies: a systematic review. Arch Intern Med. 2009 Dec 14;169(22):2064-70. PMID: 20008688

M279) Ronco C, **McCullough P**, Anker SD, Anand I, Aspromonte N, Bagshaw SM, Bellomo R, Berl T, Bobek I, Cruz DN, Daliento L, Davenport A, Haapio M, Hillege H, House AA, Katz N, Maisel A, Mankad S, Zanco P, Mebazaa A, Palazzuoli A, Ronco F, Shaw A, Sheinfeld G, Soni S, Vescovo G, Zamperetti N, Ponikowski P; for the Acute Dialysis Quality Initiative (ADQI) consensus group. Cardio-renal syndromes: report from the consensus conference of the Acute Dialysis Quality Initiative. Eur Heart J. 2010 Mar;31(6):703-11. Epub 2009 Dec 25. PMID: 20037146

M280) Whaley-Connell A, Pavey BS, **McCullough PA**, Saab G, Li S, McFarlane SI, Chen SC, Vassalotti JA, Collins AJ, Bakris G, Sowers JR; KEEP Investigators. Dysglycemia predicts cardiovascular and kidney disease in the Kidney Early Evaluation Program. J Clin Hypertens (Greenwich). 2010 Jan;12(1):51-8. PMID: 20047632

M281) **McCullough PA**, Whaley-Connell A, Brown WW, Collins AJ, Chen SC, Li S, Norris KC, Jurkovitz C, McFarlane S, Obialo C, Sowers J, Stevens L, Vassalotti JA, Bakris GL; on Behalf of the KEEP Investigators. Cardiovascular risk modification in participants with coronary disease screened by the Kidney Early Evaluation Program. Intern Med J. 2010 Dec;40(12):833-41. doi: 10.1111/j.1445-5994.2009.02158.x. PMID: 21199222

M282) Vassalotti JA, Li S, **McCullough PA**, Bakris GL. Kidney Early Evaluation Program: A Community-Based Screening Approach to Address Disparities in Chronic Kidney Disease. Semin Nephrol. 2010 Jan;30(1):66-73. PMID: 20116650

M283) Trivax JE, Franklin BA, Goldstein JA, Chinnaiyan KM, Gallagher MJ, Dejong AT, Colar JM, Haines DE, **McCullough PA.** Acute Cardiac Effects of Marathon Running. J Appl Physiol. 2010 May;108(5):1148-53. Epub 2010 Feb 11. PMID: 20150567

M284) **McCullough PA**, Vassalotti JA, Collins AJ, Chen SC, Bakris GL. NKF's Kidney Early Evaluation Program (KEEP) annual data report 2009: executive summary. Am J Kidney Dis. 2010 Mar;55(3 Suppl 2):S1-3. PMID: 20172443

M285) Stevens LA, Li S, Wang C, Huang C, Becker BN, Bomback AS, Brown WW, Burrows NR, Jurkovitz CT, McFarlane SI, Norris KC, Shlipak M, Whaley-Connell AT, Chen SC, Bakris GL, **McCullough PA.** Prevalence of CKD and comorbid illness in elderly patients in the United States: results from the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2010 Mar;55(3 Suppl 2):S23-33.PMID: 20172445

M286) Bomback AS, Kshirsagar AV, Whaley-Connell AT, Chen SC, Li S, Klemmer PJ, **McCullough PA**, Bakris GL. Racial differences in kidney function among individuals with obesity and metabolic syndrome: results from the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2010 Mar;55(3 Suppl 2):S4-S14.PMID: 20172446

M287) Bagshaw SM, Cruz DN, Aspromonte N, Daliento L, Ronco F, Sheinfeld G, Anker SD, Anand I, Bellomo R, Berl T, Bobek I, Davenport A, Haapio M, Hillege H, House A, Katz N, Maisel A, Mankad S, **McCullough P**, Mebazaa A, Palazzuoli A, Ponikowski P, Shaw A, Soni S, Vescovo G, Zamperetti N, Zanco P, Ronco C; for the Acute Dialysis Quality Initiative (ADQI) Consensus Group. Epidemiology of cardio-renal syndromes: workgroup statements from the 7th ADQI Consensus Conference. Nephrol Dial Transplant. 2010 May;25(5):1406-16. Epub 2010 Feb 25. PMID: 20185818

M288) **McCullough PA.** Transplantation: Coronary angiography prior to renal transplantation. Nat Rev Nephrol. 2010 Mar;6(3):136-7. PMID: 20186230

M289) **McCullough PA**, Verrill TA. Cardiorenal interaction: appropriate treatment of cardiovascular risk factors to improve outcomes in chronic kidney disease. Postgrad Med. 2010 Mar;122(2):25-34.PMID: 20203453

M290) Toth PP, **McCullough PA**, Wegner MS, Colley KJ. Lipoprotein-associated phospholipase A2: role in atherosclerosis and utility as a cardiovascular biomarker. Expert Rev Cardiovasc Ther. 2010 Mar;8(3):425-38.PMID: 20222820

M291) Stolker JM, **McCullough PA**, Rao S, Inzucchi SE, Spertus JA, Maddox TM, Masoudi FA, Xiao L, Kosiborod M. Pre-procedural glucose levels and the risk for contrast-induced acute kidney injury in patients undergoing coronary angiography. J Am Coll Cardiol. 2010 Apr 6;55(14):1433-40.PMID: 20359592

M292) House AA, Anand I, Bellomo R, Cruz D, Bobek I, Anker SD, Aspromonte N, Bagshaw S, Berl T, Daliento L, Davenport A, Haapio M, Hillege H, **McCullough P**, Katz N, Maisel A, Mankad S, Zanco P, Mebazaa A, Palazzuoli A, Ronco F, Shaw A, Sheinfeld G, Soni S, Vescovo G, Zamperetti N, Ponikowski P, Ronco C; for the Acute Dialysis Quality Initiative (ADQI) consensus group. Definition and classification of Cardio-Renal Syndromes: workgroup statements from the 7th ADQI Consensus Conference. Nephrol Dial Transplant. 2010 May;25(5):1416-20. Epub 2010 Mar 12. PMID: 20228069

M293) Zalesin KC, Franklin, BA, Miller WL, Nori Janosz KE, Veri Silvia, Odom JO, **McCullough PA.** Preventing Weight Regain After Bariatric Surgery: An Overview of Lifestyle and Psychosocial Modulators. American Journal of Lifestyle Medicine, Vol. 4, No. 2, 113-120 (2010) DOI:10.1177/1559827609351227

M294) **McCullough PA**, Haapio M, Mankad S, Zamperetti N, Massie B, Bellomo R, Berl T, Anker SD, Anand I, Aspromonte N, Bagshaw SM, Bobek I, Cruz DN, Daliento L, Davenport A, Hillege H, House AA, Katz N, Maisel A, Mebazaa A, Palazzuoli A, Ponikowski P, Ronco F, Shaw A, Sheinfeld G, Soni S, Vescovo G, Zanco P, Ronco C, Berl T; for the Acute Dialysis Quality Initiative (ADQI) Consensus Group. Prevention of cardio-renal syndromes: workgroup statements from the 7th ADQI Consensus Conference. Nephrol Dial Transplant. 2010 Jun;25(6):1777-84. Epub 2010 Apr 6. PMID: 20375030

M295) Vanhecke TE, Kim R, Raheem SZ, **McCullough PA.** Myocardial ischemia in patients with diastolic dysfunction and heart failure. Curr Cardiol Rep. 2010 May;12(3):216-22.PMID: 20424964

M296) Ronco C, **McCullough PA,** Anker SD, Anand I, Aspromonte N, Bagshaw SM, Bellomo R, Berl T, Bobek I, Cruz DN, Daliento L, Davenport A, Haapio M, Hillege H, House A, Katz NM, Maisel A, Mankad S, Zanco P, Mebazaa A, Palazzuoli A, Ronco F, Shaw A, Sheinfeld G, Soni S, Vescovo G, Zamperetti N, Ponikowski P. Cardiorenal Syndromes: An Executive Summary from the

Consensus Conference of the Acute Dialysis Quality Initiative (ADQI). Contrib Nephrol. 2010;165:54-67. Epub 2010 Apr 20.PMID: 20427956

M297) **McCullough PA**. Prevention of Cardiorenal Syndromes. Contrib Nephrol. 2010;165:101-111. Epub 2010 Apr 20. PMID: 20427960

M298) Signori C, Zalesin KC, Franklin B, Miller WL, **McCullough PA.** Effect of Gastric Bypass on Vitamin D and Secondary Hyperparathyroidism. Obes Surg. 2010 Jul;20(7):949-52. PMID: 20443152

M299) Davenport A, Anker SD, Mebazaa A, Palazzuoli A, Vescovo G, Bellomo R, Ponikowski P, Anand I, Aspromonte N, Bagshaw S, Berl T, Bobek I, Cruz DN, Daliento L, Haapio M, Hillege H, House A, Katz N, Maisel A, Mankad S, **McCullough P**, Ronco F, Shaw A, Sheinfeld G, Soni S, Zamperetti N, Zanco P, Ronco C; Acute Dialysis Quality Initiative (ADQI) consensus group. ADQI 7: the clinical management of the Cardio-Renal syndromes: work group statements from the 7th ADQI consensus conference. Nephrol Dial Transplant. 2010 Jul;25(7):2077-89. Epub 2010 May 20. PMID: 20494894

M300) Szczech LA, Granger CB, Dasta JF, Amin A, Peacock WF, **McCullough PA**, Devlin JW, Weir MR, Katz JN, Anderson FA Jr, Wyman A, Varon J; for the Studying the Treatment of Acute Hypertension Investigators. Acute Kidney Injury and Cardiovascular Outcomes in Acute Severe Hypertension. Circulation. 2010 May 25;121(20):2183-91. Epub 2010 May 10. PMID: 20458014

M301) Sica D, Oren RM, Gottwald MD, Mills RM; Scios 351 Investigators.(**McCullough PA**, Investigator) Natriuretic and neurohormonal responses to nesiritide, furosemide, and combined nesiritide and furosemide in patients with stable systolic dysfunction. Clin Cardiol. 2010 Jun;33(6):330-6.PMID: 20556802

M302) Soriano-Co M, Vanhecke TE, Franklin BA, Sangal RB, Hakmeh B, **McCullough PA**. Increased central adiposity in morbidly obese patients with obstructive sleep apnoea. Intern Med J. 2011 Jul;41(7):560-6. PMID: 20546056

M303) **McCullough PA**, Zerka M, Heimbach E, Musialcyzk M, Spring T, deJong A, Jafri SS, Coleman C, Washington T, Raheem S, Vanhecke T, Zalesin KC. Audiocardiography in the cardiovascular evaluation of the morbidly obese. Clin Physiol Funct Imaging. 2010 Sep;30(5):369-74. PMID: 20618361

M304) **McCullough PA,** Verrill T. Lessons learned from acute myocardial infarction in patients with chronic kidney disease. J Intern Med. 2010 Jul;268(1):38-9. No abstract available. PMID: 20642644

M305) **McCullough PA,** Franklin BA, Leifer E, Fonarow GC. Impact of Reduced Kidney Function on Cardiopulmonary Fitness in Patients with Systolic Heart Failure. Am J Nephrol. 2010 Jul 22;32(3):226-233. PMID: 20664198

M306) Warnock DG, Muntner P, **McCullough PA**, Zhang X, McClure LA, Zakai N, Cushman M, Newsome BB, Kewalramani R, Steffes MW, Howard G, McClellan WM; REGARDS Investigators. Kidney Function, Albuminuria, and All-Cause Mortality in the REGARDS (Reasons for Geographic and Racial Differences in Stroke) Study. Am J Kidney Dis. 2010 Nov;56(5):861-71. Epub 2010 Aug 8. PMID: 20692752

M307) **McCullough PA.** Editorial: Contrast-Induced Acute Kidney Injury: Shifting from Elective to Urgent Coronary Intervention. J Interv Cardiol. 2010 Oct;23(5):467-9. doi: 10.1111/j.1540-8183.2010.00589.x. Epub 2010 Aug 19. PMID: 20731756

M308) Bomback AS, Rekhtman Y, Whaley-Connell AT, Kshirsagar AV, Sowers JR, Chen SC, Li S, Chinnaiyan KM, Bakris GL, **McCullough PA**. Gestational diabetes alone, in the absence of subsequent diabetes, is associated with microalbuminuria: results from the Kidney Early Evaluation Program (KEEP). Diabetes Care. 2010 Dec;33(12):2586-91. Epub 2010 Aug 31. PMID: 20807871

M309) Neyou A, O'Neil B, Berman AD, Boura JA, **McCullough PA.** Determinants of markedly increased B-type natriuretic peptide in patients with ST-segment elevation myocardial infarction. Am J Emerg Med. 2011 Feb;29(2):141-7. Epub 2010 Mar 25. PMID: 20825778

M310) **McCullough PA.** Integration of the clinical laboratory in cardiovascular medicine. Rev Cardiovasc Med. 2010;11 Suppl 2:S1-2. PMID: 20700097

M311) Lepor NE, **McCullough PA.** Differential diagnosis and overlap of acute chest discomfort and dyspnea in the emergency department. Rev Cardiovasc Med. 2010;11 Suppl 2:S13-23.PMID: 20700098

M312) de Lemos JA, Peacock WF, **McCullough PA.** Natriuretic peptides in the prognosis and management of acute coronary syndromes. Rev Cardiovasc Med. 2010;11 Suppl 2:S24-34.PMID: 20700099

M313) **McCullough PA,** Peacock WF, O'Neil B, de Lemos JA. Capturing the pathophysiology of acute coronary syndromes with circulating biomarkers. Rev Cardiovasc Med. 2010;11 Suppl 2:S3-12.PMID: 20700100

M314) **McCullough PA,** Peacock WF, O'Neil B, de Lemos JA, Lepor NE, Berkowitz R. An evidence-based algorithm for the use of B-type natriuretic testing in acute coronary syndromes. Rev Cardiovasc Med. 2010;11 Suppl 2:S51-65.PMID: 20700103

M315) Zalesin KC, Miller WM, Franklin B, Mudugal D, Rao Buragadda A, Boura J, Nori-Janosz K, Chengelis DL, Krause KR, **McCullough PA.** Vitamin a deficiency after gastric bypass surgery: an underreported postoperative complication. J Obes. 2011;2011. pii: 760695. Epub 2010 Sep 14.PMID: 20871833

M316) Maisel AS, Katz N, Hillege HL, Shaw A, Zanco P, Bellomo R, Anand I, Anker SD, Aspromonte N, Bagshaw SM, Berl T, Bobek I, Cruz DN, Daliento L, Davenport A, Haapio M, House AA, Mankad S, **McCullough P**, Mebazaa A, Palazzuoli A, Ponikowski P, Ronco F, Sheinfeld G, Soni S, Vescovo G, Zamperetti N, Ronco C; for the Acute Dialysis Quality Initiative (ADQI) consensus group. Biomarkers in kidney and heart disease. Nephrol Dial Transplant. 2011 Jan;26(1):62-74. Epub 2010 Oct 26 PMID: 20978142

M317) **McCullough PA.** Cardiorenal syndromes: pathophysiology to prevention. Int J Nephrol. 2010 Dec 1;2010:762590.PMID: 2115153

M318) **McCullough PA**, Whaley-Connell A, Brown WW, Collins AJ, Chen SC, Li S, Norris KC, Jurkovitz C, McFarlane S, Obialo C, Sowers J, Stevens L, Vassalotti JA, Bakris GL. Cardiovascular risk modification in participants with coronary disease screened by the Kidney Early Evaluation Program. Intern Med J. 2010 Dec;40(12):833-41. doi: 10.1111/j.1445-5994.2009.02158.x.PMID: 21199222

M319) Lubanski MS, Vanhecke TE, Chinnaiyan KM, Franklin BA, **McCullough PA.** Subclinical coronary atherosclerosis identified by coronary computed tomographic angiography in asymptomatic morbidly obese patients. Heart Int. 2010 Dec 31;5(2):e15. PubMed PMID: 21977300

M320) Rose JJ, Vanhecke TE, **McCullough PA**. Subarachnoid hemorrhage with neurocardiogenic stunning. Rev Cardiovasc Med. 2010 Fall;11(4):254-63. PMID: 21389917

M321) **McCullough PA**. Micronutrients and cardiorenal disease: insights into novel assessments and treatment. Blood Purif. 2011;31(1-3):177-85. Epub 2011 Jan 10. PMID: 21228587

M322) Alexander P, David S, **McCullough PA**. Drug-eluting coronary stents in patients with kidney disease. Am J Kidney Dis. 2011 Feb;57(2):188-9. No abstract available. PMID: 21251538

M323) **McCullough PA**, Chinnaiyan KM, Gallagher MJ, Colar JM, Geddes T, Gold JM, Trivax JE. Changes in renal markers and acute kidney injury after marathon running. Nephrology (Carlton). 2011 Feb;16(2):194-9. doi: 10.1111/j.1440-1797.2010.01354.x. PMID: 21272132

M324) **McCullough PA**, Ahmad A. Cardiorenal syndromes. World J Cardiol. 2011 Jan 26;3(1):1-9. PMID: 21286212

M325) Poirier P, Cornier MA, Mazzone T, Stiles S, Cummings S, Klein S, **McCullough PA**, Ren Fielding C, Franklin BA; on behalf of the AHA Obesity Committee of the Council on Nutrition, Physical Activity, and Metabolism. Bariatric Surgery and Cardiovascular Risk Factors: A Scientific Statement From the AHA. Circulation. 2011 Apr 19;123(15):1683-701. Epub 2011 Mar 14. PMID: 21403092

M326) Goel SK, Bellovich K, **McCullough PA**. Treatment of severe metastatic calcification and calciphylaxis in dialysis patients. Goel SK, Bellovich K, McCullough PA. Int J Nephrol. 2011 Feb 24;2011:701603. PMID: 21423552

M327) **McCullough PA**, El-Ghoroury M, Yamasaki H. Early detection of acute kidney injury with neutrophil gelatinase-associated lipocalin. J Am Coll Cardiol. 2011 Apr 26;57(17):1762-4. PMID: 21511112

M328) Madder RD, Hickman L, Crimmins GM, Puri M, Marinescu V, **McCullough PA**, Safian RD. Validity of Estimated Glomerular Filtration Rates for Assessment of Baseline and Serial Renal Function in Patients with Atherosclerotic Renal Artery Stenosis: Implications for Clinical Trials of Renal Revascularization. Circ Cardiovasc Interv. 2011 Jun 1;4(3):219-25. Epub 2011 Apr 26. PMID: 21521835

M329) Whaley-Connell A, Sowers JR, **McCullough PA**. The role of oxidative stress in the metabolic syndrome. Rev Cardiovasc Med. 2011;12(1):21-9. PMID: 21546885

M330) **McCullough PA,** Capasso P. Patient Discomfort Associated with the Use of Intra-arterial Iodinated Contrast Media: A Meta-Analysis of Comparative Randomized Controlled Trials. BMC Med Imaging. 2011 May 24;11:12. doi:10.1186/1471-2342-11-12. PMID: 21609484

M331) Friedewald VE, Emmett M, **McCullough P**, Yancy CW, Roberts WC. The Editor's Roundtable: Anemia and Cardiovascular Disease. Am J Cardiol. 2011 Jun 1;107(11):1630-5. PMID: 21575751

M332) **McCullough PA**, Maynard RC. Treatment disparities in acute coronary syndromes, heart failure, and kidney disease. Contrib Nephrol. 2011;171:68-73. Epub 2011 May 23. PMID: 21625092

M333) **McCullough PA**, Vassalotti JA, Collins AJ, Chen SC, Bakris GL, Whaley-Connell AT. National Kidney Foundation's Kidney Early Evaluation Program (KEEP) Annual Data Report 2010: Executive Summary. Am J Kidney Dis. 2011 Mar;57(3 Suppl 2):S1-3. PMID: 21338845

M334) McFarlane SI, **McCullough PA**, Sowers JR, Soe K, Chen SC, Li S, Vassalotti JA, Stevens LA, Salifu MO, Kurella Tamura M, Bomback AS, Norris KC, Collins AJ, Bakris GL, Whaley-Connell AT; KEEP Steering Committee. Comparison of the CKD Epidemiology Collaboration (CKD-EPI) and Modification of Diet in Renal Disease (MDRD) Study Equations: Prevalence of and Risk Factors for Diabetes Mellitus in CKD in the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2011 Mar;57(3 Suppl 2):S24-31. PMID: 21338847

M335) **McCullough PA**, Brown WW, Gannon MR, Vassalotti JA, Collins AJ, Chen SC, Bakris GL, Whaley-Connell AT. Sustainable Community-Based CKD Screening Methods Employed by the National Kidney Foundation's Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2011 Mar;57(3 Suppl 2):S4-8. PMID: 21338848

M336) Stevens LA, Li S, Kurella Tamura M, Chen SC, Vassalotti JA, Norris KC, Whaley-Connell AT, Bakris GL, **McCullough PA**. Comparison of the CKD Epidemiology Collaboration (CKD-EPI) and Modification of Diet in Renal Disease (MDRD) Study Equations: Risk Factors for and Complications of CKD and Mortality in the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2011 Mar;57(3 Suppl 2):S9-S16. PMID: 21338849

M337) Herzog CA, Asinger RW, Berger AK, Charytan DM, Díez J, Hart RG, Eckardt KU, Kasiske BL, **McCullough PA**, Passman RS, DeLoach SS, Pun PH, Ritz E. Cardiovascular disease in chronic kidney disease. A clinical update from Kidney Disease: Improving Global Outcomes (KDIGO). Kidney Int. 2011 Sep;80(6):572-86. PMID: 21750584

M338) Gorges RD, Burke P, David W, Cole A, **McCullough PA**, David SW. Emerging practice patterns and outcomes of percutaneous aortic balloon valvuloplasty in patients with severe aortic stenosis. Rev Cardiovasc Med. 2011;12(2):e60-7. PMID: 21796084

M339) Hanna K, Seder CW, Chengelis D, **McCullough PA**, Krause K. Shorter circular staple is height associated with lower anastomotic stricture rate in laparoscopic gastric bypass. Surg Obes Relat Dis. 2012 Mar-Apr;8(2):181-4. PMID: 21798822

M340) Miller WM, Spring TJ, Zalesin KC, Kaeding KR, Nori Janosz KE, **McCullough PA**, Franklin BA. Lower Than Predicted Resting Metabolic Rate Is Associated With Severely Impaired Cardiorespiratory Fitness in Obese Individuals. Obesity (Silver Spring). 2012 Mar;20(3):505-11. PMID: 21836645

M341) Zalesin KC, Franklin BA, Miller WM, Peterson ED, **McCullough PA**. Impact of obesity on cardiovascular disease. Med Clin North Am. 2011 Sep;95(5):919-37. PMID: 21855700

M342) Khouri Y, Steigerwalt SP, Alsamara M, **McCullough PA.** What is the Ideal Blood Pressure Goal for Patients with Stage III or Higher Chronic Kidney Disease? Curr Cardiol Rep. 2011 Dec;13(6):492-501. PMID: 21887524

M343) Brown JR, **McCullough PA**, Splaine ME, Davies L, Ross CS, Dauerman HL, Robb JF, Boss R, Goldberg DJ, Fedele FA, Kellett MA, Phillips WJ, Ver Lee PN, Nelson EC, Mackenzie TA, O'Connor GT, Sarnak MJ, Malenka DJ; for the Northern New England Cardiovascular Disease Study Group. How do centres begin the process to prevent contrast-induced acute kidney injury: a report from a new regional collaborative. BMJ Qual Saf. 2012 Jan;21(1):54-62. PMID: 21890755

M344) Horwich TB, Broderick S, Chen L, **McCullough PA**, Strzelczyk T, Kitzman DW, Fletcher G, Safford RE, Ewald G, Fine LJ, Ellis SJ, Fonarow GC. Relation Among Body Mass Index, Exercise Training, and Outcomes in Chronic Systolic Heart Failure. Am J Cardiol. 2011 Dec 15;108(12):1754-9. PMID: 21907317

M345) **McCullough PA**, Khambatta S, Jazrawi A. Minimizing the renal toxicity of iodinated contrast. Circulation. 2011 Sep 13;124(11):1210-1. PMID: 21911794

M346) Marinescu V, **McCullough PA**. Nutritional and micronutrient determinants of idiopathic dilated cardiomyopathy: diagnostic and therapeutic implications. Expert Rev Cardiovasc Ther. 2011 Sep;9(9):1161-70. PubMed PMID: 21932959

M347) **McCullough PA**, Brown JR. Effects of Intra-Arterial and Intravenous Iso-Osmolar Contrast Medium (Iodixanol) on the Risk of Contrast-Induced Acute Kidney Injury: A Meta-Analysis. Cardiorenal Med. 2011;1(4):220-234. PMID: 22164156

M348) **McCullough PA**, Al-Ejel F, Maynard RC. Lipoprotein subfractions and particle size in end-stage renal disease. Clin J Am Soc Nephrol. 2011 Dec;6(12):2738-9. PMID: 22157706

M349) Lepor NE, **McCullough PA**. Assessing appropriateness of coronary intervention. Rev Cardiovasc Med. 2011;12(3):170-1. PMID: 22145194

M350) **McCullough PA,** Ahmed AB, Zughaib MT, Glanz ED, Di Loreto MJ. Treatment of hypertriglyceridemia with fibric Acid derivatives: impact on lipid subfractions and translation into a reduction in cardiovascular events. Rev Cardiovasc Med. 2011;12(4):173-85. PMID: 22249508.

M351) Palazzuoli A, Beltrami M, Nodari S, **McCullough PA,** Ronco C. Clinical impact of renal dysfunction in heart failure. Rev Cardiovasc Med. 2011;12(4):186-99. PMID: 22249509.

M352) **McCullough PA,** Olobatoke A, Vanhecke TE. Galectin-3: a novel blood test for the evaluation and management of patients with heart failure. Rev Cardiovasc Med. 2011;12(4):200-10. PMID: 22249510.

M353) Vanhecke TE, Franklin BA, Soman P, Lahiri A, Mieres JH, Sias T, Calnon DA, Wolinsky D, Udelson JE, **McCullough PA.** Influence of myocardial ischemia on outcomes in patients with systolic versus non-systolic heart failure. Am J Cardiovasc Dis. 2011;1(2):167-75. Epub 2011 Jul 27. PMID: 22254196.

M354) Whaley-Connell A, Bomback AS, McFarlane SI, Li S, Roberts T, Chen SC, Collins AJ, Norris K, Bakris GL, Sowers JR, **McCullough PA**; on behalf of the Kidney Early Evaluation Program Investigators. Diabetic Cardiovascular Disease Predicts Chronic Kidney Disease Awareness in the Kidney Early Evaluation Program. Cardiorenal Med. 2011 Jan;1(1):45-52. Epub 2011 Jan 17. PMID: 22258465.

M355) Saab G, Whaley-Connell A, Bombeck A, Kurella Tamura M, Li S, Chen SC, McFarlane SI, Sowers JR, Norris K, Bakris GL, **McCullough PA**; for the Kidney Early Evaluation Program Investigators. The Association between Parathyroid Hormone Levels and the Cardiorenal Metabolic Syndrome in Non-Diabetic Chronic Kidney Disease. Cardiorenal Med. 2011;1(2):123-130. Epub 2011 Apr 15. PMID: 22258399.

M356) Trivax JE, **McCullough PA.** Phidippides Cardiomyopathy: A Review and Case Illustration. Clin Cardiol. 2012 Feb;35(2):69-73. PMID: 22222888.

M357) Peralta CA, Norris KC, Li S, Chang TI, Tamura MK, Jolly SE, Bakris G, **McCullough PA,** Shlipak M; for the KEEP Investigators. Blood Pressure Components and End-stage Renal Disease in Persons With Chronic Kidney Disease: The Kidney Early Evaluation Program (KEEP). Arch Intern Med. 2012 Jan 9;172(1):41-47. PMID: 22232147.

M358) **McCullough PA**, Assad H. Diagnosis of Cardiovascular Disease in Patients with Chronic Kidney Disease. Blood Purif. 2012 Jan 20;33(1-3):112-118. [Epub ahead of print] PubMed PMID: 22269967.

M359) Amin AP, Salisbury AC, **McCullough PA**, Gosch K, Spertus JA, Venkitachalam L, Stolker JM, Parikh CR, Masoudi FA, Jones PG, Kosiborod M. Trends in the incidence of acute kidney injury in patients hospitalized with acute myocardial infarction. Arch Intern Med. 2012 Feb 13;172(3):246-53. PubMed PMID: 22332157.

M360) Whaley-Connell AT, Vassalotti JA, Collins AJ, Chen SC, **McCullough PA**. National Kidney Foundation's Kidney Early Evaluation Program (KEEP) Annual Data Report 2011: Executive Summary. Am J Kidney Dis. 2012 Mar;59(3 Suppl 2):S1-4. PubMed PMID: 22339897; PubMed Central PMCID: PMC3285421.

M361) Shah A, Fried LF, Chen SC, Qiu Y, Li S, Cavanaugh KL, Norris KC, Whaley-Connell AT, **McCullough PA,** Mehrotra R; KEEP Investigators. Associations Between Access to Care and Awareness of CKD. Am J Kidney Dis. 2012 Mar;59(3 Suppl 2):S16-23. PubMed PMID: 22339898.

M362) Jurkovitz CT, Elliott D, Li S, Saab G, Bomback AS, Norris KC, Chen SC, **McCullough PA**, Whaley-Connell AT; KEEP Investigators. Physician Utilization, Risk-Factor Control, and CKD Progression Among Participants in the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2012 Mar;59(3 Suppl 2):S24-33. PubMed PMID: 22339899.

M363) Saab G, Chen SC, Li S, Bomback AS, Whaley-Connell AT, Jurkovitz CT, Norris KC, **McCullough PA**; KEEP Investigators. Association of Physician Care With Mortality in Kidney Early Evaluation Program (KEEP) Participants. Am J Kidney Dis. 2012 Mar;59(3 Suppl 2):S34-9. PubMed PMID: 22339900.

M364) Agrawal V, Jaar BG, Frisby XY, Chen SC, Qiu Y, Li S, Whaley-Connell AT, **McCullough PA,** Bomback AS; KEEP Investigators. Access to Health Care Among Adults Evaluated for CKD: Findings From the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2012 Mar;59(3 Suppl 2):S5-S15. PubMed PMID: 22339901.

M365) Ismail Y, Kasmikha Z, Green HL, **McCullough PA.** Cardio-renal syndrome type 1: epidemiology, pathophysiology, and treatment. Semin Nephrol. 2012 Jan;32(1):18-25. PubMed PMID: 22365158.

M366) Khambatta S, Farkouh ME, Wright RS, Reeder GS, **McCullough PA**, Smars PA, Hickson LJ, Best PJ. Chronic kidney disease as a risk factor for acute coronary syndromes in patients presenting to the emergency room with chest pain. Transl Res. 2012 May;159(5):391-6. Epub 2012 Jan 9. PubMed PMID: 22500512.

M367) Whaley-Connell A, Shlipak MG, Inker LA, Kurella Tamura M, Bomback AS, Saab G, Szpunar SM, McFarlane SI, Li S, Chen SC, Norris K, Bakris GL, **McCullough PA**; Kidney Early Evaluation Program Investigators. Awareness of Kidney Disease and Relationship to End-stage Renal Disease and Mortality. Am J Med. 2012 Jul;125(7):661-9. PubMed PMID: 22626510.

M368) **McCullough PA**, Williams FJ, Stivers DN, Cannon L, Dixon S, Alexander P, Runyan D, David S. Neutrophil Gelatinase-Associated Lipocalin: A Novel Marker of Contrast Nephropathy Risk. Am J Nephrol. 2012 May 23;35(6):509-514. PubMed PMID: 22627273.

M369) O'Keefe JH, Patil HR, Lavie CJ, Magalski A, Vogel RA, **McCullough PA**. Potential adverse cardiovascular effects from excessive endurance exercise. Mayo Clin Proc. 2012 Jun;87(6):587-95. PubMed PMID: 22677079.

M370) **McCullough PA**, Ali S. Cardiac and renal function in patients with type 2 diabetes who have chronic kidney disease: potential effects of bardoxolone methyl. Drug Des Devel Ther. 2012;6:141-9. Epub 2012 Jun 14. PubMed PMID: 22787387; PubMed Central PMCID: PMC3392144.

M371) O'Donoghue ML, Vaidya A, Afsal R, Alfredsson J, Boden WE, Braunwald E, Cannon CP, Clayton TC, de Winter RJ, Fox KA, Lagerqvist B, **McCullough PA**, Murphy SA, Spacek R, Swahn E, Windhausen F, Sabatine MS. An Invasive or Conservative Strategy in Patients With Diabetes Mellitus and Non-ST-Segment Elevation Acute Coronary Syndromes: A Collaborative Meta-Analysis of Randomized Trials. J Am Coll Cardiol. 2012 Jul 10;60(2):106-11. PubMed PMID: 22766336.

M372) Ronco C, Cicoira M, **McCullough PA**. Cardiorenal Syndrome Type 1: Pathophysiological Crosstalk Leading to Combined Heart and Kidney Dysfunction in the Setting of Acutely Decompensated Heart Failure. J Am Coll Cardiol. 2012 Sep 18;60(12):1031-42. PubMed PMID: 22840531.

M373) Ronco C, Stacul F, **McCullough PA.** Subclinical acute kidney injury (AKI) due to iodine-based contrast media. Eur Radiol. 2013 Feb;23(2):319-23. PubMed PMID: 22895617.

M374) **McCullough PA**, Larsen T, Brown JR. Theophylline or aminophylline for the prevention of contrast-induced acute kidney injury. Am J Kidney Dis. 2012 Sep;60(3):338-9. PubMed PMID: 22901629.

M375) Patil HR, O'Keefe JH, Lavie CJ, Magalski A, Vogel RA, **McCullough PA**. Cardiovascular damage resulting from chronic excessive endurance exercise. Mo Med. 2012 Jul-Aug;109(4):312-21. PubMed PMID: 22953596.

M376) Bose S, Bomback AS, Mehta NN, Chen SC, Li S, Whaley-Connell A, Benjamin J, **McCullough PA.** Dysglycemia but not lipids is associated with abnormal urinary albumin excretion in diabetic kidney disease: a report from the Kidney Early Evaluation Program (KEEP). BMC Nephrol. 2012 Sep 7;13:104. doi:10.1186/1471-2369-13-104. PubMed PMID: 22958709.

M377) Wilson GD, Geddes TJ, Pruetz BL, Thibodeau BJ, Murawka A, Colar JM, **McCullough PA**, Trivax JE. SELDI-TOF-MS Serum Profiling Reveals Predictors of Cardiac MRI Changes in Marathon Runners. Int J Proteomics. 2012;2012:679301. Epub 2012 Sep 3. PubMed PMID: 22988506; PubMed Central PMCID: PMC3439948.

M378) **McCullough PA**, Cowan S. Mineralocorticoid receptor antagonists and mortality in heart failure with concurrent atrial fibrillation. Circ Heart Fail. 2012 Sep 1;5(5):550-1. PubMed PMID: 22991404.

M379) Saab G, Bomback AS, McFarlane SI, Li S, Chen SC, **McCullough PA**, Whaley-Connell A; for the Kidney Early Evaluation Program Investigators. The Association of Parathyroid Hormone with ESRD and Pre-ESRD Mortality in the Kidney Early Evaluation Program. J Clin Endocrinol Metab. 2012 Dec;97(12):4414-21. PubMed PMID: 23066118.

M380) Whaley-Connell A, Kurella Tamura M, **McCullough PA**. A Decade After the KDOQI CKD Guidelines: Impact on the National Kidney Foundation's Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2012 Nov;60(5):692-3. doi: 10.1053/j.ajkd.2012.08.008. PubMed PMID: 23067631.

M381) **McCullough PA**, Di Loreto MJ. Fibrates and cardiorenal outcomes. J Am Coll Cardiol. 2012 Nov 13;60(20):2072-3. doi: 10.1016/j.jacc.2012.06.058. Epub 2012 Oct 17. PubMed PMID: 23083778.

M382) Babayev R, Whaley-Connell A, Kshirsagar A, Klemmer P, Navaneethan S, Chen SC, Li S, **McCullough PA**, Bakris G, Bomback A; KEEP Investigators. Association of Race and Body Mass Index With ESRD and Mortality in CKD Stages 3-4: Results From the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2013 Mar;61(3):404-12. PubMed PMID: 23260275.

M383) Pinto de Carvalho L, **McCullough PA**, Gao F, Sim LL, Tan HC, Foo D, Ooi YW, Richards AM, Chan MY, Yeo TC. Renal function and anaemia in acute myocardial infarction. Int J Cardiol. 2013 Sep 30;168(2):1397-401. PubMed PMID: 23305857.

M384) Kashani K, Al-Khafaji A, Ardiles T, Artigas A, Bagshaw SM, Bell M, Bihorac A, Birkhahn R, Cely CM, Chawla LS, Davison DL, Feldkamp T, Forni LG, Gong MN, Gunnerson KJ, Haase M, Hackett J, Honore PM, Hoste EA, Joannes-Boyau O, Joannidis M, Kim P, Koyner JL, Laskowitz DT, Lissauer

ME, Marx G, **McCullough PA**, Mullaney S, Ostermann M, Rimmele T, Shapiro NI, Shaw AD, Shi J, Sprague AM, Vincent JL, Vinsonneau C, Wagner L, Walker MG, Wilkerson RG, Zacharowski K, Kellum JA. Discovery and validation of cell cycle arrest biomarkers in human acute kidney injury. Crit Care. 2013 Feb 6;17(1):R25. [Epub ahead of print] PubMed PMID: 23388612.

M385) Smith SW, Diercks DB, Nagurney JT, Hollander JE, Miller CD, Schrock JW, Singer AJ, Apple FS, **McCullough PA**, Ruff CT, Sesma A Jr, Peacock WF. Central versus local adjudication of myocardial infarction in a cardiac biomarker trial. Am Heart J. 2013 Mar;165(3):273-279.e1. doi: 10.1016/j.ahj.2012.12.012. Epub 2013 Jan 26. PubMed PMID: 23453092.

M386) Whaley-Connell AT, Kurella Tamura M, Jurkovitz CT, Kosiborod M, **McCullough PA.** Advances in CKD Detection and Determination of Prognosis: Executive Summary of the National Kidney Foundation-Kidney Early Evaluation Program (KEEP) 2012 Annual Data Report. Am J Kidney Dis. 2013 Apr;61(4 Suppl 2):S1-3. doi: 10.1053/j.ajkd.2013.01.006. PubMed PMID: 23507265; PubMed Central PMCID: PMC3608929.

M387) Amin AP, Whaley-Connell AT, Li S, Chen SC, **McCullough PA,** Kosiborod MN; KEEP Investigators. The Synergistic Relationship Between Estimated GFR and Microalbuminuria in Predicting Long-term Progression to ESRD or Death in Patients With Diabetes: Results From the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2013 Apr;61(4 Suppl 2):S12-23. doi: 10.1053/j.ajkd.2013.01.005. PubMed PMID: 23507266.

M388) Jurkovitz CT, Li S, Norris KC, Saab G, Bomback AS, Whaley-Connell AT, **McCullough PA;** KEEP Investigators. Association Between Lack of Health Insurance and Risk of Death and ESRD: Results From the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2013 Apr;61(4 Suppl 2):S24-32. doi: 10.1053/j.ajkd.2012.12.015. PubMed PMID: 23507267.

M389) Chang TI, Li S, Chen SC, Peralta CA, Shlipak MG, Fried LF, Whaley-Connell AT, **McCullough PA**, Kurella Tamura M; KEEP Investigators. Risk Factors for ESRD in Individuals With Preserved Estimated GFR With and Without Albuminuria: Results From the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis. 2013 Apr;61(4 Suppl 2):S4-S11. doi: 10.1053/j.ajkd.2012.12.016. PubMed PMID: 23507268.

M390) Narala KR, Hassan S, Lalonde TA, **McCullough PA.** Management of coronary atherosclerosis and acute coronary syndromes in patients with chronic kidney disease. Curr Probl Cardiol. 2013 May;38(5):165-206. doi: 10.1016/j.cpcardiol.2012.12.004. PubMed PMID: 23590761.

M391) Mehrotra R, Peralta CA, Chen SC, Li S, Sachs M, Shah A, Norris K, Saab G, Whaley-Connell A, Kestenbaum B, **McCullough PA.** No independent association of serum phosphorus with risk for death or progression to end-stage renal disease in a large screen for chronic kidney disease. Kidney Int. 2013 Nov;84(5):989-97. PubMed PMID: 23615501.

M392) Runyan D, Feldman D, **McCullough PA**, David S, Saba S, Gorges R. Long-term Follow-up of Lesion-specific Outcomes Comparing Drug-eluting Stents and Bare Metal Stents in Diseased Saphenous Vein Grafts. Rev Cardiovasc Med. 2013;14(1):1-6. PubMed PMID: 23651982.

M393) Lepor NE, Fouchia DD, **McCullough PA**. New vistas for the treatment of obesity: turning the tide against the leading cause of morbidity and cardiovascular mortality in the developed world. Rev Cardiovasc Med. 2013;14(1):20-40. PubMed PMID: 23651984.

M394) Weisbord SD, Gallagher M, Kaufman J, Cass A, Parikh CR, Chertow GM, Shunk KA, **McCullough PA**, Fine MJ, Mor MK, Lew RA, Huang GD, Conner TA, Brophy MT, Lee J, Soliva S, Palevsky PM. Prevention of Contrast-Induced AKI: A Review of Published Trials and the Design of the Prevention of Serious Adverse Events following Angiography (PRESERVE) Trial. Clin J Am Soc Nephrol. 2013 Sep;8(9):1618-31. PubMed PMID: 23660180

M395) **McCullough PA**, Bouchard J, Waikar SS, Siew ED, Endre ZH, Goldstein SL, Koyner JL, Macedo E, Doi K, Di Somma S, Lewington A, Thadhani R, Chakravarthi R, Ice C, Okusa MD, Duranteau J, Doran P, Yang L, Jaber BL, Meehan S, Kellum JA, Haase M, Murray PT, Cruz D, Maisel A, Bagshaw SM, Chawla LS, Mehta RL, Shaw AD, Ronco C. Implementation of Novel Biomarkers in the Diagnosis, Prognosis, and Management of Acute Kidney Injury: Executive Summary from the Tenth Consensus Conference of the Acute Dialysis Quality Initiative (ADQI). Contrib Nephrol. 2013;182:5-12. doi: 10.1159/000349962. Epub 2013 May 13. PubMed PMID: 23689652.

M396) **McCullough PA**, Shaw AD, Haase M, Bouchard J, Waikar SS, Siew ED, Murray PT, Mehta RL, Ronco C. Diagnosis of acute kidney injury using functional and injury biomarkers: workgroup statements from the tenth acute dialysis quality initiative consensus conference. Contrib Nephrol. 2013;182:13-29. doi: 10.1159/000349963. Epub 2013 May 13. PubMed PMID: 23689653.

M397) **McCullough PA**, Kellum JA, Haase M, Müller C, Damman K, Murray PT, Cruz D, House AA, Schmidt-Ott KM, Vescovo G, Bagshaw SM, Hoste EA, Briguori C, Braam B, Chawla LS, Costanzo MR, Tumlin JA, Herzog CA, Mehta RL, Rabb H, Shaw AD, Singbartl K, Ronco C. Pathophysiology of the Cardiorenal Syndromes: Executive Summary from the Eleventh Consensus Conference of the Acute Dialysis Quality Initiative (ADQI). Contrib Nephrol. 2013;182:82-98. doi: 10.1159/000349966. Epub 2013 May 13. PubMed PMID: 23689657.

M398) Haase M, Müller C, Damman K, Murray PT, Kellum JA, Ronco C, **McCullough PA**. Pathogenesis of Cardiorenal Syndrome Type 1 in Acute Decompensated Heart Failure: Workgroup Statements from the Eleventh Consensus Conference of the Acute Dialysis Quality Initiative (ADQI). Contrib Nephrol. 2013;182:99-116. doi: 10.1159/000349969. Epub 2013 May 13. PubMed PMID: 23689658.

M399) Cruz DN, Schmidt-Ott KM, Vescovo G, House AA, Kellum JA, Ronco C, **McCullough PA**. Pathophysiology of Cardiorenal Syndrome Type 2 in Stable Chronic Heart Failure: Workgroup Statements from the Eleventh Consensus Conference of the Acute Dialysis Quality Initiative

(ADQI). Contrib Nephrol. 2013;182:117-36. doi: 10.1159/000349968. Epub 2013 May 13. PubMed PMID: 23689659.

M400) Bagshaw SM, Hoste EA, Braam B, Briguori C, Kellum JA, **McCullough PA**, Ronco C. Cardiorenal syndrome type 3: pathophysiologic and epidemiologic considerations. Contrib Nephrol. 2013;182:137-57. doi: 10.1159/000349971. Epub 2013 May 13. PubMed PMID: 23689660.

M401) Tumlin JA, Costanzo MR, Chawla LS, Herzog CA, Kellum JA, **McCullough PA**, Ronco C. Cardiorenal Syndrome Type 4: Insights on Clinical Presentation and Pathophysiology from the Eleventh Consensus Conference of the Acute Dialysis Quality Initiative (ADQI). Contrib Nephrol. 2013;182:158-73. doi: 10.1159/000349972. Epub 2013 May 13. PubMed PMID: 23689661.

M402) Mehta RL, Rabb H, Shaw AD, Singbartl K, Ronco C, **McCullough PA**, Kellum JA. Cardiorenal Syndrome Type 5: Clinical Presentation, Pathophysiology and Management Strategies from the Eleventh Consensus Conference of the Acute Dialysis Quality Initiative (ADQI). Contrib Nephrol. 2013;182:174-94. doi: 10.1159/000349970. Epub 2013 May 13. PubMed PMID: 23689662.

M403) **McCullough PA**, Barnhart HX, Inrig JK, Reddan D, Sapp S, Patel UD, Singh AK, Szczech LA, Califf RM. Cardiovascular Toxicity of Epoetin-Alfa in Patients with Chronic Kidney Disease. Am J Nephrol. 2013 May 25;37(6):549-558. PubMed PMID: 23735819.

M404) Memon I, Norris KC, Bomback AS, Peralta C, Li S, Chen SC, **McCullough PA**, Whaley-Connell A, Jurkovitz C, Tamura MK, Saab G; for the Kidney Early Evaluation Program Investigators. The Association between Parathyroid Hormone Levels and Hemoglobin in Diabetic and Nondiabetic Participants in the National Kidney Foundation's Kidney Early Evaluation Program. Cardiorenal Med. 2013 Jul;3(2):120-127. Epub 2013 Jun 1. PubMed PMID: 23922552; PubMed Central PMCID: PMC3721130.

M405) **McCullough PA**, Barnard D, Clare R, Ellis SJ, Fleg JL, Fonarow GC, Franklin BA, Kilpatrick RD, Kitzman DW, O'Connor CM, Piña IL, Thadani U, Thohan V, Whellan DJ; for the HF-ACTION Investigators. Anemia and Associated Clinical Outcomes in Patients With Heart Failure Due to Reduced Left Ventricular Systolic Function. Clin Cardiol. 2013 Oct;36(10):611-20. PubMed PMID: 23929781.

M406) Akrawinthawong K, Shaw MK, Kachner J, Apostolov EO, Basnakian AG, Shah S, Tilak J, **McCullough PA**. Urine catalytic iron and neutrophil gelatinase-associated lipocalin as companion early markers of acute kidney injury after cardiac surgery: a prospective pilot study. Cardiorenal Med. 2013 Apr;3(1):7-16. doi: 10.1159/000346815. Epub 2013 Feb 6. PubMed PMID: 23946721; PubMed Central PMCID: PMC3743453.

M407) White WB, Cannon CP, Heller SR, Nissen SE, Bergenstal RM, Bakris GL, Perez AT, Fleck PR, Mehta CR, Kupfer S, Wilson C, Cushman WC, Zannad F; EXAMINE Investigators. (**McCullough PA**,

Data Safety Monitoring Board) Alogliptin after acute coronary syndrome in patients with type 2 diabetes. N Engl J Med. 2013 Oct 3;369(14):1327-35.

M408) **McCullough PA**, Akrawinthawong K. Ascorbic Acid for the Prevention of Contrast-Induced Acute Kidney Injury. J Am Coll Cardiol. 2013 Dec 10;62(23):2176-7. PubMed PMID: 23994411.

M409) Ronco C, **McCullough PA**, Chawla LS. Kidney attack versus heart attack: evolution of classification and diagnostic criteria. Lancet. 2013 Sep 14;382(9896):939-40. doi: 10.1016/S0140-6736(13)61932-7. PubMed PMID: 24034297.

M410) Kurella Tamura M, Li S, Chen SC, Cavanaugh KL, Whaley-Connell AT, **McCullough PA**, Mehrotra RL. Educational programs improve the preparation for dialysis and survival of patients with chronic kidney disease. Kidney Int. 2013 Sep 25. doi:10.1038/ki.2013.369. [Epub ahead of print] PubMed PMID: 24067435.

M411) Nasser M, Larsen TR, Waanbah B, Sidiqi I, **McCullough PA**. Hyperacute drug-induced hepatitis with intravenous amiodarone: case report and review of the literature. Drug Health Patient Saf. 2013 Sep 26;5:191-198. PubMed PMID: 24109195.

M412) Larsen TR, Kinni V, Zaks J, David S, **McCullough PA**. A Lethal Case of Influenza and Type 5 Cardiorenal Syndrome. Blood Purif. 2013 Nov 1;36(2):112-115. PubMed PMID: 24192807.

M413) Fried LF, Emanuele N, Zhang JH, Brophy M, Conner TA, Duckworth W, Leehey DJ, **McCullough PA**, O'Connor T, Palevsky PM, Reilly RF, Seliger SL, Warren SR, Watnick S, Peduzzi P, Guarino P; VA NEPHRON-D Investigators. Combined Angiotensin inhibition for the treatment of diabetic nephropathy. N Engl J Med. 2013 Nov 14;369(20):1892-903.

M414) Parsa A, Kao WH, Xie D, Astor BC, Li M, Hsu CY, Feldman HI, Parekh RS, Kusek JW, Greene TH, Fink JC, Anderson AH, Choi MJ, Wright JT Jr, Lash JP, Freedman BI, Ojo A, Winkler CA, Raj DS, Kopp JB, He J, Jensvold NG, Tao K, Lipkowitz MS, Appel LJ; AASK Study Investigators; CRIC Study Investigators (**McCullough PA**, External Advisory Panel). APOL1 risk variants, race, and progression of chronic kidney disease. N Engl J Med. 2013 Dec 5;369(23):2183-96.

M415) Costanzo MR, Chawla LS, Tumlin JA, Herzog CA, **McCullough PA**, Kellum JA, Ronco C. The role of early and sufficient isolated venovenous ultrafiltration in heart failure patients with pulmonary and systemic congestion. Rev Cardiovasc Med. 2013;14(2-4):e123-33. PubMed PMID: 24448253.

M416) Maioli M, Toso A, Leoncini M, Musilli N, Bellandi F, Rosner MH, **McCullough PA**, Ronco C. Pre-procedural Bioimpedance Vectorial Analysis of fluid status and prediction of Contrast-Induced Acute Kidney Injury. J Am Coll Cardiol. 2014 Jan 30. pii: S0735-1097(14)00339-8. doi: 10.1016/j.jacc.2014.01.025. [Epub ahead of print] PubMed PMID: 24530668.

M417) Chawla LS, Herzog CA, Costanzo MR, Tumlin J, Kellum JA, **McCullough PA**, Ronco C; Acute Dialysis Quality Initiative (ADQI) XI Workgroup. Viewpoint: Proposal for a Functional Classification System of Heart Failure in Patients with End-Stage Renal Disease: Proceedings of the Acute Dialysis Quality Initiative (ADQI) XI Workgroup. J Am Coll Cardiol. 2014 Jan 30. pii: S0735-1097(14)00331-3. doi: 10.1016/j.jacc.2014.01.020. [Epub ahead of print] Review. PubMed PMID: 24530671.

M418) **McCullough PA.** Calling for Targeted Trials in Cardiorenal Syndromes. Am J Kidney Dis. 2014 Apr 5. pii: S0272-6386(14)00616-7. doi:10.1053/j.ajkd.2014.03.006. [Epub ahead of print] PubMed PMID: 24713221.

M419) Toth PP, Shah PK, Wilkinson MJ, Davidson MH, **McCullough PA.** Use of microsomal triglyceride transfer protein inhibitors in patients with homozygous familial hypercholesterolemia: translating clinical trial experience into clinical practice. Rev Cardiovasc Med. 2014;15(1):1-10. PubMed PMID: 24762461.

M420) **McCullough PA**, Beaver TM, Bennett-Guerrero E, Emmett M, Fonarow GC, Goyal A, Herzog CA, Kosiborod M, Palmer BF. Acute and chronic cardiovascular effects of hyperkalemia: new insights into prevention and clinical management. Rev Cardiovasc Med. 2014;15(1):11-23. PubMed PMID: 24762462.

M421) **McCullough PA**. Practical experience using galectin-3 in heart failure. Clin Chem Lab Med. 2014 May 8. pii:/j/cclm.ahead-of-print/cclm-2014-0278/cclm-2014-0278.xml. doi: 10.1515/cclm-2014-0278. [Epub ahead of print] PubMed PMID: 24810562

M422) Chin MP, Reisman SA, Bakris GL, O'Grady M, Linde PG, **McCullough PA,** Packham D, Vaziri ND, Ward KW, Warnock DG, Meyer CJ. Mechanisms Contributing to Adverse Cardiovascular Events in Patients with Type 2 Diabetes Mellitus and Stage 4 Chronic Kidney Disease Treated with Bardoxolone Methyl. Am J Nephrol. 2014 Jun 3;39(6):499-508. [Epub ahead of print] PubMed PMID: 24903467.

M423) **McCullough PA**, Whaley-Connell AT, Vassalotti JA. The future of CKD detection: the role for the Kidney Early Evaluation Program. Nephrol News Issues. 2014 Apr;28(4):41-2. PubMed PMID: 24960988.

M424) Palazzuoli A, Pellegrini M, Ruocco G, Martini G, Franci B, Campagna MS, Gilleman M, Nuti R, **McCullough PA**, Ronco C. Continuous versus bolus intermittent loop diuretic infusion in acutely decompensated heart failure: a prospective randomized trial. Crit Care. 2014 Jun 28;18(3):R134. doi: 10.1186/cc13952. PubMed PMID: 24974232.

M425) Manatsathit W, Al-Hamid H, Leelasinjaroen P, Hashmi U, **McCullough PA**. Management of gastrointestinal bleeding in patients anticoagulated with dabigatran compared with warfarin: a retrospective, comparative case review. Cardiovasc Diagn Ther. 2014 Jun;4(3):224-31. doi:

10.3978/j.issn.2223-3652.2014.03.07. PubMed PMID: 25009791; PubMed Central PMCID: PMC4069982.

M426) Neath SX, Jefferies JL, Berger JS, Wu AH, McConnell JP, Boone JL, **McCullough PA**, Jesse RL, Maisel AS. The current and future landscape of urinary thromboxane testing to evaluate atherothrombotic risk. Rev Cardiovasc Med. 2014;15(2):119-30. Review. PubMed PMID: 25051129.

M427) Brown JR, Solomon RJ, Sarnak MJ, **McCullough PA**, Splaine ME, Davies L, Ross CS, Dauerman HL, Stender JL, Conley SM, Robb JF, Chaisson K, Boss R, Lambert P, Goldberg DJ, Lucier D, Fedele FA, Kellett MA, Horton S, Phillips WJ, Downs C, Wiseman A, MacKenzie TA, Malenka DJ; for the Northern New England Cardiovascular Disease Study Group. Reducing Contrast-Induced Acute Kidney Injury Using a Regional Multicenter Quality Improvement Intervention. Circ Cardiovasc Qual Outcomes. 2014 Jul 29. pii: CIRCOUTCOMES.114.000903. [Epub ahead of print] PubMed PMID: 25074372.

M428) Zimering MB, Zhang JH, Guarino PD, Emanuele N, **McCullough PA**, Fried LF; Investigators for the VA NEPHRON-D. Endothelial cell autoantibodies in predicting declining renal function, end-stage renal disease, or death in adult type 2 diabetic nephropathy. Front Endocrinol (Lausanne). 2014 Aug 11;5:128. doi: 10.3389/fendo.2014.00128. eCollection 2014. PubMed PMID: 25157242; PubMed Central PMCID: PMC4127944.

M429) **McCullough PA**, Kellum JA, Haase M, Müller C, Damman K, Murray PT, Cruz D, House AA, Schmidt-Ott KM, Vescovo G, Bagshaw SM, Hoste EA, Briguori C, Braam B, Chawla LS, Costanzo MR, Tumlin JA, Herzog CA, Mehta RL, Rabb H, Shaw AD, Singbartl K, Ronco C. Pathophysiology of the Cardiorenal Syndromes: Executive Summary from the Eleventh Consensus Conference of the Acute Dialysis Quality Initiative (ADQI). Blood Purif. 2014;37 Suppl 2:2-13. doi: 10.1159/000361059. Epub 2014 Jul 31. PubMed PMID: 25196564.

M430) Hoste EA, **McCullough PA**, Kashani K, Chawla LS, Joannidis M, Shaw AD, Feldkamp T, Uettwiller-Geiger DL, McCarthy P, Shi J, Walker MG, Kellum JA; for the Sapphire Investigators. Derivation and validation of cutoffs for clinical use of cell cycle arrest biomarkers. Nephrol Dial Transplant. 2014 Sep 18. pii: gfu292. [Epub ahead of print] PubMed PMID: 25237065.

M431) Chin MP, Wrolstad D, Bakris GL, Chertow GM, de Zeeuw D, Goldsberry A, Linde PG, **McCullough PA**, McMurray JJ, Wittes J, Meyer CJ. Risk factors for heart failure in patients with type 2 diabetes mellitus and stage 4 chronic kidney disease treated with bardoxolone methyl. J Card Fail. 2014 Dec;20(12):953-8. doi:10.1016/j.cardfail.2014.10.001. Epub 2014 Oct 13. PubMed PMID: 25307295.

M432) **McCullough PA**, Fazel P, Choi JW. Screening, diagnosis, and management of CAD in asymptomatic diabetic patients. JACC Cardiovasc Imaging. 2014 Oct;7(10):1011-2. doi: 10.1016/j.jcmg.2014.08.001. PubMed PMID: 25323163.

M433) Hundae A, **McCullough PA**. Cardiac and renal fibrosis in chronic cardiorenal syndromes. Nephron Clin Pract. 2014;127(1-4):106-12. doi: 10.1159/000363705. Epub 2014 Sep 24. PubMed PMID: 25343831.

M434) Shin HJ, **McCullough PA**. Focus on lipids: high-density lipoprotein cholesterol and its associated lipoproteins in cardiac and renal disease. Nephron Clin Pract. 2014;127(1-4):158-64. doi: 10.1159/000363552. Epub 2014 Sep 24. PubMed PMID:25343842.

M435) Ball T, **McCullough PA**. Statins for the prevention of contrast-induced acute kidney injury. Nephron Clin Pract. 2014;127(1-4):165-71. doi: 10.1159/000363202. Epub 2014 Sep 24. PubMed PMID: 25343843.

M436) Szczech LA, Stewart RC, Su HL, DeLoskey RJ, Astor BC, Fox CH, **McCullough PA**, Vassalotti JA. Primary Care Detection of Chronic Kidney Disease in Adults with Type-2 Diabetes: The ADD-CKD Study (Awareness, Detection and Drug Therapy in Type 2 Diabetes and Chronic Kidney Disease). PLoS One. 2014 Nov 26;9(11):e110535. doi: 10.1371/journal.pone.0110535. eCollection 2014. PubMed PMID: 25427285; PubMed Central PMCID: PMC4245114.

M437) **McCullough PA**, Roberts WC. Peter Andrew McCullough, MD, MPH: An Interview With the Editor. Am J Cardiol. 2014 Dec 1;114(11):1772-85. doi: 10.1016/j.amjcard.2014.08.034. Epub 2014 Sep 16. PubMed PMID: 25439453.

M438) Roberts JK, **McCullough PA**. The Management of Acute Coronary Syndromes in Patients With Chronic Kidney Disease. Adv Chronic Kidney Dis. 2014 Nov;21(6):472-479. doi: 10.1053/j.ackd.2014.08.005. Epub 2014 Oct 24. Review. PubMed PMID: 25443572.

M439) **McCullough PA**, Jefferies JL. Novel Markers and Therapies for Patients with Acute Heart Failure and Renal Dysfunction. Am J Med. 2014 Nov 13. pii: S0002-9343(14)00977-2. doi: 10.1016/j.amjmed.2014.10.035. [Epub ahead of print] PubMed PMID: 25446297.

M440) Ball T, Wheelan K, **McCullough PA**. Chronic anticoagulation in chronic kidney disease. J Am Coll Cardiol. 2014 Dec 16;64(23):2483-5. doi: 10.1016/j.jacc.2014.09.052. PubMed PMID: 25500232.

M441) Akrawinthawong K, Ricci J, Cannon L, Dixon S, Kupfer K, Stivers D, Alexander P, David S, **McCullough PA**. Subclinical and clinical contrast-induced acute kidney injury: data from a novel blood marker for determining the risk of developing contrast-induced nephropathy (ENCINO), a prospective study. Ren Fail. 2014 Dec 18:1-5. [Epub ahead of print] PubMed PMID: 25519207.

M442) **McCullough PA**, Mehta A, Szerlip H. Improving detection of cardiac surgery-associated acute kidney injury. J Am Coll Cardiol. 2014 Dec 30;64(25):2763-4. doi: 10.1016/j.jacc.2014.09.065. PubMed PMID: 25541129.

M443) Lepor NE, Fouchia DD, **McCullough PA**. New vistas for the treatment of obesity: turning the tide against the leading cause of morbidity and cardiovascular mortality in the developed world. Rev Cardiovasc Med. 2014;15 Suppl 2:S1-19; quiz S20-1. Review. PubMed PMID: 25662755.

M444) Watson KE, Stocker EH, Jacoby DS, **McCullough PA**. Advanced lipid testing: when, why, and in whom? Rev Cardiovasc Med. 2014;15(4):310-7; quiz 318-9. Review. PubMed PMID: 25662925.

M445) Charytan DM, Fishbane S, Malyszko J, **McCullough PA**, Goldsmith D. Cardiorenal Syndrome and the Role of the Bone-Mineral Axis and Anemia. Am J Kidney Dis. 2015 Feb 26. pii: S0272-6386(15)00084-0. doi: 10.1053/j.ajkd.2014.12.016. [Epub ahead of print] PubMed PMID: 25727384.

M446) Kassis HM, Minsinger KD, **McCullough PA**, Block CA, Sidhu MS, Brown JR. A Review of the Use of Iloprost, A Synthetic Prostacyclin, in the Prevention of Radiocontrast Nephropathy in Patients Undergoing Coronary Angiography and Intervention. Clin Cardiol. 2015 May 12. doi: 10.1002/clc.22407. [Epub ahead of print] PubMed PMID: 25963191.

M447) Palazzuoli A, **McCullough PA**, Ronco C, Nuti R. Kidney disease in heart failure: the importance of novel biomarkers for type 1 cardio-renal syndrome detection. Intern Emerg Med. 2015 May 14. [Epub ahead of print] PubMed PMID: 25972236.

M448) Robinson JG, Farnier M, Krempf M, Bergeron J, Luc G, Averna M, Stroes ES, Langslet G, Raal FJ, El Shahawy M, Koren MJ, Lepor NE, Lorenzato C, Pordy R, Chaudhari U, Kastelein JJ; ODYSSEY LONG TERM Investigators (**McCullough PA** Site PI). Efficacy and safety of alirocumab in reducing lipids and cardiovascular events. N Engl J Med. 2015 Apr 16;372(16):1489-99. doi: 10.1056/NEJMoa1501031. Epub 2015 Mar 15. PubMed PMID: 25773378.

M449) **McCullough PA**, Costanzo MR, Silver M, Spinowitz B, Zhang J, Lepor NE. Novel Agents for the Prevention and Management of Hyperkalemia. Rev Cardiovasc Med. 2015;16(2):140-55. PubMed PMID: 26198561.

M450) **McCullough PA**, Patanker G, Stoler RC. Estimating Renal Filtration, Drug Dosing, and Clinical Outcomes. J Am Coll Cardiol. 2015 Jun 30;65(25):2724-5. doi: 10.1016/j.jacc.2015.05.015. PubMed PMID: 26112196.

M451) Husain-Syed F, **McCullough PA**, Birk HW, Renker M, Brocca A, Seeger W, Ronco C. Cardio-Pulmonary-Renal Interactions: A Multidisciplinary Approach. J Am Coll Cardiol. 2015 Jun 9;65(22):2433-48. doi: 10.1016/j.jacc.2015.04.024. Review. PubMed PMID: 26046738.

M452) Anker SD, Kosiborod M, Zannad F, Piña IL, **McCullough PA**, Filippatos G, van der Meer P, Ponikowski P, Rasmussen HS, Lavin PT, Singh B, Yang A, Deedwania P. Maintenance of serum potassium with sodium zirconium cyclosilicate (ZS-9) in heart failure patients: results from a

phase 3 randomized, double-blind, placebo-controlled trial. Eur J Heart Fail. 2015 May 23. doi: 10.1002/ejhf.300. [Epub ahead of print] PubMed PMID: 26011677.

M453) Palazzuoli A, Ruocco G, Ronco C, **McCullough PA**. Loop diuretics in acute heart failure: beyond the decongestive relief for the kidney. Crit Care. 2015 Sep 3;19:296. doi: 10.1186/s13054-015-1017-3. PubMed PMID: 26335137; PubMed Central PMCID: PMC4559070.

M454) **McCullough PA**, Young A, Shutze WP. Acute Kidney Injury After Carotid Artery Stenting. JACC Cardiovasc Interv. 2015 Sep;8(11):1515-7. doi: 10.1016/j.jcin.2015.07.006. PubMed PMID: 26404205.

M455) Fallahzadeh MK, **McCullough PA**. Cardiac Electromechanical Abnormalities in Hemodialysis Patients: Indicators of Cardiomyopathy and Future Risk. Am J Nephrol. 2015;42(3):237-8. doi: 10.1159/000441100. Epub 2015 Oct 20. PubMed PMID: 26484657.

M456) Thompson-Martin Y, **McCullough PA**, Agrawal V. Impact of an Educational Program for Advanced Practice Nurses on Knowledge of Kidney Disease Outcomes Quality Initiative Guidelines. Nephrol Nurs J. 2015 Sep-Oct;42(5):455-60, 496; quiz 461. PubMed PMID: 26591270.

M457) Larsen TR, Singh G, Velocci V, Nasser M, **McCullough PA**. Frequency of fluid overload and usefulness of bioimpedance in patients requiring intensive care for sepsis syndromes. Proc (Bayl Univ Med Cent). 2016 Jan;29(1):12-5. PubMed PMID: 26722156; PubMed Central PMCID: PMC4677841.

M458) Charytan DM, Foley R, **McCullough PA**, Rogers JD, Zimetbaum P, Herzog CA, Tumlin JA; MiD Investigators and Committees. Arrhythmia and Sudden Death in Hemodialysis Patients: Protocol and Baseline Characteristics of the Monitoring in Dialysis Study. Clin J Am Soc Nephrol. 2016 Jan 13. pii: CJN.09350915. [Epub ahead of print] PubMed PMID: 26763255.

M459) Roberts WC, Hall SA, Ko JM, **McCullough PA**, Lima B. Atrophy of the Heart After Insertion of a Left Ventricular Assist Device and Closure of the Aortic Valve. Am J Cardiol. 2016 Mar 1;117(5):878-9. doi: 10.1016/j.amjcard.2015.12.008. Epub 2015 Dec 13. PubMed PMID: 26792135.

M460) Tecson KM, Silver MA, Brune SD, Cauthen C, Kwan MD, Schussler JM, Vasudevan A, Watts JA, **McCullough PA**. Impact of Enhanced External Counterpulsation on Heart Failure Rehospitalization in Patients With Ischemic Cardiomyopathy. Am J Cardiol. 2015 Dec 31. pii: S0002-9149(15)30069-2. doi: 10.1016/j.amjcard.2015.12.024. [Epub ahead of print] PubMed PMID: 26813739.

M461) **McCullough PA**, Roberts WC. Influence of Chronic Renal Failure on Cardiac Structure. J Am Coll Cardiol. 2016 Mar 15;67(10):1183-5. doi:10.1016/j.jacc.2015.11.065. PubMed PMID: 26965539.

M462) Palazzuoli A, Ruocco G, Pellegrini M, Beltrami M, Giordano N, Nuti R, **McCullough PA**. Prognostic Significance of Hyperuricemia in Patients With Acute Heart Failure. Am J Cardiol. 2016 May 15;117(10):1616-21. doi: 10.1016/j.amjcard.2016.02.039. Epub 2016 Mar 2. PubMed PMID: 27040576.

M463) **McCullough PA**, Fallahzadeh MK, Tecson KM. Predicting Acute Kidney Injury in the Catheterization Laboratory. J Am Coll Cardiol. 2016 Apr 12;67(14):1723-4. doi: 10.1016/j.jacc.2016.02.007. PubMed PMID: 27056779.

M464) Grodzinsky A, Goyal A, Gosch K, **McCullough PA**, Fonarow GC, Mebazaa A, Masoudi FA, Spertus JA, Palmer BF, Kosiborod M. Prevalence and Prognosis of Hyperkalemia in Patients with Acute Myocardial Infarction. Am J Med. 2016 Apr 7. pii:S0002-9343(16)30317-5. doi: 10.1016/j.amjmed.2016.03.008. [Epub ahead of print] PubMed PMID: 27060233.

M465) Sherwood M, **McCullough PA**. Chronic kidney disease from screening, detection, and awareness, to prevention. Lancet Glob Health. 2016 May;4(5):e288-9. doi: 10.1016/S2214-109X(16)30049-3. PubMed PMID: 27102186.

M466) **McCullough PA**, Afzal A, Kale P. Goal-Directed Heart Failure Care in Patients With Chronic Kidney Disease and End-Stage Renal Disease. JACC Heart Fail. 2016 May 30. pii: S2213-1779(16)30084-1. doi: 10.1016/j.jchf.2016.03.014. [Epub ahead of print] PubMed PMID: 27289405.

M467) Prasad A, Sohn A, Morales J, Williams K, Bailey SR, Levin D, **McCullough PA**, Mehran R, Lopez-Cruz G, Harder J. Contemporary practice patterns related to the risk of acute kidney injury in the catheterization laboratory: Results from a survey of Society of Cardiovascular Angiography and Intervention (SCAI) cardiologists. Catheter Cardiovasc Interv. 2016 Jun 17. doi: 10.1002/ccd.26628. [Epub ahead of print] PubMed PMID: 27315581.

M468) Schussler JM, Vasudevan A, von Bose LJ, Won JI, **McCullough PA**. Comparative Efficacy of Transradial Versus Transfemoral Approach for Coronary Angiography and Percutaneous Coronary Intervention. Am J Cardiol. 2016 Aug 15;118(4):482-8. doi: 10.1016/j.amjcard.2016.05.038. PubMed PMID: 27378143.

M469) Zannad F, Stough WG, Lipicky RJ, Tamargo J, Bakris GL, Borer JS, Alonso García Mde L, Hadjadj S, Koenig W, Kupfer S, **McCullough PA**, Mosenzon O, Pocock S, Scheen AJ, Sourij H, Van der Schueren B, Stahre C, White WB, Calvo G. Assessment of cardiovascular risk of new drugs for the treatment of diabetes mellitus: risk assessment vs. risk aversion. Eur Heart J Cardiovasc Pharmacother. 2016 Jul;2(3):200-5. doi: 10.1093/ehjcvp/pvw007. Review. PubMed PMID: 27418973; PubMed Central PMCID: PMC4907355.

M470) **McCullough PA**, Bennett-Guerrero E, Chawla LS, Beaver T, Mehta RL, Molitoris BA, Eldred A, Ball G, Lee HJ, Houser MT, Khan S. ABT-719 for the Prevention of Acute Kidney Injury in Patients

Undergoing High-Risk Cardiac Surgery: A Randomized Phase 2b Clinical Trial. J Am Heart Assoc. 2016 Aug 20;5(8). pii:e003549. doi: 10.1161/JAHA.116.003549. PubMed PMID: 27543797; PubMed Central PMCID: PMC5015281.

M471) Brown JR, **McCullough PA**, Matheny ME. Novel Developments in Acute Kidney Injury. Biomed Res Int. 2016;2016:2756204. doi: 10.1155/2016/2756204. PubMed PMID: 27595099; PubMed Central PMCID: PMC4995325.

M472) **McCullough PA**, Choi JP, Feghali GA, Schussler JM, Stoler RM, Vallabahn RC, Mehta A. Contrast-Induced Acute Kidney Injury. J Am Coll Cardiol. 2016 Sep 27;68(13):1465-73. doi: 10.1016/j.jacc.2016.05.099. Review. PubMed PMID:27659469.

M473) Villa G, Neri M, Bellomo R, Cerda J, De Gaudio AR, De Rosa S, Garzotto F, Honore PM, Kellum J, Lorenzin A, Payen D, Ricci Z, Samoni S, Vincent JL, Wendon J, Zaccaria M, Ronco C; Nomenclature Standardization Initiative (NSI) Alliance (**McCullough PA** member). Nomenclature for renal replacement therapy and blood purification techniques in critically ill patients: practical applications. Crit Care. 2016 Oct 10;20(1):283. Review. PubMed PMID: 27719676; PubMed Central PMCID: PMC5056485.

M474) **McCullough PA**, Fallahzadeh MK, Hegazi RM. Nutritional Deficiencies and Sarcopenia in Heart Failure: A Therapeutic Opportunity to Reduce Hospitalization and Death. Rev Cardiovasc Med. 2016;17(S1):S30-S39. PubMed PMID: 27725625.

M475) Bakris GL, Burkart JM, Weinhandl ED, **McCullough PA**, Kraus MA. Intensive Hemodialysis, Blood Pressure, and Antihypertensive Medication Use. Am J Kidney Dis. 2016 Nov;68(5S1):S15-S23. doi: 10.1053/j.ajkd.2016.05.026. PubMed PMID:27772639.

M476) Copland M, Komenda P, Weinhandl ED, **McCullough PA**, Morfin JA. Intensive Hemodialysis, Mineral and Bone Disorder, and Phosphate Binder Use. Am J Kidney Dis. 2016 Nov;68(5S1):S24-S32. doi: 10.1053/j.ajkd.2016.05.024. PubMed PMID:27772640.

M477) Morfin JA, Fluck RJ, Weinhandl ED, Kansal S, **McCullough PA**, Komenda P. Intensive Hemodialysis and Treatment Complications and Tolerability. Am J Kidney Dis. 2016 Nov;68(5S1):S43-S50. doi: 10.1053/j.ajkd.2016.05.021. PubMed PMID:27772642.

M478) **McCullough PA**, Chan CT, Weinhandl ED, Burkart JM, Bakris GL. Intensive Hemodialysis, Left Ventricular Hypertrophy, and Cardiovascular Disease. Am J Kidney Dis. 2016 Nov;68(5S1):S5-S14. doi: 10.1053/j.ajkd.2016.05.025. PubMed PMID: 27772643.

M479) **McCullough PA**, Ball T, Cox KM, Assar MD. Use of Oral Anticoagulation in the Management of Atrial Fibrillation in Patients with ESRD: Pro. Clin J Am Soc Nephrol. 2016 Nov 7;11(11):2079-2084. PubMed PMID: 27797888; PubMed Central PMCID: PMC5108189.

M480) Zhang J, **McCullough PA**. Lipoic Acid in the Prevention of Acute Kidney Injury. Nephron. 2016;134(3):133-140. PubMed PMID: 27603173.

M481) **McCullough PA**, Vasudevan A, Lopez LR, Swift C, Peterson M, Bennett-Firmin J, Schiffmann R, Bottiglieri T. Oxidative stress reflected by increased F(2)-isoprostanes is associated with increasing urinary 11-dehydro thromboxane B(2) levels in patients with coronary artery disease. Thromb Res. 2016 Oct 26;148:85-88. doi: 10.1016/j.thromres.2016.10.022. [Epub ahead of print] PubMed PMID: 27815971.

M482) Zhang J, Fallahzadeh MK, **McCullough PA**. Aging Male Spontaneously Hypertensive Rat as an Animal Model for the Evaluation of the Interplay between Contrast-Induced Acute Kidney Injury and Cardiorenal Syndrome in Humans. Cardiorenal Med. 2016 Nov;7(1):1-10. Epub 2016 Jul 21. Review. PubMed PMID:27994597; PubMed Central PMCID: PMC5159736.

M483) Vasudevan A, Bottiglieri T, Tecson KM, Sathyamoorthy M, Schussler JM, Velasco CE, Lopez LR, Swift C, Peterson M, Bennett-Firmin J, Schiffmann R, **McCullough PA**. Residual thromboxane activity and oxidative stress: influence on mortality in patients with stable coronary artery disease. Coron Artery Dis. 2017 Jun;28(4):287-293. doi: 10.1097/MCA.0000000000000461. PubMed PMID: 28005558.

M484) Krishnan DK, Pawlaczyk B, **McCullough PA**, Enright S, Kunadi A, Vanhecke TE. Point-of-Care, Ultraportable Echocardiography Predicts Diuretic Response in Patients Admitted with Acute Decompensated Heart Failure. Clin Med Insights Cardiol. 2016 Dec 19;10:201-208. doi: 10.4137/CMC.S38896. eCollection 2016. PubMed PMID: 28008296; PubMed Central PMCID: PMC5170880.

M485) Singer AJ, Than MP, Smith S, **McCullough P**, Barrett TW, Birkhahn R, Reed M, Thode HC, Arnold WD, Daniels LB, de Filippi C, Headden G, Peacock WF. Missed myocardial infarctions in ED patients prospectively categorized as low risk by established risk scores. Am J Emerg Med. 2017 Jan 5. pii: S0735-6757(17)30003-7. doi: 10.1016/j.ajem.2017.01.003. [Epub ahead of print] PubMed PMID: 28108220.

M486) Tecson KM, Arnold W, Barrett T, Birkhahn R, Daniels LB, DeFilippi C, Headden G, Peacock WF, Reed M, Singer AJ, Schussler JM, Smith S, Than MP, **McCullough PA**. Interpretation of positive troponin results among patients with and without myocardial infarction. Proc (Bayl Univ Med Cent). 2017 Jan;30(1):11-15. PubMed PMID: 28127121; PubMed Central PMCID: PMC5242102.

M487) Tecson KM, Panettiere-Kennedy KS, Won JI, Garg P, Olugbode O, **McCullough PA**. Relation between proprotein convertase subtilisin/kexin type 9 and directly measured low-density lipoprotein cholesterol. Proc (Bayl Univ Med Cent). 2017 Jan;30(1):16-20. PubMed PMID: 28127122; PubMed Central PMCID: PMC5242103.

M488) **McCullough PA**, Vasudevan A, Sathyamoorthy M, Schussler JM, Velasco CE, Lopez LR, Swift C, Peterson M, Bennett-Firmin J, Schiffmann R, Bottiglieri T. Urinary 11-Dehydro-Thromboxane

B(2) and Mortality in Patients With Stable Coronary Artery Disease. Am J Cardiol. 2017 Apr 1;119(7):972-977. doi: 10.1016/j.amjcard.2016.12.004. Epub 2017 Jan 5. PubMed PMID: 28139223

M489) Vasudevan A, Singer AJ, DeFilippi C, Headden G, Schussler JM, Daniels LB, Reed M, Than MP, Birkhahn R, Smith SW, Barrett TW, Arnold W, Peacock WF, **McCullough PA**. Renal Function and Scaled Troponin in Patients Presenting to the Emergency Department with Symptoms of Myocardial Infarction. Am J Nephrol. 2017;45(4):304-309. doi: 10.1159/000458451. Epub 2017 Feb 14. PubMed PMID:28192777.

M490) **McCullough PA**, Zhang J, Ronco C. Volume expansion and contrast-induced acute kidney injury. Lancet. 2017 Apr 1;389(10076):1277-1278. doi:10.1016/S0140-6736(17)30540-8. Epub 2017 Feb 21. PubMed PMID: 28236468.

M491) Elbehary S, Szerlip HM, **McCullough PA**. Potassium Excretion and Outcomes in CKD: Is K Intake OK? Am J Kidney Dis. 2017 Mar;69(3):325-327. doi:10.1053/j.ajkd.2016.11.009. PubMed PMID: 28236878.

M492) **McCullough PA**, Rios A, Smith B. Dialysis fistulas and heart failure. Eur Heart J. 2017 Mar 17. doi: 10.1093/eurheartj/ehx114. [Epub ahead of print] PubMed PMID:28329218.

M493) Howard CE, **McCullough PA**. Decoding Acute Myocardial Infarction among Patients on Dialysis. J Am Soc Nephrol. 2017 May;28(5):1337-1339. doi:10.1681/ASN.2017030226. Epub 2017 Apr 12. PubMed PMID: 28404663.

M494) Vasudevan A, Jazi HH, Won JI, Ball T, Patankar GR, Sarmast SA, Shin HJ, **McCullough PA**. Personalized treatment of heart failure with biomarker guidance using a novel disease severity score. Proc (Bayl Univ Med Cent). 2017 Apr;30(2):139-142. PubMed PMID: 28405060; PubMed Central PMCID: PMC5349806.

M495) Won JI, Zhang J, Tecson KM, **McCullough PA**. Balancing Low-density Lipoprotein Cholesterol Reduction and Hepatotoxicity With Lomitapide Mesylate and Mipomersen in Patients With Homozygous Familial Hypercholesterolemia. Rev Cardiovasc Med. 2017;18(1):21-28. PubMed PMID: 28509890.

M496) Afzal A, Sarmast S, Choi JW, **McCullough PA**, Schussler JM. Spontaneous Coronary Artery Dissection: A Review of Pathogenesis, Presentations, Treatment, and Outcomes. Rev Cardiovasc Med. 2017;18(1):29-36. PubMed PMID: 28509891.

M497) **McCullough PA.** How Trialists and Pharmaceutical Sponsors Have Failed Us by Thinking That Acute Heart Failure Is a 48-Hour Illness. Am J Cardiol. 2017 May 11. pii: S0002-9149(17)30795-6. doi: 10.1016/j.amjcard.2017.04.056. [Epub ahead of print] PubMed PMID: 28583677.

M498) Zhang J, Bottiglieri T, **McCullough PA**. The Central Role of Endothelial Dysfunction in Cardiorenal Syndrome. Cardiorenal Med. 2017 Feb;7(2):104-117. doi: 10.1159/000452283. Epub 2016 Dec 29. Review. PubMed PMID: 28611784; PubMed Central PMCID: PMC5465690.

M499) Tecson KM, Erhardtsen E, Eriksen PM, Gaber AO, Germain M, Golestaneh L, Lavoria MLA, Moore LW, **McCullough PA**. Optimal cut points of plasma and urine neutrophil gelatinase-associated lipocalin for the prediction of acute kidney injury among critically ill adults: retrospective determination and clinical validation of a prospective multicentre study. BMJ Open. 2017 Jul 10;7(7):e016028. doi: 10.1136/bmjopen-2017-016028. PubMed PMID: 28698338

M500) Vasudevan A, Schussler JM, Won JI, Ashcraft P, Bolanos I, Williams M, Bottiglieri T, Velasco CE, **McCullough PA**. Urinary metabolites in patients undergoing coronary catheterization via the radial versus femoral artery approach. Proc (Bayl Univ Med Cent). 2017 Oct;30(4):404-409. PubMed PMID: 28966445; PubMed Central PMCID: PMC5595375.

M501) Azzalini L, Candilio L, **McCullough PA**, Colombo A. Current Risk of Contrast-Induced Acute Kidney Injury After Coronary Angiography and Intervention: A Reappraisal of the Literature. Can J Cardiol. 2017 Oct;33(10):1225-1228. doi: 10.1016/j.cjca.2017.07.482. Epub 2017 Aug 3. Review. PubMed PMID: 28941604.

M502) Palazzuoli A, Ruocco G, De Vivo O, Nuti R, **McCullough PA**. Prevalence of Hyperuricemia in Patients With Acute Heart Failure With Either Reduced or Preserved Ejection Fraction. Am J Cardiol. 2017 Oct 1;120(7):1146-1150. doi: 10.1016/j.amjcard.2017.06.057. Epub 2017 Jul 17. PubMed PMID: 28807403.

M503) Kovesdy CP, Appel LJ, Grams ME, Gutekunst L, **McCullough PA**, Palmer BF, Pitt B, Sica DA, Townsend RR. Potassium homeostasis in health and disease: A scientific workshop cosponsored by the National Kidney Foundation and the American Society of Hypertension. J Am Soc Hypertens. 2017 Oct 10. pii: S1933-1711(17)30337-6. doi: 10.1016/j.jash.2017.09.011. [Epub ahead of print] PubMed PMID: 29030153.

M504) Afzal A, Vallabhan RC, **McCullough PA**. Acute kidney injury in cardiogenic shock: in search of early detection and clinical certainty. Eur J Heart Fail. 2017 Oct 12. doi: 10.1002/ejhf.1032. [Epub ahead of print] PubMed PMID: 29027337.

M505) Ronco C, Ronco F, **McCullough PA**. A Call to Action to Develop Integrated Curricula in Cardiorenal Medicine. Blood Purif. 2017 Oct 25;44(4):251-259. doi: 10.1159/000480318. [Epub ahead of print] PubMed PMID: 29065398.

M506) Ronco C, Ronco F, **McCullough PA**. A Call to Action to Develop Integrated Curricula in Cardiorenal Medicine. Rev Cardiovasc Med. 2017;18(3):93-99. PubMed PMID: 29111542.

M507) Butler J, Hamo CE, Filippatos G, Pocock SJ, Bernstein RA, Brueckmann M, Cheung AK, George JT, Green JB, Januzzi JL, Kaul S, Lam CSP, Lip GYH, Marx N, **McCullough PA**, Mehta CR,

Ponikowski P, Rosenstock J, Sattar N, Salsali A, Scirica BM, Shah SJ, Tsutsui H, Verma S, Wanner C, Woerle HJ, Zannad F, Anker SD; EMPEROR Trials Program. The potential role and rationale for treatment of heart failure with sodium-glucose co-transporter 2 inhibitors. Eur J Heart Fail. 2017 Nov;19(11):1390-1400. doi: 10.1002/ejhf.933. Epub 2017 Aug 24. Review. PubMed PMID: 28836359.

M508) **McCullough PA**, David G, Todoran TM, Brilakis ES, Ryan MP, Gunnarsson C. Iso-osmolar contrast media and adverse renal and cardiac events after percutaneous cardiovascular intervention. J Comp Eff Res. 2017 Nov 9. doi: 10.2217/cer-2017-0052. [Epub ahead of print] PubMed PMID: 29117715.

M509) Rocha NA, East C, Zhang J, **McCullough PA**. ApoCIII as a Cardiovascular Risk Factor and Modulation by the Novel Lipid-Lowering Agent Volanesorsen. Curr Atheroscler Rep. 2017 Nov 9;19(12):62. doi: 10.1007/s11883-017-0697-3. Review. PubMed PMID: 29124482.

M510) Rangaswami J, Mathew RO, **McCullough PA**. Resuscitation for the specialty of nephrology: is cardionephrology the answer? Kidney Int. 2017 Nov 11. pii: S0085-2538(17)30727-5. doi: 10.1016/j.kint.2017.10.002. [Epub ahead of print] PubMed PMID: 29137816.

M511) Kovesdy CP, Appel LJ, Grams ME, Gutekunst L, **McCullough PA**, Palmer BF, Pitt B, Sica DA, Townsend RR. Potassium Homeostasis in Health and Disease: A Scientific Workshop Cosponsored by the National Kidney Foundation and the American Society of Hypertension. Am J Kidney Dis. 2017 Dec;70(6):844-858. doi: 10.1053/j.ajkd.2017.09.003. Epub 2017 Oct 10. PubMed PMID: 29029808.

M512) Ostermann M, **McCullough PA**, Forni LG, Bagshaw SM, Joannidis M, Shi J, Kashani K, Honore PM, Chawla LS, Kellum JA; all SAPPHIRE Investigators. Kinetics of Urinary Cell Cycle Arrest Markers for Acute Kidney Injury Following Exposure to Potential Renal Insults. Crit Care Med. 2017 Nov 20. doi:10.1097/CCM.0000000000002847. [Epub ahead of print] PubMed PMID: 29189343

M513) Vasudevan A, Tecson KM, Bennett-Firmin J, Bottiglieri T, Lopez LR, Peterson M, Sathyamoorthy M, Schiffmann R, Schussler JM, Swift C, Velasco CE, **McCullough PA**. Prognostic value of urinary 11-dehydro-thromboxane B(2) for mortality: A cohort study of stable coronary artery disease patients treated with aspirin. Catheter Cardiovasc Interv. 2017 Nov 29. doi: 10.1002/ccd.27437. [Epub ahead of print] PubMed PMID: 29193683.

M514) Himmelfarb J, Chertow GM, **McCullough PA**, Mesana T, Shaw AD, Sundt TM, Brown C, Cortville D, Dagenais F, de Varennes B, Fontes M, Rossert J, Tardif JC. Perioperative THR-184 and AKI after Cardiac Surgery. J Am Soc Nephrol. 2017 Dec 4. pii: ASN.2017020217. doi: 10.1681/ASN.2017020217. [Epub ahead of print] PubMed PMID: 29203473.

M515) **McCullough PA**, Rangaswami J. Real or Perceived: Hyperkalemia Is a Major Deterrent for Renin-Angiotensin Aldosterone System Inhibition in Heart Failure. Nephron. 2017 Dec 5. doi: 10.1159/000485645. [Epub ahead of print] PubMed PMID: 29207385.

