FDA claims on COVID-19 vaccine safety are unsupported by reliable data – and could severely hinder vaccine access

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The FDA has provided no evidence that children died because of receiving a COVID-19 vaccine.
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The Food and Drug Administration is seeking to drastically change procedures for testing vaccine safety and approving vaccines, based on unproven claims that mRNA-based COVID-19 vaccines caused the death of at least 10 children.

The agency detailed its plans in a memo released to staff on Nov. 28, 2025, which was obtained by several news outlets and published by The Washington Post.

Citing an internal, unpublished review, the memo, written by the agency's top vaccine regulator, Vinay Prasad, attributes the children's deaths to myocarditis, an inflammation of the heart muscle. And it says the deaths were reported to the Vaccine Adverse Event Reporting System, or VAERS, but provides no evidence that the vaccines caused the deaths.

The death of children due to an unsafe vaccine is a serious allegation. I am a pediatric cardiologist who has studied the link between COVID-19 vaccines and heart-related side effects such as myocarditis in children. To my knowledge, studies to date have shown such side effects are rare, and severe outcomes even more so. However, I am open to new evidence that could change my mind.

But without sufficient justification and solid evidence, restricting access to an approved vaccine and changing well-established procedures for testing vaccines would carry serious consequences. These moves would limit access for patients, create roadblocks for companies and worsen distrust in vaccines and public health.

In my view, it's important for people reading about these FDA actions to understand how the evidence on a vaccine's safety is generally assessed.

Determining cause of death

The FDA memo claims that the deaths of these children were directly related to receiving a COVID-19 immunization.

From my perspective as a clinician, it is awful that any child should die from a routine vaccination.

However, health professionals like me owe it to the public to uphold the highest possible standards in investigating why these deaths occurred. If the FDA has evidence demonstrating something that national health agencies worldwide have missed – widespread child deaths due to myocarditis caused by the COVID-19 vaccine – I don't doubt that even the most pro-vaccine physician will listen. So far, however, no such evidence has been presented.

While a death logged in VAERS is a starting point, on its own it is insufficient to conclude whether a vaccine caused the death or other medical causes were to blame.

To demonstrate a causal link, FDA staff and physicians must align the VAERS report with physicians' assessments of the patient, as well as data from other sources for monitoring vaccine safety. These include PRISM, which logs insurance claims data, and the Vaccine Safety Datalink, which tracks safety signals in electronic medical records.

It's known that most deaths logged only in VAERS of children who recently received vaccines have been incorrectly attributed to the vaccines – either by accident or in some cases on purpose by anti-vaccine activists.

Heart-related side effects of COVID-19 vaccines

In his Substack and Twitter accounts, Prasad has said that he believes the rate of severe cardiac side effects after COVID-19 vaccination is severely underestimated and that the vaccines should be restricted far more than they currently are.

In a July 2025 presentation, Prasad quoted a risk of 27 cases per million of myocarditis in young men who received the COVID-19 vaccine. A 2024 review suggested that number was a bit lower – about 20 cases out of 1 million people. But that same study found that unvaccinated people had greater risk of heart problems after a COVID-19 infection than vaccinated people. In a different study, people who got myocarditis after a COVID-19 vaccination developed fewer complications than people who got myocarditis after a COVID-19 infection.

Existing vaccine safety infrastructure in the U.S. successfully identifies dangers posed by vaccines – and did so during the COVID-19 pandemic. Today, most COVID-19 vaccines in the U.S. rely on mRNA technology. But as vaccines were first emerging during the COVID-19 pandemic, two pharmaceutical companies, Janssen and AstraZeneca, rolled out a vaccine that used a different technology, called a viral vector. This type of vaccine had a very rare but genuine safety problem that was detected.

VAERS, the Vaccine Safety Datalink, clinical investigators in the U.S. and their European counterparts detected that these vaccines did turn out to cause blood clotting. In April 2021, the FDA formally recommended pausing their use, and they were later pulled from the market.

Death due to myocarditis from COVID-19 vaccination is exceedingly rare. Demonstrating that it occurred requires proof that the person had myocarditis, evidence that no other reasonable cause of death was present, and the absence of any additional cause of myocarditis. These factors cannot be determined from VAERS data, however – and to date, the FDA has presented no other relevant data.

A problematic vision for future vaccine approvals

Currently, vaccines are tested both by seeing how well they prevent disease and by how well they generate antibodies, which are the molecules that help your body fight viruses and bacteria.

Some vaccines, such as the COVID-19 vaccine and the influenza vaccine, need to be updated based on new strains. The FDA generally approves these updates based on how well the new versions generate antibodies. Since the previous generation of vaccines was already shown to prevent infection, if the new version can generate antibodies like the previous one, researchers assume its ability to prevent infection is comparable too. Later studies can then test how well the vaccines prevent severe disease and hospitalization.

The FDA memo says this approach is insufficient and instead argues for replacing such studies with many more placebo-controlled trials – not just for COVID-19 vaccines but also for widely used influenza and pneumonia vaccines.

That may seem reasonable theoretically. In practice, however, it is not realistic.

Today's influenza vaccines must be changed every season to reflect mutations to the virus. If the FDA were to require new placebo-controlled trials every year, the vaccine being tested would become obsolete by the time it is approved. This would be a massive waste of time and resources.

Influenza vaccines must be updated for every flu season.

Jacob Wackerhausen/iStock via Getty Images Plus

Also, detecting vaccine-related myocarditis at the low rate at which it occurs would have required clinical trials many times larger than the ones that were done to approve COVID-19 mRNA vaccines. This would have cost at least millions of dollars more, and the delay in rolling out vaccines would have also cost lives.

Placebo-controlled trials would require comparing people who receive the updated vaccine with people who remain unvaccinated. When an older version of the vaccine is already available, this means purposefully asking people to forgo that vaccine and risk infection for the sake of the trial, a practice that is widely considered unethical. Current scientific practice is that only a brand-new vaccine may be compared against placebo.

While suspected vaccine deaths should absolutely be investigated, stopping a vaccine for insufficient reasons can lead to a significant drop in public confidence. That's why it's essential to thoroughly and transparently investigate any claims that a vaccine causes harm.

Vaccine vs illness

To accurately gauge a vaccine's risks, it is also crucial to compare its side effects with the effects of the illness it prevents.

For COVID-19, data consistently shows that the disease is clearly more dangerous. From Aug. 1, 2021, to July 31, 2022, more than 800 children in the U.S. died due to COVID-19, but very few deaths from COVID-19 vaccines in children have been been verified worldwide. What's more, the disease causes many more heart-related side effects than the vaccine does.

Meanwhile, extensive evidence shows that COVID-19 vaccination reduces the risk of hospitalization by more than 70% and the risk of severe illness in adolescent children by 79%. Studies also show it dramatically reduces their risk of developing long COVID, a condition in which symptoms such as extreme fatigue or weakness persist more than three months after a COVID-19 infection.

Reporting only the vaccines' risks, and not their benefits, shows just a small part of the picture.

I am a fellow of the American Academy of Pediatrics and regularly go on social media to share pro vaccine information.

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