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

BRIEF IN SUPPORT OF TIMELY PRODUCTION

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Plaintiff, Public Health and Medical Professionals for Transparency ("**PHMPT**"), by and through its attorneys, Siri & Glimstad LLP, respectfully submits this brief in support of prompt and timely production of the documents submitted by Pfizer Inc. ("**Pfizer**") to the U.S. Food and Drug Administration (the "**FDA**") to license its COVID-19 vaccine (the "**Pfizer vaccine**").

PRELIMINARY STATEMENT

A minimum of 20,010 days (54 years and 10 months). That is how long the FDA proposes to take, at a rate of 500 pages per month, to produce only a portion of the documents in its file for the COVID-19 Pfizer vaccine that PHMPT requested pursuant to the Freedom of Information Act (the "**FOIA Request**") and 21 C.F.R. § 601.51(e). But when it came to reviewing those same documents to license this product so that Pfizer could freely sell it to the public, the FDA took **just 108 days**. It took the FDA's parent department even less time to grant Pfizer complete immunity to liability for injuries from this product, and it took a stroke of the President's pen to mandate this product for federal employees, the private sector and military personnel.

The federal government mandating that millions of people be injected with a liability-free vaccine requires complete government transparency – not the government's suppression of information. PHMPT is comprised of independent scientists working at some of our nation's premier institutions, and all they are seeking is the data the FDA has already reviewed concerning the Pfizer vaccine in order to provide the necessary peer review. The FDA knows that they, and other independent scientists, cannot properly analyze that data until it is all released. Yet, the FDA wants to wait until most of those scientists are long since dead to fully release the data. News outlets, politicians, and scientists have called the FDA's position "outrageous." They are correct.

The entire purpose of FOIA is government transparency. In multiple recent cases, in upholding the FOIA's requirement to "make the records promptly available," courts have required

agencies, including the FDA, to produce 10,000 or more pages per month, and those cases did not involve a request nearly this important – *i.e.*, the data underlying licensure of a liability-free product that the federal government requires nearly all Americans to receive. As the present pandemic rages on, independent review of these documents by outside scientists is urgently needed to assist with addressing the shortcomings and issues with the response to the pandemic to date.

The context surrounding PHMPT's FOIA request is truly unprecedented, and the request should be treated as such. Historically, there has been no consumer product that the federal government has mandated Americans to receive. Now, it has mandated Pfizer's vaccine to private sector employees, federal employees, the military, and more. States have done the same at the urging of the federal government, extending mandates for people to enter schools, universities, restaurants, and public venues, among other places. A majority of Americans are now mandated to receive this product under penalty of losing a job or worse. This is truly unparalleled in the nation's past. There has never been such a large-scale mandate of any product for society, let alone one that is injected into people. Even school mandates under state laws have almost always included an easy to obtain exemption. The current inability to say "no" to injecting a product into one's body absent serious consequences dictated by the government is truly unprecedented.

Making this even more unprecedented is that Americans, if injured, cannot sue Pfizer and otherwise have no recourse. There is virtually no other product where a consumer is prohibited from suing the company that manufactures, markets, and profits from the product. Decoupling a company's profit interest from its interest in safety is a moral hazard, and a departure from centuries of product liability doctrine. Yet we find ourselves in this truly extraordinary circumstance where not only must Americans take this product under penalty of expulsion from work, school, the military and civil life, but they cannot sue Pfizer for any resulting injuries.

And who has created this unprecedented situation? The Executive Branch, normally with little or no input from the other branches. It has granted the immunity, licensed the product, and aggressively implemented or demanded mandates. This therefore requires *unprecedented* transparency. When Americans cannot say "no" and cannot sue Pfizer for harm, then the FDA should also not be able to say "no" to forthwith releasing the Pfizer vaccine data. If the administration wants Americans to be subject to its mandates, Americans must at least be granted the dignity of access to the data supposedly supporting the safety and efficacy of Pfizer's liability-free vaccine so that independent scientists can conduct a timely review.

Even President Joe Biden, when truth was original to him as candidate Joe Biden, on January 28, 2020, told the American people that, "**You'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**." (App000338 ¶ 2.) On September 7, 2020, on national television, he stated:

> 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.**

(App000338 ¶ 3.) And then he again said to the American people that we need "**total transparency so scientists outside the government know exactly what is being approved**." (App000339 ¶ 4.) Fifteen U.S. Senators, all caucusing Democrats, similarly stated as follows in a letter to the FDA:

> **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**. … 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 … make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public**.

(App000339 ¶ 8.) Numerous Republicans have also demanded immediate release of the documents. For example, Congressman Ralph Norman recently stated:

> 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.

(App000339 ¶ 9.) Senator Ted Cruz called the FDA's position "Completely outrageous." (App000340 ¶ 10.)

The transparency sought by politicians is consistent with well-established norms in the scientific community and with the purpose of FOIA; but that purpose will be utterly frustrated unless the data is released now**, in its entirety**, to the public. Releasing this data, so independent scientists can review it, is akin to getting a second opinion from a doctor, or a peer review of a scientific paper. Every day that passes without this data's release is another day that the American people are deprived of this basic transparency and review.

The FDA does not dispute that it should produce these documents. Rather, it proposes doing so at a rate so slow that the documents will not be fully produced until almost all of the scientists, attorneys, and most of the Americans that received Pfizer's product, will have died of old age. The FDA's excuse? It cries it does not have the resources. Considering how many taxpayer dollars this administration has spent on its COVID-19 response, the FDA cannot now claim it lacks the money to timely conduct its review. This excuse is a red herring that just adds insult to the liberty-crushing approach the FDA and administration have taken with this product.

The Executive Branch gave Pfizer $1.95 billion in taxpayer funds to promote development of its vaccine through an advance-purchase agreement. (App000340 ¶ 11.) It then paid Pfizer more than $15.7 billion collected from the American people to purchase that product. (App000340-App000341 ¶¶ 12-16.) Thereafter, it spent $18.75 billion more of the American people's money promoting that product. (App000341 ¶¶ 17-19.) Yet, when it comes to being transparent with those same American people, the FDA claims it cannot muster the resources to timely produce the same documents it reviewed for licensure in 108 days. Just as the government found the resources for Operation Warp Speed, it must now do the same to produce these critical documents with the same warp speed. How about the federal government spend just 0.1% of the taxpayer money it has given Pfizer – that would be at least $17.6 million – a pittance compared to the billions given to Pfizer and more than sufficient to hire enough reviewers to timely produce the documents. Companies in private litigation produce hundreds of thousands of pages per month in discovery, reviewing each document for privilege, etc. But yet the vast federal government, on an issue this important, claims it cannot find the resources. A product the administration says everyone must take under penalty of exclusion from American life and for which they cannot even sue Pfizer if injured! Whose interests is the executive branch protecting, the American people or its own?

