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# FDA Clears New COVID-19 Vaccines in Bid to Counter Waning Effectiveness

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*U.S. drug regulators on Sept. 11 cleared new COVID-19 vaccines to try to counter the poor effectiveness provided by the current options.*

The U.S. Food and Drug Administration (FDA) cleared shots from Moderna and Pfizer that will be available to Americans as young as 6 months old later this month.

> "Vaccination remains critical to public health and continued protection against serious consequences of COVID-19, including hospitalization and death," Dr. Peter Marks, a top FDA official, said in a statement. "We very much encourage those who are eligible to consider getting vaccinated."

The FDA approved the Moderna and Pfizer vaccines for people aged 12 and older. Regulators granted emergency authorization for the shots for people aged 6 months to 11 years.

There was no mention of Novavax, whose vaccine is also currently available in the United States.

The shots target XBB.1.5, a subvariant of the Omicron virus variant. That subvariant has already largely been displaced by newer strains, including EG.5, according to the U.S. Centers for Disease Control and Prevention (CDC).

The authorizations came despite a dearth of data from clinical trials.

Moderna stated that in a trial, its new shot induced immune responses against EG.5, also known as Eris, and other newer variants.

Pfizer stated that preclinical data have shown that antibodies generated by its new

vaccine "effectively neutralize" EG.5.

The new shots were authorized based on studies on neutralizing antibody levels that appeared to show "a similar magnitude to the extent of neutralization observed with prior versions of the vaccines against corresponding prior variants against which they had been developed to provide protection," the FDA stated. "This suggests that the vaccines are a good match for protecting against the currently circulating COVID-19 variants."

The CDC plans to meet with its advisers on Sept. 12 to consider which populations it should recommend receive the new vaccines. If the panel recommends a vaccine, the federal government must pay for it.

Many countries have suggested that younger, healthy people not receive COVID-19 vaccinations as the disease has died down.

The United Kingdom, for instance, in August, said that vaccination this fall was recommended only for select groups, including people designated as at-risk.

The CDC scaled back its recommendations earlier this year for some populations.

CDC Director Dr. Mandy Cohen said earlier this year that the CDC was poised to recommend annual COVID-19 shots.

Pfizer and Moderna have said the new shots will cost about $110 to $130.

## Number of Shots

The new vaccinations are cleared for varying numbers of shots, depending on age group and prior vaccination.

People aged 5 years and older, whether or not they've received a vaccine, are eligible to receive a single dose of one of the new shots.

Children aged 6 months through 4 years who have previously been vaccinated can receive one or two doses of one of the new vaccines.

Children in that age group who haven't been vaccinated can receive three doses of the new Pfizer vaccine or two doses of the new Moderna vaccine.

## Another Replacement

The FDA cleared, and the CDC recommended, updated shots in the fall of 2022 amid waning effectiveness.

Those shots were bivalent, containing components of the Wuhan strain and Omicron.

Those shots haven't performed well against infection or severe disease, according to observational data. They were authorized and recommended based on animal testing.

Just 17 percent of the U.S. population had received a bivalent dose as of May 10, the most

recent date the CDC lists data for. Some doctors have opted against receiving them.

The FDA stated that it expects to update the vaccines on an annual basis, as it does with influenza vaccines.

A survey of more than 2,000 adults in Arizona found that the primary reason for not receiving a bivalent was having protection from prior infection.

Other common reasons included wariness about side effects and the belief that the booster wouldn't add protection.

## Novavax

Novavax said its newer shot performed well against newer variants, but the FDA didn't clear it. Novavax said in a statement that its updated vaccine is "under review" by the FDA.

> "We still expect to be available this fall and anticipate we will be a player for the season," a Novavax spokesperson told The Epoch Times via email.

An FDA spokesperson told The Epoch Times in an email: "Questions about the application's current status may be directed to the company. As the FDA has done throughout the pandemic, we will make information available as appropriate."

## Criticism

Some experts have criticized U.S. authorities for clearing the new shots without strong data.

> "There's essentially no data," Florida Surgeon General Dr. Joseph Ladapo said at a recent press conference. "Not only that, but there are a lot of red flags."

He pointed to studies finding that the effectiveness of the vaccines turns negative over time.

Other papers have found that the vaccines cause cardiac problems such as heart inflammation, the doctor noted.

> "It's truly irresponsible for FDA, CDC, and others to be championing something … when we don't know the implications of it," he said.

Dr. Paul Offit, an FDA adviser, suggested to the UK's Daily Mail that younger, healthy people who have already been vaccinated don't need one of the new doses.

> "We are best served by targeting these booster doses to those who are most at risk of severe disease," such as people older than 75, Dr. Offit said. "Boosting otherwise healthy young people is a low-risk, low-reward strategy."

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*Featured image is from Children's Health Defense*

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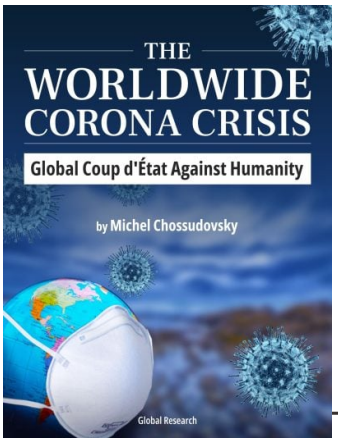

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