M516) Keuffel E, **McCullough PA**, Todoran TM, Brilakis ES, Palli SR, Ryan MP, Gunnarsson C. The effect of major adverse renal cardiovascular event (MARCE) incidence, procedure volume, and unit cost on the hospital savings resulting from contrast media use in inpatient angioplasty. J Med Econ. 2017 Dec 15:1-9. doi: 10.1080/13696998.2017.1415912. [Epub ahead of print] PubMed PMID: 29226736.

M517) Tecson KM, Brown D, Choi JW, Feghali G, Gonzalez-Stawinski GV, Hamman BL, Hebeler R, Lander SR, Lima B, Potluri S, Schussler JM, Stoler RC, Velasco C, **McCullough PA**. Major Adverse Renal and Cardiac Events After Coronary Angiography and Cardiac Surgery. Ann Thorac Surg. 2018 Jun;105(6):1724-1730. doi:10.1016/j.athoracsur.2018.01.010. Epub 2018 Feb 2. PubMed PMID: 29408241.

M518) Haase VH, Chertow GM, Block GA, Pergola PE, deGoma EM, Khawaja Z, Sharma A, Maroni BJ, **McCullough PA**. Effects of vadadustat on hemoglobin concentrations in patients receiving hemodialysis previously treated with erythropoiesis-stimulating agents. Nephrol Dial Transplant. 2018 Apr 16. doi: 10.1093/ndt/gfy055. [Epub ahead of print] PubMed PMID: 29672740.

M519) **McCullough PA**, Ballantyne CM, Sanganalmath SK, Langslet G, Baum SJ, Shah PK, Koren A, Mandel J, Davidson MH. Efficacy and Safety of Alirocumab in High-Risk Patients With Clinical Atherosclerotic Cardiovascular Disease and/or Heterozygous Familial Hypercholesterolemia (from 5 Placebo-Controlled ODYSSEY Trials). Am J Cardiol. 2018 Apr 15;121(8):940-948. doi: 10.1016/j.amjcard.2017.12.040. Epub 2018 Feb 2. PubMed PMID: 29472008.

M520) Zhang J, Tecson KM, Rocha NA, **McCullough PA**. Usefulness of alirocumab and evolocumab for the treatment of patients with diabetic dyslipidemia. Proc (Bayl Univ Med Cent). 2018 Apr 11;31(2):180-184. doi: 10.1080/08998280.2018.1441255. eCollection 2018 Apr. Review. PubMed PMID: 29706812; PubMed Central PMCID: PMC5914471.

M521) **McCullough PA**. Editorial: Robertsonian Perspectives on Atherosclerosis: The Power of Direct Observation. Am J Cardiol. 2018 Apr 3. pii: S0002-9149(18)30255-8. doi: 10.1016/j.amjcard.2018.02.019. [Epub ahead of print] PubMed PMID: 29724407.

M522) Maisel AS, Daniels LB, Anand IS, **McCullough PA**, Chow SL. Utility of natriuretic peptides to assess and manage patients with heart failure receiving angiotensin receptor blocker/neprilysin inhibitor therapy. Postgrad Med. 2018 Apr;130(3):299-307. doi: 10.1080/00325481.2018.1440873. Epub 2018 Mar 29. Review. PubMed PMID: 29596012.

M523) **McCullough PA**, Kluger AY. Interpreting the Wide Range of NT-proBNP Concentrations in Clinical Decision Making. J Am Coll Cardiol. 2018 Mar 20;71(11):1201-1203. doi: 10.1016/j.jacc.2018.01.056. PubMed PMID: 29544602.

M524) Turakhia MP, Blankestijn PJ, Carrero JJ, Clase CM, Deo R, Herzog CA, Kasner SE, Passman RS, Pecoits-Filho R, Reinecke H, Shroff GR, Zareba W, Cheung M, Wheeler DC, Winkelmayer WC, Wanner C; Conference Participants (**McCullough PA**) . Chronic kidney disease and arrhythmias: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. Eur Heart J. 2018 Mar 7. doi:10.1093/eurheartj/ehy060. [Epub ahead of print] PubMed PMID: 29522134.

M525) Cherney DZI, Lytvyn Y, **McCullough PA**. Cardiovascular Risk Reduction in Patients With Chronic Kidney Disease: Potential for Targeting Inflammation With Canakinumab. J Am Coll Cardiol. 2018 May 29;71(21):2415-2418. doi:10.1016/j.jacc.2018.04.008. PubMed PMID: 29793630.

M526) Barbin CM, Vasudevan A, Choi JW, **McCullough PA**, Schussler JM, Vallabhan RC, Stoler RC. Frequency of abnormal fractional flow reserve measurements among major coronary arteries. Cardiovasc Revasc Med. 2018 Apr 25. pii: S1553-8389(18)30145-3. doi: 10.1016/j.carrev.2018.04.015. [Epub ahead of print] PubMed PMID: 29807815.

M527) Vasudevan A, Hundae A, Borodge D, **McCullough PA**, Wells PJ. Frequency of atrial arrhythmias after atrial flutter ablation and the effect of presenting rhythm on the day of ablation. Proc (Bayl Univ Med Cent). 2018 May 14;31(3):280-283. doi: 10.1080/08998280.2018.1464305. eCollection 2018 Jul. PubMed PMID: 29904288;PubMed Central PMCID: PMC5997080.

M528) Rengarajan R, **McCullough PA**, Chowdhury A, Tecson KM. Identifying suspected familial chylomicronemia syndrome. Proc (Bayl Univ Med Cent). 2018 May 21;31(3):284-288. doi: 10.1080/08998280.2018.1463784. eCollection 2018 Jul. PubMed PMID: 29904289; PubMed Central PMCID: PMC5997083.

M529) Maioli M, Toso A, Leoncini M, Musilli N, Grippo G, Ronco C, **McCullough PA**, Bellandi F. Bioimpedance-Guided Hydration for the Prevention of Contrast-Induced Kidney Injury: The HYDRA Study. J Am Coll Cardiol. 2018 Jun 26;71(25):2880-2889. doi: 10.1016/j.jacc.2018.04.022. PubMed PMID: 29929610.

M530) **McCullough PA**, Uhlig K, Neylan JF, Pergola PE, Fishbane S. Usefulness of Oral Ferric Citrate in Patients With Iron-Deficiency Anemia and Chronic Kidney Disease With or Without Heart Failure. Am J Cardiol. 2018 Aug 15;122(4):683-688. doi: 10.1016/j.amjcard.2018.04.062. Epub 2018 May 19. PubMed PMID: 29961562.

M531) de Albuquerque Rocha N, Neeland IJ, **McCullough PA**, Toto RD, McGuire DK. Effects of sodium glucose co-transporter 2 inhibitors on the kidney. Diab Vasc Dis Res. 2018 Sep;15(5):375-386. doi: 10.1177/1479164118783756. Epub 2018 Jul 2. Review. PubMed PMID: 29963920.

M532) Chaudhry RI, Mathew RO, Sidhu MS, Sidhu-Adler P, Lyubarova R, Rangaswami J, Salman L, Asif A, Fleg JL, **McCullough PA**, Maddux F, Bangalore S. Detection of Atherosclerotic Cardiovascular Disease in Patients with Advanced Chronic Kidney Disease in the Cardiology and Nephrology Communities. Cardiorenal Med. 2018;8(4):285-295. doi: 10.1159/000490768. Epub 2018 Aug 3. PubMed PMID:30078001.

M533) Kazory A, **McCullough PA**, Rangaswami J, Ronco C. Cardionephrology: Proposal for a Futuristic Educational Approach to a Contemporary Need. Cardiorenal Med. 2018;8(4):296-301. doi: 10.1159/000490744. Epub 2018 Aug 8. Review. PubMed PMID: 30089281.

M534) Kluger AY, **McCullough PA**. Semaglutide and GLP-1 analogues as weight-loss agents. Lancet. 2018 Aug 25;392(10148):615-616. doi: 10.1016/S0140-6736(18)31826-9. Epub 2018 Aug 16. PubMed PMID: 30122306.

M535) Ambrosy AP, Mulder H, Coles A, Krauss WE, Lam CSP, **McCullough PA**, Pina I, Tromp J, Whellan DJ, O'Connor CM, Mentz RJ. Renal Function and Exercise Training in AmbulatoryHeart Failure Patients With a Reduced Ejection Fraction. Am J Cardiol. 2018 Sep 15;122(6):999-1007. doi: 10.1016/j.amjcard.2018.06.011. Epub 2018 Jun 23. PubMed PMID: 30269900.

M536) **McCullough PA**, Todoran TM, Brilakis ES, Ryan MP, Gunnarsson C. Rate of major adverse renal or cardiac events with iohexol compared to other low osmolar contrast media during interventional cardiovascular procedures. Catheter Cardiovasc Interv. 2018 Oct 2. doi: 10.1002/ccd.27807. [Epub ahead of print] PubMed PMID: 30280476.

M537) **McCullough PA**, Soman S. Cardiorenal Syndrome: A Call to Action for a Pressing Medical Issue. Adv Chronic Kidney Dis. 2018 Sep;25(5):379-381. doi: 10.1053/j.ackd.2018.08.011. PubMed PMID: 30309454.

M538) Rangaswami J, **McCullough PA**. Heart Failure in End-Stage Kidney Disease: Pathophysiology, Diagnosis, and Therapeutic Strategies. Semin Nephrol. 2018 Nov;38(6):600-617. doi: 10.1016/j.semnephrol.2018.08.005. Review. PubMed PMID: 30413254.

M539) Goyal A, Chatterjee K, Mathew RO, Sidhu MS, Bangalore S, **McCullough PA**, Rangaswami J. In-Hospital Mortality and Major Adverse Cardiovascular Events after Kidney Transplantation in the United States. Cardiorenal Med. 2018 Nov 14;9(1):51-60. doi: 10.1159/000492731. [Epub ahead of print] PubMed PMID: 30428461.

M540) **McCullough PA**. Treatment of Orthostatic Hypotension Due to Autonomic Dysfunction (Neurogenic Orthostatic Hypotension) in a Patient with Cardiovascular Disease and Parkinson's Disease. Cardiol Ther. 2019 Jun;8(1):145-150. Doi: 10.1007/s40119-018-0124-z. Epub 2019 Jan 9. PubMed PMID: 30627953.

M541) Vasudevan A, Choi JW, Feghali GA, Lander SR, Jialiang L, Schussler JM, Stoler RC, Vallabhan RC, Velasco CE, **McCullough PA**. Event dependence in the analysis of cardiovascular

readmissions postpercutaneous coronary intervention. J Investig Med. 2019 Jan 18. pii: jim-2018-000873. doi: 10.1136/jim-2018-000873. [Epub ahead of print] PubMed PMID: 30659091.

M542) Rocha NA, **McCullough PA**. Cardiovascular outcomes in diabetic kidney disease: insights from recent clinical trials. Kidney Int Suppl (2011). 2018 Jan;8(1):8-17. doi: 10.1016/j.kisu.2017.10.004. Epub 2017 Dec 29. Review. PubMed PMID: 30675434; PubMed Central PMCID: PMC6336216.

M543) Rangaswami J, Bhalla V, Blair JEA, Chang TI, Costa S, Lentine KL, Lerma EV, Mezue K, Molitch M, Mullens W, Ronco C, Tang WHW, **McCullough PA**; American Heart Association Council on the Kidney in Cardiovascular Disease and Council on Clinical Cardiology. Cardiorenal Syndrome: Classification, Pathophysiology, Diagnosis, and Treatment Strategies: A Scientific Statement From the American Heart Association. Circulation. 2019 Apr 16;139(16):e840-e878. doi: 10.1161/CIR.0000000000000664. PubMed PMID: 30852913.

M544) Ball TN, Vasudevan A, Mi Ko J, Assar MD, **McCullough PA**, Stoler RC. Analysis of electrocardiographic intervals before and after transcatheter aortic valve implantation to predict the need for permanent pacing. Proc (Bayl Univ Med Cent). 2018 Sep 11;31(4):407-413. doi: 10.1080/08998280.2018.1471884. eCollection 2018 Oct. PubMed PMID: 30948968; PubMed Central PMCID: PMC6413979.

M545) Brown K, Adams J, **McCullough PA**. Comparison of reflex, resistance training, and core activities using change in blood pressure over time after spontaneous coronary artery dissection. Proc (Bayl Univ Med Cent). 2019 Jan 14;32(1):113-115. doi: 10.1080/08998280.2018.1533308. eCollection 2019 Jan. PubMed PMID: 30956602; PubMed Central PMCID: PMC6442865.

M546) Sudhakaran S, **McCullough PA.** Common laboratory parameters as indicators of multi-organ dysfunction in acute heart failure. Eur J Heart Fail. 2019 Apr 11. doi: 10.1002/ejhf.1466. [Epub ahead of print] PubMed PMID: 30972928.

M547) Rangaswami J, Mathew RO, Parasuraman R, Tantisattamo E, Lubetzky M, Rao S, Yaqub MS, Birdwell KA, Bennett W, Dalal P, Kapoor R, Lerma EV, Lerman M, McCormick N, Bangalore S, **McCullough PA**, Dadhania DM. Cardiovascular disease in the kidney transplant recipient: epidemiology, diagnosis and management strategies. Nephrol Dial Transplant. 2019 May 1;34(5):760-773. doi: 10.1093/ndt/gfz053. PubMed PMID: 30984976.

M548) Rangaswami J, Soman S, **McCullough PA**. Key Updates in Cardio-Nephrology from 2018: Springboard to a Bright Future. Cardiorenal Med. 2019 Apr 17;9(4):222-228. doi: 10.1159/000498916. [Epub ahead of print] PubMed PMID: 30995636.

M549) Zhang J, Rocha NA, **McCullough PA**. Contribution of ApoCIII to Diabetic Dyslipidemia and Treatment With Volanesorsen. Rev Cardiovasc Med. 2018 Mar 30;19(1):13-19. doi: 10.31083/j.rcm.2018.01.890. PubMed PMID: 31032598.

M550) Tumlin JA, Roy-Chaudhury P, Koplan BA, Costea AI, Kher V, Williamson D, Pokhariyal S, Charytan DM; MiD investigators and Committees (**McCullough PA**) . Relationship between dialytic parameters and reviewer confirmed arrhythmias in hemodialysis patients in the monitoring in dialysis study. BMC Nephrol. 2019 Mar 5;20(1):80. doi: 10.1186/s12882-019-1212-6. PubMed PMID: 30836948; PubMed Central PMCID: PMC6402171.

M551) Kluger AY, Tecson KM, Barbin CM, Lee AY, Lerma EV, Rosol ZP, Rangaswami J, Lepor NE, Cobble ME, **McCullough PA**. Cardiorenal Outcomes in the CANVAS, DECLARE-TIMI 58, and EMPA-REG OUTCOME Trials: A Systematic Review. Rev Cardiovasc Med. 2018 Jun 30;19(2):41-49. doi: 10.31083/j.rcm.2018.02.907. PubMed PMID: 31032602.

M552) **McCullough PA**, Kluger AY, Tecson KM, Barbin CM, Lee AY, Lerma EV, Rosol ZP, Kluger SL, Rangaswami J. Inhibition of the Sodium-Proton Antiporter (Exchanger) is a Plausible Mechanism of Potential Benefit and Harm for Drugs Designed to Block Sodium Glucose Co-transporter 2. Rev Cardiovasc Med. 2018 Jun 30;19(2):51-63. doi: 10.31083/j.rcm.2018.02.021. PubMed PMID: 31032603.

M553) Zanoli L, Lentini P, Briet M, Castellino P, House AA, London GM, Malatino L, **McCullough PA**, Mikhailidis DP, Boutouyrie P. Arterial Stiffness in the Heart Disease of CKD. J Am Soc Nephrol. 2019 Apr 30. pii: ASN.2019020117. doi: 10.1681/ASN.2019020117. [Epub ahead of print] PubMed PMID: 31040188.

M554) House AA, Wanner C, Sarnak MJ, Piña IL, McIntyre CW, Komenda P, Kasiske BL, Deswal A, deFilippi CR, Cleland JGF, Anker SD, Herzog CA, Cheung M, Wheeler DC, Winkelmayer WC, **McCullough PA**; Conference Participants. Heart failure in chronic kidney disease: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. Kidney Int. 2019 Apr 30. pii: S0085-2538(19)30276-5. doi: 10.1016/j.kint.2019.02.022. [Epub ahead of print] PubMed PMID: 31053387.

M555) Sudhakaran S, Bottiglieri T, Tecson KM, Kluger AY, **McCullough PA**. Alteration of lipid metabolism in chronic kidney disease, the role of novel antihyperlipidemic agents, and future directions. Rev Cardiovasc Med. 2018 Sep 30;19(3):77-88. doi: 10.31083/j.rcm.2018.03.908. PubMed PMID: 31054556.

M556) Rangaswami J, Soman S, **McCullough PA**. Key updates in Cardio-Nephrology from 2018: springboard to a bright Future. Rev Cardiovasc Med. 2018 Dec 30;19(4):113-116. doi: 10.31083/j.rcm.2018.04.896. PubMed PMID: 31064161.

M557) Tecson KM, Hashemi H, Afzal A, Gong TA, Kale P, **McCullough PA**. Community-Acquired Acute Kidney Injury as a Risk Factor of de novo Heart Failure Hospitalization. Cardiorenal Med. 2019 May 10;9(4):252-260. doi: 10.1159/000499669. [Epub ahead of print] PubMed PMID: 31079099.

M558) Tumlin JA, Roy-Chaudhury P, Koplan BA, Costea AI, Kher V, Williamson D, Pokhariyal S, Charytan DM; MiD investigators and Committees (**McCullough PA**). Relationship between dialytic parameters and reviewer confirmed arrhythmias in hemodialysis patients in the monitoring in dialysis study. BMC Nephrol. 2019 Mar 5;20(1):80. doi:10.1186/s12882-019-1212-6. PubMed PMID: 30836948; PubMed Central PMCID:PMC6402171.

M559) Vijayaraghavan K, **McCullough PA**, Singh B, Gupta M, Enas E, Mohan V, Misra A, Deedwania P, Brinton EA; for the Consensus Panel Steering Committee . Cardiometabolic-Renal Disease in South Asians: Consensus Recommendations from the Cardio Renal Society of America. Cardiorenal Med. 2019 May 10;9(4):240-251. doi: 10.1159/000499341. [Epub ahead of print] PubMed PMID: 31079117.

M560) **McCullough PA**, Mehta HS, Cork DP, Barker CM, Gunnarsson C, Mollenkopf S, Van Houten J, Verta P. The healthcare burden of disease progression in Medicare patients with functional mitral regurgitation. J Med Econ. 2019 May 20:1. doi: 10.1080/13696998.2019.1621325. [Epub ahead of print] PubMed PMID: 31104524.

M561) Spinowitz BS, Fishbane S, Pergola PE, Roger SD, Lerma EV, Butler J, von Haehling S, Adler SH, Zhao J, Singh B, Lavin PT, **McCullough PA**, Kosiborod M, Packham DK; ZS-005 Study Investigators. Sodium Zirconium Cyclosilicate among Individuals with Hyperkalemia: A 12-Month Phase 3 Study. Clin J Am Soc Nephrol. 2019 May 20. pii: CJN.12651018. doi: 10.2215/CJN.12651018. [Epub ahead of print] PubMed PMID: 31110051.

M562) Rangaswami J, **McCullough PA**. Clinical Context of Dyskalemias Across the Heart Failure Spectrum and Their Associated Adverse Outcomes. JACC Heart Fail. 2019 Jun;7(6):533. doi: 10.1016/j.jchf.2019.01.005. PubMed PMID: 31146878.

M563) Ahmad FS, Kallen MA, Schifferdecker KE, Carluzzo KL, Yount SE, Gelow JM, **McCullough PA**, Kimmel SE, Fisher ES, Cella D. Development and Initial Validation of the PROMIS®-Plus-HF Profile Measure. Circ Heart Fail. 2019 Jun;12(6):e005751. doi: 10.1161/CIRCHEARTFAILURE.118.005751. Epub 2019 Jun 5. PubMed PMID: 31163985; PubMed Central PMCID: PMC6711378.

M564) Rizk DV, Silva AL, Pergola PE, Toto R, Warnock DG, Chin MP, Goldsberry A, O'Grady M, Meyer CJ, **McCullough PA**. Effects of Bardoxolone Methyl on Magnesium in Patients with Type 2 Diabetes Mellitus and Chronic Kidney Disease. Cardiorenal Med. 2019;9(5):316-325. doi: 10.1159/000500612. Epub 2019 Jun 6. PubMed PMID: 31170712.

M565) Vasudevan A, Choi JW, Feghali GA, Kluger AY, Lander SR, Tecson KM, Sathyamoorthy M, Schussler JM, Stoler RC, Vallabhan RC, Velasco CE, Yoon A, **McCullough PA**. First and recurrent events after percutaneous coronary intervention: implications for survival analyses. Scand Cardiovasc J. 2019 Jul 25:1-6. doi: 10.1080/14017431.2019.1645349. [Epub ahead of print] PubMed PMID: 31315473.

M566) Cedars A, Tecson KM, Zaidi AN, Lorts A, **McCullough PA**. Impact of Durable Ventricular Assist Device Support on Outcomes of Patients with Congenital Heart Disease Waiting for Heart Transplant. ASAIO J. 2019 Jul 15. doi:10.1097/MAT.0000000000001041. [Epub ahead of print] PubMed PMID: 31335373.

M567) Rangaswami J, Bangalore S, Kaplan B, Birdwell KA, Wiseman AC, **McCullough PA**, Dadhania DM. Cardiovascular disease care fragmentation in kidney transplantation: a call for action. Kidney Int. 2019 Sep;96(3):568-571. doi: 10.1016/j.kint.2019.04.042. Epub 2019 Jun 10. PubMed PMID: 31349974.

M568) Rossing P, Block GA, Chin MP, Goldsberry A, Heerspink HJL, **McCullough PA**, Meyer CJ, Packham D, Pergola PE, Spinowitz B, Sprague SM, Warnock DG, Chertow GM. Effect of bardoxolone methyl on the urine albumin-to-creatinine ratio in patients with type 2 diabetes and stage 4 chronic kidney disease. Kidney Int. 2019 May 16. pii: S0085-2538(19)30503-4. doi: 10.1016/j.kint.2019.04.027. [Epub ahead of print] PubMed PMID: 31377056.

M569) Kluger AY, Tecson KM, Lee AY, Lerma EV, Rangaswami J, Lepor NE, Cobble ME, **McCullough PA**. Class effects of SGLT2 inhibitors on cardiorenal outcomes. Cardiovasc Diabetol. 2019 Aug 5;18(1):99. doi: 10.1186/s12933-019-0903-4. Review. PubMed PMID: 31382965; PubMed Central PMCID: PMC6683461.

M570) **McCullough PA**, Mehta HS, Barker CM, Cork DP, Gunnarsson C, Ryan MP, Baker ER, Van Houten J, Mollenkopf S, Verta P. The Economic Impact of Mitral Regurgitation on Patients With Medically Managed Heart Failure. Am J Cardiol. 2019 Oct 15;124(8):1226-1231. doi: 10.1016/j.amjcard.2019.07.033. Epub 2019 Jul 30. PubMed PMID: 31470974.

M571) Singhania G, Ejaz AA, **McCullough PA**, Kluger AY, Balamuthusamy S, Dass B, Singhania N, Agarwal A. Continuation of Chronic Heart Failure Therapies During Heart Failure Hospitalization - a Review. Rev Cardiovasc Med. 2019 Sep 30;20(3):111-120. doi: 10.31083/j.rcm.2019.03.562. Review. PubMed PMID: 31601085.

M572) **McCullough PA**, Ostermann M, Forni LG, Bihorac A, Koyner JL, Chawla LS, Shi J, Kampf JP, McPherson P, Kellum JA; the Sapphire Investigators. Serial Urinary Tissue Inhibitor of Metalloproteinase-2 and Insulin-Like Growth Factor-Binding Protein 7 and the Prognosis for Acute Kidney Injury over the Course of Critical Illness. Cardiorenal Med. 2019;9(6):358-369. doi: 10.1159/000502837. Epub 2019 Oct 16. PubMed PMID: 31618746.

M573) Husain-Syed F, Birk HW, Ronco C, Schörmann T, Tello K, Richter MJ, Wilhelm J, Sommer N, Steyerberg E, Bauer P, Walmrath HD, Seeger W, **McCullough PA**, Gall H, Ghofrani HA. Doppler-Derived Renal Venous Stasis Index in the Prognosis of Right Heart Failure. J Am Heart Assoc. 2019 Nov 5;8(21):e013584. doi: 10.1161/JAHA.119.013584. Epub 2019 Oct 19. PubMed PMID: 31630601; PubMed Central PMCID: PMC6898799.

M574) Haq A, **McCullough PA**. The Promise of next generation sequencing micro RNA for the discovery of new targets in contrast induced acute kidney injury. Ann Transl Med. 2019 Sep;7(18):424. doi: 10.21037/atm.2019.07.83. PubMed PMID: 31700860; PubMed Central PMCID: PMC6803241.

M575) Lo KB, Gul F, Ram P, Kluger AY, Tecson KM, **McCullough PA**, Rangaswami J. The Effects of SGLT2 Inhibitors on Cardiovascular and Renal Outcomes in Diabetic Patients: A Systematic Review and Meta-Analysis. Cardiorenal Med. 2020;10(1):1-10. doi: 10.1159/000503919. Epub 2019 Nov 19. PubMed PMID: 31743918.

M576) Raju B, **McCullough PA**. Circulating plasma dipeptidyl dipeptidase 3 and the prognosis of cardiogenic shock. Eur J Heart Fail. 2020 Feb;22(2):287-289. doi:10.1002/ejhf.1623. Epub 2019 Nov 28. PubMed PMID: 31779037.

M577) Husain-Syed F, Birk HW, Tello K, Richter MJ, Ronco C, **McCullough PA**, Schörmann T, Ferrari F, Yücel G, Yazdani B, Walmrath HD, Seeger W, Gall H, Ghofrani HA. Alterations in Doppler-derived renal venous stasis index during decompensation of right heart failure and fluid overload in a patient with pulmonary hypertension. Rev Cardiovasc Med. 2019 Dec 30;20(4):263-266. doi: 10.31083/j.rcm.2019.04.564. PubMed PMID: 31912717.

M578) Weir MR, **McCullough PA**, Buse JB, Anderson J. Renal and Cardiovascular Effects of Sodium Glucose Co-Transporter 2 Inhibitors in Patients with Type 2 Diabetes and Chronic Kidney Disease: Perspectives on the Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation Trial Results. Am J Nephrol. 2020;51(4):276-288. doi: 10.1159/000506533. Epub 2020 Mar 13. PMID: 32172239.

M579) Cork DP, **McCullough PA**, Mehta HS, Barker CM, Van Houten J, Gunnarsson C, Ryan MP, Baker ER, Mollenkopf S, Verta P. The economic impact of clinically significant tricuspid regurgitation in a large, administrative claims database. J Med Econ. 2020 Mar 2:1-8. doi: 10.1080/13696998.2020.1718681. [Epub ahead of print] PubMed PMID: 31952454.

M580) Xu MX, Teng RL, Ruddy TD, Schoenhagen P, Bartel T, Di Bartolomeo R, Aksoy O, Desai M, von Kodolitsch Y, Escaned J, **McCullough PA**, Vasudevan A, Shen CX, Zhao X, Zhou YF, Xu HF, Cheng XJ, He YM; written on behalf of the AME Interventional Cardiology Collaborative Group. The CatLet score: a new coronary angiographic scoring tool accommodating the variable coronary anatomy for the first time. J Thorac Dis. 2019 Dec;11(12):5199-5209. doi: 10.21037/jtd.2019.12.18. PubMed PMID: 32030237; PubMed Central PMCID: PMC6988012.

M581) Gopalakrishnan A, Mossaid A, Lo KB, Vasudevan V, **McCullough PA**, Rangaswami J. Fulminant Acute Kidney Injury in a Young Patient with Novel Coronavirus 2019. Cardiorenal Med. 2020;10(4):217-222. doi: 10.1159/000508179. Epub 2020 May 6. PMID: 32375150; PMCID: PMC7251584.

M582) **McCullough PA**. Prevention Guidelines as Failed Minimal Standards of Care. Am J Cardiol. 2020 May 1;125(9):1441-1442. doi: 10.1016/j.amjcard.2020.02.001. Epub 2020 Feb 13. PMID: 32145899.

M583) Rosol ZP, Kopecky KF, Minehart BR, Tecson KM, Vasudevan A, **McCullough PA**, Grayburn PA, Schussler JM. Limitations of transoesophageal echocardiogram in acute ischaemic stroke. Open Heart. 2020 Mar 24;7(1):e001176. doi: 10.1136/openhrt-2019-001176. PMID: 32257245; PMCID: PMC7103838.

M584) Lo KB, **McCullough PA**, Rangaswami J. Antihypertensive drugs and risk of COVID-19? Lancet Respir Med. 2020 May;8(5):e29. doi: 10.1016/S2213-2600(20)30156-9. Epub 2020 Mar 26. PMID: 32222167; PMCID: PMC7194509.

M585) Spertus JA, Jones PG, Maron DJ, O'Brien SM, Reynolds HR, Rosenberg Y, Stone GW, Harrell FE Jr, Boden WE, Weintraub WS, Baloch K, Mavromatis K, Diaz A, Gosselin G, Newman JD, Mavromichalis S, Alexander KP, Cohen DJ, Bangalore S, Hochman JS, Mark DB; ISCHEMIA Research Group (**McCullough PA**, Optimal Medical Management Committee). Health-Status Outcomes with Invasive or Conservative Care in Coronary Disease. N Engl J Med. 2020 Apr 9;382(15):1408-1419. doi: 10.1056/NEJMoa1916370. Epub 2020 Mar 30. PMID: 32227753; PMCID: PMC7261489.

M586) Spertus JA, Jones PG, Maron DJ, Mark DB, O'Brien SM, Fleg JL, Reynolds HR, Stone GW, Sidhu MS, Chaitman BR, Chertow GM, Hochman JS, Bangalore S; ISCHEMIA-CKD Research Group (**McCullough PA** Steering Committee). Health Status after Invasive or Conservative Care in Coronary and Advanced Kidney Disease. N Engl J Med. 2020 Apr 23;382(17):1619-1628. doi: 10.1056/NEJMoa1916374. Epub 2020 Mar 30. PMID: 32227754; PMCID: PMC7255621.

M587) Maron DJ, Hochman JS, Reynolds HR, Bangalore S, O'Brien SM, Boden WE, Chaitman BR, Senior R, López-Sendón J, Alexander KP, Lopes RD, Shaw LJ, Berger JS, Newman JD, Sidhu MS, Goodman SG, Ruzyllo W, Gosselin G, Maggioni AP, White HD, Bhargava B, Min JK, Mancini GBJ, Berman DS, Picard MH, Kwong RY, Ali ZA, Mark DB, Spertus JA, Krishnan MN, Elghamaz A, Moorthy N, Hueb WA, Demkow M, Mavromatis K, Bockeria O, Peteiro J, Miller TD, Szwed H, Doerr R, Keltai M, Selvanayagam JB, Steg PG, Held C, Kohsaka S, Mavromichalis S, Kirby R, Jeffries NO, Harrell FE Jr, Rockhold FW, Broderick S, Ferguson TB Jr, Williams DO, Harrington RA, Stone GW, Rosenberg Y; ISCHEMIA Research Group (**McCullough PA**, Optimal Medical Management Committee). Initial Invasive or Conservative Strategy for Stable Coronary Disease. N Engl J Med. 2020 Apr 9;382(15):1395-1407. doi: 10.1056/NEJMoa1915922. Epub 2020 Mar 30. PMID: 32227755; PMCID: PMC7263833.

M588) Bangalore S, Maron DJ, O'Brien SM, Fleg JL, Kretov EI, Briguori C, Kaul U, Reynolds HR, Mazurek T, Sidhu MS, Berger JS, Mathew RO, Bockeria O, Broderick S, Pracon R, Herzog CA, Huang Z, Stone GW, Boden WE, Newman JD, Ali ZA, Mark DB, Spertus JA, Alexander KP, Chaitman BR, Chertow GM, Hochman JS; ISCHEMIA-CKD Research Group (**McCullough PA** Steering Committee). Management of Coronary Disease in Patients with Advanced Kidney

Disease. N Engl J Med. 2020 Apr 23;382(17):1608-1618. doi: 10.1056/NEJMoa1915925. Epub 2020 Mar 30. PMID: 32227756; PMCID: PMC7274537.

M589) Packer M, Butler J, Filippatos GS, Jamal W, Salsali A, Schnee J, Kimura K, Zeller C, George J, Brueckmann M, Anker SD, Zannad F; EMPEROR-Reduced Trial Committees and Investigators (**McCullough PA**, Steering Committee). Evaluation of the effect of sodium-glucose co-transporter 2 inhibition with empagliflozin on morbidity and mortality of patients with chronic heart failure and a reduced ejection fraction: rationale for and design of the EMPEROR-Reduced trial. Eur J Heart Fail. 2019 Oct;21(10):1270-1278. doi: 10.1002/ejhf.1536. Epub 2019 Jul 16. PubMed PMID:31584231.

M590) Anker SD, Butler J, Filippatos GS, Jamal W, Salsali A, Schnee J, Kimura K, Zeller C, George J, Brueckmann M, Zannad F, Packer M; EMPEROR-Preserved Trial Committees and Investigators (**McCullough PA**, Steering Committee). Evaluation of the effects of sodium-glucose co-transporter 2 inhibition with empagliflozin on morbidity and mortality in patients with chronic heart failure and a preserved ejection fraction: rationale for and design of the EMPEROR-Preserved Trial. Eur J Heart Fail. 2019 Oct;21(10):1279-1287. doi: 10.1002/ejhf.1596. Epub 2019 Sep 16. PubMed PMID: 31523904.

M591) Roger SD, Lavin PT, Lerma EV, **McCullough PA**, Butler J, Spinowitz BS, von Haehling S, Kosiborod M, Zhao J, Fishbane S, Packham DK. Long-term safety and efficacy of sodium zirconium cyclosilicate for hyperkalaemia in patients with mild/moderate versus severe/end-stage chronic kidney disease: comparative results from an open-label, Phase 3 study. Nephrol Dial Transplant. 2020 Feb 6. pii:gfz285. doi: 10.1093/ndt/gfz285. [Epub ahead of print] PubMed PMID: 32030422.

M592) Oliveros E, Oni ET, Shahzad A, Kluger AY, Lo KB, Rangaswami J, **McCullough PA**. Benefits and Risks of Continuing Angiotensin-Converting Enzyme Inhibitors, Angiotensin II Receptor Antagonists, and Mineralocorticoid Receptor Antagonists during Hospitalizations for Acute Heart Failure. Cardiorenal Med. 2020;10(2):69-84. doi: 10.1159/000504167. Epub 2020 Feb 14. Review. PubMed PMID: 32062648.

M593) **McCullough PA**, Eidt J, Rangaswami J, Lerma E, Tumlin J, Wheelan K, Katz N, Lepor NE, Vijay K, Soman S, Singh B, McCullough SP, McCullough HB, Palazzuoli A, Ruocco GM, Ronco C. Urgent need for individual mobile phone and institutional reporting of at home, hospitalized, and intensive care unit cases of SARS-CoV-2 (COVID-19) infection. Rev Cardiovasc Med. 2020 Mar 30;21(1):1-7. doi: 10.31083/j.rcm.2020.01.42. PMID: 32259899.

M594) Ronco F, Tarantini G, **McCullough PA**. Contrast induced acute kidney injury in interventional cardiology: an update and key guidance for clinicians. Rev Cardiovasc Med. 2020 Mar 30;21(1):9-23. doi: 10.31083/j.rcm.2020.01.44. PMID: 32259900.

M595) Agrawal A, Virk HUH, Riaz I, Jain D, Tripathi B, Krittanawong C, Bozorgnia B, Figueredo V, **McCullough PA**, Rangaswami J. Predictors of 30-day re-admissions in patients with infective

endocarditis: a national population based cohort study. Rev Cardiovasc Med. 2020 Mar 30;21(1):123-127. doi: 10.31083/j.rcm.2020.01.552. PMID: 32259911.

M596) Kazory A, Ronco C, **McCullough PA**. SARS-CoV-2 (COVID-19) and intravascular volume management strategies in the critically ill. Proc (Bayl Univ Med Cent). 2020 Apr 16;0(0):1-6. doi: 10.1080/08998280.2020.1754700. PMID: 32336959; PMCID: PMC7171388.

M597) Cedars A, Tecson KM, Zaidi AN, Lorts A, **McCullough PA**. Impact of Durable Ventricular Assist Device Support on Outcomes of Patients with Congenital Heart Disease Waiting for Heart Transplant. ASAIO J. 2020 May;66(5):513-519. doi: 10.1097/MAT.0000000000001041. PMID: 31335373.

M598) Lo KB, **McCullough PA**, Rangaswami J. Mediators of the Effects of Canagliflozin on Heart Failure: Central Role of the Cardiorenal Axis. JACC Heart Fail. 2020 May;8(5):426. doi: 10.1016/j.jchf.2020.01.013. PMID: 32354418.

M599) Glenister RT, **McCullough PA**. Analysing risk in heart failure: a Kalium check. Eur J Heart Fail. 2020 May 10. doi: 10.1002/ejhf.1855. Epub ahead of print. PMID: 32390265.

M600) **McCullough PA**, Arunthamakun J. Disconnect between community testing and hospitalization for SARS-CoV-2 (COVID-19) infection. Proc (Bayl Univ Med Cent). 2020 May 14;33(3):481. doi: 10.1080/08998280.2020.1762439. PMID: 32675999; PMCID: PMC7340440.

M601) Cork DP, **McCullough PA**, Mehta HS, Barker CM, Gunnarsson C, Ryan MP, Baker ER, Van Houten J, Mollenkopf S, Verta P. Impact of mitral regurgitation on cardiovascular hospitalization and death in newly diagnosed heart failure patients. ESC Heart Fail. 2020 Aug;7(4):1502-1509. doi: 10.1002/ehf2.12653. Epub 2020 May 29. PMID: 32469120; PMCID: PMC7373926.

M602) Gul F, Lo KB, Peterson J, **McCullough PA**, Goyal A, Rangaswami J. Meta-analysis of outcomes of patients with COVID-19 infection with versus without gastrointestinal symptoms. Proc (Bayl Univ Med Cent). 2020 May 29;33(3):366-369. doi: 10.1080/08998280.2020.1771164. PMID: 32669979; PMCID: PMC7265105.

M603) Briedis K, Aldujeli A, Aldujeili M, Briede K, Zaliunas R, Hamadeh A, Stoler RC, **McCullough PA**. Considerations for Management of Acute Coronary Syndromes During the SARS-CoV-2 (COVID-19) Pandemic. Am J Cardiol. 2020 Sep 15;131:115-119. doi: 10.1016/j.amjcard.2020.06.039. Epub 2020 Jun 30. PMID: 32723554; PMCID: PMC7324338.

M604) Hamadeh A, Aldujeli A, Briedis K, Tecson KM, Sanz-Sánchez J, Al Dujeili M, Al-Obeidi A, Diez JL, Žaliūnas R, Stoler RC, **McCullough PA**. Characteristics and Outcomes in Patients Presenting With COVID-19 and ST-Segment Elevation Myocardial Infarction. Am J Cardiol. 2020 Sep 15;131:1-6. doi: 10.1016/j.amjcard.2020.06.063. Epub 2020 Jul 3. PMID: 32732010; PMCID: PMC7333635.

M605) Raju B, Roberts CS, Sathyamoorthy M, Schiffman R, Swift C, **McCullough PA**. Ventricular Septal Myectomy for the Treatment of Left Ventricular Outflow Tract Obstruction Due to Fabry Disease. Am J Cardiol. 2020 Oct 1;132:160-164. doi: 10.1016/j.amjcard.2020.07.020. Epub 2020 Jul 13. PMID: 32773220.

M606) Velasco CE, Suarez NP, Roullard CP, **McCullough PA**, Roberts WC. Usefulness of coronary angiography in patients with left atrial myxoma. Proc (Bayl Univ Med Cent). 2020 Jul 6;33(4):529-531. doi: 10.1080/08998280.2020.1776024. PMID: 33100521; PMCID: PMC7549987.

M607) Gupta S, Hayek SS, Wang W, Chan L, Mathews KS, Melamed ML, Brenner SK, Leonberg-Yoo A, Schenck EJ, Radbel J, Reiser J, Bansal A, Srivastava A, Zhou Y, Sutherland A, Green A, Shehata AM, Goyal N, Vijayan A, Velez JCQ, Shaefi S, Parikh CR, Arunthamakun J, Athavale AM, Friedman AN, Short SAP, Kibbelaar ZA, Abu Omar S, Admon AJ, Donnelly JP, Gershengorn HB, Hernán MA, Semler MW, Leaf DE; STOP-COVID Investigators (**McCullough PA**, Site Investigator). Factors Associated With Death in Critically Ill Patients With Coronavirus Disease 2019 in the US. JAMA Intern Med. 2020 Jul 15:e203596. doi: 10.1001/jamainternmed.2020.3596. Epub ahead of print. PMID: 32667668; PMCID: PMC7364338.

M608) Molnar MZ, Bhalla A, Azhar A, Tsujita M, Talwar M, Balaraman V, Sodhi A, Kadaria D, Eason JD, Hayek SS, Coca SG, Shaefi S, Neyra JA, Gupta S, Leaf DE, Kovesdy CP; STOP-COVID Investigators (**McCullough PA**, Site Investigator). Outcomes of critically ill solid organ transplant patients with COVID-19 in the United States. Am J Transplant. 2020 Nov;20(11):3061-3071. doi: 10.1111/ajt.16280. Epub 2020 Sep 15. PMID: 32844546; PMCID: PMC7460925.

M609) Singhania N, Bansal S, Nimmatoori DP, Ejaz AA, **McCullough PA**, Singhania G. Current Overview on Hypercoagulability in COVID-19. Am J Cardiovasc Drugs. 2020 Aug 4:1–11. doi: 10.1007/s40256-020-00431-z. Epub ahead of print. PMID: 32748336; PMCID: PMC7398761.

M610) **McCullough PA**, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP, Safder T, Tecson KM, Wang DD, McKinnon JE, O'Neill WW, Zervos M, Risch HA. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. 2020 Aug 7:S0002-9343(20)30673-2. doi: 10.1016/j.amjmed.2020.07.003. Epub ahead of print. PMID: 32771461; PMCID: PMC7410805.

M611) Raal FJ, Rosenson RS, Reeskamp LF, Hovingh GK, Kastelein JJP, Rubba P, Ali S, Banerjee P, Chan KC, Gipe DA, Khilla N, Pordy R, Weinreich DM, Yancopoulos GD, Zhang Y, Gaudet D; ELIPSE HoFH Investigators (**McCullough PA** Site Investigator). Evinacumab for Homozygous Familial Hypercholesterolemia. N Engl J Med. 2020 Aug 20;383(8):711-720. doi: 10.1056/NEJMoa2004215. PMID: 32813947.

M612) Elsaid O, **McCullough PA**, Tecson KM, Williams RS, Yoon A. Ventricular Fibrillation Storm in Coronavirus 2019. Am J Cardiol. 2020 Aug 29:S0002-9149(20)30890-0. doi: 10.1016/j.amjcard.2020.08.033. Epub ahead of print. PMID: 32871109; PMCID: PMC7455792.

M613) Goyal A, Lo KB, Chatterjee K, Mathew RO, **McCullough PA**, Bangalore S, Rangaswami J. Acute coronary syndromes in the peri-operative period after kidney transplantation in United States. Clin Transplant. 2020 Sep 18:e14083. doi: 10.1111/ctr.14083. Epub ahead of print. PMID: 32946629.

M614) Palazzuoli A, Ruberto F, De Ferrari GM, Forleo G, Secco GG, Ruocco GM, D'Ascenzo F, Mojoli F, Monticone S, Paggi A, Vicenzi M, Corcione S, Palazzo AG, Landolina M, Taravelli E, Tavazzi G, Blasi F, Mancone M, Birtolo LI, Alessandri F, Infusino F, Pugliese F, Fedele F, De Rosa FG, Emmett M, Schussler JM, **McCullough PA**, Tecson KM. Inpatient Mortality According to Level of Respiratory Support Received for Severe Acute Respiratory Syndrome Coronavirus 2 (Coronavirus Disease 2019) Infection: A Prospective Multicenter Study. Crit Care Explor. 2020 Sep 18;2(9):e0220. doi: 10.1097/CCE.0000000000000220. PMID: 32984838; PMCID: PMC7505344.

M615) **McCullough PA.** Favipiravir and the Need for Early Ambulatory Treatment of SARS-CoV-2 Infection (COVID-19). Antimicrob Agents Chemother. 2020 Nov 17;64(12):e02017-20. doi: 10.1128/AAC.02017-20. PMID: 32967849; PMCID: PMC7674042.

M616) Rangaswami J, Bhalla V, de Boer IH, Staruschenko A, Sharp JA, Singh RR, Lo KB, Tuttle K, Vaduganathan M, Ventura H, **McCullough PA**; American Heart Association Council on the Kidney in Cardiovascular Disease; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular and Stroke Nursing; Council on Clinical Cardiology; and Council on Lifestyle and Cardiometabolic Health. Cardiorenal Protection With the Newer Antidiabetic Agents in Patients With Diabetes and Chronic Kidney Disease: A Scientific Statement From the American Heart Association. Circulation. 2020 Sep 28:CIR0000000000000920. doi: 10.1161/CIR.0000000000000920. Epub ahead of print. PMID: 32981345.

M617) Ruocco G, **McCullough PA**, Tecson KM, Mancone M, De Ferrari GM, D'Ascenzo F, De Rosa FG, Paggi A, Forleo G, Secco GG, Pistis G, Monticone S, Vicenzi M, Rota I, Blasi F, Pugliese F, Fedele F, Palazzuoli A. Mortality Risk Assessment Using CHA(2)DS(2)-VASc Scores in Patients Hospitalized With Coronavirus Disease 2019 Infection. Am J Cardiol. 2020 Sep 28:S0002-9149(20)31004-3. doi: 10.1016/j.amjcard.2020.09.029. Epub ahead of print. PMID: 32991860; PMCID: PMC7521434.

M618) Hayek SS, Brenner SK, Azam TU, Shadid HR, Anderson E, Berlin H, Pan M, Meloche C, Feroz R, O'Hayer P, Kaakati R, Bitar A, Padalia K, Perry D, Blakely P, Gupta S, Shaefi S, Srivastava A, Charytan DM, Bansal A, Mallappallil M, Melamed ML, Shehata AM, Sunderram J, Mathews KS, Sutherland AK, Nallamothu BK, Leaf DE; STOP-COVID Investigators (**McCullough PA** Site Investigator). In-hospital cardiac arrest in critically ill patients with covid-19: multicenter cohort

study. BMJ. 2020 Sep 30;371:m3513. doi: 10.1136/bmj.m3513. PMID: 32998872; PMCID: PMC7525342.

M619) Lo KB, Bhargav R, Salacup G, Pelayo J, Albano J, **McCullough PA**, Rangaswami J. Angiotensin converting enzyme inhibitors and angiotensin II receptor blockers and outcomes in patients with COVID-19: a systematic review and meta-analysis. Expert Rev Cardiovasc Ther. 2020 Oct 5:1-12. doi: 10.1080/14779072.2020.1826308. Epub ahead of print. PMID: 32945216.

M620) Palazzuoli A, Mancone M, De Ferrari GM, Forleo G, Secco GG, Ruocco GM, D'Ascenzo F, Monticone S, Paggi A, Vicenzi M, Palazzo AG, Landolina M, Taravelli E, Tavazzi G, Blasi F, Infusino F, Fedele F, De Rosa FG, Emmett M, Schussler JM, Tecson KM, **McCullough PA**. Antecedent Administration of Angiotensin Converting Enzyme Inhibitors or Angiotensin II Receptor Antagonists and Survival After Hospitalization for SARS-CoV-2 (COVID-19). J Am Heart Assoc. 2020 Oct 7:e017364. doi: 10.1161/JAHA.120.017364. Epub ahead of print. PMID: 33023356.

M621) Zhang J, Tecson KM, **McCullough PA**. Endothelial dysfunction contributes to COVID-19-associated vascular inflammation and coagulopathy. Reviews in Cardiovascular Medicine, 2020, 21(3): 315-319. DOI: 10.31083/j.rcm.2020.03.126 https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.03.126

M622) Zhang J, **McCullough PA**, Tecson KM. Vitamin D deficiency in association with endothelial dysfunction: Implications for patients with COVID-19. Reviews in Cardiovascular Medicine, 2020, 21(3): 339-344. DOI: 10.31083/j.rcm.2020.03.131 https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.03.131

M623) **McCullough PA** Innovative Early Sequenced Multidrug Therapy for Sars-Cov-2 (Covid-19) Infection to Reduce Hospitalization and Death International Journal of Medical Science and Clinical Invention7(12): 5139-5150, 2020 DOI:10.18535/ijmsci/v7i12.02

M624) Flythe JE, Assimon MM, Tugman MJ, Chang EH, Gupta S, Shah J, Sosa MA, Renaghan AD, Melamed ML, Wilson FP, Neyra JA, Rashidi A, Boyle SM, Anand S, Christov M, Thomas LF, Edmonston D, Leaf DE; STOP-COVID Investigators (**McCullough PA** Site Investigator). Characteristics and Outcomes of Individuals With Pre-existing Kidney Disease and COVID-19 Admitted to Intensive Care Units in the United States. Am J Kidney Dis. 2020 Sep 19:S0272-6386(20)30999-9. doi: 10.1053/j.ajkd.2020.09.003. Epub ahead of print. PMID: 32961244; PMCID: PMC7501875.

M625) Gupta S, Coca SG, Chan L, Melamed ML, Brenner SK, Hayek SS, Sutherland A, Puri S, Srivastava A, Leonberg-Yoo A, Shehata AM, Flythe JE, Rashidi A, Schenck EJ, Goyal N, Hedayati SS, Dy R, Bansal A, Athavale A, Nguyen HB, Vijayan A, Charytan DM, Schulze CE, Joo MJ, Friedman AN, Zhang J, Sosa MA, Judd E, Velez JCQ, Mallappallil M, Redfern RE, Bansal AD, Neyra JA, Liu KD, Renaghan AD, Christov M, Molnar MZ, Sharma S, Kamal O, Boateng JO, Short SAP, Admon AJ, Sise ME, Wang W, Parikh CR, Leaf DE; STOP-COVID Investigators (**McCullough PA** Site Investigator). AKI Treated with Renal Replacement Therapy in Critically Ill Patients with COVID-

19. J Am Soc Nephrol. 2020 Oct 16:ASN.2020060897. doi: 10.1681/ASN.2020060897. Epub ahead of print. PMID: 33067383.

M626) Gupta S, Wang W, Hayek SS, Chan L, Mathews KS, Melamed ML, Brenner SK, Leonberg-Yoo A, Schenck EJ, Radbel J, Reiser J, Bansal A, Srivastava A, Zhou Y, Finkel D, Green A, Mallappallil M, Faugno AJ, Zhang J, Velez JCQ, Shaefi S, Parikh CR, Charytan DM, Athavale AM, Friedman AN, Redfern RE, Short SAP, Correa S, Pokharel KK, Admon AJ, Donnelly JP, Gershengorn HB, Douin DJ, Semler MW, Hernán MA, Leaf DE; STOP-COVID Investigators (**McCullough PA** Site Investigator). Association Between Early Treatment With Tocilizumab and Mortality Among Critically Ill Patients With COVID-19. JAMA Intern Med. 2020 Oct 20:e206252. doi: 10.1001/jamainternmed.2020.6252. Epub ahead of print. PMID: 33080002; PMCID: PMC7577201.

M627) Chertow GM, Pergola PE, Agarwal R, Block GA, Farag YMK, Jardine AG, Koury MJ, Luo W, Khawaja Z, Lewis EF, Matsushita K, **McCullough PA**, Parfrey PS, Wittes J, Walters KA, Tseng C, Lin T, Sarnak MJ, Vargo DL, Winkelmayer WC, Eckardt KU. Cardiovascular Safety and Efficacy of Vadadustat for the Treatment of Anemia in Non-Dialysis Dependent CKD: Design and Baseline Characteristics. Am Heart J. 2020 Oct 29:S0002-8703(20)30354-9. doi: 10.1016/j.ahj.2020.10.068. Epub ahead of print. PMID: 33129989.

M628) **McCullough PA**, Goldstein JA. A novel strategy to prevent contrast nephropathy: "Continuous hemodiafiltration". Catheter Cardiovasc Interv. 2020 Nov;96(6):1182-1183. doi: 10.1002/ccd.29356. PMID: 33217180.

M629) Aldujeli A, Hamadeh A, Briedis K, Tecson KM, Rutland J, Krivickas Z, Stiklioraitis S, Briede K, Aldujeili M, Unikas R, Zaliaduonyte D, Zaliunas R, Vallabhan RC, **McCullough PA**. Delays in Presentation in Patients With Acute Myocardial Infarction During the COVID-19 Pandemic. Cardiol Res. 2020 Dec;11(6):386-391. doi: 10.14740/cr1175. Epub 2020 Nov 2. PMID: 33224384; PMCID: PMC7666599.

M630) Barker CM, Cork DP, **McCullough PA**, Mehta HS, Houten JV, Gunnarsson C, Mollenkopf S, Verta P. Healthcare utilization in clinically significant tricuspid regurgitation patients with and without heart failure. J Comp Eff Res. 2020 Nov 11. doi: 10.2217/cer-2020-0198. Epub ahead of print. PMID: 33174767.

M631) Eckardt KU, Agarwal R, Farag YM, Jardine AG, Khawaja Z, Koury MJ, Luo W, Matsushita K, **McCullough PA**, Parfrey P, Ross G, Sarnak MJ, Vargo D, Winkelmayer WC, Chertow GM. Global Phase 3 programme of vadadustat for treatment of anaemia of chronic kidney disease: rationale, study design and baseline characteristics of dialysis-dependent patients in the INNO2VATE trials. Nephrol Dial Transplant. 2020 Nov 14:gfaa204. doi: 10.1093/ndt/gfaa204. Epub ahead of print. PMID: 33188693.

M632) Rahimi G, Tecson KM, Elsaid O, **McCullough PA**. Role of Ischemic Heart Disease in Major Adverse Renal and Cardiac Events Among Individuals With Heart Failure With Preserved Ejection

Fraction (from the TOPCAT Trial). Am J Cardiol. 2020 Dec 3:S0002-9149(20)31296-0. doi: 10.1016/j.amjcard.2020.11.034. Epub ahead of print. PMID: 33279481.

M633) Roger SD, Lavin PT, Lerma EV, **McCullough PA**, Butler J, Spinowitz BS, von Haehling S, Kosiborod M, Zhao J, Fishbane S, Packham DK. Long-term safety and efficacy of sodium zirconium cyclosilicate for hyperkalaemia in patients with mild/moderate versus severe/end-stage chronic kidney disease: comparative results from an open-label, Phase 3 study. Nephrol Dial Transplant. 2021 Jan 1;36(1):137-150. doi: 10.1093/ndt/gfz285. PMID: 32030422.

M634) **McCullough PA**, Oskoui R. Early multidrug regimens in new potentially fatal medical problems. Rev Cardiovasc Med. 2020 Dec 30;21(4):507-508. doi: 10.31083/j.rcm.2020.04.270. PMID: 33387995.

M635) **McCullough PA**, Alexander PE, Armstrong R, Arvinte C, Bain AF, Bartlett RP, Berkowitz RL, Berry AC, Borody TJ, Brewer JH, Brufsky AM, Clarke T, Derwand R, Eck A, Eck J, Eisner RA, Fareed GC, Farella A, Fonseca SNS, Geyer CE Jr, Gonnering RS, Graves KE, Gross KBV, Hazan S, Held KS, Hight HT, Immanuel S, Jacobs MM, Ladapo JA, Lee LH, Littell J, Lozano I, Mangat HS, Marble B, McKinnon JE, Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, Risch HA, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Rev Cardiovasc Med. 2020 Dec 30;21(4):517-530. doi: 10.31083/j.rcm.2020.04.264. PMID: 33387997.

M636) Procter BC, Ross C, Pickard V, Smith E, Hanson C, **McCullough PA**. Clinical outcomes after early ambulatory multidrug therapy for high-risk SARS-CoV-2 (COVID-19) infection. Rev Cardiovasc Med. 2020 Dec 30;21(4):611-614. doi: 10.31083/j.rcm.2020.04.260. PMID: 33388006.

M637) Gupta S, Wang W, Hayek SS, Chan L, Mathews KS, Melamed ML, Brenner SK, Leonberg-Yoo A, Schenck EJ, Radbel J, Reiser J, Bansal A, Srivastava A, Zhou Y, Finkel D, Green A, Mallappallil M, Faugno AJ, Zhang J, Velez JCQ, Shaefi S, Parikh CR, Charytan DM, Athavale AM, Friedman AN, Redfern RE, Short SAP, Correa S, Pokharel KK, Admon AJ, Donnelly JP, Gershengorn HB, Douin DJ, Semler MW, Hernán MA, Leaf DE; STOP-COVID Investigators. (**McCullough PA** Site Investigator). Association Between Early Treatment With Tocilizumab and Mortality Among Critically Ill Patients With COVID-19. JAMA Intern Med. 2021 Jan 1;181(1):41-51. doi: 10.1001/jamainternmed.2020.6252. PMID: 33080002; PMCID: PMC7577201.

M638) Palazzuoli A, Ruocco G, Tecson KM, **McCullough PA**. Screening, detection, and management of heart failure in the SARS-CoV2 (COVID-19) pandemic. Heart Fail Rev. 2021 Jan 6:1–7. doi: 10.1007/s10741-020-10068-4. Epub ahead of print. PMID: 33405001; PMCID: PMC7786335.

M639) Al-Samkari H, Gupta S, Leaf RK, Wang W, Rosovsky RP, Brenner SK, Hayek SS, Berlin H, Kapoor R, Shaefi S, Melamed ML, Sutherland A, Radbel J, Green A, Garibaldi BT, Srivastava A,

Leonberg-Yoo A, Shehata AM, Flythe JE, Rashidi A, Goyal N, Chan L, Mathews KS, Hedayati SS, Dy R, Toth-Manikowski SM, Zhang J, Mallappallil M, Redfern RE, Bansal AD, Short SAP, Vangel MG, Admon AJ, Semler MW, Bauer KA, Hernán MA, Leaf DE; STOP-COVID-19 Investigators (**McCullough PA** Site Investigator). Thrombosis, Bleeding, and the Observational Effect of Early Therapeutic Anticoagulation on Survival in Critically Ill Patients With COVID-19. Ann Intern Med. 2021 Jan 26:M20-6739. doi: 10.7326/M20-6739. Epub ahead of print. PMID: 33493012; PMCID: PMC7863679.

M640) Zhang J, Tecson KM, **McCullough PA**. Role of endothelial cell receptors in the context of SARS-CoV-2 infection (COVID-19). Proc (Bayl Univ Med Cent). 2021 Jan 26;34(2):262-268. doi: 10.1080/08998280.2021.1874231. PMID: 33664552; PMCID: PMC7852287.

M641) Shaefi S, Brenner SK, Gupta S, O'Gara BP, Krajewski ML, Charytan DM, Chaudhry S, Mirza SH, Peev V, Anderson M, Bansal A, Hayek SS, Srivastava A, Mathews KS, Johns TS, Leonberg-Yoo A, Green A, Arunthamakun J, Wille KM, Shaukat T, Singh H, Admon AJ, Semler MW, Hernán MA, Mueller AL, Wang W, Leaf DE; STOP-COVID Investigators (**McCullough PA** Site Investigator). Extracorporeal membrane oxygenation in patients with severe respiratory failure from COVID-19. Intensive Care Med. 2021 Feb;47(2):208-221. doi: 10.1007/s00134-020-06331-9. Epub 2021 Feb 2. PMID: 33528595; PMCID: PMC7851810.

M642) Short SAP, Gupta S, Brenner SK, Hayek SS, Srivastava A, Shaefi S, Singh H, Wu B, Bagchi A, Al-Samkari H, Dy R, Wilkinson K, Zakai NA, Leaf DE; STOP-COVID Investigators(**McCullough PA** Site Investigator). D-dimer and Death in Critically Ill Patients With Coronavirus Disease 2019. Crit Care Med. 2021 Feb 12. doi: 10.1097/CCM.0000000000004917. Epub ahead of print. PMID: 33591017.

M643) Mathews KS, Soh H, Shaefi S, Wang W, Bose S, Coca S, Gupta S, Hayek SS, Srivastava A, Brenner SK, Radbel J, Green A, Sutherland A, Leonberg-Yoo A, Shehata A, Schenck EJ, Short SAP, Hernán MA, Chan L, Leaf DE; Study of the Treatment and Outcomes in Critically Ill Patients with Coronavirus Disease (STOP-COVID) Investigators(**McCullough PA** Site Investigator). Prone Positioning and Survival in Mechanically Ventilated Patients With Coronavirus Disease 2019-Related Respiratory Failure. Crit Care Med. 2021 Feb 17. doi: 10.1097/CCM.0000000000004938. Epub ahead of print. PMID: 33595960.

M644) Aldujeli A, Hamadeh A, Tecson KM, Krivickas Z, Maciulevicius L, Stiklioraitis S, Sukys M, Briedis K, Aldujeili M, Briede K, Braukyliene R, Pranculis A, Unikas R, Zaliaduonyte D**, McCullough PA**. Six-Month Outcomes for COVID-19 Negative Patients with Acute Myocardial Infarction Before Versus During the COVID-19 Pandemic. Am J Cardiol. 2021 Feb 23:S0002-9149(21)00161-2. doi: 10.1016/j.amjcard.2021.01.043. Epub ahead of print. PMID: 33631113; PMCID: PMC7900754.

M645) **McCullough PA**, Rahimi G, Tecson KM. Ambulatory Worsening of Renal Function in Heart Failure With Preserved Ejection Fraction. J Am Coll Cardiol. 2021 Mar 9;77(9):1222-1224. doi: 10.1016/j.jacc.2021.01.007. PMID: 33663740.

M646) Kalantar-Zadeh K, **McCullough PA**, Agarwal SK, Beddhu S, Boaz M, Bruchfeld A, Chauveau P, Chen J, de Sequera P, Gedney N, Golper TA, Gupta M, Harris T, Hartwell L, Liakopoulos V, Kopple JD, Kovesdy CP, Macdougall IC, Mann JFE, Molony D, Norris KC, Perlmutter J, Rhee CM, Riella LV, Weisbord SD, Zoccali C, Goldsmith D. Nomenclature in nephrology: preserving 'renal' and 'nephro' in the glossary of kidney health and disease. J Nephrol. 2021 Mar 13. doi: 10.1007/s40620-021-01011-3. Epub ahead of print. PMID: 33713333.

M647) **McCullough PA**. Anemia of cardiorenal syndrome. Kidney Int Suppl (2011). 2021 Apr;11(1):35-45. doi: 10.1016/j.kisu.2020.12.001. Epub 2021 Mar 18. PMID: 33777494; PMCID: PMC7983020.

M648) Lo KB, Toroghi HM, Salacup G, Jiang J, Bhargav R, Quintero E, Balestrini K, Shahzad A, Mathew RO, **McCullough PA**, Rangaswami J. Angiotensin converting enzyme inhibitors and angiotensin receptor blockers in acute heart failure: invasive hemodynamic parameters and clinical outcomes. Rev Cardiovasc Med. 2021 Mar 30;22(1):199-206. doi: 10.31083/j.rcm.2021.01.216. PMID: 33792263.

M649) Kellum JA, Artigas A, Gunnerson KJ, Honore PM, Kampf JP, Kwan T, McPherson P, Nguyen HB, Rimmelé T, Shapiro NI, Shi J, Vincent JL, Chawla LS; Sapphire Investigators (**McCullough PA** Site Investigator). Use of Biomarkers to Identify Acute Kidney Injury to Help Detect Sepsis in Patients With Infection. Crit Care Med. 2021 Apr 1;49(4):e360-e368. doi: 10.1097/CCM.0000000000004845. PMID: 33566467; PMCID: PMC7963439.

M650) Procter BC, Ross C, Pickard V, Smith E, Hanson C, **McCullough PA**. Early Ambulatory Multidrug Therapy Reduces Hospitalization and Death in High-Risk Patients with SARS-CoV-2 (COVID-19). ijirms [Internet]. 2021Mar.17 [cited 2021Apr.28];6(03):219 - 221. https://www.ijirms.in/index.php/ijirms/article/view/1100, https://www.ijirms.in/index.php/ijirms/article/view/1100#downloadTab

M651) **McCullough PA**, Vijay K. SARS-CoV-2 infection and the COVID-19 pandemic: a call to action for therapy and interventions to resolve the crisis of hospitalization, death, and handle the aftermath. Rev Cardiovasc Med. 2021 Mar 30;22(1):9-10. doi: 10.31083/j.rcm.2021.01.301. PMID: 33792243.

M652) Valdenor C, **McCullough PA**, Paculdo D, Acelajado MC, Dahlen JR, Noiri E, Sugaya T, Peabody J. Measuring the Variation in the Prevention and Treatment of CI-AKI Among Interventional Cardiologists. Curr Probl Cardiol. 2021 Apr 3:100851. doi: 10.1016/j.cpcardiol.2021.100851. Epub ahead of print. PMID: 33994040.

M653) Ishida JH, Chauhan C, Gillespie B, Gruchalla K, **McCullough PA**, Quella S, Romero A, Rossignol P, Wheeler DC, Malley MA, West M, Herzog CA. Understanding and Overcoming the Challenges Related to Cardiovascular Trials Involving Patients with Kidney Disease. Clin J Am Soc Nephrol. 2021 Apr 23:CJN.17561120. doi: 10.2215/CJN.17561120. Epub ahead of print. PMID: 33893163.

M654) Chertow GM, Pergola PE, Farag YMK, Agarwal R, Arnold S, Bako G, Block GA, Burke S, Castillo FP, Jardine AG, Khawaja Z, Koury MJ, Lewis EF, Lin T, Luo W, Maroni BJ, Matsushita K, **McCullough PA**, Parfrey PS, Roy-Chaudhury P, Sarnak MJ, Sharma A, Spinowitz B, Tseng C, Tumlin J, Vargo DL, Walters KA, Winkelmayer WC, Wittes J, Eckardt KU; PRO2TECT Study Group. Vadadustat in Patients with Anemia and Non-Dialysis-Dependent CKD. N Engl J Med. 2021 Apr 29;384(17):1589-1600. doi: 10.1056/NEJMoa2035938. PMID: 33913637.

M655) Eckardt KU, Agarwal R, Aswad A, Awad A, Block GA, Bacci MR, Farag YMK, Fishbane S, Hubert H, Jardine A, Khawaja Z, Koury MJ, Maroni BJ, Matsushita K, **McCullough PA**, Lewis EF, Luo W, Parfrey PS, Pergola P, Sarnak MJ, Spinowitz B, Tumlin J, Vargo DL, Walters KA, Winkelmayer WC, Wittes J, Zwiech R, Chertow GM. Safety and Efficacy of Vadadustat for Anemia in Patients Undergoing Dialysis. N Engl J Med. 2021 Apr 29;384(17):1601-1612. doi: 10.1056/NEJMoa2025956. PMID: 33913638.

M656) Short SAP, Gupta S, Brenner SK, Hayek SS, Srivastava A, Shaefi S, Singh H, Wu B, Bagchi A, Al-Samkari H, Dy R, Wilkinson K, Zakai NA, Leaf DE; STOP-COVID Investigators (**McCullough PA** Site Investigator). d-dimer and Death in Critically Ill Patients With Coronavirus Disease 2019. Crit Care Med. 2021 May 1;49(5):e500-e511. doi: 10.1097/CCM.0000000000004917. PMID: 33591017.

M657) Swolinsky JS, Nerger NP, Leistner DM, Edelmann F, Knebel F, Tuvshinbat E, Lemke C, Roehle R, Haase M, Costanzo MR, Rauch G, Mitrovic V, Gasanin E, Meier D, **McCullough PA**, Eckardt KU, Molitoris BA, Schmidt-Ott KM. Serum creatinine and cystatin C-based estimates of glomerular filtration rate are misleading in acute heart failure. ESC Heart Fail. 2021 May 6. doi: 10.1002/ehf2.13404. Epub ahead of print. PMID: 33955699.

M658) Palazzuoli A, Tecson KM, Ronco C, **McCullough PA**. Nomenclature for Kidney Function from KDIGO: Shortcomings of Terminology Oversimplification. Cardiorenal Med. 2021 Jun 4:1-4. doi: 10.1159/000516615. Epub ahead of print. PMID: 34091445.

M659) Vasquez CR, Gupta S, Miano TA, Roche M, Hsu J, Yang W, Holena DN, Reilly JP, Schrauben SJ, Leaf DE, Shashaty MGS; STOP-COVID Investigators (**McCullough PA** Site Investigator). Identification of Distinct Clinical Subphenotypes in Critically Ill Patients With COVID-19. Chest. 2021 May 6:S0012-3692(21)00874-6. doi: 10.1016/j.chest.2021.04.062. Epub ahead of print. PMID: 33964301; PMCID: PMC8099539.

M660) Alexander PE, Armstrong R, Fareed G, Lotus J, Oskoui R, Prodromos C, Risch HA, Tenenbaum HC, Wax CM, Dara P, **McCullough PA**, Gill KK. Early multidrug treatment of SARS-CoV-2 infection (COVID-19) and reduced mortality among nursing home (or outpatient/ambulatory) residents. Med Hypotheses. 2021 Jun 5;153:110622. doi: 10.1016/j.mehy.2021.110622. Epub ahead of print. PMID: 34130113; PMCID: PMC8178530.

M661) Mathews KS, Soh H, Shaefi S, Wang W, Bose S, Coca S, Gupta S, Hayek SS, Srivastava A, Brenner SK, Radbel J, Green A, Sutherland A, Leonberg-Yoo A, Shehata A, Schenck EJ, Short SAP, Hernán MA, Chan L, Leaf DE; STOP-COVID Investigators (**McCullough PA** Site Investigator) . Prone Positioning and Survival in Mechanically Ventilated Patients With Coronavirus Disease 2019-Related Respiratory Failure. Crit Care Med. 2021 Jul 1;49(7):1026-1037. doi: 10.1097/CCM.0000000000004938. PMID: 33595960; PMCID: PMC8277560.

M662) **McCullough PA**, Mehta HS, Barker CM, Houten JV, Mollenkopf S, Gunnarsson C, Ryan M, Cork DP. Healthcare utilization and guideline-directed medical therapy in heart failure patients with reduced ejection fraction. J Comp Eff Res. 2021 Jul 6. doi: 10.2217/cer-2021-0118. Epub ahead of print. PMID: 34225473.

M663) Palazzuoli A, Tecson KM, **McCullough PA**. Impact of renin-angiotensin-aldosterone system inhibitor continuation on outcomes for patients with severe coronavirus disease 2019 manifestations. J Hypertens. 2021 Aug 1;39(8):1725-1726. doi: 10.1097/HJH.0000000000002876. PMID: 34188007.

M664) **McCullough PA**, Mehta HS, Barker CM, Van Houten J, Mollenkopf S, Gunnarsson C, Ryan M, Cork DP. Mortality and guideline-directed medical therapy in real-world heart failure patients with reduced ejection fraction. Clin Cardiol. 2021 Aug 3. doi: 10.1002/clc.23664. Epub ahead of print. PMID: 34342033.

Published Letters

ltr1) **McCullough PA**, O'Neill WW. *Letter to the Editor:* Regional Variation Across the United States in the Management of Acute Myocardial Infarction. New Engl J Med 1996;334:194; discussion 194-5. PMID: 96127997

ltr2) **McCullough PA**, O'Neill WW. *Letter to the Editor:* Patient care after percutaneous coronary artery interventions. Ann Intern Med 1998 Apr 1;128:598; discussion 599-600. PMID: 98175287

ltr3) **McCullough PA**, Redle JD. *Letter to the Editor:* Amiodarone Prophylaxis for Atrial Fibrillation after Bypass Surgery. New Engl J Med 1998;338:1383; discussion 1384. PMID: 98223116

ltr4) Sharma ND, **McCullough PA**. *Letter to the Editor:* Predictability of left ventricular thrombus by mitral regurgitation. Am Heart J 1999 Feb;137(2):373-5. PMID: 99156058

ltr5) **McCullough PA,** Marks KR. *Letter to the Editor:* Ticlopidine and TTP after Coronary Stenting. JAMA 1999;282(18):1717-1718;discussion 1718-9. PMID: 10568636

ltr6) **McCullough PA**, Sandberg KR, Thompson RJ. *Letter to the Editor:* Predicting Outcomes after Cardiopulmonary Resuscitation. Arch Intern Med 2001;161(4):615-616. PMID: 11252131

ltr7) **McCullough PA.** *Letter to the Editor:* The Anti-inflammatory Effect of Statins. N Engl J Med. 2001 Oct 18;345(16):1209; discussion 1210-1. PMID: 11642241

ltr8) **McCullough PA,** Sandberg KR, Borzak S. *Letter to the Editor*: Cardiovascular outcomes and renal disease. Ann Intern Med. 2002 Apr 16;136(8):633-4; discussion 633-4. PMID: 11955038

ltr9) **McCullough PA.** Reply to Manhapra A, Why is chronic kidney disease the "spoiler" for cardiovascular outcomes: an alternate take from a generalist. J Am Coll Cardiol. 2004 Mar 3;43(5):924; author reply 924-5. PMID: 15006584

ltr10) Omland T, Knudsen CW, **McCullough PA**, Maisel AS. Response to LTE. #2005-624 - Schwam. Ann Emerg Med. 2006 Feb;47(2):214. PMID: 16431243

ltr11) Barker D, Artis N, Tan LB, DeJong A, Franklin BA, **McCullough PA**. Correcting data for body size may confound results. Chest. 2006 Feb;129(2):493-4. PMID: 16478872

ltr12) **McCullough PA**. Failure of beta-blockers in the reduction of perioperative events: Where did we go wrong? Response to the letter to the Editor by Souza et al. Am Heart J. 2007 Jun;153(6):e39. PMID: 17540183

ltr13) **McCullough PA**. Multimodality prevention of contrast-induced acute kidney injury, In Reply. Am J Kidney Dis. 2008 Jun;51(6):1068-1069. PMID: 18501789

ltr14) **McCullough PA**, Collins AJ, Vassalotti JA. Rapid Response: Optimal Definition of Chronic Kidney Disease as a Cardiovascular Risk State. Southern Medical Journal, Volume 101, 977 Number 10, October 2008

ltr15) Neyou A, **McCullough PA**. Response to letter to the editor. Am J Emerg Med. 2010 Dec 1. [Epub ahead of print] No abstract available. PMID: 21129890

ltr16) Palazzuoli A, Ronco C, **McCullough PA**. Letter by Palazzuoli et al regarding article, "is worsening renal function an ominous prognostic sign in patients with acute heart failure? The role of congestion and its interaction with renal function". Circ Heart Fail. 2012 Jul 1;5(4):e79. PubMed PMID: 22811554

ltr17) O'Keefe JH, Patil HR, Magalski A, Lavie CJ, Vogel RA, **McCullough PA**. In reply. Mayo Clin Proc. 2012 Nov;87(11):1133-4. doi: 10.1016/j.mayocp.2012.08.010. PubMed PMID: 23127740

ltr18) **McCullough PA**. Reply: Vitamin E May Protect Against Contrast-Induced Acute Kidney Injury. J Am Coll Cardiol. 2017 Apr 11;69(14):1878-1879. doi: 10.1016/j.jacc.2017.01.053. PubMed PMID: 28385321

ltr19) Rangaswami J, **McCullough PA**. Efficacy of Subcutaneous Versus Intravenous Administration of Furosemide in Patients With Worsening Heart Failure: The Devil Is in the Details. JACC Heart Fail. 2018 Mar;6(3):266-267. doi: 10.1016/j.jchf.2018.01.010. PubMed PMID: 29496028

ltr20) Rangaswami J, **McCullough PA**. Clinical Context of Dyskalemias Across the Heart Failure Spectrum and Their Associated Adverse Outcomes. JACC Heart Fail. 2019 Jun;7(6):533. doi: 10.1016/j.jchf.2019.01.005. PubMed PMID: 31146878.

ltr21) **McCullough PA.** The Reply. Am J Med. 2021 Mar;134(3):e222-e223. doi: 10.1016/j.amjmed.2020.10.036. PMID: 33637181; PMCID: PMC7901366.

ltr22) **McCullough PA**. The Reply. Am J Med. 2021 Apr;134(4):e298. doi: 10.1016/j.amjmed.2020.11.028. PMID: 33888224; PMCID: PMC8054639.

ltr23) **McCullough PA.** Regarding: "Hydroxychloroquine: a comprehensive review and its controversial role in coronavirus disease 2019". Ann Med. 2021 Dec;53(1):286. doi: 10.1080/07853890.2021.1872094. PMID: 33439042; PMCID: PMC7877973.

ltr24) **McCullough PA**. The Reply. Am J Med. 2021 May;134(5):e343-e344. doi: 10.1016/j.amjmed.2021.01.011. PMID: 33962708; PMCID: PMC8095713.

ltr25) **McCullough PA**. The Reply. Am J Med. 2021 May;134(5):e346-e347. doi: 10.1016/j.amjmed.2021.01.013. PMID: 33962710; PMCID: PMC8095728.

ltr26) **McCullough PA**. The Reply. Am J Med. 2021 Jul;134(7):e440-e441. doi: 10.1016/j.amjmed.2021.02.024. PMID: 34183150; PMCID: PMC8229557.

Textbook Chapters

T1) **McCullough PA**, Goldstein JG. *Chapter 5: Heart Pressures and Catheterization.* Cardiac Catheterization: Concepts, Techniques, and Applications. Uretsky BF, Editor, Blackwell Science, Inc., Boston, 1997. ISBN 9780865424067

T2) **McCullough PA**. Section III, *Chapter 7: Epidemiology of Coronary Heart Disease.* Interventional Cardiovascular Medicine: Principles and Practice, Second Edition. Roubin GS, O'Neill WW, Stack RS, Editors, Churchill Livingstone Inc., Philadelphia and New York, 2002, III, 7, 138-159. ISBN 9780443079795

T3) Franklin BA, **McCullough PA**, Timmis GC. *Chapter: Exercise.* Randomized Trials in Cardiovascular Disease: a Companion Volume to Eugene Braunwald's "Heart Disease." Hennekins CH, Buring JE, Ridker PM, Manson JE, Editors, W. B. Saunders Inc., New York, 1998.

T4) **McCullough PA.** *Chapter 4. General Examination and Examination Skills, p 41-57* Clinical Exercise Physiology. Ehrman JK, Gordon PM, Visich PS, Keteyian SJ, Editors, Human Kinetics Publishers, Inc., 2003. ISBN 9780736002523

T5) Malineni K, **McCullough PA**. Chapter: *Sudden Cardiac Death*, eMedicine.com, Textbook of Medicine, Obstetrics and Gynecology, Psychiatry, and Surgery, 2001.

T6) **McCullough PA**. Chapter 21: *Outcome of Myocardial Infarction in Patients with Renal Failure*, Harrison's Advances in Cardiology, Eugene Braunwald, M.D., Editor, 2003. pp 123-128. McGraw-Hill, New York, NY. ISBN 9780071370882

T7) **McCullough PA**. Chapter 26. *Renal Injury Following Contrast Agents*, Peripheral Vascular Disease: Basic Diagnosis and Therapeutic Approaches, Editor: George S. Abela, MD, 2003, pp 000-000. Lippincott Williams & Wilkins, Philadelphia, PA. ISBN 9780781743839

T8) **McCullough PA**. The effect of renal disease on outcomes of vascular surgery. Fast Facts in Vascular Surgery, Health Press, Alun H. Davies, MA, DM, FRCS, Editor, 2003-2004;74-86. ISBN 9781903734513

T9) **McCullough PA**. Interface between renal disease and cardiovascular illness. Braunwald's Heart Disease, 7th Edition, 2004, Zipes DP, Libby P, Bonow RO, Braunwald E, Editors, WB Saunders, Inc. ISBN 9780721604794

T10) **McCullough PA**. Interface between renal disease and cardiovascular illness. Braunwald's Heart Disease, 8th Edition, 2006, Zipes DP, Libby P, Bonow RO, Braunwald E, Editors, WB Saunders, Inc. ISBN 9781416041030

T11) **McCullough PA**. Chapter 23. Renal Complications of Contrast Media: Contrast-Induced Nephropathy, p 239-249. Interventional Cardiology, 1st Edition, 2007. King S, Yeung A, Editors. The McGraw-Hill Medical, New York. ISBN 9780071415279

T12) **McCullough PA**. Chapter 14. Natriuretic peptides in patients with renal failure, p 170-180. Markers in Cardiology: A Case Oriented Approach, 2007. Adams JE, Jaffe AS, Apple F, Editors. Blackwell Futura, 2007. ISBN 9781405134187

T13) Miller WM, **McCullough PA**. Chapter 21. Obesity, p209-218. Pollock's Textbook of Cardiovascular Disease and Rehabilitation. Durstine JL, Moore GE, LaMonte MJ, Franklin BA, Editors. Human Kinetics, 2008. ISBN 0000736059679

T14) Franklin BA, Miller WM, **McCullough PA.** Chapter 11: The Metabolic Syndrome. American Council on Exercise Advanced Health and Fitness Specialist Manual. Edited by Bryant CX, Green DJ. San Diego, CA. American Council on Exercise; 2008:239-254. ISBN 9781890720278

T15) Marso SP, **McCullough PA.** Chapter 8: Patient-Specific Approaches and Considerations: Unique Subgroups—Diabetes, Renal Failure, Advanced Age. American College of Cardiology Cardiac Catheterization and Interventional Self-Assessment Program 3 (CathSAP-3), David J. Moliterno, Editor. ACC, 2008. http://www.cardiosource.com/GenSAPX/

T16) Franklin BA, Miller WM, Nori K, **McCullough PA.** Chapter 12: Guidelines for Exercise Testing in Diabetics Starting an Exercise Program. Contemporary Diabetes: Diabetes and Exercise. Edited by Regensteiner JC, Reusch JEB, Stewart K, Veves A. Totowa, NJ: Humana Press; 2009:263-277. ISBN 9781588299260

T17) Nguyen, T, Yee T, Mai T, Phan T, **McCullough PA.** Chapter 6: Diet. Evidence Based Cardiology Practice: A 21st Century Approach. Edited by Hu D, Nguyen T, Kim MH, Kwan T, Grines CL, Saito S. Peoples Medical Publishing House—USA, Shelton, CT; 2010; 145-161. ISBN 9781607950950

T18) Kodenchery M, Bhat S, El-Ghoroury M, Yamasaki H, **McCullough PA**. "Coronary Angiography Before and After Renal Transplantation" Coronary Angiography - The Need for Improvement in Medical and Interventional Therapy, edited by Branislav Baškot. InTech - Open Access Publisher, Rijeka, Croatia, Website: http://www.intechweb.org/, permanent web address: http://www.intechopen.com/articles/show/title/coronary-angiography-before-and-after-renal-transplantation. ISBN 9789533076416

T19) Marinescu V, **McCullough PA**. Chapter 5d. Managing Comorbidities. Chronic Kidney Disease. Hypertension. Bakris G and Baliga RR Editors, Oxford American Cardiology Library, Oxford University Press, New York, NY 2012; 71-81. ISBN 9780199754908

T20) **McCullough PA.** Chapter 43. Contrast-Induced Acute Kidney Injury. Specialty Board Review: Cardiology. Baliga RR Editor. The McGraw-Hill Companies, Inc., China, 2012; 467-473. ISBN 9780071614085

T21) Zalesin KC, Franklin BA, Miller WM, Peterson ED, **McCullough PA**. Impact of obesity on cardiovascular disease. Medical Clinics of North America: Obesity. LeRoith D and Karnieli E, Editors. WB Saunders Company, New York, NY, 2011 95(5):919-937. ISBN 9781455723690

T22) **McCullough PA**. Chapter: Interface between renal disease and cardiovascular illness. Braunwald's Heart Disease, 9th Edition, 2011. Zipes DP, Libby P, Bonow RO, Braunwald E, Editors, WB Saunders, Inc. ISBN 9781437727081

T23) Hanson ID, **McCullough PA**. B-type natriuretic peptide: beyond diagnostic applications. The Kidney in Heart Failure. Bakris GL Editor. Springer, New York, NY, 2012;67-77. ISBN 9781461436935

T24) Brown JE, **McCullough PA**. Chapter 5: Contrast Nephropathy and Kidney Injury. Textbook of Cardiovascular Intervention, Thompson, CA (Editor), Springer, 2014 (5) 53-63. ISBN 9781447145288

T25) Franklin BA, Miller WM, **McCullough PA**. Chapter 12, The Metabolic Syndrome, American Medical Council, Medical Exercise Specialist Manual, Skinner JS, Bryant CX, Merrill S, Green DJ. American Council on Exercise 2015, San Diego CA. ISBN 9781890720520

T26) Stewart D, Shah G, Brown JR, **McCullough, PA**. Chapter 240 Contrast-induced acute kidney injury, Oxford Textbook of Clinical Nephrology, 4th Edition, Managing Editors Turner Goldsmith DJ, Winearls C, Lamierre N, Himmelfarb J, Remuzzi G, Editors, 2015, Oxford University Press, United Kingdom. ISBN 9780199592548

T27) Goldsmith DJ, Kumar N, Henderson H, Cameron BD, **McCullough PA**. Chapter 106 Malnutrition, obesity, and undernutrition in chronic kidney disease, Oxford Textbook of Clinical Nephrology, 4th Edition, Managing Editors Turner Goldsmith DJ, Winearls C, Lamierre N, Himmelfarb J, Remuzzi G, Editors, 2015, Oxford University Press, United Kingdom. ISBN 9780199592548

T28) **McCullough PA**. Chapter 18 Future Therapeutic Prospects for Treatment of Cardiorenal Syndromes, p 189-195, Cardiorenal Challenges. Goldsmith DA, Covic A, Spaak J. Editors, Springer International Publishing AG, Cham, 2015, Zug, Switzerland. ISBN 9783319091624

T29) **McCullough PA**. Chapter 88: Interface between renal disease and cardiovascular illness. Braunwald's Heart Disease, 10th Edition, 2015, pp 1909-1930. Zipes DP, Libby P, Bonow RO, Braunwald E, Editors, WB Saunders, Inc. ISBN 9781455751334

T30) **McCullough PA**. Chapter 24: Cardiovascular Disease in Chronic Kidney Disease. Essentials of Chronic Kidney Disease, 2015, pp 239-245. Fadem SZ, Editor, Nova Publishers, ISBN-13: 978-1634825429

T31) Prasad A, **McCullough PA**. Chapter 19: Renal Complications of Contrast Media. Interventional Cardiology, 2nd Edition, 2018, pp 293-306. Samady H, Fearon WF, Yeung AC, King SB, Editors, McGraw-Hill, ISBN-13: 978-0071820363

T32) Rangaswami J, Lerma EV, **McCullough PA**, Editors. Kidney Disease in the Cardiac Catheterization Laboratory, 1st Edition 2020, ISBN-13: 978-3030454135 ISBN-10: 3030454134, Springer Nature Switzerland AG. Chapter 27 Ronco C, Ronco F, **McCullough PA**. A Call to Action to Develop Integrated Curricula in Cardiorenal Medicine, pp 449-463.

T33) **McCullough PA**, Ronco C. Textbook of Cardiorenal Medicine, 1st Edition 2021, ISBN-13: 978-3030574598 ISBN-10: 3030574598, Springer Nature Switzerland AG. Chapter 1 **McCullough PA**, Kluger AY. Implications of Chronic Kidney Disease on the Epidemiology of

Cardiovascular Disease, pp 1-6. Chapter 8 Rocha N, **McCullough PA**. Type 2 Cardiorenal Syndrome, pp 75-94. Chapter 17 **McCullough PA** Novel Biomarkers of Chronic Cardiorenal Disease, pp 227-234.

.

