OPERATION WARP SPEED
Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges

What GAO Found
Operation Warp Speed (OWS)—a partnership between the Departments of Health and Human Services (HHS) and Defense (DOD)—aimed to help accelerate the development of a COVID-19 vaccine. GAO found that OWS and vaccine companies adopted several strategies to accelerate vaccine development and mitigate risk. For example, OWS selected vaccine candidates that use different mechanisms to stimulate an immune response (i.e., platform technologies; see figure). Vaccine companies also took steps, such as starting large-scale manufacturing during clinical trials and combining clinical trial phases or running them concurrently. Clinical trials gather data on safety and efficacy, with more participants in each successive phase (e.g., phase 3 has more participants than phase 2).

Vaccine Platform Technologies Supported by Operation Warp Speed, as of January 2021

<table>
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<tr>
<th>mRNA platform</th>
<th>Replication-defective live-vector platform</th>
<th>Recombinant-subunit-adjuvanted protein platform</th>
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<tr>
<td>SARS-CoV-2 spike RNA</td>
<td>SARS-CoV-2 spike gene</td>
<td>SARS-CoV-2 spike protein</td>
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As of January 30, 2021, five of the six OWS vaccine candidates have entered phase 3 clinical trials, two of which—Moderna’s and Pfizer/BioNTech’s vaccines—have received an emergency use authorization (EUA) from the Food and Drug Administration (FDA). For vaccines that received EUA, additional data on vaccine effectiveness will be generated from further follow-up of participants in clinical trials already underway before the EUA was issued.

Technology readiness. GAO’s analysis of the OWS vaccine candidates’ technology readiness levels (TRL)—an indicator of technology maturity—showed that COVID-19 vaccine development under OWS generally followed traditional practices, with some adaptations. FDA issued specific guidance that identified ways that vaccine development may be accelerated during the pandemic. Vaccine companies told GAO that the primary difference from a non-pandemic environment was the compressed timelines. To meet OWS timelines,
some vaccine companies relied on data from other vaccines using the same
platforms, where available, or conducted certain animal studies at the same time
as clinical trials. However, as is done in a non-pandemic environment, all vaccine
companies gathered initial safety and antibody response data with a small
number of participants before proceeding into large-scale human studies (e.g.,
phase 3 clinical trials). The two EUAs issued in December 2020 were based on
analyses of clinical trial participants and showed about 95 percent efficacy for
each vaccine. These analyses included assessments of efficacy after individuals
were given two doses of vaccine and after they were monitored for about 2
months for adverse events.

**Manufacturing.** As of January 2021, five of the six OWS vaccine companies had
started commercial scale manufacturing. OWS officials reported that as of
January 31, 2021, companies had released 63.7 million doses—about 32 percent
of the 200 million doses that, according to OWS, companies with EUAs have
been contracted to provide by March 31, 2021. Vaccine companies face a
number of challenges in scaling up manufacturing to produce hundreds of
millions of doses under OWS’s accelerated timelines. DOD and HHS are working
with vaccine companies to help mitigate manufacturing challenges, including:

- **Limited manufacturing capacity:** A shortage of facilities with capacity to
  handle the vaccine manufacturing needs can lead to production bottlenecks.
  Vaccine companies are working in partnership with OWS to expand
  production capacity. For example, one vaccine company told GAO that
  HHS’s Biomedical Advanced Research and Development Authority helped
  them identify an additional manufacturing partner to increase production.
  Additionally, the U.S. Army Corps of Engineers is overseeing construction
  projects to expand capacity at vaccine manufacturing facilities.

- **Disruptions to manufacturing supply chains:** Vaccine manufacturing supply
  chains have been strained by the global demand for certain goods and
  workforce disruptions caused by the global pandemic. For example,
  representatives from one facility manufacturing COVID-19 vaccines stated
  that they experienced challenges obtaining materials, including reagents and
  certain chemicals. They also said that due to global demand, they waited 4 to
  12 weeks for items that before the pandemic were typically available for
  shipment within one week. Vaccine companies and DOD and HHS officials
told GAO they have undertaken several efforts to address possible
manufacturing disruptions and mitigate supply chain challenges. These
efforts include federal assistance to (1) expedite procurement and delivery of
critical manufacturing equipment, (2) develop a list of critical supplies that are
common across the six OWS vaccine candidates, and (3) expedite the
delivery of necessary equipment and goods coming into the United States.
Additionally, DOD and HHS officials said that as of December 2020 they had
placed prioritized ratings on 18 supply contracts for vaccine companies under
the Defense Production Act, which allows federal agencies with delegated
authority to require contractors to prioritize those contracts for supplies
needed for vaccine production.

- **Gaps in the available workforce:** Hiring and training personnel with the
  specialized skills needed to run vaccine manufacturing processes can be
  challenging. OWS officials stated that they have worked with the Department
  of State to expedite visa approval for key technical personnel, including
  technicians and engineers to assist with installing, testing, and certifying
critical equipment manufactured overseas. OWS officials also stated that
they requested that 16 DOD personnel be detailed to serve as quality control
staff at two vaccine manufacturing sites until the organizations can hire the
required personnel.