Reflecting that the FDA can, in fact, produce documents at a far greater rate than 500 pages per month, on December 1, 2021, in an effort to avoid the hearing with this Court, it offered to produce approximately 12,658 pages, 4 .txt files, and 4 SAS files within a period of 61 days if PHMPT would agree to thereafter only receive 500 pages per month. (App000341 ¶ 20.) The FDA does not appear to recognize the gravity of its ethical breach to the American people in playing these games.

The pandemic is continuing to spiral. Despite over 83% of adults having received a COVID-19 vaccine (App000341 ¶ 21), **cases are on the rise in the most vaccinated states** (App000342 ¶ 22), **variants that evade vaccine immunity are rising** (App000342 ¶ 24), **the CDC has admitted the COVID-19 vaccines do not prevent transmission** (App000342 ¶ 23), **the number of breakthrough cases is increasing exponentially** (App000342 ¶ 25), **and boosters are now needed for everyone and will likely continue to be required every six months, if not more frequently** (App000342 ¶ 26), among numerous other issues with the vaccine program.

America has some of the greatest institutions of learning and research the world has ever known. We need all these hands on deck, both inside and outside the government, to address these serious, ongoing issues, and failings within the vaccine program. Locking out independent scientists from addressing these issues is dangerous, irresponsible, and unethical. The FDA, in both the prior and current administration, has never been free of political pressure when conducing its work and it has also been widely promoting this vaccine to the public, including before it was licensed. This all raises questions about the licensure process and whether the FDA will admit mistakes or failings of the same product, mistakes and failings that will only be identified through outside review. America needs independent scientists, like the ones from our premier universities and medical centers comprising Plaintiff, to review this data and assist with offering solutions and addressing these issues. Not 55 years from now or longer. **But today.**

BACKGROUND

A. The Need for the Transparency as Promised by Pfizer, White House, and FDA

Pfizer itself acknowledges the need for "Transparency in Clinical Trials." (App000342 ¶ 27 (Pfizer's policy statement from December 2019 explaining its "commitment to openness and transparency" including in "all aspects of research and development behind our products, including clinical trials."). *See also* App000342 – App000343 ¶ 28.) Similarly, the U.S Institute of Medicine

consensus study emphasized "that verification and replication of investigators claims [in clinical trials] were essential to the scientific process" and results in "numerous benefits to … patients, their physicians and researchers." (*Id.* (internal quotations eliminated).)

Likewise, as quoted *supra*, numerous U.S. Representatives and Senators, and the White House and FDA leadership, have all called for transparency; as Presidential candidate Joe Biden, told the American people: "You've got to make all of it [the vaccine data] available to other experts across the nation so they can look and see." (App000338 – App000340 ¶¶ 2-4, 8-10.)

These call for transparency is consistent with well-established norms in the scientific community. As explained by a PHMPT member who is also a member of the World Health Organization's COVID-19 Infection Prevention and Control Working Group:

> The importance of independent review of data in science cannot be overstated. Science is never static. … Censorship and lack of transparency have always been the enemies of progress. … 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.

(App000108 ¶ 17.) As explained by another PHMPT member, a full professor of epidemiology at Yale School of Public Health and Yale School of Medicine, Dr. Harvey Reich: "Absent an independent review, the nation is dependent on one body's review," that of the FDA. (App000008 ¶ 10.) He explains this is concerning because the FDA was "under tremendous political pressure [to license the Pfizer vaccine], which shortened the typical review process, making it impossible to carry out all analyses that are typically carried out." (*Id.*) Hence, he continues, "[a]llowing the Pfizer vaccine data to be made 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." (App000009 ¶ 12.)

Dr. Reich continues that: "Independent scientists and epidemiologist … need this data

sooner rather than later… 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… 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." (App000011 ¶ 16.)

B. PHMPT Formed to Disseminate the Promised Vaccine Data

PHMPT is a not-for-profit with more than 75 members, including professors at major universities, public health professionals, medical doctors, scientists, and journalists, and current and former WHO and HHS COVID-19 advisory group members. (App000002 ¶ 3.)

PHMPT exists for the sole purpose of making public the data in the biological product files for each licensed COVID-19 vaccine. (App000003 ¶ 5.) Many of its members, who include journalists, are primarily engaged in disseminating information to the public. (App000002 ¶ 4.) Through its members and website, PHMPT intends to disseminate to the public all records it receives. (App000003 ¶ 7.)

C. FDA Approval of the Pfizer Vaccine

On August 23, 2021, the FDA approved the Pfizer vaccine. (App000343 ¶ 29). Despite the promise of transparency, not a single page submitted by Pfizer to the FDA was released to the public. (App.000008 ¶ 10.) This is hindering the nation's response to the pandemic and, as President Biden and others predicted, has led to skepticism regarding this product.

On the one hand, prominent figures in the media, politics, and public health fields have sought to reassure the public that the data evaluated by the FDA was sufficient for licensure. For example, Dr. Peter Marks, the Director of FDA's biologics/vaccine division stated that

> [the FDA's] scientific and medical experts conducted an incredibly

> thorough and thoughtful evaluation of [the Pfizer vaccine]. We 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[.]

(App000343 ¶ 29.). Dr. 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." (*Id.*)

On the other hand, numerous prominent scientists have questioned the sufficiency of the data submitted by Pfizer and the adequacy of the FDA's review to license its vaccine. For example, on June 1, 2021, a group of 27 clinicians and scientists, including professors from Harvard Medical School, and members of PHMPT, filed a Citizen Petition 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." (App000343 ¶¶ 30-31.) Similarly, Professor Peter Doshi, a senior editor at The British Medical Journal and a PHMPT member, has publicly questioned the adequacy of the data the FDA relied on for licensure and the lack of transparency in the vaccine approval process. (App000343 ¶¶ 32-33.)

Incredibly, the FDA even denied the public the opportunity to hear discussion about the data and to offer public comment by not convening its public advisory committee, the Vaccines and Related Biological Products Advisory Committee, to discuss licensure. (App000343 ¶ 34.)

D. <u>Mandates Abound While the FDA Hides the Data</u>

While hiding Pfizer's data from the public, the federal executive has pushed an agenda to make it impossible to participate in American society without receiving the Pfizer vaccine. This includes mandates by the federal executive for private sector employees, public sector employees, health care professionals, federal contractor employees, military personnel, and certain air

travelers. (*See, e.g.*, App000344 ¶¶ 35-37.) Mandates have also been instituted by state and local governments at the urging of the federal government on university students, customers at retail stores, diners at restaurants, and virtually dozens of other everyday locations visited in the normal affairs of American life. (*See, e.g.*, App000344 ¶¶ 38-39.) Many more are expected to follow suit. (*See, e.g.*, App000344 – App000345 ¶ 40.)

