



Written by [Veronika Kyrylenko](#) on October 7, 2025

CDC Ends Blanket Covid Shot Guidance; Legal Immunity and Missing Data Remain

In a notable policy shift, the Centers for Disease Control and Prevention (CDC) has removed its universal recommendation for routine Covid-19 vaccination across all age groups and transitioned to “individual-based decision-making” for most Americans. [The update](#), posted on Monday, reflects new guidance from the CDC’s Advisory Committee on Immunization Practices (ACIP) and ends a three-year period of blanket endorsement of Covid shots.

Yet despite the headlines, a closer look reveals that critical systemic protections remain in place for vaccine manufacturers. At the same time, no meaningful actions have been taken to formally assess or communicate the risks that prompted this policy recalibration.



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Informed Consent: Rhetoric Without Substance

Deputy HHS Secretary and Acting CDC Director Jim O’Neill cast the CDC’s new vaccine guidance as a return to individual decision-making.

Informed consent is back.... CDC’s 2022 blanket recommendation for perpetual COVID-19 boosters deterred health care providers from talking about the risks and benefits of vaccination for the individual patient or parent. That changes today.

But for informed consent to be meaningful, it must be more than a slogan.

Under U.S. and international medical ethics, informed consent requires that individuals receive clear, accurate, and complete information about a medical intervention’s risks, benefits, and alternatives. Providers then must tailor this information to each person’s specific health status and social circumstances. Informed consent is not just a communication goal. It is a legal and ethical obligation, grounded in patient autonomy and medical transparency.

As the CDC itself explains, individual-based decision-making — or “shared clinical decision-making” — involves physicians, nurses, and pharmacists customizing vaccination decisions based on a patient’s unique risk factors, beyond just age, and the specific characteristics of the vaccine.

That clarity, however, is nowhere reflected in the new CDC guidance.

Unacknowledged Risks

Despite O’Neill’s assurance, the CDC and FDA have not released any updated risk-benefit analysis to



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support individualized decision-making. The CDC's current guidance still fails to meaningfully address well-documented harms, even as it [claims](#),

In COVID-19 vaccine clinical trials, most local and systemic post-vaccination reactions were mild to moderate and resolved in 1-3 days.

Myocarditis and pericarditis, it adds, are "rarely observed."

But this framing obscures much more than it reveals.

Thousands of myocarditis and pericarditis cases, particularly in young males, have been [reported](#) through VAERS and confirmed in multiple studies. Neurological events such as Guillain-Barré syndrome and small-fiber neuropathy have also appeared in the literature, yet remain absent from public-facing guidance. Menstrual irregularities, reported by large numbers of women and supported by several studies, continue to be underexplored by health authorities.

Similarly, immune dysregulation and [persistent post-vaccination symptoms](#) — sometimes referred to as "long vax" — remain poorly understood. As *The New American* [recently reported](#), serious issues such as premature deaths, reproductive harm, and DNA contamination in vaccine vials are also raising new questions, particularly regarding cancer risk and genomic integration.

Clinicians are left without up-to-date data or diagnostic frameworks to evaluate these pressing risks. Without full transparency about both frequency and severity of adverse events, any claim of informed consent becomes rhetorical.

The Questionable "Benefit"

The CDC's updated guidance claims to restore individual choice, but it still fails to clearly define the actual benefits of Covid vaccination — even for older adults and those with underlying health conditions.

The CDC quotes its outside experts from the Advisory Committee on Immunization Practices (ACIP),

ACIP's recommendation emphasized that the risk-benefit of vaccination in individuals under age 65 is most favorable for those who are at an increased risk for severe COVID-19.

Physicians such as Dr. Mary Bowden estimate that this category includes up to 70 percent of Americans. Indeed, [the CDC's broad, non-exhaustive list](#) spans a wide range of conditions — including cancer, HIV, obesity, diabetes, mood disorders, and even pregnancy.

Yet the government offers no new data to support the bold claim. There are no randomized controlled trials and no real-world outcome studies. The guidance relies instead on vague references to "benefit," resting more on assumption than on evidence.

This isn't an exaggeration. When evaluating vaccine effectiveness, the [FDA continues to rely on immunogenicity](#) — the ability of a vaccine to produce an antibody response — as the main basis for authorizing new Covid shots for people labeled "high-risk."

To explain simply, immunogenicity means your body makes antibodies after the shot. But that doesn't guarantee those antibodies will actually protect you from getting sick or dying — especially as the virus mutates, or if your immune system already has strong natural defenses. Producing antibodies is not the



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same as proving the vaccine works in the real world.

So far, the FDA has not required new randomized controlled trials or updated outcome data for the 2025 fall boosters. The guidance remains based on earlier studies with outdated variants and limited follow-up periods.

Program Update

Also on Monday, the CDC confirmed a major shift in vaccine distribution policy. [The update](#) says the U.S. government stopped purchasing and distributing Covid vaccines as of October 3, 2023, marking the formal end of the federal Covid vaccination program.

Since that date, Covid vaccines have been sold through the commercial marketplace. Private providers now determine how and when to administer them. However, vaccines are still fully [covered](#) by government-backed programs such as Medicare, Medicaid, CHIP, the Vaccines for Children Program, and ACA-regulated insurance. In other words, taxpayers continue to fund most vaccinations — even though the government no longer controls their distribution.

Oversight may have shrunk, but surveillance and data collection have not. The government no longer requires providers to issue vaccination record cards. But they must still report all Covid vaccinations to state and territorial immunization systems.

Additionally, the CDC has withdrawn all previous Covid vaccine versions from recommendation. Only the “updated” vaccine is currently authorized. Per the CDC,

All authorized/approved doses of COVID-19 vaccine in the United States are now the 2023–2024 formulas.

But, obviously, this raises question about efficacy: Those formulas target strains from two years ago. The virus has since evolved. The FDA [now plans](#) to greenlight a new booster for 2025–2026 based on the LP.8.1 variant from the JN.1 lineage. Yet by the time that formula rolls out, the virus will likely have mutated again. That means the federal playbook remains unchanged: Iterate the booster based on last year’s strain, skip outcome trials, and declare the process evidence-based.

Still No Repeal of PREP Act Immunity

Most crucially, the unconstitutional apparatus of HHS continues to shield vaccine manufacturers and all involved in distribution and administration from legal accountability. This protection stems from the PREP Act, which grants sweeping liability immunity during a declared public health emergency.

This includes immunity from lawsuits related to design defects and failure to warn. It even extends to cases of negligence, unless willful misconduct can be proven in a federal court. Although the “emergency” phase has officially ended, the PREP Act liability protections remain in effect. That is due to [extensions granted](#) by previous HHS Secretary Xavier Becerra and never repealed by Robert F. Kennedy, Jr.

If the administration is serious about restoring “informed consent,” it must also restore the right to legal recourse.



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