Invited Non-Peer Reviewed Works

1) **McCullough PA**. *Acute Renal Failure after Coronary Intervention*. American College of Cardiology Educational Highlights, Fall 1997 Issue, C.R. Conti, Editor

2) **McCullough PA**, Thompson RJ, Tobin KJ, Kahn JK, Schwender F, O'Neill WW. *Outcome of Out-of-Hospital Cardiac Arrest Survivors.* Cardiology Review, 2000;17:15-19

3) Thompson RJ, **McCullough PA**, Kahn JK, O'Neill WW. *A Simple Scoring System to Predict Clinical Outcome after Resuscitation from Cardiac Arrest.* The Journal of Critical Illness, 1998;13:298-300

4) **McCullough PA.** *Clinical Evaluation. Part I. The Cardiopulmonary System.* Clinical Exercise Physiology, 1999;1:33-41

5) **McCullough PA.** *Clinical Evaluation. Part II. The Musculoskeletal and other Body Systems.* Clinical Exercise Physiology, 1999:1:92-99

6) **McCullough PA.** *Ridogrel: Literature Evaluation.* IDdb Reports, Current Drugs Ltd, February, 1999

7) **McCullough PA.** Debate Commentary: Complete Assessment of the Lipid Profile is Advised. Medical Crossfire, 1999:5;52

8) **McCullough PA.** Narrative Fields in Hospital Records. Invited comment on Loss of Narrative Data in New Zealand Health Statistics Public Hospital Injury Files, John Langley (Australasian Epidemiologist 1998:5.4). The Australasian Epidemiologist, 1999;6.1:17-18

9) **McCullough PA.** Previews in Cardiovascular Medicine: Prediction and Prevention of Contrast Nephropathy. Rev Cardiovasc Med. 2001;2(Suppl 1):S1-S3

10) Creager MA, Faxon DP, Fonarow GC, Gross SB, Hachamovitch R, Jacobs AK, Lepor NE, **McCullough PA**, Naqvi T, Nesto RW, Prystowsky EN, Shah PK, Vogel RA, Yeung AC. Meeting Reviews: Best of the AHA Scientific Sessions, 2001. Rev Cardiovasc Med. 2002;3(1):22-48

11) **McCullough PA**. Update from the International Society on Hypertension in Blacks. Rev Cardiovasc Med. 2002 Fall;3(4):192-95. PMID: 12650156

12) Nguyen PN, Spertus JA, **McCullough PA.** Is there a Heart Failure Epidemic? Cardiology Review 2002;19(9):32-36

13) Lepor NE, Yeung AC, **McCullough PA**, Creager MA, Weber MA, Jacobs AK, Faxon DP, Vogel RA, Gersh BJ. Meeting Review: Best of the ACC Scientific Session 2002. Rev Cardiovasc Med 2002;3(2):85-104

14) Franklin BA, deJong A, **McCullough PA**. Interpreting Exercise Test-Fitness Data for Your Patients. Am J Sports 2003;5:12-17

15) **McCullough PA.** The interface between heart disease and renal dysfunction: from association to action. ACC Current Journal Review 2003;12(2):20-24

16) Fonarow GC, Prystowsky EN, **McCullough PA**, Lepor NE, Watson KE, Gersh BJ, Young JJ, Kereiakes D, Faxon DP, Weyman A, Jacobs AK, Yeung A, Holmes D, Berger P, Weber MA. Meeting Review: Best of the ACC Scientific Sessions 2003. Rev Cardiovasc Med. 2003;4(3):150-179

17) **McCullough PA.** Debate Commentary: Atrial Fibrillation: Preventing Thromboembolism and Ischemic Stroke. Medical Crossfire 2003, 4(10), 3-17

18) Creager M, Faxon DP, Gersh BJ, Jacobs AK, Lepor NE, **McCullough PA,** Naqvi T, Prystowsky EN, Shah PK, Watson KE, Weber MA, Wyman A. Meeting Review: Best of the AHA Scientific Sessions 2003. Rev Cardiovasc Med 2004;5(1)26-52

19) **McCullough PA.** The use of contrast media in peripheral, combined, and sequential procedures. Applications in Imaging: Cardiac Interventions: Contrast Use in Renally Compromised Patients 2003;Sept:47-51

20) **McCullough PA.** Chapter Four: Major Risk Factors for Chronic Kidney Disease. Kidney Early Evaluation Program Annual Data Report. Am J Kid Dis 2003;42(5):S34-S41

21) Fonarow GC, Prystowsky EN, Lepor NE, Weyman AE, Weber MA, Watson KE, Young JJ, Kereiakes DJ, **McCullough PA,** Gersh BJ**.** Best of the ACC Scientific Session 2004. Rev Cardiovasc Med. 2004;5(2)104-129

22) Franklin BA, de Jong A, Kahn JK, **McCullough PA.** Fitness and mortality in the primary and secondary prevention of coronary artery disease: Does the effort justify the outcome? Am J Med Sports 2004;6:23-27

23) **McCullough PA**, Franklin BA. Atherosclerosis: Conventional risk factors and cardiac events—debunking an old myth about prevalence. Rev Cardiovasc Med. 2004;5(3):185-186

24) Dutcher JR, **McCullough PA**. Commentary: Glycoprotein IIb/IIIa Inhibitors in Acute Coronary Syndromes. Evidenced Based Cardiovascular Medicine 2004;8:362-363

25) **McCullough PA**, Faxon DP, Fonarow GC, Jacobs AK, Watson KE, Weyman AC. Meeting Review: Best of the AHA 2004. Rev Cardiovasc Med. 2005;6(1):33-46

26) Bashore TM, Faxon DP, Fonarow GC, Jacobs AK, Lepor NE, **McCullough PA**, Shah PK, Weber MA, Yeung AC. Best of the ACC Scientific Session 2005. Rev Cardiovasc Med. 2005 Spring;6(2):98-117

27) Fonarow GC, Lepor NE, **McCullough PA**, Jacobs AK, Bashore, TM, Faxon DP. Best of the AHA Scientific Session 2005. Rev Cardiovasc Med. 2006 Winter;7(1):23-36

28) **McCullough PA**. Clinical utility of blood natriuretic peptide levels. Business Briefing: US Cardiology 2006. Touch Briefings, Touch Cardiology. www.touchcardiology.com

29) **McCullough PA**, Wase A. Do implantable cardioverter-defibrillators improve survival in dialysis patients after cardiac arrest? Nature Clinical Practice Nephrology 2006; 2(2): 70-71

30) **McCullough PA.** Ranolazine: focusing on angina pectoris. Drugs of Today 2006, 42 (3):177-183

31) Singh PP, Nesto RW, Faxon DP, Lepor NE, Watson KE, Jacobs AK, **McCullough PA.** Best of the AHA Scientific Sessions 2006. Rev Cardiovasc Med. 2007 Winter;8(1):25-35. PMID: 17401300

32) **McCullough PA.** Safety Concerns Trump Public Health Benefit in the Eyes of the FDA Cardiorenal Panel. FDA Advisory Committee Did Not Recommend Approval Of Rimonabant (ZIMULTI(R)) For Use In Obese And Overweight Patients With Associated Risks Factors. www.medicalnewstoday.com GLG NewsWatch for 6/14/2007

33) Friedewald VE, Goldfarb S, Laskey WK, **McCullough PA**, Roberts WC. The Editor's Roundtable: Contrast-Induced Nephropathy. Am J Cardiol. 2007 Aug 1;100(3):544-51. Epub 2007 Jun 4. PMID: 17659944

34) **McCullough PA**, Lepor NE. Erratum - the rosiglitazone meta-analysis. Rev Cardiovasc Med. 2007 Summer;8(3):174. PMID: 17938618

35) **McCullough PA,** Chronic Kidney Disease as a Cardiovascular Risk State and Considerations for the Use of Statins. The Fats of Life, Lipoproteins and Vascular Disease Division, American Association of Clinical Chemistry, Volume XXII, No 1, 9-16 Winter 2008

36) Lepor NE, **McCullough PA**, Jacobs AK. Best of the AHA Scientific Sessions 2007. Rev Cardiovasc Med. 2008 Winter;9(1):62-9. PMID: 18418310

37) Lepor NE, **McCullough PA.** Best of the ACC 2010 Scientific Session. Rev Cardiovasc Med. 2010 Summer;11(3):e153-63

38) Narala KR, LaLonde TA, Hassan S, **McCullough PA**. Management of Chronic Coronary Disease and Acute Coronary Syndromes in Patients with Chronic Kidney Disease. US Cardiology, 2011;8(2):123-31

39) Larsen T, Narala KR, **McCullough PA.** Type 4 Cardiorenal Syndrome: Myocardial Dysfunction, Fibrosis, and Heart Failure in Patients with Chronic Kidney Disease. J Clinic Experiment Cardiol 2012, 3:4. http://dx.doi.org/10.4172/2155-9880.1000186

INVITED LECTURES: NATIONAL AND INTERNATIONAL FORUMS

L1) "The Role of Triage Angiography in Acute Coronary Syndromes." Advances in Interventional Cardiology. WBH and the University of Maryland, Aruba, April, 1997.

L2) "New Understandings of Anticoagulation During Unstable Angina." Co-Chair, American College of Cardiology 47th Annual Scientific Session, Atlanta, Georgia, March 30, 1998.

L3) National Library of Medicine: The Emerging Health Information Infrastructure '99. "Electronic Outcomes", Washington, D.C., April 28, 1999.

L4) Kansas City Southwest Clinical Society, 77th Annual Clinical Conference, Overland Park, Kansas: "Cardiac-Renal Risk: Incorporating Scientific Evidence into Your Practice," October 29, 1999.

L5) The Health Forum, Best Practices, Chicago, Illinois. "Overview of Cardiovascular Health Fellowship," December 9, 1999.

L6) AHA Scientific Conference on Existing Databases: Do They Hold Answers to Clinical Questions in Geriatric Cardiovascular Disease and Stroke? "Resource Utilization Among Congestive Heart Failure (R.E.A.C.H.) Database Overview," Washington, DC, January 27, 2000.

L7) Health Forum Cardiovascular Health Fellowship Retreat: "Cardiovascular Risk and Health," Colorado Springs, CO, July 20, 2000.

L8) Third Annual Center for Health Futures Advisory Board Meeting: "Congestive Heart Failure," La Jolla, CA, August 24, 2000.

L9) Health Forum ACT Learning Collaborative Meeting: "Bridging Clinical, Community, and Population Health Strategies," St. Joseph, MO, September 20, 2000.

L10) "Renal Disease as an Independent Risk Factor for Cardiovascular Disease in Diabetes," The Nexus of Cardiovascular and Renal Disease, Duke Clinical Research Institute, Tyson's Corner, VA, November 4, 2000.

L11) "Atherosclerosis and Heart Disease," Winter Scientific Seminar, Missouri Society of the American College of Osteopathic Physicians, Kansas City, MO, January 27, 2001.

L12) "Routine vs Selective Intervention in Acute Coronary Syndromes," Tenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 14, 2001.

L13) "Intervention in the Patient with Renal Insufficiency," Tenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 16, 2001.

L14) "The Epidemic of Cardiovascular Disease and Cardiorenal Risk," The Nexus of Cardiovascular and Renal Disease, Duke Clinical Research Institute, Tyson's Corner, VA, February 24, 2001.

L15) "Cardiovascular Risk in Chronic Kidney Disease: Cardiorenal Risk," Symposium on Cardio-renal Consequences of Angiotensin II, Insights from AII Blockade, NKF Spring Clinical Meeting, Orlando, FL, April 18, 2001.

L16) Plenary Session: "Cardiac Emergencies and Cardiac Critical Care," American College of Chest Physicians, CHEST 2001, Philadelphia, PA, November 5, 2001.

L17) "Cardiorenal Risk," The 33rd Annual ACC Cardiovascular Conference at Snowmass, Snowmass, Colorado, January 18, 2002.

L18) "Epidemiology of Diabetes and Its Cardiovascular Risk" Eleventh Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 14, 2002.

L19) "Late-Breaking Clinical Trials II: A Prospective, Blinded Trial of B-Type Natriuretic Peptide as a Diagnostic Test for the Emergency Diagnosis of Heart Failure: The Breathing Not Properly (BNP) Multinational Study," March 19, 2002, 51st Annual Scientific Session of the American College of Cardiology, Atlanta, GA.

L20) "Scope of Cardiovascular Complications in Patients with Kidney Disease." Plenary Session III: Reversing Cardiovascular Complications in Patients with Kidney Disease. International Society on Hypertension in Blacks: 17th International Interdisciplinary Conference on Hypertension and Related Risk Factors in Ethnic Populations, Miami, FL, June 11, 2002.

L21) "Epidemiology: Renal—Chronic Kidney Disease." Atherosclerotic Vascular Disease Conference, AHA, Boston, MA, July 8, 2002.

L22) "B-type Natriuretic Peptide Should be a Part of the Diagnostic Evaluation of Heart Failure: Implications from the Breathing Not Properly (BNP) Multinational Study" International Academy of Cardiology 8th World Congress on Heart Failure—Mechanisms and Management, Washington, DC, July 15, 2002.

L23) "Epidemiology and Physiology of Radiocontrast Nephropathy and its Impact on Outcomes" Prevent the Event Transcatheter Therapeutics 2002 Satellite Symposium, Washington, DC, September 26, 2002.

L24) "Calcification or 'Phosphication'—Controversies of Calcium Phosphate Deposition: Invited Lecture: Coronary Calcification: A Predictor of Future Events or a Marker of Plaque Stability? American Society of Nephrology 2002 Annual Scientific Sessions Satellite Symposium, Philadelphia, PA, November 1, 2002.

L25) "Renal Insufficiency and Clinical Outcome" Cardiovascular Seminar, AHA Scientific Sessions, Chicago, IL, November 18, 2002.

L26) "Role of BNP in the Diagnosis of Heart Failure" ACC 34th Annual Cardiovascular Conference at Snowmass, CO, January 14, 2003.

L27) "Managing the Patient with Combined Heart and Renal Failure—the Importance of Anemia" ACC 34th Annual Cardiovascular Conference at Snowmass, CO, January 14, 2003.

L28) "The Emerging Healthcare Crisis of Obesity," Twelfth Annual Cardiovascular Conference at Beaver Creek, CO, February 10, 2003.

L29) "BNP in the Management of Heart Failure," Twelfth Annual Cardiovascular Conference at Beaver Creek, CO, February 11, 2003.

L30) "Contrast Nephropathy: Can it be Eliminated," Twelfth Annual Cardiovascular Conference at Beaver Creek, CO, February 13, 2003.

L31) "How Subtle Degrees of Renal Dysfunction Work as a Cardiac Risk Factor" First Cardiovascular Prevention Symposium: Updates and New Guidelines. AHA, Puerto Rico Chapter, San Juan, PR, March 22, 2003.

L32) "What Is the Incremental Diagnostic Value of B-Type Natriuretic Peptide in Heart Failure?" Symposium. American College of Cardiology Scientific Sessions, 2003, Chicago, IL, April 1, 2003.

L33) "Heart Failure Insights From Ejection Fraction" Session Co-Chair. Oral Contributions. American College of Cardiology Scientific Sessions, 2003, Chicago, IL, April 1, 2003.

L34) "Chronic Renal Insufficiency as a Vascular Risk Factor" 14th Annual Scientific Sessions of the Society for Vascular Biology and Medicine, Chicago, IL, June 7, 2003.

L35) "Phosphate Control and Calcification from a Cardiologist's Perspective" World Congress of Nephrology Satellite Symposium, Berlin, Germany, June 12, 2003.

L36) "Renal Disease is a Risk Factor for Cardiovascular Disease" ACC 29th Annual Tutorials in the Tetons 2003: Update in Cardiovascular Disease, August 25-27. 2003.

L37) "Diagnosis of Congestive Heart Failure: Is BNP Needed in Every Case?" ACC 29th Annual Tutorials in the Tetons 2003: Update in Cardiovascular Disease, August 25-27. 2003.

L38) "How to Treat Combined Heart and Renal Failure with Hypertension" ACC 29th Annual Tutorials in the Tetons 2003: Update in Cardiovascular Disease, August 25-27. 2003.

L39) "Which Agents Prevent Contrast-Induced Nephropathy?" European Society of Cardiology 2003 Symposium: Managing Patients at Risk for Contrast-Induced Nephropathy, Vienna, Austria, September 2, 2003.

L40) "Epidemiology of Contrast Nephropathy" Symposium Chair for "A Contrast in Risk: Radiographic Imaging in the Renally Compromised Patient", Satellite Symposium at the Transcatheter and Therapeutics Scientific Meeting, Washington, DC, September 17, 2003.

L41) "Update on Cardiovascular Risk Reduction in Acute Coronary Syndrome Patients" 14th Annual Great Wall International Congress of Cardiology, Beijing, China, October 10-13, 2003.

L42) "Renal Function and Dysfunction in Coronary Arteriography" 14th Annual Great Wall International Congress of Cardiology, Beijing, China, October 10-13, 2003.

L43) "Interventional Cardiology 2003: Bench to Bedside and Beyond, Session III: Contrast Nephropathy: Separating the Hype from the Data. Antagonist: Contrast Nephropathy Can be Prevented." AHA Scientific Sessions 2003, November 9, 2003, Orlando, FL.

L44) "Reversing Diabetes and Its Consequences: Pipe Dream or Reality?" The 35th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 12-16, 2004.

L45) "Refining the Use of B-type Natriuretic Peptide as a Diagnostic Test in Clinical Practice" The 35th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 12-16, 2004.

L46) "Practical Management of Obesity for the Cardiologist: The Future of Dietary Management and Bariatric Surgery" The 35th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 12-16, 2004.

L47) "Update from the Hypertension World: JNC 7—What's New and How Will it Influence Practice?" Thirteenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 9-13, 2003

L48) "The Lethal Couplet" Thirteenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 9-13, 2003

L49) "BNP to Differentiate Between Cardiac and Extracardiac Sources of Dyspnea" 33rd Critical Care Congress, Society of Critical Care Medicine, Orlando, Florida, February 23, 2004.

L50) "BNP Testing: Is It Ready for In-Hospital Monitoring of Therapy?" Point-of-Care Symposium, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 8, 2004.

L51) "Role of Brain Natriuretic Peptide Levels in Diagnosis" Natriuretic Peptides Symposium, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 8, 2004.

L52) "Renal Insufficiency and the Heart" Symposium Co-Chair, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 9, 2004.

L53) "Renal Insufficiency and Bypass Surgery" Renal Insufficiency and the Heart Symposium, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 9, 2004.

L54) "Causes and Consequences of Contrast-Induced Nephropathy and other Major Adverse Coronary Events" Contrast-Induced Nephropathy: Addressing the Needs of the High Risk Patient. A Satellite Symposium to the American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 9, 2004.

L55) "Chronic Kidney Disease as a Cardiovascular Risk Factor" 2nd Annual Scientific Symposium, AHA of Puerto Rico, San Juan, PR, March 13, 2004

L56) "Modern use of Angiotensin Receptor Blockade in Cardiovascular Disease" 2nd Annual Scientific Symposium, AHA of Puerto Rico, San Juan, PR, March 13, 2004

L57) "Chronic Kidney Disease and Cardiovascular Disease" Satellite Symposium: Impact of Anemia Correction in Cardiovascular Patients, American Society of Hypertension Annual Scientific Session, New York, NY, May 22, 2004.

L58) "Contrast-Induced Nephropathy—Clinical Anomaly or Reality" Satellite Symposium: Selecting Contrast Media - Implications for Patient outcomes, EuroPCR 2004, Paris, France, May 26, 2004.

L59) "Contrast Nephropathy" Intervention 2004. American College of Cardiology Nationwide Symposium, CNN Center, Atlanta, GA, June 2, 2004.

L60) "Technical Issues in Selection of the BNP Assay" Satellite Symposium of the American Association of Clinical Chemistry, Los Angeles, CA, July 28, 2004.

L61) "B-type Natriuretic Peptide in Clinical Practice" New Development in Cardiac Biomarkers for Detection and Management of Cardiovascular Diseases, EBAC Accredited Educational Programme, in conjunction with the European Society of Cardiology 2004 Annual Congress, Munich, Germany, August 30, 2004.

L62) "Hot Topics: Renal Disease and Contrast Nephropathy—Implications for the PCI Patient" Session Moderator, Transcatheter Cardiovascular Therapeutics 2004, September 27, 2004.

L63) "Definition and Pathophysiology of Contrast Nephropathy", "Hot Topics: Renal Disease and Contrast Nephropathy—Implications for the PCI Patient" Transcatheter Cardiovascular Therapeutics 2004, September 27, 2004.

L64) "Use of BNP in Clinical Practice" "Hot Topics: Clinical Utility of Biomarkers" Transcatheter Cardiovascular Therapeutics 2004, September 28, 2004.

L65) "Contrast Media, Renal Insufficiency, and Radiocontrast Nephropathy" Introduction to Cardiac Catheterization and Indications for Percutaneous Interventions, 7th Annual Interventional Cardiology Self Assessment and Review Course, Transcatheter Cardiovascular Therapeutics 2004, September 29, 2004.

L66) "Body Weight—Optimal Targets and How Good are We in Getting There" "Drug Combinations for Cardiovascular Disease" Duke Clinical Research Institute and U.S. Food and Drug Administration Think Tank, Washington, DC, October 8, 2004.

L67) "Does Coronary Calcification Imply Plaque Instability?" Managing Cardiovascular and Calcium/Phosphorus Complications of CKD. Official Luncheon Symposium, Renal Week 2004, American Society of Nephrology, St. Louis, MO, October 20, 2004.

L68) "B-type Natriuretic Peptide in the Diagnosis of Acute Heart Failure," New Advances in the Diagnosis and Management of Acute Decompensated Heart Failure, Satellite Symposium to the AHA Scientific Sessions 2004, New Orleans, LA, November 8, 2004.

L69) "Oportunidades para Aprimoramento no Tratamiento da Insuficiencia Cardiaca," 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insufiencia Cardiaca, I Encontró Multiporfissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portugese) Salvador, Bahía, Brasil, November 25-27, 2004.

L70) "Peptideo Natriuretico Intravenoso-Perspectivas para Emprego na IC Descompensada," 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insufiencia Cardiaca, I Encontro Multiprofissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portugese) Salvador, Bahia, Brasil, November 25-27, 2004.

L71) "Nesiritide (Peptideo Natriuretico Intravenoso) uma Nova Arma no Tratamento da IC Grave e Decompensada," 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insufiencia Cardiaca, I Encontro Multiporfissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portuguese) Salvador, Bahia, Brasil, November 25-27, 2004.

L72) "Conferenca Magna (Keynote Address): The Cardiorenal Intersection: Crossroads to the Future," 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insufiencia Cardiaca, I Encontro Multiporfissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portuguese) Salvador, Bahia, Brasil, November 25-27, 2004.

L73) "Practical Use of BNP in the Diagnosis and Management of Heart Failure" Medical Grand Rounds, Olathe Regional Medical Center, Olathe, KS, December 3, 2004.

L74) "Management of Heart and Renal Failure" The 36th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 18, 2005.

L75) "Contrast-Induced Nephropathy" The 36th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 18, 2005.

L76) "Combined Heart and Kidney Failure" Cardiovascular Conference at Snowmass, Aspen, CO, January 18, 2005.

L77) "Practice Strategies and Protocols to Reduce Renal Complications" PCI: Understanding and Managing In-Hospital Cardiac and Renal Complications, 3rd European Summit, Chantily, France, February 11, 2005.

L78) "HDL Cholesterol: A Powerful New Therapeutic Target" 14th (Conference Chair) Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 14, 2005.

L79) "BNP-ology, is the Enthusiasm Warranted?" (Conference Chair) 14th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 15, 2005.

L80) "Anticoagulation for Atrial Fibrillation: Can Warfarin be Replaced?" (Conference Chair) 14th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 18, 2005.

L81) "New Multimarker Strategies in the Diagnosis of Acute Coronary Syndromes" Satellite Symposium to the 54th Annual American College of Cardiology Scientific Sessions 2005, Orlando, FL, March 7, 2005.

L82) "Effect of Lowering LDL Level on Progression of Vascular Calcification" Reducing the Burden of Cardiovascular Calcification in Chronic Kidney Disease, Satellite Symposium to the Renal Physicians Association Annual Meeting, Washington, DC, March 20, 2005.

L83) "Why Chronic Kidney disease is a CVD risk factor: Practical Implications in the Care of Cardiovascular Patients" Cardiology Grand Rounds, Clinical Science Institute, Galway, Ireland, UK, May 5, 2005.

L84) "Clinical Application of B-type Natriuretic Peptide Levels in the Care of Cardiovascular Patients" EuroLab 2005, Glasgow, Scotland, UK, May 9, 2005.

L85) "Anemia Is a Cardiovascular Risk Factor in Patients With Diabetic Nephropathy" The Kidney is a Key Link between Diabetes and Cardiovascular Disease: Managing Risk; Satellite Symposia to the Annual Scientific Sessions of the American Association of Clinical Endocrinology, Washington, DC, May 18, 2005.

L86) "CIN: Emerging Trends in Identifying and Managing the At-risk Patient" Cardiovascular and Interventional Radiology Society of Europe (CIRSE) 2005, Nice, France, September 13, 2005.

L87) "Recent Advances in Cardiac Markers and their Clinical Role in Cardiovascular Disease: Update of the BNP Consensus Panel Statements and Cost Effectiveness of BNP Testing" Turning Science into Caring Programme, Abbott European Laboratory Symposium, Wiesbaden-Delkenheim, Germany, October 14, 2005.

L88) "Epidemiology and Prevention of Contrast Nephropathy" Transcatheter Therapeutics Annual Scientific Sessions, Washington, DC, October 19, 2005.

L89) "BNP—What Does it All Mean?" Heart Failure 2005: What to Do for the Failing Left Ventricle" AHA Symposium in Conjunction with the 2005 Scientific Sessions, Dallas, TX, November 11, 2005.

L90) "How to Use Cardiac Biomarkers in Heart Failure" 2005 Annual Scientific Sessions of the AHA, Dallas, TX, November 14, 2005, broadcasted nationally as "Best of Sessions 2005 on Wednesday, November 30 from 1:00-2:30PM EST"

L91) "Chronic Kidney Disease as a Cardiovascular Risk State: Practical Management for the Cardiologist" St. Vincent's Hospital, University of British Columbia, Distinguished Speakers in Cardiovascular Medicine, 2005-2006, Vancouver, BC, Canada, December, 1, 2005.

L92) "Anemia, Chronic Kidney Disease, and Cardiovascular Disease: Diagnosis, Prognosis, and Treatment. Nephrology Grand Rounds, University of British Columbia, St. Vincent's Hospital, Vancouver, BC, Canada, December 2, 2005.

L93) "The Deadly Triangle of Anemia, Kidney and Heart Disease: Implications for Treatment and Management" 37th Annual Cardiovascular Conference at Snowmass, January 20, 2006, Snowmass, CO.

L94) "Anemia in Cardiovascular Patients: Diagnosis, Prognosis, and Therapy." AHA, Prevention VIII Conference: Kidney Disease, Hypertension, and Cardiovascular Disease, January 27, 2006, Orlando, FL.

L95) "Update on Bariatric Surgery" (Conference Chair) 15th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 17, 2006.

L96) "Multimarker Approach to Chest Pain." Satellite Symposium to the Annual Scientific Sessions of the American College of Cardiology, March 11, 2006, Atlanta, GA.

L97) " Preventing Contrast Nephropathy: What Works?" American College of Cardiology Annual Scientific Sessions (ACC.06 and the i2 Summit 2006), March 14, 2006, Atlanta, GA.

L98) "Consensus statements on strategies to reduce the risk of CIN." Satellite Symposium Society for Cardiac Angiography and Intervention 29th Annual Scientific Sessions (Symposium Chair): Consensus Statements on Contrast-Induced Nephropathy (CIN): Report of an International, Multidisciplinary Panel, Chicago, IL, May 11, 2006.

L99) "Contrast-induced nephropathy: identifying and managing the patient at risk." Euro PCR 2006 Satellite Symposium: The Underestimated Impact of Contrast Media on Patient Outcomes in PCI (Symposium Chair), Paris, France, May 27, 2006.

L100) "Debate: Acute Decompensated Heart Failure--Biomarker will suffice" 17th Annual Scientific Sessions of the American Society of Echocardiography, Baltimore, MD, June 6, 2006.

L101) "Heart and Kidney: Clinical Impact of Contrast Media" Update on Cardiovascular Disease 2006, Casa Di Cura Montevergine, Napoli Castel Dell'Ovo, Naples, Italy, June 19, 2006.

L102) "Cardiovascular Disease in CKD: Where Does Calcium Fit In?" Satellite Symposia: Current Strategies for the Management of Hyperphosphatemia in End-Stage Renal Disease. European Renal Association/European Dialysis and Transplantation Association Annual Scientific Meeting, Glasgow, Scotland, July 17, 2006.

L103) "Applications of BNP in Cardiovascular Disease" Satellite Symposia: New and Evolving Markers for Cardiovascular Disease: Myeloperoxidase (MPO) and BNP. American Association of Clinical Chemistry Annual Meeting, Chicago, IL, July 26, 2006.

L104) "Clinical Applications of B-type Natriuretic Peptide Testing" Clinical Biochemistry Satellite Symposium: The Role of Biochemical Markers in Clinical Cardiology, Sponsored by the Australasian Association of Clinical Biochemists at the 54th Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand, Canberra, Australia, August 4, 2006.

L105) "Update on BNP in the Management of Heart Failure" 54th Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand, Canberra, Australia, August 6, 2006.

L106) "Update on BNP in the Management of Heart Failure" Cardiology Grand Rounds, Royal North Shore Hospital, Sydney, Australia, August 7, 2006.

L107) "Contrast-Induced Nephropathy: Identifying and Managing the Patient at Risk" Advances in Contrast-Enhanced Imaging: Improving Outcomes and Reducing Risks of Iodinated Contrast (Chairman), a CME Satellite Symposium at the Transcatheter Therapeutics 2006 Conference, Washington, DC, October 24, 2006.

L108) "Cardiorenal Syndrome: Etiology, Therapy, and Prognosis" Unresolved Issues in Heart Failure, Cardiovascular Seminars, 2006 Annual Scientific Sessions of the AHA, Chicago, IL, November 14, 2006

L109) "Prevention and Management of CAD in CKD" Coronary Artery Disease in CKD: Updating the Pathophysiology and Management. Official Symposium of the American Society of Nephrology, Sand Diego, CA, November 16, 2006.

L110) "Pharmacologic Prevention of Sudden Death in Dialysis Patients" Sudden Death in Hemodialysis Patients: Towards Prevention. American Society of Nephrology Renal Week 2007, San Diego, CA, November 17, 2006.

L111) "Contrast Nephropathy: Finding Consensus on a Rational Approach" Radiology Grand Rounds, Hôpital Notre-Dame, University of Montreal, Canada, November 23, 2006.

L112) "Contrast Nephropathy: Finding Consensus on a Rational Approach" Radiology Grand Rounds, Hôpital St-Luc, University of Montreal, Canada, November 23, 2006.

L113) "Cardiorenal Syndrome and Anemia" 3rd Annual Heart Failure University (HFU) Cardiovascular Fellows Program, Los Angeles, CA, December 2, 2006.

L114) "Implications of Age-Related Decline in Renal Function" 16th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 12, 2007.

L115) "Using BNP in Your Practice: Pearls and Pitfalls" 16th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 15, 2007.

L116) "Consensus Panel Findings on Contrast Nephropathy" 16th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 16, 2007.

L117) "Measuring BNP in ACS," American College of Cardiology Scientific Sessions Satellite Symposium, "ACS & Biomarkers: From Molecules to Patient Management", New Orleans, LA, March 24, 2007.

L118) "Anemia Correction and CVD Trials" "Ask the Experts" clinicaltrialresults.org, American College of Cardiology Scientific Sessions, New Orleans, LA, March 26, 2007.

L119) "CKD and CVD: Interaction and Risk Factors", Kidney Disease: The Unrecognized Silent Killer, NKF 2007 Scientific Meetings, Orlando, FL, April 11, 2007.

L120) "Contrast-Induced Nephropathy: A Meta-Analyses of the Renal Safety of Iodixanol" Special Lecture for the Radiological Society of the Republic of China, National Yang-Ming University, School of Medicine, Taipei, Taiwan, May 4, 2007.

L121) "Contrast-Induced Nephropathy: A Meta-Analyses of the Renal Safety of Iodixanol" Annual Meeting of Kaohsiung Society of Radiology, Chang Gung Memorial Hospital, Kaohsiung Hsien, Taiwan, May 5, 2007.

L122) "Meta-Analyses of the Renal Safety of Iodixanol", Plenary Session, 15th Annual Scientific Congress of the Hong Kong College of Cardiology, Hong Kong, SAR, May 6, 2007.

L123) "Contrast-Induced Nephropathy: A Meta-Analyses of the Renal Safety of Iodixanol" Cardiology Special Lecture, 12th Department of Cardiology, Beijing AnZhen Hospital, Beijing, Peoples Republic of China, May 7, 2007.

L124) "Prevention of CIN during PCI in Diabetic Patients: Proposal of a Guideline" (Prevencion del Fracaso Renal Inducido por Contraste en Pacientes Diabeticos Sometidos a Intervencionismo Coronario: Propestuesta de un Protocolo Actuacion), Optimizacion del Tratamiento de Revascularizacion Percutanea en Pacientes Diabeticos, TEAM (Terapia Endovascular & Miocardica), Hospital del Mar, Barcelona, Spain, May 11, 2007.

L125) "Acute Kidney Injury from Iodinated Contrast: Findings from an International Panel," Hungarian Society of Cardiology Annual Scientific Meeting (Magyar Kardiologusok Tarsasaga Tudomanyos Kongresszusa) Balatonfured, Hungary, May 12, 2007.

L126) "Which Types and Which Amount of Physical Activities to Achieve and Maintain a Healthy Body Weight?" 4th Metabolic Syndrome, Type II Diabetes, and Atherosclerosis Congress (MSDA), 2007, Lisbon, Portugal, May 19, 2007.

L127) "The Role of BNP in Patients with Shortness of Breath," Laboratory Diagnostic Technologies for Patients with Shortness of Breath, Satellite Symposium to the American Association of Clinical Chemistry Annual Scientific Meeting, San Diego, CA, July 18, 2007.

L128) "Acute Kidney Injury after Contrast: A Serious Problem by Any Name", Hemodynamics, Electrolytes, Acute Kidney Injury: Novel Considerations in Contrast Selection, Transcatheter Cardiovascular Therapeutics 2007 Annual Meeting Satellite Symposium, Washington, DC, October 23, 2007.

L129) "Vascular Calcification: Myth versus Realty: A Cardiologist's Perspective," Changing Paradigms: Evolving Bone and Mineral Metabolism Treatment in CKD, An American Society of Nephrology 2007 Official Symposia, San Francisco, CA, November 3, 2007.

L130) "Contrast-Induced Nephropathy" Cardiology Grand Rounds, Auckland City Hospital, Auckland, New Zealand, November 22, 2007.

L131) "Practical Use of Natriuretic Peptides in Cardiovascular Disease" North Shore Hospital- Waitemata Health, Takapuna, Auckland, New Zealand, November 22, 2007.

L132) "Practical Use of Natriuretic Peptides in Cardiovascular Disease" Waikato Hospital, Hamilton, New Zealand, November 23, 2007.

L133) "Practical Use of Natriuretic Peptides in Cardiovascular Disease" Wakefield Hospital, Adelaide, Australia, November 23, 2007.

L134) "Clinical Utilization of Cardiac Troponin and Natriuretic Peptides in ACS and CHF" Satellite Symposium to Australasian Emergency Meeting (ACEM), Gold Coast, Brisbane, Australia, November 27, 2007.

L135) "Clinical Utilisation of Cardiac Troponin and Natriuretic Peptides in ACS and CHF: Part 1: Congestive Heart Failure, Part 2: Acute Coronary Syndrome, Part 3: Cardio-Renal Syndrome, Kuala Lumpur, Malaysia, November 29, 2007.

L136) "Multimarker Strategies in the Management of Cardiovascular Emergencies," YMCA for Dr. H.F.Ho, Queen Elizabeth Hospital, Hong Kong, SAR, November 30, 2007.

L137) "Practical Management of Cardiovascular Disease in Patients with Kidney Disease" Williamsburg, Virginia for the 34th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 3, 2007.

L138) "New Cardiovascular Drugs" 17th Annual Cardiovascular Conference at Beaver Creek" Avon, CO, February 12, 2008.

L139) "New Insights into Atherosclerosis and Global CVD Risk," 17th Annual Cardiovascular Conference at Beaver Creek" Avon, CO, February 12, 2008.

L140) "Plenary 2 : Mini-Symposia: Acute Kidney Injury (AKI): Pathophysiology: Contrast Nephropathy: Epidemiology and Prognosis" 13th Annual International Conference on Continuous Renal Replacement Therapies, San Diego, CA, February 28, 2008.

L141) "Heart Failure and Cardio-Renal Syndrome 1: Pathophysiology" 13th Annual International Conference on Continuous Renal Replacement Therapies, San Diego, CA, February 29, 2008.

L142) "Hemodynamic Monitoring: Principles and Practice" 13th Annual International Conference on Continuous Renal Replacement Therapies, San Diego, CA, February 29, 2008.

L143) "Cardiovascular Calcification, Potential Strategies in Minimizing Cardiovascular Disease in CKD", Satellite Symposia at the 57th ACC Annual Scientific Sessions, Chicago, IL, March 30, 2008.

L144) "Emergency Evaluation of Chest Pain: Building a Better Mousetrap" Olathe Medical Center Annual Heartbeat Symposium, Olathe, KS, April 4, 2007.

L145) "Interventions and CVD Interactions in Diabetics with Proteinuria" Satellite Symposia (Chairman) Chronic Kidney Disease Interventions: Improving CKD and CVD Outcomes" NKF Clinical Meeting 2008, Dallas, TX, April 5, 2008.

L146) "Shifting Paradigms in PCI: Controversial Issues in High-Risk Patients" International Symposium (Chairman), Barcelona, Spain, April 10, 2008.

L147) "Success in Identifying Heart Failure" Satellite Symposia "Managing CVD: What Every Internist Needs to Know" Annual Scientific Sessions of the American College of Physicians, Washington, DC, May 14, 2008.

L148) "Cardiovascular Calcification in Patients with Chronic Kidney Disease" Satellite Symposia "Cardiovascular Disease in CKD: Strategies for Minimizing Mortality" Annual Scientific Sessions of the American College of Physicians, Washington, DC, May 15, 2008.

L149) "Clinical Trial Designs in Contrast Induced Acute Kidney Injury," Third Annual AKIN Conference on Research Initiatives in AKI, Bethesda, MD, June 10-12, 2008.

L150) "Neutrophil Gelatinase Associated Lipocalin (NGAL)" on Behalf of Inverness Medical, Third Annual AKIN Conference on Research Initiatives in AKI, Bethesda, MD, June 10-12, 2008.

L151) "Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy" Radiological Society of Taiwan, Taipei, Taiwan, July 17, 2008.

L152) "Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy" Radiological Society of Taiwan, Kaushiung, Taiwan, July 18, 2008.

L153) "Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy" Contrast-Induced Nephropathy Symposium, Professor Yalin Han, MD, Chairwoman of Military Cardiology Society of China, Shenyang, China, July 20, 2008.

L154) Cardiology Teaching Rounds, with Professor Runlin Gao, Beijing Fuwai Hospital, Beijing, China, July 21, 2008.

L155) Cardiology Teaching Rounds, with Professor Yujie Zhou, Beijing Anzhen Hospital, Beijing, China, July 21, 2008.

L156) Cardiology Teaching Rounds with Professor Yundai Chen, General Hospital of Military, Peoples Liberation Army, Beijing, China, July 21, 2008.

L157) "Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy" Contrast-Induced Nephropathy Symposium, Contrast-Induced Nephropathy Symposium, Professor Runlin Gao, Chairman of Chinese Cardiology Society, Beijing, China, July 22, 2008.K

L158) "New Insights on Accelerated Vascular Calcification in Patients with Kidney Disease" Plenary Session: Ischemic Heart Disease/Risk Assessment/New Treatment Strategies"

International Academy of Cardiology 14th World Congress on Heart Disease, Annual Scientific Sessions, Toronto, Ontario, Canada, July 29, 2008.

L159) "Cardiorenal Syndrome: the Diagnostic Value of Brain Natriuretic Peptide and Neutrophil Gelatinase Associated-Lipocalin in Interventional Cardiology," Cardiovascular Biomarkers which Enhance Clinical Practice in Emergency Medicine and Cardiology: the State of the Art for Markers of Necrosis, Hemodynamic Stress and Cardiorenal Syndrome, Satellite Symposium to the European Society of Cardiology Annual Scientific Sessions, Munich, Germany, September 2, 2008.

L160) "Diagnosis and Management of Diabetes, Hypertension, and Acute Dyspnea," 2008 CVD and CKD Intersection Consensus Conference, Chicago, IL, September 26, 2008.

L161) "Chronic Kidney Disease and Contrast Nephropathy (Contrast-Induced Acute Kidney Injury [CI-AKI]): From Prognostic Scores to the Latest Preventive Strategies" Complex Patients, Complex Lesions, 20th Annual Transcatheter Therapeutics Conference, Washington, DC, October 14, 2008.

L162) "Chronic Kidney Disease: a CHD Risk Equivalent" 2008 Cardiometabolic Health Congress, Harvard Medical School, Boston, MA, October 19, 2008.

L163) "Hyperphosphatemia as a Cardiovascular Risk Factor" Nephrology Conference, The Ottawa Hospital, Ottawa, Ontario, Canada, October 28, 2008.

L164) "Cardiovascular Calcification in Patients with Chronic Kidney Disease" Nephrology Division-Wide Conference, The Ottawa Hospital, Ottawa, Ontario, Canada, October 28, 2008.

L165) "Hyperphosphatemia and CVD Risk," Management of Hyperphosphatemia Across the Continuum of CKD, American Society of Nephrology Satellite Symposium, Philadelphia, PA, November 8, 2008.

L166) "Cardiovascular Calcification" Nephrology Grand Rounds, Humber River Regional Hospital, Toronto, Ontario, Canada, December 9, 2009.

L167) "Cardiovascular Calcification" Nephrology Grand Rounds, St. Joseph's Hospital, Toronto, Ontario, Canada, December 9, 2009.

L168) "Critical Concepts in the Progression of Atherosclerosis" 18th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 9, 2009.

L169) "New Molecular Targets in the Treatment of Atherosclerosis" 18th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 9, 2009.

L170) "Sudden Cardiac Death in Patients with Renal Disease" 18th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 12, 2009.

L171) "Cardiovascular and Renal Implications of Contrast Media" Radiology Grand Rounds, The Kingston Hospital, Queens University School of Medicine, Kingston, Ontario, Canada, March 3, 2009.

L172) "Recent Evidence into the Pathophysiology of Cardiovascular Calcification in Chronic Kidney Disease," NKF Symposium 2009 Spring Clinical Meetings, "Exploring Recent Evidence Related to Cardiovascular Calcification and Chronic Kidney Disease", Nashville, TN, March 27, 2009.

L173) "Chronic Kidney Disease: Implications For Patients With CAD" Managing the High Risk Coronary Patient, I2 Summit, American College of Cardiology Annual Scientific Sessions, Orlando, FL, March 30, 2009.

L174) "BNP and Cardiovascular Disease" Cardiology Grand Rounds, Hospital PróCardíaco, Rio deJaniero, Brasil, April 14, 2009.

L175) "Acute Cardiac Effects of Marathon Running" Special Guest Lecture, CLINIMEX - Clínica de Medicina do Exercício, Rio deJaniero, Brasil, April 14, 2009.

L176) "Interface entre doenca renal e cardiovascular: o rim mata o coracao ou o coracao mata o rim? Da para evitar esse extermino?" Terapeutica Cardiovascular International, Hospital Espanhol, Salvador, Brasil, April 17, 2009.

L177) "A angiotomografia coronaria deve ser empregada em todo paciente com do toracica de risco baixo-moderado?" Terapeutica Cardiovascular International, Hospital Espanhol, Salvador, Brasil, April 17, 2009.

L178) "Conferencia Internacional: Opportunidades para aperfeicoar o tratamento da insuficiencia cardiaca avancada/descompensada" Terapeutica Cardiovascular International, Hospital Espanhol, Salvador, Brasil, April 17, 2009.

L179) "Invasive Versus Non-invasive Coronary Angiography: Guidelines for Achieving Optimal Outcomes" Annual Scientific Sessions of the Society for Cardiac Angiography and Intervention, Las Vegas, NV, May 7, 2009.

L180) "Cardiorenal Syndrome" Moderator, American Society of Nephrology Annual Scientific Sessions, Renal Week 2009, San Diego, CA, October 29, 2009.

L181) "The Creatinine Changes: Now What?" Cardiorenal Syndromes, Annual Scientific Sessions, AHA, Orlando, FL, November 16, 2009.

L182) "Cardiorenal Syndromes: Strategies for Success" 19th Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 6-11, 2010.

L183) "Cardiomyopathy of Obesity" 19th Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 6-11, 2010.

L184) "Why Does Atherosclerosis Calcify: Clinical Implications" 19th Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 6-11, 2010.

L185) "Prevention Trials in AKI" 15th International Conference on Continuous Renal Replacement Therapies (CRRT: 2010) Scientific Meeting, Del Coronado, CA, February 24, 2010.

L186) "Cardiology Trials" 15th International Conference on Continuous Renal Replacement Therapies (CRRT: 2010) Scientific Meeting, Del Coronado, CA, February 24, 2010.

L187) "Contrast Nephropathy: Prevention and Management" 15th International Conference on Continuous Renal Replacement Therapies (CRRT: 2010) Scientific Meeting, Del Coronado, CA, February 26, 2010.

L188) "Lipoprotein-Associated Phospholipase A2 (Control#: 4599)" Symposium: Do New Markers & Genomics Enhance Risk Prediction? Annual Scientific Sessions of the ACC, Atlanta, GA, March 15, 2010.

L189) "New Insights Into the Role of Heart-Kidney Interactions in the Cardiorenal Syndrome" (Control#: 16660) Symposium: Recognition and Management of the Cardiorenal Syndrome in Advanced Heart Failure, Annual Scientific Sessions of the American College of Cardiology, Atlanta, GA, March 15, 2010.

L190) "B-Type Natriuretic Peptides in Cardiorenal Syndromes" 5th Annual Turning Science into Caring Symposium, Wiesbaden, Germany, March 25, 2010.

L191) "CKD and CVD Interaction in KEEP" KEEP Update: the Common Soil of CKD and CVD, NKF Spring Clinical Meetings, Orlando, FL, April 16, 2010.

L192) "Cardio Renal Intersection, Crossroads to the Future - Novel Coronary Risk Factors" NKF Spring Clinical Meetings, Orlando, FL, April 16, 2010.

L193) "Diagnostic Workup of suspected heart disease in CKD" NKF Spring Clinical Meetings, Orlando, FL, April 17, 2010.

L194) "BNP: Beyond Heart Failure (BNP más allá de la insuficiencia cardiaca)", XIX Chile 2010 Congreso Latinoamericano de Bioquimica Clinica, XVI Congreso Chileno de Quimica

Clinica, Biomarcadores en Enfermedades Cario-Renales COLABIOCLI 2010, Santiago del Chile, April 21, 2010.

L195) "Prevention of Cardiorenal Syndromes", 19th International Vicenza Course on Critical Care Nephrology, Vicenza, Italy, June 10, 2010.

L196) "La Pandemia de la Obesidad: Que podemos hacer aquí y ahora" "Importancia de la Evaluación previa y el monitoreo cardiaco en rehabilitación cardiaca" "Ergoespirometria: Diagnostico e implicaciones terapéuticas," Sociedad Columbiana de Cardiologica y Ciruga Cardiovacular Fundacion Columbiana del Corazon Comite de Prevencion y Rebabilitacion Cardiovascular Dia Mundial del Corazon, Santa Marta, Columbia, September 25, 2010.

L197) "CKD: A CHD Equivalent" 2010 Cardiometabolic Health Congress (CMHC), Boston MA, October 22, 2010.

L198) "Treatment Disparities in Patients with Acute Coronary Syndromes and Kidney Disease" AHA Scientific Sessions 2010, Chicago, IL, November 13, 2010.

L199) "Integration of Advanced Information Technology into Nephrology Practice" Moderator, at the American Society of Nephrology, Denver, CO, November 21, 2010.

L200) "Cardiorenal Syndromes" Special Lecture, Mansoura Nephrology and Urology Center, Mansoura, Egypt, November 29, 2010.

L201) "Neutrophil Gelatinase Associated Lipocalin." Al Mokhtabar Laboratories, Cairo, Egypt, December 1, 2010.

L202) "Cardiorenal Syndromes" ACC Williamsburg Conference, Williamsburg, VA, December 5, 2010.

L203) "Micronutrients and Cardiorenal Disease: Insights into Novel Assessments and Treatment" 13th International Conference on Dialysis, Advances in CKD 2011, Miami, FL, January 26, 2011.

L204) "Managing High Risk Patients in a i2 Spotlight entitled Cardiac Care Team Spotlight: Approaches for CAD Management" American College of Cardiology 60th Annual Scientific Session and i2 Summit 2011, April 2, 2011, in New Orleans, LA.

L205) "Lipid Management in Patients with Renal Insufficiency in a ACC Symposium entitled Lipid Management in Special Populations" American College of Cardiology 60th Annual Scientific Session and i2 Summit 2011, April 2, 2011, in New Orleans, LA.

L206) "KEEP Symposium 2011: KEEP A New Longitudinal Dimension for a New Decade" NKF Spring Clinical Meetings, April 29, 2011, Las Vegas, NV.

L207) "Disparities of Treatment for ACS and Heart Failure in CKD Patients" 20th International Vicenza Course on Hemodialysis and CKD, June 8, 2011, Vicenza, Italy.

L208) "AKI: Can We Prevent It?" 20th International Vicenza Course on Hemodialysis and CKD, June 9, 2011, Vicenza, Italy.

L209) "Measuring Natriuretic Peptides in Acute Coronary Syndromes" American Association of Clinical Chemistry Annual Meeting, Atlanta, GA, July 26, 2011.

L210) "Biomarkers in Stable Angina and Microvascular Dysfunction", Emerging Role of Biomarkers in Cardiorenal Syndrome and Acute Coronary Syndrome: Diagnosis Stratification and Management, Siena Italy, September 2, 2011.

L211) "Cardiorenal Syndrome Definition and Scope: Cardiac Perspective" 28th National Congress of Nephrology, Hypertension, Dialysis, and Transplantation, Antalya, Turkey, October 20, 2011.

L212) "Targeted Hypertension Management for Optimal Cardiorenal Outcomes" 28th National Congress of Nephrology, Hypertension, Dialysis, and Transplantation, Antalya, Turkey, October 22, 2011.

L213) "The KEEP Experience" 3rd International Symposium on Albuminuria – The Prognostic Role of Albuminuria: Impact on Kidney and Cardiovascular Outcomes, Groningen, Netherlands, December 1, 2011.

L214) "Cardiorenal Syndromes" Cardiology Guest Lecture, University of Chicago, Pritzker School of Medicine, Chicago, IL, January 18, 2012.

L215) "Diagnosis of Cardiovascular Disease in CKD" 14th international conference on dialysis, advances in CKD 2012, Palm, Harbor, FL, January 26, 2012

L216) "Acute Kidney Injury Guidelines" KDIGO Clinical Practice Conference: KDIGO Guidelines on Acute Kidney Injury, Glomerulonephritis, and Anemia, Shanghai, China, February 5, 2012

L217) "Galectin-3: A Novel Blood Test for the Evaluation and Management of Heart Failure" Cardiology Grand Rounds, University of Arkansas for Medical Sciences, Little Rock, Arkansas, February 8, 2012

L218) "Contrast-Induced Acute Kidney Injury" 17th Annual CRRT 2012, Acute Kidney Injury Controversies, Challenges, and Solutions, San Diego, CA February 15, 2012

L219) "Recent Trials in the Prevention of Contrast-Induced AKI: Importance of Emerging Biomarkers" 17th Annual CRRT 2012, Acute Kidney Injury Controversies, Challenges, and Solutions, San Diego, CA February 17, 2012

L220) "Role of Galectin-3 in Heart Failure" Joint American Association of Cardiologists of Indian Origin and ACC Dinner Symposium, American College of Cardiology Scientific Sessions 2012, Chicago, IL, March 25, 2012

L221) "Bariatric Surgery: A Cure for Obesity?" American College of Cardiology Scientific Sessions 2012, Joint Symposium of the American Association of Clinical Endocrinologists and the ACC: Cardiologists as Endocrinologists – Emerging Management of the Diabetic Patient, Chicago, IL, March 26, 2012

L222) "Practical Management of Obesity for the Cardiologist" 48th Annual Robert M. Jeresaty Cardiovascular Symposium, Hartford, CT, May 3, 2012

L223) "Prevention of Cardiovascular Events: Beyond Statins" 48th Annual Robert M. Jeresaty Cardiovascular Symposium, Hartford, CT, May 3, 2012

L224) "Contrast Media and Patient Safety: The Clinical Impact" Swiss Congress of Radiology, Zurich, Switzerland, May 31, 2012

L225) "Importance of Methodological Rigor in CI-AKI Meta-Analyses" 48th Congresso Nazionale Italian Society of Radiology (SIRM), Torino, Italy, June 2, 2012

L226) "Chronic Kidney Disease and Heart Failure" 2012 Cardiometabolic Health Congress (CMHC) Boston, MA, October 12, 2012

L227) "Chronic Kidney Disease and Acute Myocardial Infarction" CKD a Recipe for CVD Disaster, Kidney Week, American Society of Nephrology, San Diego, CA, October 30, 2012

L228) "Epidemiology and Pathophysiology of Coronary Artery Disease in Chronic Kidney Disease" Scientific Sessions 2012, AHA, Los Angeles, CA, November 5, 2012

L229) "The Cardiorenal Syndrome" Acute Dialysis Quality Initiative 11: Cardiorenal Syndromes, Venice, Italy, November 30, 2012

L230) "Cardiorenal Syndromes" Cardiology Grand Rounds, University of Missouri School of Medicine, Columbia, MO, December 20, 2012

L231) "Diagnosis and Management of Coronary Disease in Patients with Kidney Disease" Internal Medicine Grand Rounds, University of Missouri School of Medicine, Columbia, MO, December 20, 2012

L232) "The Hypertension Epidemic: Are We Any Further Ahead?" 22nd Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 9-16, 2013

L233) "Cardiorenal Syndromes: The Cardiac Perspective" Inaugural Cardio Renal Society of America (CRSA), 14th Annual Southwest Nephrology Conference (SWNC), Chandler, AZ, March 2, 2013

L234) "Managing Hyponatremia in Cardiorenal Syndromes" Satellite Symposia to the NKF Spring Clinical Meetings, Orlando, FL, April 3, 2013

L235) "Session Title: Debate: To Screen or Not to Screen for CKD--PRO? NKF Spring Clinical Meetings, Orlando, FL, April 5, 2013

L236) "Galectin-3: A Novel Biomarker for the Assessment and Management of Heart Failure" Heart Failure Conference, University of Pittsburgh Medical Center, Pittsburgh, PA, May 28, 2013

L237) "The Kidney in Heart Failure" 31st International Vicenza Course on Critical Care Nephrology, June 11-14, 2013, Vicenza, Italy

L238) "Contrast-Induced Acute Kidney Injury" 31st International Vicenza Course on Critical Care Nephrology, June 11-14, 2013, Vicenza, Italy

L239) "Novel Biomarkers in the Prognosis and Management of Heart Failure" BUMC Medicine Grand Rounds, August 20, 2013, Dallas, TX

L240) "Cardiorenal Syndromes: New Insights into Combined Heart and Kidney Failure" Cardiology Grand Rounds, University of Virginia Medical Center, August 26, 2013, Charlottesville, VA

L241) "Major Advances in the Treatment of Atherosclerosis: New Options for Patients with Familial Hypercholesterolemia and Those Intolerant to Conventional Lipid Lowering Therapy" Cardiology Update, University of Missouri School of Medicine, September 14, Columbia, MO

L242) "Keynote Address: Recent Advances in the Assessment of Acute Kidney Injury with Neutrophil Gelatinase Associated Lipocalin" 47th Brazilian Congress of Clinical Pathology and Laboratory Medicine, September 23, 2013, Sao Paulo, Brazil.

L243) "Advancements in Cardiometabolic Risk Assessment: Expert Analysis of Recent Evidence and Outcomes" 2013 Cardiometabolic Health Congress, October 2, 2013, Boston, MA.

L244) "Keynote Address: Cardiorenal Syndromes: New Insights to Patients with Combined Heart and Kidney Failure" Fourth Italian Great Network Congress, Focus on Innovation and Translational Research in Emergency Medicine, Sapienza Universita di Roma, October 14-18, 2013, Rome, Italy.

L245) "Practical Experience with Galectin-3" Fourth Italian Great Network Congress, Focus on Innovation and Translational Research in Emergency Medicine, Sapienza Universita di Roma, October 14-18, 2013, Rome, Italy.

L246) "Using Novel Biomarkers in the Assessment and Management of Heart Failure" Bon Secours Cardiovascular Conference, October 25, 2013, Williamsburg, VA

L247) "Detection and Consequences of Iron Deficiency Anemia in CKD Patients" Session Title: The Role of Iron in the Optimization of Anemia Management in CKD, American Society of Nephrology, Kidney Week, November 9, 2013, Atlanta, GA

L248) "Bench to Bedside: What Happens to the Physiologic Systems After an Acute Bout of High Intensity/Volume Exercise?" Session Title: Cardiovascular Seminar entitled Potential Cardiotoxicity of Extreme Endurance Exercise, Annual Scientific Sessions of the AHA, November, 20, 2013, Dallas, TX.

L249) "Atrasentan for the treatment of diabetic nephropathy: how to control the risk of heart failure?" Session Title: "Lessons Learned from First Post FDA Guidance Case Studies of Diabetes CV Outcomes Trials, 10th Global CardioVascular Clinical Trialists (CVCT) Forum, December 7, 2013, Paris, France.

L250) "Reflection: Biomarker-based modeling tools: safer drugs and faster development?" A workshop initiated by the TI-Pharma Escher project for academia, industry, and the European Medicines Agency, January 24, 2014, Amsterdam, the Netherlands.

L251) "Focus on lipids: HDL and Its Associated Lipoproteins in Cardiac and Renal Disease" Changing Paradigms in Acute Kidney Injury: From Mechanisms to Management Sponsored by UAB/UCSD O'Brien Center for AKI Research, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.

L252) "Cardiac and Renal Fibrosis in Chronic Cardiorenal Syndromes" Targeting Recovery from Acute Kidney Injury:, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.

L253) "Statins for AKI: Friend or Foe" Controversies in Critical Care Nephrology:, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.

L254) "Managing Heart Failure and Cardiorenal Syndrome" Workshop, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.

L255) "ST2: A Novel Biomarker in the Assessment and Management of Heart Failure" 2nd Annual Cardio Renal Society of America (CRSA), 15th Annual Southwest Nephrology Conference (SWNC), Ft. McDowell, AZ, March 8, 2014.

L256) "Cardiac and Renal Fibrosis in Chronic Cardiorenal Syndromes" 2nd Annual Cardio Renal Society of America (CRSA), 15th Annual Southwest Nephrology Conference (SWNC), Ft. McDowell, AZ, March 8, 2014.

L257) "New Approaches to the Management of Cardiorenal Syndromes" 2nd Annual Cardio Renal Society of America (CRSA), 15th Annual Southwest Nephrology Conference (SWNC), Ft. McDowell, AZ, March 8, 2014.

L258) "My New Favorite Biomarker: Galectin-3" 2014 UCSD Biomarkers in Clinical Practice Symposium, La Jolla, CA, April 5, 2014.

L259) "Changing Profile of Chronic Hyperkalemia" NKF Spring Clinical Meetings, Las Vegas, NV, April 24, 2014.

L260) "The Next Generation of Screening for Kidney Disease" NKF Spring Clinical Meetings, Las Vegas, NV, April 25, 2014.

L261) "Cardiorenal Syndromes" Cardiology, Diabetes & Nephrology at the Limits, Royal College of Physicians, London, UK, April 26, 2014.

L262) "Acute Cardiorenal Syndromes: New Insights into Combined Heart and Kidney Failure" Actual Problems of Extracorporeal Blood Purification in Intensive Care, Russian Scientific Society of Specialists in Extracorporeal Blood Purification, Bakoulev Scientific Center for Cardiovascular Surgery of the Russian Academy of Medical Sciences, Moscow, Russia, May 22, 2014.

L263) "Fibrosis in the Heart and Kidneys in the Pathogenesis of Chronic Cardiorenal Syndromes" Actual Problems of Extracorporeal Blood Purification in Intensive Care, Russian Scientific Society of Specialists in Extracorporeal Blood Purification, Bakoulev Scientific Center for Cardiovascular Surgery of the Russian Academy of Medical Sciences, Moscow, Russia, May 23, 2014.

L264) "Hyperkalemia: Old Foe with New Faces" 51st European Renal Association – European Dialysis and Transplantation Association Congress, Amsterdam, the Netherlands, June 2, 2014.

L265) "Contrast Induced Complications in the Cath Lab" Transcatheter Cardiovascular Therapeutics (TCT) Russia, Moscow, Russia, June 16, 2014.

L266) "The RAASi Debate: Should RAAS Continue with a Declining GFR?: Will the Path be Clearer" Co-Chair, European Society of Cardiology, Barcelona, Spain, August 31, 2014.

L267) "Novel Markers of Acute and Chronic Kidney Injury," Where Inflammation Meets Lipids: Broad Based Strategies for Risk Reduction, Cleveland Heart Labs, Cleveland, OH, September 12, 2014.

L268) "Advances in the Understanding of Acute and Chronic Cardiorenal Syndromes: Pathophysiological Crosstalk of Multiple Metabolic and Neurohormonal Systems" 41st Williamsburg Cardiovascular Conference, Williamsburg, VA, December 7, 2014.

L269) "CHADS, CHADS-VASc, HAS-BLED, What Does it Mean and How Do We Use It? Atrial Fibrillation Session, Dallas-Leipzig Valve 2104, Dallas, TX, December 11, 2014.

L270) "Soup-to-Nuts Renal Failure: Caring for the Patient with Kidney Injury" Society of Critical Care Medicine, Phoenix, AZ, January 19, 2015.

L271) "RAASi Optimization in Heart Failure" 2nd Annual Cardiorenal Society of America Meeting, Phoenix, AS, February 28, 2015.

L272) "Cardiac Surgery Associated Acute Kidney Injury" Association of Physician Assistants in Cardiac Surgery, Las Vegas, NV, March 3, 2015.

L273) "The Potassium Challenge in CKD: Managing Acute and Chronic Hyperkalemia: Novel Polymer-Based Potassium Binders: Clinical Evidence" NKF Spring Clinical Meetings, March 27, 2015.

L274) "KEEP Healthy: Insights into CKD Care" NKF Spring Clinical Meetings, March 28, 2015.

L275) "The Heart of the Matter" NKF Spring Clinical Meetings, March 28, 2015.

L276) "Literature Review: CVD" NKF Spring Clinical Meetings, March 28, 2015.

L277) "Biomarkers of Kidney and Heart Injury in Cardiorenal Syndrome" Cardionephrology 2015, Rome, Italy, April 16, 2015.

L278) "AKI after Acute Myocardial Infarction: Contrast, Organ Crosstalk and Complications" 33rd Vicenza Course on Critical Care Nephrology in Vicenza, Italy, June 9-12, 2015.

L279) "A New Mechanism of Action for Addressing Hyperkalemia: New Data on Non-Polymer Hyperkalemia Therapies" 33rd Vicenza Course on Critical Care Nephrology in Vicenza, Italy, June 9-12, 2015.

L280) "Lp-PLA2 as a marker of Vascular Inflammation and CHD Risk Assessment" Symposium: Advances in Laboratory Testing for Coronary Heart Disease; The New PLAC Test for Lp-PLA2 Activity, American Association of Clinical Chemistry Annual Meeting, Atlanta, GA, June 29, 2015.

L281) "Galectin-3 in the Prognosis and Management of Heart Failure" American Association of Clinical Chemistry Annual Meeting, Atlanta, GA, June 29, 2015.

L282) "Cardio-Renal Syndrome and Clinical Implications" AKI from Pathophysiology to Clinical Implications, Global Research on Acute Conditions Team (GREAT) Annual Meeting, Rome, Italy, September 5, 2015.

L283) "Lp-PLA2 and Testing for Primary Prevention Risk Assessment" 2015 Cardiometabolic Health Congress, Harvard Medical School, Boston, MA, October 22, 2015.

L284) "Heart and Kidney: a Dangerous Liaison" Comorbidities in Heart Failure: From Guidelines to Clinical Practice, 775 Anniversary University of Sienna, Sienna, Italy, October 29, 2015.

L285) "Role of BNP, Pro-BNP, and Elevated Left Ventricular Mass in Cardiorenal Syndrome" American Society of Nephrology Kidney Week, San Diego, CA, November 6, 2015.

L286) "How to Use Urine Thromboxane B2 to Select and Monitor Aspirin Therapy" Moderator, Scientific Sessions 2015, AHA, Orlando, FL, November 10, 2015.

L287) "Putting it All Together: How to Use Urine 11-Dehydrothromboxane B2 In Clinical Practice" Scientific Sessions 2015, AHA, Orlando, FL, November 10, 2015.

L288) "Neurogenic Orthostatic Hypotension" Moderator, Scientific Sessions 2015, AHA, Orlando, FL, November 10, 2015.

L289) "Cardiac Cachexia" Managing Disease Related Lean Body Mass Loss Through Clinical and Nutritional Interventions, The Sackler Institute for Nutrition Science The New York Academy of Sciences, New York, NY, December 4, 2015.

L290) "The Devastating Consequences of Systemic Hypertension and What To Do About It?" 42st Williamsburg Cardiovascular Conference, Williamsburg, VA, December 6-8, 2015.

L291) "The Impact and Management of Malnutrition in Patients with Heart Failure" Heart Failure University 2015, Conference Co-Chair, Los Angeles, CA, December 11-13, 2015.

L292) "Acute and Chronic Cardiovascular Effects of Hyperkalemia: New Insights Into Prevention and Clinical Management" Heart Failure University 2015, Conference Co-Chair, Los Angeles, CA, December 11-13, 2015.

L293) "Lipoic Acid in the Prevention of Acute Kidney Injury" 21st International Conference on Continuous Renal Replacement Therapies CRRT 2016, San Diego, CA, February 16-18, 2016.

L294) "Novel Approaches for Recognition and Management of Life Threatening Complications of AKI and CKD" 21st International Conference on Continuous Renal Replacement Therapies CRRT 2016, San Diego, CA, February 16-18, 2016.

L295) "Making Iodinated Contrast Less Nephrotoxic with Cyclodextrin" 21st International Conference on Continuous Renal Replacement Therapies CRRT 2016, San Diego, CA, February 16-18, 2016.

L296) "Cardiorenal Syndrome" 4th Annual Cardio-Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ, March 13, 2016.

L297) "Cardiorenal Syndromes Identification: Prevention and Management of CI-AKI" China Interventional Therapeutics (CIT), Beijing, Shanghai Zhong Shan Hospital, Shanghai, The 2nd Affiliated Hospital of Zhejiang University, Hangzhou, Xi Jing Hospital, Xi'an, Nanjing 1st Hospital, Nanjing, Peoples Republic of China, March 14-21, 2016.

L298) "Cardiorenal Syndromes" Keynote Address, Inaugural Cardio-Renal Connections Meeting, San Antonio, TX , April 16, 2016.

L299) "Galectin-3 in the Prognosis and Management of Heart Failure" American Association of Clinical Chemistry Annual Scientific Meeting, Philadelphia, PA, August 1, 2016.

L300) Hemodialysis University, "Is It Heart Failure or Fluid Overload?", Chicago, IL, September 10, 2016.

L301) "Novel Agents for the Treatment of Hyperkalemia" Heart Failure Society of America Annual Scientific Meeting, Orlando, FL, September 18, 2016.

L302) Symposium "Hyperkalemia in the Emergency Department: Updates on the Current Management of a Complex Condition." "Novel Agents for the Prevention and Treatment of Hyperkalemia" American College of Emergency Physicians Scientific Assembly, Las Vegas, NV, October 14, 2016

L303) Moderator "CVD in Patients with CKD: Update from the CRIC Study" Annual Scientific Sessions of the AHA, New Orleans, LA, November 13, 2016

L304) Program Chairman "A Night at the Museum: Inaugural Symposium of the Cardiorenal Society of America Transcending the Dinosaurs: Guiding AKI Prevention using next-gen biomarkers: Real World Experiences from modern practices" satellite Symposium at American Society of Nephrology Kidney Week, Field Museum, Chicago, IL, November 18, 2016

L305) "Pathobiologic Systems Involved in Cardiorenal Disease" 43rd Williamsburg Cardiovascular Conference, Williamsburg, VA, December 3-5, 2016

L306) "Cardiac Cachexia" Heart Failure University, MedReviews LLC, Los Angeles, CA, December 10, 2016

L307) "Is There a Role for Bariatric Surgery in Heart Failure Patients with Obesity?" Scientific Sessions 2017, American College of Cardiology , Washington, DC, March 18, 2017

L308) "Vascular and Cardiac Hypertrophy in Fabry Disease" 5th Annual Fabry Nephropathy Update, Mexico City, Mexico, April 26, 2017

L309) "Introduction to Cardiorenal Medicine" Cardiorenal University, Anaheim, CA, May 18, 2017

L310) "Sudden Death in End-Stage Renal Disease" Cardiorenal University, Anaheim, CA, May 18, 2017

L311) "Cardiorenal Syndromes and Heart Failure" Conference Chair, Disease Global Outcomes (KDIGO) Controversies Conference on Heart Failure in Chronic Kidney Disease, Athens, Greece, May 25-28, 2017

L312) "Vadadustat Does Not Prolong Corrected QT Interval In A Thorough QTC Study In Healthy Subjects" 54th ERA-EDTA Congress, Madrid, Spain, June 3-6, 2017

L313) "Cardiorenal Syndromes" 1st Annual Heart iN Diabetes: Where the Heart, Kidney, and Diabetes Meet in Clinical Practice, Philadelphia, PA, July 14-16, 2017

L314) "Cardiovascular Disease in Patients with Chronic Kidney Disease: A Serious Link" TOP 2017--Target Organ Protection Conference, Bangalore, India, August 11, 2017

L315) "Statin Therapy to Prevent Onset and Progression of Vascular Disease" TOP 2017--Target Organ Protection Conference, Bangalore, India, August 11, 2017

L316) "Keynote Address: Cardiorenal Society of America" 5th Annual Scientific Meeting of the Cardiorenal Society of America, Phoenix, AZ, October 6, 2017

L317) "Cardiovascular Benefits of Home Hemodialysis" Addressing Unmet Needs in Dialysis: Cardiovascular Care and Volume Control Symposium, Kidney Week 2017 American Society of Nephrology, New Orleans, LA, November 4, 2017

L318) "CIEDs in ESRD Patients: What Are the Long-Term Data?" Kidney Week 2017 American Society of Nephrology, New Orleans, LA, November 4, 2017

L319) "Cardiovascular Seminar Cardiorenal Syndrome: Who hurts who?" AHA Scientific Sessions 2017, Anaheim, CA, November 14, 2017

L320) "Cardiac and Renal Fibrosis in CRS" AHA Scientific Sessions 2017, Anaheim, CA, November 14, 2017

L321) Chair, Inaugural Cardiometabolic University and Nutrition Academy "The Skinny on Weight Loss: Practical Considerations for the Cardiovascular Specialist" MedReviews, Westlake, TX, December 1-3, 2017

L322) "Clinical Laboratory Advancements in Cardiometabolic Disease: Screening, Diagnosis, Prognosis, and Management" 44th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 4, 2017

L323) "The Skinny on Weight Loss: Practical Approaches for the Cardiovascular Specialist" Cardiometabolic University 2017, Conference Chair, Dallas, TX , December 1-3, 2017

L324) "Diagnosis, Evaluation, and Role of Biomarkers in Heart Failure" Heart Failure University 2017, Conference Co-Chair, Los Angeles, CA, December 10-12, 2017

L325) "Biomarkers of Kidney Dysfunction and Cardiorenal Syndrome" University of California at San Diego 14th Annual Biomarkers in Heart Failure and Acute Coronary Syndromes: Diagnosis, Treatment and Devices, San Diego, CA, March 2, 2018

L326) "What do I do to Prevent Contrast Induced Renal Injury" 23rd International Conference on Continuous Renal Replacement Therapies CRRT 2018, San Diego, CA, March 8, 2018

L327) "AKI in the patient with Cancer" 23rd International Conference on Continuous Renal Replacement Therapies CRRT 2018, San Diego, CA, March 8, 2018.

L328) "CKD-Related Anemia and Cardiac Complications" NKF Spring Clinical Meetings, Austin, TX April 14, 2018

L329) "Principles of Distributive Shock" Cardiorenal Society of America National Grand Rounds Series, Boston, MA, April 30, 2018

L330) "Biomarkers with More Muscle: Moving Beyond Serum Creatinine to Define Cardiorenal Syndrome in HF" Heart Failure Society of American Annual Scientific Sessions, Nashville, TN, September 15, 2018

L331) "Heart Failure in Cardiorenal Syndrome: Updates on Biomarkers" Cardiorenal Society of America Annual Scientific Meeting, Phoenix, AZ, October 6, 2018

L332) "Novel Approaches in Lowering LDL-C" Cardiorenal Society of America Annual Scientific Meeting, Phoenix, AZ, October 6, 2018

L333) "What Do We Know About Cardiorenal Physiology? An Overview" American Society of Nephrology Kidney Week, San Diego, CA, October 26, 2018

L334) "Prevention of Heart Failure: The Next Frontier" Cardiometabolic Health Conference, Boston, MA, October 27, 2018

L335) "AKI and Heart Failure: How to Manage Compared to the General Population" Cardiometabolic Health Conference, Boston, MA, October 27, 2018

L336) "SGLT-2 Inhibitors and Cardio-renal Outcomes: Mechanistic Role and Rationale for Treatment of Heart Failure" American Heart Association Annual Scientific Sessions, Chicago, IL, November 10, 2018

L337) "Obesity and Heart Disease" 44th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 4, 2018

L338) "Current Concepts in Hypertension Management" University of Texas Health Science Center, Tyler, TX, January 15, 2019

L339) "Managing the Heart Failure Patient with Worsening Renal Function (WRF)" 24th International Conference on Continuous Renal Replacement Therapies CRRT 2019, San Diego, CA, February 28, 2019

L340) "Cardiorenal Syndrome: What Have We Learned?" 24th International Conference on Continuous Renal Replacement Therapies CRRT 2019, San Diego, CA, February 28, 2019

L341) " Debate: Biomarker Guided Heart Failure Therapy: Con: Neuropeptides; ST2" 15th Annual USCD Biomarkers in Heart Failure and Acute Coronary Syndromes, Diagnosis, Treatment & Devices, La Jolla, CA March 1, 2019

L342) "Cardiorenal Syndromes" Cardionephrology Congress, Rome, March 12 to 14, 2019

L343) "Iron and Heart Failure" Cardiometabolic Health Congress West meeting in Phoenix, AZ on Saturday, May 4, 2019

L344) "Up to Date Management of Arrhythmias in Dialysis Patients" National Kidney Foundation Spring Clinical Meetings, May 11, 2019

L345) "Lipids in Chronic Kidney Disease" National Kidney Foundation Spring Clinical Meetings, May 11, 2019

L346) "Cardiorenal Syndromes" Helen Dunham Cardio-Renal Lecture and Cardiovascular Grand Rounds, Brigham and Women's Hospital, Boston, MA, May 23, 2019

L347) "Chronic Kidney Disease as a Cardiovascular Risk State" Helen Dunham Cardio-Renal Lecture and Cardiovascular Grand Rounds, Brigham and Women's Hospital, Boston, MA, May 23, 2019

L348) "Biomarkers and Assessment of Cardiac Function In Fabry Cardiomyopathy" 6th Update on Fabry Disease: Biomarkers, Progression and Treatment Opportunities, Prague, Czech Republic, May 26-28, 2019

L349) "Contrast-Induced Acute Kidney Injury" 37th Vicenza Course on AKI &CRRT, Vicenza, Italy, May, 28-30 2019

L350) "Cardiac Biomarkers in AKI" 37th Vicenza Course on AKI &CRRT, Vicenza, Italy, May, 28-30 2019

L351) "Risk Mitigation in the Cardiac Catheterization Laboratory" 37th Vicenza Course on AKI &CRRT, Vicenza, Italy, May, 28-30 2019

L352) "Pathophysiology and Current Concepts in Classification" Clinical Practice Clinical Science Track: Treatment of Cardiorenal Syndrome, American Heart Association Hypertension Scientific Sessions, New Orleans, LA, Sept 8, 2019

L353) "Cardiovascular Genetics" 44th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 9, 2019

L354) "Cardiorenal Syndromes" 17th World Congress on Insulin Resistance, Diabetes & Cardiovascular Disease (WCIRDC), Los Angeles, CA, December 4-7, 2019

L355) "Cardiorenal Syndromes" Internal Medicine Grand Rounds, Eastern Virginia College of Medicine, Norfolk, VA, February 19, 2020

L356) "Keynote Address: Prevention of Heart and Kidney Disease" Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 6, 2020

L357) "Cardioprotective Effects of Antidiabetic Medications: Focus on Sodium-Glucose Transporter-2 Antagonists" Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 7, 2020

L358) "Fabry Disease: A Unique Cardiorenal Model" Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 7, 2020

L359) "Biomarkers in Heart and Kidney Disease: Practical Applications" Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 7, 2020

L360) "Expert Briefing from ADA 2020 Select Sessions: Update on Heart Failure for the Diabetologist & Cardiorenal–Metabolic Axis in Diabetes" American Diabetes Association, June 14, 2020

L361) "CKD, CHD and Hyperkalaemia: Clinical Outcomes, Morbidity and Mortality" American College of Cardiology - American Society of Nephrology Masterclass September 11, 2020

L362) "RAASi Enabling in Cardiology Practice - Traditional vs New Potassium Binders; Potassium Binders for Treatment of Hyperkalaemia in HF" American College of Cardiology - American Society of Nephrology Masterclass September 11, 2020

L363) "Optimizing Transitions from Hospital to Home: Best Practices for Reducing Readmissions in Heart Failure" Hospital Management Summit, October 3, 2020.

L364) "Assessment and Management of Hyperkalemia in the Hospital Setting: Optimizing Patient Outcomes" Hospital Management Summit, October 3, 2020.

L365) "Navigating the Challenges of Cardio-Renal Syndrome" 7th Annual Kansas Cardiovascular Symposium, October 10, 2020

L366) "Management Considerations for Heart Failure in CKD" American Society of Nephrology Kidney Week 2020, October 24, 2020

L367) "Pathophysiologic Basis and Rationale for Early Ambulatory Treatment of SARS-CoV-2 (COVID-19), SciInov, November 2, 2020

L368) "CV and Renal Benefits with new anti-diabetes medications: Potential Mechanisms" CReDO Conferences Middle East North Africa (MENA) 2020, November 6, 2020

L369) "Consequences of Withholding GDMT for Heart Failure in CKD: One Step Forward, Two Steps Back" AHA 2020 November 16, 2020

L370) "Early Ambulatory Treatment for SARS-CoV-2 (COVID-19)" Early Outpatient Treatment: An Essential Part of a COVID-19 Solution. US. Senate Committee on Homeland Security and Governmental Affairs, Washington DC November 19, 2020

L371) "Pathophysiological Basis & Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection" 18th Annual World Congress Insulin Resistance Diabetes & Cardiovascular Disease, December 3, 2020

L372) "Early Ambulatory Therapy for COVID-19 and Update on Vaccine Safety" Heritage Foundation, Washington DC, June 23, 2021

L373) "Pathophysiological Basis and Clinical Rationale for Early Ambulatory Treatment of COVID-19" Question Everything Conference Lockdowns – Is Now the Time for a Better Solution?, London, UK, July 17, 2021

L374) "Pathophysiological Basis and Clinical Rationale for Early Ambulatory Treatment of COVID-19 and Update on Vaccine Safety" American Academy of Anti-Aging Medicine, Ann Arbor, MI, July 18, 2021

L375) "Keynote: Winning the War Against Therapeutic Nihilism and the Rush to Replace Trusted Treatments with Untested Novel Therapies" Association of American Physicians and Surgeons, AAPS 78th Annual Meeting, Sept. 30 to Oct. 2, 2021 – Pittsburgh, PA, October 2, 2021

INTERNAL COMMITTEE POSITIONS

1) Member, Henry Ford Medical Group Hypertension Control Committee, 1998.

2) Ranking Member and Presenter, HFHS Institutional Review Board, 1998-2000.

3) Member, HFHS Teaching and Education Committee, Co-Chair of the Research Subcommittee, 1999-2000

4) Member, HFHS Graduate Medical Education Committee, 1999-2000.

5) Member, HFHS, Internal Medicine Residency Selection Committee, 1998-2000.

6) Chair, HFHS, Cardiovascular Diseases Fellowship Program Selection Committee, 1999-2000.

7) Co-Chair, HFHS, Information Technology and Medical Records Committee, 1999-2000.

8) Member, HFHS Department of Internal Medicine, Research Committee, 1999-2000.

9) Member, UMKC Adult Health Sciences Institutional Review Board, 2001-2002

10) Member, UMKC, Cardiovascular Diseases Fellowship Program Selection Committee, 2000-2002

11) Member, Truman Medical Center (TMC) Information Technology Steering Committee, 2001-2002.

12) Member, WBH Diabetes Research Center Steering Committee, 2002-2003

13) Chairperson, WBH Staff Privileges Appeals Committee, March 31, 2004

14) Chairperson, WBH Search Committee for Medical Director of Transplantation Medicine, 2005-2006

15) WBH Research Institute Board of Governors, board member, 2007-2010

16) Oakland University William Beaumont School of Medicine, Medical Student Committee (founding) for development of Liaison Committee on Medical Education (LCME) application, 2007-2010

17) St. John Providence Health System Graduate Medical Education Steering Committee (Chair), 2010 to 2013

18) St. John Providence Health System Research Leaders Committee, Chair, 2010 to 2012; Co-Chair 2012 to 2013

19) Ascension Michigan Research Affinity Group, Chair, 2010 to 2012; Co-Chair 2012 to 2013

20) St. John Providence Health System Executive Committee, 2011 to 2013

21) St. John Providence Health System Guidelines Committee, 2012 to 2013

22) St. John Providence Health System Presidents Council, 2012 to 2013

23) St. John Providence Health System Electronic Medical Record Meaningful Use Steering Committee, 2013

24) BUMC Graduate Medical Education Committee, 2014 to present

25) BUMC Internal Medicine Residency Program Clinical Competency Committee, 2014 to 2021

26) BUMC Clinical Cardiology Fellowship Program Clinical Competency Committee, 2014 to 2021

27) BUMC Founding Member, Department of Molecular Pathology and Medicine, 2016 to 2021

28) BUMC Precision Medicine Executive Committee, 2016 to 2021

29) BUMC COVID-19 Therapeutic Task Force 2020

EXTERNAL COMMITTEE POSITIONS

1) Member, AHA National Women's Heart Disease and Stroke Campaign, Healthcare Provider Sub-Group, Dallas, TX, 1998-1999

2) Member, AHA, Chronic Coronary Disease in the Elderly National Database Planning Committee, Dallas, TX, 1998-2000

3) Chair, Michigan Chapter of the American College of Cardiology, Annual Mini-Board Review, 1999-2000

4) Member, Michigan Chapter of the American College of Cardiology, Annual Meeting Planning Committee, 1999-2000

5) Member, National Kidney Disease Outcomes Quality Initiative (K/DOQI) Clinical Practice Guidelines Committee on Chronic Kidney Disease, Andrew S. Levey, MD, Chair, 2001-2002

6) Member, K/DOQI Learning System (KLS)™ Advisory Board, NKF, New York, NY, 2003 to 2010

7) Member, International EECP Patient Registry Working Group, 2003-2008.

8) Counselor at large, Michigan Chapter of the American College of Cardiology, 2004-2006

9) Member, Planning Committee, AHA, Prevention VIII Conference: Kidney Disease, Hypertension, and Cardiovascular Disease, January 26-28, 2006, Orlando, FL

10) Chair, Contrast-Induced Nephropathy (CIN) Working Group Consensus Panel, (international, multispecialty, consensus panel with published findings) 2004-2006. Published in *Am J Cardiol* 2006 Vol 98(6)

11) Workgroup Member, Kidney Disease Improving Global Outcomes (KDIGO), United States Representative, Amsterdam, Netherlands, 2004, 2006

12) Member, Kidney Disease Improving Global Outcomes (KDIGO) Group for the development of Clinical Practice Guidelines for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease Related Mineral and Bone Disorders (CKD-MBD), Paris, France, 2007-2008

13) Board of Directors Member, Kidney Disease Improving Global Outcomes (KDIGO), United States Representative, Brussels, Belgium, 2007-2010

14) Workgroup Member, The Sixth International Acute Dialysis Quality Initiative (ADQI) Consensus Conference VI: Acute Kidney Injury in Cardiac Surgery, Vicenza, Italy May 27 – 28, 2007

15) Workgroup Leader, Prevention: The Seventh International Acute Dialysis Quality Initiative (ADQI) Consensus Conference VII: Cardiorenal Syndrome, Venice, Italy, September 4-5, 2008, with publication n *Nephrology, Dialysis, and Transplantation*, 2010.

16) Chairman, Natriuretic Peptide Testing in Acute Coronary Syndromes Consensus Panel, with published findings in *Reviews in Cardiovascular Medicine* 2010, Dallas, TX, March 2, 2010

17) Scientific Advisory Board, NKF, New York, NY, 2010 to present

18) Scientific Advisory Board, Cardiorenal Society of America, Phoenix, AZ, 2012 to present

19) Workgroup Member, "Cardiovascular Disease in CKD: What is it and what can we do about it?" Kidney Disease Improving Global Outcomes (KDIGO), October 29-31, 2010, London, England.

20) Chairman, "Cardio-Renal Syndromes II: from pathophysiology to therapy" Eleventh Consensus Conference Cardio-Renal Syndromes II November 30 – December 2, 2012, Venice, Italy.

21) Conference Co-Chair: "Kidney Disease Global Outcomes (KDIGO) Controversies Conference on Heart Failure in Chronic Kidney Disease", Athens, Greece, May 25-28, 2017

22) Chairman, "Cardiometabolic University", Dallas, TX, December 3-4, 2017

23) Chair, American Heart Association Council on the Kidney in Cardiovascular Disease and Council on Clinical Cardiology. Cardiorenal Syndrome: Classification, Pathophysiology, Diagnosis, and Treatment Strategies: A Scientific Statement From the American Heart Association, 2019

24) Committee Member, American College of Cardiology, Navigating Treatment Decisions for Patients with ASCVD and Multiple Comorbidities Committee, 2019-2020

25) Chief Medical Advisor, Truth for Health Foundation, Tucson AZ, 2021 to present

26) Advisory Board Member, TrialSite News, 2021 to present

27) National and International Advisor/Reviewer/Presenter/Contributor for 4D Molecular Therapies, ABC News, Abbott Laboratories, AbbVie, Advanced Health Media, Aegerion, Affymax, Akceia, Akebia, Alere North America, AMAG, Amersham, Amgen, Amylin, AntiSeptiscope, Aralez, Ardian, Adelyx, Arra Hitech, Astellas, AstraZeneca, Astute Medical, Atherotech, Axio, BG Medicine, Avenue Therapeutics, Aventyn, Back Bay Lifescience Advisors, Bayer, Biocritique, Bioexpertise, Biomarin, Bionest Partners, Bioporto, Biosite, Biostar, BioZ, Boehringer Ingelheim, Braintree Laboratories, Broeker, Bristol Myer Squibb, Cardiokine, Cardiorentis, Chapman and Priest, Charles River Associates, Chelsea Therapeutics, Chiesi USA, ClearView Healthcare Partners, Clinipace, Complexa, Connected Research and Consulting, CorMedix, Cornerstone Therapeutics, Corvidia, Covance, Critical Diagnostics, Cromsource, Crossover Technologies, Chrysalis BioTherapeutics, Cytopheryx, Cytel, DaVita, Daws, DeMatteo Monness, Diadexus, Daiichi Sankyo, Decision Resources, ECG Healthcare, Edwards Life Sciences, Elsevier, Espirion, F. Hoffmann-La Roche Ltd, Fast Biomedical, Fish and Richardson, LLC, Fisher Scientific, FlowMedica Inc, Frictionless Digital, Fresenius Medical Care, General Electric, Genzyme, Gerson Lehrman, Gilead, GVI Clinical Development Solutions, Health Law Partners, Healthspan DX, HealthSTAR Communications, Hershey, Hikari, Hogan Lovells, Hudson Global, ICON, Huff, Powell, and Bailey, LLC, IMC Press, Imidex, Impact Education, Instrumentation Laboratories, Intercept Pharmaceuticals, Intrinsic Life Sciences, Ischemix Technologies, Janssen, Jannsen, Johnson and Johnson, Jordan, KAI Research, Keryx, Ketchum, Inc, Knowledge Point 360, Kowa, Eli Lilly, LabCorp, Lewis Brisbois, Liberty Dialysis, Ligand, Lipocine, Litchfield Cavo, Luitpold Pharmaceuticals, Lundbeck, Maxaccess Managed Markets, MannKind, MEDACorp, MedEd Group, Medevera, Medical Exchange International, Medical Package, Medicines Company, Medicure Pharma, Inc., MedReviews, Medscape, Medtronic, Merck, Meridian 361 International Law Group, Meso Scale Diagnostics, Miller Tanner Associates, Mitsubishi, Nanomix, Nanosphere, Nabi Biopharmaceuticals, Navigant, NephroGenix, Neumedicines, Noorik GmbH, Norman, Hanson, and Detroy, LLC, Novartis, NovoNordisk, NxStage, Ortho Clinical Diagnostics, Osprey, Otsuka, Overcome, P-value Communications, Parexel, Pharmapprove, Pfizer, Phoenix Holdings, Physicians World, PLC Medical, Praetego, PriMed, Progenabiome, Quidel Corporation, Qualidigm, Quintiles, Reata, Reliant Pharmaceuticals, Renew Research, Relypsa, Repros Therapeutics, Roche Diagnostics, Rock Creek, Saferox, Saghmos Therapeutics, Salix, Sanfit, Sankyo, Sanofi, Sarepta Therapeutics, Scarritt Group, Sentinel Investment, Sloan Law Firm, Sphingotec, Spectracell, St. Jude Medical, Strataca Systems, Statprobe, Sunshine Heart, Synageva, Takeda, Tasly, TheHill, Thrasos, TrialSiteNews, Trinity, Triptych Health Partners, US Medical Management, Vasomedical, Verrow, Vindico, Visiting Physicians Association, Vitalmetrix, Vivus, Watermark, WebMD, ZS Pharma, Inc.

Exhibit E

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

DECLARATION OF AARON SIRI, ESQ.

I, Aaron Siri, declare as follows:

1. I am the Managing Partner of Siri & Glimstad LLP, counsel to Public Health and Medical Professionals for Transparency ("**PHMPT**"). I am admitted to practice *pro hac vice* in this action. I make this declaration in support of PHMPT's motion for expedited production.

2. The following is a link to a true and correct copy of a video of candidate Joe Biden stating, "[y]ou've got to make all of it [the vaccine data] available to other experts across the nation so they can look and see, so there's a consensus this is a safe vaccine" available at https://www.c-span.org/video/?c4988427/user-clip-jul-28-2020.

