FDA Releases Final Batch of Documents on Pfizer COVID-19 Vaccine Approval 2 Years Later

The FDA released the final batch of documents it relied upon in licensing Pfizer's Comirnaty COVID-19 vaccine for ages 16 and up—more than 800 days after the agency approved the shot and the vast majority of Americans were vaccinated.

The documents are "finally in the hands of the public, where they belong," the Informed Consent Action Network said in a press release. "Now, independent scientists and researchers can see everything FDA saw when it made its decision that this vaccine was 'safe and effective.'"

The recent documents were disclosed as part of a Freedom of Information Act (FOIA) lawsuit against the U.S. Food and Drug Administration (FDA) and show the agency knew its safety monitoring system was "not sufficient" for assessing the risk of heart conditions associated with Pfizer's COVID-19 vaccine

when it licensed the company's "Comirnaty" vaccine.

According to an Aug. 23, 2021, BLA Clinical Review Memorandum, there were more cardiac disorders in trial participants who received Pfizer's COVID-19 vaccine compared to the placebo group and more instances of tachycardia in the younger vaccinated age group.

Cardiac conditions were reported as the cause of death in nine participants 25 to 128 days after having received at least one dose of Pfizer's COVID-19 vaccine, including seven cases of cardiac arrest, one case of cardiovascular disease, and one case of congestive heart failure.

Five cardiac-related deaths in the placebo group occurred 15 to 81 days after having received a placebo, including two cases of myocardial infarction, one aortic rupture, and two cardiac arrests.

"Because COVID-19 mRNA and its Spike protein are found in the human heart at autopsy causing inflammation and heart damage, it is incontrovertible that the COVID-19 vaccines are cardiotoxic," according to cardiologist Dr. Peter McCullough.

"Younger individuals with healthy hearts take up more of the damaging vaccine into the cardiac tissue resulting in symptoms of chest pain, palpitations, fluctuations in blood pressure, dizziness, and sadly, some, end up with cardiac arrest either during exercise or in the early morning waking hours. At both time periods, an internal surge of adrenalin appears to be the trigger for the fatal arrhythmia in those with COVID-19 vaccine myocarditis," said McCullough.

Despite nearly double the number of reported cardiac events in vaccine recipients versus placebo recipients, the FDA concluded the deaths were "unlikely to be related to vaccination."

"As a cardiologist, these serious adverse events are

unacceptable," Dr. McCullough said. "I have called for all COVID-19 vaccines to be removed from the market with an urgent push for research strategies to prevent cardiac death after injection."

Vaccines Released Despite Manufacturing Issues

According to the Pfizer Andover Response to Form FDA 483 included in the released documents, numerous manufacturing issues and inadequacies in quality oversight were also identified. Several batches of COVID-19 vaccines were flagged for deviating from product quality standards, yet the affected batches were released to the public in various lots, the numbers of which were redacted.

In November 2021, whistleblower Brook Jackson, who worked as a regional director at testing sites by Pfizer contractor Ventavia, told the British Medical Journal that Pfizer's trial was riddled with issues. Ms. Jackson said the 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."

Jackson, a trained clinical trial auditor with more than 15 years of experience in clinical research coordination and management, emailed a complaint to the FDA and was fired later that day. She subsequently filed a lawsuit against Ventavia and Pfizer, alleging Pfizer had defrauded the government while developing its COVID-19 vaccine.

FDA Acknowledges Vaccine-Associated Enhanced Disease

In its Pharmacovigilance Plan Review Memorandum, the FDA referenced a condition called "vaccine-associated enhanced

disease." According to the journal Vaccine, VAED is the modified presentation of a clinical infection affecting individuals exposed to the wild-type pathogen after having received a vaccine for the same pathogen.

In its memo, the FDA stated there are reported deaths in the Vaccine Adverse Event Reporting System (VAERS) in patients reported to be fully vaccinated. Although the agency said that passive surveillance and spontaneous adverse event reporting generally cannot be used to conclude vaccine effectiveness because of the lack of a control group, reporter bias, and underreporting, "severe manifestations and death from COVID-19" increase the possibility of developing VAED, which has "overlapping clinical manifestations with natural SARS-CoV-2 infection, making it difficult to differentiate VAED from severe COVID-19 disease in individual VAERS reports."

The FDA said Pfizer was assessing the condition in its continuation of Phase 3 clinical studies and active surveillance studies. VAED has been observed in other vaccine trials involving the dengue virus, respiratory syncytial virus, and measles.

FDA Took More Than 2 Years to Release Data

The Public Health and Medical Professionals for Transparency, a nonprofit consisting of public health and medical professionals, scientists, and journalists, filed a FOIA lawsuit against the FDA in September 2021 to force the release of hundreds of thousands of documents relied upon by the agency in licensing Pfizer's COVID-19 vaccine for individuals age 16 and older.

Even though the FDA said in a news release it was committed to "ensuring full transparency, dialogue and efficiency" regarding COVID-19 vaccines and reiterated its commitment to

full transparency when it licensed Pfizer's Comirnaty vaccine, they wanted 75 years to produce an estimated 451,000 documents at a rate of 500 pages per month. It previously estimated it had 329,000 pages of responsive records and wanted 55 years to release them to the public.

Attorney Aaron Siri, who filed the lawsuit on behalf of the group, said the federal government was shielding Pfizer from liability, gave it billions of dollars, and forced Americans to get vaccinated while preventing the safety and efficacy data supporting the licensure of Pfizer's COVID-19 vaccine from being released until the year 2076. Yet it only took 108 days from when Pfizer started producing records to the agency for the FDA to license its vaccine.