Safe and Effective COVID-19 Vaccination

The Path From Here

September 10th, 2020

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Welcome and Overview

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Vaccine Candidates in U.S. Clinical Trials

Sponsor(s)	Clinical Trial Phase	Vaccine Platform	US Government Support
Moderna & National Institutes of Health	Phase 3 Underway	mRNA	Up to $1.5 billion for manufacture and delivery
BioNTech & Pfizer	Phase 2/3 Underway	mRNA	$1.95 billion for manufacture and delivery
AstraZeneca & University of Oxford	Phase 3 Underway	Adenovirus vector	Up to $1.2 billion for clinical trials and manufacture
Johnson & Johnson	Phase 3 Sep 2020	Adenovirus vector	$456 million for clinical trials and $1 billion for manufacturing
Inovio Pharmaceuticals	Phase 2/3 Sep 2020	DNA	---
Novavax	Phase 2 Underway	Protein	$1.6 billion for manufacturing
Sanofi & GSK	Phase 1/2 Sep 2020	Protein	Up to $2.1 billion for late-stage development and manufacturing

Data sourced from FasterCures, a center of the Milken Institute and HHS.gov press releases.

FDA Vaccine Approval and Emergency Use Authorization

- Product Approval – substantial evidence of safety and effectiveness demonstrated by adequate and well-controlled trials, and manufacturing must meet reliability and purity standards.
- Emergency Use Authorization – the known and potential benefits outweigh the known and potential risks, including manufacturing purity and reliability.
  - Emergency use may be authorized for specific populations —such as those at higher risk including healthcare workers—or potentially for a broader population.
- Per FDA guidance, for a vaccine for which there is adequate manufacturing information, issuance of an EUA may be appropriate once clinical studies have demonstrated the safety and effectiveness of the vaccine but before the submission and formal review of the full application for approval.

OPINION *This piece expresses the views of its author(s), separate from those of this publication.*

Senior FDA career executives: We're following the science to protect public health in pandemic

We are committed to making decisions guided by the best evidence. Our approach has been and must remain the gold standard that all can rely upon.

Patrizia Cavazzoni, Peter Marks, Susan Mayne, Judy McMeekin, Jeff Shuren, Steven Solomon, Janet Woodcock and Mitch Zeller
Opinion contributors

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Today's Topics

- Status of current and soon-to-begin large clinical trials
- FDA's expectations for approval of a COVID-19 vaccine
- Emergency use authorization (EUA)
- Expectations about the process from here – and transparency along the way
- Expectations for monitoring safety and improving evidence after a vaccine is approved
- What people can do to be informed about the COVID-19 vaccines

Agenda Overview

- **Fireside Chat**: How Will FDA Ensure COVID Vaccines Are Safe and Effective?
- **Session I**: Development and FDA Assessment of COVID Vaccines
- **Session II**: COVID Vaccine Distribution, Access, and Monitoring
- Looking Ahead on Vaccines

Fireside Chat: How Will FDA Ensure COVID Vaccines Are Safe and Effective?

12:05 pm – 12:45 pm

Session I: Development and FDA Assessment of COVID Vaccines

12:45 pm – 1:25 pm

Session II: COVID Vaccine Distribution, Access, and Monitoring

1:25 pm – 2:00 pm

Looking Ahead on Vaccines

2:00 pm – 2:15 pm

Mark McClellan & Scott Gottlieb

Thank You!

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