

Safe and Effective COVID-19 Vaccination The Path From Here

Duke-Margolis Center for Health Policy

September 10, 2020 | 12:00 – 2:15 pm ET

The safety, efficacy, benefits, and risks of COVID-19 vaccines are understandably attracting public attention. FDA leaders have recently asserted that FDA standards for vaccine approval will be met by any vaccine that reaches the American public. HHS has extensive plans in development to distribute the vaccine, first to high-priority groups and then to the broader public. But what are those regulatory standards at FDA, and what are their implications for the decisions that Americans will make about getting a vaccine?

This event will address two key topics related to the impact of COVID-19 vaccines. First, senior leaders at FDA's Center for Biologics Evaluation and Research will describe FDA's role in ensuring that COVID-19 vaccines are safe and effective, and how they are undertaking that role under extraordinary circumstances in the ongoing pandemic. Second, building on this review of the regulation of vaccines, the event will address key questions and concerns related to the equitable distribution and access to vaccines once they are available, with particular consideration for high-risk and minority populations suffering disproportionately from the virus.

The webinar aims to inform policymakers, state and local leaders, health care providers, and the broader public about what to expect on vaccine safety and effectiveness as these products complete clinical testing and manufacturing, and – if approved – move into distribution.

12:00 pm **Welcome and Overview**

Mark McClellan, Director, Duke-Margolis Center for Health Policy

12:05 pm **Fireside Chat: How Will FDA Ensure COVID Vaccines Are Safe and Effective?**

Current and former FDA officials will frame the key issues at play in COVID vaccine development, FDA's regulation of these candidate vaccines, and downstream implications for both availability and use in the U.S. population.

- **Peter Marks**, CBER, U.S. Food and Drug Administration
- **Mark McClellan**, Duke-Margolis Center and former FDA Commissioner
- **Margaret (Peggy) Hamburg**, National Academy of Medicine and former FDA Commissioner

12:45 pm **Session I: Development and FDA Assessment of COVID Vaccines**

Moderator: **Mark McClellan**

- **Bruce Gellin**, Sabin Vaccine Institute
- **Marion Gruber**, CBER, U.S. Food and Drug Administration
- **Michelle McMurry-Heath**, Biotechnology Innovation Organization (BIO)
- **Robert Califf**, Google and Verily Health and former FDA Commissioner

- 1:25 pm** **Session II: COVID Vaccine Distribution, Access, and Monitoring**
Moderator: **Scott Gottlieb**, American Enterprise Institute and former FDA Commissioner
- **Grace Lee**, Stanford University
 - **Hemi Tewarson**, Duke-Margolis Center for Health Policy
 - **Carlos del Rio**, Emory Vaccine Center, Emory University
 - **Steven Anderson**, CBER, U.S. Food and Drug Administration
- 2:00 pm** **Looking Ahead on Vaccines**
Scott Gottlieb, American Enterprise Institute and former FDA commissioner
Mark McClellan, Director, Duke-Margolis Center for Health Policy
- 2:15 pm** **Webinar Adjourns**