Some mandates now require three doses of Pfizer's vaccine, and the number of doses Americans must receive to simply keep their job and otherwise engage in civil society is only expected to increase over time. (App000342 ¶ 26.) What makes this all the more incredible is that Pfizer's vaccine does not prevent infection and transmission. (App000342 ¶ 23.) Meaning, at best, Pfizer's vaccine provides personal protection, akin to taking statins. We may want people to take their heart medicine, but we don't mandate them to do so. That is simply authoritarian.

E. <u>If the Above Is Not Enough, the Federal Government Granted Pfizer Immunity</u>

While hiding Pfizer's data from the public, the federal government granted Pfizer, and anyone associated with administering its vaccine, complete legal immunity for any injury caused by its vaccine. 42 U.S.C. § 247d-6d (providing that any "manufacturer" of "any vaccine, used to … prevent or mitigate COVID-19" shall be "immune from suit and liability under Federal and State law with respect to all claims … resulting from … [its] use by an individual"). Pfizer is even immune from liability for willful misconduct unless the federal government, which promoted and licensed this product, first brings this claim. *Id.* So, to be clear, Americans are forced to receive Pfizer's product, but if injured, they cannot sue anyone associated with this vaccine, yet the government is refusing to permit outside scientists to review the data supporting its safety.

F. <u>PHMPT's FOIA Request</u>

On August 27, 2021, just four days after the FDA approved the Pfizer vaccine, PHMPT submitted the FOIA Request to the agency, seeking the following documents:

> 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.

(App000345 ¶ 41.) 21 C.F.R. § 601.51(e) lists the "data and information in the biological product file" that is supposed to be "**immediately available for public disclosure**" after the FDA licenses a vaccine. (emphasis added). That data and information includes, *inter alia*, "[a]ll safety and effectiveness data and information[,]" "[a] protocol for a test or study" of the vaccine, "[a]dverse reaction reports," and "[a]ll correspondence and written summaries of oral discussions relating to the biological product file[.]" 21 C.F.R. § 601.51(e)(1)-(8). On August 31, 2021, the FDA assigned the FOIA Request case number 2021-5683. (App000345 ¶ 43.)

As part of its FOIA request, PHMPT requested expedited professing pursuant to 5 U.S.C. § 552 (a) (6)(E)(v)(II). On September 9, 2021, the FDA denied PHMPT's request (the "**Denial Letter**"). In the Denial Letter, the FDA stated in relevant part:

> 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. (App000345 ¶ 44).

G. FDA Proposes to Process the Documents Over the Next 55-plus Years

On November 15, 2021, the parties submitted a Second Joint Report to the Court. (Dkt. No. 20.) Therein, the FDA reported "that there are more than 329,000 pages potentially responsive to Plaintiff's FOIA request." (*Id.* at p. 3.) This page count does not include other files, "typically containing data in a format similar to a spreadsheet." (*Id.*). In order to produce those responsive documents, the "FDA propose[d] to process and produce the non-exempt portions of responsive records at a rate of 500 pages per month." (*Id.* at p. 4.) At that rate, it will take the FDA at least **54 years and 10 months** to produce all the responsive documents – not exactly meeting the FOIA

statute's requirement that the agency "shall make the records promptly available." 5 U.S.C. § 552(a)(3)(A). The FDA's proposed schedule is tantamount to a denial of the FOIA Request.

PHMPT therefore asked the Court to direct the FDA to produce all responsive documents by no later than March 3, 2022. (Dkt. No. 20 p. 9.) "This 108-day period [from the date the Joint Report was filed] 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." (*Id.*) In response, the Court ordered a scheduling conference for December 14, 2021, and directed the parties to file briefs or appendices that could "assist the Court in its preparation for the" conference. (Dkt. No. 21.)

In the more than three months since PHMPT submitted the FOIA request, the FDA has produced only an index of documents, 1 txt file, 1 xpt file, and 339 pages of information, most of which concerned the principal investigators for the Pfizer vaccine trials, information that was already publicly available on the clinicaltrials.gov website. Counsel for the FDA has also recently advised PHMPT's counsel that in addition to the 329,000+ pages, there are an additional "approximately 39,000 pages" plus "ten of thousands of additional pages" plus hundreds of spreadsheets and the FDA will treat each twenty lines in each spreadsheet as one page. (App000345 ¶ 45.) Meaning, the FDA's position is that the independents scientists can review the data but they will just have to wait until long after they are all dead.

ARGUMENT

I. THE REQUEST QUALIFIES FOR EXPEDITED REVIEW AND PRODUCTION

"The FOIA was enacted to 'pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny.'" *Batton v. Evers*, 598 F.3d 169, 175 (5th Cir 2010) (quoting *Dep't of the Air Force v. Rose,* 425 U.S. 352, 361 (1976)). And courts have long acknowledged that "'stale information' produced pursuant to FOIA requests 'is of little value.'" *Huddleston v. Fed. Bur. of Investigation*, No. 4:20-CV-447, 2021 WL 327510, at *3 (E.D. Tex.

Feb. 1, 2021) (quoting *Payne Enterprises v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988)). *See also Open Soc'y.*, 399 F. Supp. 3d at 164 ("Congress has long recognized that 'information is often useful only if it is timely' and that, therefore 'excessive delay by the agency in its response is often tantamount to denial.'" (*quoting* H.R. Rep. No. 93-876, at 6271 (1974)). That is why Congress amended the FOIA statute in 1996 to mandate expedited processing of important FOIA requests.

Here, PHMPT is unquestionably entitled to the information sought in the FOIA Request because the FDA's own regulations require the information to be "immediately available" to the public. 21 C.F.R. § 601.51(e). *See also Pub. Citizen Health Research Group v. F.D.A.*, 964 F. Supp. 413, 414 (D.D.C. 1997) (finding that data submitted for drug licensure had to be disclosed under FOIA because "[o]nce an approval letter has been sent, certain data and information are immediately available for disclosure"). The question is how quickly the FDA will produce those documents. Given the clear national importance, this Court should direct that all responsive documents be produced within 108 days of November 15, 2021.

