EN ES

the Defender™
CHILDREN'S HEALTH DEFENSE NEWS & VIEWS

06/28/21 • BIG PHARMA › NEWS

FDA Adds Heart Inflammation Warning to Pfizer, Moderna COVID Vaccines as Some Experts Call for Full Approval

The U.S. Food and Drug Administration added a warning to fact sheets — as advised by the CDC's Advisory Committee on Immunization Practices — for Pfizer and Moderna COVID vaccines indicating an increased risk of myocarditis and pericarditis following vaccination.

By Megan Redshaw

144

The Defender is experiencing censorship *on many social channels. Be sure to stay in touch with the news that matters by subscribing to our top news of the day.* ***It's free****.*

The U.S. Food and Drug Administration (FDA) on June 25 added a warning to patient and provider fact sheets for Pfizer and Moderna COVID vaccines indicating an increased risk of myocarditis and pericarditis following vaccination.

The warning notes reports of adverse events suggest increased risks of myocarditis and pericarditis, particularly following the second dose and with onset of symptoms within a few days after vaccination.

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

Pericarditis is often used interchangeably with myocarditis and refers to inflammation of the pericardium, the thin sac surrounding the heart.

CHD Calls on FDA to Take COVID Vaccines Off the Market - Submit a Comment

The FDA's update followed a review of information and discussion by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) meeting on June 23 where the committee acknowledged 1,200 cases of heart inflammation in 16- to 24-year-olds and said mRNA COVID vaccines should carry a warning statement.

"The data presented at this meeting reinforced the FDA's decision to revise the fact sheets and further informed the specific revisions," the FDA said in a statement.

Health officials said the benefits of receiving a COVID vaccine still outweigh any risks. Physicians and other public commenters accused the CDC during the meeting of exaggerating the risk to young people of COVID, and minimizing the risk of the vaccines.

Dr. Meryl Nass, an internal medicine physician, pointed out several flaws in the data used during the ACIP's presentation:

> "As of now, two major ways the rate of myocarditis were minimized [during the presentation] was to lump people from age 39 and down — even though the highest rates [of myocarditis] are in the youngest kids. This waters down the rate. The other method was to only include a very narrow window of time after vaccinations started in the 12-15 age group, thus omitting the vast majority of second doses, which is when about 75% or more of the myocarditis cases occur. Also, the genders were sometimes mixed. And rates in girls are much lower than boys."

During the CDC's presentation, Dr. Megan Wallance stated the overall efficacy of Pfizer's COVID vaccine in the 12 to 15 age group is 100% and Moderna's was comparable. Wallace then did a risk/benefit analysis comparing myocarditis cases versus hospitalization rates for COVID in people between the ages of 12 and 29.

"The problem with her analysis is that now the myocarditis rate used is too low. But the risk from COVID is magnified," Nass said.

Elizabeth Mumper, MD, FAAP, IFMCP and president and CEO of The RIMLAND Center, said:

> "The chance of a child less than 17 years of age dying from COVID-19 is 0.0005% according to the CDC's own numbers. Most pediatric patients have robust innate immune systems, meaning that they have strong defenses to a variety of viruses. Infections with beta coronaviruses, which kids are likely to have, induce strong and long-lasting immunity to the nucleocapsid protein that is likely to protect children from serious problems from COVID 19."

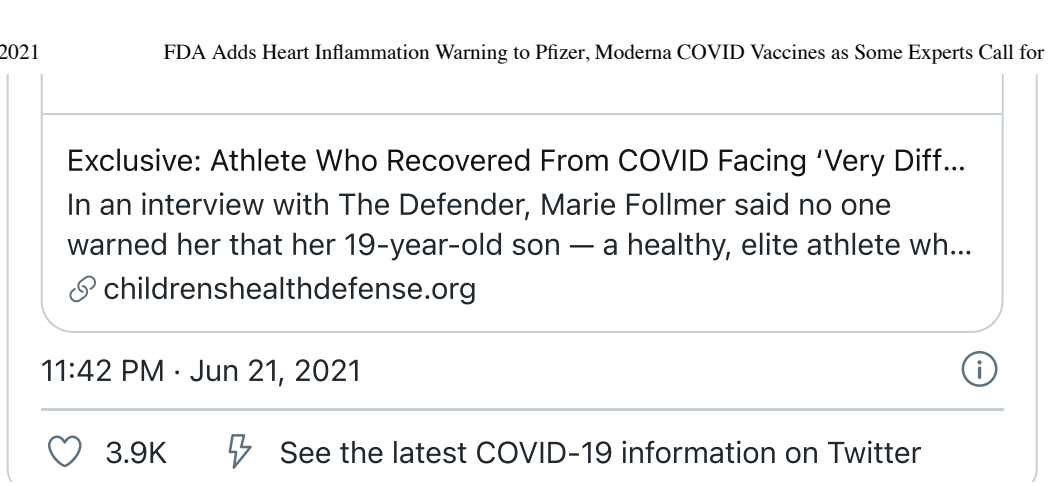
Mumper explained:

