

# How the FDA plans to build physician trust for COVID-19 vaccine

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The Food and Drug Administration (FDA) is working at top speed to vet several vaccine candidates to help protect patients from SARS-CoV-2, the novel coronavirus that causes COVID-19. The agency is also fighting to regain the public's trust in vaccines and to assure patients and physicians that science is driving the vaccine-approval process.

"Vaccine confidence is at an all-time low—at least in my lifetime," said Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research. "Vaccine confidence is the ultimate goal here."

Dr. Marks appeared with AMA President Susan R. Bailey, MD, in the first installment of an AMA-hosted webinar series for physicians addressing COVID-19 vaccine development and the FDA review process for SARS-CoV-2 vaccine candidates. The AMA has made the full webinar, along with a transcript, available.

In her first question to Dr. Marks, Dr. Bailey brought up what she described as "the big elephant in the room," and asked how patients and physicians can be assured that politics won't affect the vaccine-approval process.

Dr. Marks pointed to the FDA's "incredible staff of career scientists," which includes infectious disease physicians, statisticians and manufacturing experts from a variety of disciplines, and said the ultimate determination on whether a vaccine is safe and effective will be made by them.

## Transparency vital for trust

Fielding questions from the webinar audience, Dr. Bailey asked Dr. Marks how the FDA can restore the public's confidence so physicians and patients will have faith that COVID-19 vaccines are safe

and effective amid a climate of skepticism and doubt.

“One way we get it back is we have people who are career scientists who get out there and articulate that we are here for the American public,” Dr. Marks replied. “We’re here to make sure that our greater American family gets the same quality, safe, effective vaccine that we want for our own family.”

In addition, there is a commitment to making the process as transparent as possible. Companies seeking FDA approval of their vaccines must present data at a public meeting of the FDA’s Vaccines and Related Biological Products Advisory Committee. Documents from the companies and the FDA will be posted online at least two business days before the meetings.

Individuals can also present data, information, or views, orally or in writing, on issues pending before the committee. The next meeting is scheduled for Oct. 22 to discuss “the development, authorization and/or licensure of vaccines to prevent COVID-19.” No specific application is expected to be discussed.

Read Dr. Bailey’s AMA Leadership Viewpoints column, “We must be able to trust the FDA vaccine approval process.”

## Pathways to approval

Dr. Marks described the processes for the FDA’s two pathways to approval: emergency use authorization (EUA) and biologics license application (BLA), and he mentioned the recent FDA guidance regarding EUA.

Manufacturers for three potential multidose vaccines have agreed to trials with 30,000 people, while the maker of a single-dose vaccine has agreed to enroll 60,000. These numbers will provide large data sets capable of answering safety and efficacy questions, Dr. Marks said.

“We’re going to have to see clear and compelling efficacy in a large, well-designed phase 3 clinical trial, much the same way as we would need for the determination of a substantial evidence of effectiveness that we would see in a biologics license application,” he said.

“We’ll also be using a public advisory committee meeting to have a very transparent process here so that people can see, when this vaccine comes through, the data are robust and compelling, and they’ll have confidence in this, we hope, and as we hope physicians will.”

The BLA pathway can generate hundreds of thousands of pages for the agency to review, Dr. Marks said, adding that EUA is more streamlined but will include rigorous post-vaccination surveillance using large claims-based databases including some linked to patients’ electronic health records. If

adverse effects are detected, the FDA will issue alerts “rapidly and broadly,” he said.

Learn why Anthony S. Fauci, MD, predicts the FDA’s coronavirus vaccine review will be politics-free.

## The question of when

The other big question physicians asked was when a vaccine would be available.

Dr. Marks said there is “a reasonable likelihood” of availability at the end of the year that could be deployed for front-line workers “in a significant way by the beginning of the new year.” He added, however, that this was “speculation and a bit of wishful thinking, but I think it’s informed speculation.”

In order for people to get their lives back “as we would like them to be,” he said there needs to be a vaccine that is 70%–80% effective that is administered to 70%–80% of the population.

“But we’re not going to get 70% to 80% of people to take it unless we really come together as communities,” Dr. Marks said.

Regarding public acceptance, Dr. Marks predicted that some communities will be early adopters. As these communities demonstrate success in getting COVID-19 under control, their “success will breed success” elsewhere.

Dr. Bailey thanked Dr. Marks for his “insights and candor,” and she added that “total transparency and honesty is what’s going to make the difference between vaccine acceptance and vaccine hesitancy.”

## More to come

The next installment in the webinar series also is hosted by Dr. Bailey and focuses on the role of the Centers for Disease Control and Prevention (CDC) in prioritizing allocation and distribution of vaccines, and the physicians’ role in vaccine distribution and tackling vaccine hesitancy.

Dr. Bailey’s guests are Nancy Messonnier, MD, director of the National Center for Immunization and Respiratory Diseases (NCIRD) at the Centers for Disease Control and Prevention; and Amanda Cohn, MD, acting chief medical officer of the NCIRD and executive secretary for the Advisory Committee on Immunization Practices.