3. The following is a link to a true and correct copy of a video of Joe Biden stating, "I get asked the question, if . . . President [Trump] announced tomorrow we have a vaccine, would you take it? Only if it was completely transparent and other experts in the country could look at it. Only if we knew all of what went into it" available at https://www.facebook.com/ABCNewsPolitics/videos/902987476894155/ (at 24:10).

4. The following is a link to a true and correct copy of a video of Joe Biden stating that we need "total transparency so scientists outside the government know exactly what Is being approved" available at https://abcnews.go.com/Politics/video/biden-trust-vaccine-proven-safe-scientists-73058501.

5. Exhibit 1, attached hereto, is a true and correct copy of a document on the FDA's website titled "Detail of Full-Time Equivalents" available at https://www.fda.gov/media/132813/download.

6. Exhibit 2, attached hereto, is a true and correct copy of a page on the White House website titled "Remarks by President Biden at Virtual Global COVID-19 Summit" available at https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/22/remarks-by-president-biden-at-virtual-global-covid-19-summit/.

7. Exhibit 3, attached hereto, is a true and correct copy of an article titled "Wait what? FDA wants 55 years to process FOIA request over vaccine data" available at https://www.reuters.com/legal/government/wait-what-fda-wants-55-years-process-foia-request-over-vaccine-data-2021-11-18/.

8. Exhibit 4, attached hereto, is a true and correct copy of a letter from members of the United States Senate to The Honorable Dr. Stephen Hahn dated September 14, 2020, available at https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf.

9. Exhibit 5, attached hereto, is a true and correct copy of a press release titled "Rep. Ralph Norman Introduces Legislation to Expedite FDA Compliance with FOIA Requests for Vaccine Approval Data" available at https://norman.house.gov/news/documentsingle.aspx?DocumentID=1087.

10. Exhibit 6, attached hereto, is a true and correct screenshot of a tweet by Senator Ted Cruz, available at https://twitter.com/tedcruz/status/1461523687333666817.

11. Exhibit 7, attached hereto, is a true and correct copy of a press release titled "Pfizer and BioNTech Announce an Agreement with U.S. Government for Up To 600 Million Doses of mRNA-Based vaccine Candidate Against SARS-CoV-2" available at https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-government-600.

12. Exhibit 8, attached hereto, is a true and correct copy of a press release titled "Biden Administration purchases additional doses of COVID-19 vaccines from Pfizer and Moderna" available at https://www.hhs.gov/about/news/2021/02/11/biden-administration-purchases-additional-doses-covid-19-vaccines-from-pfizer-and-moderna.html.

13. Exhibit 9, attached hereto, is a true and correct copy of an article that appears on the Pharmacy Today website titled "U.S. buys 200 million COVID-19 vaccines from Pfizer and BioNTech at about $24 a dose" available at https://www.pharmacytoday.org/drugs/drugs-2021-07-27-story2.

14. Exhibit 10, attached hereto, is a true and correct copy of a page on the U.S. Department of Defense's website titled "Contracts For Aug. 2, 2021" available at https://www.defense.gov/News/Contracts/Contract/Article/2716710/.

15. Exhibit 11, attached hereto, is a true and correct copy of an article titled "U.S. Purchases Additional 50 Million Pediatric Doses Of Covid-19 Vaccine, Pfizer Says" available at https://www.forbes.com/sites/roberthart/2021/10/28/us-purchases-additional-50-million-pediatric-doses-of-covid-19-vaccine-pfizer-says/?sh=292ea8c72e62.

16. Exhibit 12, attached hereto, is a true and correct copy of a page on the U.S. Department of Defense's website titled "Contracts For Nov. 22, 2021" available at https://www.defense.gov/News/Contracts/Contract/Article/2851450/.

17. Exhibit 13, attached hereto, is a true and correct copy of a page on the Centers for Disease Control and Prevention's website titled "Novel Coronavirus (COVID-19)" available at https://www.cdc.gov/budget/fact-sheets/covid-19/index.html.

18. Exhibit 14, attached hereto, is a true and correct copy of a page on The White House website titled "FACT SHEET: Biden Administration Announces Historic $10 Billion Investment to Expand Access to COVID-19 Vaccines and Build Vaccine Confidence In Hardest-Hit and Highest-Risk Communities" available at https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/25/fact-sheet-biden-administration-announces-historic-10-billion-investment-to-expand-access-to-covid-19-vaccines-and-build-vaccine-confidence-in-hardest-hit-and-highest-risk-communities/.

19. Exhibit 15, attached hereto, is a true and correct copy of an article titled "White House announces new funds for COVID-19 testing and vaccination amid delta surge" available at https://thehill.com/policy/healthcare/564335-white-house-announces-new-funds-for-covid-19-testing-and-vaccination-amid.

20. Exhibit 16, attached hereto, is a true and correct copy of an email from Courtney D. Enlow dated December 1, 2021.

21. Exhibit 17, attached hereto, is a true and correct screenshot of data from the Centers for Disease Control and Prevention's COVID Data Tracker, available at https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.

22. Exhibit 18, attached hereto, is a true and correct copy of an article titled "States with High Vaccination Rates Can Still Experience COVID-19 Surges – Here's Why" available at https://www.healthline.com/health-news/states-with-high-vaccination-rates-can-still-experience-covid-19-surges-heres-why.

23. Exhibit 19, attached hereto, is a true and correct copy of a Media Statement titled "Statement from CDC Director Rochelle P. Walensky, MD, MPH on Today's MMWR" available at https://www.cdc.gov/media/releases/2021/s0730-mmwr-covid-19.html.

24. Exhibit 20, attached hereto, is a true and correct copy of an article titled "The new Omicron COVID variant Is a stark reminder that we are still In the depths of the pandemic" available at https://fortune.com/2021/11/26/omicron-south-africa-covid-variant-vaccine-resistant-pandemic/.

25. Exhibit 21, attached hereto, is a true and correct copy of an article titled "Rising Covid-19 Breakthrough Cases Hinder Efforts to Control Virus" available at https://www.wsj.com/articles/rising-covid-19-breakthrough-cases-hinder-efforts-to-control-virus-11636191003.

26. Exhibit 22, attached hereto, is a true and correct copy of a page on the Centers for Disease Control and Prevention's website titled "COVID-19 Vaccine Booster Shots" available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html.

27. Exhibit 23, attached hereto, is a true and correct copy of a page on Pfizer's website titled "Transparency In Clinical Trials" available at https://cdn.pfizer.com/pfizercom/Clinical-Trial-Transparency-Policy-Paper-FINAL-2019.pdf.

28. Exhibit 24, attached hereto, is a true and correct copy of an article titled "Transparency of COVID-19 vaccine trials: decisions without data" available at

https://archive.hshsl.umaryland.edu/bitstream/handle/10713/16360/bmjebm-2021-111735.full.pdf?sequence=1&isAllowed=y.

29. Exhibit 25, attached hereto, is a true and correct copy of an FDA News Release titled "FDA Approves First COVID-19 Vaccine" dated August 23, 2021, available at https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

30. Exhibit 26, attached hereto, is a true and correct copy of a Citizen Petition dated June 1, 2021, available at https://www.regulations.gov/document/FDA-2021-P-0521-0001.

31. Exhibit 27, attached hereto, is a true and correct copy of an article titled "Why we petitioned the FDA to refrain from fully approving any covid-19 vaccine this year" available at https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/.

32. Exhibit 28, attached hereto, is a true and correct copy of an article titled "Did the FDA understaff its review of the Pfizer/BioNTech vaccine?" available at https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-pfizer-biontech-vaccine/.

33. Exhibit 29, attached hereto, is a true and correct copy of an article titled "Does the FDA think these data justify the first full approval of a covid-19 vaccine?" available at https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/.

34. Exhibit 30, attached hereto, is a true and correct copy of an article titled "Covid-19: FDA set to grant full approval to Pfizer vaccine without public discussion of data" available at https://www.bmj.com/content/374/bmj.n2086.

35. Exhibit 31, attached hereto, is a true and correct copy of a page on the White House website titled "Fact Sheet: Biden Administration Announces Details of Two Major Vaccination Policies" available at https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/fact-sheet-biden-administration-announces-details-of-two-major-vaccination-policies/. The full version of the Emergency Temporary Standard issued by the Occupational Safety and Health Administration published in the Federal Register on November 5, 2021 is available at https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard.

36. Exhibit 32, attached hereto, is a true and correct copy of a page on the White House website titled "Path Out of the Pandemic" available at https://www.whitehouse.gov/covidplan/.

37. Exhibit 33, attached hereto, is a true and correct copy of a document titled "Memorandum for Senior Pentagon Leadership Commanders of the Combatant Commands Defense Agency and DOD Field Activity Directors" available at https://media.defense.gov/2021/Oct/04/2002867430/-1/-1/0/MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DOD-CIVILIAN-EMPLOYEES-OSD008990-21-RESP-FINAL.PDF.

38. Exhibit 34, attached hereto, is a true and correct copy of a page on the University of Colorado Boulder's website titled "COVID-19 Vaccination Requirements and Process" available at https://www.colorado.edu/covid-19-updates/covid-19-vaccination.

39. Exhibit 35, attached hereto, is a true and correct copy of a page on sf.gov titled "Vaccine required" available at https://sf.gov/information/vaccine-required.

40. Exhibit 36, attached hereto, is a true and correct copy of an article titled "Dr. Anthony Fauci: Expect 'a flood' of COVID-19 vaccine mandates after full FDA approval"

published August 6, 2021, available at https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/.

41. Exhibit 37, attached hereto, is a true and correct copy of the FOIA request at issue in this case, which is dated August 27, 2021 and was submitted by PHMPT to the Food and Drug Administration.

42. Exhibit 38, attached hereto, is a true and correct copy of the confirmation PHMPT received upon submitting the FOIA Request.

43. Exhibit 39, attached hereto, is a true and correct copy of a letter dated August 31, 2021 issued by the FDA to PHMPT.

44. Exhibit 40, attached hereto, is a true and correct copy of a letter dated September 9, 2021 issued by the FDA to PHMPT.

45. Exhibit 41, attached hereto, is a true and correct copy of an email from Courtney D. Enlow dated December 2, 2021.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge.

Dated: December 7, 2021

Aaron Siri, Esq.

Exhibit 1

DETAIL OF FULL-TIME EQUIVALENTS

	FY 2018 Actuals			FY 2019 Estimate			FY 2020 Estimate		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Center for Food Safety and Applied Nutrition	1,069	36	1,105	1,114	36	1,150	1,194	36	1,230
Center for Drug Evaluation and Research	4,697	506	5,203	4,996	506	5,502	5,118	506	5,624
Center for Biologics Evaluation and Research	1,142	60	1,202	1,103	60	1,163	1,131	60	1,191
Center for Veterinary Medicine	608	12	620	620	12	632	647	12	659
Center for Devices and Radiological Health	1,652	85	1,737	1,731	85	1,816	1,802	85	1,887
National Center for Toxicological Research	307	---	307	301	---	301	301	---	301
Office of Regulatory Affairs	4,449	338	4,787	4,601	338	4,939	4,659	338	4,997
Headquarters and Office of the Commissioner	1,094	75	1,169	926	75	1,001	943	75	1,018
Export Certification	22	---	22	26	---	26	26	---	26
Color Certification	36	---	36	37	---	37	37	---	37
Family Smoking Prevention and Tobacco Control Act	773	36	809	896	36	932	956	36	992
Priority Review Vouchers (PRV) Pediatric Disease	---	---	---	---	---	---	---	---	---
MCMi - No Year	---	---	---	---	---	---	---	---	---
Opiods - No Year	---	---	---	8	---	8	---	---	---
21st Century Cures (BA Only)	26	---	26	100	---	100	100	---	100
Total	**15,875**	**1,148**	**17,023**	**16,459**	**1,148**	**17,607**	**16,914**	**1,148**	**18,062**

Five Year History of GS/GM Average Grade

Year	Grade
FY 2016	13
FY 2017	13
FY 2018	13
FY 2019	13
FY 2020	13

* FTE figures do not include an estimated 87 reimbursable, 2 CRADA, 2 FOIA, and 36 PEPFAR.

Exhibit 2

BRIEFING ROOM

Remarks by President Biden at Virtual Global COVID-19 Summit

SEPTEMBER 22, 2021 • SPEECHES AND REMARKS

South Court Auditorium
Eisenhower Executive Office Building

11:16 A.M. EDT

THE PRESIDENT: Good morning, everyone. And thank you for joining us today.

As I said yesterday at the United Nations, nothing is more urgent than all of us working together to defeat COVID-19. And that — that world is going to be much better prepared for future pandemics. We have to do both.

This summit is about supercharging our efforts in three key areas: vaccinating the world by dramatically ramping up vaccine production, donations, delivery, and administrating the vaccine, which is a logistical — it's a logistical challenge; addressing the oxygen crisis in many hospitals around the world, making other treatments more accessible, and increasing the availability of public health tools like masks and tests; and building back better so that our global health security infrastructure is more resilient than it is today.

We've all suffered. The United States has lost more than 670,000 of our fellow Americans. Worldwide, the death toll is above 4.5 million people — 4.5 million people. And this is a global tragedy.

And we — and we're not going to solve this crisis with half-measures or middle-of-the-road ambitions. We need to go big. And we need to do our part: governments, the private sector, civil society leaders, philanthropists. This is an all-hands-on-deck crisis.

And the good news is, we know how to beat this pandemic: vaccines, public health measures, and collective action.

During the first eight months of my presidency, we have worked aggressively to get Americans and the world vaccinated. As President of the United States, my first responsibility is to protect the American people. And I am proud that we have gone from 2 million Americans being fully vaccinated when I took office in January 20th to 182 million and counting, today, in America.

But we also know that to beat the pandemic here, we need to beat it everywhere. And I made and I'm keeping the promise that America will become the arsenal of vaccines as we were the arsenal of democracy during World War Two.

We have already shipped nearly 160 million doses to 100 countries, more than every other country has donated combined. America's donations of a half a billion Pfizer vaccines through COVAX that I've announced before the G7 Summit in June have already begun to ship.

Today, I'm announcing another historic commitment. The United States is buying another half billion doses of Pfizer to donate to low- and middle-income countries around the world.

This is another half a billion doses that will all be shipped by this time next year. And it brings our total commitment to — of donati- — of donated vaccines to over 1.1 billion vaccines to be donated.

Put another way, for every one shot we've administered to date in America, we have now committed to do three shots to the rest of the world.

I want to thank Pfizer and its CEO and chairman, Albert. Albert has been a good friend and has been helpful. They've been and continue to be partners and a leader in this fight.

And the United States is leading the world on vaccination donations. We need — as we're doing that, we need other high-income countries to deliver on their own ambitious vaccine donations and pledges.

That's why, today, we're launching the EU-U.S. vaccine partnership to work more closely together and with our partners on expanding global vaccinations.

And as we do so, we should unite around the world on a few principles: that we commit to donating, not selling — donating, not selling, doses to low- and lower-income countries, and that the donations come with no political strings attached; and that we support COVAX as the main distributor for sharing WHO-approved vaccines; and that we fight vaccine disinformation and exercise transparency to build vital public trust in these lifesaving tools.

It's also important that we are working toward common goals and targets so that we can measure our progress and hold ourselves and each other accountable.

Secretary of State Blinken will be convening foreign ministers later this year to check on our collective progress. And I propose that we come together for a second high-level virtual summit in the first quarter of 2022 to help gauge our progress and keep our efforts fully aligned.

Another goal is dramatically boosting global and regional vaccine manufacturing capacity, enhancing transparency so that vaccine production and distribution is predictable and coordinated.

In fact, an important part of the reason the United States is able to make these big, historic donations is because we've worked with U.S. vaccine manufacturers to accelerate the manufacturing rate and production. And now we're working quickly to scale up vaccine manufacturing in other countries around the world so they can manufacture as well.

We're working with partner nations, pharmaceutical companies, and other manufacturers to increase their own capacity and capability to produce and manufacture safe and highly effective vaccines in their own countries. For example, our Quad partnership with India, Japan, and Australia is on track to help produce at least 1 billion vaccine doses in India to boost the global supply by the end of 2022.

And we're providing financing and helping strengthen manufacturing in South Africa and produce more than 500 million doses of J&J in Africa, for Africa next year.

And next, we also know from experience that getting those vaccines into people's arms may be the hardest logistical challenge we've faced. That's why we need to significantly step up our investment in helping countries get shots in arms.

Today, the United States is also announcing that we're providing an additional $370 million to support administering these shots and delivery globally. And we will be providing more than $380 million to assist in the Global Vaccine Alliance — GAVI — to further facilitate vaccine distribution in regions in the greatest — with the greatest need.

And while vaccinating the world is the ultimate solution to COVID-19, we know that we have to act to save lives now. That's why the United States are providing nearly $1.4 billion to reduce COVID-19 deaths and mitigate transmission through bulk oxygen support, expanded testing, and strengthening healthcare systems and more.

And we're going to help all of us build back better by supporting the establishment of a financial mechanism for global health security — to simply state — to prepare for the next pandemic, because there will be a next time. We all know that. Vice President Harris will be speaking more on this issue later today.

And finally, I want to acknowledge the leaders from the private sector, philanthropy, and civil society who are here today.

Governments can do a lot, but we cannot do everything on our own. We've asked our nongovernmental partners to take up the call for new actions that will solve the core challenges of making vaccines available to everyone, everywhere; solving the oxygen availability crisis; financing health security; and more. And I'm grateful — I'm grateful for their leadership.

And let me close by — with what I made clear yesterday at the U.N.: We can do this. This is within our capacity. We know what needs to be done. We just have to make the choice to do it.

You know, the leaders on the screen that I see here today, I know they've made that choice. And I think they know we can do this.

And I promise you, the United States will continue to lead. We'll continue to drive historic commitments in vaccine donations — 1.1 billion and counting — so we can defeat COVID-19 together.

And we'll continue to invest in creating a future of true global health security for all people. That is a big, big goal I ha- — we have — we should have. And we're going to lead with the power of our example. And we're not going to stop.

But the only way to get this done is for everyone, everywhere — is for all of us to step up, which I'm confident you will.

And now I'd like to turn this over to Ambassador Thomas-Greenfield of the United Nations. And I want to thank everybody on the screen I can see here, without going to each one of you.

11:25 A.M. EDT

Exhibit 3

Commentary | Legal Action by Jenna Greene

November 18, 2021 2:31 PM MST Last Updated 19 days ago

COVID-19 | Health | Litigation

Wait what? FDA wants 55 years to process FOIA request over vaccine data

By Jenna Greene

4 minute read

The Food and Drug Administration (FDA) headquarters in White Oak, Maryland, August 29, 2020. REUTERS/Andrew Kelly

Related documents

Complaint

View

Status report

View

(Reuters) - Freedom of Information Act requests are rarely speedy, but when a group of scientists asked the federal government to share the data it relied upon in licensing Pfizer's COVID-19 vaccine, the response went beyond typical bureaucratic foot-dragging.

As in 55 years beyond.

That's how long the Food & Drug Administration in court papers this week proposes it should be given to review and release the trove of vaccine-related documents responsive to the request. If a federal judge in Texas agrees, plaintiffs Public Health and Medical Professionals for Transparency can expect to see the full record in 2076.

The 1967 FOIA law requires federal agencies to respond to information requests within 20 business days. However, the time it takes to actually get the documents "will vary depending on the complexity of the request and any backlog of requests already pending at the agency," according to the government's central **FOIA website**.

Justice Department lawyers representing the FDA note in court papers that the plaintiffs are seeking a huge amount of vaccine-related material – about 329,000 pages.

The plaintiffs, a group of more than 30 professors and scientists from universities including Yale, Harvard, UCLA and Brown, **filed suit** in September in U.S. District Court for the Northern District of Texas, seeking expedited access to the records. They say that releasing the information could help reassure vaccine skeptics that the shot is indeed "safe and effective and, thus, increase confidence in the Pfizer vaccine."

But the FDA can't simply turn the documents over wholesale. The records must be reviewed to redact "confidential business and trade secret information of Pfizer or BioNTech and personal privacy information of patients who participated in clinical trials," wrote DOJ lawyers in a **joint status report** filed Monday.

The FDA proposes releasing 500 pages per month on a rolling basis, noting that the branch that would handle the review has only 10 employees and is currently processing about 400 other FOIA requests.

"By processing and making interim responses based on 500-page increments, FDA will be able to provide more pages to more requesters, thus avoiding a system where a few large requests monopolize finite processing resources and where fewer requesters' requests are being fulfilled," DOJ lawyers wrote, pointing to other court decisions where the 500-page-per-month schedule was upheld.

Civil division trial lawyer Courtney Enlow referred my request for further comment to the DOJ public affairs office, which did not respond.

Plaintiffs' lawyers argue that their request should be top priority, and that the FDA should release all the material no later than March 3, 2022.

"This 108-day period is the same amount of time it took the FDA to review the responsive documents for the far more intricate task of licensing Pfizer's COVID-19 vaccine," wrote Aaron Siri of Siri & Glimstad in New York and John Howie of Howie Law in Dallas in court papers.

"The entire purpose of the FOIA is to assure government transparency," they continued. "It is difficult to imagine a greater need for transparency than immediate disclosure of the documents relied upon by the FDA to license a product that is now being mandated to over 100 million Americans under penalty of losing their careers, their income, their military service status, and far worse."

They also argue that **Title 21, subchapter F** of the FDA's own regulations stipulates that the agency "is to make 'immediately available' all documents underlying licensure of a vaccine."

Given the intense public interest in the vaccine, the plaintiffs' lawyers say that the FDA "should have been preparing to release (the data) simultaneously with the licensure. Instead, it has done the opposite."

Siri declined comment.

To meet the plaintiffs' proposed FOIA deadline, the FDA would have to process a daunting 80,000 pages a month. But the plaintiffs note that the FDA has 18,000 employees and a budget of $6 billion and "has itself said that there is nothing more important than the licensure of this vaccine and being transparent about this vaccine."

To be sure, most people -- including many who sanctimoniously proclaim "I do my own research" -- lack the expertise to evaluate the information.

But the plaintiffs, who also include overseas professors from the UK, Germany, Denmark, Australia and Canada, appear to be well-positioned to do so.

As Siri and Howe argue, "Reviewing this information will settle the ongoing public debate regarding the adequacy of the FDA's review process."

U.S. District Judge Mark Pittman has set a scheduling conference for December 14 in Fort Worth to consider the timeline for processing the documents.

Opinions expressed here are those of the author. Reuters News, under the Trust Principles, is committed to integrity, independence and freedom from bias.

Jenna Greene

Jenna Greene writes about legal business and culture, taking a broad look at trends in the profession, faces behind the cases, and quirky courtroom dramas. A longtime chronicler of the legal industry and high-profile litigation, she lives in Northern California. Reach Greene at jenna.greene@thomsonreuters.com

More from Reuters

Sign up for The Daily Docket

Subscribe for our daily curated newsletter to receive the latest Reuters legal news and headlines delivered to your inbox.

Sign up

Industry Insight

Industry Insight

Kirkland shortens path to full partnership amid legal talent war

December 1, 2021

Diversity

How law firms increase DEI among business services and allied professionals

December 1, 2021

Exhibit 4

United States Senate
WASHINGTON, DC 20510

September 14, 2020

The Honorable Dr. Stephen Hahn
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Hahn:

We write to seek your commitment that the Food and Drug Administration's (FDA) review process for potential vaccinations against the coronavirus disease 2019 (COVID-19) will be fully transparent and accountable. We are encouraged by the development of a number of vaccine candidates,[1] and we share the FDA's goal of facilitating "the timely development of safe and effective vaccines to prevent COVID-19."[2] However, we are concerned that the accelerated timeline and intense political pressure around the vaccine development process could have the unintended consequence of undermining public confidence in the safety and quality of an eventual vaccine.

The rapid speed of COVID-19 vaccine development is unprecedented. Currently, more than 100 vaccines against COVID-19 are in development around the world,[3] with 37 currently in human clinical trials.[4] The previous record time for a vaccine to move from concept to approval was four years.[5] This progress reflects remarkable effort and collaboration by scientists around the world, as well as significant financial support from governments.[6] To address public concerns that the rapid speed of vaccine development could implicate the integrity of the review process,[7] the FDA issued guidelines in June 2020 to assist in the clinical development and

[1] New York Times, "Coronavirus Vaccine Tracker," Jonathan Corum, Denise Grady, Sui-Lee Wee and Carl Zimmer, September 8, 2020, https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html.
[2] Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines," press release, June 30, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-help-facilitate-timely-development-safe-effective-covid.
[3] New York Times, "Different Approaches to a Coronavirus Vaccine," Jonathan Corum, Knvul Sheikh, and Carl Zimmer, May 20, 2020, https://www.nytimes.com/interactive/2020/05/20/science/coronavirus-vaccine-development.html.
[4] New York Times, "Coronavirus Vaccine Tracker," Jonathan Corum, Denise Grady, Sui-Lee Wee and Carl Zimmer, September 8, 2020, https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html.
[5] Washington Post, "These are the top coronavirus vaccines to watch," Aaron Steckelberg, Carolyn Y. Johnson, Gabriel Florit and Chris Alcantara, September 8, 2020, https://www.washingtonpost.com/graphics/2020/health/covid-vaccine-update-coronavirus/.
[6] *Id.*
[7] JAMA, "Unwavering Regulatory Safeguards for COVID-19 Vaccines," Anand Shah, Peter W. Marks, and Stephen M. Hahn, August 7, 2020, https://jamanetwork.com/journals/jama/fullarticle/2769421.

licensure of vaccines for COVID-19.[8] Yet, the Trump Administration continues to apply political pressure on the agency—including President Trump's promise in his Republican National Convention speech that a vaccine will be approved by the end of 2020.[9] The Centers for Disease Control and Prevention's (CDC) recent announcement[10] that states should be prepared to distribute a vaccine by November 1 has further raised concerns that the approval process will be rushed.[11] That political pressure risks undermining public confidence in the FDA's review process unless the agency commits to expanding transparency even further.

President Trump has been exerting political pressure on the FDA for months, and at times, the agency has appeared to submit to this pressure. On August 22, President Trump tweeted, "The deep state, or whoever, over at the FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics. Obviously, they are hoping to delay the answer until after November 3rd,"[12] referring to the presidential election. Just one day later, at a White House briefing, President Trump announced that the FDA was issuing an emergency use authorization (EUA) for convalescent plasma, claiming that the treatment is "safe and very effective" according to the FDA,[13] even as senior government scientists and former FDA officials say that plasma has not been "proven as an effective treatment."[14] The EUA announcement came only a few days after several of the federal government's top health officials, including Dr. Francis Collins and Dr. Anthony Fauci, argued to the FDA that the evidence on the effectiveness of convalescent plasma was too weak to justify its authorization, due to the lack of a control group in the primary study of its effectiveness.[15] Moreover, you overstated the benefits of convalescent plasma and, following criticism from medical experts, apologized for the overstatement.[16]

In March, President Trump promoted an unproven treatment for COVID-19 by declaring the malaria drug hydroxychloroquine a "game changer" against COVID-19 and called on the

---

[8] Food and Drug Administration, "Development and Licensure of Vaccines to Prevent COVID-19," June 2020, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19.

[9] Stat News, "Trump pledges a Covid-19 vaccine by end of 2020 – without acknowledging the scientific uncertainty," Lev Facher, August 27, 2020, https://www.statnews.com/2020/08/27/trump-pledge-vaccine-end-2020/.

[10] Letter to Governors from CDC Director Robert Redfield, August 27, 2020, https://drive.google.com/file/d/13qdjVpfU_2VvSQNadN6yubdVdKhlzmDU/view.

[11] New York Times, "C.D.C. Tells States How to Prepare for Covid-19 Vaccine by Early November," Sheila Kaplan, Katherine J. Wu, and Katie Thomas, September 2, 2020, https://www.nytimes.com/2020/09/02/health/covid-19-vaccine-cdc-plans.html.

[12] Tweet by Donald J. Trump, August 22, 2020, https://twitter.com/realDonaldTrump/status/1297138862108663808.

[13] Remarks by President Trump in Press Briefing, August 23, 2020, https://www.whitehouse.gov/briefings-statements/remarks-president-trump-press-briefing-august-23-2020/.

[14] Politico, "FDA authorizes plasma treatment despite scientists' objections," Zachary Brennan and Sara Owermohle, August 23, 2020, https://www.politico.com/news/2020/08/23/plasma-treatment-coronavirus-fda-trump-400390.

[15] New York Times, "F.D.A.'s Emergency Approval of Blood Plasma is Now on Hold," Noah Weiland, Sharon LaFraniere, and Sheri Fink, August 28, 2020, https://www.nytimes.com/2020/08/19/us/politics/blood-plasma-covid-19.html.

[16] ABC News, "FDA chief apologizes for overstating plasma effect on virus," Matthew Perrone and Deb Riechmann, August 25, 2020, https://abcnews.go.com/Health/wireStory/fda-commissioner-overstated-effects-virus-therapy-72595122.

FDA to "put [it] in use IMMEDIATELY."[17] On March 28, the FDA issued an EUA for the drug's use with patients hospitalized with COVID-19,[18] but less than a month later, on April 24, it cautioned that hydroxychloroquine had "not been shown to be safe and effective" for treating COVID-19 and that it was aware of reports of "serious heart rhythm problems" in COVID-19 patients treated by hydroxycholoroquine.[19] The FDA revoked the EUA altogether on June 15.[20] Trump advisor Peter Navarro criticized the revocation of the EUA, calling it "a Deep State blindside by bureaucrats who hate the administration they work for more than they're concerned about saving American lives."[21] The former director of the Biomedical Advanced Research and Development Authority (BARDA), Dr. Rick Bright, has since filed a whistleblower complaint, alleging that he was demoted because he resisted pressure from the White House and Administration officials to direct resources toward this unproven and ineffective treatment, in violation of the terms of the EUA.[22]

More recently, *Axios* reported that "[t]o the alarm of some government health officials, President Trump has expressed enthusiasm for the Food and Drug Administration to permit an extract from the oleander plant to be marketed as a dietary supplement or, alternatively, approved as a drug to cure COVID-19, despite lack of proof that it works."[23] MyPillow founder and CEO Mike Lindell, who, to be clear, is not a public health expert, and has a financial stake in the company that develops oleandrin, promoted the drug to President Trump in July along with Secretary of Housing and Urban Development Ben Carson, and President Trump agreed that "the FDA should be approving it" even though there is no public data regarding oleandrin's testing in animals or humans for efficacy against COVID-19.[24] Despite this pressure, the FDA announced last week that it would not approve oleandrin to be marketed as dietary supplement.[25]

---

[17] Tweet by Donald J. Trump, March 21, 2020, https://twitter.com/realDonaldTrump/status/1241367239900778501?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1241367245143642113%7Ctwgr%5Eshare_3&ref_url=https%3A%2F%2Fabcnews.go.com%2FHealth%2Ftimeline-tracking-trump-alongside-scientific-developments-hydroxychloroquine%2Fstory%3Fid%3D72170553.

[18] Food and Drug Administration, letter to Dr. Rick Bright, March 28, 2020, https://www.fda.gov/media/136534/download.

[19] Food and Drug Administration, "FDA Drug Safety Communication: FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems," April 24, 2020, https://www.fda.gov/media/137250/download

[20] ABC News, "Timeline: Tracking Trump alongside scientific developments on hydroxychloroquine," Libby Cathey, August 8, 2020, https://abcnews.go.com/Health/timeline-tracking-trump-alongside-scientific-developments-hydroxychloroquine/story?id=72170553.

[21] New York Times, "A Mad Scramble to Stock Millions of Malaria Pills, Likely for Nothing," Sheryl Gay Stolberg, June 16, 2020, https://www.nytimes.com/2020/06/16/us/politics/trump-hydroxychloroquine-coronavirus.html?smid=tw-share.

[22] U.S. Office of Special Counsel Complaint of Prohibited Personnel Practice or Other Prohibited Activity, filed by Dr. Rick Bright, https://context-cdn.washingtonpost.com/notes/prod/default/documents/6bfde4d6-4c3d-4671-8eeb-6b3d39e47c03/note/26f73d7a-d060-4c25-af4c-a58a167ee2c7.#page=1.

[23] Axios, "Trump eyes new unproven coronavirus 'cure'," Jonathan Swan, August 16, 2020, https://www.axios.com/trump-covid-oleandrin-9896f570-6cd8-4919-af3a-65ebad113d41.html.

[24] *Id.*

[25] CNN, "FDA rejects oleandrin, an unproven coronavirus therapeutic pushed by MyPillow CEO, as a dietary supplement ingredient," Jen Christensen and Jamie Gumbrecht, September 4, 2020, https://www.cnn.com/2020/09/04/health/oleandrin-coronavirus-fda-mypillow/index.html.

Perhaps in part due to this politicization of scientific review process, polling unfortunately shows significant public skepticism about a future vaccine. A recent poll found that only 49% of American adults plan to accept a coronavirus vaccine, with 20% not planning to be vaccinated and 31% unsure.[26] The same poll found that only 25% of Black Americans and 37% of Hispanic Americans plan to be vaccinated.[27] A poll released last week from the Kaiser Family Foundation found that 62% of Americans are worried that "the political pressure from the Trump administration will lead the FDA to rush to approve a coronavirus vaccine without making sure that it is safe and effective."[28] In order to achieve broad acceptance with the public, a future vaccine for COVID-19 will need to overcome public skepticism about the speed of the process, underlying doubts about vaccine safety,[29] long-standing mistrust of the medical system among communities of color[30] – and the effects of the President's ongoing political interference.

Full transparency throughout the review and authorization process is thus essential to countering real or perceived politicization and building public confidence in any approved vaccine. Despite promises of transparency, many vaccine developers have not yet released their trial protocols, and in some cases they have disclosed information about the trials in closed-door meetings with investors that has not been made available to the general public.[31] In addition to the efforts FDA has already made to publish its recommendations regarding data needed for clinical development and licensure of vaccines, a transparent review process will require that FDA (1) make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public; (2) make the deliberations of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) open to the public; and, (3) publish in advance the details of each Phase 3 trial design, including how participants are recruited, how they will be monitored for severe side effects on an ongoing basis, and under what circumstances the trial would be terminated early.[32] Furthermore, given the disproportionate impact of the pandemic on communities of color and the history of racism in clinical trials,[33] the

---

[26] Associated Press, "AP-NORC poll: Half of Americans would get a COVID-19 vaccine," Lauran Neergaard and Hannah Fingerhut, May 27, 2020, https://apnews.com/dacdc8bc428dd4df6511bfa259cfec44.
[27] *Id.*
[28] Kaiser Family Foundation, "KFF Health Tracking Poll - September 2020: Top Issues in 2020 Election, The Role of Misinformation, and Views on A Potential Coronavirus Vaccine," Liz Hamel, Audrey Kearney, Ashley Kirzinger, Lunna Lopes, Cailey Muñana, and Mollyann Brodie, September 10, 2020, https://www.kff.org/coronavirus-covid-19/report/kff-health-tracking-poll-september-2020/.
[29] Pediatrics, "Countering Vaccine Hesitancy," Kathryn M. Edwards, Jesse M. Hackell, and the Committee on Infectious Diseases, The Committee On Practice And Ambulatory Medicine, August 2016, https://pediatrics.aappublications.org/content/early/2016/08/25/peds.2016-2146.
[30] Am J Public Health, "Racial/Ethnic Differences in Physician Distrust in the United States," Katrina Armstrong, Karima Ravenell, Suzanne McMurphy, and Mary Putt, July 2007, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1913079/; Behav Med., "Medical Mistrust, Racism, and Delays in Preventative Health Screening Among African-American Men," Wizdom Powell, Jennifer Richmond, Dinushika Mohottige, Irene Yen, Allison Joslyn, and Giselle Corbie-Smith, Apr-Jun 2019, https://pubmed.ncbi.nlm.nih.gov/31343960/.
[31] New York Times, "Vaccine Makers Keep Safety Details Quiet, Alarming Scientists," Katie Thomas, September 13, 2020, https://www.nytimes.com/2020/09/13/science/coronavirus-vaccine-trials.html.
[32] Letter to FDA Commissioner Stephen Hahn from Lilian Abbo, et al., https://cspinet.org/sites/default/files/COVID_Vaccine_Letter_to_FDA_8.5.2020.pdf.
[33] J Health Care Poor Underserved, "More Than Tuskegee: Understanding Mistrust about Research Participation," Darcell P. Scharff, Katherine J. Mathews, Pamela Jackson, Jonathan Hoffsuemmer, Emeobong Martin, and Dorothy Edwards, March 10, 2015, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4354806/; USA Today, "'Sign me up':

FDA has a responsibility to actively involve communities of color in the review and authorization process for any treatment or vaccine. The same is true for other populations that are at elevated risk from COVID-19, including older Americans and people with disabilities.

In order to understand how the FDA is addressing these concerns, we request answers to the following questions by September 28, 2020:

1. Will all meetings of the VRBPAC to discuss COVID-19 vaccine products, as well as documents reviewed during these meetings, be open to the public?

2. What steps has the FDA taken to prevent political interference in the agenda or discussions at the October 22 meeting of the VRBPAC, in light of its timing shortly before the presidential election?

3. Will data generated by COVID-19 vaccine clinical trials be made available to the public? What steps will the FDA take to ensure that enough data are made available to allow the public to evaluate the outcome of the clinical trials, including data used to inform a decision to issue an EUA, while protecting participant privacy?

4. Will the FDA require public disclosure of the design details of Phase 3 clinical trials for a COVID-19 vaccine, including the procedure for ongoing monitoring of severe side effects and the criteria under which the trial would be ended early?

5. How will the FDA assess safety and efficacy for groups with limited participation in early stage clinical trials, including pediatric patients and pregnant people?

6. What steps has the FDA taken to involve representatives of communities of color, people with disabilities, older Americans, and other groups at elevated risk from COVID-19 in the review process for vaccines?

Thank you for your consideration of this urgent matter.

Sincerely,

Elizabeth Warren
United States Senator

Margaret Wood Hassan
United States Senator

Dianne Feinstein
United States Senator

Kirsten Gillibrand
United States Senator

Why people of color are vital to getting a successful COVID-19 vaccine," Karen Weintraub, August 20, 2020, https://www.usatoday.com/story/news/health/2020/08/20/covid-19-vaccine-trials-need-diverse-volunteers/3297954001/.

Richard Blumenthal
United States Senator

Tina Smith
United States Senator

Jeffrey A. Merkley
United States Senator

Angus S. King, Jr.
United States Senator

Jack Reed
United States Senator

Christopher S. Murphy
United States Senator

Mazie K. Hirono
United States Senator

Tammy Baldwin
United States Senator

Bernard Sanders
United States Senator

Michael F. Bennet
United States Senator

Sherrod Brown
United States Senator

Exhibit 5

Press Releases

Rep. Ralph Norman Introduces Legislation to Expedite FDA Compliance with FOIA Requests for Vaccine Approval Data

Washington, D.C., December 2, 2021

Tags: ***Health Care*** , ***Coronavirus*** , ***Vaccine Mandates***

On Thursday, **Congressman Ralph Norman** (R-SC) introduced **legislation** that would require the Commissioner of the **Food and Drug Administration** (FDA) to release all records of information submitted to the FDA regarding the authorization of emergency use of, or licensing of all COVID-19 vaccines. The bill requires all records and information to be released to the public no later than 100 days.

Background

The Pfizer COVID-19 vaccine was licensed by the FDA on August 23, 2021, 108 days after Pfizer began submitting documents for approval by the FDA.

The Public Health and Medical Professionals for Transparency (PHMPT) is a group of public health and medical professionals, which includes professors and scientists from universities including Yale, Harvard, UCLA, and Brown.

Through a Freedom of Information Act, PHMPT sought an expedited request "to obtain the data and information relied upon by the FDA to license the Pfizer Vaccine" in part to "confirm the FDA's conclusion that the Pfizer Vaccine is safe and effective."

The FDA denied expedited processing of PHMPT's request, prompting that organization to file a **lawsuit** against the FDA in September 2021. In total, PHMPT is

On November 15, 2021, FDA attorneys **asked the court** to allow the FDA to release just 500 pages per month to the public, resulting in a timeline of roughly **55 years** for the disclosure of all documents. More than 256 million doses of Pfizer's vaccine have been administered in the United States since the approval of the vaccine in August 2021 by the FDA.

The FOIA request and lawsuit are exclusive to the FDA approved Pfizer vaccine, but Rep. Norman's legislation would require the public release of all documentation related to Pfizer, Moderna, and Johnson & Johnson COVID-19 vaccines.

Rep. Norman issued the following statement on Thursday:

"The FDA's only priority should be the health and safety of consumers. The agency has compromised its integrity by delaying information that belongs to the public. Since the Biden administration is hell-bent on forcing these vaccine mandates on us, the public has every right to know how this vaccine was approved, especially in such a short amount of time. After all, the FDA managed to consider all 329,000 pages of data and grant emergency approval of the Pfizer vaccine within just 108 days. So it's hard to rationalize why it now needs 55 years to fully release that information to the public."

Washington, DC Office

For questions about Rep. Norman's votes in Congress, legislation, or federal policies

569 Cannon HOB
Washington, DC 20515
Phone: (202) 225-5501
FAX: (202) 225-0464

Rock Hill Office

For assistance with departments or agencies of the federal government

454 South Anderson Rd.
Suite 302 B
Rock Hill, SC 29730
Phone: (803) 327-1114
FAX: (803) 327-4330

Home

About Ralph

Serving You

Resources

Events

Media

Contact

Exhibit 6

Ted Cruz
@tedcruz

Completely outrageous.

Want people to get vaccinated? The FDA needs to be transparent so people can make an informed decision.

theblaze.com
FDA asks federal judge for 55 years to complete FOIA request for Pfizer vaccin...
The Food and Drug Administration is asking a federal court to allow it to take nearly 55 years to release data on Pfizer's COVID-19 vaccine to the public. The ...

App000372

7:36 PM · Nov 18, 2021 · Twitter for iPhone

Exhibit 7

PFIZER AND BIONTECH ANNOUNCE AN AGREEMENT WITH U.S. GOVERNMENT FOR UP TO 600 MILLION DOSES OF MRNA-BASED VACCINE CANDIDATE AGAINST SARS-COV-2

Wednesday, July 22, 2020 - 07:10am

- *U.S. government placed an initial order of 100 million doses for $1.95 billion and can acquire up to 500 million additional doses*
- *Americans to receive the vaccine for free consistent with U.S. government's commitment for free access for COVID-19 vaccines*
- *Pfizer and BioNTech remain on track to begin an anticipated Phase 2b/3 safety and efficacy trial later this month, seek regulatory review as early as October 2020, and manufacture globally up to 100 million doses by the end of 2020 and potentially more than 1.3 billion doses by the end of 2021*

Hide

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced the execution of an agreement with the U.S. Department of Health and Human Services and the Department of Defense to meet the U.S. government's Operation Warp Speed program goal to begin delivering 300 million doses of a vaccine for COVID-19 in 2021. Under the agreement, the U.S. government will receive 100 million doses of BNT162, the COVID-19 vaccine candidate jointly developed by Pfizer and BioNTech, after Pfizer successfully manufactures and obtains approval or emergency use authorization from U.S. Food and Drug Administration (FDA).

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200722005438/en/ (https://www.businesswire.com/news/home/20200722005438/en/)

The U.S. government will pay the companies $1.95 billion upon the receipt of the first 100 million doses, following FDA authorization or approval. The U.S. government also can acquire up to an additional 500 million doses.

Americans will receive the vaccine for free consistent with U.S. government's commitment for free access for COVID-19 vaccines.

"We've been committed to making the impossible possible by working tirelessly to develop and produce in record time a safe and effective vaccine to help bring an end to this global health crisis," said Dr. Albert Bourla, Pfizer Chairman and CEO. "We made the early decision to begin clinical work and large-scale manufacturing at our own risk to ensure that product would be available

immediately if our clinical trials prove successful and an Emergency Use Authorization is granted. We are honored to be a part of this effort to provide Americans access to protection from this deadly virus."

"Expanding Operation Warp Speed's diverse portfolio by adding a vaccine from Pfizer and BioNTech increases the odds that we will have a safe, effective vaccine as soon as the end of this year," said HHS Secretary Alex Azar. "Depending on success in clinical trials, today's agreement will enable the delivery of approximately 100 million doses of this vaccine to the American people."

The BNT162 program is based on BioNTech's proprietary mRNA technology and supported by Pfizer's global vaccine development and manufacturing capabilities. The BNT162 vaccine candidates are undergoing clinical studies and are not currently approved for distribution anywhere in the world. BioNTech is the market authorization holder worldwide and will hold all trademarks for the potential product. Both collaborators are committed to developing these novel vaccines with pre-clinical and clinical data at the forefront of all their decision-making.

Hide

"We are pleased to have signed this important agreement with the U.S. government to supply the initial 100 million doses upon approval as part of our commitment to address the global health threat. This agreement is one of many steps towards providing global access to a safe and efficacious vaccines for COVID-19. We are also in advanced discussions with multiple other government bodies and we hope to announce additional supply agreements soon. Our goal remains to bring a safe and effective COVID-19 vaccine to many people around the world, as quickly as we can," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech.

The Pfizer/BioNTech vaccine development program is evaluating at least four experimental vaccines, each of which represents a unique combination of messenger RNA (mRNA) format and target antigen. On July 1st, Pfizer and BioNTech announced preliminary data from BNT162b1, the most advanced of the four mRNA formulations. The early data demonstrates that BNT162b1 is able to produce neutralizing antibodies in humans at or above the levels observed in the plasma from patients who have recovered from COVID-19, and this was shown at relatively low dose levels. Local reactions and systemic events were dose-dependent, generally mild to moderate, and transient. No serious adverse events were reported. On July 20th, the companies announced early positive update from German Phase 1/2 COVID-19 vaccine study, including first T Cell response data.

Recently, two of the companies' four investigational vaccine candidates (BNT162b1 and BNT162b2) received Fast Track designation from the U.S. Food and Drug Administration (FDA). This designation was granted based on preliminary data from Phase 1/2 studies that are currently ongoing in the United States and Germany as well as animal immunogenicity studies. Further data from the

ongoing Phase 1/2 clinical trials of the four vaccine candidates will enable the selection of a lead candidate and dose level for an anticipated large, global Phase 2b/3 safety and efficacy study that may begin as early as later this month, pending regulatory approval.

If the ongoing studies are successful, Pfizer and BioNTech expect to be ready to seek Emergency Use Authorization or some form of regulatory approval as early as October 2020. The companies currently expect to manufacture globally up to 100 million doses by the end of 2020 and potentially more than 1.3 billion doses by the end of 2021, subject to final dose selection from their clinical trial.

In addition to engagements with governments, Pfizer and BioNTech have provided an expression of interest for possible supply to the COVAX Facility, a mechanism established by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and World Health Organization (WHO) that aims to provide governments with early access to a large portfolio of COVID-19 candidate vaccines using a range of technology platforms, produced by multiple manufacturers across the world.

Hide

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com (https://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.pfizer.com%2F&esheet=52254092&newsitemid=20200722005438&lan=en-US&anchor=www.Pfizer.com&index=1&md5=6f112a969d509e17034b14f144afa93f). In addition, to learn more, please visit us on www.Pfizer.com (https://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.pfizer.com%2F&esheet=52254092&newsitemid=20200722005438&lan=en-US&anchor=www.Pfizer.com&index=2&md5=45840dd0e78d45b4d317726bbddf29ec) and follow us on Twitter at @Pfizer (https://cts.businesswire.com/ct/CT?id=smartlink&url=https%3A%2F%2Ftwitter.com%2Fpfizer&esheet=52254092&newsitemid=20200722005438&lan=en-US&anchor=%40Pfizer&index=3&md5=18c0aee73883336002d6bd4014593aa4) and @Pfizer News (https://cts.businesswire.com/ct/CT?id=smartlink&url=https%3A%2F%2Ftwitter.com%2Fpfizer_news&esheet=52254092&newsitemid=20

20072200543 8&lan=en-US&anchor=%40Pfizer+News&index=4&md5=12c74b1b7a29bc30b293f916acd426b4), LinkedIn (https://cts.businesswire.com/ct/CT?id=smartlink&url=https%3A%2F%2Fwww.linkedin.com%2Fcompany%2Fpfizer&esheet=52254092&newsitemid=20200722005438&lan=en-US&anchor=LinkedIn&index=5&md5=5c910cab1a07517c3aa51d11b12574cd), YouTube (https://cts.businesswire.com/ct/CT?id=smartlink&url=https%3A%2F%2Fwww.youtube.com%2Fpfizer&esheet=52254092&newsitemid=20200722005438&lan=en-US&anchor=YouTube&index=6&md5=21f46ef83dcb14e72260d904ccd6d761) and like us on Facebook at Facebook.com/Pfizer (https://cts.businesswire.com/ct/CT?id=smartlink&url=https%3A%2F%2Fwww.facebook.com%2FPfizer%2F&esheet=52254092&newsitemid=20200722005438&lan=en-US&anchor=Facebook.com%2FPfizer&index=7&md5=fbc1709405a01e2ebc16d7eb0c201207).

Hide

Pfizer Disclosure Notice

The information contained in this release is as of July 22, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, the BNT162 mRNA vaccine program, a collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine, an agreement with the United States to manufacture and deliver BNT162 and other potential agreements, including their potential benefits, manufacturing and distribution and the expected timing of clinical trials and regulatory submissions, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data; risks associated with preliminary data; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications; whether regulatory authorities will be satisfied with the design of and results from these and future preclinical and clinical studies; whether and when any biologics license applications may be filed in any jurisdictions for any potential vaccine candidates under the

collaboration; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether any such vaccine candidates will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of any such vaccine candidates, including development of products or therapies by other companies; manufacturing capabilities or capacity, including whether the estimated numbers of doses can be manufactured within the projected time periods indicated; whether and when a future production agreement with the United States will be reached; whether and when other supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding any such vaccine candidates and uncertainties regarding the commercial impact of any such recommendations; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov (https://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.sec.gov&esheet=52254092&newsitemid=20200722005438&lan=en-US&anchor=www.sec.gov&index=8&md5=35c2145ba6c7bb794a9bd92f7c8dfb97) and www.pfizer.com (https://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.pfizer.com%2F&esheet=52254092&newsitemid=20200722005438&lan=en-US&anchor=www.pfizer.com&index=9&md5=0e0666bbb77fefe8cbc330b3153345db).

Hide

About BioNTech

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Bayer Animal Health,

Genentech, a member of the Roche Group, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.de (https://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.BioNTech.de&esheet=52254092&newsitemid=20200722005438&lan=en-US&anchor=www.BioNTech.de&index=10&md5=fb8be4528863006c664ea37b6856d4f7).

BioNTech Forward-looking statements

This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the timing to initiate clinical trials of BNT162 and anticipated publication of data from these clinical trials; the timing for any potential emergency use authorizations or approvals; the potential to enter into additional supply agreements with other jurisdictions or the COVAX Facility; the potential safety and efficacy of BNT162; the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimates for 2020 and 2021. Any forward-looking statements in this press release are based on BioNTech current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: competition to create a vaccine for COVID-19; the ability to produce comparable clinical results in larger and more diverse clinical trials; the ability to effectively scale our productions capabilities; and other potential difficulties. For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F filed with the SEC on March 31, 2020, which is available on the SEC's website at www.sec.gov (https://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.sec.gov&esheet=52254092&newsitemid=20200722005438&lan=en-US&anchor=www.sec.gov&index=11&md5=4cc240b3adda2fc54d0e18f1cca607ef). All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

Hide

View source version on businesswire.com (http://businesswire.com): https://www.businesswire.com/news/home/20200722005438/en/ (https://www.businesswire.com/news/home/20200722005438/en/)

Pfizer:
Media Relations
Amy Rose
+1 (212) 733-7410
Amy.Rose@pfizer.com (mailto:Amy.Rose@pfizer.com)

Investor Relations
Chuck Triano
+1 (212) 733-3901
Charles.E.Triano@Pfizer.com (mailto:Charles.E.Triano@Pfizer.com)

BioNTech:
Media Relations
Jasmina Alatovic
+49 (0)6131 9084 1513 or +49 (0)151 1978 1385
Media@biontech.de (mailto:Media@biontech.de)

Investor Relations
Sylke Maas, Ph.D.
+49 (0)6131 9084 1074 Hide
Investors@biontech.de (mailto:Investors@biontech.de)

Source: Pfizer Inc.

Exhibit 8

FOR IMMEDIATE RELEASE
February 11, 2021

Contact: ASPR Press Office
202-690-6343
asprmedia@hhs.gov (mailto:asprmedia@hhs.gov)

Biden Administration purchases additional doses of COVID-19 vaccines from Pfizer and Moderna

The U.S. Department of Health and Human Services (HHS) and Department of Defense (DOD) have purchased an additional 100 million doses of COVID-19 vaccines from both Pfizer Inc. and Moderna Inc. to help meet demand for COVID-19 vaccines in the United States.

The orders placed today bring the vaccine purchased by the U.S. government from these two companies to a total of 600 million doses, enough to vaccinate 300 million people. Each company is delivering 300 million doses in regular increments through the end of July 2021. Each company will leverage U.S.-based manufacturing capacity to fill, finish and ship vials as the bulk material is produced.

“As the President directed, we are expanding our supply of COVID vaccines to protect people as quickly as possible,” said Acting HHS Secretary Norris Cochran. “These purchases will allow us to accelerate our vaccination efforts to get shots into the arms of the American people. While we rapidly ramp up the pace of vaccinations, I encourage everyone to take actions now to protect themselves and their families: wear a mask, wash your hands often, and practice physical distancing.”

The companies began manufacturing doses of their vaccines at the same time that clinical trials were getting underway last year. Beginning the complex process of scaling up to large-scale manufacturing in parallel with clinical trials expedited the traditional vaccine development timeline so that initial doses could begin shipping when the U.S. Food and Drug Administration (FDA) granted emergency use authorization.

The vaccine is available at no cost. Vaccine administration costs for private-sector administration partners are being covered by healthcare payers: private insurance, Medicare or Medicaid, and an HHS program to cover COVID-19 costs for the uninsured which is reimbursing providers at Medicare rates from the Provider Relief Fund (https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html) .

The Biomedical Advanced Research and Development Authority (BARDA (https://www.phe.gov/barda)), part of the HHS Office of the Assistant Secretary for Preparedness and Response, collaborated with the DOD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND (https://www.jpeocbrnd.osd.mil/)) and Army Contracting Command (https://www.army.mil/ACC) to provide approximately $2 billion for the additional doses of the Pfizer-BioNTech vaccine, bringing the total purchase from Pfizer to approximately $6 billion.

BARDA, JPEO-CBRND and Army Contracting Command also collaborated to provide up to approximately $1.65 billion to Moderna, bringing the total federal investment in Moderna's vaccine development, clinical trials, manufacturing and purchase to approximately $5.75 billion. Moderna's vaccine was co-developed with scientists from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, with NIAID also supporting the vaccine's nonclinical studies and clinical trials. BARDA supported phase 2/3 clinical trials, vaccine manufacturing scale up and other development activities for this vaccine.

Moderna's Phase 3 (https://www.nih.gov/news-events/news-releases/phase-3-clinical-trial-investigational-vaccine-covid-19-begins) clinical trial began July 27 as the first government-funded Phase 3 clinical trial for a COVID-19 vaccine in the U.S. and enrolled approximately 30,000 adult volunteers who did not have COVID-19. An independent data safety monitoring board overseeing the Phase 3 clinical trial reviewed the trial data (https://www.nih.gov/news-events/news-releases/promising-interim-results-clinical-trial-nih-moderna-covid-19-vaccine) and concluded that the vaccine was safe, prevented disease in 94 percent of the volunteers who received the vaccine, reduced the severity of illness in the small percentage of volunteers who contracted COVID-19, and was generally well tolerated.

The Phase 3 clinical trial for the Pfizer-BioNTech vaccine enrolled approximately 43,000 adult volunteers in the U.S. who did not have COVID-19. The clinical trial showed that the vaccine was safe, prevented disease in approximately 95 percent of the volunteers who received the vaccine, reduced the severity of illness in the five percent of volunteers who contracted COVID-19 and was generally well-tolerated.

The clinical studies of both vaccines are ongoing to gather additional data such as the vaccines' efficacy in younger populations, the duration of immunity after vaccination, and the impact of vaccination on transmissibility of the virus.

Messenger RNA (https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html) vaccines take advantage of the process that cells use to make proteins in order to trigger an immune response and build immunity to a virus. In contrast, most vaccines use weakened or inactivated versions or components of a disease-causing virus to stimulate the body's immune response to create antibodies.

HHS and DOD have contracted with four other companies to expedite development and production of vaccines that use a variety of vaccine platform technologies and are manufacturing COVID-19 vaccine doses while clinical trials are underway. If any of these other vaccine candidates are authorized by the

FDA for emergency use, HHS and DOD can negotiate agreements with the respective companies to purchase additional vaccine doses to meet the demand in the United States.

About HHS, ASPR, and BARDA

HHS works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The mission of ASPR is to save lives and protect Americans from 21st century health security threats. Within ASPR, BARDA invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures (https://www.medicalcountermeasures.gov) – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats. To date, BARDA-supported products have achieved 58 FDA approvals, licensures or clearances. To learn more about COVID-19, visit cdc.gov/coronavirus (https://www.cdc.gov/coronavirus).

About the JPEO-CBRND

The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) protects the Joint Force by providing medical countermeasures and defense equipment against chemical, biological, radiological and nuclear (CBRN) threats. JPEO-CBRND's goal is to enable the Joint Force to fight and win unencumbered by a CBRN environment. JPEO-CBRND facilitates the rapid response, advanced development, manufacturing and acquisition of medical solutions, such as vaccines, therapeutics, and diagnostics, to combat CBRN and emerging threats such as COVID-19. To learn more about JPEO-CBRND's COVID-19 response, visit https://www.jpeocbrnd.osd.mil/coronavirus (https://www.jpeocbrnd.osd.mil/coronavirus) or follow JPEO-CBRND on social media at @JPEOCBRND.

###

Note: All HHS press releases, fact sheets and other news materials are available at https://www.hhs.gov/news (/news).

Like HHS on Facebook (https://www.facebook.com/pages/US-Health-and-Human-Services/573909926312 31?ref=hl), follow HHS on Twitter @HHSgov (https://twitter.com/#!/HHSGov), and sign up for HHS Email Updates (https://cloud.connect.hhs.gov/subscriptioncenter).

Last revised: February 12, 2021

HHS Headquarters

U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Toll Free Call Center: 1-877-696-6775

Exhibit 9

U.S. buys 200 million COVID-19 vaccines from Pfizer and BioNTech at about $24 a dose

July 27, 2021

The federal government has bought another 200 million COVID-19 vaccine doses from Pfizer and partner BioNTech at roughly $24 a dose, according to Pfizer. That price is higher than the $19.50 the government paid under its earlier agreements. The most recent deal brings the overall number of doses purchased by the United States to 1 billion. Pfizer and BioNTech anticipate delivering 110 million of the additional doses by the end of the year, with the remainder arriving by the end of next April. Pfizer noted the Biden administration has the option of obtaining an updated version of the vaccine that targets variants, if available and authorized by regulators. Pfizer is currently testing doses that target the Beta variant, which was first identified in South Africa. A Pfizer spokesman said, "The price for this order accounts for the additional investment necessary to produce, package, and deliver new formulations of the vaccine, as well as the increased cost associated with delivering the vaccine in smaller pack sizes to facilitate delivery at individual provider offices, including pediatricians." FDA officials have not yet determined if booster coronavirus vaccine doses will be necessary, but Pfizer said earlier this month it would seek clearance from regulators to distribute a booster dose of its vaccine in the United States. Demand for the vaccine could also rise if its use is cleared for younger children.

Wall Street Journal (07/23/21) Hopkins, Jared S.

https://www.wsj.com/articles/u-s-buys-200-million-covid-19-vaccines-from-pfizer-and-biontech-at-about-24-a-shot-11627078710

Exhibit 10

Contracts For Aug. 2, 2021

ARMY

Pfizer Inc., New York, New York, was awarded a $3,500,000,001 firm-fixed-price contract for the procurement of 500 million doses of COVID-19 vaccine for the purpose of international donation. Bids were solicited via the internet with one received. Work will be performed in New York, New York, with an estimated completion date of Dec. 31, 2022. Fiscal 2021 research, development, test and evaluation, Army funds in the amount of $3,500,000,001 were obligated at the time of the award. U.S. Army Contracting Command, Aberdeen Proving Ground, Maryland, is the contracting activity (W58P05-21-C-0002). (Awarded July 30, 2021)

General Electric Aviation, Lynn, Massachusetts, was awarded a $208,162,355 firm-fixed-price contract for overhaul of the cold section module in support of the T700 engine. Bids were solicited via the internet with two received. Work locations and funding will be determined with each order, with an estimated completion date of Aug. 1, 2026. U.S. Army Contracting Command, Redstone Arsenal, Alabama, is the contracting activity (W58RGZ-21-D-0065).

Weeks Marine Inc., Covington, Louisiana, was awarded a $15,697,708 firm-fixed-price contract for berm reconstruction at Ocean City, Maryland. Bids were solicited via the internet with three received. Work will be performed in Ocean City, Maryland, with an estimated completion date of April 11, 2022. U.S. Army Corps of Engineers, Baltimore, Maryland, is the contracting activity (W912DR-21-C-0020).

Keller North America Inc., Alpharetta, Georgia, was awarded a $9,118,588 firm-fixed-price contract for bluff stabilization at Natchez National Cemetery. Bids were solicited via the internet with four received. Work will be performed in Natchez, Mississippi, with an estimated completion date of Aug. 1, 2022. Fiscal 2021 Department of Veterans Affairs, National Cemetery Administration funds in the amount of $9,118,588 were obligated at the time of the award. U.S. Army Corps of Engineers, Vicksburg, Mississippi, is the contracting activity (W912EE-21-C-0008).

NAVY

General Dynamics Electric Boat Corp., Groton, Connecticut, is awarded a $225,117,921 modification to previously awarded contract N00024-19-C-2125 for engineering, technical, design agent, and planning yard support for operational strategic and attack submarines. The contract provides for drawings and

related technical data; design change documentation; technical assistance; configuration management; hull, mechanical and electrical engineering; submarine safety design review; non-propulsion plant electrical system engineering; propulsion plant engineering; maintenance engineering; refit/availability technical support; on-site support; configuration change program design and installation support; configuration change program material support; submarine technical trade support; training and facility support; research development test and evaluation program support; research and development submarine/submersibles support; miscellaneous special studies; temporary alteration support; modernization of submarine/submersible systems/subsystems; and affordability/cost reduction technical support. Work will be performed in Groton, Connecticut (70%); Kings Bay, Georgia (13%); Bangor, Washington (10%); Pearl Harbor, Hawaii (3%); North Kingston, Rhode Island (2%); and Newport, Rhode Island (2%), and is expected to be completed by September 2023. Fiscal 2021 other procurement, Navy funding in the amount of $3,104,008 will be obligated at time of award and will not expire at the end of the current fiscal year. The Naval Sea Systems Command, Washington, D.C., is the contracting activity.

Lockheed Martin Corp., Owego, New York, is awarded an $117,686,514 modification (P00002) to a firm-fixed-price order (N0001921F0841) against a previously issued basic ordering agreement (N0001921G0017). This order provides non-recurring engineering and field services representative efforts to bring 12 MH-60R aircraft from standard Foreign Military Sales (FMS) configuration to a Republic of Korea Navy configuration. Work will be performed in Stratford, Connecticut (38%); Best, France (37%); Owego, New York (18%); and Portsmouth, Rhode Island (7%), and is expected to be completed in November 2026. FMS funds in the amount of $117,686,514 will be obligated at time of award, none of which will expire at the end of the current fiscal year. The Naval Air Systems Command, Patuxent River, Maryland, is the contracting activity.

Seemann Composites LLC,* Gulfport, Mississippi, is awarded an $74,922,276 indefinite-delivery/indefinite-quantity, cost-plus-fixed-fee, and cost-plus-incentive-fee contract for design engineering and manufacturing support. Work will be performed in Gulfport, Mississippi (60%); Chesapeake, Virginia (20%); and Horsham, Pennsylvania (20%), and is expected to be completed by July 2026. Fiscal 2021 research, development, test, and evaluation (Navy) funding in the amount of $18,842 will be obligated at time of award for the first order and not expire at the end of the current fiscal year. This contract was competitively procured via the Beta.Sam.gov website, with three offers received. The Naval Surface Warfare Center Carderock Division, Bethesda, Maryland, is the contracting activity (N0016721D0010).

Lockheed Martin Corp., Fort Worth, Texas, is awarded a $51,793,127 cost-plus-incentive-fee contract. This contract provides for program management support to include development of customer unique capabilities in support of the continued development of the air system for the F-35 Lightning II Joint

Strike Fighter Program Office-Foreign Military Sales (FMS) customer buy) to be performed at Fort Worth, Texas (71%); Redondo Beach, California (13%); Melbourne, Florida (1%); and various undisclosed locations outside the continental U.S. (15%), and is expected to be completed in January 2024. FMS customer funds in the amount of $18,000,000 will be obligated at time of award, none of which will expire at the end of the current fiscal year. This contract was not competitively procured pursuant to 10 U.S. Code 2304(C)(1). The Naval Air Systems Command, Patuxent River, Maryland, is the contracting activity (N0001921C0040).

Lockheed Martin Corp., Owego, New York, is awarded a not-to-exceed undefinitized $34,400,000 modification (P00028) to a previously awarded, firm-fixed-price contract (N0001919C0013). This modification adds scope to provide integration and installation of a Hellenic Navy System configuration on three USN8 time configuration remote sensors for aircraft. This modification also provides for efforts on three replace in kind aircraft to bring the aircraft into a USN8 configuration. Additionally it procures four Airborne Low Frequency Sonars in support of the MH-60R program for the Navy and Foreign Military Sales (FMS) customers. Work will be performed in Best, France (46%); Owego, New York (40%); Portsmouth, Rhode Island (9%); and Stratford, Connecticut (5%), and is expected to be completed in April 2025. Fiscal 2021 aircraft procurement (Navy) funds in the amount of $1,300,976; and FMS funds in the amount of $11,855,070 will be obligated at time of award, none of which will expire at the end of the current fiscal year. The Naval Air Systems Command, Patuxent River, Maryland, is the contracting activity.

DEFENSE MICROELECTRONICS ACTIVITY

Marvell Government Solutions LLC, Essex Junction, Vermont, is awarded a $98,216,265 ceiling increase modification (P00019) to previously awarded HQ072720C4000 for Application Specific Integrated Circuit (ASIC) design services. The modification brings the total cumulative face value of the contract to $212,348,848 from $114,132,583. Work will be performed at Burlington, Vermont, with an expected completion date of March 31, 2022. The contract is being incrementally funded and $55,969,855 in funds are being obligated at time of modification. The Defense Microelectronics Activity, McClellan, California, is the contracting activity.

DEFENSE INFORMATION SYSTEMS AGENCY

Soliel LLC, Vienna, Virginia, was awarded a competitive 8(a) hybrid (firm-fixed-price/cost-plus-fixed-fee) contract for National Bureau of Investigation Service (NBIS) Development, Deployment and Sustainment (DD&S-II). The face value of this action is $22,407,525, funded by fiscal 2021 operation and maintenance; and research, development, test and evaluation funds. The total cumulative face value of the contract is $22,407,525. Performance will be at both the government's facilities and the

contracts facilities proposals were solicited and 3 companies responding. Research, and five proposals were received from seven proposals. The period of performance is Aug. 5, 2021 – Aug. 4, 2022, with four three-month option periods. The Defense Information Technology Contracting Organization, Scott Air Force Base, Illinois, is the contracting activity (HC108421C0005).

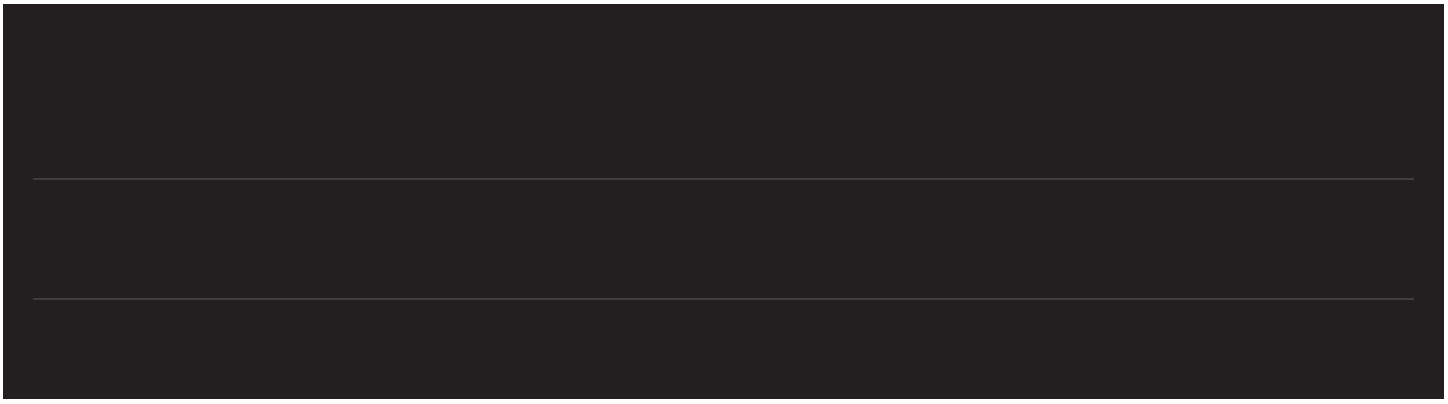
AIR FORCE

Raytheon Intelligence and Space, Aurora, Colorado, has been awarded a $13,515,800 cost-plus-incentive-fee contract modification (P00347) to the previously awarded contract FA8807-10-C-0001 for the Global Positioning System Next Generation Operational Control System (OCX). The contract modification is for an equitable adjustment for COVID-19 impacts to OCX, including late government-furnished equipment impacts and excusable delay overrun costs. The location of performance is Aurora, Colorado. The work is expected to be completed by June 30, 2022. The contract is incrementally funded with Space Force Research and Development funding, and no additional funds are being obligated at the time of award. Total cumulative face value of the contract is $3,758,106,396. Space and Missile Systems Center, Los Angeles Air Force Base, El Segundo, California, is the contracting activity.

DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

Applied Physical Sciences Corp., Groton, Connecticut, has been awarded a $9,994,747 modification (P00003) to previously awarded cost-plus-fixed-fee contract HR001120C0038 to exercise the Contract Line Item Number 0003 option to support a Defense Advanced Research Projects Agency research project. Fiscal 2021 research and development funds in the amount of $9,994,747 are being obligated at the time of award, with an estimated completion date of June 2022. The Defense Advanced Research Projects Agency, Arlington, Virginia, is the contracting activity (HR001120C0138). (Awarded July 30, 2021)

*Small business



Search...

Exhibit 11

BREAKING | Oct 28, 2021, 08:38am EDT | 1,346 views

U.S. Purchases Additional 50 Million Pediatric Doses Of Covid-19 Vaccine, Pfizer Says

Robert Hart Forbes Staff
Business
I cover breaking news.

Follow

Listen to article 3 minutes

TOPLINE The U.S. government has purchased an additional 50 million doses of Pfizer and BioNTech's pediatric Covid-19 vaccine, the two companies announced Thursday, as regulators are poised to green light the shot for use in children as young as five.

The U.S. government purchased an additional 50 million doses of Pfizer's pediatric vaccine, which is ...
[+] AFP VIA GETTY IMAGES

KEY FACTS

- The additional doses will support the government's preparations for widespread pediatric vaccination, the companies said, which will cover children as young as five if approved by regulators.

- BioNTech and Pfizer expect to deliver the doses by the end of April 2022.

- The shots—one third the strength of those intended for people ages 12 and up and meant for use in children aged 5-11—complete the U.S. government's 600 million dose purchase agreement it made with Pfizer and BioNTech at the start of the pandemic, the companies said.

- U.S. regulators are poised to clear the vaccine for use in younger children and trial data suggests the vaccine generates a "strong immune response."

KEY BACKGROUND

While children and teenagers have a much lower chance of developing severe illness or dying from Covid-19, they can and do develop life threatening illness and die from Covid-19. The Food and Drug Administration advisory committee overwhelmingly voted in favor of approving the vaccine for use in children—17 members endorsed the shot, one abstained—paving the way for the shot to be cleared by the FDA and the Centers for Disease Control and Prevention. The White House says it is prepared to distribute vaccines as soon as the shot is authorized, expected to be around early November.

BIG NUMBER

28 million. That's how many children will be eligible for the Covid-19 shot if it's approved for five- to 11-year-olds, according to the White House. Before the additional purchases, officials said the U.S. said it already had "enough supply to support vaccination" in this group, which will be delivered with smaller needles more suitable for children.

TANGENT

Moderna announced Monday it plans to submit data on its own pediatric vaccine to regulatory agencies after a clinical trial showed it to generate a strong immune response in children aged six to 11.

FURTHER READING

Here's How The White House Plans To Distribute Children's Covid Vaccines (Forbes)

FDA Advisory Committee Recommends Authorizing Pfizer's Covid Vaccine For Kids Ages 5 To 11 (Forbes)

What COVID vaccines for young kids could mean for the pandemic (Nature)

Moderna Says Its Covid Shot Generates 'Strong' Immune Response In Kids Aged 6-11 (Forbes)

Full coverage and live updates on the Coronavirus

Follow me on Twitter. Send me a secure tip.

Robert Hart

Follow

I am a London-based reporter for Forbes covering breaking news. Previously, I have worked as a reporter for a specialist legal publication... **Read More**

Exhibit 12

Contracts For Nov. 22, 2021

ARMY

Pfizer Inc., New York, New York, was awarded a $1,400,000,001 modification (P00003) to contract W58P05-21-C-0002 for an additional 200 million doses of Pfizer's COVID-19 vaccine for international donation. Work will be performed in New York, New York, with an estimated completion date of June 30, 2022. Fiscal 2022 research, development, test, and evaluation, Army funds in the amount of $1,400,000,001 were obligated at the time of the award. U.S. Army Contracting Command, Aberdeen Proving Ground, Maryland, is the contracting activity. (Awarded Nov. 19, 2021)

MEB General Contractors Inc., Chesapeake, Virginia, was awarded a $28,013,000 firm-fixed-price contract for fuel facility replacement. Work will be performed in Fort Hood, Texas, and is expected to be completed by Feb. 7, 2023. Bids were solicited via the internet with five received. Fiscal 2018 and 2021 military construction, Army; and 2022 military construction, Defense funds in the amount of $28,013,000 were obligated at the time of award. The U.S. Army Corps of Engineers, Fort Worth, Texas, is the contracting activity (W9126G-22-C-0003).

Radiance Technologies Inc.,* Huntsville, Alabama, was awarded a $25,808,362 cost-plus-fixed-fee contract for directed energy common test support. Bids were solicited via the internet with three received. Work will be performed in Huntsville and Redstone Arsenal, Alabama, with an estimated completion date of Nov. 21, 2026. Fiscal 2021 research, development, test and evaluation, Army funds in the amount of $25,808,362 were obligated at the time of the award. U.S. Army Rapid Capabilities and Critical Technologies Office, Redstone Arsenal, Alabama, is the contracting activity (W50RAJ-22-F-0002).

Dyncorp International LLC, Fort Worth, Texas, was awarded a $8,529,070 modification (P00182) to contract W58RGZ-19-C-0025 for worldwide aviation maintenance. Work will be performed in Fort Campbell and Fort Knox, Kentucky; Fort Drum, New York; Sato Cano, Honduras; Germany; and Thailand, with an estimated completion date of Nov. 30, 2022. Fiscal 2022 operation and maintenance, Army; and Foreign Military Sales funds in the amount of $8,529,070 were obligated at the time of the award. U.S. Army Contracting Command, Redstone Arsenal, Alabama, is the contracting activity.

CORRECTION: The Nov. 19, 2021, contract announcement for Dynetics Inc., Huntsville, Alabama (W50RAJ-22-9-0001), for $478,598,908 incorrectly stated that all funds would be obligated at time of award. The funds will be obligated incrementally by Other Transaction Authority modifications.

General Dynamics Information Technology Inc., Falls Church, Virginia, was awarded a $829,235,847 fixed-price, award-fee task order to provide all information technology help desk services for the Defense Intelligence Agency (DIA). Work will be performed at Joint Base Anacostia-Bolling in Washington, D.C., and other DIA sites, with an expected completion date of Jan. 27, 2032. Fiscal 2022 operations and management funds in the amount of $19,962 are being incrementally funded at the time of award for base-year labor. This contract was a competitive acquisition, and five offers were received. The Virginia Contracting Activity, Washington, D.C., is the contracting activity (HHM402-21-D-0016/0002).

NAVY

Lockheed Martin, Rotary and Mission Systems, Moorestown, New Jersey, is awarded an $114,606,157 cost-plus-incentive-fee, cost-plus-fixed-fee, and cost-only modification to previously-awarded contract N00024-13-C-5116 to exercise an option for AEGIS Combat System Engineering Agent efforts for the design, development, integration, test and delivery of Advanced Capability Build 20. Work will be performed in Moorestown, New Jersey, and is expected to be completed by December 2022. Fiscal 2021 other procurement (Navy) funds in the amount of $430,000 (53%); and fiscal 2022 research, development, test, and evaluation (Navy) funds in the amount of $382,216 (47%) will be obligated at time of award and will not expire at the end of the current fiscal year. The Naval Sea Systems Command, Washington, D.C., is the contracting activity.

Raytheon Technologies, Portsmouth, Rhode Island, is awarded a $27,596,535 firm-fixed-price modification to previously awarded contract N00024-16-C-6423 to exercise options for the production of the MK54 lightweight torpedo MOD 0 and MOD 1 common part kits and spare torpedo components. This contract combines purchases for the U.S. government (67%); and the governments of Spain and Brazil (33%) under the Foreign Military Sales (FMS) program. Work will be performed in Portsmouth, Rhode Island; and Keyport, Washington (5%), and is expected to be completed by May 2025. Fiscal 2022 weapons procurement (Navy) funds in the amount of $18,234,431 (66%); FMS Spain and FMS Brazil funds in the amount of $9,015,184 (33%), and fiscal 2021 weapons procurement (Navy) funds in the amount of $346,920 (1%) will be obligated at time of award and will not expire at the end of the current fiscal year. The Naval Sea Systems Command, Washington, D.C., is the contracting activity.

Rockwell Collins Inc., Cedar Rapids, Iowa, is awarded a $9,900,000 firm-fixed-price, cost-plus-fixed-fee modification (P00011) to a previously awarded contract (N0042118C0042). This modification exercises an option to provide for the flight management function application enterprise-wide license for all Navy, Marine Corps, and Navy led joint program aircraft. Work will be performed in Cedar Rapids, Iowa, and is

expected to be completed by July 2023. Fiscal 2021 procurement (Navy) funds in the amount of $9,900,000 will be obligated at time of award, none of which will expire at the end of the current fiscal year. The Naval Air Warfare Center Aircraft Division, Patuxent River, Maryland, is the contracting activity.

AIR FORCE

Zapata Group Inc., Charlotte, North Carolina (FA4418-22-D-0007); and ADC Engineering Inc., Hanahan, South Carolina (FA4418-22-D-0006), were awarded a $19,000,000 multiple award, indefinite-delivery/indefinite-quantity contract for architect-engineer services. The contract provides for the development of master planning documents for construction and utility infrastructure, and to accomplish studies. Work will be performed at Joint Base Charleston, South Carolina, and is expected to be completed by May 21, 2027. This award is the result of a competitive acquisition in which 16 offers were received. The 628th Contracting Squadron, Joint Base Charleston, South Carolina, is the contracting activity.

Blue Canyon Technologies Inc., Lafayette, Colorado, was awarded a $14,609,337 not-to-exceed, cost-plus-fixed-fee type contract for the Space Situational Awareness (SSA) Micro-Satellite Bus (AgileSAT) Program. This contract provides for the development and demonstration of a small satellite bus that can operate and maneuver effectively for up to three years in orbits beyond the geosynchronous equatorial orbit and has flexible support for a broad range of payloads. Work will be performed in Lafayette, Colorado, and is expected to be completed by Feb. 28, 2023. This award is the result of a competitive acquisition via the Small Business Innovative Research Program. Fiscal 2021 research and development funding in the amount of $1,600,000 is being obligated at the time of award. Air Force Research Laboratory, Wright Patterson Air Force Base, Ohio, is the contracting activity (FA8650-22-C-9211).

DEFENSE LOGISTICS AGENCY

Jo-Kell Inc.,** Chesapeake, Virginia, has been awarded a maximum $11,103,552 indefinite-quantity, firm-fixed-price long-term contract for UH-60A helicopter special purpose electrical cable assembly spare parts. This was a sole-source acquisition using justification 10 U.S. Code 2304 (c)(1), as stated in Federal Acquisition Regulation 6.302-1. This is a five-year contract with no option periods. Location of performance is Virginia, with a Nov. 29, 2026, performance completion date. Using military service is Army. Type of appropriation is fiscal 2021 through 2026 defense working capital funds. The contracting activity is the Defense Logistics Agency Aviation, Richmond, Virginia (SPE4A6-21-D-0036).

Defense Energy Support Center, Fort Belvoir, Virginia, has awarded a maximum $9,803,682,130 fixed-price with economic-price-adjustment requirements contract for fuel system icing inhibitor. This was a competitive acquisition with six responses received. This is a 30-month contract with a 90-day carryover. Locations of performance are throughout Europe and the Middle East, with a June 30, 2024, performance completion date. Using customer is Defense Logistics Agency Energy. Type of appropriation is fiscal 2022 through 2024 defense working capital funds. The contracting activity is the Defense Logistics Agency Energy, Fort Belvoir, Virginia (SPE602-22-D-0751).

*Small business
**Woman-owned small business

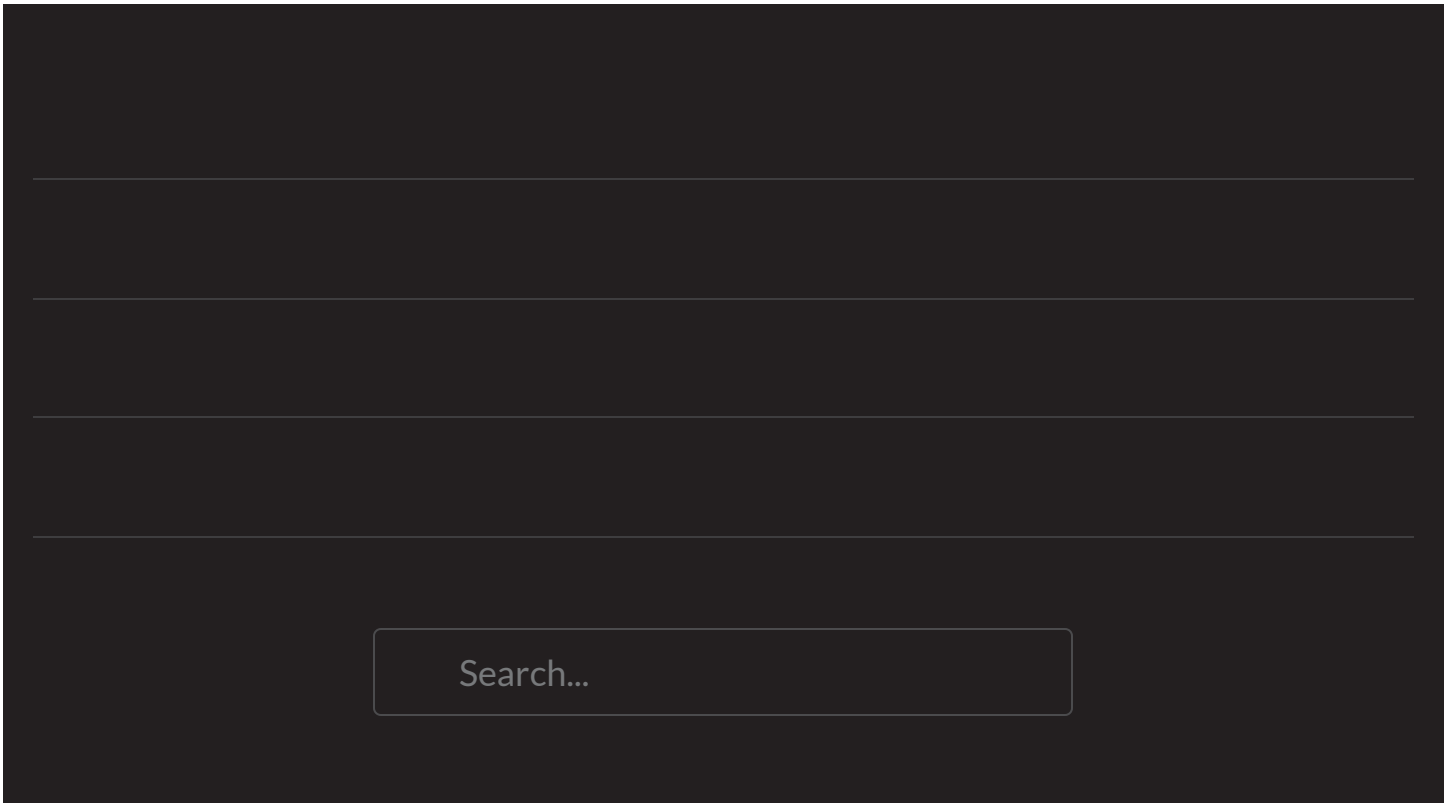


Exhibit 13

CDC Centers for Disease Control and Prevention

Novel Coronavirus (COVID-19)

To date, CDC received COVID-19 supplemental funding through:

- Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123): P.L. 116-123 provided $2.2 billion to CDC to prevent, prepare for and respond to COVID-19 domestically and internationally.
- Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136): P.L. 116-136 provided CDC $4.3 billion and ATSDR $12.5 million to prevent, prepare for and respond to COVID-19 domestically and internationally.
- Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139): P.L. 116-139 provided $1.0 billion to CDC transferred from the Public Health Social Services Emergency Fund (PHSSEF) to support surveillance, epidemiology, laboratory capacity expansion, contact tracing, public health data surveillance and analytics infrastructure modernization, disseminating information about testing, and workforce support necessary to expand and improve COVID–19 testing. In addition, $10.25 billion from the PHSSEF was awarded to health departments through the CDC Epidemiology and Laboratory Capacity program for testing and contact tracing.
- Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (P.L. 116-260): P.L. 116-260 provided $8.75 billion to CDC to plan, prepare for, promote, distribute, administer, monitor, and track coronavirus vaccines to ensure broad-based distribution, access, and vaccine coverage. On behalf of HHS, $19.11 billion from the PHSSEF was awarded to health departments through the CDC Epidemiology and Laboratory Capacity program for testing and contact tracing.
- American Rescue Plan Act of 2021 (P.L. 117-2): P.L. 117-2 provided $11.52 billion to CDC to plan, prepare for, promote, distribute, administer, monitor, and track vaccines; strengthen vaccine confidence in the US, provide information and education, and improve rates of vaccination; strengthen and expand activities and workforce related to genomic sequencing, analytics, and disease surveillance; combat COVID and other emerging infectious disease threats, global health security, global disease detection and response, global health protection, global immunization, and coordination; support surveillance and analytics infrastructure modernization initiatives and an early warning system; and encourage primary prevention of mental and behavioral health conditions for health care professionals. On behalf of HHS, CDC will provide $10 billion from the PHSSEF to states to support COVID-19 screening testing for teachers, staff and students to assist schools in reopening safely for in-person instruction.

CDC 24/7 Response to COVID-19

The CDC COVID-19 fact sheet provides an overview of CDC's support for COVID-19 response activities on federal, state, local, territorial and tribal levels. It also highlights CDC's current COVID-19 efforts.

CDC COVID-19 State, Tribal, Local, and Territorial (STLT) Funding

The CDC COVID-19 STLT Funding page shows COVID-19 funding by jurisdiction, award, and the four COVID-19 supplemental appropriations.

CDC COVID-19 Funding for Tribes

The CDC COVID-19 Funding for Tribes Fact Sheet provides information on the funding provided to tribal nations, consortia, and organizations for responding to COVID-19 across tribal communities.

CDC COVID-19 Global Response Fact Sheet

The CDC COVID-19 Global Response Fact Sheet provides an overview of the goals, objectives, activities, and spend plan of CDC's global response to COVID-19.

CDC COVID-19 Data Modernization Initiative Fact Sheet

The CDC COVID-19 Data Modernization Initiative Fact Sheet discuss how CDC is bringing together state, tribal, local, and territorial (STLT) public health jurisdictions and our private and public sector partners to create modern, interoperable, and real-time public health data and surveillance systems that will protect the American public.

CDC In Action: Accelerating and Supporting COVID-19 Vaccine Distribution

The CDC is playing an essential role in the response to the COVID-19 pandemic, working 24/7 to protect the nation's health and ensure public health partners have the resources, guidance, and scientific expertise to respond.

Paycheck Protection Program and Health Care Enhancement Act Fact Sheet

The Paycheck Protection Program and Health Care Enhancement Act Fact Sheet provides an overview of the critical activities (domestic preparedness, workforce capacity, laboratory capacity, and communication and analytics) in CDC's plan for public health response and capacity building.

Page last reviewed: August 3, 2021

Exhibit 14

BRIEFING ROOM

FACT SHEET: Biden Administration Announces Historic $10 Billion Investment to Expand Access to COVID-19 Vaccines and Build Vaccine Confidence in Hardest-Hit and Highest-Risk Communities

MARCH 25, 2021 • STATEMENTS AND RELEASES

Administration Makes Essential Workers Eligible for Vaccinations at Community Health Centers in Federal CHC Vaccination Program

Administration Also Announces New Program to Vaccinate Dialysis Patients Nationwide

As part of President Biden's continued efforts to ensure COVID-19 vaccines reach all people and all communities, the Biden-Harris Administration is announcing a series of actions to expand access to COVID-19 vaccines to the hardest-hit and highest-risk communities across the country. With funding in large part from the American Rescue Plan, the U.S. Department of Health and Human Services (HHS) will invest nearly $10 billion to expand access to vaccines and better serve communities of color, rural areas, low-income populations, and other underserved communities in the COVID-19 response. This funding will expand access to vaccines for vulnerable populations and increase vaccine confidence across the country.

