Susan Bailey, MD, explains trust in coronavirus vaccine starts with transparency

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Featured topic and speakers

In today's COVID-19 update, AMA Chief Experience Officer Todd Unger talks with AMA President Susan R. Bailey, MD, about her discussion about the development and testing of the COVID-19 vaccine with Peter Marks, MD, PhD, Director of the Center for Biologics Evaluation and Research at the FDA.

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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 will be talking about what she learned in her recent conversation with Dr. Peter Marks of the FDA regarding development and testing of the COVID-19 vaccine. You can view the entire conversation with Dr. Marks and Dr. Bailey on AMA's YouTube channel. I'm Todd Unger, AMA's chief experience officer in Chicago. Dr. Bailey, can you tell us a little bit about the topic of our first discussion with Dr. Marks, and why the AMA wanted to kick off its webinars series with this particular episode?

_Dr. Bailey:_ Well, thanks, Todd, and the AMA has wanted to create this webinar series to deliver fact-based, science-based evidence on vaccine development for the coronavirus for physicians. And we reached out to the FDA and they were very happy to cooperate with us. So this very first episode
featuring Dr. Peter Marks was to go over the process of vaccine development. There's a lot of misinformation there about what's really going on at the FDA, and it was our effort at making sure that this process is as transparent as possible and giving the FDA a direct line to physicians to tell us how they are going to proceed in the testing, evaluation and approval of a COVID-19 vaccine.

**Unger:** I think transparent is really one of the keywords coming out of the discussion and along those lines, Dr. Marks mentioned a "crisis in confidence" during the webinar. Can you talk about that issue and how he addressed it during your conversation?

**Dr. Bailey:** Yes, and we all realize that vaccine hesitancy was at an all time high before the pandemic, and now, during the pandemic, with Operation Warp Speed and our incredible rush to develop a COVID-19 vaccine, the importance of making sure that physicians and patients feel confident in a newly and quickly developed vaccine is imperative. It's very clear that the FDA is very aware of that as well. And that it's going to be very important going forward to continue transparent communication with the physician population and the public to make sure that they really feel that no corners have been cut in the development of this vaccine.

**Unger:** It's interesting that one of the things that Dr. Marks brought up was that people don't see and feel necessarily the incredible benefit of vaccines. Can you talk about that in relation to this issue of vaccine hesitancy?

**Dr. Bailey:** Yes. Vaccines are really victims of their own success. We don't see the devastating diseases that vaccines prevent, like smallpox and polio and diseases like that, that were deadly, that decimated populations. So it can be hard for folks today to understand that vaccines are a much better alternative to the diseases themselves, as opposed to worrying about side effects that may be blown out of proportion. Vaccines are not perfect. Nobody has ever claimed that they are, but they are one of the most amazing public health developments and responsible for the good health that we see today. And so helping patients understand the safety of vaccines, and, of course, if physicians are not completely confident in the safety and efficacy of a vaccine, it's going to be hard for us to convince our patients.

**Unger:** Yeah, that is critical because we have both the effectiveness of the vaccine and the percentage of people who get it are major obstacles toward moving forward from this pandemic. As part of that, Dr. Marks talked about the emergency use authorization or EUA, and how this could be implemented for a COVID vaccine. Can you talk about that?

**Dr. Bailey:** Yes. The emergency use authorization, EUA, process was put in place after 9/11 to help speed the development and the delivery of medications to patients in basically a crisis situation like we had after 9/11. But this is really the first time that the EUA has been considered for any type of modality that was going to be widespread throughout the population instead of just very special small groups. And so the, the traditional EUA process has been ramped up for the approval of vaccines, and in fact, the day before our webinar, the FDA came out with its EUA process for vaccines, which is
actually really very similar to the traditional vaccine approval process. It just speeds up some steps a bit. So we discussed that, and it's not a guarantee that this is going to be used for a vaccine approval, but it may be in the early stages. But the new EUA document is available on the FDA's website for everybody to see, to understand exactly what steps they're going to go through to approve a COVID-19 vaccine.

**Unger:** I think one of the things that he made clear was that the standard for something where the number of people that might be getting a COVID-19 vaccine, so much bigger than what we saw after 9/11. Can you talk about kind of that process of setting the standard for that?

