

Dec. 11, 2020: Advocacy spotlight on COVID-19 vaccines: Dive deep on emergency use authorization

COVID-19 vaccines: Dive deep on emergency use authorization

Amid widespread vaccine hesitancy that could delay efforts to achieve the herd immunity required to end the COVID-19 pandemic, the top official from the Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research—Peter Marks, MD, PhD—joined the AMA's President Susan R. Bailey, MD, for an in-depth webinar to answer physicians' questions and explain how emergency use authorization (EUA) fits into the coronavirus vaccine-approval process.

Guidance from the FDA states that "issuance of an emergency use authorization requires a determination that the known and potential benefits of the vaccine outweigh the known and potential risks." Or, as researchers representing the World Health Organization (WHO) Solidarity Vaccines Trial Expert Group put it in a Lancet commentary: "initial trials comparing COVID-19 vaccines versus placebo should seek reliable evidence not only of some efficacy but of worthwhile efficacy." Before a product can be approved under the EUA process, the Health and Human Services (HHS) secretary is required to first declare that circumstances exist—such as significant potential for a military or public health emergency—to justify issuing the EUA. Also, there can't be an available alternative product. Under this rubric, two candidates for FDA authorization as COVID-19 vaccines have been developed expeditiously during the public health emergency (PHE). But despite the favorable clinical data touted by their manufacturers, there are understandable questions among the general public—and even health professionals—about the safety and efficacy of vaccines that have been developed and tested in less than a year's time. So, in addition to evaluating clinical data to determine whether new vaccines are safe and effective, ensuring that what is inside the vaccine packaging "is what it says it is," and monitoring for adverse events once the vaccine is put in use, Dr. Marks said the FDA now finds that reducing vaccine hesitancy has become a significant part of the agency's job. "What has become really clear during the past year, is that all of these things really feed into what is most important for us, which is helping to ensure public confidence," said the FDA's Dr. Marks, who appeared with Dr. Bailey in the fourth installment of an AMA-hosted "COVID-19: What physicians Need to Know" webinar series to discuss the EUA process and explain how the accelerated approval process is being handled without compromising safety. Dr. Marks previously appeared with Dr. Bailey in the first webinar, which addressed the COVID-19 vaccine development and the FDA review process for

SARS-CoV-2 vaccine candidates. The AMA has made the full webinar, along with a transcript, available. Read more here.

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