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Written by **Veronika Kyrylenko** on January 7, 2022

FDA Ordered to Speed Up Pfizer Vax Data Release

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The U.S. Food and Drug Administration (FDA), which reviewed documents on Pfizer's Comirnaty COVID shot for 108 days before deciding the vaccine was suitable for use in American adults, has been ordered to release these documents in an expedited manner.

In a ruling on Thursday, District Judge Mark Pittman rejected previous arguments from the FDA that it might take decades, possibly until 2096, to complete the Freedom of Information Act (FOIA) request filed by an international organization of medical professionals, scientists, and journalists called Public Health and Medical Professionals for Transparency (PHMPT).

Underlining the crucial role of transparency in government matters, Pittman wrote:

> "'Open government is fundamentally an American issue' — it is neither a Republican nor a Democrat issue. As James Madison wrote, '[a] popular Government, without popular information, or the means of acquiring it, is but a Prologue to a Farce or a Tragedy; or, perhaps, both. Knowledge will forever govern ignorance: And a people who mean to be their own Governors, must arm themselves with the power which knowledge gives'."

Pittman further quoted late Arizona Senator John McCain, who pointed that "excessive administrative secrecy … feeds conspiracy theories and reduces the public's confidence in the government."

Therefore, the judge stressed that "there may not be a 'more important issue at the Food and Drug Administration … than the pandemic, the Pfizer vaccine, getting every American vaccinated, [and] making sure that the American public is assured that this was not … rush[ed] on behalf of the United States.'… Accordingly, the Court concludes that this FOIA request is of paramount public importance."

The judge ordered the FDA to produce "more than 12,000 pages" on or before January 31, 2022. Then, the regulators will have to speed up the process of releasing the documents and release "the remaining documents at a rate of 55,000 pages every 30 days, with the first production being due on or before March 1, 2022, until production is complete," per the order.

Considering the non-disclosure agreements between the federal government and Pfizer, the judge allowed the FDA to redact records only when it has "privilege, exemption, or exclusion" over information. Pittman also asked both plaintiffs and the regulators to submit a "joint status report" detailing the progress of the rolling disclosure by April 1, and again every 90 days afterward until it is complete.

Aaron Siri, an attorney who represents the PHMPT in the case, called Thursday's ruling a "great win for transparency" that will break a government "stranglehold" on the vaccine data. He wrote,

> No person should ever be coerced to engage in an unwanted medical procedure. And while it is bad enough the government violated this basic liberty right by mandating the Covid-19 vaccine, the government also wanted to hide the data by waiting to fully produce what it relied upon to license this product until almost every American alive today is dead. That form of governance is destructive to liberty and antithetical to the openness required in a democratic society.

Reuters' Jenna Greene applauded the court's decision. "Even if the FDA may not see it this way, I think Pittman did the agency — and the country — a big favor by expediting the document production," she wrote.

Greene noted that her readers "felt something was suspicious, even nefarious, in the FDA's proposed slo-mo timeline," and expressed the hope that "making the information public as soon as possible may help assuage the concerns of vaccine skeptics and convince them the product is safe."

As reported by *The New American*, after the FDA ignored the PHMPT's FOIA request filed in August 2021, the group filed a lawsuit (pdf) against the agency in September, demanding the FDA release "all data and information for the Pfizer vaccine," including:

(1) All safety and effectiveness data and information;

(2) 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].

The top federal regulators, who moved with a lightning speed by processing that information to assess Pfizer's shot, claimed that it would be "burdensome" for them to release unredacted documents at the same pace.

In response to the lawsuit, the FDA produced 91 pages of the documents on the Pfizer shot's safety and efficacy in late November 2021. Among the FDA documents released was a 38-page document entitled "CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021"(pdf), which showed that tens of thousands of serious adverse events and more than 1,200 deaths were reported in the first two and a half months since the beginning of Pfizer's COVID shot rollout, as reported by *The New American* here.


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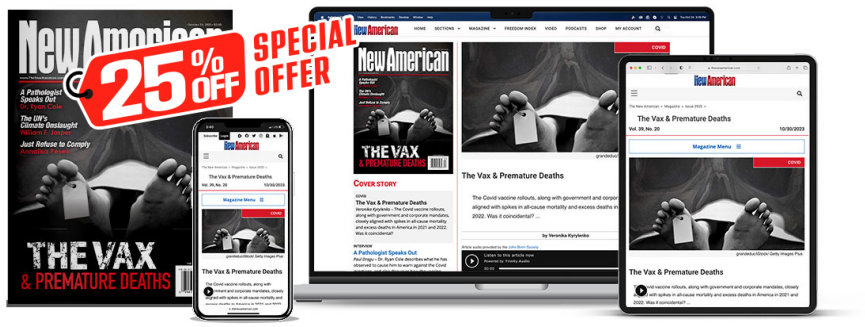

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