U.S. Health Agencies Approve Updated Experimental COVID Vaccines Based on Minimal Data

The U.S. Food and Drug Administration (FDA) on Sep. 11 authorized new single-strain COVID-19 vaccines by Pfizer and Moderna without adequate clinical data showing the shots are safe or effective.

According to the FDA, the new vaccines are authorized for emergency use for children 6 months through 11 years of age and are fully approved for people 12 and older.

“The public can be assured that these updated vaccines have met the agency’s rigorous scientific standards for safety, effectiveness, and manufacturing quality. We very much encourage those who are eligible to consider getting vaccinated, said Dr. Peter Marks, director of the FDA’s Center for Biologics Evaluation and Research.

The Centers for Disease Control and Prevention's (CDC) vaccine advisors met on Sep. 12 to discuss who should receive an updated vaccine. Some advisors questioned whether there was enough data to approve the vaccine universally for everyone, but only one member, Dr. Pablo Sanchez, voted against the recommendation.

"CDC is now recommending updated COVID-19 vaccination for everyone 6 months and older to better protect you and your loved ones," CDC director Dr. Mandy Cohen said in a press release after signing off on the panel's recommendations.

Although the vaccines are considered "updated," they still target an almost obsolete strain—omicron XXB.1.5 variant, which currently represents only 3.1% of strains.

While it's recognized the new vaccines do not target current dominant variants, vaccine makers who stand to make billions off their products say their vaccines will still offer protection against those strains as children return to school and the weather cools down. Yet, no data has been presented to support this claim.

Pfizer CEO Albert Bourla said in a press release that he expects the vaccine will be available "in the upcoming days," which is consistent with the timeline the Biden administration gave before the new shots were even authorized.

Pfizer CEO Albert Bourla and Moderna CEO Stéphane Bancel, who are not medical doctors, also urged Americans to receive their updated COVID shot during the same appointment as their annual flu shot, even though the co-administration of these two vaccines has not been tested for safety.

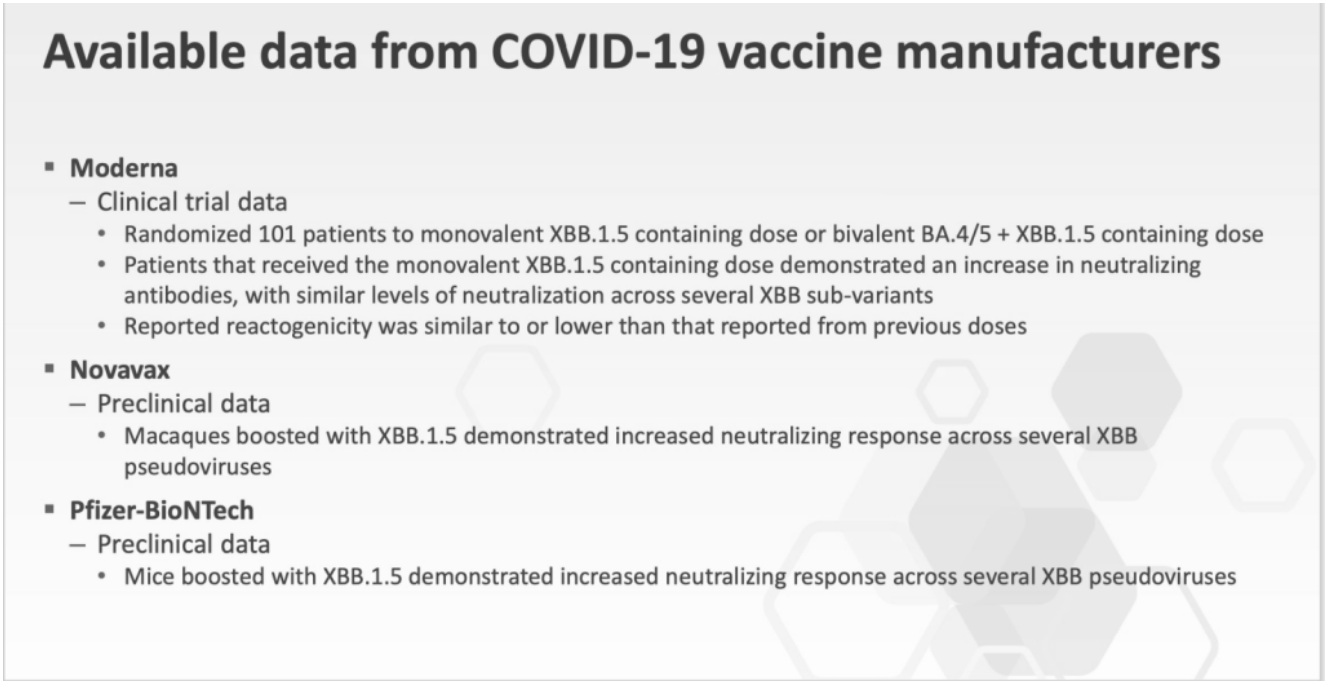
Critics Criticize Lack of Human

Clinical Trials

Numerous critics emphasized the lack of human clinical trials that formed the basis for approving the new vaccines, as Pfizer's vaccine was only tested on mice—not people.

