Safe and Effective COVID-19 Vaccination
The Path From Here

September 10th, 2020

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Welcome and Overview

Mark McClellan
Director, Duke-Margolis Center for Health Policy
# Vaccine Candidates in U.S. Clinical Trials

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

Data sourced from [FasterCures](https://www.fastercures.org/), 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.
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!

Contact Us

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