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INSIGHT

Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials

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Operation Warp Speed (OWS) is an interagency partnership between the Department of Health and Human Services (HHS) and the Department of Defense (DOD) that coordinates federal efforts to accelerate the development, acquisition, and distribution of COVID-19 medical countermeasures. Collaborating HHS components include the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA). OWS is a Trump Administration initiative, and while the Biden Administration has indicated that the interagency response to COVID-19 will continue, it plans to restructure and rename the effort.

Although the stated goals of OWS include therapeutics and diagnostics, most of the money awarded to date has focused on vaccines. This Insight summarizes OWS's vaccine-related contracts, including those for ancillary vaccination materials (e.g., needles and vials).

BARDA is currently supporting six vaccine candidates through funding research and development, funding increases in manufacturing capacity, and/or advance purchase contracts. A vaccine candidate from Merck/IAVI also received funding support from BARDA, but was discontinued in January 2021 because it failed to demonstrate sufficient efficacy against COVID-19. **Table 1** provides BARDA contract awards and additional information about these candidates.

Vaccine development, like drug development, is generally an expensive process that takes 10 or more years. To accelerate development, OWS implemented a number of measures, including supporting increased manufacturing capacity for some of the vaccine candidates while they were still in testing, rather than waiting until testing was complete to scale up production. This investment is considered "at-risk," in that the federal government is paying to develop or manufacture vaccine candidates that may not prove to be safe or effective.

Vaccine candidates that received federal government support for development include Moderna, Janssen Pharmaceuticals, Sanofi/GSK, and Merck/IAVI (see **Table 1**), whereas the Pfizer/BioNTech, Janssen, and Novavax candidates participated in OWS through federal purchase of doses only. Three manufacturers have received Emergency Use Authorization (EUA) from the Food and Drug Administration for their

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vaccine candidates: Pfizer/BioNTech, Moderna, and Johnson & Johnson. Because OWS has purchased these vaccines, all doses are federally owned and will be provided at no cost to the American public.

Table 1. Vaccine Candidates Supported by BARDA and Other Federal Agencies

Company	Type	Contract Value	Specifications	Doses per Person	Current Phase (Preliminary Effectiveness – U.S. Strain)[a]	Storage
Pfizer/BioNTech	mRNA[b]	$5.97B	300 million doses	2	Phase II/III (95%) EUA Issued	Ultra cold storage (-70° C)
Moderna	mRNA	$4.94B $954M	300 million doses Development	2	Phase III (94.5%) EUA Issued	Cold storage (6 mos, -20° C) Refrigerator (30 days, -2° to -8° C)
AstraZeneca/ Oxford Univ.	Viral Vector[c]	$1.2B	300 million doses	2	Phase II/III (70%)	Refrigerator (-2° to -8° C)
Johnson & Johnson (Janssen Pharmaceuticals)	Viral Vector	$1B $456M	100 million doses Development	1	Phase III (72%) EUA Issued	Refrigerator (3 mos, -2° to -8° C)
Novavax	Protein[d]	$1.6B	100 million doses	2	Phase III (95.6%)	Refrigerator (-2° to -8° C)
Sanofi/GSK	Protein	$2.04B $30.8M	100 million doses Development	2	Phase I/II	Refrigerator (-2° to -8° C)
Merck/IAVI[e]	Viral Vector	$38M	Development[f]	1	DISCONTINUED	N/A

Sources: https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine; https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/.

Note: Current as of March 1, 2021.

a. This data reflect vaccine effectiveness against only the predominant strain of COVID-19 in the United States. Vaccines have different efficacies against the UK and South Africa variants respectively, and vaccine makers are considering creating booster shots to improve immunity to these strains.

b. Messenger RNA (mRNA) vaccines contain harmless virus genetic material that codes for a protein that is found on the virus's surface. The body recognizes this protein as foreign and initiates an immune response.

c. Viral vector vaccines contain a weakened version of the live virus that has most of the harmful parts of the COVID-19 genetic code removed.

d. Protein subunit vaccines contain harmless pieces of the COVID-19 virus (protein), which the body recognizes as foreign and mounts an immune response against.

e. The Merck/IAVI vaccine candidate was discontinued due to lack of demonstrated efficacy. It was supported by BARDA, not by OWS.

f. Only Moderna, Janssen Pharmaceuticals, Sanofi/GSK, and Merck/IAVI received funding from the federal government to support vaccine development. The remaining candidates participated in federal purchase of vaccine doses only.

The Government Accountability Office has noted difficulties in assessing supply chain transparency for vaccines and ancillary supplies. Shortages of ancillary supplies in particular have been a concern before and throughout the vaccination campaign.

Although the Biden Administration has announced efforts to increase the production and acquisition of ancillary supplies—including entering into new contracts and invoking the Defense Production Act—monitoring and addressing potential supply issues may still be of interest to Congress. **Table 2** provides OWS contract awards for ancillary vaccination supplies.

Table 2. Federal Government Contracts for Ancillary COVID-19 Vaccine Supplies

Needles, Syringes, Glass Vials, and Vial Alternatives

Company	Contract Value	Specifications
ApiJect Systems America	$138 million	100 million prefilled syringes by the end of 2020 Expansion of manufacturing capacity to produce 500 million prefilled syringes in 2021
Corning Pharmaceutical Technologies	$204 million	Expansion of manufacturing capacity to produce an additional 164 million Valor Glass vials per year if needed
SiO2 Materials Science	$143 million	Expansion of manufacturing capacity to produce 120 million glass-coated plastic containers per year if needed
Becton, Dickinson and Co.	$42.3 million	Expansion of manufacturing capacity to produce needles and syringes
Smiths Medical, Inc.	$20.6 million	Expansion of manufacturing capacity to produce needles and syringes
Goldbelt Security, LLC	$125 million	530 million needles and syringes
Retractable Technologies, Inc.	$53.6 million	Expansion of manufacturing capacity to produce safety needles and syringes
Retractable Technologies, Inc.	$93.8 million	320 million needles and syringes
Marathon Medical Corp.	$27.5 million	
Duopross Meditech Corporation	$48 million	134 million safety syringes by the end of 2020
Cardinal Health Inc.	$15 million	500 million safety syringes over a 12-month period (August 2020–August 2021)
Gold Coast Medical Supply, LP	$14 million	
HTL STREFA Inc.	$12 million	
Quality Impact, Inc.	$9 million	
Medline Industries, Inc.	$6 million	

Sources: https://www.medicalcountermeasures.gov/barda/influenza-and-emerging-infectious-diseases/coronavirus/pharmaceutical-manufacturing-in-america/?filter=all; https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/

Notes: Current as of March 1, 2021.

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