Exhibit 575

FDA Knew COVID Vaccine Safety Monitoring System Was 'Not Sufficient,' Latest Pfizer Documents Confirm

https://childrenshealthdefense.org/defender/fda-pfizer-covid-vaccine-final-documents-product-safety/?utm_source=luminate&utm_medium=email&utm_campaign=defender&utm_id=20231206

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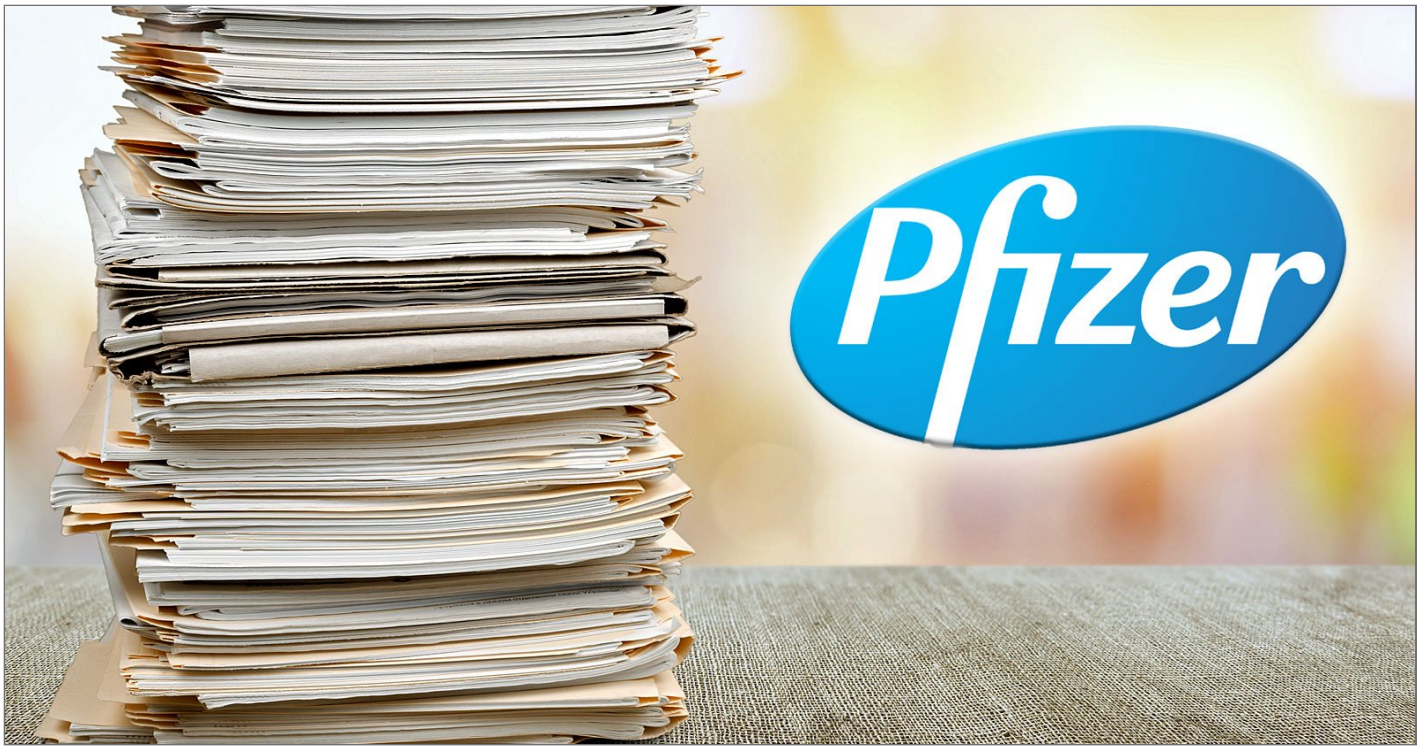
FDA Knew COVID Vaccine Safety Monitoring System Was 'Not Sufficient,' Latest Pfizer Documents Confirm

The U.S. Food and Drug Administration this week released its last batch of files related to the licensing of Pfizer's COVID-19 vaccine for ages 16 and up. The files reveal the agency knew its product safety monitoring system was "not sufficient" for assessing the risk for myocarditis and pericarditis following vaccination.

By Suzanne Burdick, Ph.D.



The U.S. Food and Drug Administration (FDA) released its final batch of documents related to licensing Pfizer's Comirnaty COVID-19 vaccine for ages 16 and up.

