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FDA Approves Moderna's Covid Shot for "At-risk" Children as Young as 6 Months

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Moderna announced that the U.S. Food and Drug Administration (FDA) granted full approval of its Covid vaccine, Spikevax, for children aged 6 months through 11 years who are considered at increased risk for Covid-19 disease. The vaccine had previously been authorized only under Emergency Use Authorization (EUA). This new designation marks a major milestone for Moderna's pediatric product.

Moderna's CEO, Stéphane Bancel, praised the decision in the company's Thursday press release, stating, "Vaccination can be an important tool for protecting our youngest against severe disease and hospitalization." He also thanked the FDA for the "diligent scientific review and approval" of the genetic shot.

The company also said that it expects to make an updated version of Spikevax, called mNEXSPIKE, available for the 2025-2026 respiratory virus season. The FDA approved that jab for use in all adults 65 and older, as well as individuals aged 12-64 years with at least one underlying risk factor, in late May.

EUA vs. Full Approval: What Changed?

Emergency Use Authorization allows products to be used during public health emergencies without the full clinical testing typically required for licensure. Full FDA approval, on the other hand, involves more extensive review, including long-term safety and efficacy data, formal manufacturing inspections, and regulatory oversight.

Critics argue, however, that the difference has narrowed. With the pace of modern "streamlined" approvals — especially those involving AI-based automation — even full licensure today may lack the rigorous depth of past standards.

The Side Effects, in Moderna's Own Words

According to Moderna, the vaccine may cause a range of side effects. The company lists severe allergic reactions as a possibility, with symptoms like breathing difficulties, swelling of the throat, and rapid heartbeat. More alarming are the known risks of myocarditis and pericarditis, especially in younger males.

Other side effects include:

- Injection site pain and swelling;
- Fatigue, fever, and muscle pain;

- Fainting and febrile seizures in some children; and
- Vomiting, irritability, poor feeding, and loss of appetite in infants.

Moderna notes that "vaccination may not protect all people who receive the vaccine." It also urges parents to report adverse effects through the Vaccine Adverse Event Reporting System (VAERS).

Notably, early in the rollout, concerns over the rate and severity of side effects from Moderna's Covid vaccine prompted several European countries to restrict its use in younger populations. Sweden, Denmark, Finland, Norway, Germany, and France issued guidance limiting the vaccine in people under 30 — especially young males — after national health data confirmed elevated risks of myocarditis and pericarditis.

Kennedy's "Gold Standard"

When Robert F. Kennedy Jr. stepped into his role as secretary of Health and Human Services (HHS), he pledged "gold standard" science, full transparency, and independent review of all medical products. But the FDA's approval of Spikevax for young children raises serious questions about whether the agency is honoring those promises.

As part of the FDA's modernization effort, Commissioner Dr. Marty Makary announced in mid-May a sweeping initiative to deploy generative AI to accelerate the review of new therapies, including genetic products. The aim is faster approvals. The risk is less human oversight — and the limitations of AI itself. The FDA already struggles to ensure new drugs undergo meaningful testing before reaching the market. Generative AI, despite the buzz, does not offer true understanding. AI mimics patterns in language. It also fabricates, bluffs, and carries forward the blind spots and biases embedded in its training data.

No one knows how much of Moderna's pediatric submission was reviewed by FDA scientists, as opposed to AI-driven algorithms. If automated modeling handled most of the process, Kennedy's promise of "rigorous, independent science" already stands on shaky ground.

Adding to the concern, the FDA has yet to make public evidence supporting Spikevax's safety and efficacy in children with compromised health. In May, Kennedy publicly announced that the government had stopped recommending routine Covid vaccination for healthy children and pregnant women. Yet, according to the FDA's top brass, the list of "risk factors" that still justify vaccination is broad and vaguely defined. It includes conditions such as cancer, diabetes, obesity, mood disorders, and Down syndrome (and, ironically, pregnancy itself).

Given the growing body of evidence suggesting these vaccines may impair immune function, the FDA's decision to approve Spikevax for the vulnerable pediatric population is, at best, medically questionable.

CHD's Past Warning

Children's Health Defense (CHD), founded by Robert F. Kennedy Jr. long before his entry into government, has long warned that no child needs a Covid vaccine. For years, it cataloged injury reports, scrutinized trial data, and published expert analyses. So far, with Moderna's shot fully approved for use in "at-risk" children, CHD's weak reaction has been directed at the company — not at the agency run by its founder.

On January 8, just days before Trump returned to the White House, CHD republished a report by the Brownstone Institute titled "Moderna Covered Up Death, Injuries in COVID Vaccine Trials. Will Trump

Hold the Company Accountable?" The article alleged that Moderna concealed the death of a preschool-age child during clinical trials and failed to disclose a tenfold increase in serious adverse events among vaccinated children under 12. The death, from cardio-respiratory arrest, was uncovered through a European filing two years after it occurred. Moderna denied any link to the shot.

If true, the cover-up violates federal law requiring disclosure of adverse trial outcomes on ClinicalTrials.gov. Such omissions fall outside the PREP Act's liability shield and could trigger civil or criminal penalties. (The PREP Act is the Public Readiness and Emergency Preparedness Act, signed into law in 2005.)

The article argued that pharmaceutical companies have largely escaped accountability for widespread harm. At the same time, it condemned industry-aligned FDA leaders like Scott Gottlieb and Robert Califf for failing to enforce vaccine-trial reporting.

The report contrasted them with Trump's FDA pick, Dr. Marty Makary, who once criticized the government's handling of pediatric vaccination. For instance, he testified before Congress in 2023 that the U.S. "gave thousands of healthy kids myocarditis for no good reason," calling the outcome "avoidable."

Untouchable Shots, Rogue Agency

The irony of these developments is hard to miss. With Makary now in charge of vaccine oversight and Kennedy at the helm of the department that includes the FDA, CHD's warning no longer targets just a rogue pharmaceutical firm. It lands squarely on the shoulders of those once seen as the loudest critics of this system. If their goal is to "restore trust" in both vaccinations and the unconstitutional public-health apparatus, they now face a sobering test: prove that accountability applies not only to private industry, but to the very institutions they vowed to reform.

It is important to note that all Covid vaccines and boosters remain largely shielded from liability. Kennedy — who once condemned the vaccination campaign as "mass murder" — now presides over its continuation.

Kennedy holds the authority to amend or revoke the PREP Act, the legal shield protecting manufacturers through December 31, 2029. He has not done so.

Moreover, his HHS is actively expanding the program through its $4.7 billion "Project NextGen." That is a next-generation Covid vaccine initiative backed, reportedly, by funding from Bill Gates and the Rockefeller Foundation.