

# FDA Claims on COVID-19 Vaccine Safety Are Unsupported By Reliable Data—And Could Severely Hinder Vaccine Access

By Frank Han

The Food and Drug Administration is seeking to drastically change procedures for testing vaccine safety<sup>1</sup> 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*.<sup>2</sup>

Citing an internal, unpublished review, the memo, written by the agency's top vaccine regulator, Vinay Prasad, attributes the children's deaths to myocarditis,<sup>3</sup> an inflammation of the heart muscle. And it says the deaths were reported to the Vaccine Adverse Event Reporting System, or VAERS,<sup>4</sup> 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.<sup>5</sup> 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.<sup>6</sup>

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,<sup>7</sup> 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.<sup>8</sup> These include PRISM, which logs insurance claims data,<sup>9</sup> and the Vaccine Safety Datalink, which tracks safety signals<sup>10</sup> 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<sup>11</sup>—either by accident or in some cases on purpose by anti-vaccine activists.<sup>12</sup>

## 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

<sup>1</sup> FDA Official Pledges New Vaccine Standards. Liz Essley Whyte. *Wall Street Journal*, November 29, 2025. <https://www.wsj.com/health/healthcare/fda-official-pledges-new-vaccine-standards-dd29b49a>

<sup>2</sup> Blaming some child deaths on covid shots, FDA vows stricter vaccine rules. *Washington Post*, November 29, 2025. <https://www.washingtonpost.com/health/2025/11/29/fda-vaccine-approval-child-covid-deaths/>

<sup>3</sup> F.D.A. Seeks More Oversight of Vaccine Trials and Approvals. *The New York Times*, Nov. 28, 2025. <https://www.nytimes.com/2025/11/28/health/fda-children-deaths-covid-vaccines.html>

<sup>4</sup> Vaccine death and side effects database relies on unverified reports – and Trump officials and right-wing media are applying it out of context. *The Conversation*, Sept. 17, 2025. <https://theconversation.com/vaccine-death-and-side-effects-database-relies-on-unverified-reports-and-trump-officials-and-right-wing-media-are-applying-it-out-of-context-265362>

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<sup>5</sup> Cardiac manifestations and outcomes of COVID-19 vaccine-associated myocarditis in the young in the USA: longitudinal results from the Myocarditis After COVID Vaccination (MACiV) multicenter study. Jain, S., et al. *eClinical Medicine*, Oct. 2024. <https://doi.org/10.1016/j.eclinm.2024.102809>

<sup>6</sup> FDA claims Covid shots killed 10 children and vows new vaccine rules. *NBC News*, Nov. 29, 2025. <https://www.nbcnews.com/health/health-news/fda-covid-vaccines-children-deaths-rcna246437>

<sup>7</sup> *Supra*, Note 4.

<sup>8</sup> FactChecked: Childhood Vaccines Are Carefully Studied—Including with Placebos—to Ensure They're Safe and Effective. *American Academy of Pediatrics*. <https://www.aap.org/en/news-room/fact-checked/fact-checked-childhood-vaccines-are-carefully-studied-including-with-placebos-to-ensure-theyre-safe-and-effective/>

<sup>9</sup> Post-licensure rapid immunization safety monitoring program (PRISM) data characterization. Baker, Meghan A., et al. *Vaccine*, Volume 31, Supplement 10, 30 December 2013, Pages K98-K112. <https://doi.org/10.1016/j.vaccine.2013.04.088>

<sup>10</sup> Monitoring vaccine safety using the vaccine safety Datalink: Assessing capacity to integrate data from Immunization Information systems. Groom, Holly C., et al. *Vaccine*, Volume 40, Issue 5, 31 January 2022, Pages 752-756. <https://doi.org/10.1016/j.vaccine.2021.12.048>

<sup>11</sup> What VAERS Is (And Isn't). *Johns Hopkins Bloomberg School of Public Health*. <https://publichealth.jhu.edu/2022/what-vaers-is-and-isnt>

