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Judge Orders FDA to Accelerate Release of COVID-19 Vaccine Trial Data to Just 2 Years

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A federal judge in Texas ordered the Food and Drug Administration (FDA) to make public data it relied on to license COVID-19 vaccines at an accelerated rate, requiring all documents to be made public by mid-2025 rather than, as the FDA wanted, over the course of about 23.5 years.

In a May 9 decision hailed as a win for transparency by the lawyer representing the plaintiffs (the parents of a child injured by a COVID-19 vaccine) in a lawsuit (pdf) against the FDA, the agency was ordered to produce the data on Moderna's vaccine

for adults and Pfizer's for children about 10 times faster than the agency wanted.

"Democracy dies behind closed doors," is how U.S. District Judge Mark Pittman opened his order (pdf), which requires the FDA to produce the data on Moderna's and Pfizer's COVID-19 vaccines at an average rate of at least 180,000 pages per month.

The FDA had argued it would be "impractical" to release the estimated 4.8 million pages at more than between 1,000 and 16,000 pages per month, which would have taken at least 23.5 years.

Aaron Siri of Siri & Glimstad, who represents the plaintiffs in the legal action against the FDA, called the decision "another blow for transparency and accountability" that builds on an earlier court order targeting Pfizer's COVID-19 vaccine data for those aged 16 and older.

The January 2022 order (pdf), also issued by Pittman, forced the FDA to produce all its data on Pfizer's COVID-19 vaccine for those aged 16 and older at a rate of 55,000 pages per month, or much faster than the 75 years the agency had sought.

"That production should be completed in a few more months," Siri said in a statement, referring to the earlier Pfizer data for those aged 16 and up.

The latest order requires the FDA to produce all of its data on Pfizer's COVID-19 vaccine for 12- to 15-year-olds (and Moderna's product for adults) by June 31, 2025.

FDA officials didn't respond by press time to a request by The Epoch Times for comment.

'Stale Information Is of Little Value'

While the judge noted in his order that the court recognizes the FDA's limited resources dedicated to freedom of information requests (FOIA), he stated that "the number of resources an agency dedicates to such requests does not dictate the bounds of an individual's FOIA rights."

"Instead, the Court must ensure that the fullest possible disclosure of the information sought is timely provided—as 'stale information is of little value,'" Pittman wrote.

In order to ensure the FDA can meet the

accelerated deadline, the judge ordered the parties to the lawsuit to confer and submit a joint production schedule for the data by May 23.

In the earlier case adjudicated by Pittman, the FDA had argued it only had the bandwidth to review and release around 500 pages per month of an estimated total of 450,000 pages of material about the Pfizer COVID-19 vaccine for those aged 16 and older.

While the FDA hasn't disputed in either case that it has an obligation to make the information public, it has argued that its short-staffed FOIA office couldn't meet the pace of production sought by the plaintiffs.

The judge disagreed, arguing in both cases that the imperatives of transparency and accountability are of paramount importance.

In the January order, Pittman said that too much foot-dragging and secrecy on the part of federal agencies feeds conspiracy theories and reduces the public's trust in government.

Confidence in the FDA over COVID-19 vaccine approvals was shaken by the disclosure that

regulators sped up the approval of Pfizer's vaccine.

Republicans on the House Select Subcommittee on the Coronavirus Pandemic in March announced they were seeking answers after recently released emails indicated that the FDA rushed the approval of COVID-19 vaccines and boosters to accommodate vaccine mandates.