Why a Judge Ordered FDA to Release Covid-19 Vaccine Data Pronto

Description

USA: In response to a Freedom of Information Act request, the Food and Drug Administration asked a federal judge for permission to make the public wait until the year 2096 to disclose all of the data it relied upon to license Pfizer's Covid-19 vaccine.

That is not a typo. The FDA wanted court approval to have up to 75 years to publicly disclose this information.

In its attempts to build public support for Covid-19 vaccinations, the FDA repeatedly promised "full transparency," and reaffirmed its "commitment to transparency" when licensing Pfizer's Covid-19 vaccine.

With that promise in mind, after the vaccine's licensure in August 2020, Public Health and Medical Professionals for Transparency, a group of highly credentialed scientists submitted a FOIA request to the FDA for the data submitted by Pfizer. The scientists explained that, until all the data is produced, a proper review cannot be conducted because missing even a single data set could throw off any analysis.

In response, the FDA produced nothing. Therefore, in September 2021, the scientists, represented by their attorneys at Siri & Glimstad, sued the FDA demanding it produce this data by March 2022.

The agency originally estimated it would need to produce 329,000 pages, and asked the court for permission to produce just 500 pages per month, which would have taken 55 years. In its final brief to the Court, the FDA admitted that the total page count was at least 451,000, but still sought permission to produce just 500 pages per month. Meaning that it could have taken 75 years, when most Americans alive today would be dead, to fully publicly disclose this information.

On Jan. 6, a federal court in the Northern District of Texas ordered the expedited release. As of Jan. 12, the FDA hasn't indicated it intends to appeal.

Scientists Requested Data After FDA Licensing

The FDA licensed the Pfizer vaccine on Aug. 23, 2021, just 108 days after Pfizer started producing the records to the agency. During that period, the FDA asserts it conducted an intense, robust, and thorough analysis of those documents to assure the public that the Pfizer vaccine was safe and effective.

Yet, when asked to share those documents with the public, the FDA claimed it needed over 20,000 days. The FDA's production schedule clashed with its promise of transparency.

The purpose of FOIA is government transparency. When it comes to the Pfizer vaccine, the need for transparency is unprecedented. A majority of Americans are now mandated to receive a Covid-19 vaccine under penalty of losing a job, or worse.

This has never been done before. Typically adult vaccine mandates have been limited; even the seminal U.S. Supreme Court vaccine mandate decision, *Jacobson v. Massachusetts,* only involved a state-imposed $5 penalty, and school vaccine mandates have historically had liberal religious or personal belief exemption policies.

Even more problematic is that Americans, if injured, cannot sue Pfizer. 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 creates a moral hazard and departs from centuries of product liability doctrine. Thus, it is extraordinary that Americans must take this product under penalty of expulsion from work, school, the military and civil life, but they cannot sue Pfizer for any resulting injuries.

The federal government created this unprecedented situation. It granted the immunity, licensed the product, and aggressively sought mandates. This situation therefore warrants unprecedented transparency.

As then-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." He repeated that need to share the data numerous times. So did senators and representatives on both sides of the aisle.

FDA Claimed It Can't Comply, Judge Orders Compliance

The FDA apparently disagreed. During a hearing on Dec. 14, 2021, its counsel steadfastly maintained that the court should not require the agency to produce more than 500 pages per month, harping on the FDA's purported limited resources, its need to redact personal information, and duty to protect Pfizer's trade secret interests, all the while ignoring the interests of the American people.

The FDA's excuses were incredible. The FDA has more than 18,000 employees and a budget of over $6.5 billion. It would be laughable if any multibillion-dollar company came before a court and claimed poverty to escape making a document production, but that was the FDA's position.

U.S. District Judge Mark T. Pittman, Northern District of Texas, expressed dismay at the FDA's proposed rate of production. He found the duration requested by the FDA unreasonable, comparing it to the actions of totalitarian nations. As such, the judge on Jan. 6 ordered the FDA to produce at least 55,000 pages per month.

In his ruling, the judge recognized that the release of this data is of paramount public importance and should be one of the FDA's highest priorities. He quoted James Madison as saying a "popular Government, without popular information, or the means of acquiring it, is but a Prologue to a Farce or a Tragedy" and John F. Kennedy as explaining that a "nation that is afraid to let its people judge the truth and falsehood in an open market is a nation that is afraid of its people."

America has some of the greatest institutions of learning the world has ever known. We need the scientific community, both inside and outside the government, to address the serious ongoing issues with the vaccine program, including waning immunity, variants evading vaccines, and that vaccinated individuals can still transmit the virus.

The FDA's attempt to close the door and lock out independent scientists from the data necessary to address these issues was irresponsible.

Transparent, Independent Review Is Needed

The failure of the government's closed-door approach is exemplified by the fact that the FDA did not send a representative to the court hearing because, as the government attorney explained, the FDA's Covid-19 protocols would not permit it.

Meaning, despite a reported vaccination rate of over 96% across federal health agencies back in November 2021, and the FDA's claim that the vaccines are "effective," Covid-19 is still disrupting everyday life. This brings into stark focus the need to open the door and involve independent scientists.

As Pittman recognized, America needs transparency and independent scientists to review this data—not in 75 years, but now.

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Date Created
01/24/2022