1. The Standard For Reviewing Requests to Expedite

FOIA provides for "expedited processing of request for records" when there is a "compelling need." 5 U.S.C. § 552 (a)(6)(E). The statute states that a compelling need includes: "**with respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity**." *Bloomberg, L.P. v. United States Food and Drug Admin.*, 500 F. Supp. 2d 371, 376-77 (S.D.N.Y. 2007) (quoting 5 U.S.C. § 552 (a)(6)(E)(v)); *Citizens for Responsibility and Ethics in Washington v. U.S. Dept. of Justice*, 436 F. Supp. 3d 354, 358 (D.D.C. 2020) (applying the same standard). The FDA's regulations contain the same definition of when a compelling need exists. 21 C.F.R. § 20.44 (a). "'Unlike the review of other agency action that must be upheld if supported by

substantial evidence and not arbitrary or capricious, the FOIA expressly places the burden on the agency to sustain its action and directs the district courts to determine the matter de novo.'" *Avondale Indus., Inc. v. N.L.R.B.*, 90 F.3d 955, 958 (5th Cir. 1996) (quoting *United States Dept. of Justice v. Reporters Committee*, 489 U.S. 749, 755 (1989)). *See also Bloomberg, L.P.*, 500 F. Supp. 2d at 374 ("The Court reviews agency decisions, including those regarding expedited processing of FOIA requests, *de novo.*").

2. PHMPT's Request Must be Expedited

There is no question PHMPT is "primarily engaged in disseminating information" because, as explained on its website, it "exists solely to obtain and disseminate the data relied upon by the FDA to license COVID-19 vaccines" and that "[a]ny data received will be made public on this website." (App000003 ¶¶ 5, 7.) *See also Bloomberg, L.P.*, 500 F. Supp. 2d at 378 (holding that the "inability of the general public to understand the raw data submitted by the drug manufacturers" has no bearing on the urgent need to produce that data).

As for showing an "urgency to inform the public concerning actual or alleged Federal Government activity," PHMPT's request easily meets this standard. 5 U.S.C. § 552 (a)(6)(E)(v). In answering this question, "[c]ourts must consider at least the following three factors …: (1) 'whether the request concerns a matter of exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns federal government activity.'" *Bloomberg, L.P.*, 500 F. Supp. 2d at 377 (quoting *Al-Fayed v. C.I.A.*, 254 F.3d 300, 310 (D.C. Cir. 2001)). The FDA's FOIA regulations present a similar tripartite analysis, and ask whether: (1) "[t]here is an urgent need for the requested information[,]" (2) the information "has a particular value that will be lost if not obtained and disseminated quickly[,]" and (3) "[t]he request … specifically concerns identifiable operations or activities of the Federal Government." 21 C.F.R. § 20.44(c)(2)-(3). PHMPT's FOIA

Request satisfies both of these tests.

i. Urgent Need for Independent Review of Pfizer Vaccine Data

Independent review of Pfizer's vaccine data is a matter of current "exigency to the American public." *Bloomberg, L.P.*, 500 F. Supp. 2d at 377. There can be no question that the FDA's approval of Pfizer's vaccine, and its safety and efficacy, is one of the most covered news stories of the last decade. The need for rapid independent review of the data Pfizer submitted to the FDA is central to this story, and disseminating this data is PHMPT's *raison d'etre*.

As discussed above, there exists unanimity from all quarters for the need for transparency and independent review of the clinical trial data. Pfizer has made fostering transparency with regard to clinical trial data part of its corporate policy, as have U.S. and European pharmaceutical trade organizations. (App000342 – App000343 ¶¶ 27-28.) The U.S. Institute of Medicine has made the same endorsement. (App000342 – App000343 ¶ 28) As has the FDA itself, when it acknowledged not only the need to disclose data relied upon for licensure, but that it be released straightaway. That is why FDA regulations provide that "[a]fter a license has been issued, the … data and information in the biological product file are **immediately available for public disclosure** unless extraordinary circumstances are shown. . . ." 21 C.F.R. § 601.51(e) (emphasis added).

With respect to the Pfizer vaccine in particular, as quoted *supra*, numerous politicians have called for greater transparency concerning the FDA's approval of the Pfizer vaccine. As noted, even the current President of the United States has repeatedly urged the government to "**make all of it [the vaccine data] available to other experts across the nation.**" (*See* App000338 ¶ 2 (emphasis added).) Nor has the President retreated from this rhetoric, imploring during a "Global COVID-19 Summit" in September 2021 that the nations of the world must "exercise transparency to build vital public trust in these lifesaving tools." (App000339 ¶ 6.)

Transparency is critical because "[i]ndependent review is essential to scientific integrity." (App000163 ¶ 25.) "Professionals working in the scientific and healthcare professions all seek second opinions." (App000009 ¶ 12.) Likewise, the "[c]ollective 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." (App000011 ¶ 16.) With regard to the Pfizer vaccine, the need for peer review is even more acute because of the "drastically shorted regulatory approval process" that the FDA undertook to rush the Pfizer vaccine to licensure. (App000009 – App000010 ¶ 14.) "It is nearly impossible that the FDA could have done everything it typically does in its review of a vaccine in the short time period within which Pfizer's vaccine was reviewed and approved." (*Id.*)

For true independent analysis to occur, half-measures will not do. "Scientists and healthcare professionals need **all** of the documents submitted by Pfizer to conduct a proper analysis" since missing even a single dataset could throw off any analysis. (App000162 ¶ 21. *See also* App000008 ¶ 10.) This is because "[a]ll scientific analyses rely on **complete** sets of information[.]" (App000162 ¶ 21.) "Attempting to recreate analyses on efficacy or safety without all the relevant data – data already limited by the short time period of the [Pfizer vaccine] trials – would prove useless." (App000009 ¶ 11.) As such, even though the FDA proposes a rolling production, that will do nothing to expedite the independent review.

The urgent need for the FDA to release the data sought by PHMPT can be seen from the media's shocked reaction to the FDA's request in this case to take 55 years to respond to the FOIA Request. For example, Reuters published an article titled: "Wait what? FDA wants 55 years to process FOIA request over vaccine data," and other media outlets have expressed similar surprise and often outrage that it would take so long to release the Pfizer data. (App000339 ¶ 7.) Furthermore, the shock was not confined to domestic media.

Independent review of the data is precisely what PHMPT is seeking here. It filed the FOIA Request within days of the FDA approving the Pfizer vaccine. The organization's website states that it "takes no position on the data other than that it should be made publicly available to allow independent experts to conduct their own review and analyses." (App000003 ¶ 5.) To achieve this goal, the site states that "[a]ny data received will be made public on this website."

ii. The Value of Independent Review is Lost if Not Done Forthwith

Time is of the essence with regard to reviewing the data sought in the FOIA Request. (App000011 ¶ 16.) Governments, employers, and individuals are making decisions every day regarding the Pfizer vaccine. The longer it takes the FDA to produce documents responsive to the FOIA Request, the more of those decisions will be made without the benefit of any independent review of the Pfizer data. The best way to improve decision making and otherwise reassure Americans about the decisions being made is to have independent review of the Pfizer data. Thus, the value of the information decreases every day that the FDA delays in producing the full data set.

