FDA Doubles Down: Asks Federal Judge to Grant it Until at Least the Year 2096 to Fully Release Pfizer's COVID-19 Vaccine Data

The fed gov't gives Pfizer billions in taxpayer money + makes Americans take its product + won't let Americans sue for harm + shields disclosure of its licensure documents = 1984


Aaron Siri
Dec 7 ♡ 280 💬 125

A prior post explained that the FDA has asked a federal judge to make the public wait until the year 2076 to disclose all of the data and information it relied upon to license Pfizer's COVID-19 vaccine. Literally, a 55-year delay. My firm, on behalf of PHMPT, asked that this information be disclosed in 108 days – the same amount of time it took for the FDA to review and license Pfizer's vaccine.

The Court ordered the parties to submit briefs in support of their respective positions by December 6, 2021. The FDA's brief, incredibly, doubles down. It now effectively asks to have until at least 2096 to produce the Pfizer documents. Not a typo. **A total of at least 75 years**.

Other than producing an initial ~12,000 pages in around two months, the FDA thereafter only wants to commit to producing 500 pages per month. The FDA also disclosed that it actually has approximately at least 451,000 pages to produce.*

Each side gets to file response briefs on December 13, 2021, and then there is oral argument on December 14, 2021 before the Judge. If you want to read the response to the FDA's position, a copy of the introduction in the brief my firm filed is below. And below that, a downloadable copy of each side's full briefing is available.

Enjoy. And if you find what you are reading difficult to believe – that is because it is dystopian for the government to give Pfizer billions, mandate Americans to take its product, prohibit Americans from suing for harms, but yet refuse to let Americans see the data underlying its licensure. **The lesson yet again is that civil and individual rights should never be contingent upon a medical procedure.**

EXCERPT FROM BRIEF DEMANDING TIMELY PRODUCTION

INTRODUCTION

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?

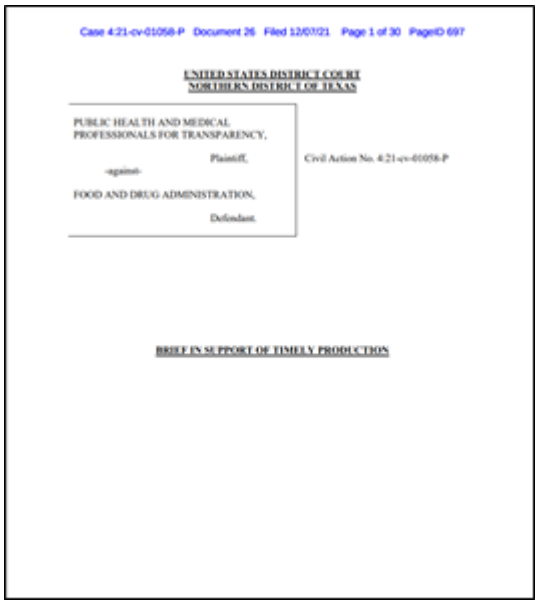
Reflecting that the FDA can, in fact, produce documents at a far greater rate than 500 pages per month, on December 1, 2021, in an effort to avoid the hearing with this Court, it offered to produce approximately 12,658 pages, 4 .txt files, and 4 SAS files within a period of 61 days if PHMPT would agree 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.**

PHMPT's Brief & Appendix



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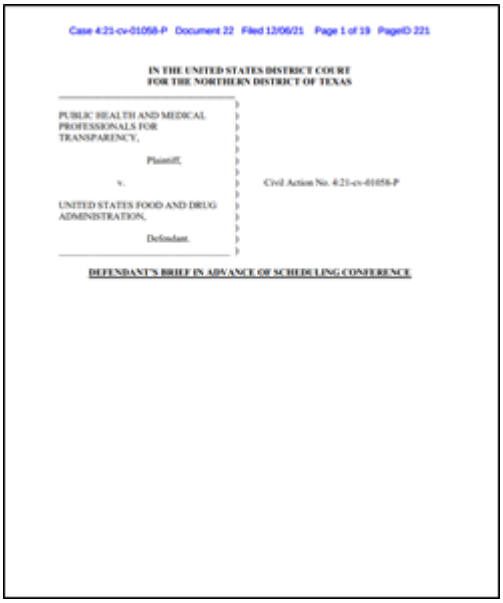
UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY,
Plaintiff,
-against-
FOOD AND DRUG ADMINISTRATION,
Defendant.

Civil Action No. 4:21-cv-01058-P

BRIEF IN SUPPORT OF TIMELY PRODUCTION

FDA's Brief & Appendix



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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No. 4:21-cv-01058-P

DEFENDANT'S BRIEF IN ADVANCE OF SCHEDULING CONFERENCE

In addition to the original 329,000+ pages, the FDA discloses there is another "approximately 39,000 pages," an additional "tens of thousands of additional pages," and an additional 126 data files, many of which have over ten thousand rows for which the FDA intends to treat twenty rows as one page. Assuming an average of only ten thousand rows per data file, and that its amorphous "tens of thousands of additional pages" amounts to 20,000 pages, the grand total is at least 451,000 pages.

Juan Linde Dec 7

All I can do is thank you for your work.

88 Reply

2 replies

David Watson Writes To Your Health · Dec 8

Fact -- FDA did not read, certainly did not evaluate, 451,000 pages to approve the licenses. Perhaps it would be constructive to see the actual documents FDA actually read before issuing the approvals. That should take about 10 minutes at the copier, then 15 minutes to drop them in the

mail basket. Then negotiate the 450,900 pages they can't find because they didn't actually read them.

This is all a fraud, what some call a kabuki dance, after the ceremonial Japanese show with lots of drama but no discernable meaning. Better to just focus on the real objective -- they don't work, and are dangerous. Doesn't matter why they were approved. Plenty of evidence available to indict the perps. Later. For now, all efforts should be on making them stop the damage.

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> **6 replies**

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