What full FDA approval of Pfizer's vaccine means for the future of the pandemic

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After evaluating data from clinical trials and millions of doses administered in the real world, the U.S. Food and Drug Administration (FDA) this week approved Pfizer-BioNTech's COVID-19 vaccine for individuals 16 years of age and older. It is the first of three vaccines with FDA Emergency Use Authorization (EUA) to be approved. Moderna is also expected to get its full FDA approval soon.

The clinical trials for the COVID-19 vaccines are among the largest ever conducted, enrolling thousands of volunteers and producing large amounts of data. More than 200 million people in the U.S. have received at least one dose of vaccine.

Emory University has been involved in testing all three vaccines currently in use in the U.S—Pfizer, Moderna and Johnson & Johnson (Janssen). We spoke with two Emory infectious diseases physicians, Aneesh Mehta and Colleen Kelley, about what FDA vaccine approval means for the future.

Q: Does the FDA approval mean that the vaccine is safe and effective?

A: The data from vaccine clinical trials indicate that vaccines are safe and effective at reducing the transmission of COVID-19 and severe illness. The Centers for Disease Control and Prevention (CDC) made public robust data from these trials that indicated generally low frequency and low severity of side effects.

"We have more evidence of the safety of this vaccine than we do for any other vaccine in the history of medicine," says Kelley. "Millions of people have been vaccinated, some of them as long as a year ago, and we are still not seeing any indications of safety concerns." If individuals still have questions, they should reach out to their health care providers.

Q: What is the difference between Emergency Use Authorization (EUA) and full FDA approval?

A: An EUA can be invoked in public health emergencies when there are no other effective treatments or prevention strategies for the disease. The Pfizer, Moderna and Johnson & Johnson vaccines all received EUA

based on safety and efficacy data from the clinical trials.

"Because we have a long history of very successful vaccines that have been implemented for many infectious diseases, we know well how long we should monitor people after vaccination to observe any side effects," Kelley says. "In almost all cases, any side effect from a vaccine is generally seen within six weeks of vaccination. For that reason, FDA requires eight weeks of clinical follow up of safety data before they would consider a vaccine for emergency use or full approval review."

After receiving EUA, the vaccine manufacturers submit for full FDA approval through a Biologics License Application (BLA). Pfizer is the first vaccine to receive full BLA approval after extensive evaluation of both the safety and manufacturing processes of the vaccine.

Q: When will the FDA issue EUA for vaccines for children under age 12?

A: Vaccines for children require separate evaluations for efficacy and safety because children's immune systems work differently than those of adults. "Children are not just little adults," says Mehta. "They require specific approaches for medical care and prevention of disease, such as vaccines."

The FDA needs to review vaccine clinical trial data for children ages 5 to 11 to determine the appropriate dosages and intervals for vaccinating children. This could happen later this year or early 2022.

Q: What's the difference between a third shot and a booster?

A: A booster is an additional dose of vaccine administered when the

initial immune response to a primary vaccine series is sufficient but may have waned over time. The Biden administration hopes to have comment from the FDA and CDC by Sept. 20 on who should receive booster shots and when they should be administered.

A third dose of vaccine is administered when the immune response following a primary vaccine series is likely to be insufficient. The FDA has already authorized third doses for a small percentage of adults with severely weakened immune systems, such as patients who receive chemotherapy, take immunosuppressive medications, have advanced HIV or are organ transplant recipients.

"We have seen data from our colleagues around the world showing that even after two doses of the mRNA vaccines, many of our transplant patients don't have significant levels of protection, which is measured by the number of antibodies, T cells and B cells in their blood," Mehta says. "The FDA has authorized a third dose to help get patients in these special categories a higher level of protection."

Q: Is the vaccine effective against the Delta and Lambda variants?

A: As new COVID-19 variants develop, scientists are evaluating how well the current vaccines work against them. Health experts know that the vaccines are effective at preventing severe illness and hospitalizations due to COVID-19.

"A very small percentage of people who have been vaccinated actually end up getting very ill, and that is what the vaccines were designed to do," says Kelley. "They are doing exactly what we hoped they would do, which is save lives and reduce morbidity and mortality."

Researchers also continue to develop vaccines designed to better combat variants moving forward.

Q: What are the current masking guidelines for vaccinated individuals?

A: Masks are now necessary for everyone in public indoor settings, regardless of vaccination status. "It's a no-brainer right now because there is so much transmission," says Kelley. "For lower-risk environments such as small indoor gatherings of vaccinated people, individuals must assess their personal risk tolerance when deciding whether to wear a mask."

Q: How can we protect children under 12 who are returning to school but are not eligible for the vaccine?

A: Masking is essential to protect young children who are not eligible for the vaccine. "I have young children, and I think it's really critical for us to get our children back in school safely," says Mehta. "I am very much a believer that children wearing masks while indoors in school is important for preventing the spread, keeping children in school and protecting their teachers."

Q: How do vaccinations impact hospital capacities?

A: Most people who are critically ill with COVID-19 are unvaccinated. The recent influx of unvaccinated patients with severe COVID-19 is filling up intensive care units (ICUs) and stretching hospital systems across the country.

"When our ICUs are full, we put critical stress on the staff, on the supply lines, and on the tools that we use to take care of critically ill patients," Mehta says. "We have to have the ability to care for all the sick members of our community, and if we have tools such as vaccines to prevent people from being in the hospital and ICUs, it is critical that we use those tools to establish health and wellness for everyone in the community."

Q: Will the FDA's approval lead to more vaccine mandates?

A: Scientists have excellent data to support the benefits of vaccine mandates in schools, workplaces and health care settings. The hope is that FDA approval and any subsequent vaccination mandates will increase the uptake of vaccine in our communities.

Provided by Emory University

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