Equity is at the center of the Administration's COVID-19 response. The President has set up federally-run community vaccination centers in hard-hit areas; sent vaccines directly to local pharmacies and Community Health Centers that disproportionately serve vulnerable populations; launched hundreds of mobile clinics to meet people where they are; and created the COVID-19 Health Equity Task Force.

These actions are garnering initial results. In the past two months, 60 percent of doses at federally-run Community Vaccination sites were administered to people of color. In the federal retail pharmacy program, 45 percent of sites were located in zip codes with high social vulnerability scores – a CDC index that uses 15 U.S. census variables to identify communities that may need support. Finally, over 65 percent of the federal doses allocated to Community Health Centers have been administered to people of color.

But there is more work to do. That is why we're doubling down on the progress we are seeing through federal programs. Today's announcements include:

$6 Billion Investment in Community Health Centers to Expand Access to Vaccines in Underserved Communities. HHS will invest more than $6 billion from the American Rescue Plan into Community Health Centers nationwide to expand COVID-19 vaccinations, testing, and treatment for vulnerable populations; deliver preventive and primary health care services to people at higher risk for COVID-19; and expand health centers' operational capacity during the pandemic and beyond, including modifying and improving physical infrastructure and adding mobile units. The Health Resources and Services Administration (HRSA), will provide funding starting in April to nearly 1,400 centers across the country. Community Health Centers serve 1 in 5 people living in rural communities. More than 91% of health center patients are individuals or families living at or below 200% of the Federal Poverty Guidelines, and more than 60% are racial or ethnic minorities.

For detailed information on how this funding is being distributed to health centers nationwide, including state-by-state breakdowns and an interactive health center funding map, please visit: https://bphc.hrsa.gov/program-opportunities/american-rescue-plan/awards .

Expanding Eligibility for Vaccines to Patients Served by Community Health Centers. In addition to today's historic investment in Community Health Centers, Community Health Centers participating in the federal Health Center COVID-19 Vaccine Program are invited to expand eligibility to populations in the ACIP's 1C eligibility tier – this includes frontline essential workers and all persons 16 years and older with high-risk medical conditions. This means approximately 83% of the adults seen at Community Health Centers participating in the federal Health Center COVID-19 Vaccine Program will now be eligible for vaccinations. This follows the President's announcement that all adults will be eligible for vaccinations no later than May 1. Today's news will enable more people in need to receive vaccine doses.

$3 Billion to Strengthen Vaccine Confidence. HHS, through the Centers for Disease Control and Prevention (CDC), will invest $3 billion to support local efforts to increase vaccine uptake and equity. This funding will go directly to states, territories, and some large cities, enabling them to support local health departments and community-based organizations in launching new programs and initiatives intended to increase vaccine access, acceptance, and uptake. This funding will focus on reaching communities hit hardest by the pandemic, including those with a high social vulnerability index, minority communities, and rural areas. The awards will be made in early April and administered through CDC's existing immunization cooperative

agreement with 64 jurisdictions. More than half of this funding is being made available thanks to the American Rescue Plan.

Examples of new programs this funding to jurisdictions could support include:

- A rural, faith-based organization could receive funding to conduct door-to-door outreach to schedule vaccination appointments in partnership with a community health center;
- A food assistance and housing nonprofit in a high-poverty community could receive funding to conduct vaccine outreach and education, and to ensure its clients, including those with disabilities or limited mobility, have transportation to a FEMA-supported mass vaccination site;
- Funding could support hiring or extending the hours of community health workers who do culturally-competent bilingual health outreach, so they can make sure uninsured people who are receiving care also have the information they need to get a free vaccination.

Launch a Partnership to Vaccinate Dialysis Patients. The Administration is announcing a new partnership with dialysis clinics to provide COVID-19 vaccinations to people receiving dialysis and health care personnel in outpatient dialysis clinics. Kidney disease disproportionately affects racial and ethnic minorities as 34% of patients on dialysis are Black and 19% are Hispanic. People on dialysis who contract COVID-19 often have severe health outcomes and have a 50% hospitalization rate and a mortality rate between 20-30% from COVID-19. There are about 500,000 people in the U.S. who receive regular dialysis treatment. Through this partnership, the Administration will provide vaccines directly to dialysis treatment centers so patients who typically go three times a week for treatment are able to get vaccinated at their place of care.

$330 Million to Invest in Community Health Workers. HHS, through CDC, will provide $300 million to jurisdictions for community health worker services to support COVID-19 prevention and control, and an additional $32 million for training, technical assistance, and evaluation. This funding will be used to address disparities in access to COVID-19 related services, such as testing, contact tracing, and vaccinations, and it will help address factors that increase risk of severe COVID-19 illness such as chronic diseases, pregnancy, and food insecurity. For example, this funding could support nurses who are serving hard-hit areas or local community health workers conducting outreach efforts to make those at highest risk aware of vaccination opportunities. This effort will benefit populations with increased prevalence of COVID-19 and disproportionately impacted by long-standing health disparities related to sociodemographic characteristics, geographic regions, and economic strata.

###

Exhibit 14

BRIEFING ROOM

FACT SHEET: Biden Administration Announces Historic $10 Billion Investment to Expand Access to COVID-19 Vaccines and Build Vaccine Confidence in Hardest-Hit and Highest-Risk Communities

MARCH 25, 2021 • STATEMENTS AND RELEASES

Administration Makes Essential Workers Eligible for Vaccinations at Community Health Centers in Federal CHC Vaccination Program

Administration Also Announces New Program to Vaccinate Dialysis Patients Nationwide

As part of President Biden's continued efforts to ensure COVID-19 vaccines reach all people and all communities, the Biden-Harris Administration is announcing a series of actions to expand access to COVID-19 vaccines to the hardest-hit and highest-risk communities across the country. With funding in large part from the American Rescue Plan, the U.S. Department of Health and Human Services (HHS) will invest nearly $10 billion to expand access to vaccines and better serve communities of color, rural areas, low-income populations, and other underserved communities in the COVID-19 response. This funding will expand access to vaccines for vulnerable populations and increase vaccine confidence across the country.

Equity is at the center of the Administration's COVID-19 response. The President has set up federally-run community vaccination centers in hard-hit areas; sent vaccines directly to local pharmacies and Community Health Centers that disproportionately serve vulnerable populations; launched hundreds of mobile clinics to meet people where they are; and created the COVID-19 Health Equity Task Force.

These actions are garnering initial results. In the past two months, 60 percent of doses at federally-run Community Vaccination sites were administered to people of color. In the federal retail pharmacy program, 45 percent of sites were located in zip codes with high social vulnerability scores – a CDC index that uses 15 U.S. census variables to identify communities that may need support. Finally, over 65 percent of the federal doses allocated to Community Health Centers have been administered to people of color.

But there is more work to do. That is why we're doubling down on the progress we are seeing through federal programs. Today's announcements include:

$6 Billion Investment in Community Health Centers to Expand Access to Vaccines in Underserved Communities. HHS will invest more than $6 billion from the American Rescue Plan into Community Health Centers nationwide to expand COVID-19 vaccinations, testing, and treatment for vulnerable populations; deliver preventive and primary health care services to people at higher risk for COVID-19; and expand health centers' operational capacity during the pandemic and beyond, including modifying and improving physical infrastructure and adding mobile units. The Health Resources and Services Administration (HRSA), will provide funding starting in April to nearly 1,400 centers across the country. Community Health Centers serve 1 in 5 people living in rural communities. More than 91% of health center patients are individuals or families living at or below 200% of the Federal Poverty Guidelines, and more than 60% are racial or ethnic minorities.

For detailed information on how this funding is being distributed to health centers nationwide, including state-by-state breakdowns and an interactive health center funding map, please visit: https://bphc.hrsa.gov/program-opportunities/american-rescue-plan/awards .

Expanding Eligibility for Vaccines to Patients Served by Community Health Centers. In addition to today's historic investment in Community Health Centers, Community Health Centers participating in the federal Health Center COVID-19 Vaccine Program are invited to expand eligibility to populations in the ACIP's 1C eligibility tier – this includes frontline essential workers and all persons 16 years and older with high-risk medical conditions. This means approximately 83% of the adults seen at Community Health Centers participating in the federal Health Center COVID-19 Vaccine Program will now be eligible for vaccinations. This follows the President's announcement that all adults will be eligible for vaccinations no later than May 1. Today's news will enable more people in need to receive vaccine doses.

$3 Billion to Strengthen Vaccine Confidence. HHS, through the Centers for Disease Control and Prevention (CDC), will invest $3 billion to support local efforts to increase vaccine uptake and equity. This funding will go directly to states, territories, and some large cities, enabling them to support local health departments and community-based organizations in launching new programs and initiatives intended to increase vaccine access, acceptance, and uptake. This funding will focus on reaching communities hit hardest by the pandemic, including those with a high social vulnerability index, minority communities, and rural areas. The awards will be made in early April and administered through CDC's existing immunization cooperative

agreement with 64 jurisdictions. More than half of this funding is being made available thanks to the American Rescue Plan.

Examples of new programs this funding to jurisdictions could support include:

- A rural, faith-based organization could receive funding to conduct door-to-door outreach to schedule vaccination appointments in partnership with a community health center;
- A food assistance and housing nonprofit in a high-poverty community could receive funding to conduct vaccine outreach and education, and to ensure its clients, including those with disabilities or limited mobility, have transportation to a FEMA-supported mass vaccination site;
- Funding could support hiring or extending the hours of community health workers who do culturally-competent bilingual health outreach, so they can make sure uninsured people who are receiving care also have the information they need to get a free vaccination.

Launch a Partnership to Vaccinate Dialysis Patients. The Administration is announcing a new partnership with dialysis clinics to provide COVID-19 vaccinations to people receiving dialysis and health care personnel in outpatient dialysis clinics. Kidney disease disproportionately affects racial and ethnic minorities as 34% of patients on dialysis are Black and 19% are Hispanic. People on dialysis who contract COVID-19 often have severe health outcomes and have a 50% hospitalization rate and a mortality rate between 20-30% from COVID-19. There are about 500,000 people in the U.S. who receive regular dialysis treatment. Through this partnership, the Administration will provide vaccines directly to dialysis treatment centers so patients who typically go three times a week for treatment are able to get vaccinated at their place of care.

$330 Million to Invest in Community Health Workers. HHS, through CDC, will provide $300 million to jurisdictions for community health worker services to support COVID-19 prevention and control, and an additional $32 million for training, technical assistance, and evaluation. This funding will be used to address disparities in access to COVID-19 related services, such as testing, contact tracing, and vaccinations, and it will help address factors that increase risk of severe COVID-19 illness such as chronic diseases, pregnancy, and food insecurity. For example, this funding could support nurses who are serving hard-hit areas or local community health workers conducting outreach efforts to make those at highest risk aware of vaccination opportunities. This effort will benefit populations with increased prevalence of COVID-19 and disproportionately impacted by long-standing health disparities related to sociodemographic characteristics, geographic regions, and economic strata.

###

Exhibit 15

White House announces new funds for COVID-19 testing and vaccination amid delta surge

BY PETER SULLIVAN - 07/22/21 12:15 PM EDT
137 SHARES

© getty: Jeff Zients

The White House on Thursday announced new funding for vaccination and testing efforts as the delta variant fuels COVID-19 outbreaks, particularly among the unvaccinated.

The administration announced the release of about $100 million for rural health clinics to do vaccine outreach, given that many rural areas have lower vaccination rates and local health clinics can be a trusted source of information about vaccines.

“This funding will give trusted messengers in rural communities the tools they need to counsel patients on how COVID-19 vaccines can help protect them and their loved ones," said Health and Human Services Secretary Xavier Becerra.

In addition, the administration announced $1.6 billion to support testing in prisons, homeless shelters, domestic violence shelters and other congregate settings.

"These resources will help local health officials and communities identify potential outbreaks before they happen and prevent the further spread of COVID-19," said White House COVID-19 response coordinator Jeff Zients.

The money comes from funding approved by Congress as part of the American Rescue Plan relief package passed earlier this year.

Just In...

The Memo: Biden, bruised by Afghanistan, faces a critical test in Ukraine
THE MEMO — 5M 40S AGO

Study: Test detects signs of dementia at least six months earlier than standard method
HEALTHCARE — 12M 28S AGO

Biden holds call with European leaders to talk Russia
ADMINISTRATION — 26M 12S AGO

Jan. 6 committee getting 'significant cooperation' from top Pence aide: CNN
ADMINISTRATION — 37M 55S AGO

France to close nightclubs for four weeks
HEALTHCARE — 45M 29S AGO

Schumer steps on the gas to move Biden agenda
ENERGY & ENVIRONMENT — 1H 9M AGO

Build Back Better Is bad for the states
OPINION — 1H 12M AGO

Democratic lawmaker: Biden's diplomatic boycott of Beijing 'does not go far enough'

HOUSE ELECTIONS

VIEW ALL

New York mayor announces vaccine mandate for private-sector employers

Overnight Health Care — Biden touts drug price push

Overall, though, as the delta variant fuels an increase in cases, the White House is still emphasizing that vaccinated people are largely protected, and the main action needed is for unvaccinated people to get the shots.

"We are concerned with the rise in cases among the unvaccinated," Zients said at a press briefing Thursday, but added: "The threat is now predominantly only to the unvaccinated."

The U.S. is averaging about 38,000 cases per day, an increase, but still well below the peaks from last winter of over 250,000 cases per day.

TAGS XAVIER BECERRA JEFF ZIENTS COVID-19 VACCINE CORONAVIRUS DELTA VARIANT

SHARE TWEET

Related News by

Sponsored

Three brands that are avoiding Christmas...

Exhibit 16

From: Enlow, Courtney D. (CIV)
To: Aaron Siri; Gabrielle Palmer
Cc: Elizabeth Brehm
Subject: RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)
Date: Wednesday, December 1, 2021 8:35:51 AM

Good morning Aaron,

With regard to *PHMPT v. FDA*, No. 21-cv-1058 (N.D. Tex.), FDA has now had the opportunity to assess the number of responsive pages and to estimate processing times for additional portions of Plaintiff's priority list. In light of that assessment, FDA proposes that it produce the non-exempt portions of the following records by the below dates:

- By December 13, 2021, FDA plans to produce publicly releasable information from:
  - ***Plaintiff's priority item #1***- CRF files for site 1055 (~2,030 pages);
  - ***Completion of Plaintiff's priority item #5***-
    - Four additional .txt files that were listed on p. 10 of the index;
    - Four additional SAS files (not specifically listed on Plaintiff's priority list, but mentioned as something Plaintiff was interested in).
  - Publicly releasable information from the following additional sections of the original Comirnaty BLA:
    - Section 2.5 – Clinical Overview (~333 pages)
    - Section 2.7.3 – Summary of Clinical Efficacy (~182 pages)
    - Section 2.7.4 – Summary of Clinical Safety (~344 pages)
- By December 30, 2021, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #2*** – CRF files for site 1081 (~3,380 pages);
- By January 18, 2022, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #3*** – CRF files for site 1096 (~2,937 pages); and
- By January 31, 2022, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #4*** – CRF files for site 1128 (~3,452 pages).

Under this schedule, by the end of January 2022, FDA expects to have produced publicly releasable information from more than 12,000 pages of records and 10 unpaginated .txt or SAS data files. (This page and file count includes records produced to Plaintiff on November 17, 2021, and records that will be produced to Plaintiff later today.) FDA will also have completed production of seven of the first eight items on the priority list Plaintiff provided to FDA on November 4, 2021.

After the January 31, 2022 production, FDA proposes to make one production at the end of each

subsequent month totaling a minimum the non-exempt portions of 500 pages. (For purposes of calculating a "page count" of data records that are not paginated, FDA proposes considering twenty lines of spreadsheet data the equivalent of one page. For example, production of a spreadsheet containing 2,000 lines of data would be counted the equivalent of a 100-page PDF record.) To the extent feasible, FDA plans to continue to prioritize records from Plaintiff's priority list. Although FDA proposes a minimum rate of 500 pages a month, FDA will continue to produce records at a faster rate where feasible.

Please let me know if Plaintiff is amenable to this proposed schedule. If so, I propose that the parties file a joint status report setting out the agreed-upon schedule and requesting that the Court cancel the hearing set for December 14 and the briefing deadlines.

Thanks,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Enlow, Courtney D. (CIV)
Sent: Wednesday, November 17, 2021 1:40 PM
To: Aaron Siri <aaron@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>
Subject: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon Aaron and Gabrielle,

I've attached correspondence from FDA and a release of records in *PHMPT v. FDA*, No. 21-cv-1058 (N.D. Tex.). Kindly confirm receipt.

Thanks,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch

1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

Exhibit 17

App000424

Exhibit 18

HEALTH NEWS ✓ Fact Checked

States with High Vaccination Rates Can Still Experience COVID-19 Surges — Here's Why

Written by Bob Curley on November 28, 2021 — Fact checked by Jennifer Chesak

Places such as Vermont where cold weather has set in are seeing an increase in COVID-19 cases. Spencer Platt/Getty Images

- **The average daily number of new COVID-19 cases has been rising in the United States during the past month.**

- **They also note that new cases aren't necessarily the best indicators of the seriousness of the current state of the pandemic. Deaths and hospitalizations should be examined, too.**

New COVID-19 cases are rising in a number of U.S. states again, including some with high rates of vaccination.

But weather may have as much to do with the trend than vaccination rates, experts say.

The 7-day daily average of new COVID-19 cases had fallen below 50,000 during the middle of the summer before increasing in August and then decreasing again in early autumn, according to data compiled by the Centers for Disease Control and Prevention (CDC).

The upward trend has now started to reappear.

New daily COVID-19 cases have topped 100,000 three times this past week, with a 7-day average reaching about 94,000 new cases per day by midweek last week.

In addition, 39 states experienced increases in COVID-19 cases during the week that ended Nov. 21, according to data compiled by Reuters.

Among the states with rising caseloads:

- Missouri: 102 percent increase
- Connecticut: 85 percent increase
- Michigan: 65 percent increase
- Oklahoma: 49 percent increase
- Massachusetts: 48 percent hike

rates.

“We went through the same cycle last year with different parts of the country… going up at different times,” Dr. Robert C. Bollinger, a professor of infectious diseases at Johns Hopkins University School of Medicine in Baltimore and a founding member of emocha Health.

a professor of infectious diseases, medicine, public health, and nursing as well as director of the Center for Clinical Global Health Education at Johns Hopkins University School of Medicine in Baltimore, told Healthline.

“There are probably a number of factors contributing to the current spike,” Dr. Karen Edwards, chair of the department of epidemiology and biostatistics at the University of California, Irvine Program in Public Health, told Healthline. “Some of the most likely factors are that as the weather gets colder, more people are gathering indoors and in closer proximity to each other, which facilitates transmission between individuals.”

“There may also be less adherence to mask wearing, good hygiene, and social distancing, which combined with more indoor activities, will increase opportunities for infection, especially among the unvaccinated,” said Edwards.

She noted that there are still significant numbers of unvaccinated people even in states with higher vaccination rates, “and are more likely to be infected, have more severe illness, and contribute to the spikes.”

What the coming months may bring

Dr. Joseph Iser, a fellow of the American College of Preventive Medicine, told Healthline that the current increase in COVID-19 cases is likely to get worse in the coming months.

“If you’re looking at the flu season, it really doesn’t start until the cold of late fall or early winter,” said Iser. “I think the COVID surge is going to look pretty serious. I think it’s going to continue to rise until we get more adults vaccinated, more adults to get boosters, and more kids ages 5 to 11 to get vaccinated.”

As for states that seem to be behind the curve of rising case rates despite low vaccination rates, Iser said, “Give it time.”

“Once the cooler weather sets, we’re going to see an uptick in those places, too,” he predicted.

Waning immunity against COVID-19, among both vaccinated people and those who previously contracted the coronavirus, may also be a contributing factor to the upward trend in cases, according to Bollinger.

“People who were vaccinated more than 6 months ago now need a booster,” Bollinger noted.

The prevalence of the highly infectious Delta variant also plays a role in driving cases upward, said Bollinger.

He said it’s likely that at least 90 percent of Americans will need to be immune to the novel coronavirus before COVID-19 is brought under control.

These concerns were paramount even before the announcement late last

unvaccinated people to drive rates up when you have a highly infectious disease like this."

Cases aren't the only indicator

Case rates don't tell the whole story about the latest spike in infections, according to Iser.

Vaccinated people may be getting so-called "breakthrough infections" that add to the case count, but such cases tend to be milder, whereas unvaccinated people are still far more likely to develop severe COVID-19 illnesses.

"Looking at case rates gives you a sense of transmissions in that community," said Iser. "But if you want to see the seriousness of illness you need to look at hospitalizations and death rates."

So, while there may seem to be a contradiction in states with lower

Yet with the COVID-19 death toll already topping 777,000 in the United States, Bollinger said the prospect of 1 million total deaths from COVID-19 this winter or next spring seems likely “if we don’t really turn things around.”

FEEDBACK:

HEALTH NEWS ✓ Fact Checked

Why Hospitalizations, Deaths May Be Better Indicators of the COVID-19 Pandemic Than New Cases

Written by Tony Hicks on November 21, 2021 — Fact checked by Maria Gifford

Exhibit 19

CDC Centers for Disease Control and Prevention

Statement from CDC Director Rochelle P. Walensky, MD, MPH on Today's MMWR

Media Statement

For Immediate Release: Friday, July 30, 2021
Contact: Media Relations
(404) 639-3286

On July 27th, CDC updated its guidance for fully vaccinated people, recommending that everyone wear a mask in indoor public settings in areas of substantial and high transmission, regardless of vaccination status. This decision was made with the data and science available to CDC at the time, including a valuable public health partnership resulting in rapid receipt and review of unpublished data.

Today, some of those data were published in CDC's *Morbidity and Mortality Weekly Report (MMWR)*, demonstrating that Delta infection resulted in similarly high SARS-CoV-2 viral loads in vaccinated and unvaccinated people. High viral loads suggest an increased risk of transmission and raised concern that, unlike with other variants, vaccinated people infected with Delta can transmit the virus. This finding is concerning and was a pivotal discovery leading to CDC's updated mask recommendation. The masking recommendation was updated to ensure the vaccinated public would not unknowingly transmit virus to others, including their unvaccinated or immunocompromised loved ones.

This outbreak investigation and the published report were a collaboration between the Commonwealth of Massachusetts Department of Public Health and CDC. I am grateful to the commonwealth for their collaboration and rigorous investigation. I would also like to humbly thank the residents of Barnstable County who leaned in to assist with the investigation through their swift participation in interviews by contact tracers, willingness to provide samples for testing, and adherence to safety protocols following notification of exposure.

This outbreak investigation is one of many CDC has been involved in across the country and data from those investigations will be rapidly shared with the public when available. The agency works every day to use the best available science and data to quickly and transparently inform the American public about threats to health.

###

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CDC works 24/7 protecting America's health, safety and security. Whether disease start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC responds to America's most pressing health threats. CDC is headquartered in Atlanta and has experts located throughout the United States and the world.

Page last reviewed: July 30, 2021

Exhibit 20

HEALTH • COVID-19

The new Omicron COVID variant is a stark reminder that we are still in the depths of the pandemic

BY **MARCO QUIROZ-GUTIERREZ**

November 26, 2021 10:46 AM PST

community.

"Unfortunately, there's a new variant that is concerning," Dr. Ashish K Jha, a professor at Brown University, tweeted Friday morning. "Is it more transmissible than the current strain, Delta? Does it cause more severe disease? And will it render prior infections or vaccines less effective? ... We will know more in the coming days to weeks," he said.

And while we are still learning about this new strain, another medical expert, Georgetown immunologist Dr. Mark Dybul, has already reached a stark conclusion: We are still in the depths of the pandemic. Even if Omicron does not prove to be worrisome, a more transmissible, vaccine-resistant variant is just around the corner, a reality Dybal calls "inevitable."

In fact, Dybul predicts the pandemic will prevent a return to normal due to continued mutations and trailing treatments for another two or three years.

Dybul, the CEO of Enochian BioSciences and professor at Georgetown University Medical Center's Department of Medicine, said early information about Omicron did not look good.

With about 30 mutations in its spike protein, the variant has the potential to be vaccine resistant, Dybul said. Although we don't know where the strain initially developed, it has already spread to some individuals in South Africa, Botswana, Hong Kong, Israel, and Belgium. Although some countries including Italy, Singapore, and France have already put travel restrictions in place, the World Health Organization has cautioned nations to not jump to conclusions.

Thousands of COVID variants already exist, and new ones emerge constantly. In the next couple of weeks, we will know if the newly identified variant has the potential to be more transmissible and vaccine resistant, which would be the worst possible combination, said Dybul.

The most prominent strain of COVID-19, the Delta variant, has largely outperformed other variants, but it will be outcompeted eventually. The Delta strain has been positive in a way for vaccinated individuals because it is able to reproduce in vaccinated people but is still vulnerable to vaccines, said Dybul. Many of the shots have been doing a good job of protecting people against death and serious illness despite the Delta variant reproducing within them at times.

To become a major problem, the new strain would have to be more transmissible and vaccine resistant, and outperform the Delta variant. It's too early to tell whether this will occur, said Dybul, but that doesn't mean it won't happen eventually.

A mutation like that "is going to happen," he said. "We can't predict when. This could be it. It could already be somewhere else in the world and hasn't reared its head yet, but it's inevitable."

Even if the new variant outperforms Delta, the vaccines we have currently can be adjusted. Yet, it would take between three to five months for the adjusted vaccines to go through adjustment, testing, and the regulatory process, Dybul said. Even then, people would have to get revaccinated or get a booster shot.

To avoid a cycle of vaccination and re-vaccination, Dybul said, new strategies and treatments are needed. This could include a COVID-treating pill developed by Pfizer or easy-to-administer inhaled products that can be used to prevent or treat COVID.

"A vaccine-only approach is never going to work," Dybul said. Instead, he believes a 5-part strategy that includes mandatory boosters every 6 months, continued mask

wearing and the development of more treatments is the best way forward.

Related Articles

INTERNATIONAL

New COVID variant with 'unusual constellation' of mutations is already more dominant than Delta in South Africa

November 26, 2021

BY YVONNE LAU

HEALTH

Children, contagiousness, severity: What we know (and don't know) about the Omicron COVID variant so far

December 3, 2021

BY SOPHIE MELLOR

HEALTH

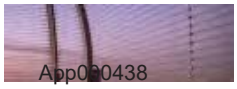
What's Omicron? Here's what we know and don't know about the new COVID variant that's roiling markets and ...

November 26, 2021

BY DAVID MEYER

HEALTH

Does Omicron cause milder COVID? Do vaccines work against it? Three experts



answer pressing questions about the new ...

November 29, 2021

BY GRADY MCGREGOR

HEALTH

South Africa has found a COVID-19 'mutation variant of serious concern'

November 25, 2021

BY PRINESHA NAIDOO, S'THEMBILE CELEAND OTHERS

Sponsored Financial Content

Sponsored Financial Content

Revealed: The True Cost of a Financial Advisor

smartasset

Tax-Smart Portfolio Tips

Charles Schwab

Rare "All In" Buy Alert. We're "All In" on This One Stock.

The Motley Fool

Earn up to $1,500 with a new Citigold account and required activities

CITIGOLD® OFFER

Wall St. legend's biggest prediction in 50 years

Stansberry Research

Man Who Called Cloud, Smartphones & AI: Get in This Now

Banyan Hill

See The 3 Essential Steps You Need To Take To Financial Freedom.

Personal Capital

Exhibit 21

https://www.wsj.com/articles/rising-covid-19-breakthrough-cases-hinder-efforts-to-control-virus-11636191003

U.K.

Rising Covid-19 Breakthrough Cases Hinder Efforts to Control Virus

People in their 40s show biggest case rise among U.K. vaccinated, likely due to their children

The U.K. has seen a rise in breakthrough Covid-19 infections, but vaccines have helped keep hospitalizations and deaths lower than in previous phases of the pandemic.

PHOTO: DINENDRA HARIA/ZUMA PRESS

By Denise Roland

Nov. 6, 2021 5:30 am ET

LONDON—Covid-19 infections among vaccinated people are complicating the fight to bring the coronavirus under control. And in the U.K., where the path of the disease has been more closely tracked than just about anywhere in the world, they are on the rise.

Breakthroughs happen because vaccines, while still offering strong protection against severe illness and death, aren't bulletproof. The virus can still in some cases infect the body and replicate, causing illness, before the immune response can tackle it. Immunity from vaccination also wanes over time, prompting many countries, including the U.K., to roll out booster-shot campaigns.

Breaking Through

Four-week Covid-19 infections per 100,000 in fully vaccinated people in England

Source: U.K. Health Security Agency

Breakthrough infections are expected to become more common as more people get vaccinated: if 100% of the population were vaccinated, every infection would be a breakthrough infection. However, U.K. data also suggest that among vaccinated people, the chances of getting a breakthrough infection are rising.

The rise in breakthroughs in the U.K. is being driven in part by children, still largely unvaccinated in the U.K., passing on the virus to their vaccinated parents. A detailed study on household transmission in the U.K. suggests that a vaccinated person who shares a home with somebody with symptomatic Covid-19 has a 25% chance of catching the virus.

In addition, breakthrough infections contribute to the spread of the virus, posing a risk to vulnerable and unvaccinated people. The household-transmission study also found that a vaccinated person with symptomatic Covid-19 is as likely to pass the virus on to someone who shares their home as an unvaccinated person.

Also contributing to stubbornly high case numbers in the U.K. are the tenaciousness of the fast-transmitting Delta variant and, some scientists say, the lack of social-distancing and other measures aimed at curbing transmission. Still, thanks to the vaccines, hospitalizations and deaths, while higher than in the summer when cases were low, are a fraction of what they were in previous phases of the pandemic.

"Breakthrough infections are not rare, and they're not unexpected, and they're not very concerning," said Dan Barouch, director of the Center for Virology and Vaccine Research at Beth Israel Deaconess Medical Center in Boston, Mass.

The U.K. in September started offering booster shots to people aged 50 and older.

PHOTO: DINENDRA HARIA/ZUMA PRESS

In most age groups in England, breakthrough infections are higher now than they were in mid-August, according to data from the U.K. Health Security Agency, formerly Public Health England.

That rise has been especially stark in people in their 40s. In the four weeks to Oct. 31, 2.1% of fully vaccinated 40-to-49-year-olds tested positive for the virus. That is up around 90% from a four-week infection rate of 1.1% in mid-August. Other age groups have seen more modest increases—between 22% and 56%—in the rate of breakthrough infections. In under-30s, the rate is now lower than it was in mid-August.

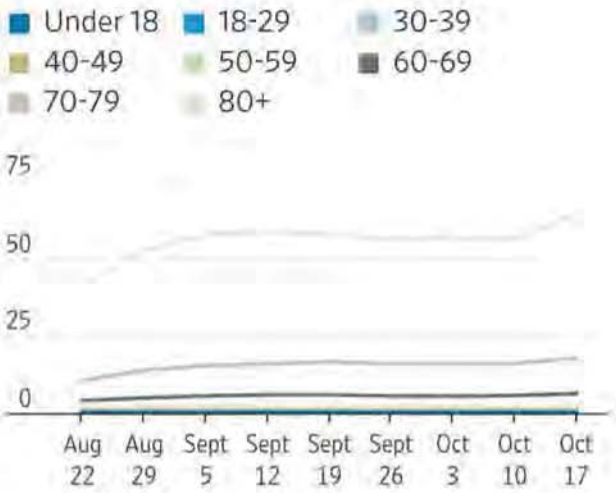
Ajit Lalvani, chair of infectious diseases at Imperial College London and lead author of the household-transmission study, said people in their 40s were at higher risk of breakthrough infection for two reasons. "Waning immunity plus pools of unvaccinated people acting as vectors of infection into the household where it transmits effectively to vaccinated parents," he said. "Both are happening."

Most people in their 40s received their second vaccination at least four months ago. A recent study from UKHSA found that vaccine effectiveness started to wane as early as 10 weeks after the second dose for the vaccines developed both by Pfizer Inc. and BioNTech SE, and by AstraZeneca PLC and the University of Oxford, the two most commonly used in Britain. Protection against symptomatic disease peaked in the early weeks after the

second dose then faded over a five-month period, to 69.7% and 47.3% respectively. The study hasn't been peer-reviewed.

Breakthrough Deaths

Four-week Covid-19 deaths per 100,000 in fully vaccinated people in England



Note: Deaths are counted as those within 60 days of first positive Covid-19 test or where Covid-19 is mentioned in the death certificate
Source: U.K. Health Security Agency

They are also the most-likely age band to share a home with teenage children, a group that is still mostly unvaccinated in the U.K. and in which case numbers have been surging. The household-transmission study, which tracked 205 vaccinated and unvaccinated household contacts of a symptomatic case of Covid-19, found that around a quarter of those who were fully vaccinated went on to develop a breakthrough infection. The study, published in the medical journal Lancet Infectious Diseases last week, found that unvaccinated household members had a 38% chance of infection.

Yet the four-week death rate from breakthrough infections in 40-to-49-year-olds has remained low and is currently at seven in a million. Death rates from breakthrough infections have crept up, however, in those ages 60 and over. These older age groups were more vulnerable to begin with and were also vaccinated early in the year, making it more likely that their immunity has waned. The U.K. in September started offering booster shots to people 50 and older.

In the four weeks to Oct. 31, 2.1% of fully vaccinated 40-to-49-year-olds in England tested positive for the virus, up around 90% from mid-August.

PHOTO: ANDY RAIN/EPA/SHUTTERSTOCK

Several studies have shown that in people who do suffer a breakthrough infection, vaccination doesn't diminish the peak viral load but it does help the body to clear infection more quickly. "That helps to explain why vaccinated people, even when infected, get fewer symptoms, quicker resolution of their symptoms and less risk of developing severe disease," said Imperial's Prof. Lalvani, whose study corroborated this finding.

Official data released on Monday from the U.K.'s Office for National Statistics further underscored the benefit of vaccination in warding off the worst effects of the virus.

Based on deaths between Jan. 2 and Sept. 24 this year, the ONS calculated that 849.7 out of every 100,000 unvaccinated people would die annually from Covid-19. For fully vaccinated people, the figure is just 26.2 per 100,000. The calculation is age-standardized, an established statistical technique that aims to compensate for the older age profiles of the vaccinated compared with the unvaccinated population.

That difference is likely exaggerated somewhat by the fact that the unvaccinated include people in older age groups who decline a shot because of their already poor health, according to James Doidge, senior statistician at the Intensive Care National Audit and Research Centre.

While they rarely lead to serious illness, breakthrough infections can be very unpleasant. Sarah Davies, a 39-year-old assistant professor of biology, spent two weeks feeling feverish, achy and tired after contracting the virus. Sometimes she was breathless, and she also lost her sense of smell.

"It was really relentless," said Mrs. Davies, who lives in Boston, Mass. "I cannot imagine how sick I would have been if I hadn't been vaccinated."

Covid-19 Vaccines

Related coverage, selected by the editors

Why It's So Hard to Tell if a Vaccine Card Is Fake

Vaccines and the Omicron Variant

Vaccine or Infection: Which Carries Stronger Immunity?

Should There Be More Time Between Shots?

Biden's Vaccine Mandate: What to Know

Researchers Probe Links Between Vaccines, Heart Inflammation

Are Vaccines Safe for Kids?

Covid-19 Boosters: What to Know

Write to Denise Roland at Denise.Roland@wsj.com

Appeared in the November 8, 2021, print edition as 'Breakthrough Cases Hinder Fight.'

Exhibit 22

Centers for Disease Control and Prevention

COVID-19

COVID-19 Vaccine Booster Shots

Updated Nov. 29, 2021

NEW Everyone ages 18 and older should get a booster shot

Everyone Ages 18 and Older Should Get a Booster Shot

IF YOU RECEIVED
Pfizer-BioNTech or Moderna

Who should get a booster:
Everyone 18 years or older

When to get a booster:
At least 6 months after completing your primary COVID-19 vaccination series.

Which booster should you get?
Any of the COVID-19 vaccines authorized in the United States.

IF YOU RECEIVED
Johnson & Johnson's Janssen

Who should get a booster:
Everyone 18 years or older

When to get a booster:
At least 2 months after completing your primary COVID-19 vaccination.

Which booster should you get?
Any of the COVID-19 vaccines authorized in the United States.

Choosing Your COVID-19 Booster Shot

You may choose which COVID-19 vaccine you receive as a booster shot. Some people may prefer the vaccine type that they originally received, and others may prefer to get a different booster. CDC's recommendations now allow for this type of mix and match dosing for booster shots.

Scheduling Your Booster Shot

If you need help scheduling your booster shot, contact the location that set up your previous appointment. If you need to get your booster shot in a location different from where you received your previous shot, there are several ways you can find a vaccine provider.

What to Expect during and after Your Booster Shot Appointment

- Bring your CDC COVID-19 Vaccination Record card to your booster shot appointment so your provider can fill in the information about your booster dose. If you did not receive a card at your first appointment, contact the vaccination site where you got your first shot or your state health department to find out how you can get a card.
- You may experience side effects after getting a COVID-19 vaccine. These are normal signs that your body is building protection against COVID-19.

- Use v-safe to tell CDC about any side effects. If you enter your booster shot in your v-safe account, the system will send you daily health check-ins.

Frequently Asked Questions

Are booster shots the same formulation as existing vaccines?

Yes. COVID-19 booster shots are the same formulation as the current COVID-19 vaccines. However, in the case of the Moderna COVID-19 vaccine booster shot, it is half the dose of the vaccine people get for their primary series.

If we need a booster shot, are the vaccines working?

Yes. COVID-19 vaccines are working well to prevent severe illness, hospitalization, and death, even against the widely circulating Delta variant. However, public health experts are starting to see reduced protection, especially among certain populations, against mild and moderate disease.

What are the risks to getting a booster shot?

So far, reactions reported after getting a booster shot were similar to those of the two-shot or single-dose primary series. You can use v-safe to tell CDC about any side effects. If you enter your booster shot in your v-safe account, the system will send you daily health check-ins. Fever, headache, fatigue and pain at the injection site were the most commonly reported side effects, and overall, most side effects were mild to moderate. However, as with the two-shot or single-dose primary series, serious side effects are rare, but may occur.

Am I still considered "fully vaccinated" if I don't get a booster shot?

Yes. Everyone is still considered fully vaccinated two weeks after their second dose in a two-shot series, such as the Pfizer-BioNTech or Moderna vaccines, or two weeks after a single-dose vaccine, such as the J&J/Janssen vaccine.

Data Supporting Need for a Booster Shot

Studies show after getting vaccinated against COVID-19, protection against the virus and the ability to prevent infection with variants may decrease over time.

Although COVID-19 vaccination remains effective in preventing severe disease, recent data [1 MB, 68 pages] suggest vaccination becomes less effective over time, especially in people aged 65 and older and at preventing infection or milder illness with symptoms.

- The recent emergence of the Omicron variant (B.1.1.529) further emphasizes the importance of vaccination, boosters, and prevention efforts needed to protect against COVID-19. Early data from South Africa suggest increased transmissibility of the Omicron variant and the potential for immune evasion.
- Emerging evidence also shows that among healthcare and other frontline workers, vaccine effectiveness against COVID-19 infections is also decreasing over time.
- This lower effectiveness is likely due to the combination of decreasing protection as time passes since getting vaccinated, as well as the greater infectiousness of the Delta variant.

Data from clinical trials showed that a booster shot increased the immune response in trial participants who finished a Pfizer-BioNTech or Moderna primary series 6 months earlier or who received a J&J/Janssen single-dose vaccine 2 months earlier. With an increased immune response, people should have improved protection against COVID-19, including the Delta variant. For Pfizer-BioNTech and J&J/Janssen, clinical trials also showed that a booster shot helped prevent COVID-19 with symptoms.

Related Pages

- Understanding How COVID-19 Vaccines Work
- Ensuring COVID-19 Vaccines Work
- Frequently Asked Questions about COVID-19 Vaccination
- Examples of Workers Who May Get Pfizer-BioNTech Booster Shots
- COVID-19 Vaccines for Moderately to Severely Immunocompromised People

For Healthcare and Public Health

Considerations for Use of a COVID-19 Vaccine Booster Dose

More Information

ACIP Presentation Slides, November 19, 2021

ACIP Presentation Slides, October 21, 2021

ACIP Presentation Slides, September 22–23, 2021

Last Updated Nov. 29, 2021

Exhibit 23

Transparency in Clinical Trials

Clinical trials are crucial to helping researchers understand the safety and effectiveness of an investigational drug. Pfizer's commitment to openness and transparency includes all aspects of research and development behind our products, including clinical trials. Enhanced transparency in clinical trials fosters trust among research participants, health care professionals, and biopharmaceutical companies, while increasing knowledge of potential new treatments in development. Transparency also enables patients, physicians, and others to see the progress being made to address unmet medical needs. Pfizer's policies support clinical trial transparency to advance scientific knowledge and public health, while balancing the need to protect participant privacy and respect the regulatory process.

Background

The study of how a medicine works in people is a pivotal step in the research and development process of new treatments for diseases and medical conditions. Researchers spend years in the laboratory before conducting carefully controlled studies in research participants, known as clinical trials. Regulatory authorities issue rules regarding the conduct of clinical trials and the sharing of the results of these studies to make sure that research sponsors abide by a clearly defined set of standards. A drug is approved only when the data, collected through clinical trials, prove that the drug is both safe and effective. Clinical trials help answer questions about risks, benefits, and side effects of a potential new treatment. In addition, clinical trials are also conducted on already approved medicines to increase knowledge about their potential uses, benefits, safety, and long-term effects.

Transparency of clinical trials is an important issue to patients, the research community, and policymakers. Certain jurisdictions require registration and posting of summary results from clinical trials of regulated medical products. To facilitate these requirements and recommendations, public registries, such as ClinicalTrials.gov and EudraCT, have been created for clinical trials conducted in the U.S. and Europe, respectively.[1,2] The World Health Organization International Clinical Trials Registry Platform is a voluntary global network that was established to provide a single point of access to multiple clinical trial databases, conforming to a set of international standards for clinical trial registries.[3]

An increasing call to have access to detailed clinical trial data has resulted in several additional regulations, policies, and clinical trial sponsor-led efforts. In July 2013, Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) jointly published commitments to responsible data sharing practices by biopharmaceutical companies.[4] In 2016, the European Medicines Agency (EMA) released a policy on the requirements for publishing clinical data to support regulatory applications.[5] The Food and Drug Administration (FDA) has explored policies designed to use and share de-identified and masked trial data from marketing applications.[6] In 2018, FDA launched a pilot program to assess the feasibility of releasing portions of clinical study reports (CSRs) in an effort to provide usable summaries of clinical evidence.[7] The International Committee of Medical Journal Editors (ICMJE) has a policy that medical journals require the registration of clinical trials as a condition of publication.[8]

Key Facts

- Pfizer invested more than $8 billion during 2018 in the research and development of new products,[9] and as of November 30, 2019 had 96 products in its development pipeline.[10]
- Pfizer currently has 205 open, ongoing trials registered on www.ClinicalTrials.gov.[11]

Pfizer Policy Positions

Pfizer believes it is important for researchers, trial participants, regulators, and others acting in the best interest of patients to have access to clinical trial information to advance medical understanding and progress. It is also important that this access protect participant privacy, preserve regulatory authority, and maintain incentives for those who generate research data.

Pfizer offers access to the clinical data gathered in company-sponsored clinical trials, in the hope and belief that greater openness may accelerate medical progress and benefit patient outcomes and public health. Pfizer publicly shares results from our clinical trials, whether the results are positive, neutral, or negative. We also share data gathered in clinical trials we sponsor with trial participants, researchers, and others. Pfizer's data access policies and practices meet or exceed the five transparency principles endorsed by PhRMA and EFPIA.[8]

Pfizer's clinical trial results and data sharing approaches include:

- **Regulatory Requirements**: Pfizer is committed to meeting or exceeding regulatory requirements for the registration of our clinical trials and provision of results upon completion.
- **Public Access to Clinical Study Information:** Pfizer publicly posts electronic synopses of Clinical Study Reports (CSRs) submitted to regulators, relating to approved products.[12] These reports include summary results for all primary and secondary endpoints with any personally identifiable information removed.
- **Sharing Results with Clinical Trial Participants:** Pfizer believes that data collected during a clinical trial should be returned to the study participants, if they wish and where permitted, so that they may better understand the research in which they participated and use the data gathered about their health. Pfizer returns clinical trial data to participants along with summaries of aggregate clinical trial results in easy-to-read, non-technical language so that they can understand why the study was done, how it was done, and the results.
- **Data Sharing with Researchers:** Pfizer provides access to de-identified patient-level data upon request from qualified scientific and medical researchers who have submitted a scientifically valid research proposal. Requests are managed through the global clinical research data sharing platform, Vivli.[13]
- **Publication of Clinical Trial Results:** Pfizer submits the primary results of all interventional clinical studies for publication in peer-reviewed biomedical journals within 18 months of study completion, regardless of the outcome.

How Patients and Health Care Systems Benefit

Clinical trials provide valuable information to help regulators ensure new medicines are safe and effective prior to being prescribed to patients. Trials also help biopharmaceutical companies, regulators, and public health officials monitor the safety and effectiveness of treatments already available to patients.

Transparency in clinical trials engenders trust between participants, health care professionals, and biopharmaceutical companies and increases patient knowledge of available medications, as well as potential new treatments in development. Pfizer's policies are designed to promote effective and ethical collaborations and build trust throughout the health care system. Finally, transparency in clinical trials enables monitoring of the progress being made to address unmet medical needs in our health care system.

[1] See: www.clinicatrials.gov.
[2] See: eudract.ema.europa.eu.
[3] See: www.who.int/ictrp/en.
[4] PhRMA & EFPIA —Principles for Responsible Clinical Trial Data Sharing. See: phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf.
[5] See: www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication.
[6] Federal Register notice, Docket No. FDA-2013-N-0271, Availability of Masked and De-identified Non-Summary Safety and Efficacy Data; Request for Comments; June 4, 2013. Available at http://www.gpo.gov/fdsys/pkg/FR-2013-06-04/html/2013-13083.htm.
[7] See: www.fda.gov/drugs/development-approval-process-drugs/clinical-data-summary-pilot-program.
[8] ICMJE Clinical Trials Recommendations: http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html.
[9] Pfizer 2018 Financial Report available at: s21.q4cdn.com/317678438/files/doc_financials/Annual/2018/2018-Financial-Report.pdf.
[10] See: www.pfizer.com/science/drug-product-pipeline.
[11] National Institutes of Health. ClinicalTrials.gov. Available at http://www.clinicaltrials.gov/ct2/search, accessed November 7, 2019.
[12] See: www.pfizer.com/research/research_clinical_trials/trial_results.
[13] See: vivli.org.

Exhibit 24

Transparency of COVID-19 vaccine trials: decisions without data

EBM analysis

Transparency of COVID-19 vaccine trials: decisions without data

Sarah Tanveer [1], Anisa Rowhani-Farid [1], Kyungwan Hong,[1] Tom Jefferson [2], Peter Doshi [1]

10.1136/bmjebm-2021-111735

[1]Department of Pharmaceutical Health Services Research, University of Maryland Baltimore, Baltimore, Maryland, USA
[2]Department for Continuing Education, University of Oxford, Oxford, UK

Correspondence to:
Dr Peter Doshi,
Pharmaceutical Health Services Research, University of Maryland School of Pharmacy, Baltimore, MD 21201, USA; pdoshi@rx.umaryland.edu

To cite: Tanveer S, Rowhani-Farid A, Hong K, *et al*. *BMJ Evidence-Based Medicine* Epub ahead of print: [please include Day Month Year]. doi:10.1136/bmjebm-2021-111735

Transparency in clinical trials: an established norm across sectors

Access to data for drugs and vaccines has historically been fairly limited to journal article publications and hard-to-access and difficult to read regulatory reports.[1] But the past decade has witnessed strides in clinical trial data transparency. A wide range of institutions, from pharmaceutical companies, government agencies, trade organisations, journals and not-for-profit organisations, have all acknowledged the importance of data sharing, including the release of deidentified individual participant data. Many policies, regulations and platforms now exist to facilitate data access, including landmark transparency policies from the European Medicines Agency (EMA)[2 3] and Health Canada.[4] Both regulators now post on their websites, sections of the licensure dossier received by the industry (https://clinicaldata.ema.europa.eu/ and https://clinical-information.canada.ca/). There are also industry and academic platforms to facilitate third-party access to trial data and documents, including ClinicalStudyDataRequest.com, Yale University Open Data Access (YODA) Project and Vivli.[5] In 2013, the US and European industry trade organisations endorsed a joint statement on clinical trial data sharing, making a series of commitments that 'recognise the importance of sharing clinical trial data in the interest of patients, healthcare and the economy"[6] In 2015, the US Institute of Medicine similarly endorsed benefits of sharing clinical trial data, emphasising that 'verification and replication of investigators' claims' were essential to the scientific process, and noting the numerous benefits to stakeholders 'including payers of healthcare as well as patients, their physicians and researchers.'[7]

Why we need access to COVID-19 vaccine trial data and documents

Clinical trial transparency is always important, but is especially critical during the COVID-19 pandemic (or any public health emergency) where regulatory decisions are being made quickly by government health officials, novel vaccine platforms are being used, vaccines are being administered widely and taxpayer funds have contributed heavily to research and development. Critical appraisal of clinical trials is vital to inform decision making at the personal, professional and governmental level, but cannot be credibly performed on journal publications alone.[8 9] Access to clinical trial data and related trial documents (see box 1) allows for independent and informed assessment of trials. By understanding details of how studies were designed and how data were collected, one can understand if endpoints were reliably operationalised and measured. Similarly, release of underlying data from clinical trials allows for independent verification of results, assessment of heterogeneity of treatment effects for specific subgroups, and facilitates the formation of new research questions.[10]

There are specific issues in COVID-19 vaccine trials that merit scrutiny. Consider blinding, an essential feature in randomised trials investigating efficacy against subjective endpoints, as in the COVID-19 vaccine trials. Assessing the reliability of blinding involves analysing endpoint definitions and data collection. The primary endpoint in many trials is laboratory-confirmed, symptomatic

Summary box

- Data transparency has become a well-established norm in biomedical research, and is especially important for broadly used public health interventions like COVID-19 vaccines.
- Tax payers helped fund COVID-19 vaccine trials and should have the right to access the results.
- There is inadequate availability of COVID-19 vaccine trial documents and data; individual participant data will not be available for months, perhaps years, for most vaccines.
- Widespread use of interventions without full data transparency raises concerns over the rational use of COVID-19 vaccines.
- Trial transparency must start early and be continuous. Trial protocols should be released once finalised, before trial results are reported, and should be accompanied with the release of trial documents and data before clinicians and the public make decisions regarding product use.

Box 1 Types of trial documents

Case report forms (CRFs)
The original paper or electronic forms on which individual participants' data (demographic, efficacy measurements, adverse events, etc) are recorded during the clinical trial. These documents contain structured fields which make it easier to analyse and report trial data. Access to blank case report forms (CRFs) allows for independent evaluation of how data were collected and endpoints were operationalised.

Clinical study reports(CSRs)
Unabridged, structured report of a clinical study written for regulators.[30] A complete clinical study reports (CSRs), including study appendices, includes documentation of trial design, results of trial included adverse events, trial protocol, statistical analysis plans and blank CRFs. CSRs on average span thousands of pages, making them a rich source of information. European Medicines Agency and Heath Canada are the only two regulatory agencies that publish CSRs at this time.

Certificate of analysis
Provides a description of the chemical analysis and physical appearance of the study interventions actually used in the trial (both experimental and comparators).

Protocol
Document written prior to study start date which details plans on how the study will be conducted, analysed and reported. Any changes or deviations from the trial protocol should be tracked and provided, with a rationale for the change, in the form of a formal protocol amendment.

Statistical analysis plan (SAP)
A written plan of how trial data will be analysed and which statistical methods and definitions will be used.

Informed consent form (ICF)
A document required to be provided to study subjects that contains information related to the description of the study, purpose, study intervention(s), any procedures, adverse events, risk and benefits, compensation and rights of participants enrolled in the study.

Serious adverse event (SAE) narratives
Unstructured paragraphs of text providing details and context of the serious adverse events that occurred in study participants. Narratives are usually contained within a CSR.

Electronic individual participant data (IPD)
Complete electronic computerised dataset for each participant in the trial which allows for full replication of study findings using statistical software. Complete CSRs also contain participant level data, mostly in appendices, but these are in text (not dataset) form as individual line listings.

Investigational Medicinal Product Dossier (IMPD)
Document that describes the quality of the placebo and investigational product, how the product(s) were manufactured, non-clinical and clinical study results. An Investigational Medicinal Product Dossier is required for all clinical trials conducted in the European Union.

Investigator's Brochure (IB):
A living document containing a summary of the clinical and nonclinical data of an investigational product, including its pharmacology, pharmacokinetics, toxicology and adverse event profile, among other items.

Sources: Restoring Invisible and Abandoned Trials (RIAT) declaration,[31] RIAT Support Center Glossary.[32]

COVID-19. However, prior to the release of trial protocols, few details were known about this endpoint. Registry entries were vague (eg, Pfizer's largest study[11] only stated 'confirmed COVID-19' as one of 35 primary outcome measures), leaving unclear how the definition was operationalised. While the subsequent release of some protocols addressed some questions, it raised new questions that can only be answered with underlying data. Protocols make clear that the symptomatic component of the primary endpoint was reported by trial participants, typically via a smartphone app, and defined by one or more signs and symptoms, many of which were subjective (eg, in Pfizer's trial, COVID-19 symptoms included at least one of the following: fever, cough, shortness of breath, chills, muscle pain, loss of taste or smell, sore throat, diarrhoea or vomiting.) The fact that the placebo was saline and the vaccines cause short term adverse events in the majority of people raises concerns about unofficial unblinding—that is, the ability of trial participants and investigators to make educated guesses as to treatment allocation. Only a thorough analysis of the underlying individual participant data will allow for an exploration of the extent to which unofficial unblinding may have occurred and biased data collection for the primary endpoint. Access to data would also allow for straightforward replication studies, perhaps particularly important when real-world results appear incompatible with reported trial results. For example, at the time of writing (27 June 2021), Seychelles, Mongolia, Bahrain, Uruguay, and Chile were experiencing COVID-19 outbreaks despite high uptake of WHO-authorised vaccines.

In addition, trial protocols from Pfizer and Moderna indicate that event adjudication committees were involved in counting COVID-19 cases. Considering that the primary endpoint was defined as a positive lab test and patient-reported symptoms, it is unclear how an adjudication committee might affect the primary endpoint evaluation process. Transparency of the committee's charter may provide additional detail on what data committee members had access to in forming their judgements (eg, did they have access to data on patients' symptoms in the first week after vaccination, when vaccine-related adverse events could be expected?), and what criteria they used to form their judgements. Access to such documents, therefore, is also important.

Regarding adverse events, detailed narratives of serious adverse events that occurred in a trial are a standard element found within clinical study reports and can enable a more thorough understanding of potential harms. Patterns in adverse

Table 1 Currently available COVID-19 vaccine trial data for selected trials

Trial ID; no enrolled; included ages	Pre-study documents	Post-study documents†					Total pages available§
		Press release	Pub	CSR	Other‡	IPD	
Pfizer BNT162b2 mRNA vaccine							
NCT04368728; n=43 998; 12–85 years	Protocol, SAP, Blank CRF	Press release 1, 2, 3	Pub 1,2,3	CSR	Other	No	3880
NCT04713553; n=1530; 12–50 years	None	No	N/A: trial ongoing				0
NCT04816643; n=4644; 6 months to 11 years	None	No	N/A: trial ongoing				0
Moderna mRNA-127 vaccine							
NCT04470427; n=30 420; ≥18 years	Protocol, SAP	Press release	Pub	No	Other	No	3293
NCT04811664; n=37 500; 18–26 years	None	No	N/A: trial ongoing				0
NCT04796896; n=6750; 6 months to 12 years	None	No	N/A: trial ongoing				0
Oxford/AstraZeneca ChAdOx1 vaccine							
ISRCTN89951424; n=10 300; ≥18 years	Protocol	Press release	Pub 1¶, 2¶	No	No	No	123
NCT04400838; n=12 390; ≥18 years	Protocol	Press release	Pub 1¶, 2¶	No	No	No	214
ISRCTN15638344; n=300; 6–17 years	None	No	N/A: trial ongoing				0
Janssen (Johnson & Johnson) Ad26.COV2.S vaccine							
NCT04505722; n=44 325; ≥18 years	Protocol, SAP, Blank ICF	Press release	Pub	No	No	No	530
NCT04535453; n=1210; 12 to 55, ≥65 years	None	No	N/A: trial ongoing				0
NCT04614948; n=30 000; ≥18 years	Protocol	No	N/A: trial ongoing				166
Novavax SARS-CoV-2 rS/Matrix-M1 Adjuvanted vaccine							
NCT04611802; n=30 000; ≥18 years	Protocol	No	N/A: trial ongoing				128
NCT04368988; n=1419; 18–84 years	Protocol, SAP	Press release	N/A: trial ongoing				189
NCT04583995; n=15 187; 18–84 years	Protocol, SAP	Press release	Pub	No	No	No	128
Gamaleya Research Institute Sputnik V/Gam-COVID-Vac vaccine							
NCT04530396; n=33 758; ≥18 years	None	Press release	Pub	No	No	No	11
NCT04741061; n=6000; ≥18 years	None	No	N/A: trial ongoing				0
NCT04642339; n=2000; ≥18 years	None	No	N/A: trial ongoing				0
Sinopharm (BIBP) vaccine							
ChiCTR2000032459; n=2128; ≥3 years	None	No	Pub	No	No	No	13
NCT04510207; n=45 000; ≥18 years	Protocol, SAP	No	Pub	No	No	No	102
NCT04612972; n=12 000; ≥18 years	None	No	N/A: trial ongoing				0
Sinovac (CoronaVac) vaccine							
NCT04456595; n=12 688; ≥18 years	Protocol	Press release	Pub	No	No	No	201
NCT04551547; n=552; 3–17 years	None	No	Pub	No	No	No	22
NCT04582344; n=13 000; 18–59 years	Protocol	Press release	No	No	No	No	57

Data current as of 27 June 2021.

*Pre-study documents include: protocol, statistical analysis plan, blank informed consent form, blank case report form, data monitoring board charter, event adjudication committee charter, investigational medicinal product dossier and investigator's brochure.

†Post-study documents include: press releases (that contain any results), journal publication (including pre-prints), clinical study report and individual participant data.

‡Other includes documents released by Health Canada and EMA other than the CSR.

§Total pages available excludes press releases. Access to the dataset used to determine page count for trials where additional data were available through Health Canada and the European Medicines Agency is available in the Zenodo repository (http://doi.org/10.5281/zenodo.4737417).

¶Pooled trial analysis publication listed if there were no individual trial publications.

CRF, case report form; CSR, clinical study report; EMA, European Medicines Agency; ICF, informed consent form; IPD, individual participant data; n, number enrolled in trial; N/A, not applicable; Pub, journal publication ; SAP, statistical analysis plan.

events can be explored through access to electronic individual participant-level data.

What data have been released

For eight COVID-19 vaccines being used, or under consideration for use globally (Pfizer, Moderna, Oxford/AstraZeneca, Janssen/Johnson & Johnson, Novavax, Gamaleya Institute, Sinopharm and Sinovac), we evaluated the public availability of a variety of important pre-study documents (eg, trial protocol, statistical analysis plan, blank informed consent form, blank case report form, data monitoring board charter, and event adjudication committee charter) and post-study documents (eg, press releases with trial

Table 2 Timing of release of individual participant data from COVID-19 vaccine trials

Phase 3 trial	Protocol released before results released?	Pledge to share IPD	Estimated date of availability (based on data sharing statement in protocol or publication)
Pfizer phase 2/3; 43 998 participants (NCT04368728)	Yes	Yes	April 2025, based on statement in trial protocol that data will be made available '24 months after study completion'
Moderna phase 3; 30 420 participants (NCT04470427)	Yes	Unclear	October 2022, based on statement in trial publication that data "may be available … once the trial is complete"
Oxford/AstraZeneca phase 3; 10 300 participants (ISRCTN89951424)	No	Yes	December 2021, based on statement in trial publication that trial data 'will be made available when the trials are complete'
Janssen (Johnson & Johnson) phase 3; 44 325 participants (NCT04505722)	Yes	Yes	Unclear. April 2021 publication suggested data availability will begin 'with publication,' but as of June, still not listed on Yale Open Data Access Project website.
Novavax phase 3; 30 000 participants (NCT04611802)	Yes	No*	We could not locate any other written statement regarding patient-level data sharing. It is not discussed in the trial protocol or publication.
Gamaleya Research Institute phase 3; 33 758 participants (NCT04530396)	No	Yes*	May 2021, based on statement in trial publication that data will be made available 'on completion of clinical trials'
Sinopharm phase 3; 45 000 participants (NCT04510207)	No	Yes	December 2022, based on statement in trial publication that data will be available between December 2022 and December 2027, with reasonable request to the sponsor and principal investigator.
Sinovac phase 3; 13 000 participants (NCT04582344)	Yes	No*	We could not locate any other written statement regarding patient-level data sharing. It is not discussed in the full-length study protocol. Also, a structured summary of study protocol states 'Not applicable' under the availability of data and material.

Data current as of 27 June 2021.
*According to the 'Plan to Share IPD' field in the ClinicalTrials.gov entry.
IPD, individual participant data.

results, journal publication, clinical study report and individual participant data availability) at the time of writing (27 June 2021). We counted the total number of pages available as a crude proxy for the level of detail, as some documents, like clinical study reports, can be highly variable in length depending on the availability of appendices.

The overall picture is one of varied transparency. While several trials have at this point published protocols and statistical analysis plans along with the study publications, with some even released while the trials were underway, many key trial documents remain inaccessible (table 1). For example, a WHO report found that out of 86 clinical trials for 20 COVID-19 vaccines, 12% of clinical trial protocols were made publically available.[12] In our analysis, trial protocols and informed consent forms were not available for trials involving special populations such as children (NCT04816643) and pregnant women (NCT04754594). And despite vaccine roll-out, electronic individual participant data is not available for most trials.[12] Some sponsors, such as Moderna, have sent mixed messages on whether they even intend to share data, while others, such as Pfizer and Sinopharm, indicate they will not even begin accepting data requests for many months or years (table 2). In other cases, trialists have indicated very narrow time frames for sharing data, for example, 'beginning 3 months and ending 1 year after publication' (ChiCTR2000032459).[13]

The greatest availability of data at present comes from the EMA, Health Canada, and Japanese Pharmaceuticals and Medical Devices Agency which have released thousands of pages from company submissions for COVID-19 vaccines, far exceeding what is available elsewhere. The Food and Drug Administration (FDA) does not routinely make any industry documents it receives publicly available. It should be noted, however, that the EMA and Health Canada's commitment to transparency does not necessarily equate with the public availability of critical study documents. Judging from the availability of documents, regulators themselves appear to be receiving less complete and granular data than normal due to the compressed timeline from study start to regulatory decision making. For example, in July 2020, Canada granted emergency approval for the use of remdesivir, a drug used for the treatment of COVID-19, without receiving a copy of the clinical study report.[14] This is also the case for the Moderna vaccine, for which a variety of trial documents have been posted by Health Canada and the EMA, but not the clinical study report.[15] For Cuba, Russia, India and China state-developed vaccines, access to data prior to regulatory approval is even less clear.[16]

The world's most used COVID-19 vaccines: Sinovac and Sinopharm

Sinovac and Sinopharm, developed by Chinese pharmaceutical companies, account for the majority of vaccines being in Asia, South America, the Carribean and Africa.[17] They are authorised by the WHO and included in the WHO COVID-19 Vaccines Global Access initiative. However, transparency of trial data and documents is extremely limited, similar to other COVID-19 vaccines. Because neither Chinese vaccine has thus far been authorised by the EMA, Health Canada, or the Japanese Pharmaceuticals and Medical Devices Agency (the three regulators publishing data to their websites), there is also no expectation that data on these vaccines will become publicly available via regulators (table 3). Sinovac vaccines have been administered for nearly 1 year (since July 2020), and still have yet to publish clinical trial data (as at 27 June 2021). Trial results have largely been limited to government media reports and press releases.[18]

Transparency of regulatory decision making

Apart from data and documents tied to a specific trial, credible analysis and interpretation of data may require understanding regulatory decision making. For example, the fact that many

Table 3 Availability of regulatory reviews and additional data for COVID-19 vaccines

Manufacturer	Regulatory reviews and additional data
Pfizer	**USA FDA:** main webpage, Emergency Use Authorisation review memorandum (57 pages), EUA review memorandum for 12–15 year olds (43 pages), advisory committee briefing documents (FDA, Pfizer) **UK MHRA:** main webpage, public assessment report (51 pages) **AUS TGA:** main webpage, public assessment report (42 pages) **EU EMA:** main webpage, public assessment report (140 pages), clinical information (6990 pages) **Canada HC:** main webpage, summary basis of decision (63 pages), clinical information (5910 pages) **Japan PMDA:** main webpage (English, Japanese), public assessment reportok (74 pages), clinical and non-clinical information (1239 pages) **WHO:** main webpage, background document to the WHO interim recommendations (44 pages)
Moderna	**USA FDA:** main webpage, Emergency Use Authorisation review memorandum (61 pages), advisory committee meeting briefing documents (FDA, Moderna) **UK MHRA:** main webpage, public assessment report (7 pages) **EU EMA:** main webpage, public assessment report (169 pages), clinical information (6095 pages) **Canada HC:** main webpage, summary basis of decision (61 pages), clinical information (6095 pages) **Japan PMDA:** main webpage (English, Japanese), public assessment report (74 pages), clinical and non-clinical information (542 pages) **WHO:** main webpage, background document to the WHO interim recommendations (41 pages)
Oxford/AZ	**UK MHRA:** main webpage, public assessment report (58 pages) **AUS TGA:** main webpage, public assessment report (49 pages) **EU EMA:** main webpage, public assessment report (181 pages) **Canada HC:** main webpage, summary basis of decision (66 pages) **Japan PMDA:** main webpage (English, Japanese), public assessment report (122 pages), clinical and non-clinical information (1134 pages) **WHO:** main webpage, background document to the WHO interim recommendations (56 pages)
Janssen	**USA FDA:** main webpage, Emergency Use Authorisation review memorandum (69 pages), advisory committee meeting briefing documents (FDA, Janssen) **UK MHRA:** main webpage, public assessment report (11 pages) **EU EMA:** main webpage, public assessment report (218 pages) **Canada HC:** main webpage, summary basis of decision (60 pages) **WHO:** main webpage, background document to the WHO interim recommendations (54 pages)
Novavax	None
Gamaleya Research Institute	None
Sinopharm	**WHO:** main webpage, background document to the WHO interim recommendations (23 pages)
Sinovac	**WHO:** main webpage, background document to the WHO interim recommendations (30 pages)

Data current as of 27 June 2021.

Regulatory agencies for each country.: USA FDA; UK MHRA; Canada HC; Japan PDMA; International/non-country entity WHO.

AUS, Australia; EMA, European Medicines Agency; EU, European Union; FDA, Food and Drug Administration; HC, Heath Canada; MHRA, Medicines and Healthcare products Regulatory Agency; PMDA, Pharmaceuticals and Medical Devices Agency; TGA, Therapeutic Goods Administration; USA, United States of America; WHO, World Health Organization.

experts had originally believed the trials were designed to study a reduction in hospitalisation, intensive care utilisation and death,[19] points to a need to better understand the rationale for primary endpoint selection. Regulators played a major role in shaping this. An FDA guidance document from June 2020, before phase 3 trials commenced, stated that laboratory-confirmed COVID-19 (of essentially any severity) was an acceptable primary endpoint. But there remains limited transparency on the rationale for the selection of this endpoint: why was it chosen? What other endpoints were considered? More information about the internal deliberations is essential to understand whether the decisions made were reasonable.[20]

Additionally, there is a need for transparency around any deliberations regarding the length of follow-up necessary to adequately assess efficacy and safety prior to licensure. Longer follow-up for investigational products such as COVID-19 vaccines and therapeutic agents are necessary to evaluate duration of protection and ensure public and professional confidence.[21] The International Coalition of Medicines Regulatory Authorities (ICMRA), a global collaborative coalition of 30 medicine regulators including the FDA, Health Canada and EMA, published a statement in November 2020 stating that follow-up for treatment and placebo arms should continue 'for as long as possible after any regulatory approval' and recommended a follow-up period of 'at least 1 year or more from completion of assigned doses'.[22] Despite this, placebo controlled follow-up, originally planned for 2 years in many trials, was eliminated after a few months, when manufacturers began offering vaccine to placebo recipients within weeks of receiving emergency use authorisations. (Debates took place regarding the ethics of denying placebo recipients vaccine, and proposals to redesign the trials as cross-over trials were not taken up).[23] In addition to ensuring the public accessibility of follow-up data from continuing trials, greater transparency is necessary into the ongoing deliberations and thinking of regulators who are currently evaluating applications from sponsors seeking to move from emergency use authorisations to actual approval or licensure.

Other regulatory documents produced by regulators that can provide greater insight into trials and the evidence development programme include scientific review memos and public assessment reports. In the USA, documents such as review memos and presentations presented to the federal advisory committee are also released. These are all invaluable, providing insight into regulatory decision making (table 3). At around 50–150 pages, they can

be substantially longer than journal articles but still one or two orders of magnitude shorter than clinical study reports, and represent the regulators' analyses of data, not the data itself. Therefore, they should be regarded as complementary to, not substitutes for, trial data.[24]

Real-time transparency

Transparency should begin as trials get underway, and not be left as a bureaucratic exercise to be conducted after results are announced and decisions are made. This should be the case for all trials, but especially COVID-19 vaccines given their global significance.

Before trialists begin recruiting participants, there are already a variety of pre-study documents in place, and release of these documents would allow for broader awareness and scrutiny of the trials. Are the right endpoints being studied? Are the right populations being recruited? Do informed consent forms convey sufficient information about study purpose?[25] The power of real-time release of trial protocols was on display last summer when some manufacturers—Pfizer, Moderna, Janssen and AstraZeneca (for its US trial)—released study protocols for their phase 3 trials.[26] That transparency not only revealed the inadequacy of what had been disclosed about the studies' primary endpoint in trial registry entries, but helped stimulate public discussion and debate about what primary endpoint was acceptable, including at the FDA's advisory committee the following month—all while the trials were ongoing.[19 27 28]

Mechanisms to stimulate greater transparency

Although trade-offs will need to be weighed in the context of a global public emergency, there are several immediate steps that governments agencies, regulators, pharmaceutical companies and professional bodies can take to achieve greater transparency of COVID-19 vaccine trials. To start, government agencies and regulators can create infrastructure to support submission and deposits of protocols, informed consent forms, committee charters and other pre-study documents. This could be done by using existing resources such as ClinicalTrials.gov. Moreover, regulatory documents, memos, and scientific reviews used to make decisions on vaccine approval can also be shared on (or linked from) the trial registry entry. Platforms for sharing individual participant data already exist and can be leveraged (eg, Vivli, ClinicalStudyDataRequest.com and YODA), reducing overall monetary cost associated with publishing of trial data.

Drug sponsors and companies can likewise create a dedicated section of their website for pre-study documentation (as some have done). This should not cause an undue burden as such documents are already written and shared with regulators, and they contain no identifying patient information. All that needs to occur is the act of publicly posting a copy. Additionally, sponsors can provide clear and updated statements regarding their timeline for access to electronic individual participant data.

Professional bodies and academic organisations can also play a large role in promoting transparency. Public statements that convey the unacceptability of promises to begin sharing months and years from now, despite vaccine roll-out, would help. More powerfully, professionals could pledge not to endorse new therapeutic agents until full access to data is provided. Doing so would send a strong message that transparency is not a 'nice to have,' but a fundamental component of any intervention that purports to be based on science.[29] These mechanisms and levers can serve as initial starting points to create greater transparency. Longer-term solutions to advance data transparency may require further changes in policy and law.

Conclusion

Although progress has been made over the past decades in clinical trial transparency, and there are some successes for COVID-19 vaccines, there is still much room for improvement. The lack of adequate transparency about COVID-19 vaccine trials and their regulation cannot be dismissed as unfortunate, stubborn problems emblematic of the present culture in biomedicine. In a time of increasing public scrutiny, transparency of regulatory decision making leading to the approval of drug treatments and vaccines for COVID-19 is important to ensure patient and stakeholder trust. It is a scientific, moral and ethical imperative that access to complete trial data of these global public health interventions is urgently granted to patients, researchers and other key stakeholders.

Twitter Anisa Rowhani-Farid @AnisaFarid and Peter Doshi @RIATinitiative

Contributors ST and PD conceptualised the article and ST wrote the first draft. AR-F and KH led the data extraction and analysis. All authors (ST, AR-F, KH, TJ, PD) were involved in reviewing and editing the final manuscript.

Funding The Laura and John Arnold Foundation funds the RIAT Support Center, which supports the salaries of ST, AR-F, KH, TJ and PD.

Disclaimer The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS, The University of Maryland, or the US Government.

Competing interests KH was supported by the Food and Drug Administration (FDA) of the US Department of Health and Human Services (HHS) as part of a financial assistance award U01FD005946, unrelated to this manuscript, totaling US$5000 with 100% funded by FDA/HHS. PD has received travel funds from the European Respiratory Society (2012) and Uppsala Monitoring Center (2018); grants from the FDA (through University of Maryland M-CERSI; 2020), Laura and John Arnold Foundation (2017–2022), American Association of Colleges of Pharmacy (2015), Patient-Centered Outcomes Research Institute (2014–2016), Cochrane Methods Innovations Fund (2016-2018) and UK National Institute for Health Research (2011–2014); was an unpaid IMEDS steering committee member at the Reagan-Udall Foundation for the FDA (2016–2020), and is an editor at The BMJ. The Laura and John Arnold Foundation funds the RIAT Support Center, which supports the salaries of ST, ARF, KH, TJ, and PD. TJ's competing interests are online (https://restoringtrials.org/competing-interests-tom-jefferson/).

Patient consent for publication Not required.

Provenance and peer review Commissioned; externally peer reviewed.

ORCID iDs
Sarah Tanveer http://orcid.org/0000-0002-6408-9855
Anisa Rowhani-Farid http://orcid.org/0000-0003-3637-2423
Tom Jefferson http://orcid.org/0000-0002-4778-2949
Peter Doshi http://orcid.org/0000-0002-7804-4113

References

1 **Turner EH**. How to access and process FDA drug approval packages for use in research. BMJ 2013;347:f5992.
2 **European Medicines Agency**. European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use) POLICY/0043 [Internet], 2018. Available: https://www.ema.europa.eu/en/documents/other/policy/0043-european-medicines-agency-policy-access-documents_en.pdf
3 **European Medicines Agency**. European Medicines Agency policy on publication of clinical data for medicinal products for human use (policy/0070; ema/240810/2013); 2014.
4 **Health Canada**. Public Release of Clinical Information: consultation [Internet], 2017. Available: https://www.canada.ca/en/health-canada/programs/consultation-public-release-clinical-information-drug-submissions-medical-device-applications.html
5 Institutions offering data access [Internet]Restoring Invisible and Abandoned Trials (RIAT) Support Center. Available: https://restoringtrials.org/institutions-offering-data-access
6 EFPIA and PhRMA release joint principles for responsible clinical trial data sharing to benefit patients [Internet]. Available: https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/130724-efpia-and-phrma-release-joint-principles-for-responsible-clinical-trial-data-sharing-to-benefit-patients
7 **Institute of Medicine**. Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk [Internet], 2015. Available: https://www.nap.edu/catalog/18998/sharing-clinical-trial-data-maximizing-benefits-minimizing-risk
8 **Doshi P**, Jones M, Jefferson T. Rethinking credible evidence synthesis. BMJ 2012;344:d7898.
9 **Eichler H-G**, Rasi G. Clinical trial publications: a sufficient basis for healthcare decisions? Eur J Intern Med 2020;71:13–14.
10 **Gøtzsche PC**. Why we need easy access to all data from all clinical trials and how to accomplish it. Trials 2011;12:249.
11 Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals [Internet]. Available: https://clinicaltrials.gov/ct2/show/NCT04368728
12 For Whose Benefit? Transparency in the development and procurement of COVID-19 vaccines [Internet]. Available: https://ti-health.org/content/for-whose-benefit-transparency-in-the-development-and-procurement-of-covid-19-vaccines
13 **Xia S**, Zhang Y, Wang Y, *et al*. Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBIBP-CorV: a randomised, double-blind, placebo-controlled, phase 1/2 trial. *Lancet Infect Dis* 2021;**21**:39–51.
14 **Health Canada**. Available information for VEKLURY - Submission control number 240551 [Internet], 2020. Available: https://clinical-information.canada.ca/ci-rc/item/240551
15 **Government of Canada HC**. Remdesivir authorized with conditions for the treatment of patients in Canada with severe COVID-19 symptoms [Internet], 2020. Available: https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73621a-eng.php
16 **Fonseca P**. Brazil institute says CoronaVac efficacy above 50% but delays full results [Internet], 2020. Reuters. Available: https://www.reuters.com/business/healthcare-pharmaceuticals/sinovacs-covid-19-vaccine-over-50-effective-brazil-tests-reports-newspaper-folha-2020-12-23
17 **Mallapaty S**. China is vaccinating a staggering 20 million people a day. Nature 2021. doi:10.1038/d41586-021-01545-3. [Epub ahead of print: 09 Jun 2021].
18 **Rhodes N**, Wright T, Rusu V. For Whose Benefit? Transparency in the development and procurement of COVID-19 vaccines [Internet], 2021. Available: http://ti-health.org/wp-content/uploads/2021/05/For-Whose-Benefit-Transparency-International.pdf
19 **Doshi P**. Will covid-19 vaccines save lives? Current trials aren't designed to tell us. BMJ 2020;371:m4037.
20 **Mehrotra DV**, Janes HE, Fleming TR, *et al*. Clinical endpoints for evaluating efficacy in COVID-19 vaccine trials. Ann Intern Med 2021;174:221–8.
21 **WHO Ad Hoc Expert Group on the Next Steps for Covid-19 Vaccine Evaluation, Krause PR**, Fleming TR, *et al*. Placebo-Controlled Trials of Covid-19 Vaccines - Why We Still Need Them. N Engl J Med 2021;384:e2.
22 **International Coalition of Medicines Regulatory Authorities (ICMRA)**. Statement on continuation of vaccine trials [Internet]. Available: http://www.icmra.info/drupal/covid-19/statement_on_continuation_of_vaccine_trials
23 **Doshi P**. Covid-19 vaccines: in the rush for regulatory approval, do we need more data? BMJ 2021;373:n1244.
24 **Jefferson T**, Jones MA, Doshi P, *et al*. Neuraminidase inhibitors for preventing and treating influenza in adults and children. Cochrane Database Syst Rev 2014;19.
25 **Doshi P**, Hur P, Jones M, *et al*. Informed consent to study purpose in randomized clinical trials of antibiotics, 1991 through 2011. JAMA Intern Med 2017;177:1452–9.
26 **Doshi P**. Covid-19 vaccine trial protocols released. BMJ 2020;371:m4058.
27 **Doshi P**, Topol E. Opinion, 2020. Available: https://www.nytimes.com/2020/09/22/opinion/covid-vaccine-coronavirus.html
28 **U.S. Food and Drug Administration**. 161st vaccines and related biological products Advisory Committee (VRBPAC) meeting, 2020. Available: https://www.fda.gov/media/143982/download
29 **Johnson RM**, Doshi P, Healy D. Covid-19: should doctors recommend treatments and vaccines when full data are not publicly available? BMJ 2020;370:m3260.
30 **Center for Drug Evaluation, Research**. E3 structure and content of clinical study reports, 2020. Available: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e3-structure-and-content-clinical-study-reports
31 **Doshi P**, Dickersin K, Healy D, *et al*. Restoring invisible and abandoned trials: a call for people to publish the findings. BMJ 2013;346:f2865.
32 Glossary [Internet]Restoring Invisible and Abandoned Trials (RIAT) Support Center. Available: https://restoringtrials.org/glossary

Exhibit 25

FDA NEWS RELEASE

FDA Approves First COVID-19 Vaccine

Approval Signifies Key Achievement for Public Health

For Immediate Release:

August 23, 2021

Español (https://www.fda.gov/news-events/press-announcements/la-fda-aprueba-la-primera-vacuna-contra-el-covid-19)

Today, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty (koe-mir'-na-tee), for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

"The FDA's approval of this vaccine is a milestone as we continue to battle the COVID-19 pandemic. While this and other vaccines have met the FDA's rigorous, scientific standards for emergency use authorization, as the first FDA-approved COVID-19 vaccine, the public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product," said Acting FDA Commissioner Janet Woodcock, M.D. "While millions of people have already safely received COVID-19 vaccines, we recognize that for some, the FDA approval of a vaccine may now instill additional confidence to get vaccinated. Today's milestone puts us one step closer to altering the course of this pandemic in the U.S."

Since Dec. 11, 2020, the Pfizer-BioNTech COVID-19 Vaccine has been available under EUA in individuals 16 years of age and older, and the authorization was expanded to include those 12 through 15 years of age on May 10, 2021. EUAs can be used by the FDA during public health emergencies to provide access to medical products that may be effective in preventing, diagnosing, or treating a disease, provided that the FDA determines that the known and potential benefits of a product, when used to prevent, diagnose, or treat the disease, outweigh the known and potential risks of the product.

FDA-approved vaccines undergo the agency's standard process for reviewing the quality, safety and effectiveness of medical products. For all vaccines, the FDA evaluates data and information included in the manufacturer's submission of a biologics license application (BLA). A BLA is a

comprehensive document that is submitted to the agency providing very specific requirements. For Comirnaty, the BLA builds on the extensive data and information previously submitted that supported the EUA, such as preclinical and clinical data and information, as well as details of the manufacturing process, vaccine testing results to ensure vaccine quality, and inspections of the sites where the vaccine is made. The agency conducts its own analyses of the information in the BLA to make sure the vaccine is safe and effective and meets the FDA's standards for approval.

Comirnaty contains messenger RNA (mRNA), a kind of genetic material. The mRNA is used by the body to make a mimic of one of the proteins in the virus that causes COVID-19. The result of a person receiving this vaccine is that their immune system will ultimately react defensively to the virus that causes COVID-19. The mRNA in Comirnaty is only present in the body for a short time and is not incorporated into - nor does it alter - an individual's genetic material. Comirnaty has the same formulation as the EUA vaccine and is administered as a series of two doses, three weeks apart.

"Our scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of this vaccine. We evaluated scientific data and information included in hundreds of thousands of pages, conducted our own analyses of Comirnaty's safety and effectiveness, and performed a detailed assessment of the manufacturing processes, including inspections of the manufacturing facilities," said Peter Marks, M.D., Ph.D., director of FDA's Center for Biologics Evaluation and Research. "We have not lost sight that the COVID-19 public health crisis continues in the U.S. and that the public is counting on safe and effective vaccines. The public and medical community can be confident that although we approved this vaccine expeditiously, it was fully in keeping with our existing high standards for vaccines in the U.S."

FDA Evaluation of Safety and Effectiveness Data for Approval for 16 Years of Age and Older

The first EUA (https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19), issued Dec. 11, for the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years of age and older was based on safety and effectiveness data (https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19) from a randomized, controlled, blinded ongoing clinical trial of thousands of individuals.

To support the FDA's approval decision today, the FDA reviewed updated data from the clinical trial which supported the EUA and included a longer duration of follow-up in a larger clinical trial population.

Specifically, in the FDA's review for approval, the agency analyzed effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients ages 16 and older who did not have evidence of the COVID-19 virus infection within a week of receiving the second dose. The safety of Comirnaty was evaluated in approximately 22,000 people who received the vaccine and 22,000 people who received a placebo 16 years of age and older.

Based on results from the clinical trial, the vaccine was 91% effective in preventing COVID-19 disease.

More than half of the clinical trial participants were followed for safety outcomes for at least four months after the second dose. Overall, approximately 12,000 recipients have been followed for at least 6 months.

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle or joint pain, chills, and fever. The vaccine is effective in preventing COVID-19 and potentially serious outcomes including hospitalization and death.

Additionally, the FDA conducted a rigorous evaluation of the post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine and has determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes. The Comirnaty Prescribing Information includes a warning about these risks.

Ongoing Safety Monitoring

The FDA and Centers for Disease Control and Prevention have monitoring systems in place to ensure that any safety concerns continue to be identified and evaluated in a timely manner. In addition, the FDA is requiring the company to conduct postmarketing studies to further assess the risks of myocarditis and pericarditis following vaccination with Comirnaty. These studies will include an evaluation of long-term outcomes among individuals who develop myocarditis following vaccination with Comirnaty. In addition, although not FDA requirements, the company has committed to additional post-marketing safety studies, including conducting a pregnancy registry study to evaluate pregnancy and infant outcomes after receipt of Comirnaty during pregnancy.

The FDA granted this application Priority Review (https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review). The approval was granted to BioNTech Manufacturing GmbH.

Related Information

- Comirnaty Prescribing Information (http://www.fda.gov/vaccines-blood-biologics/comirnaty)
- Cormirnaty and Pfizer-BioNTech COVID-19 Vaccine | FDA (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine)

###

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Inquiries

Media:

FDA Office of Media Affairs (mailto:fdaoma@fda.hhs.gov)

301-796-4540

Consumer:

888-INFO-FDA

More Press Announcements (/news-events/newsroom/press-announcements)

Exhibit 26

June 1, 2021

Electronic Submission

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

This petition for administrative action is submitted on behalf of the undersigned petitioners ("Petitioners") pursuant to 21 C.F.R. § 10.30 and related relevant provisions of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act to request that the Commissioner of Food and Drugs (the "Commissioner") require that the vaccine manufacturers provide the FDA with the data outlined in the "Actions Requested" section below before approval of any COVID-19 vaccine.

The Food and Drug Administration (FDA) has granted Emergency Use Authorizations (EUAs) to three COVID-19 vaccines, enabling rapid, and widespread vaccine rollout across the United States. These EUAs do not have any built-in expiration date, and therefore vaccines can continue to be lawfully distributed under EUA even after a future date when a public health emergency no longer exists.

Approximately five months have passed since the first EUAs were granted, and one vaccine manufacturer now seeks licensure (approval) and has submitted a Biologics License Application (BLA). Other manufacturers have indicated similar intentions, as well as intentions for EUAs for additional pediatric populations.

We believe the FDA should not prematurely grant a license to any COVID-19 vaccine until all necessary efficacy and safety studies are completed and substantial evidence demonstrates the benefits of an individual COVID-19 vaccine product outweigh the harms for the indicated, recipient population. We are concerned that the premature licensure of a COVID-19 vaccine can seriously undermine public confidence in regulatory authorities, particularly if long-term safety issues were to emerge following licensure.

In this petition, we outline **efficacy and safety measures that must be met before serious consideration is given to granting a BLA of any COVID-19 vaccine**. These measures include:

1. **Completing at least 2 years of follow-up** of participants originally enrolled in pivotal clinical trials, even if the trials were unblinded and now lack a placebo control. All vaccine manufacturer phase 3 trials were already designed with this planned duration.

2. Ensuring, prior to including in the list of populations for which a vaccine is approved, that there is **substantial evidence of clinical effectiveness that outweighs harms in special populations** such as: infants, children, and adolescents; those with past SARS-CoV-2 infection; immunocompromised; pregnant women; nursing women; frail older adults; and individuals with cancer, autoimmune disorders, and hematological conditions.
3. Requiring thorough **safety assessment of spike proteins** being produced in-situ by the body tissues following vaccine administration, and spike proteins' full biodistribution, pharmacokinetics, and tissue specific toxicity.
4. Completion of **vaccine biodistribution studies** from administration site and safety implications of mRNA translation in distant tissues.
5. **Thorough investigation of all severe adverse reactions reported following COVID-19 vaccination**, such as deaths, reported in the United States and global pharmacovigilance systems.
6. Assessment of **safety in individuals receiving more than two doses.**
7. **Inclusion of gene delivery and therapy experts in the Vaccines and Related Biological Products Advisory Committee (VRBPAC)**, in recognition of the fact that the novel COVID vaccines work on the premise of gene delivery, in contrast to conventional vaccines.
8. **Enforcing stringent conflict of interest requirements** to ensure individuals involved in data analysis and BLA-related decision making processes have no conflict of interests with vaccine manufacturers.

A COVID-19 vaccine BLA should be approved when—and only when—substantial evidence demonstrates the benefits of a specific product outweigh the harms for the indicated, recipient population.

This means that the following are **invalid reasons** to approve a COVID-19 vaccine:

- **To ensure vaccines are accessible after the public health emergency has ended.** COVID-19 vaccines granted an emergency use authorization (EUA) can be lawfully used after the expiry of the SARS-CoV-2 public health emergency declaration. (This is made clear by the many products for Ebola and Zika viruses which still have active EUAs.[1])

- **To ensure adequate access to vaccines across the population.** A BLA is not necessary to assure access to COVID-19 vaccines. Unlike normal licensing, in which widespread use of a drug or vaccine follows approval, EUAs for COVID-19 vaccines have enabled, and continue to enable, their widespread use. Ensuring access to vaccines is irrelevant to the considerations for issuance of a BLA because broad access to COVID-19 vaccines has already been accomplished.

- **To enable vaccine mandates.** Consideration of vaccine mandates is outside of FDA's purview. Furthermore, a mandate should only be considered once the evidentiary conditions are met for a BLA (demonstrating that benefits outweigh harms).

