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FDA Asks Federal Judge for 55 Years to Complete FOIA Request for Pfizer Vaccine Information

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The Food and Drug Administration is asking a federal court to allow it to take nearly 55 years to release data on Pfizer's COVID-19 vaccine to the public.

The agency said in a court filing Monday that in order to complete a Freedom of Information Act request for data and information on the Pfizer-BioNTech vaccine, it will need to process 329,000 pages of documents and can only do so at a rate of 500 pages per month. At that rate, the information requested will not be fully released until the year 2076.

The FOIA request was submitted to the FDA in August by Public Health and Medical Professionals for Transparency, a group of more than 30 international public health professionals, medical professionals, scientists, and journalists that "exist solely to obtain and disseminate the data relied upon by the FDA to license COVID-19 vaccines." The group includes academics and medical experts from Yale, Harvard Medical School, and UCLA; alumni from the Trump administration; and prominent health experts from around the world.

PHMPT is being represented by Siri & Glimstad, a New York-based law firm that has performed millions of dollars of legal work on behalf of groups opposed to vaccine mandates.

The medical transparency group had requested "all data and information for the Pfizer vaccine" including safety and effectiveness data; a protocol for a test or study; adverse reaction reports, product experience reports, consumer complaints, and other similar data and information; a list of all active ingredients and any inactive ingredients; an assay method or other analytical method; all correspondence and written summaries of oral discussions relating to the vaccine; all records showing Pfizer and BioNTech's testing of a particular lot; and all records showing the testing of and action on a particular lot by the FDA.

PHMPT also made a request for expedited processing of its FOIA submission, arguing there is a "compelling need" for the FDA to speedily release Pfizer vaccine data "because a lack of

transparency erodes the confidence the medical and scientific community and the public have in the conclusions reached by the FDA."

> "During a time when COVID-19 vaccine mandates are being implemented over the objection of those that have questions about the data and information supporting the safety and efficacy of the Pfizer Vaccine, and individuals with these questions are being expelled from employment, school, transportation, and the military, the public has an urgent and immediate need to have access to this data," PHMPT said in its FOIA request.

The group filed a lawsuit in September after the FDA denied their request to expedite the release of its records. In Monday's court filing, the plaintiff and the defendant are seeking a decision from a judge to resolve a dispute over the disclosure schedule for the requested documents.

> "The FDA's promise of transparency is, to put it mildly, a pile of illusions," attorney **Aaron Siri** wrote Wednesday in a blog post about the case.
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> "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," he wrote.
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> "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."

The FDA argued in the court filing that to comply with federal law it must redact certain information that is exempt from the records request filed by the plaintiff. Information about Pfizer-BioNTech's confidential business and trade secrets and personal privacy data on patients who participated in clinical trials are examples of documents the FDA is prohibited by law from releasing.

> "Reviewing and redacting records for exempt information is a time-consuming process that often requires government information specialists to review each page line-by-line," the FDA told the court. "When a party requests a large amount of records, like Plaintiff did here, courts typically set a schedule whereby the processing and production of the non-exempt portions of records is made on a rolling basis."

The FDA said that court precedent has determined a rate of 500 pages per month to be an efficient response to a large request like the one filed by PHMPT. The agency also said it's FOIA response office does not have enough funding or staff to answer the request at a quicker pace and that if the plaintiff wishes to hurry the process along, the group can do so by narrowing the scope of their document request.

The plaintiff argues the FDA should complete the FOIA request no later than March 3, 2022. "This 108-day period is the same amount of time it took the FDA to review the responsive documents for the far more intricate task of licensing Pfizer's COVID-19 vaccine," the plaintiff told the court.

> "The ability of a majority of Americans to participate in civil society, and even exercise

> basic liberty rights, are now contingent on receiving this product," PHMPT's lawyers wrote, noting that President Joe Biden's vaccine mandates have made vaccination a condition of employment for millions of Americans.
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> "There are few whose livelihood, education, service, and participation in civil society are not contingent on a government requirement to receive this product. On this basis alone, basic liberty and government transparency demand that the documents and data submitted by Pfizer to license this product be made available to Plaintiff and the public forthwith, precisely as contemplated by federal regulations," the plaintiff said.
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> "The entire purpose of the FOIA is to assure government transparency," the plaintiff told the judge. "It is difficult to imagine a greater need for transparency than immediate disclosure of the documents relied upon by the FDA to license a product that is now being mandated to over 100 million Americans under penalty of losing their careers, their income, their military service status, and far worse."

The FDA granted full approval for Pfizer-BioNTech's COVID-19 vaccine on August 23, 2021, under the label Comirnaty.

Earlier this month, a now-former employee of Ventavia Research Group, one of the companies contracted with Pfizer to run its Phase III vaccine clinical trials, made allegations that raised questions about the data submitted before Comirnaty received FDA approval.

Brook Jackson, a former regional director for Ventavia, told the British Medical Journal that her company "falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase III trial."

After Jackson notified Ventavia of these issues, she emailed a complaint to the FDA and was fired within hours.

According to investigative reporter Paul Thacker, the FDA did not inspect Ventavia's trial sites even though it was alerted to the issues.

Ventavia has since said it is investigating the allegations.

In a statement to the Epoch Times, the FDA declined to comment on the Ventavia matter but said it "has full confidence in the data that were used to support the Pfizer-BioNTech COVID-19 vaccine authorization and the Comirnaty approval."

As of Nov. 17, more than 258,642,454 doses of Pfizer's COVID-19 vaccine have been administered in the United States.

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