

# FDA chief updates doctors on COVID-19 tests, treatments, vaccines

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The volume of information about COVID-19 tests, therapeutics and vaccines in development can be overwhelming for patients and physicians alike. The commissioner of the Food and Drug Administration (FDA), Stephen M. Hahn, MD, simplifies the news and describes what his agency is doing to ensure the safety and efficacy of interventions throughout the pandemic.

On a videoconference with AMA President Susan R. Bailey, MD, in partnership with the Reagan-Udall Foundation, Dr. Hahn outlined the FDA's special role in containing the pandemic and talked about how to effectively answer questions from patients to imbue confidence in the U.S. health care system's response to COVID-19.

The AMA has developed a [COVID-19 resource center](#) as well as a [physician's guide to COVID-19](#) to give doctors a comprehensive place to find the latest resources and updates from the Centers for Disease Control and Prevention and the World Health Organization.

## Antigen tests coming soon

Testing remains one of the biggest challenges, and the FDA is working to address this, Dr. Hahn said.

"I can only imagine the frustration of having to wait four to six days for a test to come back. I think we are making some progress there, but there are issues out there, particularly with some of the commercial labs," he said, noting that the FDA is looking at antigen tests, or rapid diagnostic tests, to complement PCR tests.

"We have a number of those in the pipeline that we're expecting to receive authorization fairly soon," he said, noting that more than 200 companies are developing new tests.

Get the [latest updates on COVID-19 testing procedures, best practices and guidelines for billing.](#)

## Facilitating treatments

One top-level tool the FDA has used during public health emergencies is the emergency use authorization (EUA), which allows use of unapproved medical products, or unapproved uses of approved medical products, when there are no adequate, approved and available alternatives. EUAs have already been issued for the antiviral drug remdesivir and the anti-inflammatory medication dexamethasone.

“These decisions have been an important part of the FDA’s efforts to shape an effective and timely response,” Dr. Hahn said, adding that although EUAs may have been made in a public health emergency, “they are still guided by science and the continuous review of the most recent, up-to-date data and evidence available” to ensure that the known and potential benefits of products outweigh the known and potential risks.

Check out the AMA’s [COVID-19 medication and treatment guidance.](#)

## Ensuring the integrity of vaccines

Because of the speed with which the FDA must make decisions, some physicians have wondered whether the agency’s scientific principles could be compromised when it evaluates new products, Dr. Hahn said.

“Let me assure you that we will not cut corners,” he said. “All of our decisions will continue to be based on good science and the same careful, deliberative processes we have always used when reviewing medical products.”

It’s important that physicians reassure their patients of this, he noted.

“We have seen surveys reporting that significant percentages of the public would be reluctant to take a vaccine once available,” Dr. Hahn said, adding that the FDA will review COVID-19 vaccine candidates using its established, rigorous and deliberative scientific review process and that the agency has set a floor of 50% efficacy.

“We all understand that only by engaging in an open review process and relying on good science and sound data can the public, and you as providers, have confidence in the integrity of our decisions,” he said.

Dr. Hahn and his colleagues expanded on this point in a recent *JAMA* Viewpoint, “Unwavering Regulatory Safeguards for COVID-19 Vaccines.”

## More insights from the FDA

Commissioner Hahn and Dr. Bailey also discussed the difference in roles between the FDA and the Centers for Disease Control and Prevention; the promise of convalescent plasma, monoclonal antibodies and other therapies for COVID-19; the importance of the annual flu vaccine during the pandemic; and the development of tests to detect both flu and SARS-CoV-2.

Read the full text of Dr. Hahn’s remarks.

You or your patients can volunteer for a SARS-CoV-2 vaccine trial by visiting [coronaviruspreventionnetwork.org](https://www.coronaviruspreventionnetwork.org).