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Health COVID-19 Public Policy

'Paramount importance': Judge orders FDA to hasten release of Pfizer vaccine docs

By Jenna Greene

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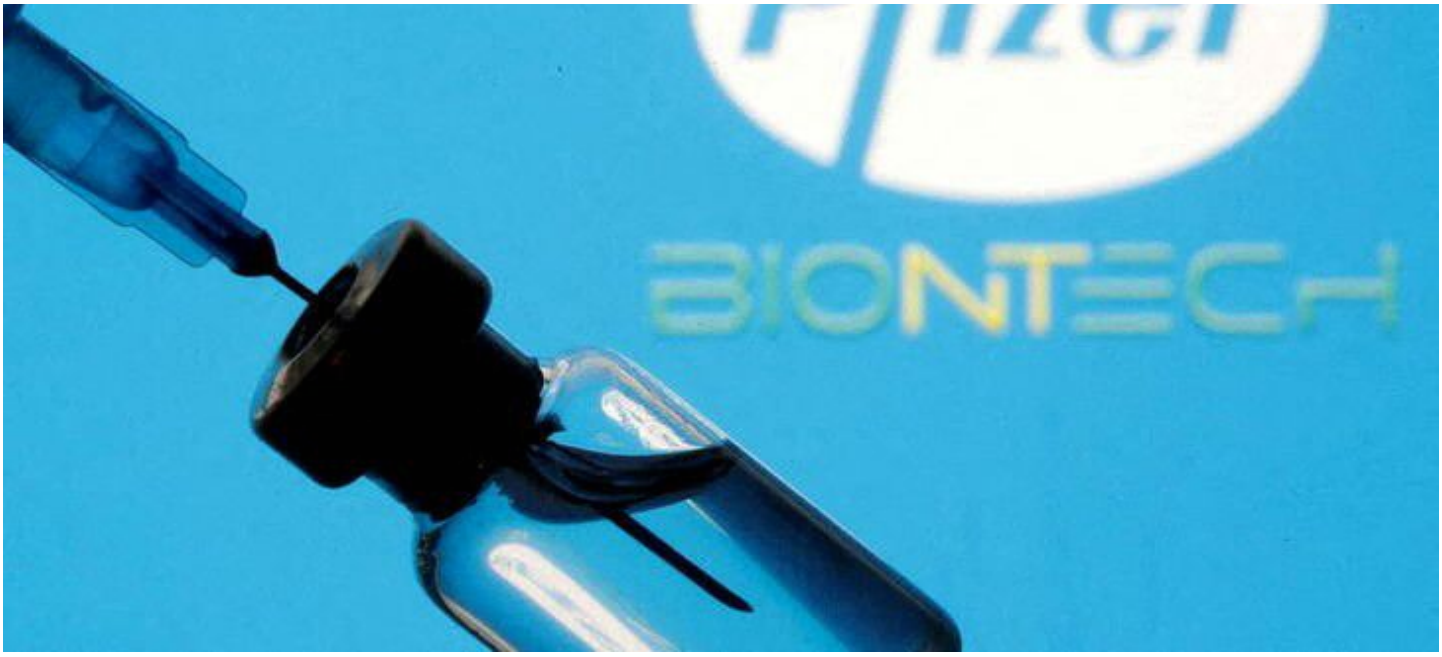

A vial and sryinge are seen in front of a displayed Pfizer and Biontech logo.REUTERS/Dado Ruvic/Illustration

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Jan 7 - Score one for transparency.

A federal judge in Texas on Thursday ordered the Food and Drug Administration to make public the data it relied on to license Pfizer's COVID-19 vaccine, imposing a dramatically accelerated schedule that should result in the release of all information within about eight months.

That's roughly 75 years and four months faster than the FDA said it could take to complete a Freedom of Information Act request by a group of doctors and scientists seeking an estimated 450,000 pages of material about the vaccine.

The court "concludes that this FOIA request is of paramount public importance," wrote U.S. District Judge Mark Pittman in Fort Worth, who was appointed to the bench by former President Donald Trump in 2019.

The FDA didn't dispute it had an obligation to make the information public but argued that its short-staffed FOIA office only had the bandwidth to review and release 500 pages a month.

While Pittman recognized "the 'unduly burdensome' challenges that this FOIA request may present to the FDA," in his **four-page order**, he resoundingly rejected the agency's suggested schedule.

Rather than producing 500 pages a month — the FDA's proposed timeline — he ordered the agency to turn over 55,000 a month. That means all the Pfizer vaccine data should be public by the end of the summer rather than, say, the year 2097.

Even if the FDA may not see it this way, I think Pittman did the agency — and the country — a big favor by expediting the document production.

I've been **chronicling this fight** since November and have heard from of readers who said they felt something was suspicious, even nefarious, in the FDA's proposed slo-mo timeline. Making the information public as soon as possible may help assuage the concerns of vaccine skeptics and convince them the product is safe.

Pittman in his order nodded to this as well, including a quote from the late senator John McCain, who said that excessive administrative secrecy "feeds conspiracy theories and reduces the public's confidence in the government."

Still, the FDA is likely to be hard-pressed to process 55,000 pages a month.

The office that reviews FOIA requests has just 10 employees, according to a declaration filed with the court by Suzann Burk, who heads the FDA's Division of Disclosure and Oversight Management. Burk said it takes eight minutes a page for a worker "to perform a careful line-by-line, word-by-word review of all responsive records before producing them in response to a FOIA request."

At that rate, the 10 employees would have to work non-stop 24 hours a day, seven days a week to produce the 55,000 pages a month (and would still fall a bit short).

But as lawyers for the plaintiffs Public Health and Medical Professionals for Transparency pointed out in **court papers**, the FDA as of 2020 had 18,062 employees. Surely some can be dispatched to pitch in at the FOIA office.

Aaron Siri of Siri & Glimstad, who represents the plaintiffs, in an email said the decision "came down on the side of transparency and accountability."

His clients — a group that includes more than 200 doctors, scientists, professors and public health professionals, including some who have publicly questioned the efficacy of lockdown policies, mask mandates and the vaccine itself — have pledged to publish all the information they receive from the FDA on their website.

The Justice Department, which represented the FDA in the litigation, did not immediately respond to a request for comment on Thursday evening. Pfizer, not a party to the suit, also did not immediately respond to a request for comment.

Pittman in his order made clear that the FOIA request, even if burdensome, has to be a priority for the FDA.

Quoting from remarks made during the hearing before him on December 14, he wrote that "there may not be a 'more important issue at the Food and Drug Administration . . . than the pandemic, the Pfizer vaccine, getting every American vaccinated," and assuring the public that the vaccine was not "'rush[ed] on behalf of the United States.'"

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