In many ways, what is occurring is unprecedented. "An estimated 9.5 billion doses [of the COVID-19 vaccines] have been administered thus far making it the largest medical intervention in the history of humankind." (App000107 ¶ 14.) Not only are the COVID-19 vaccines unparalleled in scale, the way in which that scale has been achieved is also unprecedented. There is no other consumer product that the federal government has ever mandated that millions of Americans receive in order to earn a living.

The unprecedented nature of these mandates have been met with skepticism and protests. According to a tracking poll by Morning Consult, as of mid-November 2021, 27% of the respondents in the United States were either uncertain or unwilling to be vaccinated. Of those respondents, 48% were skeptical about being vaccinated because they were either "worried the

clinical trials moved too fast" (29%), do not "think the vaccine will be effective" (9%), or do not "trust the companies making vaccines" (10%). Having multiple trusted independent authorities review the safety and effectiveness data sought in the FOIA Request, which is what PHMPT intends, will almost certainly play a role in how these people evaluate their vaccine decisions. (*See* App000342 ¶ 27 (Pfizer policy statement noting that transparency of clinical trial data "fosters trust"); App000342 – App000343 ¶ 28 ("In a time of increasing public scrutiny, transparency of regulatory decision making leading to the approval of … vaccines for COVID-19 is important to ensure patient and stakeholder trust.").)

Furthermore, skepticism regarding the Pfizer vaccine is not unfounded, nor is it confined to the general populous. Prominent members of the scientific community have raised serious concerns regarding its clinical trials, its safety and efficacy, and the FDA's drastically abbreviated licensing process. "There has never been a vaccine approved [by the FDA] in such a short time period." (App000009 – App000010 ¶ 14.) The abbreviated schedule led researchers to question everything from the adequacy of the data the FDA relied on to whether the FDA permitted Pfizer to use fewer test subjects than would normally be required. In an article published last month in the medical journal "BMJ Evidence-Based Medicine," its five authors noted that there "are issues in COVID-19 vaccine trials that merit scrutiny" and then went on to discuss some of those unresolved issues in detail. (App000342 – App000343 ¶ 28.) Other scientists have noted that adverse reactions in VAERS and other data signal tremendous issues with the safety of the Pfizer vaccine. (*See, e.g.*, App000162 – App000163 ¶ 23 ("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.").)

Further contributing to the unprecedented nature of the situation is that Americans, if injured, cannot sue Pfizer, the FDA, or the doctors that administer the vaccines. 42 U.S.C. § 247d-6d. There is almost no other product where an injured consumer cannot sue the company that makes, sells, and profits from the product. Thus, consumers, who in many cases are being mandated by the government to receive the COVID-19 vaccines, have no way to be compensated if they are injured nor do they have any way to force the manufacturer to improve the safety of the product.

This extraordinary state of affairs leads to an **unprecedented** need for transparency. *See Bloomberg, L.P.*, 500 F. Supp. 2d at 378 (holding that the need for the public to have information collected by the FDA disseminated widely and reviewed by independent experts was a major factor in the need for expedited production). Currently, the only entities that have reviewed the full data are Pfizer and the FDA, both of which are immune from suit and are under enormous political pressure to deliver vaccines quickly. If Americans cannot say no and cannot sue for harm, then the safety and efficacy of the vaccines must be put through the most rigorous review possible. In the scientific and healthcare fields, rigorous review means independent peer review.

Nevertheless, peer review will be meaningless if it cannot happen for another 55 years. Even if delayed one year from now, the value of the review will be lost because the pandemic and technology will have moved on. That is why rapid production of all the documents within 108 days, at most, even if unprecedented, is necessary. Governments, employers, and individuals are making decisions about the vaccines every day and the data can potentially shape how we move forward in continuing to combat an ongoing global pandemic.

iii. The FDA's Approval of the Pfizer Vaccine is Government Activity

The FOIA Request also meets the third factor required for a showing of urgent need because the information PHMPT seeks concerns actual federal government activity. It involves the sufficiency and accuracy of the review the FDA conducted to license the Pfizer vaccine, and more broadly, the central role HHS – FDA's parent department – played in developing, testing, and promoting Pfizer's vaccine. As such, there is no reasonable argument that PHMPT's FOIA Request seeks anything other than documents concerning "identifiable operations or activities of the Federal Government." 21 C.F.R. § 20.44 (c)(2)-(3).

II. THE FDA'S POSITION IS IRRATIONAL AND HIGHLY CONCERNING

The FDA claims it has identified over 329,000+ pages of documents, in addition to data, that are responsive to the FOIA Request. (Dkt. No. 20 p. 3.) Nevertheless, it proposes to produce just 500 pages every month for nearly 55 years before it will fully produce the documents. None of the FDA's arguments for this position in the parties Second Joint Report justifies its patently irrational proposal to produce documents over the course of the next five *decades*! And none of its arguments acknowledge the most obvious factor: the importance and unprecedented nature of the documents at issue. Each of the FDA's arguments are addressed in turn.

1. The FDA Has the Resources to Expeditiously Produce all Responsive Documents

The FDA's first argument for wanting to take decades to produce is that its FOIA office does not have the capacity to produce the documents any faster. This argument is specious on numerous levels. First, while the FOIA office itself may only have a few employees, the FDA has 18,062 employees as of 2020. (App000339 ¶ 5.) For expedited productions, courts regularly instruct agencies to redirect resources, or to acquire new resources, in order to expeditiously produce documents. *E.g., Diocesan Migrant & Refugee Services, Inc. v. United States Immigration and Customs Enf't*, No. EP-19-CV-00236-FM, 2021 WL 289548, at *4 (W.D. Tex.

Jan. 28, 2021) (nothing that by using software programs, and reassigning personnel to the task, ICE was able to review 86,000 potentially responsive documents within four months in order to meet the court's production deadline); *Open Soc'y. Justice Initiative v. Cent. Intelligence Agency*, 399 F. Supp. 3d 161, 169 (S.D.N.Y. 2019) (requiring the Department of Defense to produce documents at a rate of 5,000 pages a month, "even if meeting this demand calls upon DOD to augment, temporarily or permanently, its review resources, human and/or technological").