"Now, independent scientists and researchers can see everything FDA saw when it made its decision that this vaccine was 'safe and effective," according to a Dec. 4 press release by the Informed Consent Action Network (ICAN), a nonprofit that funded a lawsuit to get the files released.

This news comes more than two years after the agency on Aug. 23, 2021, approved Pfizer's vaccine. ICAN said:

> "With this final batch, the documents, presumably those relied upon by FDA to approve the vaccine, are finally in the hands of the public, where they belong, 800 days after approval!"

ICAN told The Defender it looks forward to seeing what independent researchers who review the documents will report. However, a few revelations from the 51,893 pages already stand out, the nonprofit said.

For example, a May 18, 2021, FDA memo reveals the agency was aware its national electronic system for monitoring product safety was "not sufficient" for evaluating the risk for myocarditis and pericarditis following receipt of the Pfizer vaccine.

CBER's Sentinel Program, which aims "to improve post-licensure safety surveillance of vaccines and other biologics," is part of the FDA's Sentinel Initiative to monitor the safety of FDA-regulated medical products, including drugs, vaccines and biologics.

The memo, "CBER Sentinel Program Sufficiency Assessment," concluded:

> "The CBER Sentinel Program is NOT sufficient to assess the serious risks of myocarditis and pericarditis, and subclinical myocarditis associated with COMIRNATY (BNT162b2) in lieu of PMR [post-market requirement] safety studies under FDAAA [the Food and Drug Administration Amendments Act].
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> "At the time of BLA [Biologics License Application] approval, the data sources in the CBER Sentinel Program are not sufficient to identify the outcomes due to lack of sufficient power to assess the magnitude of risk in patients 12-30 years of age.
>
> "In addition, CBER Sentinel Program is not sufficient to follow up cases for recovery status and long-term sequelae, or for identification and characterization of subclinical myocarditis cases."

The CBER Sentinel Program's inability to provide critical data is important, especially "when one looks at the bigger picture," ICAN said, adding:

> "Federal health authorities consistently claim the COVID-19 vaccines have been subject to the most robust safety surveillance programs in history.
>
> "Those programs are VAERS (which they always claim can never 'prove causation' and which has numerous issues), v-safe (data which should have troubled authorities), VSD (data the public does not have access to and cannot replicate), and the Sentinel/BEST systems.
>
> "When looked at individually, each of these has serious shortcomings, to say the least."

More cardiac deaths in vaccine vs. placebo group

Other documents in this final cache revealed that, during at least one of Pfizer's clinical trials, there were more fatal cardiac events in the vaccine group versus the placebo group.

Nine individuals who received the vaccine died due to a cardiac event while only five who received a placebo reported a cardiac-related death, the FDA's clinical review memo said.

The FDA concluded these cardiac-related deaths were "unlikely to be related to vaccination."

FDA wanted 75 years to release the data

The documents were released as a result of a Freedom of Information Act (FOIA) request filed in August 2021 by Public Health and Medical Professionals for Transparency (PHMPT), a group of more than 30 medical and public health professionals and scientists from institutions such as Harvard, Yale and UCLA.

In its FOIA 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.

After the FDA failed to respond to the request, PHMPT on Sept. 16, 2021, sued the FDA in the U.S. District Court for the Northern District of Texas.

According to FDA regulations, "After a license has been issued … data and information in the biological product file are immediately available for public disclosure."

Nonetheless, ICAN said, "PHMPT had to FOIA for the records, was denied expedited processing for the records, and had to sue FDA."

FDA lawyers told U.S. District Judge Mark Pittman the agency should be allowed to disclose the data slowly over 75 years, arguing that its small staff team needed a lot of time to redact trade secrets and personal information and could only release 500 pages a month.

However, Judge Pittman on Jan. 6, 2022, ruled the FDA must hand over the files at a rate of 55,000 pages every 30 days over a span of roughly eight months.

Since the court order, the batches of documents released by the FDA have shown concerning facts. For example, a cache released in May 2022 showed many adverse events in Pfizer's clinical trials were classified by the FDA as "unrelated" to the vaccine.

PHMPT's "only goal" was to obtain the records and disseminate them to the public, ICAN said. "It has done just that."

The FDA continues to claim on its COVID-19 vaccines website that its regulatory processes "facilitate the development of COVID-19 vaccines that meet the FDA's rigorous scientific standards."

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