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COVID

FDA Approves New COVID Vaccines — for Virus Strains ‘Largely Faded From Circulation’

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The U.S. Food and Drug Administration **(FDA) approved updated mRNA COVID-19 vaccines** manufactured by Pfizer and Moderna which target the currently dominant Omicron variant KP.2 strain of SARS-CoV-2, the agency announced Thursday.

The new shots are recommended for all people ages 6 months and older. However, according to the FDA, the new vaccines remain under emergency use authorization (EUA) for people between ages 6 months and 11 years.

According to NBC News, the **new vaccines** could be available within days.

The vaccines were approved even though their **clinical trial data have not been released**. Manufacturers claim that "testing in animals shows the shots trigger neutralizing antibodies," The Epoch Times reported.

According to MedPageToday, the new vaccines "are manufactured using a similar process as previous formulas of these vaccines" and "the **FDA assessed** manufacturing and nonclinical data" in its approval process.

NBC News quoted a Pfizer spokesperson who said the data the company submitted to the FDA indicates a "substantially improved" **immune response** against the currently circulating **COVID-19** variants.

Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research, said in the FDA's statement, "Vaccination continues to be the cornerstone of COVID-19 prevention."

"These updated vaccines meet the **agency**'s rigorous, scientific standards for safety, effectiveness, and manufacturing quality," Marks said.

Pfizer, Moderna not liable for kids' injuries from EUA vaccines

Physicians and scientists who spoke with **The Defender** criticized the FDA's decision.

"With no clinical data released at all, the FDA and Marks are saying 'trust us' where they have not earned their trust," said Brian Hooker, Ph.D., chief scientific officer for **Children's Health Defense** (CHD).

"The COVID shots have no benefit whatsoever," said Steve Kirsch, founder of the **Vaccine Safety Research Foundation**. "They actually increase your risk of infection. They don't reduce your risk of hospitalization or death. They do increase your **all-cause mortality**. They are all downside."

Kirsch called it "astonishing" that public health agencies have not evaluated "all the evidence in plain sight" regarding the risks and **adverse effects of the vaccines**.

Dr. Peter McCullough told The Defender, "FDA approval of these vaccines is reckless and reprehensible. The new COVID-19 shots are not medically necessary nor clinically indicated. Pfizer and Moderna have not done cumulative dose **toxicity** studies or said how much mRNA and **spike protein** build up in the body with each shot."

Pediatrician Dr. Michelle Perro said children and pregnant women are at risk from the new vaccines. She said the vaccines have "caused innumerable harms to children, including neurologic, immunologic, and cardiac toxicity."

"There is never a time women or children should receive this genetic engineered product which has been shown to contain **contamination with DNA fragments** that are potentially genotoxic," Perro said.

Because the new vaccines remain under an EUA for children under 11, they are still subject to the immunity shield manufacturers enjoy under the **Public Readiness and Emergency Preparedness Act** (PREP Act).

"There are still **no licensed COVID-19 vaccines available for children**," said Ray Flores, senior outside counsel for CHD. Even though the **White House ended** the **COVID-19 public health emergency** in May 2023, the PREP Act's liability protections were extended through the end of 2024 — and may be extended again.

"The fact that COVID-19 vaccines are still being approved and authorized gives me pause," Flores said. "The FDA's announcement concerning these late-model vaccines all but guarantees that PREP Act liability protection will continue well into 2025 and beyond," Flores said.

Flores noted that both the **Pfizer** and **Moderna contracts** allow distribution in the U.S. only if these vaccines are **covered by the PREP Act**."

Waning efficacy, risk of injury among reasons cited for low uptake rates

In an **interview with NPR** Thursday, Marks appears to have hedged concerning the effectiveness of the new vaccines.

"The vaccine is not intended to be perfect," Marks said. "It's not going to absolutely prevent COVID-19. … But if we can prevent people from getting serious cases that end them up in emergency rooms, hospitals or worse — dead — that's what we're trying to do with these vaccines."