Furthermore, the FDA's claimed lack of resources rings hollow in the face of the fact that the public has paid enormous sums to develop, manufacture, and market the Pfizer vaccine, and the public is statutorily entitled to see what it is getting for its money. This includes giving Pfizer $1.95 billion of taxpayer money to promote development of its vaccine and then an additional $15.7 billion of taxpayer money to purchase this product. Beyond the money directly handed to Pfizer, federal health authorities spent $18.75 billion of taxpayer money promoting this product. Thus, federal health authorities have had no issue with rapidly spending in total at least $35 billion of American taxpayer money supporting Pfizer's vaccine. Even if one just takes the $17.6 billion given directly to Pfizer, that amounts to giving the company over $48 million in taxpayer money every day for over a year, plus spending more than that amount per day promoting Pfizer's product. Given this, these same federal health authorities cannot claim that they are incapable of meeting their statutory requirements to produce documents due to a lack of resources.

As noted, there is near universal agreement that transparency and independent review are extremely valuable for society. The FDA must therefore explain why it could not use a fraction of the billions of taxpayer dollars it has given to Pfizer for its vaccine in order to ensure a timely production of the documents the FDA used to approve the vaccine's licensure.

2. Even Absent the Current Exigency, Courts Regularly Order Agencies to Produce Large Volumes of Documents in Short Periods of Time

The FDA further tries to justify its incredulous request to produce just 500 page per month by arguing this rate has been adopted by other courts, even when the production would take years to complete. The FDA's claim is highly misleading.

First, the FDA cites sixteen cases in the November 11, 2021 Joint Report where it says the court directed the agency to produce documents at a rate of 500 per month. (Dkt. No. 20 pp. 4 n.3, 7-8.) However, in **none** of those cases did the Court or agency decide that the production qualified for expedited processing. *See, e.g., Freedom Watch v. Bureau of Land Mgmt.*, No. 16 Civ. 2320 (D.D.C.), Minute Order of June 13, 2017 (plaintiff failed to show any reasons for expediting). In other cases cited by the FDA, the requester never even questioned the rate of production or sought expedited production. *See, e.g., Judicial Watch, Inc. v. U.S. Dep't of State*, No. 15 Civ. 687 (D.D.C.), Minute Order of April 4, 2017; *Citizens United v. U.S. Dep't of State*, No. 15 Civ. 1720 (D.D.C.), Dkt. 11 ¶ 10. In other cases, the underlying acts that the FOIA request concerned occurred years or even decades before the requests were made, meaning that there was no urgency to the requests. *See, e.g., Colbert v. FBI*, No. 16 Civ. 1790 (DLF), 2018 WL 6299966, at *3 (D.D.C. Sept. 3, 2018) (seeking documents concerning the D.B. Cooper incident in 1971).

Likewise, in none of those cases did the Court contemplate a production schedule that would last over five decades. To the contrary, most courts reviewing expedited productions seek to ensure productions are completed expeditiously. *See, e.g., Diocesan Migrant & Refugee Services, Inc.*, 2021 WL 289548, at *4 (setting a goal for the agency to produce documents within four months); *Inst. for Justice v. Internal Revenue Serv.*, 1:18-CV-01477 (CJN), 2021 WL 4935536, at *7 (D.D.C. July 8, 2021) ("it would be inappropriate for productions to extend over multiple years"); *Seavey v. Dept. of Justice*, 266 F. Supp. 3d 241, 248 (D.D.C. 2017) (rejecting

FBI proposal to produce 500 pages per month over the course of 17 years).

Instead, where expedited processing is warranted and an agency refuses to timely produce, courts regularly require production at many times the FDA's proposed 500 pages per month. The following are samples of production rates endorsed by such courts before and during the pandemic:

- In *Diocesan Migrant*, 2021 WL 289548, to meet the court's deadline, ICE produced 86,000 pages in four months, for an average rate of **21,500 pages per month**.
- In *Treatment Action Group v. FDA*, Case No. 15-cv-00976-VAB (D. Conn. 2016) the FDA produced 82,668 pages and 1,045 electronic files in approximately 7 months for an average production rate of approximately **11,800 pages per month**.
- In *Seife v. FDA*, 492 F. Supp. 3d 269, 273 (S.D.N.Y. 2020), the FDA agreed to produce 45,000 pages in approximately four months for an average of **10,000 pages per month**.
- In *Open Soc'y Justice Initiative v. CIA*, 399 F. Supp. 3d 161 (S.D.N.Y. 2019), the CIA produced 288,000 pages at the rate of around **8,000 pages per month**.
- *In NRDC v. Dep't of Energy*, 191 F. Supp. 2d 41, 43 n.5 (D.D.C. 2002) the court ordered the Department of Energy to produce around **7,500 pages in a month**.

Even with these large production numbers, none of these cases involved documents as consequential to American life as the documents PHMPT seeks here. The *Seife v. FDA* matter presents an apt example. There the plaintiff sought "documents and records regarding the testing and approval process for eteplirsen … a drug … for the treatment of Duchenne Muscular Dystrophy …, a rare neuromuscular disease." 492 F. Supp. 3d at 271, 273. In 2016 the FDA granted "accelerated approval" of eteplirsen. *Id.* at 272. Nevertheless, the next year the FDA produced tens of thousands of pages of documents concerning eteplirsen, most of which were substantially similar to those at issue in this case, many requiring redactions. *Id.* at 273. *Seife*

concerned a product rarely used by a small fraction of the population, but the FDA was able to timely produce all the responsive documents. *Id.* at 271. This fact raises serious questions here about why, where PHMPT seeks similar documents concerning a liability-free vaccine mandated by the government for use by millions of Americans, the FDA has proposed a monthly production rate **20 times slower** than it produced in *Seife*. Similarly, *Treatment Action Group* concerned the approval of two Hepatitis C drugs, again drugs that are not mandated nor used by nearly the same number of people who will receive the Pfizer vaccine, but still the FDA could produce documents similar to those sought in the instant case at an average rate of nearly 12,000 pages per month, at one point even producing 25,000 pages, with redactions, in just six weeks. Case No. 15-cv-00976-VAB (D. Conn. 2016) Dkt. No. 87 pp. 4-5.

In addition, the FDA has simply proposed producing 500 pages per month regardless of whether those pages contain exempt material or are otherwise easily producible. "The D.C. Circuit has found that unreasonable delays in disclosing non-exempt documents violate the intent and purpose of the FOIA, and the courts have a duty to prevent [such] abuses." *Clemente v. Fed. Bur. of Investigation*, 71 F. Supp. 3d 262, 269 (DDC 2014) (internal quotations omitted). Given this goal, the FDA's one size fits all approach is inappropriate, and a higher rate of production for at least some of the documents is achievable and necessary.

