# Susan Bailey, MD, AMA President, recaps vaccine development series

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## Featured topic and speakers

In today's COVID-19 update, AMA President, Susan R. Bailey, MD, recaps her second discussion with Peter Marks, MD, PhD, director of the Center for Biologics Evaluation and Research at the FDA. Including the Emergency Use Authorization (EUA) process and physician confidence in a COVID-19 vaccine.

Watch the full conversation in episode 4 of the AMA's vaccine webinar series.

Learn more at the AMA COVID-19 resource center.

### Speakers

- Susan R. Bailey, MD, president, AMA

## Transcript

**Unger:** Hello, this is the American Medical Association's COVID-19 Update. Today, I'm joined by the AMA's president, Dr. Susan Bailey, an allergist and immunologist in Fort Worth, Texas, who'll be talking about what she learned in a recent conversation with Dr. Peter Marks of the FDA about the COVID-19 vaccines. You can view the entire conversation with Dr. Marks on the AMA's YouTube channel. I'm Todd Unger, AMA's chief experience officer. Dr. Bailey, this is the second time you've talked with Dr. Marks in the past couple of months, and now there are two prominent vaccines with the FDA for review. What do you hope that physicians will learn from your recent conversation?

**Dr. Bailey:** Well, as you know, Dr. Peter Marks is the head of the FDA's Center for Biologics Evaluation and Research. So, his team is tasked with all of the COVID-19 vaccine trials, going over

all of the data. And what we wanted to do was to help physicians understand and have some confidence in the vaccine research that's going on right now and have chances to ask questions. Because if physicians are not completely comfortable with the data showing the safety and efficacy of COVID-19 vaccines, we'll never be able to convince our patients to take them.

**Unger:** Well, Dr. Bailey, how did we get to a place where we are potentially seeing multiple vaccine approvals in less than a year when normally this process takes a much longer time, several years?

**Dr. Bailey:** Well, that's what Operation Warp Speed is all about. There are so many vaccine candidates out there, and Dr. Marks explained, during the webinar, that COVID-19 vaccine development is really a de-risked activity, were the terms that he used, there have been no steps skipped, there have not been any corners cut. What has happened is individual steps that are usually taken one at a time with time to evaluate the data in between and make sure that the company is willing to assume the financial risk. Those have all been compressed and overlapped because they went ahead and manufactured the vaccine before they even knew if it was safe and effective.

And so, the government provided the funding for that. And so that is how that has been able to happen so quickly. And with the initial results of the trials now being in and the FDA reviewing that data, they wanted to make sure they had two months to evaluate side effects, because most of the side effects happen within six weeks.

**Unger:** I thought that term de-risk was an interesting way to think about it, given that, that process is much slower and generally sequential before moving onto the next period and what you have is a situation where that has been sped up, but not increasing risk. So, I guess that eliminates what we would call the dead space in that process, is that what he was basically saying?

**Dr. Bailey:** Yes. And so, everything has, yes, been very compressed, but they're doing all the same amount of work that they would do in any other vaccine trial. And these trials are actually larger than many vaccine trials have been in the past. So, they have more data to analyze, which I just think makes the whole thing even more amazing that they've gotten so much done in such a short period of time.

**Unger:** As with so many things in the pandemic, when people confront something that is not necessarily intuitive, it does cause fear. So, when you think about what you heard yesterday from Dr. Marks, how does what you now know affect how you feel as a physician about this vaccine?

**Dr. Bailey:** I feel very confident that the FDA is doing everything they can to make sure that these vaccines are safe and effective and that no corners have been cut or steps skipped. The amount of work, the workforce they have working round the clock. He talked about FDA folks eating turkey sandwiches on Thanksgiving day to make sure that they evaluate all of this data from the ... the 44,000 patients in the Pfizer trial and the 30,000 patients in the Moderna trial. I feel very comfortable

that they're doing all they can to make sure that the vaccine is safe and effective, and the initial data is very encouraging too, so that always helps make you feel better about the process.

**Unger:** It does. So, let's talk a little bit more about that data. What data is the FDA looking for in terms of vaccine safety? Is that something that he discussed?

**Dr. Bailey:** Yes. In terms of safety, obviously, side effects are a major concern and we would expect some degree of fever, achiness, maybe a sore arm after taking a vaccine, that's pretty typical and we've seen that with many other vaccines. But Dr. Marks said that they were looking at 20 areas of interest, things like Guillain-Barre syndrome or transverse myelitis, some of the more devastating side effects that have been seen with previous viral vaccines. So, they're really, really looking out for those signals in the safety process. They're going to continue to look at participants in the trial for a total of two years. So, any unusual things that might fall out later will still be included, but with the reassurance that most side effects happen pretty quickly. And so, those will be picked up before they're approved.

