

December 11, 2020

## FDA Authorizes Pfizer COVID-19 Vaccine for Emergency Use

*Data Indicates First Approved Candidate Is 95% Effective with No Significant Safety Issues*

The Food and Drug Administration today granted an [emergency use authorization](#) to Pfizer, Inc. for its BNT162b2 mRNA COVID-19 vaccine, paving the way for its immediate administration across the country. The vaccine is administered in two doses, 21 days apart, and requires ultracold (minus-70 degrees Celsius) temperature storage. Health care workers and nursing home residents will receive first priority and the first shots could be given out within days.

[Peer-reviewed data](#) published Dec. 10 in the New England Journal of Medicine confirmed the vaccine's safety and efficacy, concluding that a two-dose regimen of BNT162b2 conferred 95% protection against COVID-19 in individuals 16 years of age or older, with safety over a median of two months similar to that of other viral vaccines.

“America’s hospitals and health systems believe the announcement by the Food and Drug Administration of an Emergency Use Authorization of the Pfizer COVID-19 vaccine is an important step forward in ending this pandemic,” said Rick Pollack, AHA President and CEO. “This authorization was made on the advice after a careful review by scientific and clinical experts through a thoughtful process. We will continue to be guided by science and follow the evidence that the FDA lays out on the safety and efficacy of the various vaccines in development.

“In addition to playing an important role in vaccination efforts across the country, we also know that along with our physician and nursing partners that we have an important role to play in providing the public with clear and concise information that informs them about the benefits of being vaccinated. This is especially important so that the public has the necessary confidence to allow them to make this important decision for their families and loved ones. Because of the long road ahead of us until COVID-19 vaccines are widely available, the AHA continues to urge the American public to wear masks, maintain physical distancing and wash their hands.”

Watch for another Special Bulletin soon with additional details on the EUA.

### NEXT STEPS

Visit AHA’s [website](#) to review a host of resources on COVID-19 vaccines and therapeutics, including materials on distribution and workforce issues.

## **FURTHER QUESTIONS**

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