Susan Bailey, MD, recaps role of therapeutics in COVID response

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In today's COVID-19 Update, AMA President Susan Bailey, MD, shares what she learned in her recent conversation with three physician leaders from the FDA about therapeutics for COVID-19. Dr. Bailey also mentions the use of monoclonal antibodies in treatment and the importance of having a robust research ecosystem in place to react rapidly to any future pandemics.

View Dr. Bailey's full conversation with FDA leaders.

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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 AMA's President, Dr. Susan Bailey, an allergist and immunologist in Fort Worth, Texas, who will be talking about what she learned in a recent conversation with three physician leaders from the FDA about therapeutics for COVID-19. You can view the entire conversation on AMA's YouTube channel. I'm Todd Unger, AMA's chief experience officer in Chicago. Well, Dr. Bailey, we haven't heard a lot about therapeutics lately. We hear a lot about vaccines. As the focus has shifted from treatment to prevention, what role do you see therapeutics playing in the pandemic response?

Dr. Bailey: Well, Todd, it’s such a good point because even though we’re so focused on vaccinations...
and reaching herd immunity, and the fact of the matter is, is that we'll never completely eradicate this virus from the population. I think it's with us for the long run. And so it's going to be more and more important going forward that physicians know how to treat COVID-19 infections. They need to know all the options available to them, what to start early, what to save for later. And so this webinar just covered all the things that physicians need to know about the status of current therapeutics and what's being researched now.

**Unger:** So that's kind of an important thing, what you said, which is that the new normal is not that it goes away, that it's kind of around for a while. And there are treatment, just kind of like for the flu, in some sense, that will need to be on hand to treat that. And that these kinds of therapeutics are going to be important over the long haul. I'm interested in hearing more about the challenges that have faced so far. One of this has been about research. And why don't you talk a little bit about what you heard as the status of research right now, what some of the key challenges have been regarding therapeutics?

**Dr. Bailey:** It was really pretty amazing. We started off with Dr. Janet Woodcock, who is the acting director of the FDA. And she went over the state of clinical trials for COVID. There have been more than 2000 trials and arms of trials that have been conducted with therapeutics, but only 5% of them have been randomized and adequately powered to give actionable information. I found that just... but the fact of the matter is, is that our health care system was overwhelmed. We were scrambling to do the best we could to take care of our patients. It was hard to get answer. Setting up a clinical trial in the situation that we've been in the past year has been pretty daunting. So I think one of the things that this has showed us that we need to be better prepared in the future to be able to plug and play clinical trials as quickly as possible when new situations come up. And we need a more robust screening mechanism for new drugs and a better ability to make sure that these trials are going to yield actionable information.

**Unger:** So what I'm hearing you saying, it's really important for whatever that next public health crisis might be, that we've got some kind of research and testing infrastructure in place so that we get that kind of critical amount of data while we're learning about a new virus for instance.

**Dr. Bailey:** Yes. And we talked, during the webinar, about the importance of establishing a robust research ecosystem for the future. Now it's really the ideal time to be looking at that, to make sure that we've got the structures that we needed in place to be able to act rapidly when situation changes as they always do.

**Unger:** Well, thanks, Dr. Bailey. Monoclonal antibodies have been among the most talked about and effective therapeutics for COVID-19. Can you talk about your takeaways from your conversation about this particular type of treatment?

**Dr. Bailey:** Yes. We heard from two other physicians during the webinar, Dr. John Farley, who's the director for Infectious Diseases in the Center for Drug Evaluation and Research. And also Dr. Sally
Seymour, who's the deputy director of safety for pulmonary, allergy and rheumatology drugs. And the monoclonal antibodies situation really has come a long way. Of course, these antibodies go in and block the SARS-CoV-2 attachment to human cells and neutralize the virus. We have three treatments that have authorization at this point in time. I was encouraged to learn that we can use monoclonal antibodies down to age 12. Whereas for vaccinations, only 16 is the bottom age for Pfizer and 18 is the lower age for the Moderna and J&J vaccines.

