Susan Bailey, MD, on what physicians need to know about J&J vaccine

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Featured topic and speakers

In today’s COVID-19 Update, Susan Bailey, MD, AMA president, recaps her discussion with Peter Marks, MD, PhD, director of the Center for Biologics Evaluation and Research at the Food and Drug Administration, covering the most up-to-date information on the rollout of the Janssen Pharmaceuticals vaccine and the other FDA-approved vaccines for COVID-19.

View the full conversation with Peter Marks, MD, PhD.?

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Speakers

- Susan 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 summarizing for us what she learned in a recent conversation with Dr. Peter Marks of the FDA about 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 in Chicago.

Dr. Bailey, thanks for joining us. A lot has happened in the last three months since your last conversation with Dr. Marks following the approval of the J&J vaccine for emergencies in February. And as we know, the FDA and the CDC have now recommended pausing the use of the Johnson & Johnson vaccine. Can you walk us through the discussion with Dr. Marks, starting with the pause? What do we know thus far?

Dr. Bailey: Well, as most doctors know, Dr. Marks is the director for the Center for Biologics Evaluation and Research at the FDA, and we've talked to him a number of times over the past year about COVID vaccines. We just got lucky and had this conversation scheduled the same day that Johnson & Johnson announced that they were putting a pause on their vaccine. There have been six case reports in almost 7 million doses of the J&J vaccine being given, all of them in women with very unusual clotting syndromes, very serious clots, not typical that you would see. Cerebral venous sinus thrombosis is the most common one, and unfortunately one of the women died.

And the fact that these reports started coming through the normal reporting systems when they had six of them, they decided, "Hey, wait, let's pause. Let's look at these cases," anticipating that when they took the pause, they might get some more case reports. I'm not sure if they have or not, but to look at the data to see if there's a relationship, to let the advisory committee on immunization practices, which met yesterday, look at it as well. And they also recommended, "Let's hold tight now so that we can really look at this out of an abundance of caution," he said, to make sure that this vaccine is safe before we proceed.

Unger: You mentioned blood clots, can you talk more specifically about the adverse effects that some patients have experienced?

Dr. Bailey: Yes, these blood clots, like I said, the cerebral venous sinus thrombosis, also blood clots in the abdominal splanchnic bed, which is a very unusual place to have this kind of thrombosis, but they've also seen pulmonary emboli, other types of clots that we see more commonly. And these patients often have a severe headache, they may have stroke-like symptoms, have weakness on one side, difficulty speaking and abdominal pain, leg pain, the things that you might see with clotting disorders. And the thing that we really wanted to get the message out as quickly as we could is that typically when patients with these symptoms go to the emergency room with suspicion of having a blood clot, they're given heparin. And we now know that heparin is not indicated in this situation and can actually make the situation worse. So we wanted to make sure that we got that message out to physicians right away.

Unger: Well, in addition to talking about the Johnson & Johnson vaccine, you also talked about variants. Did Dr. Marks discuss the efficacy of the vaccines? Anything that we're learning relative to combating the current and known variants?

Dr. Bailey: Yes. And we have a number of variants that are circulating in the United States now, but the good news is that all of the vaccines that we have, including the Johnson & Johnson vaccine on pause, but particularly the mRNA vaccines, are effective against the variants. We think it's because they engender such a high and robust immune response that they get the variants, but there's always a concern that other variants might emerge that these vaccines don't handle quite as well. So it's kind of a race against time to get as many people vaccinated as possible so that the variants don't have a chance to develop.

Unger: Is there any understanding or further understanding about how long patients will continue to have immunity after getting a shot?

Dr. Bailey: The Pfizer and Moderna vaccines have been shown to have at least six months of protection. Those were reports from the original study groups that were in the trials last summer. Unfortunately, this has been misinterpreted by some to mean that it only lasts for six months. We know it lasts for at least six months and we have no reason to think that it won't continue to last. The thousand dollar question is, how long will it last? And so we're hopeful that it will continue to last for a number of months more, but we'll just have to follow these patients month by month to see how long this immunity lasts.

Unger: When you think about this in total, what was the big takeaway that you want to leave physicians from your conversation with Dr. Marks?

Dr. Bailey: I think the big takeaway is that the Johnson & Johnson vaccine, along with the mRNA vaccines, overall are incredibly safe and effective. We're not sure if these six case reports are even related to the vaccine. We have more investigation to do. They do seem to be similar to some clots that have been seen in AstraZeneca vaccine patients in Europe. Of course, the AstraZeneca vaccine has not been approved for use in the United States yet, but it seems to be the adenovirus vector vaccines that engender this immune response, which resembles heparin-induced thrombocytopenia. So we want physicians to know what to look for, to have a high index of suspicion, not to give heparin, to use other anti-coagulants and consult a hematologist, and maybe use intravenous immunoglobulin for these patients rather than giving them heparin. Hopefully, most of them will have a good outcome if they're properly treated.

Unger: Well, thank you so much, Dr. Bailey. These discussions with Dr. Marks had been such a great opportunity for physicians to hear firsthand from this health care leader, and we appreciate you continuing this series.

That's it for today's COVID-19 Update. We'll be back with another segment shortly. In the meantime, for resources on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us today. Please take care.