> *The new FDA approved covid shots were tested*
>
> *On four rats*
>
> *Yes, four rats*
>
> *Four. Rats.*
>
> *— Jordan Schachtel @ dossier.today (@JordanSchachtel) September 12, 2023*

Here's the available data on COVID-19 vaccines presented by manufacturers Moderna, Pfizer, and Novavax:



For Moderna, there is clinical data on just 101 patients—half of whom received the new monovalent vaccine and half who received the bivalent vaccine. Per the data, no individuals received a placebo, which is essential for a risk-benefit analysis.

For Pfizer, there is preclinical data from 10 mice. Pfizer data on efficacy or adverse events is entirely unknown.

Although an updated Novavax vaccine has not yet been authorized, it appears their preclinical data isn't much different.

Of the 50 study participants who received Moderna's new monovalent vaccine, 1 in 50 people had a medically-attended adverse event related to the vaccine, yet the CDC said with certainty that the vaccine's benefits outweigh the risks for all individuals.

It's important to note this trial began four months ago, yet Moderna only reported 14-day side effects.

Table S4. Unsolicited Treatment-emergent Adverse Reactions (Safety Set)

n (%)	Monovalent mRNA-1273.815 (XBB.1.5) 50 µg (N=50)	Bivalent mRNA-1273.231 (XBB.1.5 + BA.4/BA.5) 50 µg (N=51)
Unsolicited AEs Regardless of Relationship to Study Vaccination		
All	5 (10.0)	7 (13.7)
Serious	0	0
Fatal	0	0
Medically-Attended	4 (8.0)	4 (7.8)
Unsolicited AEs Related to Study Vaccination		
All	1 (2.0)	2 (3.9)
Serious	0	0
Fatal	0	0
Medically-Attended	1 (2.0)	0

AEs = adverse reactions. AE=adverse event. An adverse event was defined as any event not present prior to study vaccination or any event already present that worsened in intensity or frequency after vaccination. Percentages are based on the number of participants in the safety set.

"What if I told you 1 in 50 people who took a new medication had a "medically-attended adverse event," and the manufacturer refused to disclose what the complication was, would you take it," Dr. Marty Makary, physician and professor at Johns Hopkins posted on "X."

"And what if the theoretical benefit only lasted for a 3-mo window, after which time the benefit is gone? And that the FDA cleared it without any human outcomes data, would you take it?

And that European regulators are not universally recommending the same medication for everyone as the CDC is?

“And that Drs. Ashish Jha and Mandy Cohen are making unsupported claims that it reduces hospitalizations, long-COVID, and makes you less likely to spread COVID (if the manufacturers made those same claims, they could be fined by the FDA for making false marketing claims beyond its approved indication).

“That’s the new Moderna COVID vaccine. FDA or Moderna (I can’t tell the difference sometimes) should disclose the details of the clinical trial complication rather than keeping it secret.”

The only “study” we have from Moderna is this pre-print published Sep. 7 on MedRxiv, and the data it provides is exclusive to antibody production. Although they state they have vaccine efficacy data, the CDC and FDA have not published or requested it.

Journalist Alex Berenson looked at the CDC’s COVID-19 vaccine data and pointed out that 1 million mRNA COVID vaccines for teens will prevent 0 to 1 COVID-19 deaths while causing 100,000-200,000 severe side effects.

> *Again, from @CDCgov’s OWN data:*
>
> *1 million mRNA Covid shots for teens will prevent*
>
> *0-1 Covid deaths*
>
> *and CAUSE*
>
> *100,000-200,000 severe side effects.*
>
> *Yes, you read that right. pic.twitter.com/GXpgIw3DvC*
>
> *— Alex Berenson (@AlexBerenson) September 13, 2023*

“The math: Moderna trial teen subjects had a 25% risk of Grade 3/4 adverse events if they received the shot, 5% for placebo,” Berenson posted on “X.”

“For Pfizer, the rates were about 11% and 2% (Pfizer is a lower dose; why the placebo rates were different IDK.) That’s a gap of 0.09 to 0.2, x1MM shots.”

Biden Administration Orders More COVID Vaccines for Kids

Despite the fact that only 17% of Americans chose to get “boosted” last fall, the Biden administration upped its orders two weeks ago for the pediatric version of the new COVID vaccines from 14.5 million doses at $1.3 billion to 20 million doses for $1.7 billion. They appear to be gearing up to push the vaccine on children, which is a group European regulators are not targeting.

Moderna’s vaccine isn’t even approved in parts of Europe for people under 30 due to its propensity to cause heart damage.

“Pushing a new COVID vaccine without human-outcomes data makes a mockery of the scientific method and our regulatory process. In fact, why have an FDA if White House doctors can simply declare a drug to be safe after discussing secret data in private meetings with pharma,” wrote Makary and epidemiologist Dr. Tracy Høeg in The New York Post.

“If public health officials don’t want a repeat disappointing turnout of Americans who get the COVID booster shot, they should require a proper clinical trial to show the American people the benefit,” they added. “Public health leaders cannot afford to squander any more credibility and money on interventions with no scientific support.”