- **To bolster public confidence.** Like mandates, approving a medical product in order to bolster public confidence is backward logic and is outside the FDA's purview. Approving before substantial evidence that population-based evidence of clinical effectiveness is superior to harms may contribute to public wariness and hesitancy, not only about COVID-19 vaccines, but other vaccines and public health authorities more broadly. An approval may bolster public confidence, but it is not a valid reason to approve.

Regardless of any legitimacy of each of the above reasons, none provides grounds to approve a COVID-19 vaccine.

The widespread use of a COVID-19 vaccine under EUA, particularly for a limited amount of time, also is not a valid reason to approve a product. Even if vaccine recipients are followed up within observational studies, such studies may have important design biases and flaws, and their conclusions, especially concerning clinical effectiveness outcomes, may not be reliable.

Premature FDA approval of any COVID-19 vaccine could negatively impact the health and safety of US residents, with global ramifications considering the international importance of FDA decisions. It also could set a precedent of lowered standards for future vaccine approvals. For these reasons and due to the compelling need to ensure the safety and efficacy of any COVID-19 vaccine licensed by the FDA and to allow Petitioners the opportunity to seek emergency judicial relief should the instant Petition be denied, it is respectfully requested that FDA act on the instant Petition by June 11, 2021.

I. ACTIONS REQUESTED

Petitioners request that the FDA, prior to granting any license for a COVID-19 vaccine:

1. Confirm, in revised Guidance, that the FDA expects a minimum of 2 years of follow-up of participants enrolled in pivotal clinical trials, even if trials are unblinded and lack a placebo control.

2. Require data demonstrating substantial evidence of clinical effectiveness that outweighs harms, in all special populations, as a condition of consideration of including these populations among the indicated populations. Special populations include: infants, children, and adolescents; those with past SARS-CoV-2 infection; immunosuppressed individuals; those with history of or current cancer; individuals with hematological disorders or autoimmune diseases; pregnant or nursing women; and frail older adults.

3. Require data on the safety and pharmacokinetic profiles of the spike protein.

4. Require data from biodistribution studies investigating the actual COVID-19 vaccines.

5. Require data from pharmacovigilance systems in the US and globally documenting a thorough investigation of serious adverse events, carried out by independent, impartial individuals.

6. Clarify in revised Guidance that safety data from individuals receiving more than 2 vaccine doses must be submitted.

7. Ensure the inclusion of experts in gene therapy in the VRBPAC.

8. Ensure that the analysis of data and decisions regarding any COVID-19 vaccine BLA application are informed by experts with no financial or research relationships with any vaccine manufacturers within the last 36 months, both within FDA and amongst the composition of the VRBPAC.

II. STATEMENT OF GROUNDS

Here, in the order as above, we set out the rationale for each requested action.

1. **Confirm, in revised Guidance, that the FDA expects a minimum of 2 years of follow-up of participants enrolled in pivotal clinical trials, even if trials are unblinded and lack a placebo control. Rationale:**
    a. Requiring at least 2 years is consistent with the 2 year follow-up duration prospectively proposed by the manufacturers when they registered their ongoing phase 3 trials of COVID-19 vaccines (Moderna: NCT04470427, Pfizer: NCT04368728, Janssen: NCT04505722) and consistent with the June 2020 FDA guidance on COVID-19 vaccines which stated participants should be followed for COVID-19 outcomes for "as long as feasible, ideally at least one to two years."[2]
    b. Important adverse event signals can be detected in clinical trials. This is true despite enrolling tens of thousands of participants, which is still too few to assess rare adverse events. For example, a serious blood clot occurring in the phase 3 Janssen clinical trial led to an initial trial pause in October 2020.[3]
    c. Two year follow-up from trials allows the detection of commonly experienced longer-term adverse effects that may not manifest until many months following vaccination.
    d. Two year follow-up from trials would also allow for more detailed assessment of infection, re-infection, infectiousness, and the monitoring of immune response over time, among all vaccinated participants.
    e. The quality of data collection in clinical trials can be expected to be superior to passive data collection systems like the Vaccine Adverse Event Reporting System (VAERS). Therefore, trials of at least 2 years duration provide a valuable chance to develop a more complete understanding of the adverse event profile in the general population as well as in specific groups, such as individuals of

reproductive age, immunocompromised individuals, and different age groups, including adolescents and young children.

f. The quality of data on adverse events during an ongoing trial can be improved while the trial is ongoing (e.g., improving the range of types of adverse events that are systematically assessed), as and when evidence from other data sources (e.g., pre-clinical or pharmacovigilance) show any trends or indicate specific types of adverse events of special interest.

g. Finally, the expectation of at least 2 years of follow-up prior to BLA also carries the advantage of longer-term data collection from other available sources (e.g., MedWatch/VAERS, V-safe, Vaccine Safety Datalink, FDA-CMS, BEST & PRISM, VA Electronic Health Records & data warehouse, Department of Defense DMSS, and Genesis HealthCare (Brown University & NIH-National Institute of Aging), as well as other medical claims databases).

2. **Require data demonstrating substantial evidence of clinical effectiveness that outweighs harms, in all special populations, as a condition of consideration of including these populations among the indicated populations. Special populations include: infants, children, and adolescents; those with past SARS-CoV-2 infection; immunosuppressed individuals; those with history of or current cancer; individuals with hematological disorders or autoimmune diseases; pregnant or nursing women; and frail older adults. Rationale:**

   a. The efficacy and safety of medicines often differs amongst populations such as healthy young adults vs. older adults, men vs. women, or SARS-CoV-2 survivors vs. never-exposed individuals.

   b. For example, the relative risks of SARS-CoV-2 infection, hospitalization, and death are considerably lower in infants, children, and adolescents in comparison to adults.[4,5]

   c. For example, individuals who experienced past SARS-CoV-2 infection (which are now believed to be a significant minority of many subpopulations[6]) are likely to have immunity to subsequent infections for as long or longer than immunity conferred by vaccine,[7–10] and may also be at heightened risk for adverse effects.[11–14]

   d. The ongoing phase 3 trials of COVID-19 vaccines (Moderna: NCT04470427, Pfizer: NCT04368728, Janssen: NCT04505722) largely (or wholly) excluded the following important populations in which there is reason to believe the effects of the product may differ from the populations enrolled in the trial:

      i. Infants, children, and adolescents
      ii. Those with past SARS-CoV-2 infection
      iii. Those who are immunosuppressed
      iv. Those with history of or current cancer
      v. Those with hematological disorders
      vi. Those with autoimmune diseases
      vii. Those who are pregnant or nursing
      viii. Frail older adults (including those living in nursing homes)

e. The question is not simply whether there is efficacy, but how much efficacy exists in these populations, what kind of efficacy (e.g. reduction in risk of symptomatic COVID-19 vs. reduction in risk of hospitalization or death), and do efficacy advantages outweigh potential harms in these populations.
f. Before these special populations can be considered for inclusion amongst the approved indicated populations, data demonstrating substantial evidence of clinical effectiveness that outweighs harms in these specific populations, are needed.

3. **Require data on the safety and pharmacokinetic profiles of the spike protein.**
Rationale:
   a. In-situ production of SARS-CoV-2 spike protein is the target mechanism of action of all COVID-19 vaccines with an EUA at present. Therefore, the safety profile of spike protein itself (i.e., in the absence of virus) must be thoroughly understood in the range of populations on the indications list.
   b. Recently, evidence of systemic circulation of spike protein or its components in subjects post-immunization was reported.[15] All studies we are aware of to date raise concerns about the safety of spike protein,[16–28] and the concentration of circulatory spikes was correlated to the disease severity in COVID-19 patients.[29]
   c. Required studies must, at a minimum, address these concerns:
      i. Coagulopathy issues, including blood clots, hemorrhage, thrombocytopenia, heart attack, and strokes. According to the VAERS, as of May 21, 2021, there have been a total of 1,222 reports of thrombocytopenia/low platelets; and 6,494 (112 in 0-24 year-olds) reports of blood clots/strokes.
      ii. Reproductive issues, including menstrual irregularities, reduced fertility, miscarriages, and preterm births. According to VAERS, as of May 21, 2021, there were 511 reports of miscarriage and 522 reports of uterine hemorrhage (including 88 in women older than 50 years). The vaccines induce the generation of antibodies to attack spike protein, which are genetically similar to proteins produced by the placenta.[30] To date, no vaccine sponsors have conducted immunologic studies of spike protein involvement with proteins involved in placental development.
      iii. Carcinogenesis. There is preliminary and theoretical evidence that the spike protein may promote cancer.[31,32] Considering the potential for annual booster vaccinations, COVID-19 vaccines should be treated similarly to medication taken for chronic conditions on a long term basis. Carcinogenic potential is important to characterize.
      iv. Transmission of spike protein (or its fragments) from vaccinated individuals, such as through breast milk and associated risk in neonates and infants. According to the UK Medicines & Healthcare products Regulatory Agency, there are 921 reports of exposure via breast milk following AstraZeneca's vaccine and 215 reports following Pfizer's vaccine.

v. Neurological disorders, including Guillain-Barré syndrome, acute disseminated encephalomyelitis, transverse myelitis, encephalitis, myelitis, encephalomyelitis, meningoencephalitis, meningitis, encephalopathy, demyelinating diseases, and multiple sclerosis.
vi. Cardiac issues, including myocardial infarction, myocarditis and pericarditis, among others. According to the VAERS, as of May 21, 2021, there have been a total of 1,598 reports of heart attacks (24 reported in 0-24 year-olds; 501 resulted in death).
vii. Autoimmune diseases, including thyroiditis and diabetes mellitus, immune thrombocytopenia, autoimmune hepatitis, primary biliary cholangitis, systemic sclerosis, autoimmune disease for skeletal muscles (myasthenia gravis, myositis such as polymyositis, dermatomyositis, or other inflammatory myopathies)
viii. Studies should be conducted in individuals of both sexes[33] and all ages. We cannot assume that the effects of spike protein are the same across populations of all ages, sex, and across pre-existing conditions.

4. **Require data from biodistribution studies investigating the actual COVID-19 vaccines. Rationale:**
   a. Data from the biodistribution studies submitted by Moderna and Pfizer suggests that the vaccines distribute widely in the body, including to the liver, brain, heart, lung, adrenals, ovaries, and testes, among many other tissues.[34,35] (**See Tables 1a, 1b, and 2 below for studies R-[?]-0072 and 185350 submitted by Pfizer and study 5002121 submitted by Moderna.**)
   b. However these were not studies of the currently authorized products: Pfizer's BNT162b2, Moderna's mRNA-1273, or Janssen's Ad26.COV2.S.[34–36]
   c. Instead of presenting novel biodistribution studies of the COVID-19 vaccine formulations, sponsors presented substitute studies to FDA for an EUA during the pandemic.[34–36]
   d. Therefore, novel biodistribution studies investigating the actual COVID-19 vaccines are necessary.
   e. Biodistribution studies would be required for any small molecule pharmaceutical drug submitted for approval (i.e. New Drug Application), and should be conducted on the COVID-19 vaccines as well as these novel vaccines which work on the premise of gene delivery--very different to conventional vaccines.
   f. Biodistribution studies help inform an understanding of vaccine transfection to various tissues (away from injection site) spurring various distant tissues to produce spike proteins and consequent autoimmune response against the body's cells. These studies will therefore help enhance our understanding of the nature of potential short and long term adverse events. At this point in time, in which other data sources exist to characterize short term harms of COVID-19 vaccines with an EUA, the utility of biodistribution studies to characterize long term adverse effects and better understand potential mechanism(s) of action of short and long term harms, remains critically important.

g. Necessary studies must, at a minimum, address these concerns related to biodistribution, as well as the effects of vaccines in the body:
    i. The need to know basic pharmacokinetic parameters, including absorption, distribution, metabolism, and excretion (ADME).
    ii. Effects of multiple doses. ADME may change depending on dose and cumulative dose and should be investigated. This is more important than usual as the whole purpose of all COVID-19 vaccines with an EUA at present is to change the body's way of processing spike protein, and therefore repeated injections should result in different rates of clearance of spike protein from the blood, and different rates of immune attack on spike protein producing cells.
    iii. The impact of body mass index (size of deltoid muscle) and vaccine distribution away from injection site, implications for dose estimation for lean or younger age groups or frail older adults.
    iv. The duration of the studies must be sufficient to fully understand the complete distribution and elimination of the injected vaccine and its carrier and other constituents. For example, data from the substitute study submitted for Pfizer's vaccine (**see Tables 1a, 1b, and 2 below for studies R-[?]-0072 and 185350 submitted by Pfizer and study 5002121 submitted by Moderna**) showed levels of drug product increasing at the 48 hour mark, but it is unknown what occurred after 48 hours as this was apparently the study cut off.[37]
    v. Potential side effects (safety review) in those organs/tissues with a detectable proportion of injected vaccine (antigen or novel excipients) from the circulatory system.

5. **Require data from pharmacovigilance systems in the US and globally documenting a thorough investigation of serious adverse events, carried out by independent, impartial individuals. Rationale:**
    a. A major testament to the overall short-term safety of a medical product is the absence of serious adverse events (SAEs) when administered to millions. COVID-19 vaccines have now been administered to hundreds of millions of individuals, and it is vital that all reports of SAEs are thoroughly investigated to determine whether the vaccine played any role in the SAE.
    b. The most serious of all SAEs is death, and a CDC webpage on VAERS discusses 4,863 reports of death after COVID-19 vaccination reported between December 14, 2020 and May 24, 2021.[38] CDC states that:
        i. "CDC follows up on any report of death to request additional information to learn more about what occurred and to determine whether the death was a result of the vaccine or was unrelated."
        ii. "CDC and FDA physicians review each case report of death as soon as notified and CDC requests medical records to further assess reports."

iii. "A review of available clinical information, including death certificates, autopsy, and medical records has not established a causal link to COVID-19 vaccines."[38]

c. However, the FDA has stated that VAERS staff do not contact family members to learn more about the deaths. It stated: "Because the VAERS system is not designed to determine causality of adverse events, there is not a mechanism to follow-up with families for additional details. The determination of the cause of death is done by the certifying official who completes the death certificate or the pathologist who conducts the autopsy."[39]

d. Regulators in other countries have conducted detailed case investigations (e.g. Norway's investigation of 100 deaths amongst frail elderly following COVID-19 vaccination[40,41]).

e. FDA must require evidence of a thorough investigation into deaths and other SAEs—investigations that include contacting families to obtain a full medical history and personal accounts (in the case of deaths) and those who experienced the adverse event (in the case of other SAEs). Event adjudication, as done on data safety monitoring boards, must be in place in order to carry out detailed case investigations, and must be carried out by independent, impartial individuals.

6. **Clarify in revised Guidance that safety data from individuals receiving more than 2 vaccine doses must be submitted by vaccine manufacturers. Rationale:**

a. There is wide speculation that COVID-19 vaccines may become offered as annual vaccines, much like influenza vaccines, and regulators have already released guidance to this effect.[42]

b. Some manufacturers, such as Pfizer and Moderna, have indicated that a third dose may be necessary within the first 12 months. Other manufacturers may present similar claims in the future.[43]

c. The safety profile of multiple doses, possibly more than 70 doses across an average lifetime, must be considered at the time of licensure. Phase 3 trial data make clear that the safety profile differs by dose (e.g. dose 2 of the Pfizer and Moderna vaccines induce more severe systemic adverse events than dose 1).[44,45]

d. Information on the types and severity of adverse events that emerge following the administration of additional doses is necessary to better characterize long term safety.

7. **Ensure the inclusion of experts in gene therapy in the VRBPAC.** Rationale:

a. The COVID-19 vaccines produced by Pfizer, Moderna, and Janssen (as well as AstraZeneca, CanSinoBio (China) and Gamaleya Research Institute (Russia)) are gene based vaccines. Their mechanism of action differs substantially from all other vaccines that have been used on populations globally, as these novel vaccines work on the premise of gene delivery, and may therefore be considered a type of gene therapy. These gene based vaccines involve entering the cell, where the overwhelming majority of critical body activities occur, and utilizing

the host's cells to produce spike protein. This is an entirely different mechanism than that utilized by traditional vaccines such as inactivated, attenuated, subunit or protein-based (that are not intended to invade cells). Therefore, there is a need to consider safety with the informed perspectives of those with expertise in gene therapies.

8. **Ensure that the analysis of data and decisions regarding any COVID-19 vaccine BLA application are informed by experts with no financial or research relationships with any vaccine manufacturers within the last 36 months, both within FDA and amongst the composition of the VRBPAC. Rationale:**
    a. The public interest weighs strongly in favor of the evaluation of data and all decision making to be performed by competent individuals with independence from vaccine manufacturers (institutions that stand to gain or lose from a BLA decision on a COVID-19 vaccine). Disclosure requirements should be at least as stringent, if not more, than what is expected for writing a manuscript in a medical journal—namely, disclosure of relationships within the last 36 months, as requested by the International Committee of Medical Journal Editors (ICMJE). Insisting on this level of disclosure, and transparency of the disclosures, can publicly demonstrate the independence of the FDA's decision making process.[46]

Table 1a. Pfizer study report R-[?]-0072, biodistribution study submitted by Pfizer to Japanese regulator (PMDA).

2.6.5.5A. PHARMACOKINETICS: ORGAN DISTRIBUTION		**Test Article: modRNA encoding luciferase in LNP Report Number: R-[redacted]-0072**
Species (Strain):	Mice (BALB/c)	
Sex/Number of Animals:	Female/3 per group	
Feeding Condition:	Fed ad libitum	
Vehicle/Formulation:	Phosphate-buffered saline	
Method of Administration:	Intramuscular injection	
Dose (mg/kg):	1 µg/hind leg in gastrocnemius muscle (2 µg total)	
Number of Doses:	1	
Detection:	Bioluminescence measurement	
Sampling Time (hour):	6, 24, 48, 72 hours; 6 and 9 days post-injection	
Time point	**Total Mean Bioluminescence signal (photons/second)**	**Mean Bioluminescence signal in the liver (photons/second)**
	Buffer control / **modRNALuciferase in LNP**	**modRNALuciferase in LNP**
6 hours	1.28×10^{5} / 1.26×10^{9}	4.94×10^{7}
24 hours	2.28×10^{5} / 7.31×10^{8}	2.4×10^{6}
48 hours	1.40×10^{5} / 2.10×10^{8}	Below detection[a]
72 hours	1.33×10^{5} / 7.87×10^{7}	Below detection[a]
6 days	1.62×10^{5} / 2.92×10^{6}	Below detection[a]
9 days	7.66×10^{4} / 5.09×10^{5}	Below detection[a]

LNP = Lipid nanoparticle; modRNA = Nucleoside modified messenger RNA.
a. At or below the background level of the buffer control.

Source: Japan PMDA (PDF page 15).[37]

Table 1b. Pfizer study report 185350, biodistribution study submitted by Pfizer to Japanese regulator (PMDA).

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Test Article: [^{3}H]-Labelled LNP-mRNA formulation containing ALC-0315 and ALC-0159
Report Number: 185350

Species (Strain):	Rat (Wistar Han)
Sex/Number of Animals:	Male and female/3 animals/sex/timepoint (21 animals/sex total for the 50 µg dose)
Feeding Condition:	Fed ad libitum
Method of Administration:	Intramuscular injection
Dose:	50 µg [^{3}H]-08-A01-C0 (lot # NC-0552-1)
Number of Doses:	1
Detection:	Radioactivity quantitation using liquid scintillation counting
Sampling Time (hour):	0.25, 1, 2, 4, 8, 24, and 48 hours post-injection

Sample	Mean total lipid concentration (µg lipid equivalent/g (or mL) (males and females combined)							% of administered dose (males and females combined)						
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h
Adipose tissue	0.057	0.100	0.126	0.128	0.093	0.084	0.181	--	--	--	--	--	--	--
Adrenal glands	0.271	1.48	2.72	2.89	6.80	13.8	18.2	0.001	0.007	0.010	0.015	0.035	0.066	0.106
Bladder	0.041	0.130	0.146	0.167	0.148	0.247	0.365	0.000	0.001	0.001	0.001	0.001	0.002	0.002
Bone (femur)	0.091	0.195	0.266	0.276	0.340	0.342	0.687	--	--	--	--	--	--	--
Bone marrow (femur)	0.479	0.960	1.24	1.24	1.84	2.49	3.77	--	--	--	--	--	--	--
Brain	0.045	0.100	0.138	0.115	0.073	0.069	0.068	0.007	0.013	0.020	0.016	0.011	0.010	0.009
Eyes	0.010	0.035	0.052	0.067	0.059	0.091	0.112	0.000	0.001	0.001	0.002	0.002	0.002	0.003
Heart	0.282	1.03	1.40	0.987	0.790	0.451	0.546	0.018	0.056	0.084	0.060	0.042	0.027	0.030
Injection site	128	394	311	338	213	195	165	19.9	52.6	31.6	28.4	21.9	29.1	24.6
Kidneys	0.391	1.16	2.05	0.924	0.590	0.426	0.425	0.050	0.124	0.211	0.109	0.075	0.054	0.057
Large intestine	0.013	0.048	0.093	0.287	0.649	1.10	1.34	0.008	0.025	0.065	0.192	0.405	0.692	0.762
Liver	0.737	4.63	11.0	16.5	26.5	19.2	24.3	0.602	2.87	7.33	11.9	18.1	15.4	16.2
Lung	0.492	1.21	1.83	1.50	1.15	1.04	1.09	0.052	0.101	0.178	0.169	0.122	0.101	0.101
Sample	**Total Lipid concentration (µg lipid equivalent/g [or mL]) (males and females combined)**							**% of Administered Dose (males and females combined)**						
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727	--	--	--	--	--	--	--
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.37	--	--	--	--	--	--	--
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192	--	--	--	--	--	--	--
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.3	0.001	0.009	0.008	0.016	0.025	0.037	0.095
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599	0.003	0.007	0.014	0.015	0.015	0.011	0.019
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694	0.000	0.001	0.001	0.001	0.000	0.000	0.001
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170	0.001	0.001	0.002	0.003	0.003	0.004	0.003
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264	0.003	0.007	0.008	0.008	0.005	0.006	0.009
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253	--	--	--	--	--	--	--
Small intestine	0.030	0.221	0.476	0.879	1.28	1.30	1.47	0.024	0.130	0.319	0.543	0.776	0.906	0.835
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112	0.001	0.002	0.002	0.003	0.001	0.001	0.001
Spleen	0.334	2.47	7.73	10.3	22.1	20.1	23.4	0.013	0.093	0.325	0.385	0.982	0.821	1.03
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215	0.006	0.019	0.034	0.030	0.040	0.037	0.039
Testes (males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320	0.007	0.010	0.017	0.030	0.034	0.074	0.074
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331	0.004	0.007	0.010	0.012	0.008	0.007	0.008
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.00	0.000	0.001	0.001	0.001	0.001	0.001	0.001
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456	0.002	0.011	0.015	0.008	0.016	0.018	0.022
Whole blood	1.97	4.37	5.40	3.05	1.31	0.909	0.420	--	--	--	--	--	--	--
Plasma	3.97	8.13	8.90	6.50	2.36	1.78	0.805	--	--	--	--	--	--	--
Blood:Plasma ratio[a]	0.815	0.515	0.550	0.510	0.555	0.530	0.540	--	--	--	--	--	--	--

Source: Japan PMDA (PDF page 16).[37]

Table 2. Modern study report 5002121, biodistribution study submitted by Moderna to Japanese regulator (PMDA).

表 2.6.4.4-3　雄性 Sprague Dawley ラットに mRNA-1647 100 µg を単回筋肉内接種したときの各組織における薬物動態パラメータ

Matrix	mRNA Construct	T_{max} (h)[a]	C_{max} (ng/mL)[a]	$AUC_{(0-t)}$ (ng × h/mL)[a,b]	$T_{1/2}$ (h)[a,c]	$AUC_{(0-t)}$ Ratio (Tissue/Plasma)[d]	$AUC_{(0-t)}$ Ratio (Tissue/Plasma) Average
Bone marrow	gB	NC	NC	NC	NC	NC	NR
	gH	8.0	0.254 ± 0.0871	7.85 ± 2.03	NC	0.316	
	gL	8.0	0.224 ± 0.0920	2.78 ± 1.03	NC	0.119	
	UL128	8.0	0.292 ± 0.120	3.53 ± 1.33	NC	0.147	
	UL130	NC	NC	NC	NC	NC	
	UL131A	8.0	0.186 ± 0.0829	2.05 ± 0.912	NC	0.0825	
Brain	gB	NC	NC	NC	NC	NC	NR
	gH	24.0	0.0800 ± 0.0491	2.19 ± 1.08	NC	0.0880	
	gL	2.0	0.0360 ± 0.0360	0.144 ± 0.144	NC	0.00615	
	UL128	2.0	0.0340 ± 0.0340	0.136 ± 0.136	NC	0.00564	
	UL130	NC	NC	NC	NC	NC	
	UL131A	NC	NC	NC	NC	NC	
Distal lymph node	gB	8.0	108 ± 101	1,460 ± 1,110	31.6	64.1	62.8
	gH	8.0	110 ± 102	1,490 ± 1,130	36.2	59.8	
	gL	8.0	117 ± 109	1,460 ± 1,200	30.6	62.6	
	UL128	8.0	125 ± 117	1,620 ± 1,290	32.1	67.1	
	UL130	8.0	129 ± 121	1,630 ± 1,330	27.9	64	
	UL131A	8.0	114 ± 108	1,470 ± 1,190	28.5	59.2	
Eye	gB	2.0	4.72 ± 2.77	26.7 ± 13.6	NC	1.18	1.24
	gH	2.0	3.92 ± 2.19	37.6 ± 11.0	NC	1.51	
	gL	2.0	3.23 ± 1.84	29.2 ± 9.75	NC	1.25	
	UL128	2.0	3.91 ± 2.19	34.5 ± 12.2	NC	1.43	
	UL130	2.0	3.61 ± 2.14	21.3 ± 11.0	NC	0.838	
	UL131A	2.0	3.43 ± 1.96	31.1 ± 10.2	NC	1.26	
Heart	gB	NC	NC	NC	NC	NC	NR
	gH	8.0	0.548 ± 0.107	9.94 ± 1.85	NC	0.400	
	gL	8.0	0.220 ± 0.0907	2.96 ± 1.05	NC	0.127	
	UL128	8.0	0.276 ± 0.113	4.49 ± 1.51	NC	0.186	
	UL130	NC	NC	NC	NC	NC	
	UL131A	8.0	0.312 ± 0.0896	3.71 ± 1.02	NC	0.150	
Injection site, muscle	gB	2.0	1,770 ± 803	27,100 ± 4,880	13.5	1190	939
	gH	2.0	1,720 ± 828	26,100 ± 4,700	17.1	1050	
	gL	2.0	1,310 ± 638	20,900 ± 3,720	15.2	893	
	UL128	2.0	1,620 ± 720	25,300 ± 4,090	14.9	1050	
	UL130	2.0	1,630 ± 777	24,500 ± 4,240	13.8	961	
	UL131A	8.0	427 ± 210	12,100 ± 2,830	15.0	487	
Jejunum	gB	NC	NC	NC	NC	NC	NR
	gH	8.0	0.0800 ± 0.0490	2.06 ± 1.04	NC	0.0827	
	gL	2.0	0.0700 ± 0.0429	0.720 ± 0.472	NC	0.0308	
	UL128	NC	NC	NC	NC	NC	
	UL130	NC	NC	NC	NC	NC	
	UL131A	NC	NC	NC	NC	NC	
Kidney	gB	NC	NC	NC	NC	NC	NR
	gH	NC	NC	NC	NC	NC	
	gL	NC	NC	NC	NC	NC	
	UL128	NC	NC	NC	NC	NC	
	UL130	NC	NC	NC	NC	NC	
	UL131A	NC	NC	NC	NC	NC	
Liver	gB	2.0	2.16 ± 1.21	8.65 ± 4.83	NC	0.381	0.499
	gH	2.0	2.12 ± 0.982	16.8 ± 4.15	NC	0.674	
	gL	2.0	1.30 ± 0.432	11.0 ± 2.37	NC	0.470	
	UL128	2.0	2.00 ± 0.814	13.7 ± 3.72	NC	0.570	
	UL130	2.0	1.87 ± 1.01	7.46 ± 4.04	NC	0.293	
	UL131A	2.0	1.99 ± 0.928	13.9 ± 4.04	NC	0.562	
Lung	gB	NC	NC	NC	NC	NC	NR
	gH	8.0	0.442 ± 0.130	8.04 ± 1.96	NC	0.323	
	gL	8.0	0.274 ± 0.0984	3.45 ± 1.12	NC	0.148	
	UL128	8.0	0.340 ± 0.129	5.40 ± 1.74	NC	0.224	
	UL130	8.0	0.188 ± 0.188	2.07 ± 2.07	NC	0.0812	
	UL131A	8.0	0.310 ± 0.111	4.86 ± 1.49	NC	0.196	

Proximal lymph nodes	gB	2.0	260 ± 121	5,850 ± 949	33.5	257	201
	gH	8.0	206 ± 51.6	4,860 ± 722	38.2	195	
	gL	2.0	175 ± 81.9	3,460 ± 538	36.3	148	
	UL128	8.0	246 ± 66.6	5,190 ± 875	32.8	215	
	UL130	8.0	252 ± 67.2	5,240 ± 881	35.7	206	
	UL131A	2.0	225 ± 106	4,600 ± 719	32.2	185	
Spleen	gB	2.0	7.36 ± 3.81	460 ± 52.9	46.9	20.2	13.4
	gH	24.0	5.63 ± 1.28	371 ± 39.5	83.0	14.9	
	gL	8.0	3.83 ± 1.04	196 ± 21.0	68.2	8.36	
	UL128	24.0	4.87 ± 1.22	297 ± 34.8	68.8	12.3	
	UL130	8.0	5.03 ± 1.41	288 ± 33.0	64.9	11.3	
	UL131A	2.0	5.10 ± 2.64	277 ± 33.1	46.2	11.2	
Stomach	gB	NC	NC	NC	NC	NC	NR
	gH	8.0	0.110 ± 0.0696	3.49 ± 1.59	NC	0.140	
	gL	8.0	0.0800 ± 0.0499	2.07 ± 1.19	NC	0.0886	
	UL128	24.0	0.102 ± 0.0648	2.85 ± 1.47	NC	0.118	
	UL130	NC	NC	NC	NC	NC	
	UL131A	24.0	0.0980 ± 0.0634	2.53 ± 1.39	NC	0.102	
Testes	gB	2.0	1.16 ± 0.719	4.64 ± 2.88	NC	0.204	0.209
	gH	2.0	1.11 ± 0.480	5.52 ± 2.20	NC	0.222	
	gL	8.0	0.420 ± 0.335	6.08 ± 3.73	NC	0.260	
	UL128	2.0	0.946 ± 0.397	4.73 ± 1.85	NC	0.196	
	UL130	2.0	0.682 ± 0.442	2.73 ± 1.77	NC	0.107	
	UL131A	2.0	0.872 ± 0.380	4.54 ± 1.85	NC	0.183	

Abbreviations: gB = glycoprotein B; gH = glycoprotein H; gL = glycoprotein L; IM = intramuscular; NC = not calculable (insufficient data points above the lower limit of quantitation); NR = not reported (some constructs measured all samples as below limit of quantitation).

[a] T_{max} and $T_{1/2}$ data reported as the mean; C_{max} and $AUC_{(0-t)}$ data reported as the mean ± standard error.

[b] For the bone marrow, brain, jejunum, heart, liver, lung, stomach, and testes, $AUC_{(0-t)}$ was calculated using less than 3 quantifiable mean concentrations and therefore is an estimate.

[c] Due to the lack of a distinct elimination phase in plasma, the $T_{1/2}$ of the mRNA constructs could not be calculated; however, the $T_{1/2}$ was estimated to range from 2.7 to 3.8 hours.

[d] For $AUC_{(0-t)}$ Ratio, samples listed as NC were not calculable because all samples were below limit of quantitation.

Source: Report 5002121 Amendment 1 (Appendix 8, Table 2 and Table 3)

Source: Japan PMDA (PDF page 7).[47]

III. ENVIRONMENT IMPACT

The petitioners hereby state that the relief requested in this petition will have no environmental impact and therefore an environmental assessment is not required under 21 C.F.R. Sections 25.30 and 25.31.

IV. ECONOMIC IMPACT

Economic impact information will be submitted upon request of the commissioner.

V. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes

representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Linda Wastila, BSPharm, MSPH, PhD[*†]
Professor, Pharmaceutical Health Services Research
University of Maryland School of Pharmacy
220 Arch Street, Baltimore, Maryland 21201, U.S.A.
[*] Lead petitioner, will accept all correspondence.
[†] Dr. Wastila's organizational affiliation is included for identification purposes only.

Peter Doshi, PhD[†]
Associate Professor, Pharmaceutical Health Services Research
University of Maryland School of Pharmacy
Baltimore, Maryland, U.S.A.
[†] Dr. Doshi's organizational affiliation is included for identification purposes only.

Hamid A. Merchant, BPharm, MPharm, PhD, RPh, CQP, PGCertHE, FHEA, SRPharmS[†]
Subject Leader in Pharmacy
University of Huddersfield
Huddersfield, United Kingdom
[†] Dr. Merchant's organizational affiliation is included for identification purposes only.

Kim Witczak
President/Co-Founder
Woodymatters
Minneapolis, Minnesota, U.S.A.

Peter Aaby, MSc, DMSc[†]
Head of Bandim Health Project, Guinea-Bissau
University of Southern Denmark
Copenhagen, Denmark
[†] Dr. Aaby's organizational affiliation is included for identification purposes only.

Christine Stabell Benn, MD, PhD, DMSc[†]
Professor of Global Health
University of Southern Denmark
Copenhagen, Denmark
[†] Dr. Benn's organizational affiliation is included for identification purposes only.

Florence T. Bourgeois MD, MPH[†]
Associate Professor of Pediatrics
Harvard Medical School
Boston, Massachusetts, U.S.A.
[†] Dr. Bourgeois's organizational affiliation is included for identification purposes only.

Anthony J Brookes, PhD†
Professor of Genetics
University of Leicester
Leicester, United Kingdom
† *Dr. Brookes's organizational affiliation is included for identification purposes only.*

Byram W. Bridle, PhD†
Associate Professor of Viral Immunology
University of Guelph
Ontario, Canada
† *Dr. Bridle's organizational affiliation is included for identification purposes only.*

Peter Collignon AM, MB, BS(Hons), BSc(Med), FRACP, FRCPA, FASM†
Professor
Australian National University Medical School
Canberra, Australia
† *Dr. Collignon's organizational affiliation is included for identification purposes only.*

Juan Erviti, PharmD, PhD†
Unit of Innovation and Organization
Navarre Health Service, Spain
Pamplona, Spain
† *Dr. Erviti's organizational affiliation is included for identification purposes only.*

Peter C. Gøtzsche, Professor, DrMedSci, MD, MSc
Director
Institute for Scientific Freedom
Copenhagen, Denmark

David Healy, MD FRCPsych†
Professor of Psychiatry
McMaster University
Ontario, Canada
† *Dr. Healy's organizational affiliation is included for identification purposes only.*

Iona Heath, CBE FRCGP†
Past president of the Royal College of General Practitioners
London, United Kingdom
† *Dr. Heath's former affiliation is included for identification purposes only.*

Matthew Herder, JSM LLM†
Director, Health Law Institute
Dalhousie University
Nova Scotia, Canada
† *Prof. Herder's organizational affiliation is included for identification purposes only.*

Tom Jefferson, MD MRCGP FFPHM†
Senior Associate Tutor
University of Oxford
† *Dr. Jefferson's organizational affiliation is included for identification purposes only.*

Robert M. Kaplan, PhD†
Distinguished Research Professor
UCLA Fielding School of Public Health
Los Angeles, California, U.S.A.
† *Dr. Kaplan's organizational affiliation is included for identification purposes only.*

Ulrich Keil, MD, PhD, FRCP (London)†
Professor Emeritus
University of Muenster
Muenster, Germany
† *Dr. Keil's organizational affiliation is included for identification purposes only.*

Joseph A. Ladapo, MD, PhD
Associate Professor of Medicine
David Geffen School of Medicine at UCLA
Los Angeles, California, U.S.A.
† *Dr. Ladapo's organizational affiliation is included for identification purposes only.*

Donald W. Light, PhD†
Professor of Comparative Health Policy and Psychiatry
Rowan University School of Osteopathic Medicine
Glassboro, New Jersey, U.S.A.
† *Dr. Light's organizational affiliation is included for identification purposes only.*

Peter A. McCullough, MD, MPH†
Professor of Medicine
Texas A & M College of Medicine
Dallas, Texas, U.S.A.
† *Dr. McCullough's organizational affiliation is included for identification purposes only.*

Barbara Mintzes, BA, MSc, PhD†
Associate Professor, School of Pharmacy
The University of Sydney
Sydney, Australia
† Dr. Mintzes' organizational affiliation is included for identification purposes only.

Huseyin Naci, MHS, PhD†
Associate Professor of Health Policy
London School of Economics and Political Science
London, United Kingdom
† Dr. Naci's organizational affiliation is included for identification purposes only.

Allyson M Pollock, MBChB, FRCPH, FRCP (Ed) FRCGP†
Clinical Professor of Public Health
Institute of Health and Society, Newcastle University
Newcastle upon Tyne, United Kingdom
† Dr. Pollock's organizational affiliation is included for identification purposes only.

Angela Spelsberg, MD, SM†
Comprehensive Cancer Center Aachen
Aachen, Germany
† Dr. Spelsberg's organizational affiliation is included for identification purposes only.

Erick Turner, MD†
Associate Professor of Psychiatry
Oregon Health & Science University
Portland, Oregon, U.S.A.
† Dr. Turner's organizational affiliation is included for identification purposes only.

Patrick Whelan, MD PhD†
Associate Clinical Professor of Pediatrics
David Geffen School of Medicine at UCLA
Los Angeles, California, U.S.A.
† Dr. Whelan's organizational affiliation is included for identification purposes only.

References

1. Zuckerman DM. Emergency Use Authorizations (EUAs) Versus FDA Approval: Implications for COVID-19 and Public Health. Am J Public Health [Internet]. 2021 Jun;111(6):1065–9. Available from: http://dx.doi.org/10.2105/AJPH.2021.306273

2. Food and Drug Administration. Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry [Internet]. 2020 [cited 2020 Oct 6]. Available from: https://www.fda.gov/media/139638/download

3. Food and Drug Administration. FDA Briefing Document. Janssen Ad26.COV2.S Vaccine for the Prevention of COVID-19 [Internet]. 2021 [cited 2021 May 28]. Available from: https://www.fda.gov/media/146217/download

4. CDC. Risk for COVID-19 infection, hospitalization, and death by age group [Internet]. 2021 [cited 2021 May 28]. Available from: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html

5. CDC. COVID-19 Pandemic Planning Scenarios [Internet]. 2021 [cited 2021 May 28]. Available from: https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html

6. CDC. Estimated disease burden of COVID-19 [Internet]. 2021 [cited 2021 May 28]. Available from: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

7. Dan JM, Mateus J, Kato Y, Hastie KM, Yu ED, Faliti CE, et al. Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. Science [Internet]. 2021 Feb 5;371(6529). Available

from: http://dx.doi.org/10.1126/science.abf4063

8. Turner JS, Kim W, Kalaidina E, Goss CW, Rauseo AM, Schmitz AJ, et al. SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans. Nature [Internet]. 2021 May 24; Available from: http://dx.doi.org/10.1038/s41586-021-03647-4

9. Breton G, Mendoza P, Hagglof T, Oliveira TY, Schaefer-Babajew D, Gaebler C, et al. Persistent Cellular Immunity to SARS-CoV-2 Infection. bioRxiv [Internet]. 2020 Dec 9; Available from: http://dx.doi.org/10.1101/2020.12.08.416636

10. Hall VJ, Foulkes S, Charlett A, Atti A, Monk EJM, Simmons R, et al. SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study (SIREN). Lancet [Internet]. 2021 Apr 17;397(10283):1459–69. Available from: http://dx.doi.org/10.1016/S0140-6736(21)00675-9

11. Krammer F, Srivastava K, Simon V, the PARIS team. Robust spike antibody responses and increased reactogenicity in seropositive individuals after a single dose of SARS-CoV-2 mRNA vaccine [Internet]. bioRxiv. medRxiv; 2021. Available from: http://medrxiv.org/lookup/doi/10.1101/2021.01.29.21250653

12. Samanovic MI, Cornelius AR, Wilson JP, Karmacharya T, Gray-Gaillard SL, Allen JR, et al. Poor antigen-specific responses to the second BNT162b2 mRNA vaccine dose in SARS-CoV-2-experienced individuals. medRxiv [Internet]. 2021 Feb 9; Available from: http://dx.doi.org/10.1101/2021.02.07.21251311

13. Camara C, Lozano-Ojalvo D, Lopez-Granados E, Paz-Artal E, Pion M, Correa-Rocha R, et al. Differential effects of the second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naïve and COVID-19 recovered individuals [Internet]. bioRxiv. 2021 [cited 2021 May 28]. p. 2021.03.22.436441. Available from: https://www.biorxiv.org/content/10.1101/2021.03.22.436441v1

14. Levi R, Azzolini E, Pozzi C, Ubaldi L, Lagioia M, Mantovani A, et al. A cautionary note on recall vaccination in ex-COVID-19 subjects [Internet]. bioRxiv. medRxiv; 2021. Available from: http://medrxiv.org/lookup/doi/10.1101/2021.02.01.21250923

15. Ogata AF, Cheng C-A, Desjardins M, Senussi Y, Sherman AC, Powell M, et al. Circulating SARS-CoV-2 Vaccine Antigen Detected in the Plasma of mRNA-1273 Vaccine Recipients. Clin Infect Dis [Internet]. 2021 May 20; Available from: http://dx.doi.org/10.1093/cid/ciab465

16. Kuba K, Imai Y, Rao S, Gao H, Guo F, Guan B, et al. A crucial role of angiotensin converting enzyme 2 (ACE2) in SARS coronavirus-induced lung injury. Nat Med [Internet]. 2005 Aug;11(8):875–9. Available from: http://dx.doi.org/10.1038/nm1267

17. Chen I-Y, Chang SC, Wu H-Y, Yu T-C, Wei W-C, Lin S, et al. Upregulation of the chemokine (C-C motif) ligand 2 via a severe acute respiratory syndrome coronavirus spike-ACE2 signaling pathway. J Virol [Internet]. 2010 Aug;84(15):7703–12. Available from: http://dx.doi.org/10.1128/JVI.02560-09

18. Patra T, Meyer K, Geerling L, Isbell TS, Hoft DF, Brien J, et al. SARS-CoV-2 spike protein promotes IL-6 trans-signaling by activation of angiotensin II receptor signaling in epithelial cells. PLoS Pathog [Internet]. 2020 Dec;16(12):e1009128. Available from:

http://dx.doi.org/10.1371/journal.ppat.1009128

19. Zhang S, Liu Y, Wang X, Yang L, Li H, Wang Y, et al. SARS-CoV-2 binds platelet ACE2 to enhance thrombosis in COVID-19. J Hematol Oncol [Internet]. 2020 Sep 4;13(1):120. Available from: http://dx.doi.org/10.1186/s13045-020-00954-7

20. Suresh SJ, Suzuki YJ. SARS-CoV-2 Spike Protein and Lung Vascular Cells. Journal of Respiration [Internet]. 2020 Dec 31 [cited 2021 May 25];1(1):40–8. Available from: https://www.mdpi.com/2673-527X/1/1/4

21. Angeli F, Spanevello A, Reboldi G, Visca D, Verdecchia P. SARS-CoV-2 vaccines: Lights and shadows. Eur J Intern Med [Internet]. 2021 Apr 30; Available from: http://dx.doi.org/10.1016/j.ejim.2021.04.019

22. Han M, Pandey D. ZMPSTE24 Regulates SARS-CoV-2 Spike Protein-enhanced Expression of Endothelial Plasminogen Activator Inhibitor-1. Am J Respir Cell Mol Biol [Internet]. 2021 May 18; Available from: http://dx.doi.org/10.1165/rcmb.2020-0544OC

23. Rhea EM, Logsdon AF, Hansen KM, Williams LM, Reed MJ, Baumann KK, et al. The S1 protein of SARS-CoV-2 crosses the blood-brain barrier in mice. Nat Neurosci [Internet]. 2021 Mar;24(3):368–78. Available from: http://dx.doi.org/10.1038/s41593-020-00771-8

24. Idrees D, Kumar V. SARS-CoV-2 spike protein interactions with amyloidogenic proteins: Potential clues to neurodegeneration. Biochem Biophys Res Commun [Internet]. 2021 May 21;554:94–8. Available from: http://dx.doi.org/10.1016/j.bbrc.2021.03.100

25. Lei Y, Zhang J, Schiavon CR, He M, Chen L, Shen H, et al. SARS-CoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE 2. Circ Res [Internet]. 2021 Apr 30;128(9):1323–6. Available from: http://dx.doi.org/10.1161/CIRCRESAHA.121.318902

26. Zhang L, Richards A, Barrasa MI, Hughes SH, Young RA, Jaenisch R. Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues. Proc Natl Acad Sci U S A [Internet]. 2021 May 25;118(21). Available from: http://dx.doi.org/10.1073/pnas.2105968118

27. Suzuki YJ, Nikolaienko SI, Dibrova VA, Dibrova YV, Vasylyk VM, Novikov MY, et al. SARS-CoV-2 spike protein-mediated cell signaling in lung vascular cells. Vascul Pharmacol [Internet]. 2021 Apr;137:106823. Available from: http://dx.doi.org/10.1016/j.vph.2020.106823

28. Suzuki YJ, Gychka SG. SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells: Implications for Possible Consequences of COVID-19 Vaccines. Vaccines (Basel) [Internet]. 2021 Jan 11;9(1). Available from: http://dx.doi.org/10.3390/vaccines9010036

29. Ogata AF, Maley AM, Wu C, Gilboa T, Norman M, Lazarovits R, et al. Ultra-sensitive Serial Profiling of SARS-CoV-2 Antigens and Antibodies in Plasma to Understand Disease Progression in COVID-19 Patients with Severe Disease. Clin Chem [Internet]. 2020 Sep 8; Available from: http://dx.doi.org/10.1093/clinchem/hvaa213

30. Kloc M, Uosef A, Kubiak JZ, Ghobrial RM. Exaptation of Retroviral Syncytin for Development of Syncytialized Placenta, Its Limited Homology to the SARS-CoV-2 Spike Protein and Arguments

against Disturbing Narrative in the Context of COVID-19 Vaccination. Biology [Internet]. 2021 Mar 19;10(3). Available from: http://dx.doi.org/10.3390/biology10030238

31. Khan I, Hatiboglu MA. Can COVID-19 induce glioma tumorogenesis through binding cell receptors? Med Hypotheses [Internet]. 2020 Nov;144:110009. Available from: http://dx.doi.org/10.1016/j.mehy.2020.110009

32. Singh N, Bharara Singh A. S2 subunit of SARS-nCoV-2 interacts with tumor suppressor protein p53 and BRCA: an in silico study. Transl Oncol [Internet]. 2020 Oct;13(10):100814. Available from: http://dx.doi.org/10.1016/j.tranon.2020.100814

33. Madla CM, Gavins FKH, Merchant H, Orlu M, Murdan S, Basit AW. Let's Talk About Sex: Differences in Drug Therapy in Males and Females. Adv Drug Deliv Rev [Internet]. 2021 May 17; Available from: http://dx.doi.org/10.1016/j.addr.2021.05.014

34. European Medicines Agency. Assessment Report. Comirnaty (COVID-19 mRNA vaccine (nucleoside-modified)), EMA/707383/2020 Corr.1 [Internet]. 2021 Feb [cited 2021 Apr 13]. Available from: https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf#page=45

35. European Medicines Agency. Assessment Report. COVID-19 Vaccine Moderna (COVID-19 mRNA Vaccine (nucleoside-modified)), EMA/15689/2021 Corr.1 [Internet]. 2021 Mar [cited 2021 Apr 13]. Available from: https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf#page=47

36. European Medicines Agency. Assessment Report. COVID-19 Vaccine Janssen, EMA/158424/2021 [Internet]. 2021 Mar [cited 2021 Apr 13]. Available from: https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-janssen-epar-public-assessment-report_en.pdf#page=50

37. Pfizer. SARS-CoV- 2 mRNA Vaccine (BNT162, PF-07302048) 2.6.4 Yakubutsu dōtai shiken no gaiyō bun [summary of pharmacokinetic studies] [Internet]. 2021 [cited 2021 May 28]. Available from: https://www.pmda.go.jp/drugs/2021/P20210212001/672212000_30300AMX00231_I100_1.pdf#page=16

38. CDC. Selected adverse events reported after COVID-19 vaccination [Internet]. 2021 [cited 2021 May 28]. Available from: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

39. Doshi P. FDA response to BMJ on reports of death after covid-19 vaccination [Internet]. 2021 [cited 2021 May 28]. Available from: https://www.bmj.com/content/372/bmj.n149/rr-25

40. Wyller TB, Kittang BR, Ranhoff AH, Harg P, Myrstad M. Nursing home deaths after COVID-19 vaccination. Tidsskr Nor Laegeforen [Internet]. 2021 May 20;141. Available from: http://dx.doi.org/10.4045/tidsskr.21.0383

41. Torjesen I. Covid-19: Pfizer-BioNTech vaccine is "likely" responsible for deaths of some elderly patients, Norwegian review finds. BMJ [Internet]. 2021 May 27 [cited 2021 May 28];373. Available from: https://www.bmj.com/content/373/bmj.n1372

42. Food and Drug Administration. Coronavirus (COVID-19) update: FDA Issues Policies to guide medical product developers addressing virus variants [Internet]. 2021 [cited 2021 May 28]. Available from: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-policies-guide-medical-product-developers-addressing-virus

43. Owens C. Vaccine boosters could be necessary as soon as September [Internet]. Axios. 2021 [cited 2021 May 28]. Available from: https://www.axios.com/coronavirus-vaccines-boosters-pfizer-moderna-e8d6bed6-8238-4e52-9959-ca4c6a6e0d5a.html

44. Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med [Internet]. 2020 Dec 31;383(27):2603–15. Available from: http://dx.doi.org/10.1056/NEJMoa2034577

45. Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. N Engl J Med [Internet]. 2021 Feb 4;384(5):403–16. Available from: http://dx.doi.org/10.1056/NEJMoa2035389

46. Thacker PD. Covid-19: How independent were the US and British vaccine advisory committees? BMJ [Internet]. 2021 May 26;373:n1283. Available from: http://dx.doi.org/10.1136/bmj.n1283

47. Moderna. SARS-CoV- 2 mRNA Vaccine (Moderna) 2.6.4 Yakubutsu dōtai shiken no gaiyō bun [summary of pharmacokinetic studies] [Internet]. 2021 [cited 2021 May 29]. Available from: https://www.pmda.go.jp/drugs/2021/P20210519003/400256000_30300AMX00266_I100_1.pdf#page=7

Exhibit 27

Why we petitioned the FDA to refrain from fully approving any covid-19 vaccine this year

June 8, 2021

We are part of a group of clinicians, scientists, and patient advocates who have lodged a formal "Citizen Petition" with the United States Food and Drug Administration (FDA), asking the agency to delay any consideration of a "full approval" of a covid-19 vaccine. The message of our petition is "slow down and get the science right—there is no legitimate reason to hurry to grant a license to a coronavirus vaccine." We believe the existing evidence base—both pre- and post-authorization—is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations.

The covid-19 vaccines in widespread use have emergency authorizations (EUA), not actual approvals, a crucial regulatory distinction that reflects major differences in the level of regulatory scrutiny and certainty about the risk-benefit balance.

Our petition doesn't argue that risks outweigh benefits—or that benefits outweigh risks. Rather, we focus on methods and processes, outlining the many remaining unknowns about safety and effectiveness—and suggest the kinds of studies needed to address the open questions.

If the FDA listens to us, they won't give serious consideration to approving a covid-19 vaccine until 2022. Our first request is that the FDA require manufacturers to submit data from completed Phase III trials—not interim results. Trials by vaccine manufacturers were designed to follow participants for two years, and should be completed before they are evaluated for full approval, even if they are now unblinded and lack placebo groups. These Phase III trials are not simply efficacy studies; they also are necessary and important safety studies (as the study titles say), and all collected data remain invaluable.

We also call on FDA to require a more thorough assessment of spike proteins produced *in-situ* by the body following vaccination—including studies on their full biodistribution, pharmacokinetics, and tissue-specific toxicities. We ask the FDA to demand manufacturers complete proper biodistribution studies that would be expected of any new drug and request additional studies to better understand the implications of mRNA translation in distant tissues. We call on data demonstrating a thorough investigation of **all** serious adverse events reported to pharmacovigilance systems, carried out by independent, impartial individuals, and for safety data from individuals receiving more than two vaccine doses, in consideration of plans for future booster shots. We ask the FDA to request necessary studies in specific populations, including those previously infected with SARS-CoV-2, pediatric subjects, and those with immunological or other underlying medical complexities. Given the nature of the novel vaccine platforms, our petition asks for experts in gene therapy to be included among the external committee advising the FDA.

These are several of our major requests. The petition has been signed by a group of 27 clinicians, researchers, and consumer advocates with diverse experiences and thoughts about the pandemic. We all agree that there remain many open, unanswered questions surrounding the efficacy and safety of covid-19 vaccines that must be answered before the FDA gives serious consideration to granting full approval.

These are the reasons why we lodged our petition. There is no need to rush approval to help stop the pandemic because the vaccines already have Emergency Use Authorization. Yet a rushed process is the very possibility that now confronts us. In the past month, Pfizer and Moderna submitted formal applications for "full approval."

Covid-19 vaccines are already fully accessible to all Americans who want one. EUAs have enabled their widespread use, and can remain in place even after the expiry of the SARS-CoV-2 public health emergency declaration, as is the case for various Zika products. Even without full approval, covid-19 vaccines will remain available for all who want them under EUA.

Some surveys suggest that vaccine hesitancy in the United States is due, in part, to lack of full FDA approval. While approval might lead to increased public confidence in covid-19 vaccines, as well as provide legal support for employer-instituted vaccine mandates, to approve a medical product for these reasons is outside FDA's regulatory purview. Approval decisions must be driven by the safety and efficacy data. The potential unintended consequences of a rushed approval may contribute to growing mistrust of the US public health and regulatory institutions.

Finally, regarding the elephant in the room: publicly raising any element of hesitation about covid-19 vaccines will be seen by some as irresponsible, stoking unfounded fears in the public's mind and contributing to the "vaccine hesitancy" problem trumpeted every day. But the alternatives—privately raising concerns or simply remaining silent—are arguably more detrimental to public trust in the long run. Staying silent is not the responsible option. And the implications of only privately raising concerns to regulatory bodies are murky—most would probably not be acted upon, and if they were, it would promulgate the baggage of insufficient accountability and transparency in decision making.

To us, the Citizen Petition seemed the most responsible approach: voice our concerns in our own words, in a professional and transparent manner, through a formal mechanism that can promote accountability in regulatory decision making.

Approving a covid-19 vaccine now risks setting a precedent of lowered standards for future vaccine approvals. The "FDA approved" seal must represent a high bar—and premature licensure of a covid-19 vaccine could seriously damage public confidence in regulatory authorities, particularly if long-term safety issues were to emerge following licensure. Keeping covid-19 vaccines under EUA regulations would also encourage vaccine manufacturers to continue investing resources in completing the necessary safety and efficacy studies for a potential FDA consideration of full licensure in the future.

For each covid-19 vaccine, the benefits may ultimately outweigh the harms. Or not. Or we may end up in a more nuanced position, finding that benefits outweigh harms for some populations, but not others. Only time—and better evidence—will tell. And so it is vital we allow the scientific process the time required to gather and assess the evidence to be confident in the decisions we ultimately have to make.

Our citizen petition is filed under Docket ID FDA-2021-P-0786 on regulations.gov. Anybody can comment on the petition, or read others' comments, including the FDA's official reply once it arrives.

See also:

- Covid-19 vaccines: In the rush for regulatory approval, do we need more data?
- US college covid-19 vaccine mandates don't consider immunity or pregnancy, and may run foul of the law

Linda Wastila *is Professor and Parke-Davis Endowed Chair of Geriatric Pharmacotherapy at the University of Maryland Baltimore School of Pharmacy. She has conducted policy and epidemiological research focusing on intended and unintended outcomes of clinical and policy interventions involving medications and their safety over the past 30 years.*

Peter Doshi *is an associate professor of pharmaceutical health services research at University of Maryland Baltimore School of Pharmacy and senior editor at* The BMJ. *He has been calling for greater independence and transparency in covid-19 vaccine related decision making.*

Hamid Merchant *is a subject lead in pharmacy at The University of Huddersfield and has experience in pharmaceutical research and development both from industry and academia. His clinical knowledge and expertise in pharmaceutical formulation helps in understanding the clinical and therapeutic principles underpinning drug delivery and the science of dosage-form design.*

Kim Witczak *is a global drug safety advocate with over 25 years of advertising and marketing experience. She co-founded Woodymatters, an organization started after the death of her husband due to undisclosed side effects of antidepressants. Kim is currently Consumer Representative on the FDA Psychopharmacologic Drugs Advisory Committee.*

Competing interests: *PD has received travel funds from the European Respiratory Society (2012) and Uppsala Monitoring Center (2018); grants from the FDA (through University of Maryland M-CERSI; 2020), Laura and John Arnold Foundation (2017-22), American Association of Colleges of Pharmacy (2015), Patient-Centered Outcomes Research Institute (2014-16), Cochrane Methods Innovations Fund (2016-18), and UK National Institute for Health Research (2011-14); was an unpaid IMEDS steering committee member at the Reagan-Udall Foundation for the FDA (2016-20), and is an editor at The BMJ. None further declared.*

The views and opinions expressed here are those of the authors and do not necessarily reflect official policy or position of the University of Maryland or the University of Huddersfield.

Editor's note 30 July 2021: The links in this article have been updated to reflect the re-filing of this petition under the group name Coalition Advocating for Adequately Licensed Medicines (CAALM), which has been assigned a new docket number (FDA-2021-P-0786).

US healthcare

« Richard Hurley: Celebrating NHS staff to find sense in the sorrow

Why "groupthink" detracts from an explanation of the organisational failures of the UK pandemic response »

john barr • 5 months ago • edited

How encouraging to see the bmj publishing opinion pieces like this, instead of merely parrottng the accepted orthodoxy from government and industry, or even blocking proper scientific discussion.

There currently seems to be enough reported adverse events to merit having severe reservations about the safety of all of the vaccines, while recent reports seem to suggest that the Chinese vaccine isn't working very well at all. Look at the figures for the Seychelles.

As a GP, I will have to deal with complaints/questions from patients who may have been harmed by vaccines recommended by the "experts", such as SAGE, whose track record is not really very good. They appear to be lacking in real-life experience.

14 • Reply • Share ›

Katie P • 6 months ago • edited

This is a great petition! Everything must be considered before final approval of any vaccine, including possible long term side effects as well as side effects which take a longer time for symptoms to manifest.

21 1 • Reply • Share ›

Elia B. • 6 months ago

The group called on the FDA to provide an answer by June 11 2021:

"…to allow Petitioners the opportunity to seek emergency judicial relief should the instant Petition be denied."

It is now June 16th and I am unable to find any updates about this Petition. Can someone please provide an update?

8 ^ | v • Reply • Share ›

catalyzer • 5 months ago

FDA full approval will mean that many more people will be vaccinated, which in turn will mean many less deaths, an earlier return to normalcy, and decreased chances of new variants emerging. Conversely, delay of full FDA approval will mean more deaths, perhaps "only" in the thousands, but perhaps even in the millions.

5 ^ | v 16 • Reply • Share ›

catalyzer • 5 months ago

Has this group formulated a best estimate as to how many fewer people will get vaccinated as long as there is no FDA approval, and therefore how many more thousands or hundreds of thousands of deaths will result, while also taking into account the emergence of new variants as a result? Or are they not concerned with that side of the risk-benefit equation?

4 ^ | v 13 • Reply • Share ›

Kelly West • 5 months ago

How many people will die because of this delay? I know numerous people who will not get the vaccine until after full FDA approval.

4 ^ | v 13 • Reply • Share ›

Sergio Kas ↗ Kelly West • 5 months ago

The delay for full approval is more than justified.

18 ^ | v 2 • Reply • Share ›

David Robinette • 5 months ago

While it sure sounds good, if these very well intentioned doctors would spend a bit of time on Social Media, they would notice how many folks are downright refusing to take the vaccine because 'it is not approved.' Delaying that approval in a health emergency will lead to further massive outbreaks as we are now experiencing with the Delta Variant.

4 ^ | v 16 • Reply • Share ›

Graham Barden • 4 months ago

The only for the pandemic to fade is for everyone to be vaccinated or have the disease. In the US, we have plenty of vaccine. The limiting step is to convince people that the vaccine is safer than the disease. Several times a day I hear, "It is not FDA approved!" The FDA has never had the combined experience of hundreds of millions of people already vaccinated! What more do they want or need? If they are worried about making a mistake they should have never approved Alduhelm with its shaky data on Alzheimer's! This vaccine clearly works. Do the paperwork! Help us get it into arms.

1 ^ | v 13 • Reply • Share ›

Greg Inman • 6 months ago

How do you sign and submit this petition?

^ | v • Reply • Share ›

Sarahsworld ➚ Greg Inman • 5 months ago

You don't. It's already been submitted to the FDA by the petitioners (27 medical/scientific community members). It's is being posted here for information purposes as the public is entitled to be aware of its existence and the FDA's response (whenever that happens).

3 ^ | v • Reply • Share ›

Linda F Groom • 5 months ago • edited

When will the FDA approve the covid vaccine for all people. Not just the emergency vaccines that is happening now? What are they waiting on?

^ | v 3 • Reply • Share ›

Synthia Fagen ➚ Linda F Groom • 5 months ago

Meaning when will they approve it for emergency use for people under 12 years old?

2 ^ | v • Reply • Share ›

Comment and opinion from The BMJ's international community of readers, authors, and editors

Search BMJ Opinion Search

MOST READ

Does the FDA think these data justify the first full...

Significant proportions of people admitted to...

Covid vaccines for children should not get emergency...

CATEGORIES

- Author's perspective
- BMJ Clinical Evidence
- Brexit
- China
- Christmas appeal
- Climate change

- Columnists
- Covid-19 known unknowns webinars
- Editors at large
- From the archive
- Global health
- Guest writers
- Junior doctors
- Literature and medicine
- Medical ethics
- MSF
- NHS
- Open data
- Partnership in practice
- Patient and public perspectives
- People's covid inquiry
- Richard Lehman's weekly review of medical journals
- South Asia
- Students
- Too much medicine
- Unreported trial of the week
- US healthcare
- Weekly review of medical journals
- Wellbeing

BMJ CAREERS

Information for Authors

BMJ Opinion provides comment and opinion written by The BMJ's international community of readers, authors, and editors.

We welcome submissions for consideration. Your article should be clear, compelling, and appeal to our international readership of doctors and other health professionals. The best pieces make a single topical point. They are well argued with new insights.

For more information on how to submit, please see our **instructions for authors.**

Exhibit 28

Skip to Main Content
STAT

Did the FDA understaff its review of the Pfizer/BioNTech vaccine?

By Peter Doshi *and* Matthew Herder Dec. 17, 2020

A vial of the Pfizer/BioNTech Covid-19 vaccine. *TIMOTHY A. CLARY/AFP via Getty Images*

Editor's note: *The day after this First Opinion was published, STAT received by email a letter written by by Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, disputing the fact that the FDA used only one reviewer for each of three parts of its review of the Pfizer/BioNTech vaccine, as Peter Doshi and Matthew Herder suggest here. You can read the full FDA letter and the authors' response to it here.*

In what is arguably the most important decision the Food and Drug Administration has made this year — its emergency use authorization of the Pfizer/BioNTech Covid-19 vaccine — the agency apparently assigned only a

single reviewer in each of two key scientific disciplines (clinical and statistics) to do the work in three weeks that usually takes months to do.

The FDA's authorization last week followed similar authorizations in the United Kingdom and Canada. But the FDA's decision is particularly important because of its reputation for being the international "gold standard" in regulatory rigor.

Unlike its counterparts in other countries, the FDA is believed to be the only drug regulator in the world that consistently receives and reviews patient-level data from the clinical trials that underpin drug and vaccine approvals. To perform such rigorous analyses, the FDA typically spends around 10 months (a mere six months for applications given "priority review" designation) in an effort that involves reviews by experts representing various scientific disciplines: clinical medicine, statistics, pharmacology, chemistry, pharmacovigilance, and more. Together, these reviews form an "action package" which, by law, must be made publicly available 30 days after approval.

Given the urgency of the pandemic, the review of the Pfizer/BioNTech vaccine was conducted far faster than usual. The centerpiece of the analysis was data from the company's 44,000-participant Phase 3 trial. FDA reviewers had just three weeks, from Nov. 20 to Dec. 11, to complete their analyses. It was a monumental task, which raises the question: Why didn't the FDA devote additional reviewers to it? According to the FDA's review memo, some scientific disciplines, such as pharmacovigilance, had multiple reviewers involved. But the two disciplines tasked with examining the clinical trial data and results, the clinical and statistical reviewers, were seemingly left to do their work solo. (**Editor's note:** The FDA disputes this assertion in the letter below.)

This seems wholly inadequate on at least two levels. First, without additional reviewers it is hard to comprehend how the work of several months could be

squeezed into a matter of 22 days (including Saturdays and Sundays). In-depth review calls for examining patient-level data — a large feat that involves auditing and reviewing individual case records as well as independently rerunning analyses on the raw data.

Before the pandemic, it was typical to see just one clinical reviewer's name for any given application. But given the stakes — and the time crunch — involved with reviewing Covid-19 vaccines, we would have thought the agency would do an even more thorough job than normal. But that does not appear to be the case.

One of us (P.D.) raised questions about potential unblinding in the trials through the vaccine's side effects, as well as about the confounding effects of fever- and pain-reducing medications, which participants in the vaccine arm took three to four times more often than those in the placebo arm. Yet the FDA's review shows no evidence that any of its scientists investigated either of these issues, and without more scientific staff devoted to the task it is hard to imagine how they could.

As one of us (M.H.) has investigated in the past with respect to FDA approvals not related to Covid-19, disagreements within the agency about whether to approve an intervention or set limitations upon its use are relatively common during the review process. Among 174 approvals examined between 2011 and 2015, 42 (24%) contained at least one disagreement among reviewers.

A key takeaway from this research is that a real strength of the FDA is its capacity to entertain dissent with a view to making better judgments about complex scientific evidence.

Such differing opinions were on display at last week's FDA advisory committee meeting, where four advisers voted against the emergency use authorization that the FDA ultimately granted the next day. But that was the FDA's external advisory committee.

Whether such disagreement also exists within the FDA is unclear. By seemingly assigning only one clinical, one statistical, and one toxicology scientist to review the Pfizer/BioNTech Covid-19 vaccine, it seems that discussion, let alone disagreement, was curtailed by design. The pressure on those lone FDA reviewers to do their work in record time, and do it without raising serious questions about the data, was likely immense.

Having an official second or third reviewer for all core scientific disciplines would have helped. Not making more reviewers available strikes us as an effective way to prevent in-depth assessment of the underlying data and limit the possibility of dissent. Shortcuts in the regulatory process undermine the very purpose of regulation to protect the public. If the goal was speed at all costs, we should just get rid of regulators. Otherwise, they need all the resources they can get to do their job, including the fast-approaching decision about whether to authorize Moderna's Covid-19 vaccine.

Peter Doshi leads the Restoring Invisible and Abandoned Trials initiative and is an associate professor of pharmaceutical health services research at the University of Maryland School of Pharmacy. Matthew Herder is director of the Health Law Institute at the Schulich School of Law and an associate professor of pharmacology in the faculty of medicine, both at Dalhousie University in Canada.

Competing interests: Doshi has received grants from the FDA, and the Laura and John Arnold Foundation, and is an unpaid member of the Reagan-Udall Foundation for the FDA. Herder is a member of the Patented Medicine Prices Review Board, Canada's national drug price regulator, and holds grants from the Canadian Institutes of Health Research.

To the Editor: The December 17 opinion from Peter Doshi and Matthew Herder is inaccurate and mischaracterizes the work of FDA career scientific staff involved in the review of the request for emergency use authorization (EUA) for the Pfizer-BioNTech Covid-19 vaccine. The authors' opinion does

not demonstrate an understanding of FDA's team review processes that went into review of the EUA request.

Agency staff have been working around the clock for months, including nights, weekends, and holidays — long before the EUA request was submitted — providing feedback and advice to all sponsors developing Covid-19 vaccines. The authors cite FDA's clinical review memo regarding the Pfizer-BioNTech Covid-19 EUA as evidence that more staff should have been assigned to conduct reviews. In fact, more than one hundred staff — including senior management from across FDA's Center for Biologics Evaluation and Research, and FDA as a whole — contributed to this effort.

The authors clearly fail to understand that this is not the equivalent of an academic manuscript. The individuals listed are simply the leads for each review discipline, and do not represent the entire team of dedicated scientific review staff who worked tirelessly to provide thorough review of the EUA request.

The effort put forth by FDA staff to complete its review and authorize Pfizer-BioNTech's Covid-19 vaccine for emergency use in 22 days following formal submission of the EUA request was heroic. This was not business as usual. FDA undertook an all-hands-on-deck approach to this work.

Because of the suffering caused by this pandemic, our career scientific review staff felt the responsibility to work through the review process with a tremendous sense of urgency while carefully doing their jobs to ensure that any authorized vaccine meets our rigorous scientific standards that Americans — and the world — have come to expect. To suggest otherwise is an affront to their incredible effort.

Peter Marks
Director, Center for Biologics Evaluation and Research
Food and Drug Administration

The authors respond: We appreciate Peter Marks' response to our commentary raising questions about the rigor of the FDA's review process for the Pfizer/BioNTech vaccine emergency use authorization. Marks faults us for taking at face value what is written in the agency's review memo, which lists just one medical reviewer and one statistical reviewer as being involved in the review, which had a 22-day timeline from receipt of the application on Nov. 20 to the FDA's decision on Dec. 11.

Marks says that the FDA staff has been working for months. We believe that. But it misses our concern that review of the results of the Phase 3 trial — which was completed just weeks ago and was submitted to the FDA on Nov. 20 — means the trial data were reviewed in three weeks, lightning speed compared to FDA's normal months-long process. Marks provides no examples of how the underlying patient-level data were critically analyzed during that 22-day period. As our commentary suggests, we believe that a thorough examination of these data is not feasible within that time frame, at least not by a single clinical and statistical reviewer.

Regarding the depth of the FDA's review, Marks says that more than 100 staffers "contributed to the effort" and that the individual names listed in the "Review Team" are "simply the leads for each review discipline." We believe this, too, but wonder why two individuals are listed for pharmacovigilance and three for chemistry, manufacturing, and controls (CMC), but only one each is listed for clinical, biostatistics, and toxicology?

More importantly, as we explained, our concern is not simply about the quantity of reviewers — it is about quality of the process. We saw no sign that the agency assessed the possible impact of potential unblinding in the trial given the side-effects of the vaccine. And we wondered how many people were officially tasked with the responsibility of forming an independent view of the science. We remain concerned that there were no clear structural mechanisms by which reviewers who might have held dissenting views about

the strengths and limitations of the application could freely document and discuss their concerns.

We are heartened to hear that the agency mustered "an all-hands-on-deck approach" to this review. It remains curious to us as to why the memo, combining all disciplines' reviews, totals just 57 pages — much smaller than many solely clinical reviews. Ensuring that the memo accurately reflects all the work that went into the review, especially how and what was analyzed during the 22-day span, and lists all those involved in the effort is, in our estimation, the best course to building trust in the agency's decision-making.

Peter Doshi and Matthew Herder

About the Authors

Peter Doshi

pdoshi@rx.umaryland.edu

Matthew Herder

matthew.herder@dal.ca
@cmrherder

Exhibit 29

Does the FDA think these data justify the first full approval of a covid-19 vaccine?

August 23, 2021

The FDA should demand adequate, controlled studies with long term follow up, and make data publicly available, before granting full approval to covid-19 vaccines, says Peter Doshi

On 28 July 2021, Pfizer and BioNTech posted updated results for their ongoing phase 3 covid-19 vaccine trial. The preprint came almost a year to the day after the historical trial commenced, and nearly four months since the companies announced vaccine efficacy estimates "up to six months."

But you won't find 10 month follow-up data here. While the preprint is new, the results it contains aren't particularly up to date. In fact, the paper is based on the same data cut-off date (13 March 2021) as the 1 April press release, and its topline efficacy result is identical: 91.3% (95% CI 89.0 to 93.2) vaccine efficacy against symptomatic covid-19 through "up to six months of follow-up."

The 20 page preprint matters because it represents the most detailed public account of the pivotal trial data Pfizer submitted in pursuit of the world's first "full approval" of a coronavirus vaccine from the Food and Drug Administration. It deserves careful scrutiny.

The elephant named "waning immunity"

Since late last year, we've heard that Pfizer and Moderna's vaccines are "95% effective" with even greater efficacy against severe disease ("100% effective," Moderna said).

Whatever one thinks about the "95% effective" claims (my thoughts are here), even the most enthusiastic commentators have acknowledged that measuring vaccine efficacy two months after dosing says little about just how long vaccine-induced immunity will last. "We're going to be looking very intently at the durability of protection," Pfizer senior vice president William Gruber, an author on the recent preprint, told the FDA's advisory committee last December.

The concern, of course, was decreased efficacy over time. "Waning immunity" is a known problem for influenza vaccines, with some studies showing near zero effectiveness after just three months, meaning a vaccine taken early may ultimately provide no protection by the time "flu season" arrives some months later. If vaccine efficacy wanes over time, the crucial question becomes what level of effectiveness will the vaccine provide when a person is actually exposed to the virus? Unlike covid vaccines, influenza vaccine performance has always been judged over a full season, not a couple months.

And so the recent reports from Israel's Ministry of Health caught my eye. In early July, they reported that efficacy against infection and symptomatic disease "fell to 64%." By late July it had fallen to 39% where Delta is the dominant strain. This is very low. For context, the FDA's expectation is of "at least 50%" efficacy for any approvable vaccine.

Now Israel, which almost exclusively used Pfizer vaccine, has begun administering a third "booster" dose to all adults over 40. And starting 20 September 2021, the US plans to follow suit for all "fully vaccinated" adults eight months past their second dose.

Delta may not be responsible

Enter Pfizer's preprint. As an RCT reporting "up to six months of follow-up," it is notable that evidence of waning immunity was already visible in the data by the 13 March 2021 data cut-off.

"From its peak post-dose 2," the study authors write, "observed VE [vaccine efficacy] declined." From 96% to 90% (from two months to <4 months), then to 84% (95% CI 75 to 90) "from four months to the data cut-off," which, by my calculation (see footnote at the end of the piece), was about one month later.

But although this additional information was available to Pfizer in April, it was not published until the end of July.

And it's hard to imagine how the Delta variant could play a real role here, for 77% of trial participants were from the United States, where Delta was not established until months after data cut-off.

Waning efficacy has the potential to be far more than a minor inconvenience; it can dramatically change the risk-benefit calculus. And whatever its cause—intrinsic properties of the vaccine, the circulation of new variants, some combination of the two, or something else—the bottom line is that vaccines need to be effective.

Until new clinical trials demonstrate that boosters increase efficacy above 50%, without increasing serious adverse events, it is unclear whether the 2-dose series would even meet the FDA's approval standard at six or nine months.

The "six month" preprint based on the 7% of trial participants who remained blinded at six months

The final efficacy timepoint reported in Pfizer's preprint is "from four months to the data cut-off." The confidence interval here is wider than earlier time points because only half of trial participants (53%) made it to the four month mark, and mean follow-up is around 4.4 months (see footnote).

This all happened because starting last December, Pfizer allowed all trial participants to be formally unblinded, and placebo recipients to get vaccinated. By 13 March 2021 (data cut-off), 93% of trial participants (41,128 of 44,060; Fig 1) were unblinded, officially entering "open-label followup." (Ditto for Moderna: by mid April, 98% of placebo recipients had been vaccinated.)

Despite the reference to "six month safety and efficacy" in the preprint's title, the paper only reports on vaccine efficacy "up to six months," but not *from* six months. This is not semantics, as it turns out only 7% of trial participants actually reached six months of blinded follow-up ("8% of BNT162b2 recipients and 6% of placebo recipients had ≥6 months follow-up post-dose 2.") So despite this preprint appearing a year after the trial began, it provides no data on vaccine efficacy past six months, which is the period Israel says vaccine efficacy has dropped to 39%.

It is hard to imagine that the <10% of trial participants who remained blinded at six months (which presumably further dwindled after 13 March 2021) could constitute a reliable or valid sample to produce further findings. And the preprint does not report any demographic comparisons to justify future analyses.

Severe disease

With the US awash in news about rising cases of the Delta variant, including among the "fully vaccinated," the vaccine's efficacy profile is in question. But some medical commentators are delivering an upbeat message. Former FDA commissioner Scott Gottlieb, who is on Pfizer's board, said: "Remember, the original premise behind these vaccines were [sic] that they would substantially reduce the risk of death and severe disease and hospitalization. And that was the data that came out of the initial clinical trials."

Yet, the trials were not designed to study severe disease. In the data that supported Pfizer's EUA, the company itself characterized the "severe covid-19" endpoint results as "preliminary evidence." Hospital admission numbers were not reported, and zero covid-19 deaths occurred.

In the preprint, high efficacy against "severe covid-19" is reported based on all follow-up time (one event in the vaccinated group vs 30 in placebo), but the number of hospital admissions is not reported so we don't know which, if any, of these patients were ill enough to require hospital treatment. (In Moderna's trial, data last year showed that 21 of 30 "severe covid-19" cases were not admitted to hospital; Table S14).

And on preventing death from covid-19, there are too few data to draw conclusions—a total of three covid-19 related deaths (one on vaccine, two on placebo). There were 29 total deaths during blinded follow-up (15 in the vaccine arm; 14 in placebo).

The crucial question, however, is whether the waning efficacy seen in the primary endpoint data also applies to the vaccine's efficacy against severe disease. Unfortunately, Pfizer's new preprint does not report the results in a way that allows for evaluating this question.

Approval imminent without data transparency, or even an advisory committee meeting?

Last December, with limited data, the FDA granted Pfizer's vaccine an EUA, enabling access to all Americans who wanted one. It sent a clear message that the FDA could both address the enormous demand for vaccines without compromising on the science. A "full approval" could remain a high bar.

But here we are, with FDA reportedly on the verge of granting a marketing license 13 months into the still ongoing, two year pivotal trial, with no reported data past 13 March 2021, unclear efficacy after six months due to unblinding, evidence of waning protection irrespective of the Delta variant, and limited reporting of safety data. (The preprint reports "decreased appetite, lethargy, asthenia, malaise, night sweats, and hyperhidrosis were new adverse events attributable to BNT162b2 not previously identified in earlier reports," but provides no data tables showing the frequency of these, or other, adverse events.)

It's not helping matters that FDA now says it won't convene its advisory committee to discuss the data ahead of approving Pfizer's vaccine. (Last August, to address vaccine hesitancy, the agency had "committed to use an advisory committee composed of independent experts to ensure deliberations about authorization or licensure are transparent for the public.")

Prior to the preprint, my view, along with a group of around 30 clinicians, scientists, and patient advocates, was that there were simply too many open questions about all covid-19 vaccines to support approving any this year. The preprint has, unfortunately, addressed very few of those open questions, and has raised some new ones.

I reiterate our call: "slow down and get the science right—there is no legitimate reason to hurry to grant a license to a coronavirus vaccine."

FDA should be demanding that the companies complete the two year follow-up, as originally planned (even without a placebo group, much can still be learned about safety). They should demand adequate, controlled studies using patient outcomes in the now substantial population of people who have recovered from covid. And regulators should bolster public trust by helping ensure that everyone can access the underlying data.

Peter Doshi, *senior editor,* The BMJ.

Competing interests: *I helped organize the Coalition Advocating for Adequately Licensed Medicines (CAALM), which has formally petitioned the FDA to refrain from fully approving any covid-19 vaccine this year (docket FDA-2021-P-0786). A full list of competing interests is available here. The views and opinions expressed here are mine and do not necessarily reflect official policy or the position of the University of Maryland.*

Provenance: *commissioned; externally peer-reviewed.*

Footnote: *Calculations in this article are as follows. "About 1 month" past month 4 is based on the final row of Fig 2 in the preprint: 1030/12670*12 = 0.98 months (vaccine group) and 895/11802*12 = 0.91 months (placebo group). "53%" is based on Fig 2: (12670+11802)/(23040+23037). "4.4 months" is based on the average of 8412/22505*12 = 4.5 (vaccine) and 8124/22434*12 = 4.3 (placebo) in Fig 2.*

Editors at large

« The global health security agenda rewards rich nations for their selfish behaviour

Academics and social media hostility: should we give up or do more? »

16 Comments BMJ blogs Login

Favorite 753 Tweet Share Sort by Best

Join the discussion…

LOG IN WITH

OR SIGN UP WITH DISQUS

Name

King Slechtvalk • 3 months ago

Appreciate the full clarity. Unfortunately it doesnt look like the FDA will even consider you points and approved it anyways.

18 • Reply • Share ›

dephyant • 3 months ago

Comment and opinion from The BMJ's international community of readers, authors, and editors

Search BMJ Opinion Search

MOST READ

Does the FDA think these data justify the first full...

Significant proportions of people admitted to...

Covid vaccines for children should not get emergency...

CATEGORIES

- Author's perspective
- BMJ Clinical Evidence
- Brexit
- China
- Christmas appeal
- Climate change
- Columnists
- Covid-19 known unknowns webinars
- Editors at large
- From the archive
- Global health
- Guest writers
- Junior doctors
- Literature and medicine
- Medical ethics
- MSF
- NHS
- Open data

- Partnership in practice
- Patient and public perspectives
- People's covid inquiry
- Richard Lehman's weekly review of medical journals
- South Asia
- Students
- Too much medicine
- Unreported trial of the week
- US healthcare
- Weekly review of medical journals
- Wellbeing

BMJ CAREERS

Information for Authors

BMJ Opinion provides comment and opinion written by The BMJ's international community of readers, authors, and editors.

We welcome submissions for consideration. Your article should be clear, compelling, and appeal to our international readership of doctors and other health professionals. The best pieces make a single topical point. They are well argued with new insights.

For more information on how to submit, please see our **instructions for authors.**

Exhibit 30

News

Covid-19: FDA set to grant full approval to Pfizer vaccine without public discussion of data

BMJ 2021; 374 doi: https://doi.org/10.1136/bmj.n2086 (Published 20 August 2021) Cite this as: BMJ 2021;374:n2086

Linked Opinion

Does the FDA think these data justify the first full approval of a covid-19 vaccine?

- Article
- Related content
- Metrics
- Responses
- Peer review
- ✎

Gareth Iacobucci

Author affiliations

The BMJ

Transparency advocates have criticised the US Food and Drug Administration's (FDA) decision not to hold a formal advisory committee meeting to discuss Pfizer's application for full approval of its covid-19 vaccine.

Last year the FDA said it was "committed to use an advisory committee composed of independent experts to ensure deliberations about authorisation or licensure are transparent for the public."1 But in a statement, the FDA told *The BMJ* that it did not believe a meeting was necessary ahead of the expected granting of full approval.

"The FDA has held numerous meetings of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) related to covid-19 vaccines, including a 22 October 20202 meeting to discuss, in general, the development, authorisation, and licensure of covid-19 vaccines," an FDA spokesperson said.

"The FDA also has held meetings of the VRBPAC on all three covid-19 vaccines authorised for emergency use and does not believe a meeting is needed related to this biologics license application."

The spokesperson added, "The Pfizer BioNTech covid-19 vaccine was discussed at the VRBPAC meeting on 10 December 2020.3 If the agency had any questions or concerns that required input from the advisory committee

members we would have scheduled a meeting to discuss."

The vaccine has already been rolled out to millions of Americans through an emergency use authorisation. Companies typically apply for full approval after a longer period has elapsed so that more data are available for review.

But with the US government indicating this week that it plans to start making booster shots widely available next month, experts said the decision not to meet to discuss the data was politically driven.

Data scrutiny

Kim Witczak, a drug safety advocate who serves as a consumer representative on the FDA's Psychopharmacologic Drugs Advisory Committee,[4] said the decision removed an important mechanism for scrutinising the data.

"These public meetings are imperative in building trust and confidence especially when the vaccines came to market at lightning speed under emergency use authorisation," she said. "The public deserves a transparent process, especially as the call for boosters and mandates are rapidly increasing. These meetings offer a platform where questions can be raised, problems tackled, and data scrutinised in advance of an approval."

Witczak is one of the more than 30 signatories of a citizen petition[5] calling on the FDA to refrain from fully approving any covid-19 vaccine this year to gather more data. She warned that without a meeting "we have no idea what the data looks like."

"It is already concerning that full approval is being based on 6 months' worth of data despite the clinical trials designed for two years," she said. "There is no control group after Pfizer offered the product to placebo participants before the trials were completed.

"Full approval of covid-19 vaccines must be done in an open public forum for all to see. It could set a precedent of lowered standards for future vaccine approvals."

Public discussion

Diana Zuckerman, president of the National Center for Health Research, who has also spoken at recent VRBPAC meetings, told *The BMJ*, "It's obvious that the FDA has no intention of hearing anyone else's opinion. But if you make decisions behind closed doors it can feed into hesitancy. It's important to have a public discussion about what kind of data are there and what the limitations are. As we think about risk versus benefit, we need to know."

Joshua Sharfstein, vice dean for public health practice and community engagement at the Johns Hopkins Bloomberg School of Public Health and former FDA deputy commissioner during the Obama administration, said that advisory committee meetings were more than just a way of receiving scientific input from outside experts. "It's also an opportunity to educate the public about the important work that the FDA has done reviewing an enormous amount of data about a product," he told *The BMJ*. "It's a chance for questions to be asked and answered, building public confidence.

"If there are no advisory committee meetings prior to licensure, the FDA should consider taking extra steps to explain the basis of its decisions to the public."

On 18 August, before the news that the FDA would not be holding a formal committee meeting, the president of the Infectious Diseases Society of America Barbara Alexander praised the impact of the VRBPAC meetings as "a critical and necessary part" of the process for assessing whether to give booster doses.[6]

Footnotes

- ***Correction: We amended the reference list on 20 August 2021 to replace reference 5.***

References

1. Shah A, Marks P, Hahn S. Ensuring the safety and effectiveness of a covid-19 vaccine. www.healthaffairs.org/do/10.1377/hblog20200814.996612/full.
2. FDA. Vaccines and related biological products advisory committee, October 22 2020, meeting announcement. 2020. www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-22-2020-meeting-announcement.
3. FDA. Vaccines and related biological products advisory committee, December 10 2020, meeting announcement. 2020. www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement.
4. FDA. Psychopharmacologic drugs advisory committee roster. www.fda.gov/advisory-committees/psychopharmacologic-drugs-advisory-committee/psychopharmacologic-drugs-advisory-committee-roster.
5. Wastila L, Doshi P, Merchant M, Witczak K. Why we petitioned the FDA to refrain from fully approving any covid-19 vaccine this year. BMJ Opinion. 8 June 2021. https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year.
6. IDSA. Response to plan for supplemental vaccine doses for vaccinated individuals. 18 August 2021. www.idsociety.org/news-publications-new/articles/2021/response-to-plan-for-supplemental-vaccine-doses-for-vaccinated-individuals.

View Abstract

Article tools

PDF 2 responses

- Respond to this article
- Print
- Alerts & updates

Article alerts

Please note: your email address is provided to the journal, which may use this information for marketing purposes.

Log in or register:

Username *

Password *

Log in

Register for alerts

If you have registered for alerts, you should use your registered email address as your username

- Citation tools

Download this article to citation manager

Iacobucci G. Covid-19: FDA set to grant full approval to Pfizer vaccine without public discussion of data BMJ 2021; 374 :n2086 doi:10.1136/bmj.n2086

• BibTeX (win & mac)	Download
• EndNote (tagged)	Download
• EndNote 8 (xml)	Download
• RefWorks Tagged (win & mac)	Download
• RIS (win only)	Download
• Medlars	Download

Help

If you are unable to import citations, please contact technical support for your product directly (links go to external sites):

- EndNote
- ProCite
- Reference Manager
- RefWorks
- Zotero

- Request permissions

- Author citation

- Articles by Gareth Iacobucci
- Add article to BMJ Portfolio

Email to a friend

Forward this page

Thank you for your interest in spreading the word about The BMJ.

NOTE: We only request your email address so that the person you are recommending the page to knows that you wanted them to see it, and that it is not junk mail. We do not capture any email address.

Username *

Your Email *

Send To *

You are going to email the following Covid-19: FDA set to grant full approval to Pfizer vaccine without public discussion of data
Your Personal Message

CAPTCHA
This question is for testing whether or not you are a human visitor and to prevent automated spam submissions.

I'm not a robot
reCAPTCHA
Privacy - Terms

Send

- UK jobs
- International jobs

Hampshire Hospitals NHS Foundation Trust: Consultant in Acute Medicine
Stennack Surgery: Salaried GP
Church Street Practice (Weybridge): Salaried GP
Taurus Healthcare: Flexible opportunities for GPs
Livi: Become a Digital Healthcare GP
View more

Altmetric

Who is talking about this article?

Picked up by **3** news outlets
Blogged by **3**
Tweeted by **8505**
On **6** Facebook pages
Reddited by **6**
On **1** videos

11 readers on Mendeley

See more details

Check for updates

This week's poll

Read related article

See previous polls

Other content recommended for you,

Covid-19 vaccines: In the rush for regulatory approval, do we need more data?

