

FDA's SARS-CoV-2 vaccine review needs major dose of transparency

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What's the news: As the federal government's "Operation Warp Speed" works to quickly deliver a safe, effective vaccine to protect against SARS-CoV-2 infection, the AMA is calling for a big boost in the transparency of the process.

"With COVID-19 vaccine development moving at a rapid pace, it is critical that we ensure physicians are continuously informed of the U.S. Food and Drug Administration's (FDA) plans for review and that they are provided with the utmost level of transparency regarding the process for authorization or licensure, standards for review, and safety and efficacy data as soon as possible," AMA Executive Vice President and CEO James L. Madara, MD, wrote in a letter to FDA Commissioner Stephen Hahn, MD.

Why it's important: A safe, effective, widely available vaccine is essential to slowing the spread of COVID-19 and allowing fuller reopening of businesses and schools. Yet, Dr. Madara wrote, "public polling suggests that vaccine hesitancy is at an all-time high, which could hobble efforts to ensure widespread vaccination when one or more vaccine candidates are made available."

Doctors have long relied on the FDA to ensure that vaccines, drugs and other medical products are safe and effective. But the unprecedented nature of the pandemic and the challenges involved in quickly getting a COVID-19 vaccine to market are raising questions among physicians as well as patients.

"While vaccine hesitancy among the public has been rapidly increasing in recent years, it appears to be reaching unprecedented levels due to a number of factors including concerns about the rapid pace of vaccine development and significant spread of misinformation through channels such as social media," Dr. Madara wrote. "We are also beginning to field increasing numbers of questions and concerns from our physician members, mostly due to the pace of development for a type of vaccine yet to be successfully brought to market for use in humans, as well as what has been perceived as

very little available information about the vaccines in development and the planned FDA review process.”

The FDA should immediately start offering more information, education and transparency regarding its process for SARS-CoV-2 vaccine authorization or licensure, including the standards for how the agency “will review vaccine candidates and the clinical endpoints which the FDA hopes to achieve,” Dr. Madara wrote.

“New processes for continuous updates for physicians about the review process and any available safety and efficacy data must be in place as soon as possible so that we can ensure widespread education about vaccine candidates and promptly address questions or concerns raised by physicians. These efforts will be critical to ensure vaccine literacy and acceptance among all demographics, and will be especially important to ensure vaccine education and acceptance among communities hardest hit by COVID-19, such as Black, Latinx and Indigenous communities,” he added.

The AMA is strongly urging the FDA “to work more closely with the physician community—starting now—to develop a plan for further education and transparency surrounding COVID-19 vaccine candidates.”

Learn more: Find out about the “bottleneck” issues ahead for a COVID-19 vaccine from health policy and medical ethics expert Ezekiel Emanuel, MD.

Read about the?AMA’s COVID-19 advocacy efforts?and track pandemic developments with the?AMA's COVID-19 resource center, which offers a library of the most up-to-date resources from?JAMA Network™, the Centers for Disease Control and Prevention, and the World Health Organization.?