<sup>12</sup> How anti-vaxxers target grieving moms and turn them into crusaders against vaccines. *NBC News*, Sept. 24, 2019. <https://www.nbcnews.com/tech/social-media/how-anti-vaxxers-target-grieving-moms-turn-them-crusaders-n1057566>

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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<sup>13</sup> 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.<sup>14</sup> 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<sup>15</sup> 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.<sup>16</sup> 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<sup>17</sup> to cause blood clotting.<sup>18</sup> In April 2021, the FDA formally recommended pausing their use,<sup>19</sup> and they were later pulled from the market.

Death due to myocarditis from COVID-19 vaccination is exceedingly rare.<sup>20</sup> 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<sup>21</sup> both by seeing how well they prevent disease and by how well they generate antibodies,<sup>22</sup> which are the molecules that help your body fight viruses and bacteria.

Some vaccines, such as the COVID-19 vaccine<sup>23</sup> and the influenza vaccine,<sup>24</sup> 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<sup>25</sup> with many more placebo-controlled trials<sup>26</sup>—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.

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<sup>27</sup> COVID-19 mRNA

<sup>13</sup> FDA to look again at myocarditis risk from mRNA-based COVID-19 jabs in young men. Dennis, Matthew. First Word Pharma, July 2, 2025. <https://firstwordpharma.com/story/5977619>

<sup>14</sup> Myocarditis Associated with COVID-19 Vaccination. Florek, K and Sokolski, M. Vaccines, 2024, 12(10), 1193. <https://doi.org/10.3390/vaccines12101193>

<sup>15</sup> Long-Term Prognosis of Patients With Myocarditis Attributed to COVID-19 mRNA Vaccination, SARS-CoV-2 Infection, or Conventional Etiologies. Semenzato, Laura, et al. JAMA, 2024;332(16):1367–1377. <https://doi.org/10.1001/jama.2024.16380>

<sup>16</sup> How RFK Jr.'s misguided science on mRNA vaccines is shaping policy – a vaccine expert examines the false claims. Fuller, Deborah. The Conversation, Sept. 5, 2025. <https://theconversation.com/how-rfk-jr-s-misguided-science-on-mrna-vaccines-is-shaping-policy-a-vaccine-expert-examines-the-false-claims-263027>

<sup>17</sup> US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021. See, Isaac, et al. JAMA. 2021;325(24):2448–2456. <https://jamanetwork.com/journals/jama/fullarticle/2779731>

<sup>18</sup> Cerebral Vein Thrombosis With Vaccine-Induced Immune Thrombotic Thrombocytopenia. Siegler, James E., et al. Stroke, 2021 Aug;52(9):3045–3053. <https://pubmed.ncbi.nlm.nih.gov/34304601/>

<sup>19</sup> Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021. MacNeil JR, Su JR, Broder KR, et al. MMWR Morb Mortal Wkly Rep 2021;70:651–656. <https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm>

<sup>20</sup> Prognosis of Myocarditis Developing After mRNA COVID-19 Vaccination Compared With Viral Myocarditis. Lai, F.T.T., et al. J Am Coll Cardiol. 2022 Dec 13;80(24):2255–2265. <https://pubmed.ncbi.nlm.nih.gov/36480967/>

<sup>21</sup> FDA official proposes 'impossible' standards for vaccine testing that could curtail access to immunizations. Liz Szabo, MA, CIDRAP, Dec. 1, 2025. <https://www.cidrap.umn.edu/childhood-vaccines/fda-official-proposes-impossible-standards-vaccine-testing-could-curtail-access>

<sup>22</sup> Antibodies. Cleveland Clinic. <https://my.clevelandclinic.org/health/body/22971-antibodies>

<sup>23</sup> COVID Vaccine. Cleveland Clinic. <https://my.clevelandclinic.org/health/procedures/covid-vaccine>