Peter Doshi et al., The BMJ, 2021

Covid-19: FDA approves Pfizer-BioNTech vaccine in record time
Janice Hopkins Tanne, The BMJ, 2021

Covid-19: FDA panel votes to authorise Pfizer BioNTech vaccine
Janice Hopkins Tanne, The BMJ, 2020

Covid-19: Should vaccine trials be unblinded?
Jeanne Lenzer, The BMJ, 2020

Covid-19: FDA puts Moderna's paediatric application on hold to investigate side effects
Owen Dyer, The BMJ, 2021

AAP: COVID-19 vaccine recommendation a 'milestone,' more research needed on vaccines in children
Melissa Jenco et al., AAP News

The US Regulatory System and COVID-19 Vaccines: The Importance of a Strong and Capable FDA
Joshua M. Sharfstein et al., Journal of American Medical Association, 2021

FDA panel recommends COVID-19 booster for some, excludes teens
AAP News

Back to top

Exhibit 31

BRIEFING ROOM

Fact Sheet: Biden Administration Announces Details of Two Major Vaccination Policies

NOVEMBER 04, 2021 • STATEMENTS AND RELEASES

New OSHA and CMS Rules Mean Two-Thirds of All Workers Now Covered by Vaccination Rules

Thanks to President Biden's focus on getting Americans vaccinated, 70 percent of adult Americans are now fully vaccinated—up from less than one percent when the President took office. This is significant progress, made possible by a vaccinations program that made shots free and convenient for months. But more vaccinations are needed to save lives, protect the economy, and accelerate the path out of the pandemic. To that end, in July, President Biden began rolling out vaccination requirements for federal employees and contractors and calling on employers to do the same. Thousands of organizations across the country have answered the President's call, and vaccination requirements have already helped reduce the number of unvaccinated Americans by approximately 40 percent since July.

Today, the Biden Administration is announcing the details of two policies to fight COVID-19 that will drive even more progress and result in millions of Americans getting vaccinated, protecting workers, preventing hospitalization, saving lives, and strengthening the economy.

First, the Department of Labor's Occupational Safety and Health Administration (OSHA) is announcing the details of a requirement for employers with 100 or more employees to ensure each of their workers is fully vaccinated or tests for COVID-19 on at least a weekly basis. The OSHA rule will also require that these employers provide paid-time for employees to get vaccinated, and ensure all unvaccinated workers wear a face mask in the workplace. OSHA has a strong 50-year record of requiring employers to take common sense actions to prevent workers from getting sick or injured on the job. This rule will cover 84 million employees.

Second, the Centers for Medicare & Medicaid Services (CMS) at the Department of Health and Human Services is announcing the details of its requirement that health care workers at facilities participating in Medicare and Medicaid are fully vaccinated. The rule applies to more

than 17 million workers at approximately 76,000 health care facilities, including hospitals and long-term care facilities.

The Administration has previously implemented policies requiring millions of federal employees and federal contractors to be fully vaccinated. To make it easy for businesses and workers to comply, the Administration is announcing today that the deadline for workers to receive their shots will be the same for the OSHA rule, the CMS rule, and the previously-announced federal contractor vaccination requirement. Employees falling under the ETS, CMS, or federal contractor rules will need to have their final vaccination dose – either their second dose of Pfizer or Moderna, or single dose of Johnson & Johnson – by January 4, 2022. OSHA is also clarifying that it will not apply its new rule to workplaces covered by either the CMS rule or the federal contractor vaccination requirement. And, both OSHA and CMS are making clear that their new rules preempt any inconsistent state or local laws, including laws that ban or limit an employer's authority to require vaccination, masks, or testing.

The Administration is calling on all employers to ensure that as many of their workers are vaccinated as quickly as possible. As detailed in a recent White House report, vaccination requirements work and are good for the economy. Vaccination requirements have increased vaccination rates by more than 20 percentage points – to over 90 percent – across a wide range of businesses and organizations. According to Wall Street analysts, vaccination requirements could result in as many as 5 million American workers going back to work, and a survey of prominent, independent economists found unanimous agreement that vaccination requirements will "promote a faster and stronger economic recovery."

Today's announcements include:

New Vaccination Requirement for Employers With 100 or More Employees: OSHA is issuing a COVID-19 Vaccination and Testing Emergency Temporary Standard (ETS) to require employers with 100 or more employees (i.e., "covered employers") to:

- **Get Their Employees Vaccinated by January 4th and Require Unvaccinated Employees to Produce a Negative Test on at Least a Weekly Basis:** All covered employers must ensure that their employees have received the necessary shots to be fully vaccinated – either two doses of Pfizer or Moderna, or one dose of Johnson & Johnson – by January 4th. After that, all covered employers must ensure that any employees who have not received the necessary shots begin producing a verified negative test to their employer

on at least a weekly basis, and they must remove from the workplace any employee who receives a positive COVID-19 test or is diagnosed with COVID-19 by a licensed health care provider. The ETS lays out the wide variety of tests that comply with the standard. Given that vaccines are safe, free, and the most effective way for workers to be protected from COVID-19 transmission at work, the ETS does not require employers to provide or pay for tests. Employers may be required to pay for testing because of other laws or collective bargaining agreements.

- **Pay Employees for the Time it Takes to Get Vaccinated:** All covered employers are required to provide paid-time for their employees to get vaccinated and, if needed, sick leave to recover from side effects experienced that keep them from working.
- **Ensure All Unvaccinated Employees are Masked:** All covered employers must ensure that unvaccinated employees wear a face mask while in the workplace.
- **Other Requirements and Compliance Date:** Employers are subject to requirements for reporting and recordkeeping that are spelled out in the detailed OSHA materials available here . While the testing requirement for unvaccinated workers will begin after January 4th, employers must be in compliance with all other requirements – such as providing paid-time for employees to get vaccinated and masking for unvaccinated workers – on December 5th. The Administration is calling on all employers to step up and make these changes as quickly as possible.

New Vaccination Requirements for Health Care Workers: CMS is requiring workers at health care facilities participating in Medicare or Medicaid to have received the necessary shots to be fully vaccinated – either two doses of Pfizer or Moderna, or one dose of Johnson & Johnson – by January 4th. The rule covers approximately 76,000 health care facilities and more than 17 million health care workers – the majority of health care workers in America – and will enhance patient safety in health care settings. The rule applies to employees regardless of whether their positions are clinical or non-clinical and includes employees, students, trainees, and volunteers who work at a covered facility that receives federal funding from Medicare or Medicaid. It also includes individuals who provide treatment or other services for the facility under contract or other arrangements. Among the facility types covered by the rule are hospitals, ambulatory surgery centers, dialysis facilities, home health agencies, and long-term care facilities. Today's action will help provide patients assurance about the vaccination status of those delivering care, create a level playing field across health care facilities, and help to address challenges facilities have faced with staff sickness and quarantines impacting delivery of care.

Streamlining Implementation and Setting One Deadline Across Different Vaccination Requirements: The rules released today ensure employers know which requirements apply to which workplaces. Federal contractors may have some workplaces subject to requirements for federal contractors and other workplaces subject to the newly-released COVID-19 Vaccination and Testing ETS. To make it easy for all employers to comply with the requirements, the deadline for the federal contractor vaccination requirement will be aligned with those for the CMS rule and the ETS. Employees falling under the ETS, CMS, or federal contractor rules will need to have their final vaccination dose – either their second dose of Pfizer or Moderna, or single dose of Johnson & Johnson – by January 4, 2022. This will make it easier for employers to ensure their workforce is vaccinated, safe, and healthy, and ensure that federal contractors implement their requirements on the same timeline as other employers in their industries. And, the newly-released ETS will not be applied to workplaces subject to the federal contractor requirement or CMS rule, so employers will not have to track multiple vaccination requirements for the same employees.

Exhibit 32

Path out of the Pandemic

PRESIDENT BIDEN'S COVID-19 ACTION PLAN

President Biden is implementing a six-pronged, comprehensive national strategy that employs the same science-based approach that was used to successfully combat previous variants of COVID-19 earlier this year. This plan will ensure that we are using every available tool to combat COVID-19 and save even more lives in the months ahead, while also keeping schools open and safe, and protecting our economy from lockdowns and damage.

Vaccinating the Unvaccinated

Further Protecting the Vaccinated

Keeping Schools Safely Open

Increasing Testing & Requiring Masking

Protecting Our Economic Recovery

Improving Care for those with COVID-19

Vaccinating the Unvaccinated

Since January, the Administration has taken actions to make vaccination conveniently available to all. COVID vaccines have been available to every individual age 16 and older since April 19th and to those age 12 and older since May. The Administration took steps to make vaccines available at over 80,000 locations nationwide, worked with pharmacies to offer walk-in appointments, and put out a call to action to businesses and organizations across the nation.

The President announced vaccination requirements for the federal government in July and called on the private sector to do more to encourage vaccination as well. Since that time, employers, schools, nursing homes, restaurants, hospitals, and cities in all 50 states have announced new vaccination requirements. Since July, the share of job postings that require vaccination are up 90%. And we know these requirements work. At the beginning of August, when Tyson Foods announced its requirement—only 45% of its workforce had gotten a shot.

Today, it stands at 72%, meaning half of Tyson's unvaccinated workers have now gotten a shot —well ahead of the company's November 1st deadline. After United Airlines announced its vaccination requirement, more than half of its unvaccinated employees went out and got vaccinated with weeks left to go before the deadline. In Washington State, the weekly vaccination rate jumped 34% after the Governor announced requirements for state workers.

All told, these efforts—and countless other Administration initiatives and policies—have resulted in over 175 million fully vaccinated Americans. But there are still nearly 80 million Americans eligible to be vaccinated who have not yet gotten their first shot.

The President's plan will reduce the number of unvaccinated Americans by using regulatory powers and other actions to substantially increase the number of Americans covered by vaccination requirements—these requirements will become dominant in the workplace. In addition, the plan will provide paid time off for vaccination for most workers in the country.

Requiring All Employers with 100+ Employees to Ensure their Workers are Vaccinated or Tested Weekly

The Department of Labor's Occupational Safety and Health Administration (OSHA) is developing a rule that will require all employers with 100 or more employees to ensure their workforce is fully vaccinated or require any workers who remain unvaccinated to produce a negative test result on at least a weekly basis before coming to work. OSHA will issue an Emergency Temporary Standard (ETS) to implement this requirement. This requirement will impact over 80 million workers in private sector businesses with 100+ employees.

Requiring Vaccinations for all Federal Workers and for Millions of Contractors that Do Business with the Federal Government

Building on the President's announcement in July to strengthen safety requirements for unvaccinated federal workers, the President has signed an Executive Order to take those actions a step further and require all federal executive branch workers to be vaccinated. The President also signed an Executive Order directing that this standard be extended to employees of contractors that do business with the federal government. As part of this effort, the Department of Defense, the Department of Veterans Affairs, the Indian Health Service, and the National Institute of Health will complete implementation of their previously announced vaccination requirements that cover 2.5 million people.

Requiring COVID-19 Vaccinations for Over 17 Million Health Care Workers at Medicare and Medicaid Participating Hospitals and Other Health Care Settings

The Centers for Medicare & Medicaid Services (CMS) is taking action to require COVID-19 vaccinations for workers in most health care settings that receive Medicare or Medicaid reimbursement, including but not limited to hospitals, dialysis facilities, ambulatory surgical settings, and home health agencies. This action builds on the vaccination requirement for nursing facilities recently announced by CMS, and will apply to nursing home staff as well as staff in hospitals and other CMS-regulated settings, including clinical staff, individuals providing services under arrangements, volunteers, and staff who are not involved in direct patient, resident, or client care. These requirements will apply to approximately 50,000 providers and cover a majority of health care workers across the country. Some facilities and states have begun to adopt hospital staff or health care sector vaccination mandates. This action will create a consistent standard across the country, while giving patients assurance of the vaccination status of those delivering care.

Calling on Large Entertainment Venues to Require Proof of Vaccination or Testing for Entry

The President's plan calls on entertainment venues like sports arenas, large concert halls, and other venues where large groups of people gather to require that their patrons be vaccinated or show a negative test for entry.

Requiring Employers to Provide Paid Time Off to Get Vaccinated

To continue efforts to ensure that no worker loses a dollar of pay because they get vaccinated, OSHA is developing a rule that will require employers with more than 100 employees to provide paid time off for the time it takes for workers to get vaccinated or to recover if they are under the weather post-vaccination. This requirement will be implemented through the ETS.

Further Protecting the Vaccinated

There are over 175 million fully vaccinated Americans who are largely protected from severe illness from COVID-19. While so-called "breakthrough infections" among this group do happen, they remain the exception: In fact, recent data indicates there is only 1 confirmed positive case per 5,000 fully vaccinated Americans per week.

But COVID-19 vaccination protection can be made even stronger. In August, the nation's top health officials—Dr. Rochelle Walensky, CDC Director; Dr. Janet Woodcock, Acting FDA Commissioner; Dr. Francis Collins, NIH Director; Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases; Surgeon General Dr. Vivek Murthy; Dr. David Kessler, COVID-19 Chief Science Officer; Dr. Rachel Levine, HHS Assistant Secretary for Health; and Dr. Marcella Nunez-Smith, Chair of the COVID-19 Health Equity Task Force—released an initial plan for booster shots aimed at staying ahead of the virus. The plan released by our nation's doctors allows for states, pharmacies, doctors' offices, health insurers and others to prepare for the administration of boosters. In the beginning weeks of the initial vaccination program in December 2020, the country lost precious time because we were unprepared to administer shots. By planning now, we will be able to quickly get booster shots into the arms of eligible Americans once approved.

A booster promises to give Americans their highest level of protection yet. Three-shot vaccines are common (Hepatitis B, Tetanus) and offer some of the most durable and robust protection.

Implementation of this plan depends on authorization of boosters by the Food and Drug Administration (FDA) and recommendations by the CDC's independent Advisory Committee on Immunization Practices (ACIP). As soon as authorizations are given, the Administration will be prepared to offer booster shots, starting the week of September 20th.

Providing Easy Access to Booster Shots for All Eligible Americans

Ensuring Americans Know Where to Get a Booster

Keeping Schools Safely Open

A top priority for the Biden Administration since Day One has been to reopen schools safely and keep them open. The Administration has taken significant actions to get our kids back in the classroom, including providing $130 billion in American Rescue Plan (ARP) funds to help schools reopen, accelerate students' academic growth, address inequities exacerbated by the pandemic, allow local school districts to implement CDC-recommended COVID-19 prevention strategies, and support student and educators' social, emotional, and mental health needs. We know how to keep students safe in schools by taking the right steps to prevent transmission—including getting all staff and eligible students vaccinated, implementing universal indoor masking, maintaining physical distancing, improving ventilation, and performing regular screening testing for students and school staff. The President's plan calls for additional actions to ensure all schools consistently implement these science-based prevention strategies recommended by the CDC so that they can remain open for in-person learning and maintain the health and safety of all students, staff, and families.

As we work to ensure our children are protected, we know that vaccination remains the best line of defense against COVID-19. For those adolescents aged 12 and above who are eligible for vaccination, the most important step parents can take is to get them vaccinated. To date, over half of the nation's adolescents have been vaccinated. For those too young to be vaccinated, it is especially critical that they are surrounded by vaccinated people and mask in public indoor spaces, including schools. Studies released by the CDC found that the rate of hospitalization for children was nearly four times higher in states with the lowest vaccination rates compared to states with high vaccination rates.

The FDA is undergoing a process now to evaluate a vaccine for children under the age of 12, and under the President's plan, the Administration will do whatever it takes to support those efforts, while continuing to respect and defer to the scientific decision-making of the agency.

Requiring Staff in Head Start Programs, Department of Defense Schools, and Bureau of Indian Education-Operated Schools to be Vaccinated

Calling on All States to Adopt Vaccine Requirements for All School Employees

Providing Additional Funding to School Districts for Safe School Reopening, Including Backfilling Salaries and Other Funding Withheld by States for Implementing COVID Safety Measures

Using the Department of Education's Full Legal Authority to Protect Students' Access to In-Person Instruction

Getting Students and School Staff Tested Regularly

Providing Every Resource to the FDA to Support Timely Review of Vaccines for Individuals Under the Age of 12

Increasing Testing & Requiring Masking

It will take time for the newly vaccinated to get protection from the virus. As we continue to combat COVID-19, testing is a key tool to identify infected individuals and prevent spread to others. Likewise, masking can also help slow and contain the spread of the virus—and the combination of increased vaccinations and masking will have a major impact on COVID-19 transmission. President Biden's plan takes new actions to increase the amount of testing—in your own home, at pharmacies, and in your doctor's office—and ensures that strong mask requirements remain in place.

Mobilizing Industry to Expand Easy-to-Use Testing Production

Making At-Home Tests More Affordable

Sending Free Rapid, At-Home Tests to Food Banks and Community Health Centers

Expanding Free, Pharmacy Testing

Continuing to Require Masking for Interstate Travel and Double Fines

Continue to Require Masking on Federal Property

Protecting Our Economic Recovery

President Biden's economic plan is working. Since Day One in office, the President has focused on jumpstarting the economy and rebuilding it from the bottom up and the middle out. America is getting back to work, and workers and small businesses are seeing the results. Since President Biden took office, there has been historic job growth—more than 4 million jobs created– the most in any President's first six months, with 750,000 jobs created on average per month over the last three months. Despite the challenges posed by the Delta variant, the economy created 235,000 jobs last month, and the unemployment rate fell to its lowest level since before the pandemic. The average number of new unemployment insurance claims has been cut by more than half since President Biden took office, and more than 70 percent of Americans say that now is a good time to find a quality job, up from less than 30 percent this time last year. The U.S. is the only major economy that has now exceeded its pre-pandemic growth projections, and independent forecasters believe America will this year reach the highest levels of growth in decades.

COVID-19 impacts our economy, no doubt. But, the President's plan will limit the damage and ensure that the Delta variant cannot undo this progress. The policies outlined throughout this plan will ensure that we do not return to lockdowns and shutdowns. Additionally, we will offer new support to small businesses as they continue to weather the surge caused by the Delta variant. Supporting small businesses is critical to our economic growth, since they create two-

thirds of net new jobs and employ nearly half of America's private workforce. These reforms include:

New Support for Small Businesses Impacted by COVID-19

Streamlining the Paycheck Protection Program (PPP) Loan Forgiveness Process

Launching the Community Navigator Program to Connect Small Businesses to the Help They Need

Improving Care for those with COVID-19

As we work to reduce cases, hospitalizations, and deaths, we will maintain our focus on treating people infected with COVID-19—and helping hard-hit health care systems in the most impacted areas. In early July, the Administration launched Surge Response Teams to help states experiencing case increases. Since then, the Administration has worked with 18 states, deploying nearly 1,000 personnel, including hundreds of EMTs, nurses and doctors on the ground providing emergency medical care; surged hundreds of ventilators, ambulances and other critical assets to support strained health care systems; stood up dozens of new, free testing sites; and assisted with local outbreak investigations.

As we continue to battle the Delta surge, the President's plan will continue to send response teams to states that request them and take additional actions to accelerate this work.

Increasing Support for COVID-Burdened Hospitals

Getting Life-Saving Monoclonal Antibody Treatment to Those Who Need It

Expanding the Pool of Health Care Professionals Providing Treatment by Deploying Federal Monoclonal Antibody Strike Teams

President Biden's plan to continue to combat COVID-19 this fall is comprehensive, science-based and relies on the power of the federal government working hand-in-hand with states, local communities, the private sector, and all Americans to put this pandemic behind us. The strategy outlined here is domestic focused. **In the weeks ahead, the President will announce additional steps to build on the progress the Administration has made to combat this pandemic globally.** President Biden and his Administration will continue to use every tool necessary to protect the American people from COVID-19.

COVID-19

Exhibit 33

DEPUTY SECRETARY OF DEFENSE
1010 DEFENSE PENTAGON
WASHINGTON, DC 20301-1010

OCT - 1 2021

MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP
COMMANDERS OF THE COMBATANT COMMANDS
DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Mandatory Coronavirus Disease 2019 Vaccination of DoD Civilian Employees

To defend the Nation and protect the American people, we need a healthy and ready Total Force. To accomplish this, the Secretary of Defense directed the mandatory vaccination of Service members against the coronavirus disease 2019 (COVID-19) by signing the memorandum, "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members," on August 24, 2021.

On September 9, 2021, the President of the United States directed Executive Branch agencies to implement a COVID-19 vaccination requirement for Federal employees to ensure the health and safety of the Federal workforce and members of the public with whom they interact by signing Executive Order 14043, "Requiring Coronavirus Disease 2019 Vaccination for Federal Employees."

All DoD civilian employees must be fully vaccinated by November 22, 2021, subject to exemptions as required by law. Employees are considered fully vaccinated 2 weeks after completing the second dose of a two-dose COVID-19 vaccine or 2 weeks after receiving a single dose of a one-dose COVID-19 vaccine.

New DoD civilian employees must be fully vaccinated by their entry on duty (start) date or November 22, 2021, whichever is later.

To meet this requirement, individuals must be vaccinated with vaccines that are either fully licensed or authorized for emergency use by the Food and Drug Administration (FDA) (e.g., Comirnaty/Pfizer-BioNTech, Moderna, Johnson & Johnson/Janssen); listed for emergency use on the World Health Organization Emergency Use Listing (e.g., AstraZeneca/Oxford); or approved for use in a clinical trial vaccine for which vaccine efficacy has been independently confirmed (e.g., Novavax). Those with previous COVID-19 infection(s) or previous serology are not considered fully vaccinated on that basis for the purposes of this mandate.

Those who are not currently fully vaccinated must meet the following deadlines, if using vaccines that are fully licensed or authorized for emergency use by the FDA, in order to be fully vaccinated by November 22, 2021:

- October 11: first dose deadline (if receiving the Moderna vaccine);
- October 18: first dose deadline (if receiving the Comirnaty/Pfizer-BioNTech vaccine);

- November 8: second dose deadline (if receiving the Moderna and Comirnaty/Pfizer-BioNTech vaccines); and

- November 8: first (only) dose deadline (if receiving the Johnson & Johnson/Janssen vaccine).

In accordance with Deputy Secretary of Defense Memorandum, "Coronavirus Disease 2019 Vaccine Guidance," December 7, 2020, DoD civilian employees are eligible to receive the COVID-19 vaccine at any DoD vaccination site, including military medical treatment facilities. They may also opt to receive the COVID-19 vaccine at locations other than DoD vaccination sites, including retail stores, private medical practices, and/or local and State public health department sites. Employees, including those who have already received COVID-19 vaccines, must be prepared to provide a copy of their COVID-19 vaccine record in order to meet forthcoming procedures for DoD COVID-19 vaccination verification.

Additional guidance, including procedures for processing vaccination exemption requests, will be published by the Under Secretary of Defense for Personnel and Readiness (USD(P&R)). The USD(P&R) is authorized to rescind this memorandum as necessary for purposes of providing updated guidance.

Vaccinating DoD civilian employees against COVID-19 will save lives and allow for the defense of our Nation. Thank you for your focus on this critical mission.

Exhibit 34

COVID-19 Vaccination Requirements & Process

In support of the university's commitment to health and safety, CU Boulder will require faculty, staff and students to receive the COVID-19 vaccine before the start of the fall 2021 semester. This is in alignment with the decision to institute this requirement for the CU System and will enable the campus to more fully return to a traditional campus experience for the fall 2021 semester.

CU Boulder will have a vaccine verification process to determine that the requirement has been met for all CU affiliates. Students, staff and faculty should not inquire about an individual's vaccine status, which is considered protected health information.

COVID-19 Vaccine Requirement

There are two ways to complete the vaccine requirement:

- Proof of vaccination
- Vaccine exemption

How to complete the requirement

- Instructions for faculty and staff
- Instructions for undergraduate and graduate students

Students, staff and faculty will not get a confirmation that proof of vaccination or vaccine exemption was successfully submitted. However, faculty and staff will receive an email stating the COVID-19 vaccination requirement was completed after the submission is verified. Students will receive an email stating they have completed their requirement only when all vaccination requirements are complete. In either case, the process of verifying records and sending confirmation of receipt may take 7-10 business days.

Deadline

Based on federal regulations announced Sept. 9, 2021, only medical and religious exemptions are allowed. CU Boulder announced on Nov. 11, 2021 that Boulder students, staff and faculty who submitted a non-medical exemption form for the COVID-19 vaccine must submit a new exemption or provide proof of vaccination by **Jan. 1, 2022**.

Only vaccines that are approved by the World Health Organization (WHO) will meet the CU vaccine requirements.

COVID-19 Vaccination Requirement Frequently Asked Questions

Can I ask students in my class or co-workers if they've been vaccinated?

No. Students, staff and faculty should not inquire about an individual's vaccine status, which is considered protected health information.

How does this decision benefit the campus?

This decision will solidify the ability for CU Boulder to offer a full range of in-person campus experiences in the fall, including co-curricular activities and events. Vaccination remains the most effective way to bring this pandemic to an end and prevent a resurgence in local and campus communities. Continuity of our operations and the ability to provide high quality education to members of our community remain our top priority.

Will visitors to campus be required to show proof of vaccination, or need to ask for an exemption, before coming on a campus tour or attending an event?

No. Campus visitors will not be required to provide proof of vaccination.

If I take classes remotely, do I need to complete the vaccine requirement?

The requirement to receive a COVID-19 vaccination will take effect for all students, staff and faculty. Students enrolled solely in Coursera courses are exempt.

Will faculty and staff be required to receive any other vaccinations? Why is the COVID vaccination being required for faculty and staff when you don't require other vaccinations?

No. Faculty and staff members will not be required to receive other vaccinations at this time, but are encouraged to follow public health guidance and recommendations for other immunizations, such as flu.

Why is CU requiring vaccination when it is still in emergency use designation?

The U.S. Food and Drug Administration (FDA) gave full approval to the Pfizer-BioNTech Monday, August 23, 2021. The FDA continues to approve Emergency Use Authorization (EUA) for Moderna and Janssen (J&J) COVID-19 vaccines. The FDA grants EUA approval for vaccines after extensive safety analysis and determined that COVID-19 vaccines are highly effective in minimizing risks to public health. The university is taking action to mitigate the possibility of future spikes in COVID-19 cases on the Boulder campus and in our community.

Where to Get a COVID-19 Vaccine

Everyone age 5 and over are eligible in Colorado.

Medical Services is providing free COVID-19 vaccines to CU Boulder students, staff and faculty. Vaccines are available by appointment or during one of our drop-in clinics.

Local COVID-19 vaccination opportunities

Medical Services is providing free COVID-19 vaccines to CU Boulder students, staff and faculty. Drop-in vaccine clinics and appointments are available at Wardenburg Health Center. Appointments can be scheduled through the MyCuHealth portal.

Note: In collaboration with Boulder County Health and in order to best support vaccination needs in the community, the mobile vaccination bus will not be available on the CU Boulder campus after Aug. 31. Additional vaccination clinic options can be found at Boulder County's "COVID-19 Vaccines" webpage and Colorado's "Find out where you can get vaccinated" webpage. Locations with mobile vaccination busses offer the J&J (Janssen) vaccine.

Vaccine Information

COVID-19 Vaccines

- Moderna: The Moderna vaccine is 2 doses given 28 days or approximately one month apart. CU Boulder will provide both doses to eligible individuals. For more information visit the Moderna vaccine website.
- Pfizer: The Pfizer vaccine is 2 doses given 21 days or approximately three weeks apart. For more information visit the Pfizer vaccine website.
- Janssen (Johnson & Johnson): The Janssen vaccine is one dose. For more information visit the Janssen fact sheet.

Medical information on why to get vaccinated, COVID-19 vaccine safety and COVID-19 vaccine side effects.

Vaccine Distribution Data

CU can provide information on how many vaccines are distributed on campus, but the cadence of that will vary greatly based on vaccine supply. The total number of CU Boulder faculty, staff and students who have been fully vaccinated through CU Boulder Medical Services is available on the COVID-19 ready dashboard.

Exhibit 35

Part of Stay safe. Get vaccinated. Save lives.

Vaccine required

As of August 20, you must show proof of vaccination to go into bars, restaurants, clubs, and gyms.

Show proof of vaccination

You will need to show proof that you have been vaccinated to go indoors in some places in San Francisco, like:

- Bars
- Restaurants
- Clubs
- Gyms
- Large indoor events
- Any business or event serving food or drinks indoors

In these places everyone 12 and older will need to show proof of vaccination. You will still need to wear a mask in most of these places, even if you are vaccinated.

You cannot use a self-attestation of vaccination or a negative COVID-19 test. You must have proof that you are vaccinated.

We're requiring vaccines to protect everyone against the continued spread of COVID-19. We want to cut down the spread of COVID-19 and keep San Francisco businesses open.

You can show your Vaccination Record Card (CRC) from the CDC. Or you can show an image of the card, if you have a picture on your phone.

If you don't have your card, find out other ways to verify you have been vaccinated.

Businesses

If you run a business that will need to verify vaccination, get more information on what you need to do.

We also have posters you can download and print out. You will need to have these procedures in place by August 20, 2021.

Healthcare workers

The health order requires proof of vaccination for some health care providers, including people who work at:

- Adult day centers
- Residential care facilities
- Dental offices
- Home health aides
- Pharmacists

Updates to the health order

The updates to San Francisco's Safer Return Together Health Order are a response to the city's efforts against COVID-19. We should celebrate that most San Franciscans are fully vaccinated.

San Francisco fully reopened for business on June 15. We have seen encouraging signs that the economy is coming back to life. San Francisco businesses want to stay open, and we want to support them.

Find out more about the Safer Return Together Health Order and the vaccine requirement.

Last updated October 14, 2021

Related

Get vaccinated against COVID-19

Sign up for an appointment or drop in to get a COVID-19 vaccine.

Get verification for your COVID-19 vaccine status

Store your CDC vaccine card in a safe place. If you lose your card, see your options.

Was this page helpful?

Yes **No**

Report something wrong with this page

City and County
of San Francisco

Exhibit 36

USA TODAY

HEALTH

Dr. Anthony Fauci: Expect 'a flood' of COVID-19 vaccine mandates after full FDA approval

Elizabeth Weise USA TODAY

Published 7:09 p.m. ET Aug. 6, 2021 | **Updated 5:11 p.m. ET Aug. 8, 2021**

As soon as the Food and Drug Administration issues a full approval for a COVID-19 vaccine, there will be "a flood" of vaccine mandates at businesses and schools across the nation, Dr. Anthony Fauci told USA TODAY's Editorial Board on Friday.

Mandates aren't going to happen at the federal level, but vaccine approval will embolden many groups, he predicted.

"Organizations, enterprises, universities, colleges that have been reluctant to mandate at the local level will feel much more confident," he said.

"They can say: 'If you want to come to this college or this university, you've got to get vaccinated. If you want to work in this plant, you have to get vaccinated. If you want to work in this enterprise, you've got to get vaccinated. If you want to work in this hospital, you've got to get vaccinated.'"

Fauci said he doesn't see more lockdowns coming. They were issued early in the pandemic to keep hospitals from being overwhelmed, known as "flattening the curve."

"The rationale for shutting down was that the hospital system would not be able to handle the surge of cases because everybody was getting sick," he said.

With more than 70% of adults having had at least one dose of vaccine, the epidemic has shifted to one of the unvaccinated, he said.

"When you walk into a hospital, what you're going to see is a lot of young people, some of whom are seriously ill, but you're not seeing an overwhelming outstripping of the capability of the hospitals throughout the country," he said.

Lies, mistruths and death

Though he's attacked online and in conservative media every day, Faucisaid, he worries less about himself than for the nation as a whole.

"This is a dystopian world we're living in," he said. The public is awash in lies and misinformation about COVID-19 and the vaccines, he said, and "they are being misled."

The Backstory: My brother is one of millions who won't get the COVID-19 vaccine. I asked why. Here are his reasons, my responses.

With COVID-19 cases rising among the unvaccinated as the highly contagious delta variant spreads, Fauci hopes people's "better angels" will prevail over the sea of lies on social media.

Americans, he hopes, will say: "I'm not going to take any of this. I'm seeing everybody around me get sick and dying. Let me just go ahead and get vaccinated.'"

Protecting children

The delta variant has thrown the danger of COVID-19 to young children into sharp relief. In Tennessee, the Department of Health projects the state's children's hospitals are on pace to be full by the end of next week.

The state's health commissioner, Dr. Lisa Piercey, said the delta variant is rapidly spreading among children, who are quickly showing symptoms after possible exposure, possibly amounting to a much faster incubation time than previous versions of the virus.

Children under 12 are not yet eligible for the vaccine, so the adults around them must be their protection, Fauci said.

At schools, everyone needs to be vaccinated, he said, teachers, assistants, janitors, "anybody who is anywhere near a child in what should be a protected environment of a school."

Because in today's political environment that won't happen, Fauci said, masks are the next best thing. Schools are crucial for children's mental health and intellectual, physical and social development, so it's important they stay open.

"I would rather have a child be a little bit uncomfortable with a mask on and be healthy than a comfortable child without a mask in an ICU," he said. "It just doesn't make any sense to me why you would want to not protect the children."

A 'smoldering' future for US

The epidemic in the United States could be endedonce and for all if everyone would get vaccinated, Fauci said. Barring that, he worries we're in it for the long term.

"You will get a smoldering level of infection that will just go right into the fall, get confused with influenza in the winter and then come back again in the spring," he said.

The unvaccinated will continue to get sick, and some will die. The young and healthy are statistically not likely to become seriously ill if infected, but they don't live in a vacuum, he said. The more people who are infected, the more chance the virus has to mutate into an even more dangerous variant.

When will everyone be vaccinated for COVID-19? Here's how the vaccine rollout is going

"All of the sudden, your decision not to get vaccinated goes beyond your own vacuum and influences society," he said.

That holds true for the world as well – unless the virus is stopped everywhere, it will continue to mutate and could come back in a form that can evade current vaccines.

That's different from many vaccine-preventable diseases such as measles, which doesn't mutate. And it's why getting vaccines to the rest of the world is crucial.

"If we're protected against measles here and there are a million cases of measles in Afghanistan or in India or in Uganda or in Kenya and somebody comes over here, it almost doesn't matter. But if we're protected against one group of (COVID-19) variants and a bizarre variant emerges somewhere in a low- or middle-income country, then we're vulnerable," he said.

Fauci ended by emphasizing that while the COVID-19 vaccines are not perfect, they do one thing extraordinarily well: keep people who get COVID-19 from becoming severely ill or dying.

"The reason to get vaccinated is not so that you can go around without wearing a mask," he said. The reason is "because we don't want you to wind up in the ICU. And I can guarantee you 99% that if you get vaccinated, you are not going to wind up in the ICU."

Exhibit 37

FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL August 27, 2021

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Pfizer-BioNTech COVID-19 Vaccine Biological Product File (IR#0546)

Dear Sir or Madam:

This firm represents Public Health and Medical Professionals for Transparency ("**PHMPT**").

On August 23, 2021, the Food and Drug Administration ("**FDA**") approved the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty (the "**Pfizer Vaccine**") for individuals 16 years of age and older. On behalf of PHMPT and its individual members, please provide the following records to foia@sirillp.com in electronic form:

> **All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)[1] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[2]**

[1] 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

[2] For the avoidance of doubt, this request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

Expedited Processing Requested

PHMPT requests expedited processing for this request. FOIA provides for "expedited processing of requests for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(II). When the person requesting information is "primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity" constitutes a "compelling need" for expedited processing. 5 U.S.C. § 552(a)(6)(E)(v)(II).

PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. PHMPT intends to make any records produced in response to this FOIA request immediately available to the public through both its website and its individual members' platforms. Many of PHMPT's individual members, including all its members that are journalists, are primarily engaged in disseminating information to the public and do so across various platforms, including through interviews,[3] articles,[4] blogs,[5] essays,[6] and podcasts.[7] Therefore, PHMPT and many of its members are "primarily engaged in disseminating information to the general public," and, as explained below, there is a clear "urgency to inform the public concerning actual or alleged Federal Government activity," here, the data and information underlying the licensure of the Pfizer Vaccine. Accordingly, expedited processing of this request is warranted.

[3] *See, e.g.*, https://www.foxnews.com/transcript/ingraham-angle-on-mask-mandates-bidens-failure-in-his-role (Harvey Risch) (last visited 8/26/2021)

[4] *See, e.g.*, https://www.bmj.com/content/373/bmj.n1244 (Peter Doshi) (last visited 8/27/2021); https://www.bmj.com/content/371/bmj.m4058 (Peter Doshi) (last visited 8/27/2021); https://www.bmj.com/content/371/bmj.m4037 (Peter Doshi) (last visited 8/27/2021); https://www.wsj.com/articles/are-covid-vaccines-riskier-than-advertised-11624381749 (last visited 8/25/2021); https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (Aaron Kheriaty and Gerard V. Bradley) (last visited 8/27/2021); https://thefederalist.com/2021/07/05/how-college-covid-vaccine-mandates-put-students-in-danger/ (Andrew Bostom, Aaron Kheriaty, Peter A. McCullough, Harvey A. Rish, Michelle Cretella, and Gerard V. Bradley) (last visited 8/27/2021); https://thefederalist.com/2021/08/18/why-forcing-unvaccinated-students-to-wear-cloth-masks-is-anti-science/ (Andrew Bostom, Gerard Bradley, Aaron Kheriaty, and Harvey Risch) (last visited 8/27/2021); https://www.bmj.com/content/bmj/374/bmj.n1737.full.pdf (Serena Tinari and Catherine Riva) (last visited 8/27/2021); https://www.bmj.com/content/372/bmj.n627 (Serena Tinari) (last visited 8/27/2021); https://ebm.bmj.com/content/early/2021/08/08/bmjebm-2021-111735 (Sarah Tanveer, Anisa Rowhani-Farid, Kyungwan Hong, Tom Jefferson, Peter Doshi) (last visited 8/27/2021); https://www.arcdigital.media/p/medical-ethicist-sues-the-university (Justin Lee) (last visited 8/27/2021).

[5] *See, e.g.*, https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (Peter Doshi) (last visited 8/27/2021); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (Peter Doshi) (last visited 8/27/2021). *See also* https://www.re-check.ch/wordpress/en/covid-certificate/ (Catherine Riva and Serena Tinari) (last visited 8/27/2021).

[6] *See* https://www.andrewbostom.org/2021/06/why-collegiate-covid-19-vaccine-mandates-are-lysenkoist-anti-science/ (Andrew Bostom) (last visited 8/27/2021).

[7] *See, e.g.*, https://www.andrewbostom.org/2021/05/dr-andrew-bostom-discusses-the-unfavorable-risk-benefit-ratio-of-covid-19-vaccination-of-very-low-covid-19-risk-12-to-17-year-olds-with-pfizers-emergency-use-authorization-only-mrna-vaccine/ (Andrew Bostom) (last visited 8/27/2021).

Recognizing the urgency to inform the public concerning the data and information underlying a licensed vaccine, the Code of Federal Regulations expressly provides that "[a]fter a license has been issued, the following data and information in the biological product file are *immediately available for public disclosure* unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information…" 21 C.F.R. § 601.51(e) (emphasis added). The FDA's own regulations thus expressly recognize the importance of having the data and information relied upon to license a vaccine "immediately available for public disclosure." *Id.* The FDA's regulation not only supports the need for expedited treatment under FOIA but is also an independent legal basis that requires expedited treatment of this request.

This policy is not surprising given the FDA's commitment to transparency and its entire program to assure transparency, because a lack of transparency erodes the confidence the medical and scientific community and the public have in the conclusions reached by the FDA.[8] There is an urgent public need for such transparency with regard to the Pfizer Vaccine. As required by Congress, the FDA may only license vaccines that have been proven to be "safe and effective," *see, e.g.*, 21 U.S.C. § 393, and the FDA makes this determination based on, *inter alia*, clinical trial reports provided by the sponsor which must be sufficient to demonstrate the product is both "safe" and "effective."[9] 21 C.F.R. 601.2(a). On August 23, 2021, the FDA granted approval to the Pfizer Vaccine[10] and, beyond the FDA's own regulations which admit the urgent need for transparency and disclosure in this situation, there are two additional reasons that warrant expedited treatment of this request.

First, there is an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the Pfizer Vaccine. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the Pfizer Vaccine is more than sufficient for licensure. For example, in a press release issued on August 23, 2021, acting FDA Commissioner Janet Woodcock stated that "the public can be very confident that [the Pfizer Vaccine] meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product."[11] Peter Marks, the director of FDA's Center for Biologics Evaluation and Research, made similar remarks, stating that

> [The FDA's] scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of [the Pfizer Vaccine]. We

[8] https://www.fda.gov/about-fda/transparency (last visited 8/27/2021).

[9] The FDA explains in its guidance materials that the clinical trials relied upon for approval are typically "1 to 4 years" (https://www.fda.gov/patients/drug-development-process/step-3-clinical-research) and the duration of clinical trials should "reflect the product and target condition." https://www.fda.gov/media/102332/download (last visited 8/27/2021). *See also* https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved (last visited 8/27/2021); https://www.fda.gov/about-fda/what-we-do (last visited 8/27/2021).

[10] *See* https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited 8/27/2021). *See also* https://www.cnn.com/2021/08/23/health/fda-approval-pfizer-covid-vaccine/index.html (last visited 8/27/2021). The Washington Post claims that approval of the Pfizer Vaccine was the "fastest in the agency's history." https://www.washingtonpost.com/health/2021/08/23/pfizer-vaccine-full-approval/ (last visited 8/27/2021).

[11] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited 8/27/2021).

> evaluated scientific data and information included in hundreds of thousands of pages, conducted our own analyses of [the Pfizer Vaccine's] safety and effectiveness, and performed a detailed assessment of the manufacturing processes, including inspections of the manufacturing facilities[.][12]

Peter Marks further stated that "although [the FDA] approved [the Pfizer Vaccine] expeditiously, it was fully in keeping with [the FDA's] existing high standards for vaccines in the U.S."[13] President Biden also stated that the FDA's approval meets the "gold standard."[14] Even prior to FDA approval of the Pfizer Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines are "safe and effective."[15]

On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and appropriateness of the analyses relied upon to license the Pfizer Vaccine, including a number of the scientists and journalists that are members of PHMPT. For example, on June 1, 2021, a group of 27 clinicians, scientists, and patient advocates, including PHMPT members Peter Doshi, senior editor for The BMJ and associate professor of pharmaceutical health services research at the University of Maryland School of Pharmacy,[16] and Peter A. McCullough, professor of medicine at Texas A&M College of Medicine, filed a Citizen Petition[17] with the FDA, claiming that the available evidence for licensure of the Pfizer Vaccine "is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations."[18] Separately, Peter Doshi has publicly questioned the lack of transparency regarding the vaccine approval process[19] which Peter Marks publicly disputed.[20] Andrew Kheriaty, professor of psychiatry at UCI

[12] *Id.*

[13] *Id.*

[14] https://www.cbsnews.com/news/biden-address-covid-19-vaccine-pfizer-fda-approval-watch-live-stream-today-2021-08-23/ (last visited 8/27/2021).

[15] *See, e.g.*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=COVID%2D19%20vaccines%20are%20safe,vaccine%20as%20soon%20as%20possible. (last visited 8/27/2021). *See also* https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection ("COVID-19 vaccines have proven to be safe, effective and life-saving.") (last visited 8/27/2021); https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness ("COVID-19 vaccines are safe") (last visited 8/27/2021); https://www.wlns.com/news/gov-whitmer-and-dr-khaldun-respond-to-the-fda-approval-of-pfizers-covid-19-vaccine/ (quoting Governor Whitmer referring to the Pfizer Vaccine as a "safe, effective COVID-19 vaccine") (last visited 8/27/2021).

[16] https://www.bmj.com/about-bmj/editorial-staff/peter-doshi (last visited 8/27/2021).

[17] https://www.regulations.gov/document/FDA-2021-P-0521-0001 (last visited 8/27/2021).

[18] *See* https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/ (last visited 8/27/2021).

[19] *See* https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (last visited 8/27/2021); https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/ (last visited 8/27/2021); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (last visited 8/27/2021).

[20] https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-pfizer-biontech-vaccine/ (last visited 8/27/2021).

School of Medicine, Director of the Medical Ethics Program at UCI Health,[21] and a member of PHMPT, has also questioned the FDA's approval process. For example, in an article published in the Wall Street Journal, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review[22] by the FDA's Vaccines and Related Biological Products Advisory Committee that indicates a risk of heart inflammation after vaccination.[23] Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is "essential" for the FDA to, among other things, "make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public[.]"[24] PHMPT incorporated by reference, as if cited and fully set forth herein, any and all articles, media, and publications regarding or reflecting the public discussion, discourse and debate regarding the Pfizer Vaccine, including all matters related to the licensure of this product.

Given this widespread and ongoing public debate, the medical and scientific community and the public has an immediate need to review the data and information underlying the licensure of the Pfizer Vaccine. Public disclosure of this information will inform this ongoing public debate. Releasing this data should also confirm the FDA's conclusion and thus increase confidence in the safety and efficacy of the Pfizer Vaccine. The FDA should produce the data and information necessary to address this widespread public debate by immediately producing the information requested in this FOIA request.

There is also an urgent need for the public to have immediate access to the data and information underlying the licensure of the Pfizer Vaccine because, over the objections of many, this product is being mandated to individuals across the country by the federal government,[25] local

[21] https://www.aaronkheriaty.com/bio (last visited 8/27/2021).

[22] https://www.fda.gov/media/150054/download (last visited 8/27/2021).

[23] https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (last visited 8/27/2021).

[24] https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf (last visited 8/27/2021). *See also* https://www.washingtontimes.com/news/2021/aug/23/editorial-the-coincidental-timing-of-pfizers-vacci/ (last visited 8/27/2021).

[25] *See, e.g.*, https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1 (last visited 8/27/2021); https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c (last visited 8/27/2021); https://www.forbes.com/sites/joewalsh/2021/08/09/us-military-will-require-covid-vaccinations-by-mid-september/?sh=78defacd6c9f (last visited 8/27/2021); https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/fact-sheet-president-biden-to-announce-new-actions-to-get-more-americans-vaccinated-and-slow-the-spread-of-the-delta-variant/ (last visited 8/27/2021).

governments, [26] public and private employers, [27] universities, [28] schools, [29] and various other institutions, [30] and many are expected to follow suit. [31] At the federal level, legislation was recently introduced that would require COVID-19 vaccines for air travel into or out of the United States [32] and the Pentagon has mandated the COVID-19 vaccines for all military personnel. [33] At the state

[26] *See, e.g.*, https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html (last visited 8/27/2021); https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page (last visited 8/27/2021); https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html (last visited 8/27/2021).

[27] *See, e.g.*, https://www.cnbc.com/2021/08/06/united-airlines-vaccine-mandate-employees.html (last visited 8/27/2021); https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/ (last visited 8/27/2021); https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220 (last visited 8/27/2021); https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/ (last visited 8/27/2021); https://www.cnbc.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html (last visited 8/27/2021); https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/ (last visited 8/27/2021); https://thehill.com/policy/healthcare/569051-pfizers-full-approval-triggers-new-vaccine-mandates (last visited 8/27/2021); https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees (last visited 8/27/2021).

[28] *See* https://universitybusiness.com/state-by-state-look-at-colleges-requiring-vaccines/ (last visited 8/27/2021). *See also, e.g.*, https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916 (last visited 8/27/2021); https://www.colorado.edu/covid-19-updates/covid-19-vaccination (last visited 8/27/2021); https://uhs.berkeley.edu/requirements/covid19 (last visited 8/27/2021); https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs (last visited 8/27/2021); https://www2.gmu.edu/safe-return-campus/vaccination-requirements (last visited 8/27/2021); https://www.pc.pitt.edu/news/vaccine-disclosure-requirements-2021-2022-campus-housing (last visited 8/27/2021)

[29] *See, e.g.*, https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students (last visited 8/27/2021); https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band (last visited 8/27/2021); https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/ (last visited 8/27/2021); https://www.nj.com/hudson/2021/08/hoboken-believed-to-be-first-in-state-to-issue-mandate-for-students-12-and-up-get-vaccine-or-face-weekly-testing.html (last visited 8/27/2021); https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/ (last visited 8/27/2021).

[30] *See, e.g.*, https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/ (last visited 8/27/2021); https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/ (last visited 8/27/2021); https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html (last visited 8/27/2021); https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers (last visited 8/27/2021); https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx (last visited 8/27/2021); https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html (last visited 8/27/2021); https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees (last visited 8/27/2021); *See* https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/ (last visited 8/27/2021).

[31] *See* https://www.mississippifreepress.org/15126/fda-fully-approves-pfizer-biontech-vaccine-mandates-to-follow/ (last visited 8/27/2021); https://www.huffpost.com/entry/vaccine-mandates-roll-out-fda-approval_n_6123e028e4b0df3eacd5d657 (last visited 8/27/2021); https://www.theadvocate.com/baton_rouge/news/coronavirus/article_9be6d02c-0434-11ec-b7b1-cb17d8495274.html?utm_medium=social&utm_source=twitternoladotcom&utm_campaign=snd (last visited 8/27/2021). *See also* https://www.latimes.com/california/story/2021-08-26/california-lawmakers-grapple-with-statewide-covid-19-vaccine-mandate (last visited 8/27/2021).

[32] https://www.congress.gov/bill/117th-congress/house-bill/4980?q=%7B%22search%22:%5b%224980%252 (last visited 8/23/2021).

[33] https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military (last visited 8/23/2021).

level, legislation has been introduced to require COVID-19 vaccines for all post-secondary students,[34] all state employees, [35] and even for all citizens of the state.[36] As explained by Dr. Anthony Fauci, "a flood" of vaccine mandates will follow FDA approval of a COVID-19 vaccine[37] and President Biden is actively encouraging "companies in the private sector to step up the vaccine requirements[.]"[38] During a time when COVID-19 vaccine mandates are being implemented over the objection of those that have questions about the data and information supporting the safety and efficacy of the Pfizer Vaccine, and individuals with these questions are being expelled from employment, school, transportation, and the military, the public has an urgent and immediate need to have access to this data. PHMPT incorporates by reference, as if cited and fully set forth herein, any and all articles, media, and publications regarding or reflecting the public discussion, discourse and debate regarding mandated or potential mandates of the Pfizer Vaccine.

PHMPT certifies that the information in this request is true and correct to the best of its knowledge and belief.

PHMPT is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" Specifically, disclosure of the requested information will immediately address the ongoing public debate about the safety and efficacy of the Pfizer Vaccine and the clinical trials underlying the FDA's approval of same. The information PHMPT requests will not contribute to any commercial activities.

Note that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable or can be deidentified. We further request that you describe any redacted, deleted, or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the

[34] *See* New York bill S6495 available at https://www.nysenate.gov/legislation/bills/2021/S6495 (last visited 8/27/2021).

[35] *See, e.g.*, https://www.nj.com/coronavirus/2021/08/murphy-orders-vaccination-requirement-for-all-nj-state-workers-including-at-public-colleges.html (last visited 8/27/2021).

[36] *See* New York bill A11179 available at https://www.nysenate.gov/legislation/bills/2019/A11179. *See generally* https://eastcountytoday.net/buffy-wicks-transportation-bill-could-become-california-vaccine-passport-bill/ (last visited 8/27/2021).

[37] https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/ (last visited 8/27/2021).

[38] https://www.msn.com/en-us/news/us/biden-urges-private-companies-to-implement-covid-19-vaccine-requirements-following-pfizer-e2-80-99s-fda-approval/ar-AANEcYs?ocid=uxbndlbing (last visited 8/27/2021). *See also* https://www.nytimes.com/2021/08/23/us/pfizer-vaccine-mandates.html (noting that FDA approval of the Pfizer Vaccine "is opening the way for institutions like the military, corporate employers, hospitals and school districts to announce vaccine mandates for their employees") (last visited 8/23/2021); https://www.msn.com/en-us/news/us/now-that-a-covid-19-shot-is-fully-approved-employer-mandates-are-rolling-in-but-will-vaccination-rates-in-the-us-go-up/ar-AANGDTy?ocid=uxbndlbing (last visited 8/23/2021); https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html (quoting the Surgeon General referring to vaccine mandates as "reasonable") (last visited 8/23/2021).

public interest. Such statements may help to avoid unnecessary appeal and litigation. PHMPT reserves all rights to appeal the withholding or deletion of any information.

A determination regarding expedited processing should be made within ten (10) days. Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and PHMPT may immediately file an administrative appeal or an action.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact Aaron Siri at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth Brehm, Esq.
Gabrielle G. Palmer, Esq.

Exhibit 38

U.S. Food and Drug Administration

FOIA Request Confirmation

Confirmation Number: FDA2176603

Requester:

General

Description of Requester:	**Consumer**
Max Amount Willing to Pay:	**$25.00**

Organization

Organization Name:	**Public Health and Medical Professionals for Transparency**				
Primary Phone:	**212-532-1091**	Other Phone:		Email:	**foia@sirillp.com**

Mailing Address

Address 1:	**200 Park Avenue**
Address 2:	**17th Floor**
City:	**New York**
State:	**NY**
Zip Code:	**10166**

Billing Address

Address 1:	**200 Park Avenue**
Address 2:	**17th Floor**
City:	**New York**
State:	**NY**
Zip Code:	**10166**

Details

Requester Name:	**Aaron Siri**		
Requester File #:	**IR#0546**	Request Letter:	**IR#0546 - FDA - Pfizer Approval FINAL.pdf**
Requested Date From:		Requested Date To:	
Subject of Request:	**All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine**		

Waiver of Fees

Justification:	**PHMPT is a nonprofit. The information it seeks will contribute to the public debate about the safety and efficacy of the Pfizer vaccine. See letter for further details.**

Expedited Processing

Reason:	**Demonstrated Urgency to Inform the Public**
Justification:	**PHMPT disseminates information to the public. There is an immediate need to inform the public of the data and information underlying licensure of the Pfizer Vaccine. See letter for further details.**

Print Create Another Request Close

Within 10 business days of the submission of your online request, you will receive by electronic mail an FOIA Control Number. If you need to communicate with FDA regarding your request, please refer to this Control Number. Requests received after 4:00 P.M. E.S.T. will be considered to have been received on the following business day.

If your informational needs change, and you need to cancel your request, please contact the Division of Freedom of Information by telephone, mail, or fax. Please include your control number in the correspondence. For contact information, please see FDA's FOIA page.

Exhibit 39

U.S. FOOD & DRUG ADMINISTRATION

August 31, 2021

In Reply refer to
FOIA Control #:
2021-5683

Requester reference:

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY
AARON SIRI
200 Park Avenue
17th Floor
New York NY 10166 USA

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Claire B. Stansbury, Information Technician, at (301) 796-8979 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone:202-741-5770
Toll-Free: 1-877-684-6448
Email:ogis@nara.gov
Fax: 202-741-5769

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food Administration
5630 Fishers Lane, Room 1050
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director

Exhibit 40

U.S. FOOD & DRUG ADMINISTRATION

September 09, 2021

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY
AARON SIRI
200 Park Avenue
17th Floor
New York NY 10166 USA

In Reply refer to FOIA Control #: 2021-5683

Requester reference: IR#0546

Dear Requester:

This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).

All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."

I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing. The responding agency office will process your request in the order in which it was received.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

You may also contact the FDA FOIA Public Liaison, Office of the Executive Secretariat, 5630 Fishers Lane, Room 1050, Rockville, MD 20857; email: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001, Telephone: 202-741-5770, Toll-Free: 1-877-684-6448, E-mail: ogis@nara.gov, Fax: 202-741-5769.

Sincerely,

SARAH KOTLER
Director

Exhibit 41

From:	Enlow, Courtney D. (CIV)
To:	Aaron Siri
Cc:	Elizabeth Brehm; Gabrielle Palmer
Subject:	RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)
Date:	Thursday, December 2, 2021 2:25:33 PM

Good afternoon Aaron,

With regard to your first two questions, FDA will not be able to make those assessments at this time. In order for FDA to determine (1) the number of lines of spreadsheet data or (2) the total number of pages for each line of the 87-page Index, FDA would need to perform a search by hand. In other words, an individual would have to click open each file listed on the 87-page Index to determine the size of the file, and then manually record the file's size. To perform that search for the number of lines of spreadsheet data, FDA estimates that it would take 1.5 days of a staff member's time; to provide the page counts for each entry in the Index, FDA estimates that it would take several days of a staff member's time. Due to the heavy burden such an effort would place on FDA's limited resources, it is not feasible for FDA to provide those estimates.

With regard to your third question, are you asking whether there is any data in the Comirnaty biological product file that are not accounted for in the Index or the estimated 329,000+ page count? If so, the Cominarty biological product file also contains supplements, amendments, and product correspondence. FDA estimates that there are approximately 39,000 pages of records in that category. In addition, there may be investigational new drug records that may be supportive of the BLA. Although FDA cannot provide a precise count at this time, FDA estimates that there would be tens of thousands of additional pages in this category. These page counts are in addition to FDA's estimate of 329,000+ pages (plus data files) in the original Cominarty BLA.

If Plaintiff is amenable to the schedule I proposed yesterday, please let me know this week so that we can inform the Court.

Thanks,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Aaron Siri <aaron@sirillp.com>

Sent: Wednesday, December 01, 2021 5:56 PM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: [EXTERNAL] RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon Courtney,

Thank you for the note. In order for me to have a meaningful conversation with my client, can you please let me know (1) approximately how many lines of spreadsheet data would need to be processed, (2) the approximate total number of pages for each line item in the Index of Comirnaty BLA you previously provided (copy attached) and (3) what else is in the biological product file for Comirnaty that is not reflected in the attached and is that included in the estimated 329,000 page count (and if not, how many pages does that consist of).

Thank you,
Aaron

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Wednesday, December 1, 2021 8:35 AM
To: Aaron Siri <aaron@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good morning Aaron,

With regard to *PHMPT v. FDA*, No. 21-cv-1058 (N.D. Tex.), FDA has now had the opportunity to assess the number of responsive pages and to estimate processing times for additional portions of Plaintiff's priority list. In light of that assessment, FDA proposes that it produce the non-exempt portions of the following records by the below dates:

- By December 13, 2021, FDA plans to produce publicly releasable information from:
  - ***Plaintiff's priority item #1***- CRF files for site 1055 (~2,030 pages);
  - ***Completion of Plaintiff's priority item #5***-
    - Four additional .txt files that were listed on p. 10 of the index;
    - Four additional SAS files (not specifically listed on Plaintiff's priority list, but mentioned as something Plaintiff was interested in).
  - Publicly releasable information from the following additional sections of the original Comirnaty BLA:
    - Section 2.5 – Clinical Overview (~333 pages)

  - Section 2.7.3 – Summary of Clinical Efficacy (~182 pages)
  - Section 2.7.4 – Summary of Clinical Safety (~344 pages)

- By December 30, 2021, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #2*** – CRF files for site 1081 (~3,380 pages);
- By January 18, 2022, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #3*** – CRF files for site 1096 (~2,937 pages); and
- By January 31, 2022, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #4*** – CRF files for site 1128 (~3,452 pages).

Under this schedule, by the end of January 2022, FDA expects to have produced publicly releasable information from more than 12,000 pages of records and 10 unpaginated .txt or SAS data files. (This page and file count includes records produced to Plaintiff on November 17, 2021, and records that will be produced to Plaintiff later today.) FDA will also have completed production of seven of the first eight items on the priority list Plaintiff provided to FDA on November 4, 2021.

After the January 31, 2022 production, FDA proposes to make one production at the end of each subsequent month totaling a minimum the non-exempt portions of 500 pages. (For purposes of calculating a "page count" of data records that are not paginated, FDA proposes considering twenty lines of spreadsheet data the equivalent of one page. For example, production of a spreadsheet containing 2,000 lines of data would be counted the equivalent of a 100-page PDF record.) To the extent feasible, FDA plans to continue to prioritize records from Plaintiff's priority list. Although FDA proposes a minimum rate of 500 pages a month, FDA will continue to produce records at a faster rate where feasible.

Please let me know if Plaintiff is amenable to this proposed schedule. If so, I propose that the parties file a joint status report setting out the agreed-upon schedule and requesting that the Court cancel the hearing set for December 14 and the briefing deadlines.

Thanks,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

From: Enlow, Courtney D. (CIV)
Sent: Wednesday, November 17, 2021 1:40 PM
To: Aaron Siri <aaron@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>
Subject: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon Aaron and Gabrielle,

I've attached correspondence from FDA and a release of records in *PHMPT v. FDA*, No. 21-cv-1058 (N.D. Tex.). Kindly confirm receipt.

Thanks,
Courtney

Courtney Enlow
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W., Room 12102
Washington, D.C. 20005
(202) 616-8467
courtney.d.enlow@usdoj.gov

Unpublished Cases

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

TREATMENT ACTION GROUP and GLOBAL HEALTH JUSTICE PARTNERSHIP,

Case No: 15-cv-00976-VAB

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.
_____/

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO SUPPLEMENT THE SUMMARY JUDGMENT RECORD

Plaintiffs' motion to supplement the summary judgment record is another attempt by the Plaintiffs to impermissibly supplement the administrative record. The Court should deny Plaintiffs' motion because the Freedom of Information Act ("FOIA") explicitly limits judicial review of an expedited processing denial to "the record before the agency at the time of the determination." *See* 5 U.S.C. 552(a)(6)(E)(iii).[1]

[1] Plaintiffs' motion to supplement should also be denied to the extent Plaintiffs are seeking to supplement their opposition to FDA's motion for a stay. *See* Pls.' Mem. Supp. Mot. Supplement Summ. J. Record, ECF No. 56-1 at 6 ("Pls.' Mem.") (stating that "[t]he declarations and exhibits are directly and materially relevant to the motion to stay the litigation"). The materials Plaintiffs seek to add to the record are not relevant to FDA's motion for a stay. The Court may grant FDA's request for a stay and provide the agency additional time to process Plaintiffs' FOIA request upon FDA showing that exceptional circumstances exist and that the agency is exercising due diligence in responding to the request. *See* 5 U.S.C. § 552(a)(6)(C)(i). "Exceptional circumstances" exist (1) when an agency is deluged with a volume of requests for information vastly in excess of that anticipated by Congress, (2) when the existing resources are inadequate to deal with the volume of such requests within the time limits provided by FOIA, and (3) when an agency can show that it is exercising "due diligence." *Open Am. v. Watergate Special Prosecution Force*, 547 F.2d 605, 616 (D.C. Cir. 1976). The declaration of Mark Harrington and articles from the *Journal of Hepatology* are not material to the Court's analysis of the above factors.

I. REVIEW IS LIMITED TO THE RECORD BEFORE THE AGENCY AT THE TIME OF THE DETERMINATION

Plaintiffs, now recognizing that they bear the burden of proof,[2] are attempting to supplement the administrative record in order to show a "compelling need" to support their expedited processing request. This is impermissible. The FOIA itself constrains judicial review of an agency's denial of an expedited processing request to the "record before the agency at the time of the determination." 5 U.S.C. § 552(a)(6)(E)(iii). Accordingly, Plaintiffs' motion should be denied.

Plaintiffs urge the Court to ignore the FOIA's unequivocal limitation regarding the record on review, arguing that courts have discretion to supplement summary judgment records if the supplemental information is "probative of a material fact" and would not prejudice Defendants. *See* Pls.' Mem. Supp. Mot. Supplement Summ. J. Record, ECF No. 56-1 at 6-7 ("Pls.' Mem."). None of the cases cited by Plaintiffs in support of this proposition,[3] however, involve litigation under the FOIA, and thus are wholly inapplicable to this FOIA case. Indeed, there is no need to seek guidance from the caselaw, when the controlling language of the FOIA is clear and unambiguous: "[a]gency action to deny or affirm denial of a request for expedited processing . . . shall be subject to [*de novo*] judicial review . . . **except that the judicial review shall be based on the record before the agency at the time of the determination**." 5 U.S.C.

[2] *See* Pls.' Opp. to Defs.' Cross-Mot. for Summ. J. on Expedited Processing, ECF No. 42 at 7 n.4 ("Pls.' Opp."). Citing *Bloomberg*, Plaintiffs previously claimed that district courts in the Second Circuit have not specified who bears the burden of proving a compelling need. *See* Pls.' Opp. at 7 n.4. The district court in *Bloomberg* clearly stated, however, that the burden to demonstrate a compelling need falls on the requesting party. *See Bloomberg L.P. v. FDA*, 500 F. Supp. 2d 371, 374 (S.D.N.Y. 2007) ("FOIA requires expedited processing of requests if the relevant party demonstrates a compelling need for the materials.").

[3] *Ortiz v. Town of Stratford*, No. 3:07-cv-1144, 2008 WL 3992710, at *1 (D. Conn. Aug. 22, 2008), and *Tackman v. Goord*, No. 1:99-cv-00438, 2005 WL 2347111, at *12 (W.D.N.Y. Sept. 26, 2005), involved civil rights suits brought pursuant to 42 U.S.C. § 1983. *FTC v. Medical Billers Network, Inc*., 543 F. Supp. 2d 283, 308 n. 26 (S.D.N.Y. 2008), was an action to enforce the Federal Trade Commission Act and Telemarketing Sales Rule. *Dalton v. Subaru-Isuzu Auto*., 141 F.3d 667, 675 (7th Cir. 1998), involved litigation under the Americans with Disabilities Act. *Martinson v. U.S. Parole Comm'n*, No. 1:02-cv-04913, 2003 WL 21688241, at *2 (S.D.N.Y. July 18, 2003), was a habeas corpus action.

§ 552(a)(6)(E)(iii) (emphasis added).[4]

II. EVEN IF THE COURT CONSIDERS THE ADDITIONAL MATERIALS, PLAINTIFFS HAVE STILL FAILED TO MEET THEIR BURDEN OF DEMONSTRATING A "COMPELLING NEED" FOR THE REQUESTED INFORMATION

Even if the Court exercises its equitable authority and considers the additional materials Plaintiffs seek to introduce, Plaintiffs still cannot meet their burden of demonstrating a "compelling need" for the specific information they have requested under the FOIA.[5] *See Landmark Legal Found. v. EPA*, 910 F. Supp. 2d 270, 277 (D.D.C. 2012) (considering extra-record materials when FOIA requestor sought preliminary injunction ordering expedited processing, ultimately determining that FOIA requestor could not meet either the expedited processing or preliminary injunction standards). In order to prove a "compelling need" warranting expedited processing, a FOIA requester must demonstrate either that: (1) a failure to obtain the requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or safety of an individual; or (2) as to a request from a person

[4] Additionally, without citing any authority, Plaintiffs assert that they have "supplemented the administrative record by providing the FDA and HHS the opportunity to reconsider their denial of plaintiffs request to expedite." Pls.' Mem., ECF No. 56-1 at 6. Plaintiffs have *not* supplemented the administrative record. HHS's February 19, 2015 letter made clear that it "constitute[d] the *final* decision of the Department in this matter." Exhibit G to Pls.' Mem. Supp. Mot. Partial Summ. J. Expedited Processing, ECF No. 19-8 at 4 (emphasis added). Neither the FOIA statute nor Defendants' regulations provide for further consideration of a request for expected processing after a determination on an appeal is made.

[5] Even so, to the extent Plaintiffs are seeking to have the Court order that FDA move their FOIA request "to the top of the queue," such a request is now moot. Plaintiffs' FOIA request has recently reached the top of CDER's FOIA queue, and CDER has already begun the process of searching for responsive records. *See* Declaration of Howard Philips ("Philips Decl."), attached hereto as Exhibit A, ¶ 5. Given the breadth of Plaintiffs' FOIA request and the FOIA's statutory obligation for FDA to conduct an adequate search, *Carney v. U.S. Dep't of Justice*, 19 F.3d 807, 812 (2d Cir. 1994), CDER estimates that it will take approximately four weeks to complete its search and identify the responsive records. Philips Decl. ¶¶ 6-7. Although it is difficult at this time to approximate the total volume of responsive records, CDER anticipates that it will need to review approximately 8,000 electronic files and 4,600 documents, which range in length from one page to 500 pages each. Id. ¶ 7. Once CDER identifies responsive records, CDER will then review the records and redact information exempt from disclosure. Id. ¶ 8. CDER will then prepare a *Vaughn* index to document any withholdings. Id. ¶ 9. Based on the foregoing, CDER anticipates that it will be able to fully respond to Plaintiffs' FOIA request by March 31, 2017. Id. ¶ 10. FDA remains amenable to discussing with Plaintiffs ways in which they might narrow their request, so FDA can finish processing the request sooner.

primarily engaged in disseminating information, that there is an urgency to inform the public concerning actual or alleged federal government activity. 5 U.S.C. § 552(a)(6)(E)(v); *see also* 21 C.F.R. § 20.44. None of the "eleventh hour" materials Plaintiffs now seek to introduce, however, support a finding of a "compelling need" for the records actually requested by Plaintiffs.

More specifically, Plaintiffs are attempting to introduce two recent scientific studies, which suggest a possibility of higher recurrence rates of liver cancer in Hepatitis C Virus-positive patients receiving treatment with direct-acting antivirals ("DAAs") like Solvadi and Harvoni, as well as a third scientific article and one editorial that refute those findings.[6] *See* Exhibits D, Amended E, F, and G to Pls.' Mem., ECF Nos. 56-6, 57, 56-8, and 56-9, respectively. Plaintiffs claim that these articles demonstrate "the need for immediate release of the clinical trial data at the heart of this lawsuit." Pls.' Mem., ECF No. 56-1 at 4. Saying it, however, does not make it so.

Indeed, Plaintiffs' argument is fundamentally flawed because the mere existence of two scientific articles that suggest a higher recurrence rate of liver cancer after treatment with DAAs, especially when countered by a third scientific article and one editorial that directly contradict those suggestions, does not lead to the conclusion that the failure to obtain the raw clinical trial data for Solvadi and Harvoni on an expedited basis could "reasonably be expected to pose an imminent threat to the life or safety of an individual." *See* 5 U.S.C. § 552(a)(6)(E)(v).[7]

---

[6] Assuming *arguendo* that the three articles and one editorial are admissible to support Plaintiffs' compelling need argument, they would not be admissible to establish the truth of matters referenced therein, but rather only as proof that the matters were stated. *See, e.g., United States v. Certified Environmental Servs.*, 753 F.3d 72, 89 (2d Cir. 2013) (citing Fed. R. Evid. 801(c) and *United States v. Kohan,* 806 F.2d 18, 22 (2d Cir. 1986) (noting that hearsay is an out-of-court statement offered to prove the truth of the matter asserted, but however, that an out-of-court statement offered for some other purpose, such as to show that a statement was made, is not hearsay)); *ACLU of N. Cal. v. U.S. Dep't of Defense*, No. C 06-01698 WHA, 2006 WL 1469418, at *1 (N.D. Cal. May 25, 2006).

[7] For the reasons stated in Defendants' Memorandum in Opposition to Plaintiffs' Motion for Partial Summary

Furthermore, any implication that the underlying clinical trial data for Solvadi and Harvoni will contain information regarding the recurrence rates of liver cancer following treatment with DAAs is nothing more than speculation on the part of Plaintiffs.[8]

Moreover, if the Court agrees with Plaintiffs that two scientific articles involving small patient populations that preliminarily suggest a higher incidence of an adverse event or negative outcome after taking an FDA-approved drug are sufficient to demonstrate a "compelling need" to expedite processing of raw clinical trial data, then it is no exaggeration to state that nearly every FOIA request submitted to the agency for underlying clinical trial data for almost any FDA-approved drug would need to be expedited. Courts have repeatedly cautioned against such an outcome. *See Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001) (quoting H.R. Rep. No. 104-795, at 26 (1996)) ("[A]n unduly generous approach [to expedited processing] would also disadvantage those requestors who do qualify for expedition, because prioritizing all requests would effectively prioritize none."); *see also Landmark*, 910 F. Supp. 2d at 275; *Elec. Privacy Info. Ctr. v. Dep't of Def.,* 355 F. Supp. 2d 98, 103-04 (D.D.C. 2004).

For all of these reasons, Plaintiffs' Motion to Supplement the Summary Judgment Record should be denied.

Judgment, ECF No. 37-1 at 11-14, Plaintiffs are not "primarily engaged in disseminating information," and thus, they cannot meet the second prong of the "compelling need" standard.

[8] Plaintiffs' arguments before this Court questioning the safety of Solvadi and Harvoni are not only self-serving, but also disingenuous. In fact, when discussing this very lawsuit with the press, Gregg Gonsalves of Plaintiff Global Health Justice Partnership stated "[w]e're not asking because we think there's some horrible side effect lurking in the data." *See* Attachment 1 to Declaration of Laurie Himebaugh, ECF No. 37-5. The FOIA contemplates expedited processing when the FOIA requestor can demonstrate a compelling need —a fishing expedition is insufficient.

Dated: August 28, 2016

DEIDRE M. DALY

United States Attorney

OF COUNSEL:

MARGARET M. DOTZEL
Acting General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

SHANNON M. SINGLETON
Associate Chief Counsel for Enforcement
United States Department of Health and Human Services
Office of the General Counsel
White Oak Bldg. 31, Room 4532
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
(301) 796-8717

s/ Alan M. Soloway
Alan M. Soloway, AUSA
U.S. Attorney's Office
District of Connecticut
157 Church Street-25th Floor
New Haven, Ct. 06510
(203) 821-3700
Fax: (203) 773-5373
Federal Bar #: ct 01581
alan.soloway@usdoj.gov

Exhibit A

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

TREATMENT ACTION GROUP and GLOBAL HEALTH JUSTICE PARTNERSHIP,

Case No: 15-cv-00976-VAB

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.
_____/

DECLARATION OF HOWARD R. PHILIPS

I, Howard R. Philips, hereby declare as follows:

1. I am the Deputy Director of the Division of Information Disclosure Policy ("DIDP"), Center for Drug Evaluation and Research ("CDER"), United States Food and Drug Administration ("FDA"), in Silver Spring, Maryland. I submit this declaration in support of Defendants' Opposition to Plaintiffs' Motion to Supplement the Summary Judgment Record in the above-captioned matter.

2. The statements made in this declaration are based upon my personal knowledge and information available to me in my official capacity and about which I have become knowledgeable.

3. I have supervisory authority over DIDP, which processes and responds to requests made pursuant to the Freedom of Information Act ("FOIA") for documents in the possession of CDER.

4. At my direction, DIDP personnel search for records under CDER's control to identify documents and other information that may be responsive to particular information requests. DIDP staff gathers and reviews potentially responsive documents to determine whether, before being made available for public disclosure, they should be redacted, in part or in their entirety, under any applicable FOIA exemption or other statutory provision.

5. Because Plaintiffs' FOIA request has now reached the front of the queue, CDER has begun the process of searching for responsive records.

6. Due to the breadth of information requested by Plaintiffs in their FOIA request, CDER anticipates a voluminous number of records responsive to the request.

7. CDER anticipates that it will take at least four weeks to conduct an adequate search and collect potentially responsive records. Based on current estimates, CDER anticipates that it will need to review at least 8,000 electronic files and 4,600 documents, which range in length from one page to 500 pages each.

8. Once CDER has identified those records that are responsive to Plaintiffs' request, CDER must review each record to determine whether CDER needs to redact, under any applicable FOIA exemption or other statutory provision, the record in full or in part.

9. CDER will then prepare a *Vaughn* index to document any withholdings.

10. Based on the foregoing, CDER anticipates that it will complete processing Plaintiffs' FOIA request by March 31, 2017.

[SIGNATURE ON NEXT PAGE]

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct.

Howard R Philips

HOWARD R. PHILIPS
Deputy Director
Division of Information Disclosure Policy
Center for Drug Evaluation and Research
Food and Drug Administration
U.S. Dep't of Health and Human Services

Executed on August 26, 2016, in Silver Spring, Maryland.

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

TREATMENT ACTION GROUP and GLOBAL HEALTH JUSTICE PARTNERSHIP,

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.
_____/

Case No: 15-cv-00976-VAB

May 12, 2017

JOINT STATUS REPORT

Plaintiffs, Treatment Action Group ("TAG") and Global Health Justice Partnership ("GHJP"); Defendants, the Food and Drug Administration ("FDA") and the Department of Health and Human Services ("HHS"); and Intervenor, Gilead Sciences, Inc. ("Gilead"), file this Joint Status Report pursuant to the Court's May 3, 2017 Order. ECF No. 77. The parties submit this Joint Status Report to apprise the Court of their progress in reaching a resolution.

1. On November 29, 2016, Plaintiffs and Defendants filed a Joint Status Report ("November 29, 2016 Joint Status Report") to notify the Court that they had agreed on a narrowed scope of Plaintiffs' Freedom of Information Act ("FOIA") request and a production timeline. ECF No. 75.

2. On February 21, 2017, Plaintiffs and Defendants met and conferred pursuant to the terms of the November 29, 2016 Joint Status Report to discuss potential "Additional Records." ECF No. 75.

3. FDA completed production of responsive records to Plaintiffs on April 6, 2017. FDA produced 82,668 pages of records and 1,045 electronic files with redactions.

4. On April 11, 2017, FDA produced to Plaintiffs a Vaughn index of the electronic files FDA withheld in full.

5. On May 2, 2017, Plaintiffs identified certain electronic files they believed were "Additional Records" not included in FDA's productions.

6. On May 10, 2017, FDA informed Plaintiffs by letter that the records identified by Plaintiffs had either: (1) already been produced by FDA; (2) already were withheld in full by FDA; or (3) did not exist in FDA's records. Accordingly, FDA has completed productions.

7. The parties continue to engage in productive discussions to narrow or eliminate the scope of disagreement on the withholdings.

8. Because the parties are working together productively to resolve this matter, and because additional time is needed to determine the scope of any disagreement that might require briefing, the parties propose to file another Joint Status Report on or before June 19, 2017. A proposed order is attached.

Dated: New Haven, Connecticut
May 12, 2017

Respectfully submitted,

/s/ Cortelyou C. Kenney
Cortelyou C. Kenney (ct30084)
Margaret McCarthy (phv08382)
Media Freedom and Information
Access Clinic, Yale Law School
P.O. Box 208215
New Haven, CT 06520
(203) 436-5830
Attorneys for Plaintiffs

Deirdre M. Daly
United States Attorney for the
District of Connecticut

/s/ Alan M. Soloway
Alan M. Soloway, AUSA (ct01581)
U.S. Attorney's Office
District of Connecticut
157 Church Street-25th Floor

New Haven, Ct. 06510
(203) 821-3700

/s/ Shannon M. Singleton
Shannon M. Singleton
U.S. Food and Drug Administration
U.S. Department of Health and Human Services (phv08399)
Office of the General Counsel
White Oak Bldg. 31, Room 4432
10903 New Hampshire Ave.
Silver Spring, MD 20993
(301) 796-8717
Attorneys for Defendants

/s/ John P. D'Ambrosio
John P. D'Ambrosio (ct29101)
Cowdery & Murphy, LLC
280 Trumbull Street
Hartford, CT 06103
(860) 278-5555

Mingham Ji (phv07938)
Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000
Attorneys for Intervenor

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

TREATMENT ACTION GROUP and GLOBAL HEALTH JUSTICE PARTNERSHIP,

Case No: 15-cv-00976-VAB

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.
_____/

ORDER

UPON CONSIDERATION of the parties' Joint Status Report, it is hereby

ORDERED that the parties will submit another Joint Status Report on or before June 19, 2017.

SO ORDERED.

_____ _____
Date United States District Judge

CERTIFICATE OF SERVICE

I certify that on May 12, 2016, I filed this JOINT STATUS REPORT with the Clerk of the Court using the CM/ECF docketing system which will mail a copy to all counsel of record capable of receiving electronic pleadings.

/s/
Alan M. Soloway

Huddleston v. FBI

United States District Court for the Eastern District of Texas, Sherman Division

February 1, 2021, Decided; February 1, 2021, Filed

Civil Action No. 4:20-cv-447

Reporter
2021 U.S. Dist. LEXIS 18199 *; 2021 WL 327510

BRIAN HUDDLESTON, v. FEDERAL BUREAU OF INVESTIGATION and UNITED STATES DEPARTMENT OF JUSTICE.

Subsequent History: Stay granted by *Huddleston v. FBI, 2021 U.S. Dist. LEXIS 87553 (E.D. Tex., May 7, 2021)*

Core Terms

requests, processing, scheduling order, Deadlines, exceptional circumstances, responding

Counsel: [*1] For Brian Huddleston, Plaintiff: Ty Odell Clevenger, Ty Odell Clevenger, Attorney At Law, Brooklyn, NY.

For Federal Bureau of Investigation, U.S. Department of Justice, Defendants: Andrea Hedrick Parker, LEAD ATTORNEY, U S Attorney, Beaumont, TX.

Judges: AMOS L. MAZZANT, UNITED STATES DISTRICT JUDGE.

Opinion by: AMOS L. MAZZANT

Opinion

MEMORANDUM OPINION AND ORDER

Pending before the Court is Defendants' Motion to Stay Scheduling Order Deadlines (Dkt. #10). After reviewing the Motion and the relevant pleadings, the Court finds the Motion should be granted in part and denied in part.

BACKGROUND

This case arises out of Plaintiff Brian Huddleston's FOIA requests against Defendants the Federal Bureau of Investigation ("FBI") and the Department of Justice ("DOJ") (Dkt. #1), which are pending before Defendants now (Dkt. #3, Exhibits 1-3). On October 22, 2020, the Court entered a scheduling order (Dkt. #9).

On December 16, 2020, Defendants filed their Motion to Stay Scheduling Order Deadlines (Dkt. #10), currently before the Court. On December 30, 2020, Plaintiff filed his response (Dkt. #11). On January 6, 2021, Defendants filed their reply (Dkt. #12). On January 7, 2021, Plaintiff filed his first sur-reply (Dkt. #13). On January [*2] 14, 2021, Defendants filed a sur-reply (Dkt. #15). And on January 20, 2021, Plaintiff filed his second sur-reply (Dkt. #18).

LEGAL STANDARD

The authority to stay proceedings is "incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v.*

N. Am. Co., 299 U.S. 248, 254, 57 S. Ct. 163, 81 L. Ed. 153 (1936). Because stays are "an 'intrusion into the ordinary processes of administration and judicial review,'" *Nken v. Holder, 556 U.S. 418, 427, 129 S. Ct. 1749, 173 L. Ed. 2d 550 (2009)* (quoting *Va. Petroleum Jobbers Ass'n v. FPC, 259 F.2d 921, 925, 104 U.S. App. D.C. 106 (D.C. Cir. 1958)* (per curiam)), they are "not a matter of right, even if irreparable injury might otherwise result," *Virginian R. Co. v. United States, 272 U.S. 658, 672, 47 S. Ct. 222, 71 L. Ed. 463 (1926)*. Instead, stays are "an exercise of judicial discretion, and the 'party requesting a stay bears the burden of showing that the circumstances justify an exercise of that discretion.'" *Ind. State Police Pension Tr. v. Chrysler LLC, 556 U.S. 960, 961, 129 S. Ct. 2275, 173 L. Ed. 2d 1285 (2009)* (per curiam) (quoting *Nken, 556 U.S. at 433-34*); *see Exner v. FBI, 542 F.2d 1121, 1123 (9th Cir. 1976)* (explaining that the responding agency bears the burden to demonstrate its due diligence in fulfilling its FOIA-related obligations).

The decision to stay proceedings is "left to the sound discretion of the district court, and it is the district court's responsibility to weigh the competing interests of the parties relating to the appropriateness of a stay." *Wolf Designs, Inc. v. Donald McEvoy Ltd., Inc., 355 F. Supp. 2d 848, 853 (N.D. Tex. 2005)* (citing *Landis, 299 U.S. at 254-55*). Since "FOIA imposes no limits on courts' equitable [*3] powers in enforcing its terms," deciding whether to grant a stay is unaffected by FOIA. *Payne Enters., Inc. v. United States, 837 F.2d 486, 494, 267 U.S. App. D.C. 63 (D.C. Cir. 1988)* (citing *Renegotiation Bd. v. Bannercraft Clothing Co., 415 U.S. 1, 19-20, 94 S. Ct. 1028, 39 L. Ed. 2d 123 (1974)*).

ANALYSIS

Under FOIA, once the responding agency receives a records request, it must, among other things,

> determine within 20 days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefor.

5 U.S.C. § 552(a)(6)(A)(i)(I). "[R]equesting parties constructively exhaust their available administrative remedies with respect to their request if the responding agency fails to comply with the statutory deadlines." *Moore v. United States Immigration & Customs Enforcement, No. EP-19-CV-00279-DCG, 2021 U.S. Dist. LEXIS 5464, 2021 WL 107214, at *2 (W.D. Tex. Jan. 12, 2021)* (citing *5 U.S.C. § 552(a)(6)(C)(i)*). But "[i]f the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request," courts "may retain jurisdiction and allow the agency additional time to complete its review of the records." *5 U.S.C. § 552(a)(6)(C)(i)*; *see Daily Caller News Found. v. FBI, 387 F. Supp. 3d 112, 115-16 (D.D.C. 2019)*.

Even though Defendants do not invoke *§ 552(a)(6)(C)(i)*'s exceptional-circumstances exception in the Motion or subsequent pleadings, it appears to be the argument Defendants effectively offer here. Their rationale breaks down into two parts: there are a lot [*4] of documents to review (Dkt. #10 at pp. 2-3; Dkt. #12 at p. 3; Dkt. #15 at p. 2), and FOIA-response resources have lessened due to the COVID-19 pandemic (Dkt. #10 at pp. 3-4; Dkt. #12 at p. 2; Dkt. #15 at p. 2).

The latter of these arguments is entirely understandable. The COVID-19 pandemic has severely disrupted the normal functioning of government, and processing FOIA requests is no exception. *See* OFF. OF INFO. POL'Y, U.S. DEP'T OF JUST., *Guidance for Agency FOIA Administration in Light of COVID-19 Impacts*,

https://www.justice.gov/oip/guidance-agency-foia-administration-light-covid-19-impacts (last updated May 28, 2020). If the COVID-19 crisis is not an "exceptional circumstance" under *§ 552(a)(6)(C)(i)*, the Court is unsure when the exception would ever apply.

Notwithstanding, the problem with the Motion Defendants advance is the due-diligence element required by FOIA. *5 U.S.C. § 552(a)(6)(C)(i)* ("If the Government can show exceptional circumstances exist and that *the agency is exercising due diligence in responding to the request* . . . ." (emphasis added)). For one thing, Defendants' requested relief is too pliable for the Court's comfort. The Motion initially requests "an additional three months to complete the tasks" described [*5] therein, at which time Defendants plan to provide the Court with "an updated search status" and proposed "production schedule" (Dkt. #10 at p. 4). In their reply, Defendants reaffirm that their request is "reasonable" and "in good faith" (Dkt. #12 at p. 1). Only in their sur-reply do Defendants—for the first time—begin to outline what a production schedule *might* look like (*see* Dkt. #15 at p. 2). Even in these extraordinary times, the degree of malleability Defendants propose for the proceedings is unreasonable. FOIA "represents a strong Congressional commitment to transparency in government through the disclosure of government information." *Judicial Watch, Inc. v. Soc. Sec. Admin., 799 F. Supp. 2d 91, 93 (D.D.C. 2011)*, *aff'd*, *701 F.3d 379, 403 U.S. App. D.C. 141 (D.C. Cir. 2012)*. The shapeless nature of the relief Defendants seek is anything but transparent.

As well, the rate at which Defendants intend to process and produce documents is murky at best. The FBI has identified "over 20,000 pages" potentially within the scope of Plaintiff's requests (Dlt. #10 at p. 2). The DOJ "is continuing to review" its search results, and to this point, has "similarly located tens of thousands of pages" possibly within the purview of Plaintiff's requests (Dkt. #10 at p. 3). Defendants state they still need to review these documents [*6] "to determine responsiveness and, as to the responsive material, to make release determinations in accordance with applicable exemptions" (Dkt. #12 at p. 3).

The Court recognizes the "unprecedented workload" Defendants face on this front given current global circumstances (Dkt. #12 at p. 3). But the proposed processing rate is impermissible. Given the information currently before the Court, processing 250 pages per month during this reduced-staffing period and 500 pages per month when staffing returns to normal would be an unreasonable delay. As Plaintiff indicates, this rate would mean that at best, producing just the FBI materials would take three years and fourth months, and at worst, nearly seven years (Dkt. #18 at p. 4).[1] *See, e.g.*, *Hayden v. DOJ, 413 F. Supp. 1285, 1289 (D.D.C. 1976)* (explaining that when Congress created FOIA's due-diligence requirement, it did not intend for production to take years). Further, this timeline is only for the FBI's processing and production—the information the Court currently has does not relate where the DOJ is in its process. All that is provided in this regard is that the average time it takes the DOJ to work through requests of this nature is "about 10 months" (Dkt. #10 at p. 3).

FOIA sets out [*7] temporal guidelines for its procedures to ensure expeditious processing and production of information under the statutory scheme. *Wash. Post v. DHS, 459 F. Supp. 2d 61, 74 (D.D.C. 2006)* ("FOIA was created to foster public awareness,

[1] While Plaintiff's argument regarding timeliness is well taken (Dkt. #13 at pp. 1-2; Dkt. #18 at p. 4), the Court agrees with Defendants that comparisons to document production by private entities is inapt (Dkt. #15 at p. 1).

and failure to process FOIA requests in a timely fashion is 'tantamount to denial.'" (quoting H.R. REP. NO. 93-876, at 6 (1974)). The vague and dragged-out timeline Defendants suggest cannot be sustained without a greater showing of exceptional circumstances because "stale information" produced pursuant to FOIA requests "is of little value." *Payne Enters., Inc., 837 F.2d at 486*. Granting the relief Defendants seek would thwart FOIA's "basic purpose" of "open[ing] agency action to the light of public scrutiny." *Dep't of Air Force v. Rose, 425 U.S. 352, 372, 96 S. Ct. 1592, 48 L. Ed. 2d 11 (1976)* (internal quotation marks omitted).

To be sure, were Defendants to (1) explain the exceptional circumstances associated with the handling of Huddleston's FOIA requests more precisely, and (2) present a less amorphous processing and production schedule, the Court would be open to considering a reasonable delay of the proceedings. But given the Motion and relevant pleadings, the Court does not find the exceptional-circumstances FOIA exception applicable and utilizes its inherent authority to extend the scheduling order deadlines for an appropriate [*8] length of time.