**Dr. Bailey:** Yes. An EUA for a medication is going to be typically very limited in an emergency situation, but the EUA for vaccines is really EUA process on steroids. It just is such a much greater scale. There's so much more information that is demanded from pharmaceutical companies. So much more that is done in terms of the double blind placebo controlled trials that are necessary to make sure that the trials are large enough to make sure that enough individuals actually come down with the disease in the placebo group to make the results statistically significant.

**Unger:** Dr. Marks and the FDA clearly looking for transparency and building confidence. He actually talked about a public advisory committee. What would that do?

**Dr. Bailey:** Yes, the public advisory committee will help review everything that goes on in terms of the FDA's approval process and the EUA, and it will compliment the FDA's own vaccine and related biological products advisory committee, which is a committee of outside experts that are very thoroughly vetted in terms of conflict of interest and expertise, not people that work for the FDA, but well-known scientists in their own right. And to actually review everything that the FDA reviews and make recommendations for the approval of a vaccine.

**Unger:** So important. I know nobody has a crystal ball at this point, but did Dr. Marks give any idea of when we might see a successful vaccine come through?

**Dr. Bailey:** Well, he made it clear that this was just a guess on his part. He wasn't promising anything, but he said that a late November, December time is probably the earliest timeframe where we might see a vaccine, but he was hopeful that we would see an approval of at least one product before the end of this calendar year.

**Unger:** Well, you asked a really critical question about something that's on everybody's mind and a major issue regarding confidence, and that is whether politics are playing a role in this process. I'm going to play a little clip of that about your exchange,

**Dr. Bailey:** How can physicians be assured that politics don't impact the approval
process? And how do we reassure our patients about this?

**Dr. Marks:** We have an incredible staff of career scientists who are infectious diseases physicians, along with the statisticians, risk communicators, who are all working on this. And they will be the ones who need, by necessity, they need to be the ones who look at this and who make this determination about whether the vaccine is safe and effective. If I could ask for anything, as like a gift, it would be that everyone would just take a pledge to just stop politicizing vaccines. Let's just keep this out of the realm. This is just too important for all of us.

**Unger:** Dr. Bailey, what was your reaction to his response about politics playing a role in the vaccine development and approval process?

**Dr. Bailey:** Well, it was apparent to me that, of course, everyone at FDA is incredibly aware of the politics surrounding the situation, but it also made it very clear to me that the people that are going to be working on this, the people that are going to be ushering these vaccines through the approval process are career scientists. They're not political appointees. They've been at the FDA and have been working at this for a long time. Dr. Marks has been at the FDA for a long time, and that they were going to go through their normal process and that transparency in their actions would be really the remedy to outside political influence.

**Unger:** Last question. Can you talk about any kind of key messages that you have for physicians based on what you learned during your conversation with Dr. Marks?

**Dr. Bailey:** Yes. I am really hopeful that physicians are going to feel comfortable with this process because all the information is going to be made available to us. There's going to be an open meeting available to the public, you can watch it online, of the FDA's vaccine and related biological products advisory committee on Thursday, October 22nd. Dr. Marks made it very clear that there they were not going to approve any vaccines at that meeting.

**Dr. Bailey:** They were just going to go through the process and make it clear to everybody what steps were going to be taken when a product is submitted to the FDA for approval and how that will play out. All of the briefing documents for that committee meeting will be available to the public, and he also reassured me that all of the briefing documents submitted by the pharmaceutical companies to the FDA about the details of the studies would also be made public. So I feel very good about that, and they're working as hard as they can as fast as they can, and I'm optimistic that we're going to have a transparent, open process and hope that we come out with a good vaccine on the end.

**Unger:** Well, thank you so much, the AMA will continue to make sure that physicians have science-based perspective and data on vaccine development and distribution. Again, if you'd like to watch the conversation between Dr. Bailey and Dr. Marks, you can check that out on AMA's YouTube channel. That concludes today's COVID-19 update. Thanks so much Dr. Bailey for being here with us today.
We'll have a recap of a second webinar in the series soon, and we'll be back on Monday with another COVID-19 update. For resources on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us. Stay safe.

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