Judge Rejects FDA, Pfizer Attempt to Stall Release of COVID Vaccine Safety Data

A federal judge Wednesday rejected a bid by the U.S. Food and Drug Administration (FDA), with the support of Pfizer, to delay the court-ordered release of nearly 400,000 pages of documents pertaining to the approval of Pfizer's COVID vaccine.

Federal judge Mark Pittman of the U.S. District Court for the Northern District of Texas, in an order issued Feb. 2, said the FDA must release redacted versions of the documents in question according to the following disclosure schedule:

- 10,000 pages apiece, due on or before March 1 and April 1, 2022.
- 80,000 pages apiece, to be produced on or before May 2, June 1 and July 1, 2022.
- 70,000 pages to be produced on or before Aug. 1, 2022.
- 55,000 pages per month, on or before the first business day of each month thereafter, until the release of the

documents has been completed.

The order grants the FDA the ability to "bank" excess pages as part of this release schedule — meaning that if the agency exceeds its monthly quota in any given month it can apply those extra pages to a subsequent month.

Last week's ruling is the most recent development in an ongoing court case that began with a Freedom of Information Act (FOIA) request filed in August 2021 by Public Health and Medical Professionals for Transparency (PHMPT), a group of doctors and public health professionals.

PHMPT, a group of more than 30 medical and public health professionals and scientists from institutions such as Harvard, Yale, and UCLA, in September 2021 filed a lawsuit against the FDA after the agency denied its original FOIA request.

In that request, PHMPT asked the FDA to release "all data and information for the Pfizer vaccine," including safety and effectiveness data, adverse reaction reports, and a list of active and inactive ingredients.

The FDA argued it didn't have enough staff to process the redaction and release of hundreds of thousands of pages of documents, claiming it could process only 500 pages per month.

This would have meant the cache of documents would not be fully released for approximately 75 years.

In his Jan. 6 order, Pittmann rejected the FDA's claim and instead required the agency to release 12,000 pages of documents by Jan. 31 and an additional 55,000 pages per month thereafter.

Pfizer responded, to the Jan. 6 order by filing a memorandum with the court on Jan. 21, requesting to intervene in the case for the "limited purpose of ensuring

that information exempt from disclosure under FOIA is adequately protected as FDA complies with this Court's order."

Pfizer claimed to support the disclosure of the documents, but asked to intervene in the case to ensure that information legally exempt from disclosure will not be "disclosed inappropriately."

This request, if granted, would have also meant further delay for the release of the next tranche of documents, until May 1.

Lawyers for PHMPT, in a brief submitted Jan. 25, asked Pittman to reject Pfizer's motion, prompting Pittman's Feb. 2 order.

The first batch of documents produced in Nov. 2021, which totaled a mere 500 pages, revealed there were more than 1,200 vaccine-related deaths within the first 90 days following the release of the Pfizer-BioNTech COVID vaccine.