

# Pfizer's COVID-19 vaccine earns FDA nod. Here's what comes next.

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**What's the news:** The Food and Drug Administration (FDA) has granted emergency use authorization to the Pfizer-BioNTech COVID-19 vaccine for people 16 or older. The authorization came after a positive recommendation by the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC), whose meeting was livestreamed on YouTube.

This follows similar moves by the governments of Canada and the United Kingdom, where Margaret Keenan, a 90-year-old woman from Northern Ireland, on Dec. 8 became the first person not enrolled in a clinical trial to receive the vaccine.

"For much of this year, physicians, nurses and front-line health care personnel have done Herculean, unprecedented work to care for patients and prevent the spread of COVID-19—all while scientists and researchers sprinted to develop a safe and effective vaccine," said AMA President Susan R. Bailey, MD.

"After a thorough, rigorous, transparent review process, today's decision by the FDA to grant an emergency use authorization (EUA) for the first COVID-19 vaccine developed by Pfizer and BioNTech is a monumental milestone with the potential to set us on a road to recovery," Dr. Bailey added. "The comprehensive, science-based, transparent nature of this process is critical to inspiring the public's confidence in this vaccine."

**Learn more about the FDA's emergency use authorization process for COVID-19 vaccines.**

**Why it's important:** More than 15 million Americans have had a COVID-19 infection and there are now more than 100,000 COVID-19 patients in U.S. hospitals. Close to 280,000 Americans have died from COVID-19, and the University of Washington's Institute for Health Metrics and Evaluation projects the pandemic will kill 55,000 each month into next year.

“A highly effective vaccine, with sufficient uptake as supplies become available, may be able to induce population herd immunity to bring the pandemic under control,” states the briefing book Pfizer-BioNTech provided the FDA before the Dec. 10 VRBPAC hearing.

“The ongoing COVID-19 pandemic has a significant impact on public health, and currently there is no broadly effective treatment or prevention available,” Pfizer-BioNTech added. “An effective vaccine can impact the trajectory of the pandemic at this critical time.”

**What’s next:** The interim recommendation of the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) calls for allocating initial supplies of COVID-19 vaccines to health care personnel and residents of long-term care facilities, citing ethical principles and SARS-CoV-2 epidemiology.

The committee met Dec. 11 and will meet again Dec. 12 to make recommendations specific to the Pfizer-BioNTech vaccine. Read more about who’s first in line for coronavirus vaccination.

CDC figures indicate that, as of Nov. 15, about 500,000 COVID-19 cases and 70,000 deaths have been reported among residents of skilled nursing facilities. As of Dec. 1, about 245,000 COVID-19 cases and 858 associated deaths have been reported among U.S. health care personnel, the CDC says.

One vaccine expert has warned that immunizing hospital staff will take planning and coordinating because some may experience their bodies’ natural immune response induced by the vaccine and they could potentially experience low-grade fever, headache, muscle aches or fatigue.

“You’re not going to vaccinate your whole emergency staff at the same time and have them all out the next day,” said Paul A. Offit, MD, director of the Vaccine Education Center and an attending physician in infectious diseases at Children’s Hospital of Philadelphia, during a JAMA Network™ livestreamed video interview.

The Pfizer-BioNTech product is not the only one on the FDA’s radar. Data for Moderna’s candidate vaccine will be reviewed by the VRBPAC panel Dec. 17.

The benefits for the Pfizer-BioNTech vaccine were determined to significantly outweigh risks in terms of safety and efficacy, but the FDA will continue its analysis of the vaccine. In particular, the FDA briefing book presented at the VRBPAC hearing identified the following elements that will be further studied:

- Duration of protection provided by the vaccine.
- Effectiveness in certain populations at high-risk of severe COVID-19, people previously infected with SARS-CoV-2, and children.

- Future vaccine effectiveness as influenced by characteristics of the pandemic, changes in the virus, or potential effects of co-infections.
- Vaccine effectiveness against asymptomatic infection, long-term effects of COVID-19 disease, mortality, and transmission of SARS-CoV-2.

Learn more about top HHS officials' answers to physician questions on COVID-19 vaccines.