But these monoclonal antibodies really should be reserved for use early in COVID-19 treatment. These are outpatient drugs that are designed to try to keep patients from becoming ill, from needing hospitalization or developing severe disease. They're not much good once a patient goes into the hospital. So we talked about the barriers in monoclonal antibody treatment. A lot of people don't know that they're available. They don't know where to go to get them. They don't know how to order them. Initially, we were doing them in the hospital and that really didn't make much sense. But now we've got infusion centers set up to deliver these treatments and even home infusion therapy to help keep patients out of the hospital. So they definitely have a place, but they definitely have limitations.

Unger: And back when the first kind of authorizations came out, I think there was a concern there would be too much demand for these of treatments. But those things that you outlined there, which is, does rely on somebody very early in the stage to say, hey, this is something I need and then to get over those kind of logistical obstacles, that must’ve been quite a challenge, is that right?

Dr. Bailey: Yes. But I have had personal experience with patients who were diagnosed very high risk. Another point is that these treatments right now are reserved for patients that are at high risk for developing severe disease, either because of their age or because of their core morbidities. But I'm convinced that monoclonal antibody treatments kept these patients out of the hospital. And then we talked about a couple of more classifications of therapeutics. We talked about immunomodulatory agents, including steroids, and we also talked about antiviral drugs.

Unger: So let's talk a little bit more about those. Dexamethasone, there was early data on that back in the process. What are you finding out about when something like that is appropriate in the treatment? You said monoclonal antibodies, very early in the process of treatment. Where do the steroids fit in and some of these other treatments that you’re outlining?

Dr. Bailey: Yes. Definitely learned that steroids should not be used early in the treatment of COVID-19. That they should be reserved for later on in a patient's course. And the key time seems to be when the patient develops hypoxemia, when they're having trouble keeping their oxygen levels up. Typically, they're in the hospital at that time. That's when dexamethasone needs to be started and not any earlier. But we've got great data on that now. And they seem to be really effective. And then another category of medications, the antiviral medications. Lots of research being done on those. It would be wonderful to have a medication like we have Tamiflu for influenza that we could give early, orally, on an outpatient basis to decrease the length and the severity of disease. So those drugs are
being worked on. You've heard about remdesivir. The data on that really, it's okay, but it's not great. And we're still learning where those fit in our toolbox.

**Unger:** There's some other different treatments that are kind of currently under investigation. One of them is ivermectin. Any kind of conclusive results on that?

**Dr. Bailey:** We had a lot of questions about ivermectin from attendees. And there are, and have been a number of small clinical trials that have taken place all over the world. There are a number of physicians that really believe in its antiviral property. But many of the studies were small. The results are mixed, I would say. But the FDA really wants and is looking at platform trials to get them going in the U.S., so we can really get better data on ivermectin. And there's some other therapeutics that are being looked at but the verdict is still out on those as well.

**Unger:** Well, one final question for you. You mentioned earlier in this conversation about the research ecosystem and kind of setting up a better infrastructure so that we're prepared to deal with whatever that next pandemic is and all of these treatments that are being explored in real-time. What would characterize something like that research ecosystem? What needs to get put in place?

**Dr. Bailey:** Well, we need to have a capability to gather evidence and data quickly and efficiently. We need to be able to analyze the data. We need to have diverse sources of information to guide public health decision-making. We need clinical trials, clinical populations that can be stood up really quickly to start the trials. We need to be able to run trials, maybe not seeing patients in-person, but maybe doing things virtually using electronic health records. And we definitely need more community support. We don't need all clinical trials to be in an academic medical center, which may not be real accessible to patients. So we need more community support for clinical trials. And just to incorporate the lessons that we've learned from what we've been through. Let's not get into a situation where we do over 2000 trials and are only able to use 5% of the data.

**Unger:** That is an amazing conclusion there. And it's so valuable to capture that data in real-time. So I just want to say also, thank you, Dr. Bailey. This continuing series that we've been conducting with the FDA has been an amazing chance for physicians to connect directly with people at the FDA and hear firsthand what they're working on right now. That's it for today's COVID-19 Update. We'll be back with another segment shortly. In the meantime, for additional information on COVID-19, visit ama-assn.org/COVID-19. And for information on yesterday's webinar, please check out AMA's YouTube channel. Thanks, Dr. Bailey. Thanks to everyone out there. Please take care.

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