<sup>24</sup> Why do we need new flu shots every year? Komaroff, Anthony L. Harvard Health Publishing, Aug. 26, 2025. <https://www.health.harvard.edu/staying-healthy/why-do-we-need-new-flu-shots-every-year>

<sup>25</sup> FDA's Prasad tells staffers agency plans to get tougher on vaccine regulation, blames child deaths on COVID shots. Dunleavy, Kevin. Fierce Pharma, Dec. 1, 2025. <https://www.fiercepharma.com/pharma/prasad-tells-staffers-fda-planning-tighten-vaccine-recommendations>

<sup>26</sup> Experts say strict new FDA protocol for vaccine approval is 'dangerous and irresponsible'. The Guardian, Nov. 29, 2025. <https://www.theguardian.com/society/2025/nov/29/regulator-fda-stricter-protocols-vaccine-approvals>

<sup>27</sup> Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. Polack, Fernando P., et al. N Engl J Med 2020;383:2603–2615. <https://doi.org/10.1056/NEJMoa2034577>

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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<sup>28</sup> and risk infection for the sake of the trial, a practice that is widely considered unethical.<sup>29</sup> 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

<sup>28</sup> How to continue COVID-19 vaccine clinical trials? The ethics of vaccine research in a time of pandemic. Ceruti S, Cosentino M, Picozzi M. *Clinical Ethics*. 2021;17(1):32-40. <https://doi.org/10.1177/14777509211052467>  
<sup>29</sup> Fool's-gold science. Caplan, A., Pasady, F.L. & Mamo, N. F. *EMBO Rep* 26, 3979–3981 (2025). <https://doi.org/10.1038/s44319-025-00530-5>

confidence.<sup>30</sup> 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,<sup>31</sup> but very few deaths from COVID-19 vaccines in children have been verified worldwide. What's more, the disease causes many more heart-related side effects<sup>32</sup> than the vaccine does.

<sup>30</sup> Loss of confidence in vaccines following media reports of infant deaths after hepatitis B vaccination in China. Yu, Wenzhou, et al. *International Journal of Epidemiology*, Volume 45, Issue 2, April 2016, Pages 441–449. <https://doi.org/10.1093/ije/dyv349>

<sup>31</sup> Assessment of COVID-19 as the Underlying Cause of Death Among Children and Young People Aged 0 to 19 Years in the US. Flaxman S, Whittaker C, Semenova E, et al. *JAMA Netw Open*. 2023;6(1):e2253590. doi:10.1001/jamanetworkopen.2022.53590

<sup>32</sup> Risk of Myocarditis After Sequential Doses of COVID-19 Vaccine and SARS-CoV-2 Infection by Age and Sex. Patone,

Meanwhile, extensive evidence shows that COVID-19 vaccination reduces the risk of hospitalization by more than 70%<sup>33</sup> and the risk of severe illness in adolescent children by 79%.<sup>34</sup> Studies also show it dramatically reduces their risk of developing long COVID,<sup>35</sup> 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. ■

Martina, et al. *Circulation* Vol. 146, Number 10, August 2022. <https://doi.org/10.1161/CIRCULATIONAHA.122.059970>

<sup>33</sup> The effectiveness of COVID-19 vaccines in reducing the incidence, hospitalization, and mortality from COVID-19: A systematic review and meta-analysis. Rahmani, Kazem, et al. *Frontiers in Public Health*, Vol. 10, August 25, 2022. <https://doi.org/10.3389/fpubh.2022.873596>

<sup>34</sup> BNT162b2 Protection against the Omicron Variant in Children and Adolescents. Price, Ashley M., et al. *N Engl J Med* 2022; 386: 1899-1909. <https://doi.org/10.1056/NEJMoa2202826>

<sup>35</sup> Postacute Sequelae of SARS-CoV-2 Infection in the Pre-Delta, Delta, and Omicron Eras. Xie, Yan, et al. *N Engl J Med* 2024; 391: 515-525. <https://doi.org/10.1056/NEJMoa2403211>