



Written by [Veronika Kyrylenko](#) on December 15, 2025

Report: FDA Plans “Black Box” Warning for Covid Vaccines. Is It Enough?

The U.S. Food and Drug Administration (FDA) intends to put a “black box” warning on Covid-19 vaccines, [CNN reported](#) on Friday. If such a plan exists, it remains unfinished and opaque:

The plan has not been finalized and may still change. It wasn’t immediately clear whether the plans for the warnings, expected to be unveiled by the end of the year, would be applied only to mRNA vaccines or to all Covid-19 vaccines, or whether they would apply to all age groups.



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The infamous outlet denounced the possible move as unscientific, “shocking,” and “irresponsible.” CNN quoted “experts” who believed there “was no basis for the warning.”

Irresponsible the plan may be, but for a different reason. A warning label does not resolve the deeper problem of keeping these products on the market at all. In 2021, current Health and Human Services (HHS) Secretary Robert F. Kennedy Jr. [described](#) the Covid vaccine as “the deadliest” one ever made. Much of the responsibility for deaths and severe injuries linked to these products rests with the FDA, which has kept them on the market despite mounting evidence of harm. That includes [Pfizer’s own early safety data](#) shared with federal regulators. No official has been held accountable for the damage that followed.

Even under new leadership, the agency continues to approve updated versions of the shots while [evaluating only limited data](#). At the same time, Children’s Health Defense (CHD), the nonprofit founded by Kennedy, is [formally petitioning](#) the FDA to revoke the Covid vaccine licenses granted to Pfizer and Moderna.

What Is a Black Box Warning?

A black box warning is the most serious safety alert the FDA can place on a drug or vaccine label. In [federal regulations](#), it is formally called a “boxed warning.” It appears at the very top of the label, enclosed in a bold black outline, so it cannot be missed by doctors or patients.

The FDA requires this warning when evidence shows a risk of death or serious injury. It is used when harm is severe enough that it must shape prescribing decisions, limit who should receive the product, or require close monitoring. The warning is based on clinical trial data, post-marketing reports, or other compelling safety evidence.

In practical terms, a black box warning signals that a product carries extraordinary risk. It tells physicians that use demands heightened caution and clear informed consent. When the FDA applies one, it marks a fundamental shift in how the product is regulated, prescribed, and judged in both



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medicine and law.

CNN's report does not specify which risks would justify such a warning for Covid vaccines. Based on the abundant scientific evidence, Covid vaccines are linked to such [serious side effects](#) as premature death; cancer; reproductive damage; cardiovascular conditions including blood clots, myocarditis, and pericarditis; [neurological disorders](#); and many others.

Dr. Vinay Prasad: FDA's Approach to Covid Jabs

CNN says that the move is "orchestrated by Dr. Vinay Prasad, the FDA's chief medical and scientific officer and director of the agency's Center for Biologics Evaluation and Research [CBER]."

The outlet painted Prasad as a "critic" of the early Covid response who is trying to "undermine a vaccine that was a standout victory of [Donald Trump's first] term." Yet so far, he has not mounted a serious challenge to federal orthodoxy driven by Big Pharma.

Instead, Prasad and FDA Commissioner Dr. Marty Makary advanced the agency's ["new" Covid vaccine framework](#). It allows regulators to lean heavily on surrogate markers like immunogenicity when evaluating new Covid boosters for "high-risk" and older Americans.

Under this framework, the FDA has already approved updated Covid vaccines. In August, the agency cleared the 2025-2026 formulations of Pfizer BioNTech's Comirnaty and Moderna's Spikevax and mNEXSPIKE. It also granted full approval to Novavax's protein-based Nuvaxovid 2025-2026 formulation.

All four products appear on the [FDA's list of vaccines](#) licensed for use in the United States, reflecting a regulatory approach that allows annual Covid vaccine updates without requiring new large randomized trials demonstrating reductions in severe disease or death for "vulnerable" Americans.

Prasad's Memo on Children's Deaths

Most likely, any proposed black box warning would focus on the risk of myocarditis and pericarditis, particularly in young men. Earlier this month, Prasad made headlines over an internal memo ([pdf](#)) to CBER staff. In it, he made allegations of exceptional gravity.

Prasad wrote that FDA safety reviewers found that "at least 10 children have died after and because of receiving COVID-19 vaccination." He added that "the real number is higher," due to underreporting and attribution bias.

Prasad called the finding "a profound revelation," writing:

For the first time, the US FDA will acknowledge that COVID 19 vaccines have killed American children.

He emphasized that these were "healthy young children who faced tremendously low risk of death" from Covid itself. He further argued that vaccine mandates imposed through schools and institutions "may have been harmful."

Prasad revisited myocarditis risks, noting that young and healthy boys and men "bore the greatest risk." At the same time, federal agencies delayed public acknowledgment. He wrote that deaths reported between 2021 and 2024 were "ignored for years."



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The official also conceded that the FDA lacks reliable evidence of benefit in healthy children. He stated plainly:

FDA has never requested [that] manufacturers demonstrate in randomized fashion that vaccinating children improves these outcomes.

He further criticized prior leadership, writing that Dr. Peter Marks, the longtime head of the FDA's vaccine division, "pushed through a [Biologics License Application] for the COVID-19 shots." That enabled "unethical COVID-19 mandates" under Joe Biden's administration, per the memo.

Prasad closed the memo by outlining a "path forward" for vaccine regulation, calling for higher evidentiary standards and reduced reliance on surrogate markers.

If taken at face value, these statements demand immediate consequences. A senior FDA official asserting that vaccines "have killed American children" would be expected to advise pulling the products from the market and to prosecute officials who approved and defended the regulatory framework that allowed this outcome.

The memo does neither.

Is Warning Enough?

As extensively reported by *The New American*, the evidence of harm linked to Covid vaccines is substantial and growing. Against that backdrop, a reported black box warning barely scratches the surface. It does not begin to capture the scale of injury associated with products born out of the [largely secretive](#) Operation Warp Speed, mainly led by the U.S. military.

At the same time, many critics argue that the vaccines were [co-developed](#) alongside the Covid virus itself. And the latter is widely suspected of being a bioweapon. No individual has ever been held accountable for its development.

Just as important, the legal shield remains firmly in place. The unconstitutional apparatus of HHS continues to protect vaccine manufacturers and everyone involved in distribution and administration from meaningful legal scrutiny. That protection flows from the [PREP Act](#) (Public Readiness and Emergency Preparedness Act), which grants sweeping liability immunity during a declared public health emergency (PHE). The Covid PHE ended in May 2023, yet the PREP Act protections remain intact. They were [extended](#) under former HHS Secretary Xavier Becerra and never repealed by his successor, Robert F. Kennedy Jr.

Until that immunity is lifted, warnings and regulatory gestures ring hollow. Accountability remains out of reach, and the machinery that enabled harm continues to operate without consequence.



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