

# COVID-19 vaccine approvals: The AMA helps answer your questions

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As a pediatric allergist and immunologist for more than 30 years, I know firsthand the critical role physicians play as vaccine ambassadors for our patients. We need to assure them that a vaccine is not only safe and effective, but also that a rigorous scientific review was completed before it was made available to the public.

Never has our role as vaccine ambassadors been more important, and more urgent, than it is right now as the COVID-19 pandemic continues to reach record-high levels across the country.

We know that you probably have a lot of questions and some concerns about the accelerated vaccine process that has led to such encouraging news reports of late. Ensuring that your questions are answered, and that you can confidently ease vaccine concerns conveyed by your patients, is an important role for the AMA as we move closer to a safe and effective vaccine.

One of many tools we've used to advance our mission involves a series of COVID-19 webinars featuring the nation's highest-ranking subject matter experts, including leading scientists and researchers, who are working tirelessly to protect us during the most severe threat to public health in a century.

The fourth installment of our "COVID-19: What Physicians Need to Know" series is set for 1 p.m. CST, Thursday, Dec. 3. That is when Peter Marks, MD, PhD, will join me for a deep dive into the emergency use authorization process and what it means for the creation and distribution of a safe and effective vaccine for COVID-19. Learn more and register now.

As a career employee and the director of the Food and Drug Administration's Center for Biologics Evaluation and Research, Dr. Marks leads a highly skilled and experienced team of scientists charged with scrutinizing mountains of data before deciding whether one or more COVID-19 vaccine formulations is both safe and effective. Dr. Marks was also featured in the first webinar in this series.

All of these webinars are available free on our website.

Preliminary results from the phase 3 trials of multiple vaccine candidates have been extremely encouraging, but even so a monumental task awaits us in allocating, distributing and administering one or more FDA-approved vaccines. The logistics involved in manufacturing, shipping and storing approved vaccines in the quantities needed to vaccinate tens of millions initially, and hundreds of millions eventually, are staggering.

## Remaining on guard

Our hope and optimism around a COVID-19 vaccine is tempered by the reality we now face. COVID-19 case counts are surging in record numbers around the country. Hospitals, even in some of our largest metro regions, are maxed to capacity as we head into the holiday season. Deaths continue to climb.

Increased volumes of air and highway travel during the just-concluded Thanksgiving weekend threatens to further aggravate the current situation in our nation, which finds us posting 1 million new cases each week. The mounting death toll includes thousands of physicians, nurses and other frontline health care personnel, whose heroism will be remembered and honored always.

Our fight against this virus is far from over. While encouraging reports about vaccines inspire hope for what will come in 2021, it is crucial that physicians continue to reinforce the measures we know will limit the spread of COVID-19: Wearing masks when outside the home, washing hands, maintaining safe physical distancing, and limiting time spent indoors with others. Until a vaccine is available for mass distribution, these simple tactics remain our best defense in this pandemic.

Given the grim projections by some epidemiologists, the next few months may prove to be the most challenging we have encountered. Dr. Marks and the career scientists at the FDA have earned my trust by adhering to the strictest scientific protocols in completing a rigorous, transparent and evidence-based vaccine approval process, so that we all may be fully confident of the final result.

COVID-19 fatigue is every bit as real as the virus itself, but we cannot let our guard down now. Even as we take the first steps to recover the world we knew before this pandemic struck, physicians and the entire health care community must continue to model the behavior shown to lower rates of transmission while restoring the health of those who have fallen ill. Together we can, and we will, prevail.