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Written by **Veronika Kyrylenko** on November 19, 2021

FDA Says It Needs 55 Years to Release Pfizer Vaccine Safety & Efficacy Data

AP Images

It might take 55 years for the U.S. Food and Drug Administration (FDA) to release all the documents it used to determine the safety and efficacy of the Pfizer-BioNTech COVID-19 shot.

When in August an international group of medical professionals, scientists, and journalists called Public Health and Medical Professionals for Transparency (PHMPT) submitted a Freedom of Information Act (FOIA) request for a "vaccine biological product file" on the Pfizer COVID shot, which the FDA used to license the vaccine, the agency ignored the inquiry.

In September, the group filed a lawsuit (pdf) 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]."

PHMPT made a request for expedited processing of its FOIA submission, insisting there is a "compelling need" for the FDA to make Pfizer vaccine data public because "a lack of transparency erodes the confidence the medical and scientific community and the public have in the conclusions reached by the FDA," and also since "this product is being mandated to individuals across the country."

The group asked the FDA to fully release the documents in four months, the same time it took the regulators to review them to fully approve the shot.

While not a single page of the documents was made public, the FDA asked a federal judge to give the agency until 2076 to fully produce this information, per the lawsuit (pdf) filed by PHMPT this week.

In the lawsuit, the group asked the FDA to schedule a conference to discuss the issue.

Per the lawsuit,

> Defendant respectfully requests a scheduling conference with the Court for the Court to set a schedule for the processing of documents.

But the FDA appears to be reluctant to sit down with the group to discuss Pfizer's safety and efficacy data. Instead, it proposes to release the documents "on a rolling basis," or 500 pages per month, after finishing releasing some of the sections of the Biologics License Application on November 17 and December 1.

The counsel set to handle the case argued that the plaintiff's request should be rejected in court because the FDA could not process and produce the non-exempt portions of the documents in four months.

The counsel argued the FDA does not have enough personnel or resources in its FOIA office to process the plaintiff's request at the proposed rate, which is more than 80,000 pages per month.

Also, "[r]equiring the agency to process and produce these materials under an abbreviated deadline raises a significant risk of inadvertent disclosure of records properly subject to exemption under FOIA." In other words, some of Pfizer's safety data is legally not meant to become public under the non-disclosure agreements between the pharmaceutical company and the federal regulator. Careful redaction of such portions would take a lot of time.

It was also argued the defendants should not expect the FDA administrators to work at the same pace as the agency's scientists who were able to process such amounts of information when reviewing the Pfizer's BLA:

> The Court should flatly reject Plaintiff's specious argument that because the scientists reviewing Pfizer's Biologics License Application could do so on an expedited timeframe, the government information specialists should be able to do so in the same period of time.

PHMPT argued that a meeting between the world-class scientists and the FDA officials would be necessary to shed light on the crucial issues of America's most popular COVID shot.

The plaintiffs also contended that there is an acute need for transparency regarding Pfizer's shot since the secretary of health and human services has granted Pfizer complete immunity from financial liability for any injury caused by its product. "If injured — including suffering one of the injuries even federal health authorities admit occur from Pfizer's product — the injured individual effectively has no recourse," per the suit.

"The FDA's promise of transparency is, to put it mildly, a pile of illusions," Aaron Siri, an attorney representing the group, wrote on his page on Wednesday. He continued:

> It took the FDA precisely 108 days from when Pfizer started producing the records for licensure (on May 7, 2021) to when the FDA licensed the Pfizer vaccine (on August 23, 2021). Taking the FDA at its word, it conducted an intense, robust, thorough, and complete review and analysis of those documents in order to assure that the Pfizer vaccine was safe and effective for licensure. While it can conduct that intense review of Pfizer's documents in 108 days, it now asks for over 20,000 days to make these documents available to the public.

Siri added that the federal government is shielding Pfizer from liability and mandates Americans to get

injected with their jab while refusing to publicize any data on its safety and efficacy. “Who does the government work for?” Siri wondered.

FDA first issued an emergency use authorization (EUA) for the Pfizer-BioNTech jab on December 11, 2020, and has reissued the EUA several times since then, such as to authorize the vaccine for additional groups — for example, children ages 12 to 15 and then ages 5 to 11. On August 23, 2021, the FDA approved Pfizer’s shot under the brand name Comirnaty. On Friday, FDA expanded and EUA of Pfizer booster shots to include individuals 18 and older.