GlobalResearch
Center for Research on Globalization

FDA Should Need Only '12 Weeks' to Release Pfizer Data, Not 75 Years, Plaintiff Calculates

The nonprofit group suing the U.S. Food and Drug Administration for the release of documents related to the approval of Pfizer's Comirnaty vaccine calculated it should take the agency only 12 weeks with 19 reviewers working full-time to review and produce the documents.

By Seth Hancock
Global Research, December 20, 2021
The Defender

Region: USA
Theme: Law and Justice, Science and Medicine

U.S. Food and Drug Administration (FDA) officials skipped the start of oral arguments Tuesday as a federal district court weighed whether the agency can take 75 years to fully release documents on Pfizer's Comirnaty COVID vaccine, according to a lawyer representing plaintiffs who sued the FDA for the documents.

A U.S. Department of Justice lawyer representing the FDA told the U.S. District Court for the Northern District of Texas the agency will produce more than 329,000 related documents as fast as it can, while safeguarding personally identifiable information and Pfizer trade secrets.

Public Health and Medical Professionals for Transparency (PHMPT), the group behind the Freedom of Information Act (FOIA) request and subsequent lawsuit, is seeking safety and effectiveness data, adverse reaction reports and a list of active and inactive vaccine ingredients.

PHMPT is a group of more than 30 scientists, medical professionals, international public health professionals and journalists. The group's lawsuit argues the FDA is overestimating the time needed and understaffing the job.

"Assuming a low average of 50 pages per hour per person, even to review the hundreds of thousands of pages the FDA estimates, the agency would need just 19 reviewers to work full-time for 12 weeks to review and produce these documents — which is a tiny fraction of its approximately 18,000 employees," said PHMPT in a legal brief filed Monday.

The day before oral arguments, the FDA released 14 document files, the largest file including 2,030 pages. PHMPT posted an updated list which shows documents released since Nov. 17.

FOIA does not mandate any particular processing schedule, only that the agency process requests "as soon as practicable," the FDA said in a legal brief filed Monday.

"The bottom-line issue still remains what processing schedule is 'practicable' for the agency," the FDA said.

At the agency's proposed rate of 500 documents per month, the last documents would be released in 2096.

Urgent: 3 Ways to Help Stop Biden's Vaccine Mandates

A quote from Business Intelligence Associates, an e-discovery company, estimated 400,000 pages could be produced within six to eight weeks at a cost of $132,000, according to PHMPT.

PHMPT wants the FDA documents released within 108 days. That's the same amount of time the FDA spent reviewing the responsive documents for "the far more intricate task" of licensing Pfizer's vaccine, the group said in its lawsuit.

Attorney Aaron Siri, who represents PHMPT, said:

"Americans must routinely produce documents, pay fines, and otherwise expend resources to comply with the law. Courts don't inquire as to the ability or financial resources to comply with the law — they must comply.

"In fact, it would be laughable if a billionaire defendant came before a court and claimed poverty to escape making a document production, but that is the FDA's position."

The FDA budget for fiscal year 2019 was $6.1 billion.

In the FDA's 64-page briefing, the agency argued it needed the full 75 years to redact and release the documents out of "fairness" to other FOIA requesters.

PHMPT defined fairness differently in its responding brief:

"Fairness would be giving millions of Americans who are mandated to receive this liability-free vaccine today assurance regarding the FDA's review by allowing independent scientists access to the same data the FDA reviewed, without making them wait decades.

"Fairness would be allowing Americans injured by the vaccine today, who cannot sue Pfizer or anyone else for the harm, hope that independent scientists with access to that data can more readily develop treatments for their ailments.

"Fairness would be our federal health authorities allocating more than one person spending a few hours each month to review Pfizer's documents for public disclosure after having given Pfizer over $17 billion of taxpayer money to develop and market the product.

"That would be fair to the American people."

Siri noted that no decision has been made by the court and that a transcript of this week's hearing should be released soon.

U.S. Rep. Ralph Norman (R-S.C.) earlier this month introduced a bill that would force the FDA to release them in 100 days.

Comment on Global Research Articles on our Facebook page

Become a Member of Global Research

Articles by: Seth Hancock