The FDA also tries to argue that its proposed 55+-year production schedule is PHMPT's fault for requesting too many documents. This is a red herring. PHMPT merely requested the documents that are supposed to be publicly available under 21 C.F.R. § 601.51(e), and as explained above, all of those documents are required for a true independent evaluation of the data.

3. The FDA is Dramatically Overemphasizing the Risk of Inadvertent Disclosure

The FDA also claims that an expedited production of documents could risk the inadvertent disclosure of personal privacy information. This concern, however, is unfounded and greatly

overblown because the FDA's own regulations require that "[t]he names and other information which would identify patients or research subjects should be deleted from any record **before it is submitted to the Food and Drug Administration**." 21 C.F.R § 20.63(b) (emphasis added). Thus, the documents submitted by Pfizer, which are the subject of the FOIA Request, would have already been anonymized, and therefore, the risk of disclosing such information is minimal.

4. The FDA's Regulations Require Immediate Production

The FDA further argues that even though 21 C.F.R. § 601.51(e) states that the agency must make "the biological product file … **immediately available for public disclosure**" that has no bearing on its over 55-year production schedule. This claim makes a mockery of the regulation. It is hard to see how anyone could interpret "immediately available" as being intended to mean that the documents would be made available to the public over 55 years after the vaccine was licensed. The FDA further asserts that the regulation does not actually require production of anything to the public and, instead, requires that the public make a separate FOIA request in order for those documents to actually become public. A wholistic reading of the regulation reflects the opposite. In the paragraph preceding paragraph (e), the regulation instructs that the "FDA will make available to the public *upon request*" other documents concerning pre-licensure applications, and specifically states that "[p]ersons wishing to request this information shall submit a request under" FOIA. 21 C.F.R. § 601.51 (d)(2) (emphasis added). In contrast, paragraph (e) says nothing about a member of the public needing to make a specific request in order to view the information listed in that paragraph regarding vaccine licensure applications. This difference in language should reflect that paragraph (e) obligates the FDA to make those documents (*i.e.*, the documents sought in the FOIA Request) "immediately available" just as it says.

CONCLUSION

For the foregoing reasons, during the upcoming scheduling conference, the Court should

order the FDA to produce all documents responsive to the PHMPT's FOIA Request on or before March 3, 2022, which is 108 days from the parties Second Joint Report to the Court.

Dated: December 7, 2021

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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.

Exhibit	Description	Page No.
A	Declaration of Peter McCullough, MD, MPH, President of Public Health and Medical Professionals for Transparency (PHMPT)	App000001 – App000003
B	Declaration of Harvey Risch, MD, PhD	App000004 – App000102
C	Declaration of Tom Jefferson, MD MRCGP FFPHM	App000103 – App000150
D	Declaration of Peter McCullough, MD, MPH	App000151 – App000336
E	Declaration of Aaron Siri, Esq.	App000337 – App000579
	Unpublished Cases	App000580 – App000631

Dated: December 7, 2021

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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-

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[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;

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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.

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[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/;

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[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.

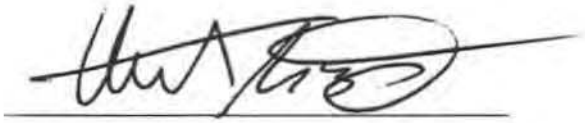
17. Finally, every person infected with SARS-CoV-2 makes thousands of variants of SARS-CoV-2 every day. For a person who has never been infected with this virus and has not been vaccinated, the strain of SARS-CoV-2 infecting that individual will vastly outnumber any variants arising in that individual. 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

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60 College Street, LEPH 413
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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,

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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)

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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.

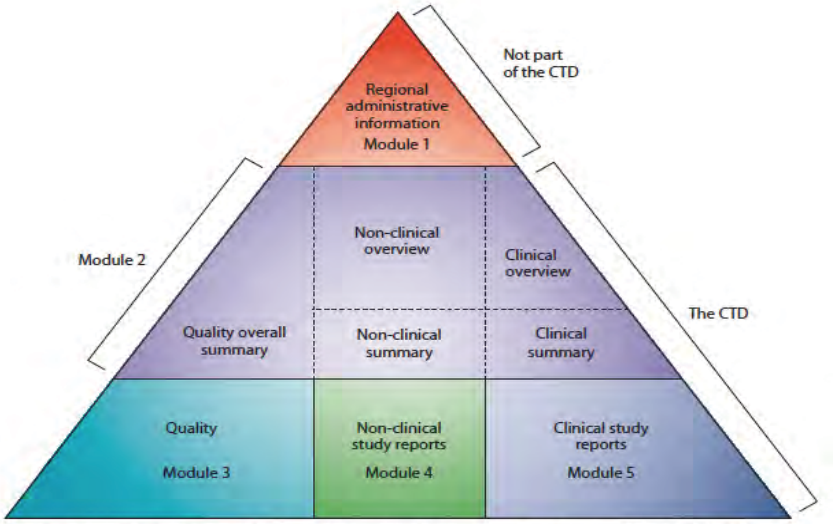
Opinion

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.)

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[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

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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.

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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

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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.

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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.

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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.

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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.

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economists on generalising from economic evaluations.

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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.

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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.

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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.

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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
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Rome, 17 November October 2021

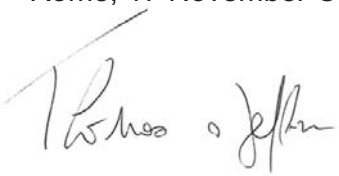

Exhibit D

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.

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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

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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].

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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].

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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.

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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

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(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

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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

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[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]

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[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

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[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

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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 ...

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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*

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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.

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"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.

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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).

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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).

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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.

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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.

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Note: All HHS press releases, fact sheets and other news materials are available at https://www.hhs.gov/news (/news).