Marks suggested people recently infected with COVID-19 should wait two to three months before getting the new vaccine, in a nod toward **natural immunity**.

But other experts argued immunity makes it unnecessary to get vaccinated.

"By now, almost everyone has had a bout of COVID — more than **87% of Americans** according to the Centers for Disease Control and Prevention [CDC] — so most everyone has some degree of natural immunity, making new infections much less worrisome than in the past," said **Harvey Risch, M.D., Ph.D.**, professor emeritus and senior research scientist in epidemiology (chronic diseases) at the Yale School of Public Health.

NBC News and The Epoch Times both noted that the protection offered by previous versions of the COVID-19 vaccines quickly waned.

Citing the **New England Journal of Medicine**, NBC News reported that protection from prior versions of the vaccine peaked "about a month after the shot" before waning, "even when the vaccine is well matched to the circulating strains."

The Epoch Times cited **CDC figures** noting that protection against hospitalization afforded by prior COVID-19 vaccines "**plunged to 4 percent** after several months."

Yet, Marks told NPR the new vaccines will reduce the risk of contracting COVID-19 by 60%-70% and will cut the risk of serious illness by 80%-90%.

Despite these safety assurances, there are indications that many people are wary of the shots. Citing **CDC data**, NBC News reported that 22.5% of adults and 14.4% of children ages 6 months through 17 years received last year's version of the updated vaccines.

According to **MedPageToday**, even in the high-risk group of seniors ages 75 and over, less than half — 42% — received the COVID-19 vaccines in 2023-2024.

The FDA also claimed a low risk of serious adverse events connected to the COVID-19 vaccines.

"Serious side effects, such as the life-threatening allergic reaction called **anaphylaxis**," following COVID-19 vaccination, "are rare," the FDA stated.

According to NBC News, "Pfizer and Moderna's vaccines have been associated with a small but **increased risk of myocarditis**," adding that "Most people make a full recovery." The FDA's announcement makes little mention of potential adverse reactions, but says the vaccine's "benefits outweigh the risks."

But Perro told The Defender, "For individuals who have unfortunately developed **cardiac toxicity**, recovery is difficult due to persistent **circulation of spike protein**."

She added:

> "The theory that spike protein is quickly broken down has not proven to be true. It can persist in some people. The ongoing idiocy of injecting a gene-altering therapy into an individual to produce a toxic protein which may not get broken down should be immediately abandoned."

New vaccines target strains that 'have largely faded from circulation'

According to NBC News, this is "the third time the vaccines have been updated to match circulating strains since the original series," noting that the new vaccines are being released amid an uptick in positive COVID-19 cases, emergency room visits and hospitalizations related to the disease.

The FDA said it **advised vaccine manufacturers in June** that new versions of the COVID-19 vaccines should target the JN.1 variant. However, the **FDA later revised its recommendation**, advising manufacturers to target the KP.2 strain.

Yet, **according to NPR**, both of the new vaccines "target strains that have already been overtaken by even newer variants."

According to a June 13 **NBC News article**, "As of Saturday, a sister strain called KP.3.1.1 accounts for about 36% of all new Covid cases, while another sister strain, KP.3, accounts for about 17%."

"**JN.1 and KP.2** have largely faded from circulation," NBC News said in December 2023, citing the **CDC COVID Data Tracker**.

The FDA is also reviewing an application from Novavax for its own updated COVID-19 vaccine — which targets JN.1, according to NPR.

Yet, according to Marks, "Given waning immunity of the population from previous exposure to the virus and from prior vaccination, we strongly encourage those who are eligible to consider receiving an updated COVID-19 vaccine to provide better protection against currently circulating variants."

Experts questioned these claims.

"Introduction of this 'new' vaccine designed for evolving strains is flawed science. By the time they are developed, the virus will have again evolved," Perro said.

"By the time that the vaccine is received and new immunity developed, it will be mostly gone, with KP.3 variants in the great majority," Risch said. "At this point, the benefit of another dose of COVID vaccine is pretty doubtful," Risch said.

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