CONCLUSION

It is therefore **ORDERED** that Defendants' Motion to Stay Scheduling Order Deadlines (Dkt. #10) is hereby **GRANTED in part** and **DENIED in part**. It is **FURTHER ORDERED** the Scheduling Order in this case is amended as follows:

Go to table1

IT IS SO ORDERED.

SIGNED this 1st day of February, 2021.

/s/ Amos L. Mazzant

AMOS L. MAZZANT

UNITED STATES DISTRICT JUDGE

Table1 (Return to related document text)

April 23, 2021	Deadline for Defendants' Complete Production of Documents and *Vaughn* Index
May 24, 2021	Defendants' Motion for Summary Judgment
June 23, 2021	Plaintiff's Opposition and Cross-Motion for Summary Judgment
July 7, 2021	Defendants' Reply and Opposition
July 21, 2021	Plaintiff's Reply

Table1 (Return to related document text)

End of Document

Diocesan Migrant & Refugee Servs. v. United States Immigration & Customs Enforcement

United States District Court for the Western District of Texas, El Paso Division

January 28, 2021, Decided; January 28, 2021, Filed

EP-19-CV-00236-FM

Reporter
2021 U.S. Dist. LEXIS 16469 *; 2021 WL 289548

DIOCESAN MIGRANT & REFUGEE SERVICES, INC., Plaintiff, v. UNITED STATES IMMIGRATION AND CUSTOMS ENFORCEMENT, Defendant.

Core Terms

documents, records, attorney's fees, redactions, exemptions, immigration, requests, Sheet, pages, deadline, field office, hourly rate, costs, asylum, email, billing, seekers, reasonable basis, disclosure, searches, withhold, inlaw, prevailed, lodestar, thirty-three, calculate, practices, uncover, reasonable attorney's fees, privileges

Counsel: [*1] For Diocesan Migrant & Refugee Services, Inc., Plaintiff: Christopher Benoit, LEAD ATTORNEY, Law Office of Lynn Coyle, PLLC, El Paso, TX; Lynn A. Coyle, The Law Office of Lynn Coyle, PLLC, El Paso, TX.

For United States Immigration and Customs Enforcement, Defendant: Manuel Romero, LEAD ATTORNEY, U.S. Attorney, Western District of Texas, El Paso, TX.

Judges: FRANK MONTALVO, UNITED STATES DISTRICT JUDGE.

Opinion by: FRANK MONTALVO

Opinion

ORDER GRANTING APPLICATION FOR ATTORNEY FEES AND COSTS

Before the court are "Plaintiff's Opposed Application for Attorney Fees and Costs" ("Motion") [ECF No. 56], filed November 2, 2020 by Diocesan Migrant & Refugee Services, Inc. ("DMRS"); "Response to Plaintiff's Application for Attorney Fees and Costs" [ECF No. 65], filed November 23, 2020 by United States Immigration and Customs Enforcement ("ICE"); and "Plaintiff's Reply to Defendant's Response to Plaintiff's Application for Attorney Fees and Costs" ("Reply") [ECF No. 66], filed November 25, 2020. After due consideration of the Motion, Response, Reply, and applicable law, the Motion is **GRANTED**.

I. BACKGROUND

A. Pre-Trial

In 2019, the United States government implemented a policy titled the Migrant Protection Protocols ("MPP"). Pursuant [*2] to the MPP, selected asylum seekers

must remain in Mexico while they wait for U.S. immigration judges to hear their asylum cases.[1] The MPP was first implemented at the San Ysidro port of entry in January 2019.[2] It was then implemented at the El Paso port of entry in May 2019 and at the Laredo and Brownsville ports of entry later in 2019.[3]

DMRS is a non-profit organization that provides know-your-rights information and legal representation for asylum seekers prior to their appearances before an immigration judge.[4] It provided know-your-rights information to asylum seekers subject to the MPP during the brief time the asylum seekers were in the United States prior to immigration hearings.[5] In June 2019, ICE and the United States Department of Justice Executive Officer for Immigration Review ("DOJ-EOIR") informed DMRS that it would no longer be permitted to provide know-your-rights-information to asylum seekers waiting for immigration hearings.[6]

On July 1, 2019, DMRS submitted a request for information to ICE pursuant to the *Freedom of Information Act ("FOIA"), 5 U.S.C. §§ 552 et seq.*[7] It sought records related to the implementation of the MPP and asylee access to attorneys prior to immigration hearings. [*3] [8] ICE did not produce any responsive documents within the twenty-day statutory deadline.[9] DMRS filed suit to compel production on August 22, 2019.[10]

Toni Fuentes ("Fuentes"), a Deputy FOIA Officer for ICE, was immediately responsible for supervising ICE responses to requests for records under FOIA.[11] Due to an ICE administrative error, ICE did not become aware of DMRS's FOIA request until after the initiation of this lawsuit.[12] Fuentes assisted in locating DMRS's FOIA request, at which time she assigned the request to the litigation team of the ICE FOIA Office for expedited processing of the request.[13]

Approximately four-and-a-half months after the statutory deadline to respond, on December 16, 2019, ICE notified DMRS it identified ninety-two pages of potentially responsive records.[14] Ten pages were provided in full, twenty-eight pages contained redacted information, fourteen pages were deemed non-responsive or duplicates, and the remaining forty pages required "consultation with other agencies or components" and ICE stated they would "be produced

---

[1] "Findings of Fact and Conclusions of Law" 3, ECF No. 44, entered Oct. 19, 2020.

[2] *Id.*

[3] *Id.*

[4] "Plaintiff's Original Complaint" ("Compl.") 2 6, ECF No. 1, filed Aug. 22, 2019; "FOIA Request," Ex. 1. *See also* Plaintiff's Opposed Application for Attorney Fees and Costs" ("Mot."), ECF No. 56, filed Nov. 2, 2020, "Declaration of Melissa M. Lopez" 3, ECF No. 56-1, Ex. 3.

[5] *Id.*

[6] *Id.* at 2 7.

[7] Findings of Fact and Conclusions of Law 3.

[8] *Id.*

[9] *See id.* at 5. *See also 5 U.S.C. § 552(a)(6)(A)(i)*.

[10] *See generally* Compl.

[11] *Id.* at 2-3.

[12] "Transcript of Bench Trial" 15, ECF No. 63, filed Nov. 16, 2020.

[13] *Id.* at 13.

[14] Findings of Fact and Conclusions of Law 2.

at a later date."[15] On May 22, 2019, DMRS filed its motion for summary judgment arguing ICE had not conducted a search reasonably [*4] calculated to uncover responsive records and had not met its burden to show that records it withheld were exempt from disclosure.[16]

On May 29, 2020, nine months after Plaintiff filed suit and almost eleven months after Plaintiff sent its original FOIA request, ICE forwarded the pages requiring consultation to other agencies for review.[17] ICE admitted that a second administrative error prevented timely referral of these documents.[18] While the consultations were pending, ICE filed five motions for extensions of the deadline to respond to DMRS's motion for summary judgment. ICE finally responded on June 25, 2020, twenty days after the original deadline. That same day, almost eleven months after the statutory deadline, ICE produced thirty-three of the forty pages requiring consultation.[19] ICE did not address these documents in its response. DMRS challenged redactions to the thirty-three pages produced after its motion for summary judgment but withdrew its objections to previously produced materials.[20]

B. Trial

On October 5, 2020 the court held a bench trial to resolve two issues: 1) whether ICE conducted a search reasonably calculated to uncover responsive records; and 2) whether [*5] redactions pursuant to *5 U.S.C. § 552(b)(5)* ("exemption (b)(5)") to the thirty-three pages produced June 25, 2020 were exempt from disclosure.[21] The parties were present and represented by counsel. Fuentes was ICE's sole witness.

One subdivision of ICE Enforcement and Removal Operations ("ERO") is ERO Field Operations ("FOPS"), the office responsible for providing MPP guidance to all ERO field offices.[22] After consideration of Fuentes's testimony, the court found ICE was on notice that DMRS's request sought communications between ICE ERO agents and their contractors at the field office level about implementation of the MPP; correspondence to ICE ERO officers and, their contractors who were responsible for movement and custody of respondents subjected to the MPP; emails by or between ERO field offices where the MPP was implemented; and emails of guidance between officers and contractors at the field office level regarding the MPP participants' access to counsel before their immigration court hearings.[23]

The court also found:

> ICE program offices have no written guidelines on how to conduct searches for records responsive to

---

[15] *Id.*

[16] *See generally* "Plaintiff's Motion for Summary Judgment," ECF No. 14, filed May 22, 2020.

[17] Findings of Fact and Conclusions of Law 11.

[18] "Transcript of Bench Trial" 61, ECF No. 63, filed Nov. 16, 2020.

[19] Findings of Fact and Conclusions of Law 2. *See also 5 U.S.C. § 552(a)(6)(A)(i)* (providing a twenty-day deadline, excluding weekends and holidays for agencies to respond to FOIA requests).

[20] "Plaintiff's Reply to Defendant's Response to Plaintiff's Motion for Summary Judgment" 2-3, ECF No. 29, filed July 29, 2020.

[21] Findings of Fact and Conclusions of Law 2.

[22] *Id.* at 9.

[23] *Id.* at 4-5.

FOIA requests.[24]

Each program office within ICE has its own guidelines for record keeping, [*6] retention schedule, and records liaison officers.[25]

Fuentes instructed her points of contact ("POCs") in three program offices to conduct searches for responsive documents: the ICE Office of Policy, ICE Office of the Principal Legal Advisor ("OPLA"), and ICE ERO.[26]

No uniform set of search terms was used across the various ICE program offices.[27]

No POC described to what extent, if any, they took into consideration the particular record keeping practices of their respective program offices in searching for responsive documents.[28]

ERO FOPS, the office responsible for providing MPP guidance to all ERO field offices, determined the requested information did not fall in its area of responsibility and did not conduct any search for responsive documents.[29]

The court then turned to the thirty-three pages of redacted documents produced to Plaintiff after consultation with Customs and Border Patrol and the Department of Homeland Security Office of Privacy.[30] ICE provided only a letter to accompany the produced documents.[31] Two paragraphs in the letter address the redactions made pursuant to *exemption (b)(5)*.[32] The letter did not identify which privilege supported each redaction made under [*7] redaction *(b)(5)*.[33] Nor did either provide DMRS with any factual basis for the application of *exemption (b)(5)* to any individual redaction.[34] Fuentes's testimony was equally inadequate.

Upon conclusion of ICE's case, DMRS moved for judgment as a matter of law as to both issues. The court granted the motion and, on October 19, 2020, entered corresponding "Findings of Fact and Conclusions of Law" [ECF No. 44]. The court ordered that the thirty-three pages originally produced to DMRS on June 25, 2020 be unredacted and produced to DMRS by October 26, 2020.[35] It also ordered ICE to conduct a new search for documents responsive to DMRS's FOIA request by November 2, 2020.[36]

C. Post-Trial

On November 2, 2020, the deadline for ICE to conduct its new search, ICE informed the court it had not yet conducted any search and moved for an extension of

---

[24] *Id.*

[25] *Id.* at 6.

[26] *Id.*

[27] Findings of Fact and Conclusions of Law 6.

[28] *Id.*

[29] *Id.* at 9. *See also* Memorandum from Nathalie R. Asher, Acting Executive Associate Director, U.S. Immigration and Customs Enforcement, to Field Office Directors, Enforcement and Removal Operations, "Migrant Protection Protocols Guidance" (Feb. 12, 2019).

[30] Findings of Fact and Conclusions of Law 11.

[31] *Id.* at 12.

[32] *Id.*

[33] *Id.* at 12.

[34] *Id.*

[35] "Final Judgment" 1, ECF No. 45, entered Oct. 19, 2020.

[36] *Id.*

time do so.[37] ICE requested the deadline be extended to November 23, 2020 with respect to a search for responsive records from the El Paso Field Office and asked for an additional thirty days upon completion of a search of the El Paso Field Office to search for responsive records from the San Antonio and San Diego Field Offices.[38] ICE did not express any concern [*8] about the procedural feasibility of the deadline, merely citing counsel's personal circumstances. The court granted ICE an additional extension of all search deadlines to November 23, 2020.[39]

A week after the second deadline, on November 30, 2020, ICE moved for yet another extension of time to comply with the court's order.[40] For the first time, ICE informed the court of the procedure it intended to follow in conducting its new, more thorough, search for responsive documents. ICE also expressed concern for the impossibility of the court's deadline in light of the search requirements. ICE informed the court it conducted an examination of its records utilizing thirteen search terms in records from forty-nine custodians. That examination identified approximately 2.3 million potentially responsive documents.[41] After using software to extract irrelevant and duplicative documents, approximately 86,000 potentially responsive documents remained.[42] ICE then assigned thirty percent of its FOIA staff to conduct first-line review full-time.[43] Ten to fifteen attorneys would dedicate half of every work day to second-line review.[44] ICE estimated staff would require four months to produce all responsive records [*9] from the El Paso field office.[45] Thereafter, the parties would confer to present a new scheduling order for remaining documents.[46] The court entered an order granting the extension.[47] ICE did not appeal any part of the court's judgment. As a result, the court's Findings of Fact and Conclusions of Law are now the law of the case. ICE cannot contest either.[48]

II. LEGAL STANDARD

FOIA states "[t]he court may assess against the United

---

[37] "Defendant's Unopposed Motion for Extension of Time, or in the Alternative, Motion to Alter or Amend a Judgment," ECF No. 53, filed Nov. 2, 2020.

[38] *Id.* at 8.

[39] "Order Granting in Part and Denying in Part Motion for Extension of Time" 2, ECF No. 57, entered Nov. 3, 2020.

[40] *See generally* Defendant's Amended Unopposed Motion for Extension of Time to Produce Documents," ("Nov. Mot. For Extension") ECF No. 70, filed Nov. 30. 2020.

[41] *Id.* at 7-8.

[42] *Id.* at 11.

[43] *Id.* at 47.

[44] *Id.* at 48.

[45] *Id.* at 59.

[46] Nov. Mot. For Extension 59.

[47] *See generally* "Order Granting Second Motion for Extension of Time," ECF No. 71, entered Dec. 1, 2020.

[48] *See* Arizona v. California, 460 U.S. 605, 618, 103 S. Ct. 1382, 75 L. Ed. 2d 318 (1983) (The law-of-the-case doctrine "posits that when a court decides upon a rule of law, that decision should continue to govern the same issue in subsequent stages in the same case.") *See also* Ashe v. Swenson, 397 U.S. 436, 443, 90 S. Ct. 1189, 25 L. Ed. 2d 469 (1970) (The collateral estoppel doctrine stands for the principle that "when an issue of ultimate fact has once been determined by a valid and final judgment, that issue cannot again be litigated between the same parties in any future lawsuit.")

States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed."[49] Accordingly, the court must apply a two-prong test to determine: (1) "whether a plaintiff has substantially prevailed" and, if so, (2) "whether the plaintiff *should* receive fees."[50]

A Plaintiff has "substantially prevailed" and therefore satisfied the first prong if it obtained requested relief through a judicial order.[51] The second prong, also known as the "entitlement" prong, requires courts to consider: "(1) the benefit to the public deriving from the case; (2) the commercial benefit to the complainant; (3) the nature of the complainant's interest in the [*10] records sought; and (4) whether the government's withholding of the records had a reasonable basis in law."[52] The entitlement prong requires courts to conduct analysis through the lens of the three fundamental purposes of FOIA's legal fee provision. The provision is designed: (1) "as an incentive for private individuals to pursue vigorously their claims for information" and overcome barriers "that government may erect in an effort to escape compliance with the law;" (2) to "deter the government from opposing justifiable requests;" and (3) "to punish the government where such opposition is unreasonable."[53] An award of attorneys' fees is particularly appropriate where "'government officials have been recalcitrant in their opposition to a valid claim or have been otherwise engaged in obdurate behavior.'"[54]

III. DISCUSSION

A. Whether DMRS Should Receive Attorney Fees

The Final Judgment entered in this action definitively establishes DMRS substantially prevailed in its FOIA action as this court granted all of the requested relief.[55] This is not contested. Accordingly, the court proceeds to a determination of whether DMRS should receive attorney fees in light of the circumstances of the case and the [*11] essential purposes of the FOIA legal fee provision.

1. The Benefit to the Public Deriving from the Case

"The basic purpose of FOIA is to ensure an informed citizenry, vital to the functioning of a democratic society, needed to check against corruption and to hold the government accountable to the governed."[56] Viewing the public benefit factor through the lens of FOIA's high-minded central purpose, attorneys fees are more appropriate "where the complainant's victory is likely to add to the fund of information that citizens may use in

---

[49] *5 U.S.C. § 552(a)(4)(E)(i)*.

[50] *Batton v. IRS, 718 F.3d 522, 525 (5th Cir. 2013)* (emphasis in original).

[51] *5 USC § 552(a)(4)(E)(ii)*; *Batton, 718 F.3d at 525*.

[52] *Texas v. ICC, 935 F.2d 728, 730 (5th Cir. 1991)*.

[53] *Cazalas v. Dep't of Justice, 709 F.2d 1051, 1057 (5th Cir. 1983)*.

[54] *Id. at 1054* (quoting S.Rep. No. 93-854, at 19 (1974)).

[55] *See 5 USC § 552(a)(4)(E)(ii)(I)* ("a complainant has substantially prevailed if the complainant has obtained relief through . . . a judicial order . . ."); *Batton, 718 F.3d at 525*.

[56] *NLRB v. Robbins Tire & Rubber Co., 437 U.S. 214, 242, 98 S. Ct. 2311, 57 L. Ed. 2d 159 (1978)*.

making vital political choices."[57] Courts take into consideration "the degree of dissemination and the likely public impact that might be expected from a particular disclosure."[58]

DMRS requested information about ICE's decision to prohibit asylum seekers' access to attorneys and to know your rights information. Denial of access to counsel and rights information has broad-ranging due process consequences for asylum seekers fleeing persecution. The documents responsive to DMRS's FOIA request are very likely to be of significant consequence to the large numbers of asylees and their advocates. As DMRS intends to use the requested records to "determine how to move [*12] forward with providing information and representation to asylum seekers in the MPP program,"[59] it has already begun the process of making documents obtained through this litigation available to other non-profit legal service organizations in the El Paso area, fellow advocates, and members of the press.[60]

Our nation's comprehensive immigration policy has been part of the national dialogue for well over a decade. In the recently concluded presidential cycle it figured prominently in the campaigns of every presidential candidate and most candidates seeking federal office. An element of that policy is the treatment of refuge and asylum seekers. Responsive documents would provide valuable insight into the execution of a rapidly evolving and controversial policy dealing with that segment of the immigrants pursuing admission to our country. As this information is both of public concern and useful to political decision making, the diffusion of documents will spread beyond legal service providers to the wider public. An award of attorney fees will foster the spirit of private litigants to vigorously pursue claims for information vital for democratic society and discourage the government from the [*13] cavalier treatment of appropriate and lawful requests such as DMRS is pursuing.

The public benefit is not reduced by the change in administration since the initiation of this lawsuit and before ICE has finished reviewing and producing all responsive documents. The delays are completely attributable to ICE's own administrative errors, absence of clearly defined methods and procedures to determine places and databases to search, lack of effective and comprehensive procedures for adequately processing FOIA requests, and repeated requests for extensions of deadlines. ICE's ineptitude in responding to valid requests for information and failure to comply with this court's deadlines cannot be counted in its favor. To do so would make a mockery of the accountability principles underlying FOIA.

ICE's handling of this FOIA request is precisely encompassed in the Fifth Circuit's holding that attorney fees are particularly appropriate where "'government officials have been recalcitrant in their opposition to a valid claim or have been otherwise engaged in obdurate behavior.'"[61] Potential FOIA complainants must be incentivized to pursue meritorious claims without fear that the duration of the lawsuit [*14] would make the information sought "old news," no longer in the public

---

[57] *Blue v. Bureau of Prisons, 570 F.2d 529, 534 (5th Cir. 1978)*.

[58] *Id. at 533*.

[59] Mot. 5.

[60] Mot., "Declaration of Melissa M. Lopez" 3, ECF No. 56-1, Ex. 3.

[61] *Cazalas v. Dep't of Justice, 709 F.2d 1051, 1054 (5th Cir. 1983)* (quoting S.Rep. No. 93-854, at 19 (1974)).

eye, and defeat a motion for compensation by simply delaying response. Therefore, this factor weighs strongly in favor of granting attorney fees.

2. The Commercial Benefit to the Complainant and Nature of Complainant's Interest in the Records Sought

When the commercial benefit to a plaintiff and the nature of the plaintiff's interest in records sought are similar it is useful to consider these factors together.[62] In weighing the commercial benefit factor, courts consider whether the party requesting fees is indigent or a non-profit organization rather than a large corporate interest.[63] Similarly, the nature of the complainant's interest weighs in favor of granting attorney fees if the plaintiff seeks to protect the public interest, rather than merely a private interest.[64] These factors further congressional intent that the prohibitive costs of litigation not exclude the indigent and public interest groups from pursuing relief.[65]

There is no commercial benefit to DMRS in the records sought. DMRS is a non-profit organization that provides know-your-rights information and legal representation to indigent asylum seekers. [*15] Its central purposes in seeking the documents are to protect its constituents' due process rights and to facilitate the fair adjudication of political asylum claims. Receipt of responsive records furthers DMRS's organizational purpose by bolstering its ability to protect the public interest in the administration of justice in the immigration system. Responsive records are also likely to raise public awareness of issues of political importance through the distribution of responsive records to other immigrant advocacy groups and the media. As such, both factors weigh in favor of granting attorney fees.

3. Whether the Government's Withholding of the Records had a Reasonable Basis in Law.

FOIA requires federal agencies to make their records promptly available to any person who makes a proper request for records.[66] "[T]he threshold question in any FOIA suit is whether the requester can even *see* the documents the character of which determines whether they can be released."[67] Accordingly, the FOIA statute provides that, when the government withholds information from disclosure, the agency has the initial burden to prove *de novo* that the information is exempt from disclosure.[68] This court's findings [*16] of fact document the abysmal inadequacy of the search and the unsupported redactions. In considering whether to award attorney fees, the threshold is lower. The government's withholding needs only to have had a reasonable basis in law for ICE to avoid attorney fees.[69] ICE showed no reasonable basis to withhold the documents.

a. Adequacy of Search

ICE failed to establish even a colorable basis in law exists to support the adequacy of its search for

---

[62] *Id.*

[63] *Blue v. Bureau of Prisons, 570 F.2d 529, 533-34 (5th Cir. 1978)*.

[64] *Id. at 534*

[65] *Id.* (citing S.Rep. No. 854, 93d Cong., 2d Sess. 19 (1974)).

[66] *5 U.S.C. § 552(a)(3)(A)*.

[67] *Cooper Cameron Corp. v. U.S. Dep't of Labor, OSHA, 280 F.3d 539, 543 (5th Cir. 2002)*.

[68] *5 U.S.C. § 552(a)(4)(B)*; *Batton v. Evers, 598 F.3d 169, 175 (5th Cir. 2010)*.

[69] *See Texas v. ICC, 935 F.2d 728, 730 (5th Cir. 1991)*.

documents responsive to DMRS's FOIA request. "Even when an agency does not deny a FOIA request outright, the requesting party may still be able to claim 'improper' withholding by alleging that the agency has responded in an inadequate manner."[70] An agency's search is adequate if it is "reasonably calculated to uncover all relevant documents."[71] "The adequacy of an agency's search is measured by a standard of reasonableness and is dependent upon the circumstances of the case."[72] The focus is on the reasonableness of the search, not the result.[73] An agency must "make more than perfunctory searches and, indeed, [] follow through on obvious leads to discover requested documents."[74]

There is no reasonable basis in law to believe ICE's search [*17] was reasonably calculated to uncover all responsive documents. Testimony about ICE's search was inconsistent and generalized. Fuentes described general ICE procedure for responding to FOIA requests without knowledge of the specifics. Fuentes did not conduct any search herself.[75] Nor could she testify as to the precise search procedure—Fuentes conceded her knowledge was limited to information on search forms POCs provided to her office.[76] ICE had all the time it requested to prepare for trial and to marshal all evidence it deemed appropriate. Even so, it did not call a single witness able to explain the rationale for the search conducted at any single program office.

In explanation of ICE's failure to conduct a methodical agency-wide search for responsive records, Fuentes stated the agency was "young" and "playing catch-up," seemingly acknowledging deficiencies.[77] In an apparent contradiction, she then said the reason for the lack of uniformity was to honor the subject-matter expertise within individual program offices.[78] Since record keeping practices vary across program offices, Fuentes reasoned, ICE conducts non-uniform searches.

Due to this model, Fuentes could not testify as to either the [*18] record keeping or searching practices of any program offices or their subdivisions. POCs did not provide that information in their search forms. The returned search forms indicate different search terms were used across program offices without any apparent reason for the lack of uniformity. Fuentes could not say whether a given search was reasonable in the context of the recordkeeping practices of a program office as she was not familiar with those practices and the POCs provided no explanation.

ICE's deference to the subject-matter expertise of

---

[70] *U.S. Dep't of Justice v. Tax Analysts, 492 U.S. 136, 151 n.12 (1991), 109 S. Ct. 2841, 106 L. Ed. 2d 112* (citations omitted). *See also Kissinger v. Reporters Comm. for Freedom of the Press, 445 U.S. 136, 150, 100 S. Ct. 960, 63 L. Ed. 2d 267 (1980)* (recognizing the judicial authority conferred by the FOIA to devise remedies for agencies contravening the statute through improper withholdings).

[71] *Weisberg v. U.S. Dep't. of Justice, 705 F.2d 1344, 1351, 227 U.S. App. D.C. 253 (D.C. Cir. 1983)*; *Batton v. Evers, 598 F.3d 169, 176 (5th Cir. 2010)*.

[72] *Id.*

[73] *Steinberg v. U.S. Dep't of Justice, 23 F.3d 548, 551, 306 U.S. App. D.C. 240 (D.C. Cir. 1994)*.

[74] *Valencia-Lucena v. U.S. Coast Guard, 180 F.3d 321, 325, 336 U.S. App. D.C. 386 (D.C. Cir. 1999)*.

[75] Findings of Fact and Conclusions of Law 6.

[76] "Transcript of Bench Trial" 35-36, 83-84, ECF No. 63, filed Nov. 16, 2020.

[77] *Id.* at 19-20.

[78] *Id.* at 20.

individuals within each program office is neither strategic nor efficient. It shows indifference to the purpose of the search. Without testimony about each program office's record keeping practices, ICE cannot show the search process was reasonably calculated to uncover all responsive documents.

The search was too narrow to be expected to uncover all responsive documents. Only five individuals in an agency of several thousand searched their email accounts for responsive correspondence.[79] These individuals used a variety of inconsistent search terms. The entirety of the search within the ERO Enforcement Division records was for a single search term [*19] within the Deputy Assistant Director's email account: the acronym "MPP."[80] Fuentes could not say with any level of assurance that this search uncovered responsive documents containing the spelled-out acronym.[81] Some individuals may have searched only within specific folders.[82] Some may have excluded deleted, archived, or sent emails by searching only within their inboxes.[83] Fuentes could not be sure and could only interpret the returned search forms.

ICE failed to show it conducted a reasonable search within ERO FOPS. DMRS's request sought communications about guidance and instruction to employees regarding day-to-day movement of MPP participants wherever the MPP was established. FOPS is responsible for providing guidance and coordination to the twenty-four ERO field offices.[84] ERO field offices are responsible for the custody of all MPP participants from the port of entry to the immigration court.[85] A publicly available memorandum by the Acting Executive Associate Director of ICE instructs field office directors to assign a lead POC for MPP issues within their offices.[86] The memorandum tasks these POCs with issuing local operational guidance applicable to the MPP.[87] These facts conclusively indicate [*20] FOPS is reasonably likely to have records responsive to DMRS's FOIA request. They also indicate ICE was aware that field offices possess records responsive to FOIA requests for information related to the MPP.

Inexplicably, FOPS determined DMRS's FOIA request did not fall within its area of responsibility and declined to conduct any search. It is troubling FOPS disregarded the plain language of a publicly available memo in determining it had no records responsive to DMRS's FOIA request. There is no reasonable basis in law to support ICE's inadequate search.

b. Exemptions

ICE gave no reasonable basis in law to redact the thirty-three pages it produced on June 25, 2020. When the applicability of an exemption to disclosure under FOIA is in dispute, an agency is required to provide a detailed

---

[79] "Transcript of Bench Trial" 77, ECF No. 63, filed Nov. 16, 2020.

[80] *Id.* at 95.

[81] *Id.* at 96.

[82] *Id.* at 87.

[83] *Id.* at 88.

[84] Findings of Fact and Conclusions of Law 9.

[85] "Transcript of Bench Trial" 68, ECF No. 63, filed Nov. 16, 2020.

[86] Memorandum from Nathalie R. Asher, Acting Executive Associate Director, U.S. Immigration and Customs Enforcement, to Field Office Directors, Enforcement and Removal Operations, "Migrant Protection Protocols Guidance" (Feb. 12, 2019).

[87] *Id.*

justification for exemption claims, correlating justifications for refusal to disclose with actual portions of records claimed to be exempt.[88] A common way in which agencies do so is through a *Vaughn* index.[89] In *Vaughn*, the D.C. Circuit held that a system of itemizing and indexing exemptions' legal and factual bases would easily remedy the problem of conclusory and generalized allegations of exemptions. [*21] [90] This procedure makes clear the factual nature of the information sought and the specific reason it falls within the statutory exemption asserted.[91] Since *Vaughn*, it has become standard practice for agencies to supply the court with a *Vaughn* index.[92]

Under *FOIA exemption (b)(5)*, an agency can withhold information covered by a recognized evidentiary or discovery privilege.[93] *Exemption (b)(5)* protects from disclosure:

> inter-agency or intra-agency memorandums or letters that would not be available by law to a party other than an agency in litigation with the agency, provided that the deliberative process privilege shall not apply to records created 25 years or more before the date on which the records were requested.[94]

Thus, "*[e]xemption 5* incorporates the privileges which the government enjoys under the relevant statutory and *case law* in the pretrial discovery context."[95] Three common law privileges encompassed in *exemption (b)(5)* include: (1) the attorney work-product privilege; (2) the attorney-client privilege; and (3) the governmental deliberative process privilege.[96]

After repeated opportunities to demonstrate to this court how *exemption (b)(5)* applies to the records ICE sought to [*22] withhold, ICE did not meet its burden to support exempting any information redacted pursuant to *exemption (b)(5)* from disclosure. ICE presented no evidence at either the summary judgment phase or at trial supplying the factual or legal basis for any application of *exemption (b)(5)*. Although settled law establishes the preparation of a Vaughn index, ICE did not generate one. ICE simply provided a brief letter to accompany the thirty-three pages of responsive documents at issue. The letter stated that redactions under *exemption (b)(5)* qualified for protection under one or more of the three named privileges, without specifying which, and without any factual basis for the application of *exemption (b)(5)* to any individual redaction.

ICE's only witness shed no more light on the factual

---

[88] *Batton v. Evers, 598 F.3d 169, 175 (5th Cir. 2010)* (citing *Vaughn v. Rosen, 484 F.2d 820, 157 U.S. App. D.C. 340 (D.C. Cir. 1973)*.

[89] *See Vaughn, 484 F.2d at 827*.

[90] *Id. at 826-27*.

[91] *Stephenson v. IRS, 629 F.2d 1140, 1144 (5th Cir. 1980)*.

[92] *See, e.g., Batton, 598 F.3d at 178-79*; *Flight Safety Servs. Corp. v. Dep't of Labor, 326 F.3d 607, 613 (5th Cir. 2003)*; *Stephenson, 629 F.2d at 1145*.

[93] *Judicial Watch, Inc. v. U.S. Dep't of Def., 847 F.3d 735, 738-39, 427 U.S. App. D.C. 356 (D.C. Cir. 2017)*.

[94] *5 U.S.C. § 552(b)(5)*.

[95] *United States v. Weber Aircraft Corp., 465 U.S. 792, 799, 104 S. Ct. 1488, 79 L. Ed. 2d 814 (14)* (citations omitted) (emphasis in original).

[96] *Tax Analysts v. IRS, 294 F.3d 71, 76, 352 U.S. App. D.C. 273 (D.C. Cir. 2002)*.

basis for the exemptions. Fuentes admitted she was not involved in redacting the documents at issue and therefore had no personal knowledge to speak of.[97] Nor did she seem to have secondary knowledge on which the court could rely due to her role as agency representative. Fuentes stated she reviewed the exemptions claimed and agreed with them.[98] However, when asked directly about why entire pages had been subject [*23] to *exemption (b)(5)*, she stated she did not know what the pages contained.[99] When asked about a specific redacted page, she could not say whether it was the end of the preceding document, an attachment, or part of a subsequent document.[100]

Fuentes's lack of knowledge regarding the substance of the redactions often led her to speculate to fill in the gaps. When asked whether redacted emails were sent to agents executing the MPP on-the-ground, she responded, "they do not appear that way as redacted."[101] In reference to another redacted email, Fuentes stated that, as two attorneys were included among other undisclosed recipients, she believed the email to contain legal advice.[102] She later admitted she did not know who else received the email and was aware emails are not necessarily privileged just because an attorney is included in an email chain.[103]

Fuentes was not only uncertain of the content of responsive records; she was uncertain and inconsistent in providing underlying reasons for redactions. She alternated between identifying the specific privilege applied and admitting she could not state with any confidence which privilege supported each redaction. She openly speculated about which privilege [*24] may have applied based on context clues in the released portions. More than once, she equivocated, stating perhaps the redactor had relied on one of the three privileges cited or perhaps on all three.[104] Fuentes's testimony was not reliable. Even had Fuentes confidently testified as to the privileges relied upon by the redactors, she is not a lawyer.[105] She therefore does not have the education or training to provide an explanation as to *why* a particular privilege was invoked.

While Fuentes was knowledgeable about the procedure ICE uses to apply exemptions generally, she was unable to bridge the gap between that procedure and the factual basis for exemptions applied in this case. Both the fundamental principle of public access to government documents and the general principle of full agency disclosure require agency representatives to have more than mere confidence in the procedure followed. They require clear statements of both the factual nature of the information withheld and whether it falls within a specific statutory exemption.[106] Without

---

[97] "Transcript of Bench Trial" 57-58, ECF No. 63, filed Nov. 16, 2020.

[98] *Id.* at 120.

[99] *Id.* at 144.

[100] *Id.*

[101] *Id.* at 103.

[102] *Id.* at 140-41.

[103] "Transcript of Bench Trial" 146, ECF No. 63, filed Nov. 16, 2020.

[104] *Id.* at 146-47.

[105] *Id.* at 132-33.

[106] *See Batton v. Evers, 598 F.3d 169, 176 (5th Cir. 2010)* ("The central issue . . . is whether the [evidence] submitted by [the agency] . . . sufficiently identif[ies] the documents at issue, including the relevant information contained in each document, and explain[s] why the asserted exemptions justify

either, the explanation is not only legally insufficient, it lacks any reasonable basis in the law. ICE did less than the bare minimum to justify its [*25] exemptions and instead attempted to shift the burden to the court and to DMRS. This forced DMRS to expend considerably more in attorney labor and fees to litigate exemptions to documents produced at the eleventh hour and without the easy remedy of a *Vaughn* index. Therefore, the final factor in the entitlement prong, like all others, weighs in favor of granting attorney fees.

B. Whether the Amount of Attorney Fees Requested is Reasonable

As DMRS substantially prevailed and is entitled to attorney fees, the court must consider whether the amount requested is reasonable.[107] District courts have broad discretion in calculating reasonable attorney fee awards.[108] Reasonable attorney fees are determined in two steps. First, the court calculates the "lodestar."[109] The lodestar is the product of the reasonable hourly rate multiplied by the number of hours reasonably expended on the litigation.[110] The party requesting fees bears the burden of establishing the reasonableness of fees, hours billed, and billing judgment exercised.[111] There is a presumption that the lodestar amount is a reasonable fee.[112]

In step two, the court may adjust the fee award up or down after consideration of the factors articulated [*26] in *Johnson v. Georgia Highway Express, Inc.* not already included in the calculation of the lodestar.[113] However, neither party requests attorney fees depart from the lodestar. Accordingly, the court will not advance to the second step of the attorney fee inquiry and calculation of the lodestar alone will determine the amount of the attorney fee award.

1. Compensable Hours

To calculate the lodestar, a district court must first determine the compensable hours from the attorney's time records, including only hours reasonably spent.[114] Each hour claimed must be supported by attorney billing records.[115] The court must exclude "excessive,

---

withholding.").

[107] *See* 5 U.S.C. § 552(a)(4)(E)(i) ("The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred . . .").

[108] *Hensley v. Eckerhart, 461 U.S. 424, 434, 103 S. Ct. 1933, 76 L. Ed. 2d 40 (1983)*; *Watkins v. Fordice, 7 F.3d 453, 457 (5th Cir. 1993)*.

[109] *League of United Latin Am. Citizens No. 4552 v. Roscoe Indep. Sch. Dist., 119 F.3d 1228, 1232 (5th Cir. 1997)*.

[110] *Hensley, 461 U.S. at 434*.

[111] *Saizan v. Delta Concrete Pro. Co., 448 F.3d 795, 799 (5th Cir. 2006)*.

[112] *City of Burlington v. Dague, 505 U.S. 557, 562, 112 S. Ct. 2638, 120 L. Ed. 2d 449 (1992)*. *See also* *Walker v. U.S. Dep't. of Hous. and Urban Dev., 99 F.3d 761, 771-72 (5th Cir. 1996)* (describing the limited circumstances in which an adjustment to the lodestar is permitted).

[113] *488 F.2d 714, 717-19 (5th Cir. 1974)*. *See also* *Pennsylvania v. Del. Valley Citizens' Council for Clean Air, 478 U.S. 546, 565, 106 S. Ct. 3088, 92 L. Ed. 2d 439 (1986)* (holding that *Johnson* factors that are subsumed in the calculation of the lodestar may not provide an independent basis for increasing the fee award).

[114] *Hensley, 461 U.S. at 436-37*.

[115] *Watkins v. Fordice, 7 F.3d 453, 457 (5th Cir. 1993)*.

redundant, or otherwise unnecessary" hours.

DMRS requests compensation for 125.7 hours worked by lead counsel, Christopher Benoit ("Benoit").[116] In support, it submits a billing statement detailing hours worked by Benoit. According to the billing statement, the billed hours are reduced from a total of 132 hours to eliminate redundant or administrative hours.[117] In order to prevent duplication of work, DMRS also does not request compensation for hours worked by co-counsel or counsel's administrative assistant.[118] At the time DMRS filed its Motion DMRS estimated [*27] an additional ten hours of work would be performed to cooperate with ICE in creating and completing a new search in compliance with this court's order.[119] ICE disputed only that the FOIA fee shifting provision permitted compensation for work yet to be performed.[120] DMRS then submitted documentation of an additional 12.8 hours worked in compliance with the court's order to construct a new search and amended its request to substitute these hours for the prospective fees.[121] These hours are therefore no longer speculative and will be considered alongside all other hours.

The hours billed reasonably reflect the time spent on litigation and are compensable. FOIA matters present legal complexities requiring a significant investment of time to fully research and brief. This case proceeded to trial, which required significant time to prepare opening and closing statements, exhibits, an expert witness, and cross-examination. The quality of pleadings submitted and trial advocacy displayed by Mr. Benoit was of the first order. It is remarkable that he and his litigation team did so much quality work in the time claimed.

Benoit represents DMRS on a contingent fee basis.[122] He charged no hourly rate and will [*28] not be compensated beyond court awarded attorney fees. Benoit exercised reasonable billing judgment by omitting any charge for time contributed by co-counsel and his administrative assistant. The court finds no excessive, redundant, or otherwise unnecessary hours in counsel's billing statement.

Besides the usual time requirement for actions proceeding to trial, this case presented unusual complications resulting from the government's own obstructionist behavior. ICE's repeated delays and administrative errors needlessly extended the duration of this action and required numerous phone calls, emails, and conferences that would otherwise have been unnecessary. ICE also complicated the summary judgment phase by untimely producing responsive documents after DMRS filed its motion and the dispositive motion deadline had passed, thereby preventing DMRS from disputing redactions to those documents before its reply. In turn, as both parties had not had an opportunity to brief the issue, this court was unable to address the contested redactions at that phase and carried the issue over to trial.[123]

---

[116] Mot. 10.

[117] Mot., "19-cv-00236 Billing Statement" 2, ECF No. 56-1, Ex. 1-B.

[118] Mot. 8.

[119] *Id.* at 10.

[120] Resp. 3 fn. 2.

[121] *See* "Plaintiff's Reply to Defendant's Response to Plaintiff's Application for Attorney Fees and Costs" 6, ECF No. 66, filed Nov. 25, 2020.

[122] Mot. 7.

[123] *See* "Order Denying Motion for Summary Judgment" 6, ECF No. 30, entered Aug. 25, 2020; *Medina Cnty. Envtl.*

Even now, ICE continues to stall and delay its search for responsive documents. For the first time, [*29] ICE claims the substantial backlog of FOIA requests and its limited personnel makes timely compliance impossible. However, administrative backlog does not form a reasonable basis in law to withhold responsive documents.[124]

As ICE did not have a faintly colorable claim that its search complied with the statute, this newfound claim of impossibility proves how indifferent ICE was to its statutory duty. Had ICE responded in conformity with the statute, the enormity of the task they now claim would have been identified in the summer of 2019 and not in the winter of 2020. Meanwhile, DMRS and its counsel must continue to expend time and resources pursuing its claim, even after completely prevailing at trial. DMRS has met its burden to show the reasonableness of the 138.5 hours billed by Benoit.

2. Hourly Rate

Next, the district court must "select an appropriate hourly rate based on prevailing community standards for attorneys of similar experience in similar cases."[125] "Generally, the reasonable hourly rate for a particular community is established through affidavits of other attorneys practicing there."[126]

DMRS requests an hourly rate of 325-375.[127] In support of its requested rate, DMRS provides a [*30] declaration from Benoit, expanding on the time and effort expended by counsel;[128] a declaration from attorney Lynn Coyle, attesting to both the work done by Benoit in this case and the prevailing rate for comparable legal work;[129] and a declaration from John P. Mobbs ("Mobbs"), a seasoned El Paso attorney qualified as an expert in attorney fees, opining that the fees requested in this case are below the reasonable contingency fee range in El Paso.[130]

ICE contends the proposed rate is excessive and unreasonable as it exceeds the hourly rate of El Paso attorneys with comparable experience as listed in the 2015 State Bar of Texas Hourly Rate Fact Sheet ("Fact Sheet").[131] ICE cites to a string of unreported district court opinions relying on the Fact Sheet to calculate reasonable attorney fees according to various statutory fee-shifting provisions.[132] The line of cases relying on

---

Action Ass'n v. Surface Transp. Bd., 602 F.3d 687, 702 (5th Cir. 2010).

[124] *See* *Miller v. U.S. Dep't of State, 779 F.2d 1378, 1390 (8th Cir. 1985)*(holding that attorney fees cannot be denied on the reasonableness of the government's position where the government cites processing backlogs, confusion, and administrative error, because these "are practical explanations, not reasonable bases.").

[125] *Shipes v. Trinity Indus., 987 F.2d 311, 319 (5th Cir. 1993)*.

[126] *Tollett v. City of Kemah, 285 F.3d 357, 368 (5th Cir. 2002)*.

[127] *Id.* at 7.

[128] *See generally* Mot., "Declaration of Christopher Benoit," ECF No. 56-1, Ex. 1.

[129] *See generally* Mot., "Declaration of Lynn Coyle Pursuant to *28 U.S.C. § 1746*." ECF No. 56-1, Ex. 5.

[130] *See generally* Mot., "Declaration of John P. Mobbs," ECF No. 56-1, Ex. 2.

[131] Resp. 5. *See also*, Resp., "State Bar of Texas 2015 Hourly Fact Sheet" ("Fact Sheet") ECF No. 65-1, Ex. A.

[132] *See e.g.,* [*31] *Alvarez v. McCarthy, No. 6:16-CV-00172-ADA, 2020 U.S. Dist. LEXIS 59790, 2020 WL 1677715, at *6*

the Fact Sheet is unpersuasive. First, the Texas Bar has not published an updated Fact Sheet since 2015. Five-year-old fee data is unreliable and likely to skew lower than current attorney fees. The Fact sheet itself notes a 7.4 increase in median rates from 2013 to 2015.[133]

Second, it is uncertain that even a 2021 Fact Sheet would accurately represent the reasonable hourly rate for the El Paso legal community. DMRS included with its motion a Review of the State Bar of Texas *2015 Hourly Fact Sheet* by Statistician N. Shirlene Pearson, Ph.D. ("Dr. Pearson").[134] Dr. Pearson stated the Texas Bar survey underlying the Fact Sheet data suffered from the fatal defects of a limited sample size, selection bias, and suboptimal methodology.[135] Moreover, the hourly rates listed on the Fact Sheet do not distinguish between reported billing method: hourly fees, flat rates, contingency fees, or discounted fees for volume clients.[136] Dr. Pearson concluded the Fact Sheet does not reliably reflect the hourly rates of attorneys in Texas.[137] Tellingly, the Texas Bar itself warns against using the Fact Sheet to set attorney fees.[138]

Finally, the Fifth Circuit has not adopted the Fact Sheet as a determinative measure of reasonable attorney fees in a given community. Instead, Fifth Circuit jurisprudence is based on trial court reliance on attorney affidavits.[139] ICE does not dispute the unreliability of the Fact Sheet [*32] or offer its own attorney affidavits. Instead, it merely points to non-binding law and argues the court should blindly follow it. After consideration of the significant limitations of the Fact Sheet, this court relies on the three attorney declarations supporting the Motion, which compellingly concur that the requested rate is reasonable.

The large amount of work done in such a low number of hours is the direct result of Benoit's high level of litigation skills and accompanying effectiveness. Given the delays and conduct of ICE in this case, a less experienced attorney would have easily spent a substantially higher number of hours. By way of illustration, 190 compensable hours at 275 would yield a total of 52,250 in attorney fees—more than Benoit requested. ICE's objection to the proposed hourly rate is solely based on a much-discredited study and not on Fifth Circuit jurisprudence. To follow ICE's rationale would simply discourage highly skilled attorneys like Benoit from taking on difficult cases like this one. DMRS has met its burden to show the reasonableness of its requested fee.

Considering the applicable law and pertinent facts before this court, an hourly rate of 375 will [*33] be applied to calculate the lodestar. After multiplying this rate by the 138.5 compensable hours, reasonable attorney fees in this case are 51,937.50.

(W.D. Tex. Apr. 6, 2020).

[133] Fact Sheet 4.

[134] *See generally* Mot. "Review of the State Bar of Texas *2015 Hourly Fact Sheet* report and its Use by the Texas Judiciary in Deciding Plaintiff Attorney Hourly Fees in Labor-Employment Cases" ("Review of Fact Sheet") ECF No. 56-1, Ex. 1-C.

[135] *Id.*

[136] *See generally* Fact Sheet. *See also* Review of Fact Sheet 5.

[137] Review of Fact Sheet 6.

[138] Texas State Bar, Demographic & Economic Trends: Economic Trends, available at https://www.texasbar.com/AM/Template.cfm Section Demographic and Economic Trends (last accessed Jan. 20, 2021).

[139] *See Tollett v. City of Kemah, 285 F.3d 357, 368 (5th Cir. 2002)*.

UNITED STATES DISTRICT JUDGE

End of Document

C. Plaintiff's Bill of Costs

Pursuant to *28 U.S.C. § 1920*, a judge may include costs for fees of the clerk of court and service of summons of subpoena in a judgment upon filing of a bill of costs. In its bill of costs, DMRS requests such reimbursement in the amount of 432.20.[140] ICE does not challenge these costs.[141] After due consideration, the court finds it in the interest of justice to grant DMRS's bill of costs.

IV. CONCLUSION

Accordingly, the court enters the following orders:

1. **IT IS HEREBY ORDERED** that "Plaintiff's Opposed Application for Attorney Fees and Costs" [ECF No. 56] is **GRANTED**.

2. **IT IS FURTHER ORDERED** that Plaintiff Diocesan Migrant & Refugee Services shall **RECOVER** from Defendant United States Immigration and Customs Enforcement **$51,937.50** for work performed in this case.

3. **IT IS FURTHER ORDERED** that Plaintiff Diocesan Migrant & Refugee Services shall **RECOVER** from Defendant United States Immigration and Customs Enforcement costs of the court in the amount of **$432.20**.

SIGNED AND ENTERED this **28th** day of **January 2021**.

/s/ Frank Montalvo

FRANK MONTALVO [*34]

---

[140] "Bill of Costs" 1, ECF No. 55, filed Nov. 2, 2020.

[141] Resp. 1 fn. 1.

Colbert v. FBI

United States District Court for the District of Columbia

September 3, 2018, Decided; September 3, 2018, Filed

Civil Action No. 16-cv-1790 (DLF)

Reporter
2018 U.S. Dist. LEXIS 233651 *

THOMAS J. COLBERT, Plaintiff, v. FEDERAL BUREAU OF INVESTIGATION, et al., Defendants.

Core Terms

requests, records, discovery, privacy interest, processing, public interest, disclosure, pages

Counsel: [*1] For THOMAS J. COLBERT, TJC Consulting, LLC, Plaintiff: Mark Steven Zaid, LEAD ATTORNEY, Bradley Prescott Moss, LAW OFFICES OF MARK S. ZAID, P.C., Washington, DC.

For FEDERAL BUREAU OF INVESTIGATION, DEPARTMENT OF JUSTICE, Defendants: Jeremy S. Simon, LEAD ATTORNEY, U.S. ATTORNEY'S OFFICE FOR THE DISTRICT OF COLUMBIA, Washington, DC.

ROBERT RACKSTRAW, Movant, Pro se, Coronado, CA.

Judges: DABNEY L. FRIEDRICH, United States District Judge.

Opinion by: DABNEY L. FRIEDRICH

Opinion

MEMORANDUM OPINION AND ORDER

On September 8, 2016, the plaintiff, Thomas J. Colbert, filed a complaint to compel the FBI to disclose the investigative file of the D.B. Cooper skyjacking incident. Colbert believes that the FBI bungled the investigation and allowed the alleged perpetrator, Robert Rackstraw, to escape justice. Although the FBI has not yet completed the processing of approximately 71,000 pages of potentially responsive records, Colbert filed a Motion for Partial Summary Judgment or Alternatively Discovery. Dkt. 21. Colbert asks the Court to determine whether the FBI is entitled to withhold any information under FOIA exemptions 6 and 7(C).[1] *5 U.S.C. §§ 552(b)(6)*, *(7)* Alternatively, Colbert asks the Court to grant his request for discovery. For the reasons [*2] discussed below, the Court will deny Colbert's motion.

Under exemption 7(C), an agency may "withhold 'investigatory records compiled for law enforcement purposes, or information which if written would be contained in such records, but only to the extent that the production of such records or information would

[1] Exemptions 6 and 7(C) protect information that would invade the privacy of third parties. Because Exemption 7(C) provides a lower bar for the agency to meet in that it requires the agency to show an "unwarranted"—as opposed to "clearly unwarranted"—invasion of personal privacy, this opinion only addresses whether the FBI has met its burden under Exemption 7(C).

constitute an unwarranted invasion of personal privacy.'" *Nation Magazine v. U.S. Customs Serv., 71 F.3d 885, 893, 315 U.S. App. D.C. 177 (D.C. Cir. 1995)* (internal quotation marks omitted); *see also* *5 U.S.C. § 552(b)(7)(C)*. Once an agency has shown that the disclosure of certain records would implicate privacy concerns, a FOIA requester can still obtain the records if the requester can show that the public interest in disclosing the records outweighs the privacy interests at stake. *Id.* To satisfy this burden, a FOIA requester must show that (1) the public interest sought to be advanced is a significant one, an interest more specific than having the information for its own sake, and (2) the information is likely to advance that interest." *Martin v. DOJ, 488 F.3d 446, 458, 376 U.S. App. D.C. 293 (D.C. Cir. 2007)* (internal quotation marks omitted). That "balancing test must be applied to the specific facts of each case." *Stern v. FBI, 737 F.2d 84, 91, 237 U.S. App. D.C. 302 (D.C. Cir. 1984)*. And it is possible that a "particular record may be protected in one set of circumstances, but not in others." *Id.* When the claimed public interest [*3] "is government wrongdoing, then the requester must produce evidence that would warrant a belief by a reasonable person that the alleged Government impropriety might have occurred." *Martin, 488 F.3d at 458* (internal quotation marks omitted).

Here, Colbert argues that the FBI mishandled the D.B. Cooper case, and the public therefore has an interest in knowing the path that the investigation took. Pl.'s Mot. at 20-21, Dkt. 21. The FBI disputes Colbert's characterization of the investigation and asserts that Rackstraw has a substantial privacy interest in not being associated with criminal activity. Def.'s Opp'n at 4-5, Dkt. 25. At this stage, however, the FBI does not argue that Rackstraw's privacy interest *categorically* outweighs the public interest in disclosure of the requested records. Rather, the FBI contends that it should be afforded the opportunity to balance the competing interests as it processes Colbert's request. Third Hardy Declaration 13, Dkt. 25.

The D.C. Circuit has "long recognized" that "the mention of an individual's name in a law enforcement file will engender comment and speculation and carries a stigmatizing connotation." *Roth v. DOJ, 642 F.3d 1161, 1174, 395 U.S. App. D.C. 340 (D.C. Cir. 2011)*. Thus, the D.C. Circuit has "held that not only the targets of [*4] law-enforcement investigations, but also witnesses, informants, and . . . investigating agents have a substantial interest in ensuring that that their relationship to the investigations remains secret." *Id.* (internal quotation marks omitted). Even when the existence of an investigation has been made public, the subject of an investigation retains "a privacy interest . . . in avoiding disclosure of the details of the investigation." *Kimberlin v. DOJ, 139 F.3d 944, 949, 329 U.S. App. D.C. 251 (D.C. Cir. 1998)*; *see* *CREW v. DOJ, 846 F. Supp. 2d 63, 72 (D.D.C. 2012)* (congressman retained privacy interest in the substance of an investigation even though the FBI and congressman publicly acknowledged investigation's existence).

The FBI acknowledges that the agency "followed a lead regarding Rackstraw" in the D.B. Cooper investigation. Def.'s Opp'n at 4, Dkt. 25. But the FBI also represents that it pursued numerous leads during the now closed investigation, *see* Third Hardy Decl. at 13, and ultimately cleared Rackstraw. Def.'s Opp'n at 2, 4. Rackstraw's privacy interest in the substance of the D.B. Cooper investigation thus remains, despite the extensive publicity about him in connection with the investigation.[2]

[2] Rackstraw was permitted to file an amicus brief in this case. He asserts that he is not D.B. Cooper and makes clear that he does not want the FBI to release any documents to Colbert. Dkt. 30.

Balanced against Rackstraw's privacy interest is Colbert's claim that the FBI mishandled the D.B. Cooper [*5] investigation. But Colbert has offered only conclusory allegations that the FBI failed to zealously pursue investigatory leads, and he has provided no evidence to support these allegations. Thus, the Court cannot conclude that the public interest in the disclosure of records related to the D.B. Cooper investigation categorically outweighs Rackstraw's substantial privacy interest in not having the records released to the public. Consistent with other FOIA cases, the Court will assess the appropriateness of any claimed withholdings after the FBI has processed the requested records and asserted exemptions.[3]

Colbert also requests discovery in three areas. First, Colbert requests discovery to determine that Rackstraw was investigated as a suspect in the D.B. Cooper case. The FBI has conceded that fact, so discovery is not warranted on this basis. Second, Colbert requests discovery to determine whether the FBI authorized the disclosure of official investigative files, but the FBI has confirmed that any release of FBI records was unauthorized. Third Hardy Declaration 11, Dkt. 25. But Colbert has not offered evidence of bad faith, therefore, discovery is not justified. *See* *Baker & Hostetler LLP v. Dep't of Commerce, 473 F.3d 312, 318, 374 U.S. App. D.C. 172 (D.C. Cir. 2006)*. Finally, Colbert [*6] requests discovery to determine why the FBI disregarded Rackstraw as a suspect. Discovery in FOIA cases is "rare" and "only appropriate when an agency has not taken adequate steps to uncover responsive documents." *Schrecker v. United States DOJ, 217 F. Supp. 2d 29, 35 (D.D.C. 2002)*, aff'd, *349 F.3d 657, 358 U.S. App. D.C. 334 (D.C. Cir. 2003)* (cited favorably in *Baker & Hostetler LLP v. U.S. Dep't of Commerce, 473 F.3d 312, 318, 374 U.S. App. D.C. 172 (D.C. Cir. 2006))*. Here, Colbert does not allege that the FBI has not adequately searched for responsive documents. Instead, Colbert seeks to use discovery to shortcut the agency's review and production process. Accordingly, the Court denies Colbert's request for discovery.

Separately, the parties dispute whether 500 pages per month is a reasonable production rate for the approximately 71,000 pages of responsive records. The FBI has explained that the agency's standard policy is to process 500 pages per month for medium and large requests. Hardy Declaration 8, Dkt. 15. The FBI adheres to that policy because it is based on sound FOIA business practice, promotes efficiency, and allows the FBI to maintain proper information security. *Id.* The policy also allows the FBI to process multiple complex requests simultaneously and meet litigation demands. *Id.* 14, 15, 16. Colbert requests that the FBI process 3,000 pages per month because at the current processing rate, [*7] it will take the FBI over a decade to process the responsive records. Dkt. 31. Alternatively, Colbert requests limited discovery related to the processing rate. Dkt. 33.

Courts have broad discretion to determine a reasonable processing rate for a FOIA request. Several factors inform the analysis, including the size and compelling need of the request compared to others, as well as the effect of the request on the FBI's ability to review other FOIA requests. *See, e.g.*, *Middle E. Forum v. DHS, 297 F. Supp. 3d 183, 186 (D.D.C. 2018)*; *Clemente v. FBI, 71 F. Supp. 3d 262, 269 (D.D.C. 2014)*. When determining the rate at which a federal agency must respond to FOIA requests, courts often give deference to the agency's release policies. *See* *Negley v. DOJ, No. 15-cv-1004, 305 F. Supp. 3d 36, 2018 WL 1610950,*

[3] For the reasons stated, the Court also rejects Colbert's request for a Vaughn Index which would reveal details about the number and type of documents in which Rackstraw's name appears.

*at *7 (D.D.C. Apr. 3, 2018)*, *appeal filed*, No. 18-5133 (D.C. Cir. May 2, 2018) (applying DOJ's 500-page interim release policy because the policy would "promote efficient responses to a larger number of requesters" and "the Court sees no basis to expedite release"). At this time, the Court will not order the FBI to adjust its standard processing rate, but it directs the FBI to submit a status report within 90 days updating the Court on its progress responding to Colbert's records request. Thereafter, the Court will schedule a status conference to consider whether the [*8] standard processing rate remains reasonable.

For the foregoing reasons, it is ORDERED that Colbert's motion for summary judgment or in the alternative for discovery is DENIED.

/s/ Dabney L. Friedrich

DABNEY L. FRIEDRICH

United States District Judge

Date: September 3, 2018

End of Document

Inst. for Justice v. IRS

United States District Court for the District of Columbia

July 8, 2021, Decided; July 8, 2021, Filed

Civil Action No. 1:18-cv-01477 (CJN)

Reporter
2021 U.S. Dist. LEXIS 205698 *

INSTITUTE FOR JUSTICE, Plaintiff, v. INTERNAL REVENUE SERVICE, et al., Defendants.

Core Terms

REDACTED, records, exempt, structuring, withhold, pages, emails, disclosure, documents, currency, divorce, deliberative process, investigators, predecisional, cases, deliberative, interview, identification, guidelines, processing, petitions, agencies, deposits, Partial, productions, withheld, privacy, talking

Counsel: [*1] For Internal Revenue Service, Defendant: Catriona M. Coppler, U.S. DEPARTMENT OF JUSTICE, Washington, DC; Kristina Marie Portner, LEAD ATTORNEY, TAX, Washington, DC; Ryan O'Connor McMonagle, LEAD ATTORNEY, U.S. DEPARTMENT OF JUSTICE, Washington, DC.

For Institute for Justice, Plaintiff: Ryan S. Baasch, TEXAS OFFICE OF THE ATTORNEY GENERAL, Austin, TX; Andrew D. Prins, LATHAM & WATKINS LLP, Washington, DC.

For Department of Justice, Defendant: John Moustakas, LEAD ATTORNEY, U.S. ATTORNEY'S OFFICE FOR THE DISTRICT OF COLUMBIA, Washington, DC.

Judges: CARL J. NICHOLS, United States District Judge.

Opinion by: CARL J. NICHOLS

Opinion

MEMORANDUM OPINION

This case involves a series of Freedom of Information Act ("FOIA") requests about a controversial form of civil asset forfeiture carried out by the Internal Revenue Service. The IRS has processed tens of thousands of pages, but tens of thousands remain, and the Institute for Justice (the requester, "IJ") now challenges the scope of the IRS's redactions under several FOIA exemptions. Before the Court are the Parties' Motions for Partial Summary Judgment, which the Court determined would promote the resolution of this litigation. ECF Nos. 49, 50. For the reasons below, the Court will grant in part and deny in [*2] part each Party's respective motion.

I. BACKGROUND

In 2016, IJ lodged a FOIA request to secure information about how the IRS enforces its structuring laws. Structuring laws help the IRS detect money laundering by prohibiting individuals from avoiding financial reporting requirements under the *Bank Secrecy Act*

("Act"). 31 U.S.C. § 5313(a). Under the Act, banks must file with regulators currency transaction reports, which list all transactions over 10,000. *Id.* § 5313(a). Structuring laws support the Act by prohibiting individuals from "breaking down . . . a single sum of currency exceeding 10,000 into small sums," 31 C.F.R. § 1010.100(xx), "for the purpose of evading reporting requirements." 31 U.S.C. § 5324(a).

While structuring laws are designed to "detect[] and deter[] [underlying] criminal behavior" (like fraud or money laundering), a 2017 investigation by the Treasury Inspector General for Tax Administration found that the IRS "largely pursued [structuring] cases against legal source funds from business accounts," not against suspected "criminal enterprises." Treasury Inspector Gen. Tax Admin., *Criminal Investigation Enforced Structuring Primarily Again Legal Source Funds and Compromised the Rights of Some Individuals and* Businesses, Ref. No. 2017-30-025, at 2-3 (Mar. 30, [*3] 2017), ECF No. 50-8 ("TIGTA Report"). The practice of seizing money from legal businesses that happen to make large cash deposits led to widespread criticism. *See, e.g.,* Leonard v. Texas, 137 S. Ct. 847, 848, 197 L. Ed. 2d 474 (2017) (Thomas, J., concurring in denial of cert.) ("[B]ecause the law enforcement entity responsible for seizing the property often keeps it, these entities have strong incentives to pursue forfeiture."). And in the wake of the Inspector General's investigation, the IRS pledged that it would "no longer pursue the seizure and forfeiture of funds associated solely with 'legal source' structuring cases unless there are exceptional circumstances." TIGTA Report at 3.

IJ submitted FOIA requests seeking records relating to that pledge, and over the last 26 months the IRS has produced approximately 26,000 pages of records, withholding or redacting certain records under various FOIA Exemptions. *See* Pl.'s Partial Cross-Mot. Summ. J. 1-3, ECF No. 50 ("Pl.'s Mot."). Although the IRS's production continues, on January 15, 2020, the Court determined that a decision regarding the appropriateness of certain categories of withholdings would promote the resolution of this litigation. *See* Minute Order *dated* Jan. 15, 2020. In particular, IJ [*4] now challenges the IRS's decision to either fully or significantly redact three categories of records: (1) policy documents describing the agency's approach to legal-source structuring cases; (2) agency-level documents about how the IRS considers petitions for remission or mitigation filed by individuals "seeking the return of money seized under the structuring laws;" and (3) the case files and decision letters the IRS complied for a number of individuals who filed petitions to get their money back. Pl.'s Mot. at 10-11. Following briefing on the Parties' Motions for Partial Summary Judgment, the Court directed the agency to submit a representative sample of those disputed records under seal. *See* Minute Order *dated* Jan. 26, 2021. After reviewing those records *in camera*, the Court heard oral argument. *See* Minute Order *dated* Feb. 18, 2021.

II. STANDARD OF REVIEW

FOIA "generally require[es] federal agencies to make their records available to the public upon request." DiBacco v. U.S. Army, 795 F.3d 178, 183, 417 U.S. App. D.C. 441 (D.C. Cir. 2015). An agency may redact or withhold information covered by one of the exemptions listed in 5 U.S.C. § 552(b). If a plaintiff objects, "the agency has the burden of showing that [the] requested information comes within a FOIA exemption." Pub. Citizen Health Research Grp. v. FDA, 185 F.3d 898, 904, 337 U.S. App. D.C. 343 (D.C. Cir. 1999) (citation [*5] omitted). To do so, an agency must "describe the justifications for nondisclosure with reasonably specific detail, demonstrate that the

information withheld logically falls within the claimed exemption," *Citizens for Responsibility & Ethics in Wash. v. U.S. Dep't of Justice, 746 F.3d 1082, 1088, 409 U.S. App. D.C. 113 (D.C. Cir. 2014)* (citation omitted), and "reveal as much detail as possible" about "the nature of the document, without actually disclosing information that deserves protection." *Oglesby v. U.S. Dep't of the Army, 79 F.3d 1172, 1176, 316 U.S. App. D.C. 372 (D.C. Cir. 1996)*. The Court must then decide "whether [the agency's] non-disclosure was permissible." *Elec. Privacy Info. Ctr. V. U.S. Dep't of Homeland Sec., 777 F.3d 518, 522, 414 U.S. App. D.C. 151 (D.C. Cir. 2015)*.

III. ANALYSIS

A. The Privacy Exemptions

Most of the Parties' current dispute turns on FOIA's privacy exemptions. Those exemptions let agencies redact "names and identifying information" from "personnel and medical files" (Exemption 6) and "law enforcement" records (*Exemption 7(C)*) to prevent "unwarranted invasion[s] of personal privacy." *5 U.S.C. § 552(b)(6)* & *(b)(7)(C)*. IJ argues that the IRS has impermissibly redacted interview notes that cannot be used to identify any individual. Pl.'s Mot. at 13-19.[1] Those notes memorialized interviews between IRS Task Force Officers and bank employees and became part of the case files the IRS compiled on individuals who attempted to recover their assets. *Id.* at 14. The IRS largely sidesteps IJ's identification principle, focusing instead on its [*6] perceived obligation to redact any non-public information that is personal in nature. *See, e.g.*, Defs.' Opp'n & Reply 4, 7-8, ECF No. 53 ("Defs.' Opp'n"). IJ has the better argument.

Identification is the touchstone of FOIA's privacy exemptions. The Supreme Court has held that *Exemption 6* "cover[s] detailed Government records on an individual which can be identified as applying to that individual." *Dep't of State v. Wash. Post Co., 456 U.S. 595, 602, 102 S. Ct. 1957, 72 L. Ed. 2d 358 (1982)* (citation omitted). *Exemption 7(C)* sweeps more broadly, covering traditional examples of personally-identifiable information like "names, addresses, [and] dates of birth," as well as information whose "mosaic effect" may "lead to the identification" of "third parties." *BuzzFeed Inc. v. U.S. Dep't of Educ., 2019 WL 3718928, at *2 (D.D.C. Aug. 7, 2019)* (comparing cases).[2] But neither exemption authorizes agencies to withhold information that (either on its own or in combination with other disclosed information) cannot reasonably be used to identify a specific individual. *See Citizens for Resp. & Ethics in Washington, 746 F.3d at 1094* (agencies may not redact "all of the material in" a responsive record "solely on the grounds that the record includes some information which identifies a private citizen or provides that person's name and address"). Courts thus regularly require agencies to disclose information that some may deem personal, so long as strategic [*7] redactions are used to stop readers from linking those records to any particular person. *See Dep't of the Air Force v. Rose,*

[1] IJ concedes, as it must, that the government may redact information that can plausibly lead to the identification of individuals discussed in those interviews, like "names, addresses, social security numbers, birth dates, or bank account numbers." *See* Pl.'s Mot. at 14 (citing *Citizens for Resp. & Ethics in Wash., 746 F.3d at 1094*).

[2] When an agency justifies its redactions under both *Exemption 6* and *Exemption 7(C)*, "the Court need only address whether the agency has properly withheld . . . documents under" the lower bar, "*Exemption 7(C)*." *Braga v. FBI, 910 F. Supp. 2d 258, 267 (D.D.C. 2012)*.

425 U.S. 352, 380, 96 S. Ct. 1592, 48 L. Ed. 2d 11 (1976) (summaries of Air Force Academy disciplinary proceedings released "with personal references . . . deleted"); U.S. Dep't of State v. Ray, 502 U.S. 164, 169, 178 (1991), 112 S. Ct. 541, 116 L. Ed. 2d 526 (interviews between immigration officers and deported non-citizens released after redacting all names); Arieff v. Dep't of Navy, 712 F.2d 1462, 1467, 229 U.S. App. D.C. 430 (D.C. Cir. 1983) (released records listing prescription medications taken by unnamed members of Congress); New Orleans Workers' Ctr. For Racial Just v. U.S. Immigr. & Customs Enf't, 373 F. Supp. 3d 16, 63 (D.D.C. 2019) (immigration "case history" descriptions released without "personally identifying information"); BuzzFeed Inc., 2019 WL 3718928, at *2 (Title IX investigation letters released, which had language "too general to allow for identification of individuals involved").

In each case, the key question is not whether the "investigative details" described in an agency's records touch on personal matters in the abstract, but whether those details "would reveal the identity or otherwise implicate the privacy interests of any third party." Mays v. DEA, 234 F.3d 1324, 1327-28, 344 U.S. App. D.C. 194 (D.C. Cir. 2000). When an agency finds material likely to reveal the identity of a third party, it must redact that "specific information" and release the rest. Id. at 1327; *see also* Powell v. U.S. Bureau of Prisons, 927 F.2d 1239, 1242-43, 288 U.S. App. D.C. 384 (D.C. Cir. 1991). And to ensure that it does so, the agency must "provide[ ] a detailed justification and not just conclusory statements to demonstrate that all reasonably [*8] segregable information has been released." Sciacca v. FBI, 23 F. Supp. 3d 17, 26 (D.D.C. 2014) (citation omitted).

Here, the IRS has failed to show that it redacted no more than the information necessary to prevent readers from identifying third parties. For example, the IRS justifies its decision to fully redact 389 pages and partially redact another 785 documents with this: "[the following] information can be identified as applying to the petitioner(s) whose property was subject to seizure." *See* Decl. of William M. Rowe 42-47, ECF No. 49-1 ("Rowe Decl."). But the IRS does not limit its focus to personally identifiable information. *See id.* Instead, it withholds all information that it considers personal, like "financial records, criminal investigation history, driving history, child support obligations, and other personal factual information about petitioners' cases and backgrounds." Defs.' Opp'n at 7. The IRS has made essentially no effort to show that, once all personal identifiers are removed, the remaining information would lead readers to identify a particular person.

Of course, if the generic description of a crime is paired with a person's name or the date and location of an arrest, then the information (in combination) likely [*9] would identify a particular person. But the Court struggles to see how after names, dates, and locations are removed, readers could tie any one of the three-hundred-and-thirty million people in this Country to a general description of criminal history. The same is true of driving history, business history, or an anonymous history of divorce and child support obligations. Once all names, dates, times, locations, and traceable numbers are redacted, it is difficult to see how readers could link most of the information the IRS chose to redact to any specific person.

Consider the following hypothetical. Say the agency is about to redact the summary of an interview between IRS investigators and a person suspected of unlawfully structuring bank deposits. The summary might look like this:

> Cathy Ames said she served in the Air Force for ten years, and she had been retired since 2004. Since

her retirement, she has been working as a certified schoolteacher and teaches ballet lessons on the side. Ames said her divorce started in 2010 and was finalized in 2011. Before her divorce, she was married to Adam Trask for three years and has two sons from that marriage. Ames stated to investigators Sherlock [*10] and Holmes that she took 150,000 out of her bank account in 2009 because her marriage had started to sour, and she knew it would end in divorce. Ames stated that after the divorce, she began depositing the money into a new account with the Security Service Federal Credit Union in 9,999.00 increments to avoid filling out paperwork with the Credit Union. Investigators Sherlock and Holmes asked if Ames knew that she wasn't supposed to make small deposits to avoid reporting large transactions. Ames said she knew it wasn't right. But as she had served her country and earned the money, she thought she could do whatever she wanted with it. The investigators thanked Ames for coming to talk this matter through. And then ended the conversation with Ames and walked her to the door.

In this hypothetical interview, it is easy to see how the various names, dates, and account information might lead readers to identify the people involved. But the appropriate remedy is to redact those exempt pieces of information and release everything else. *Mays, 234 F.3d at 1327*; *see also Nation Magazine v. U.S. Customs Serv., 71 F.3d 885, 896, 315 U.S. App. D.C. 177 (D.C. Cir. 1995)*. Indeed, FOIA does not "permit[] an agency to exempt from disclosure all of the material in an investigatory record solely on the grounds that the [*11] record includes some information which identifies a private citizen." *Id.* Now consider the same interview with obvious identifiers removed:

> [TEXT REDACTED BY THE COURT] said she served in the [TEXT REDACTED BY THE COURT] for ten years, and she had been retired since [TEXT REDACTED BY THE COURT]. Since her retirement, she has been working as a certified schoolteacher [TEXT REDACTED BY THE COURT] lessons on the side. [TEXT REDACTED BY THE COURT] said her divorce started in [TEXT REDACTED BY THE COURT] and was finalized in [TEXT REDACTED BY THE COURT]. Before her divorce, she was married to [TEXT REDACTED BY THE COURT] for three years and has [TEXT REDACTED BY THE COURT] from that marriage. [TEXT REDACTED BY THE COURT] stated to investigators [TEXT REDACTED BY THE COURT] that she took [TEXT REDACTED BY THE COURT] out of her bank account in [TEXT REDACTED BY THE COURT] because her marriage had started to sour, and she knew it would end in divorce. [TEXT REDACTED BY THE COURT] stated that after the divorce, she began depositing the money into a new account with the [TEXT REDACTED BY THE COURT] Credit Union in 9,999.00 increments to avoid filling out paperwork with the Credit Union. Investigators [*12] [TEXT REDACTED BY THE COURT] asked if [TEXT REDACTED BY THE COURT] knew that she wasn't supposed to make small deposits to avoid reporting large transactions. [TEXT REDACTED BY THE COURT] said she knew it wasn't right. But as she had [TEXT REDACTED BY THE COURT] earned the money, she thought she could do whatever she wanted with it. The investigators thanked [TEXT REDACTED BY THE COURT] for coming to talk this matter through. And then ended the conversation with [TEXT REDACTED BY THE COURT] and walked her to the door.

Once names, dates, and obvious identifiers are removed, thousands, if not millions, of people potentially

fit the profile of this interviewee. But in the Court's *in camera* review of the disputed records, it was apparent that the IRS has redacted nearly every word of similar interviews, rather than strategically withholding identifying information and disclosing the rest. And by redacting information "too general to allow for identification of individuals involved," it overstepped its authority under FOIA. *See* BuzzFeed Inc., 2019 WL 3718928, at *2.

As the IRS reassesses its productions in light of this decision, the Court expects it to change course and limit its redactions to information likely to trigger [*13] the identification of a particular individual.[3] Should the IRS opt to redact more than personally identifiable information, it bears the burden of articulating the logical path a reader might take to link those additional pieces of information to a specific person, Citizens for Responsibility & Ethics in Wash., 746 F.3d at 1088, so it can show that it has released all "reasonably segregable" portions of records that contain some exempt material, 5 U.S.C. § 552(b).[4] If the agency fails to prove that it has released all non-exempt material not "inextricably intertwined with" exempt material, then IJ may seek further relief at a later stage in this litigation. Gatore v. Dep't of Homeland Sec., 327 F. Supp. 3d 76, 89 (D.D.C. 2018).

B. The Deliberative Process Privilege

IJ also challenges the IRS's decision to withhold forty pages in full and eleven pages in part under the deliberative process privilege. Pl.'s Mot. at 21-23 (discussing 5 U.S.C. § 552(b)(5)). The privilege exempts documents that are "predecisional" and "deliberative." Coastal States Gas Corp. v. Dep't of Energy, 617 F.2d 854, 866, 199 U.S. App. D.C. 272 (D.C. Cir. 1980). A document is predecisional when it contributes to "an agency decision or policy," Senate of the Commonwealth of P.R. v. U.S. Dep't of Justice, 823 F.2d 574, 585 (D.C. Cir. 1987), and it is deliberative when it "reflect[s] an agency's preliminary positions or ruminations about how to exercise discretion on some policy matter" or "policy-implicating judgment," [*14] Petrol. Info. Corp. v. U.S Dep't of the Interior, 976 F.2d 1429, 1435, 298 U.S. App. D.C. 125 (D.C. Cir. 1992). Assessing the "predecisional" and "deliberative" dimensions of an agency record helps courts answer the "key question" behind the deliberative process exemption: "whether disclosure would tend to diminish

[3] While the agency must adjust its redaction practices, it is not required to (as IJ requests) create anonymous identifiers for the officers or agents listed in its records. FOIA "does not obligate agencies to create or retain documents; it only obligates them to provide access to those which it in fact has created and retained." Kissinger v. Reporters Comm. For Freedom of the Press, 445 U.S. 136, 152, 100 S. Ct. 960, 63 L. Ed. 2d 267 (1980). Here, the case files IJ seeks do not contain anonymous identifying numbers for agency investigators. The IRS would have to create them. To support its request, IJ cites *Lahr v. National Transpiration Safety Board*. *See* Pl.'s Mot. at 23 n.10 (citing 453 F. Supp. 2d 1153, 1183-84 (C.D. Cal. 2006)). But in Lahr, the agency tried to withhold witness identification numbers that were already in the disputed records. The agency was not asked to create them from scratch. *Id.*; *see also* NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 162, 95 S. Ct. 1504, 44 L. Ed. 2d 29 (1975) ("[I]nsofar as the order of the court below requires the agency to create explanatory material, it is baseless.").'

[4] As the IRS has yet to show that releasing information that cannot be linked to any particular person implicates a privacy interest under 5 U.S.C. § 552(b)(6) or (b)(7)(C), the Court does not have occasion to balance the public's interest in learning more about how the IRS processes petitions to recover seized assets against any protected privacy interest. *See* Wilson v. DOJ, 42 F. Supp. 3d 207, 217 (D.D.C. 2014).

candor within an agency." *Id.* (citing *Access Reports v. Dep't of Justice, 926 F.2d 1192, 1195, 288 U.S. App. D.C. 319 (D.C. Cir. 1991)*).

The Court does not doubt that compelling the release of the documents withheld under the deliberative process privilege would diminish candor within the IRS. Consider each of the three types of records disputed here: First, emails exchanged between an IRS special agent and other IRS officials discussing talking points about "legislative proposals to codify certain policy changes made by the Service in structuring cases." *See* Rowe Decl. 33(b). Second, a draft version of the Treasury Inspector General for Tax Administration ("TIGTA") Report entitled "Fiscal Year 2016 Review of Compliance with Legal Guidelines When Conducting Seizures of Taxpayers' Property." *Id.* And, third, a draft letter to a congressman about how the IRS reviews petitions for remission or mitigation of seized assets and an email accompanying that letter. *Id.*

Turning first to the emails about talking points. To demonstrate that the emails are predecisional, the IRS must "identify [*15] a decisionmaking process to which the document contributed." *Judicial Watch v. U.S. Postal Serv., 297 F. Supp. 2d 252, 259 (D.D.C. 2004)*. IJ argues that the IRS is using the deliberative process privilege to shield Congress's legislative process. Pl.'s Reply Support Partial Cross-Mot. for Summ. J. 14 n.6, ECF No. 55 ("Pl.'s Reply"). The Court is not convinced.

Each email contains an agency employee's thoughts about what should and should not appear in a final set of talking points about several legislative proposals. Rowe Decl. 33(b); *see also* Tr. of Hr'g (forthcoming). An employee's thoughts about what the agency's position should be are not themselves a final statement of the agency's position. *Gold Anti-Tr. Action Comm., Inc. v. Bd. Of Governors of Fed. Reserve Sys., 762 F. Supp. 2d 123, 135 (D.D.C. 2011)* (noting that the agency need only describe "what deliberative process is involved, and the role played by the documents at issue in the course of that process"). In doctrinal terms, the emails are predecisional because they were part of the agency's process to develop its "opinions with respect to legislative proposals" and deliberative because the emails reflect the agency's ruminations about what policy stance it should adopt toward those proposals. Rowe Decl. 33(b). The IRS was thus entitled to withhold those emails.

The draft TIGTA Report was similarly "predecisional," [*16] as the draft was part of the deliberative process that led to the final report. Rowe Decl. 33(a)(3); *see also Abtew v. DHS, 808 F.3d 895, 898 (D.C. Cir. 2015)* ("A document is 'predecisional' if it precedes, in temporal sequence, the 'decision' to which it relates." (internal quotations and citations omitted)). IJ nevertheless contends that the IRS has failed to demonstrate that the draft report is deliberative because it does not reveal any "exercise of agency policy-oriented judgement." *See* Pl.'s Reply 16, ECF No. 55 (quoting *Petrol. Info. Corp., 976 F.2d at 1435*). Not so.

The draft report revealed "opinions" and "recommendations" about what facts the final report should contain. Rowe Decl. 33(a)(3). And the act of "culling out relevant" facts involves a deliberative "judgmental process which could be compromised by disclosure." *Petrol. Info. Corp., 976 F.2d at 1434-35* & n.6 (discussing *Montrose Chem. Corp. v. Train, 491 F.2d 63, 68, 160 U.S. App. D.C. 270 (D.C. Cir. 1974)*); *see also Nat'l Wildlife Fed'n v. U.S. Forest Serv., 861 F.2d 1114, 1119 (9th Cir. 1988)* (holding documents exempt because disclosure would reveal agency's evaluation of its preferred facts). The IRS has thus appropriately justified its decision to withhold the draft TIGTA Report. As for the draft letter to a congressman

and an email about that letter, IJ concedes that the records are predecisional, as they led to a final letter. Pl.s' Mot. at 23-24. But it contends that neither record is likely [*17] deliberative because the final letter (which IJ has already received) contains only "factual material." *Id.* at 23. The IRS responds by stressing that those records reflect the agency's internal "advisory opinions, recommendations and deliberations" about how to respond to a congressional inquiry. Defs.' Opp'n at 20 (quoting *Petrol. Info. Corp, 976 F.2d at 1433*).

The agency's internal deliberations about whether and how to respond to a congressman involve discretionary, policy-oriented judgment calls about which facts are responsive and most appropriate to disclose to another branch of government. *See Petrol. Info. Corp., 976 F.2d at 1434-35* & n.6. Moreover, the IRS has represented that its employees will be less likely to respond candidly and creatively when invited to comment on agency responses to congressional inquiries if their internal advisory opinions and drafts are subject to disclosure. *See* Tr. of Hr'g (forthcoming). Enabling and encouraging candor among agency actors is, of course, the primary objective of the deliberative process privilege. *Access Reports, 926 F.2d at 1195*. The IRS has appropriately withheld the draft congressional letter and accompanying email.

C. The *Bank Secrecy Act*

The Parties' dispute over records withheld under the *Bank Secrecy Act* is largely semantic. Under *5 U.S.C. § 552(b)(3)*, the IRS is empowered to withhold [*18] records that are "specifically exempted from disclosure by statute." And the Act specifically exempts currency transaction "reports and records of reports" from disclosure. *31 U.S.C. § 5319*. That exemption shields the information in currency transaction reports, even if the information is quoted in other agency documents. *Ortiz v. DOJ, 67 F. Supp. 3d 109, 118 (D.D.C. 2014)*.

IJ quibbles with the IRS's decision to withhold "references" to currency transaction reports in its internal memoranda. Pl.'s Mot. at 24-25. To be sure, "references" might include something other than information taken directly from a currency transaction report. *Cf. Davis v. FBI, 2019 U.S. Dist. LEXIS 111274, 2019 WL 2870729, at *6 (D.D.C. July 3, 2019)* ("[D]ocuments that involve [currency transaction] reports or records of reports . . . are not, strictly speaking, the same thing as actual reports or records of reports."). But the IRS has represented that it used the word "references" to refer to information taken directly from currency transaction reports, see Tr. of Hr'g (forthcoming), and the agency is entitled to the presumption that it made that representation in good faith, *Middle East Forum v. Dep't of Homeland Sec., 297 F. Supp. 3d 183, 186 (D.D.C. 2018)*. The Court thus concludes that the IRS has withheld information directly extracted or taken from currency transaction reports, and therefore its withholdings are permissible under *FOIA Exemption 3* and the [*19] *Bank Secrecy Act*. *See Ortiz, 67 F. Supp. 3d at 118*.

D. Exemption 7(E)

IJ argues that the IRS is redacting too much information under *FOIA Exemption 7(E)* as well. *Exemption 7(E)* shields records that "would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law." *5 U.S.C. § 552(b)(7)(E)*. The documents need not be made during an ongoing criminal investigation, but they must describe administrative or operational guidelines which, if disclosed, would help criminals circumvent the law. *See*

*Peter S. Herrick's Customs & Int'l Trade Newsletter v. U.S. Customs & Border Prot., 2006 WL 1826185, at *7 (D.D.C. June 30, 2006)*.

Here, the IRS redacted portions of a document that describes "guidelines and steps for processing [petitions for remission or mitigation] as well as guidance in corroborating the information submitted by the petitioner." Defs.' Reply 19, ECF No. 54 (discussing IFJ 0018-000500). The IRS says that disclosing those guidelines would enable "individuals seeking to circumvent structuring laws to operate in a manner that would avoid detection of their criminal activity." Rowe Decl. 48(a). The guidelines "describ[e] specific investigative techniques to be employed by Special Agents in structuring cases" and would "reveal the scope of investigative activity" so that disclosure would, at a minimum, help criminals [*20] avoid seizure by (as IJ acknowledges) concealing their identities. *Id.*; *see also* Pl.'s Reply 22. By identifying the specific laws (structuring laws) "that would be easier to violate if the information were released," as well as the way in which those laws would be easier to exploit, the IRS has adequately justified its withholdings under *Exemption 7(E)*. *Bloche v. Dep't of Defense, 370 F. Supp. 3d 40, 58 (D.D.C. 2019)*.

E. Production Rate

Finally, the Parties dispute the appropriate monthly production rate. Over two years ago, Judge Kollar-Kotelly noted that it would be inappropriate for productions to extend over multiple years. *See* Minute Order *dated* May 29, 2019. Nevertheless, productions drag on. At the present rate, the IRS will not finish producing records for several years. *See* Joint Status Report (April 30, 2020), ECF No. 52.

The IRS has been processing 1,000 pages per month for over a year-and-a-half. *See* Decl. of Elizabeth Hill 23, 43-47, ECF No. 36-1. During the intervening time, the IRS's FOIA caseload has dropped from 60 to 49 cases and the agency has added six additional attorneys to review that smaller caseload. Supp. Decl. of Jamie Song Decl. 13. The IRS has confirmed that all the remaining records are case files and decision letters related [*21] to individual petitions for remission or mitigation. *See* Tr. of Hr'g (forthcoming). And this Opinion affords the agency direct guidance about how to process those remaining petitions.[5] The Court is thus not persuaded that the IRS has submitted sufficiently "clear, specific, and reasonably detailed" justifications for continuing to process no more than 1,000 pages per month. *See Voinche v. FBI, 412 F. Supp. 2d 60, 64 (D.D.C. 2006)*.

Courts regularly direct agencies to process records at far higher rates than what the IRS has been held to here. *See, e.g., NRDC v. Dep't of Energy, 191 F. Supp. 2d 41, 43 n.5 (D.D.C. 2002)* (ordering the majority of 7,500 pages to be processed within thirty-two days); *Clemente v. FBI, 71 F. Supp. 3d 262, 269 (D.D.C. 2014)* (5,000 pages per month). And as the IRS's resources to process FOIA requests have substantially improved since the Court first granted its request to limit productions to 1,000 pages per month, the Court believes it is appropriate to require the IRS to now process 3,000 pages per month. After three months of

---

[5] As this Opinion provides specific guidance about the appropriate application of *FOIA Exemptions 3*, 5, 6(b), 7(C), and 7(E), the Court will not at this time order the IRS to refrain from using any particular exemption to withhold information in future productions. The Court trusts that the agency will exercise good faith and comply with the Court's directives. But IJ is welcome to press for further *in camera* review if the agency deviates from the Court's guidance. *See* Pl.'s Reply at 23-24.

processing records at that higher pace, the IRS may submit a status report detailing the consequences of complying with its new production rate. At that point, the Court will reevaluate the agency's production schedule and decide whether any adjustment is warranted.

CONCLUSION

For the foregoing [*22] reasons, the Parties' Motions for Summary Judgment, ECF Nos. 49, 50, are granted in part and denied in part. An appropriate order will be entered contemporaneously with this Memorandum Opinion.

DATE: July 8, 2021

/s/ Carl J. Nichols

CARL J. NICHOLS

United States District Judge

ORDER

For the reasons stated in the accompanying Memorandum Opinion, ECF No. 58, it is hereby

ORDERED that the Parties' Motions for Partial Summary Judgment, ECF Nos. 49, 50, are **GRANTED IN PART** and **DENIED IN PART**; it is further

ORDERED that Defendants reassess previous and ongoing productions in light of this decision; it is further

ORDERED that Defendants shall process a minimum of 3,000 pages per month, and, after three months of processing records at that pace, Defendants may submit a status report detailing the consequences of complying with that production rate.

DATE: July 8, 2021

/s/ Carl J. Nichols

CARL J. NICHOLS

United States District Judge

End of Document