> "Healthy teen athletes have had the trajectory of their lives changed by having serious reactions to these vaccines — myocarditis, clots in the brain, postural hypotension and extreme fatigue to name but a few. I have seen alarming vaccine reactions in my practice in the short time that a small fraction of my patient population has received a novel vaccine."

Robert F. Kennedy Jr
@RobertKennedyJr

Another horrifying story! OSU student, elite athlete + member of ROTC developed severe heart complications following his second dose of Pfizer's COVID vaccine.

SUBSCRIBE to #TheDefender: bit.ly/3s5twWJ



Both the FDA and CDC are monitoring reports of heart inflammation and will follow up to assess long-term outcomes.

According to the latest data from the CDC's Vaccine Adverse Events Reporting System (VAERS), there have been 1,342 cases of myocarditis and pericarditis in all age groups reported in the U.S. following COVID vaccination between Dec.14, 2020 and June 18, 2021. Of the 1,342 cases reported, 835 cases were attributed to Pfizer, 458 cases to Moderna and 45 cases to Johnson & Johnson's COVID vaccine.

There have been 237 reports of myocarditis and pericarditis in 12- to 17-year-olds with 234 cases attributed to Pfizer's COVID vaccine.

Calls rise for FDA to fully approve COVID vaccines

According to The Hill, calls are rising from some experts for the FDA to fully approve COVID vaccines, as some unvaccinated people view current Emergency Use Authorizations for vaccines as an indicator they are experimental and not fully tested.

Pfizer submitted data for full approval May 7, but it is unclear when the FDA will act, leading to calls to pick up the pace. Moderna applied for full approval of its vaccine on June 1.

Gigi Gronvall, senior scholar at the Johns Hopkins Center for Health Security, said that while there should not be "political pressure" on the FDA, she would be interested in knowing what the holdup is.

"It could have a big impact on people getting [vaccinated] if it is FDA approved," Gronvall said. "I think it's worth asking why it hasn't happened yet."

Ashish Jha, dean of Brown University School of Public Health, said "Pfizer initiated request on May 7. It's 6 weeks later. Data is in. Vaccines are safe and effective. It's time for full approval."

Other experts said the FDA could undermine public confidence if they cut corners.

"If they hurry it up and don't complete their review very carefully, that will actually have the opposite effect," said Jesse Goodman, former FDA chief scientist. "I think that would really undermine confidence."

Nancy Allen LaPointe, faculty fellow at the Duke-Margolis Center for Health Policy, said it is important for confidence in vaccines that there not be "any perception or actuality of cutting a corner" in the FDA review for full approval.

Full approval of COVID vaccines will likely lead to more employee mandates. Boston Herald, a major hospital in Boston, announced June 24 it would require more than 80,000 Mass General Brigham employees be vaccinated against COVID once one of the three vaccines gain approval from the FDA.

According to the Los Angeles Times, the city of San Francisco announced last week it would require its 35,000 employees to get vaccinated against COVID or risk losing their jobs. Workers who refuse or fail to provide a religious or medical exemption could be terminated. The mandatory vaccination requirement goes into effect once COVID vaccines have been formally approved by the FDA, and extends to all city government employees, including police, firefighters, custodians and city hall clerks.

SUGGEST A CORRECTION

Megan Redshaw

Megan Redshaw is a freelance reporter for The Defender. She has a background in political science, a law degree and extensive training in natural health.