Pfizer Misses FDA Deadline to Provide Results of Heart Inflammation Study

Pfizer missed its deadline to submit the results of a study designed to assess the frequency of heart inflammation in those who receive its COVID-19 vaccine. The U.S. Food and Drug Administration (FDA) in Aug. 2021 required Pfizer to conduct studies on its vaccine so that regulators could assess "known serious risks of myocarditis and pericarditis" reported in those who receive the shot.

Regulators also expressed concern about the risk of subclinical myocarditis—heart inflammation that occurs without typical symptoms. There have been numerous reported deaths in recipients of Pfizer's vaccine whose autopsies showed severe heart damage, yet their only reported symptom prior to death was fatigue.

Pfizer was told to conduct six studies and report those results to the FDA. The first deadline on Dec. 13 came and went. Pfizer was to complete the first study on subclinical

myocarditis following a third dose (or first booster) by June 30, 2022, in people aged 16 to 30 and was given six additional months to submit the final results.

When the FDA signed off on Pfizer's bivalent booster without clinical date or human trials on Dec. 8, the agency noted that Pfizer was "conducting additional safety-related post-authorization/post-marketing studies for the PfizerBioNTech COVID-19 Vaccine, including post-marketing requirements to assess known serious risks of myocarditis and pericarditis and an unexpected serious risk of subclinical myocarditis."

Myocarditis is heart muscle inflammation that can lead to cardiac arrhythmia and death. According to the National Organization for Rare Disorders, myocarditis can result from infections but is more commonly the result of the body's immune reaction to initial heart damage.

Pericarditis is inflammation of the tissue surrounding the heart that can cause sharp chest pain and other symptoms.

The FDA, on June 25, 2021, added a warning to patient and provider fact sheets for the Pfizer and Moderna COVID vaccines to indicate a risk of heart inflammation. In addition, the fact sheets were revised to include a warning about myocarditis and pericarditis after the second dose and with the onset of symptoms occurring within a few days after receiving the vaccine.

"The risk of myocarditis and pericarditis appears to be very low given the number of vaccine doses that have been administered," Janet Woodcock, acting FDA commissioner, said in a statement at the time. "The benefits of COVID-19 vaccination continue to outweigh the risks, given the risk of Covid-19 diseases and related, potentially severe, complications."

"The current evidence supports a causal association between mRNA COVID-19 vaccination and myocarditis and pericarditis,"

Dr. Tom Shimabukuro, a CDC official, said during a meeting in 2022.

At the same time, the CDC is not tracking all potential myocarditis cases occurring after receiving a COVID vaccine. The agency uses a narrowed case definition of "myocarditis," which allows them to exclude cases of cardiac arrest, ischemic strokes, and deaths due to heart problems that occur before one has the chance to go to the hospital, obtain a diagnosis, or "dies suddenly."

To meet the case definition of myocarditis, people must have had "symptoms such as chest pain, shortness of breath and feelings of having a fast-beating, fluttering or pounding heart, and medical tests to support the diagnosis of myocarditis and rule out other causes."

The CDC's website does not state what happens to these cases, but there is no indication they are tracked or included in the CDC's myocarditis numbers.

As of Dec. 30, 2022, 24,999 cases of myocarditis and pericarditis were reported to the CDC's Vaccine Adverse Event Reporting System, with 18,941 cases attributed to Pfizer, 5,569 cases to Moderna and 431 to Johnson & Johnson. It is well-known the agency has withheld and removed numerous myocarditis reports from the system and has yet to acknowledge the deaths in recently vaccinated young people attributable to the condition.