

Frontline News

1199 MEMBERS ON THE FRONT LINES OF THE FIGHT AGAINST COVID-19

FDA GRANTS FULL APPROVAL TO PFIZER VACCINE

On Aug. 23 the U.S. Food and Drug Administration (FDA) announced that it had granted full approval of the Pfizer coronavirus vaccine for people 16 years and older. The drug will be marketed under the name Comirnaty, the FDA said in its announcement. Of the more than 170 million people in the U.S. vaccinated against COVID-19, 92 million have received the Pfizer vaccine.

While all COVID-19 vaccines are currently being administered under an Emergency Use Authorization (EUA), the FDA announcement makes Pfizer's drug the first COVID-19 vaccine available in the US beyond emergency use status. To be eligible for use under an EUA, the FDA requires at least half of the participants of the original studies to be followed for at least two months post-vaccination. This is because the vast majority of vaccine-related side effects occur right after vaccination. Full FDA approval requires participants in the original studies to be followed for at least six months. Reviewers



look at data from the same study participants but collected over a longer period. All adverse events are examined.

Pfizer presented data to the FDA showing the vaccine was 91 percent effective in preventing COVID-19 infections. While Pfizer's vaccine is fully approved for adults, the vaccine will still be authorized for emergency use for children ages 12 to 15.

"While this and other vaccines have met the FDA's rigorous scientific standards for emergency use authorization, as the first FDA-approved COVID-19 vaccine, the public can be confident that this vaccine meets the FDA's gold standard for safety, effectiveness, and manufacturing quality that we require for an approved product," said FDA acting Commissioner Dr. Janet Woodcock.

Regulators are still reviewing Moderna's application for full approval of its vaccine. That decision could take several weeks. Johnson & Johnson is expected to apply soon for full approval.

NEW STUDY: VACCINATIONS PREVENT COVID-19 HOSPITALIZATION

The New York State Department of Health recently released findings from another study showing that the currently available vaccines are highly effective in preventing hospitalization from COVID-19. New York State officials reviewed hospitalizations among vaccinated New Yorkers aged 18 years and older, comparing those rates among the unvaccinated from May 3 to July 25. Researchers found vaccines remain about 92 to 95 percent effective at preventing hospitalizations among those who have been vaccinated. Effectiveness of the vaccines dropped from 92 to 80 percent in reducing COVID-19 cases, but researchers stressed the vaccines remain key in lowering new cases and hospitalizations.

QUESTION OF THE WEEK

Q: *How can I protect my children from the Delta variant?*



A: Because delta is more contagious than earlier variants, children are at somewhat greater risk of infection. Those who are 12 and older are eligible for the Pfizer-BioNTech vaccine, and federal health

officials recommend that families inoculate eligible children to provide them greater protection. Paul A. Offit, a pediatrician and the director of the Vaccine Education Center at Children's Hospital of Philadelphia, suggests parents make sure that unvaccinated children ages 2 and older wear masks when they are in indoor public spaces, in accordance with CDC guidance. The CDC also recommends parents make sure their unvaccinated children wash their hands often with soap and water; avoid close contact with those who are coughing, sneezing or complaining of feeling unwell; and limit interactions with people who are at high risk of developing severe disease.