

August 23, 2021

FDA Gives Full Approval to Pfizer-BioNTech COVID-19 Vaccine

See statement from AHA, AMA and ANA, as well as resources hospitals and health systems can use to promote vaccination efforts

The Food and Drug Administration today granted full approval for the Pfizer-BioNTech COVID-19 vaccine for individuals age 16 and over. The vaccine, which will now be marketed as Comirnaty, is the first COVID-19 vaccine to go beyond emergency use status in the United States. The vaccine continues to be available under emergency use authorization, including for individuals ages 12 through 15 and for the administration of a third dose in certain immunocompromised individuals. For more details, see the [FDA press release](#), as well as FAQs and fact sheets [available here](#).

In a [statement shared with the media](#) today following the full approval, the AHA, American Medical Association and American Nurses Association, said:

“Today’s full approval of the Pfizer-BioNTech COVID-19 vaccine by the U.S. Food and Drug Administration (FDA) – the result of many months of work, robust data evaluation, and a thorough, comprehensive review process that has already protected more than one hundred million Americans from severe COVID-19 complications – is a major step forward in the worldwide effort to end this pandemic. The vaccines to prevent COVID-19 are effective; we have known that for months as health care professionals were among the first to get vaccinated and have advocated for our patients to get vaccinated to save lives. But today’s news marks a critical moment for people who were concerned about getting vaccinated due to the vaccines being authorized for emergency use. With millions of data points on the vaccine’s safety and efficacy over nearly nine months of vaccinations, every ‘i’ is dotted and every ‘t’ is crossed. This vaccine is safe, it prevents severe COVID-19, hospitalization, and deaths, and it will save your life.

“According to recent polling, 30 percent of unvaccinated people said they were waiting for vaccines to receive full approval before getting vaccinated. We are there now; this vaccine is fully approved. If uncertainty was holding you back, now is the time to act. And if you still have questions about the vaccines or about COVID-19, please consult your health care professional.

“Science, data, and thorough research have given us the tools to defeat COVID-19. With the delta variant surging, there has never been a better time to get vaccinated.

“FDA approval also should further reinforce efforts in the health care field to achieve high levels of vaccination.”

RESOURCES TO HELP WITH COVID-19 VACCINATIONS

The AHA continues to provide the field and the public with new resources to promote vaccine confidence. Please visit our [vaccine confidence webpage](#) for a host of resources that you can use and customize for your community, as well as our [consumer vaccine webpage](#) that addresses common questions about vaccine use.

FURTHER QUESTIONS

If you have questions, please contact AHA at 800-424-4301.