Judge Orders FDA To Expedite Release Of COVID-19 Vaccine Trial Data

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A federal judge has ordered the Food and Drug Administration (FDA) to accelerate the release of trial data for COVID-19.

U.S. District Judge Mark Pittman ordered the release of all documents related to Moderna's trial data for adults, as well as Pfizer's data for children, to be released by mid-2025. The FDA had previously planned to release the data over a span of 23.5 years. Now, the FDA must release roughly 180,000 pages per month.

The FDA had argued that it would be "impractical" to release upwards of 4.8 million pages at a rate higher than 1,000 to 16,000 pages per month, which would have taken nearly 24 years.

The ruling was made in a case where plaintiffs sued the FDA after their child was injured as a result of COVID-19 vaccination. "Democracy dies behind closed doors," wrote Pittman in his ruling. The judge did note that he understands the FDA has limited resources to fulfill Freedom of Information Act (FOIA) requests, he argued 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.

The latest decision builds on a previous court order, also issued by Pittman, that required the FDA to release all its data on Pfizer's COVID-19 vaccine for those aged 16 and up at a rate of 55,000 pages per month. Prior to that January 2022 ruling, the department had planned on releasing the trial data over a span of 75 years.

Aaron Siri, an attorney for the plaintiffs, said the ruling was "another blow for transparency and accountability," referencing the earlier order. "That production should be completed in a few more months," Siri said in a statement.

In the January 2022 order, Pittman argued that delays in releasing trial data lowers public confidence in public health officials.