**Unger:** Now, did he talk about the Emergency Use Authorization and how that would work in terms of the standard?

**Dr. Bailey:** Yes. When we had our first webinar with Dr. Marks, it was the day after the EUA for vaccines had been released. And there was some real concern that that was really going to be an issue of decreasing the quality of the approval process. And it's really not at all. This special EUA for vaccines is very, very similar to the Biologic License Application that they'll eventually have to make. That's one thing I learned yesterday, it's just because of vaccine gets an EUA, that doesn't take it off the hook to eventually be actually licensed by the FDA later, it's just a first step to make it available to the public. And so, really the processes are very similar and I felt much more comfortable. I was very skeptical in the early days about using an EUA for a vaccine approval, but now I feel much better about it.

**Unger:** Well, timing is the big thing on everyone's mind. Did he give any sense of timing with the vaccines?

**Dr. Bailey:** Yes. The Pfizer vaccine is going to be looked at by their special external advisory committee on December the 10th. And the Moderna vaccine will be looked at on December 17th. And he said, shortly after that, it may be up to a week. I don't want people to be disappointed if we don't have something the next day, because there's still a lot of data and information that the FDA needs to look at to give the EUA. But I'm really hopeful that we're going to see some vaccines rolling out before Christmas.

**Unger:** Dr. Bailey, one question that you asked Dr. Marks was, how should physicians be talking to their patients about the safety of these first vaccines? Can you share what he said and if that answer

would help you as a physician in dealing with your own patients?

**Dr. Bailey:** Dr. Marks talked about the incredibly large sizes of the trials and how many patients had participated, how carefully we're looking at them. He talked about, even though the studies have been done in a very compressed manner, that everything that's typically done in a vaccine trial is being done for COVID-19 vaccines. And that made me feel very comfortable about the process and feeling that I'm being told everything I need to know when I talk to my patients.

**Unger:** Well, you also brought up the idea of public education and I loved what Dr. Marks had to say to physicians in response. Let's take a look at this clip from the webinar.

> **Dr. Marks:** And I can just tell you some late breaking news, which is very relevant to providers listening. It's you who people will believe more than anyone else about taking a vaccine. They're going to be looking to say, if you say that you're comfortable taking the vaccine, they are going to be willing to take the vaccine. Providers, head and shoulders above the rest, really are trusted and to the extent that we can help educate and that you're learning about these and that you have questions, we want to answer them, because if you're comfortable with these vaccines, that's going to rub off on your patients.

**Unger:** Dr. Bailey, do you have any comments on that? What do you think the biggest challenges are right now for physicians in terms of feeling confident in vaccines?

**Dr. Bailey:** I think it's about looking, having access to the data and being able to make their own conclusions. And I so agree about the importance of the one-on-one relationship between a patient and a physician when it comes to making important medical decisions like that. The advice of a physician to a patient is very often the most valuable piece of information that patients get and make them feel the most comfortable about making big decisions. And so, physicians feeling confident in the vaccine, maybe have already even had it themselves and then conveying that information to their patients, I think will be very powerful.

**Unger:** Well, last question. What is the one key message you would have for physicians based on what you learned at this webinar?

**Dr. Bailey:** I think that we, as physicians, should be incredibly proud of our medical community, not only the frontline health care workers, but the medical scientists that have been working so hard. The amount of work that has been accomplished in an incredibly short period of time to me is just breathtaking. And I think we should really give a lot of thanks to our colleagues in the labs, as well as to everyone that's participated in these trials, the spirit of cooperation that people have shown working together, we are going to get good vaccines and we are going to get this pandemic behind us. I feel very confident of that.

**Unger:** Yeah, well, there was a lot covered in that webinar that we didn't have a chance to discuss today and I do want to encourage all our viewers to visit AMA's YouTube channel to see the conversation. It's an exceptional chance to hear from Dr. Marks and they are clearly making every effort to increase transparency and confidence in the vaccine program. Dr. Bailey, thank you so much for that conversation and for giving all physicians a chance to pass their questions on through you to Dr. Marks. We'll be back soon with another COVID-19 Update. For resources on COVID-19 visit ama-assn.org/covid-19. Thanks for joining us today and please take care.

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