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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

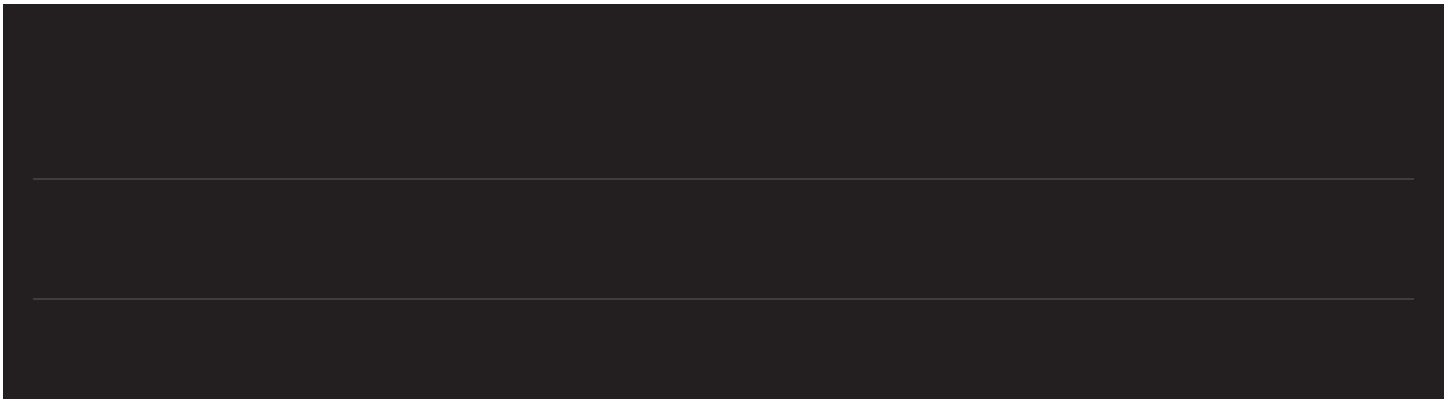

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Exhibit 11

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
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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

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Robert Hart

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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

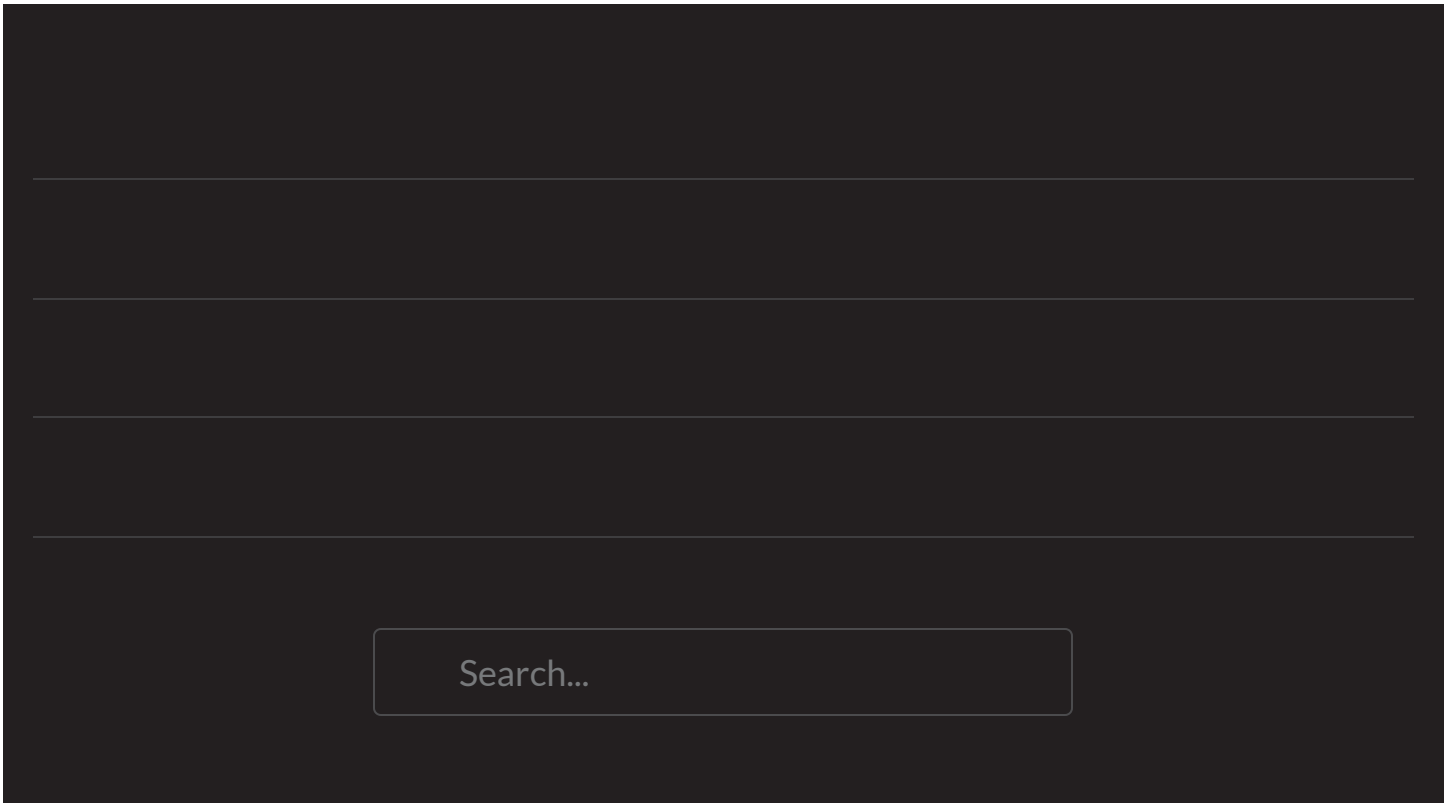

Exhibit 13

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.

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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.

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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

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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
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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
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Exhibit 17

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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

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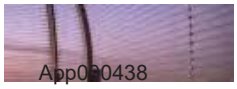

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Exhibit 21

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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.

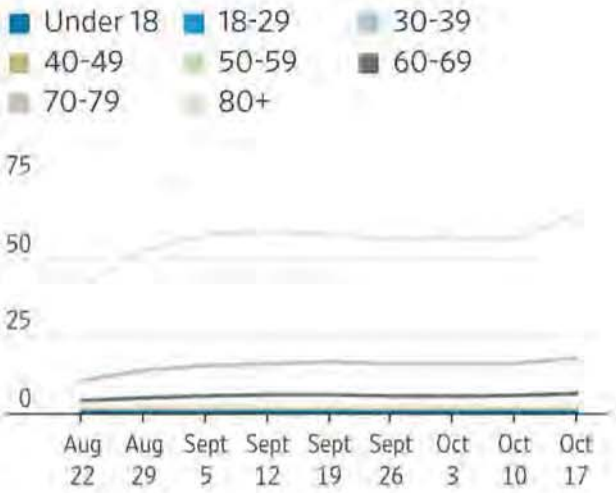
Ajit Lalvani, chair of infectious diseases at Imperial College London and lead author of the household-transmission study, said people in their 40s were at higher risk of breakthrough infection for two reasons. "Waning immunity plus pools of unvaccinated people acting as vectors of infection into the 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

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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

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10.1136/bmjebm-2021-111735

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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.

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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)

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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.

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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.

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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 ›

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Exhibit 28

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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

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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.*

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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

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Gareth Iacobucci

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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.***

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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
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(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)
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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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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,

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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]

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[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

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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

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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]

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[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

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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

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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

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[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

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