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INSIGHT

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

December 22, 2020

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). 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 seven vaccine candidates through funding research and development, funding increases in manufacturing capacity, and/or advance purchase contracts. Of these candidates, only six are also being supported by OWS (Merck/IAVI is supported by BARDA, but not OWS). **Table 1** provides information regarding these contracts, as well as details regarding the vaccine candidates themselves, including storage temperature, technology type, and preliminary effectiveness. OWS has invested in multiple candidates and different underlying technologies to protect against the risk of one or more vaccine candidates failing to demonstrate safety or efficacy at any point in the development process. Vaccine development, like drug development, in general, is typically an expensive process that takes 10 or more years. To speed up the vaccine development process, OWS implemented a number of measures. One measure, as stated by HHS, is that OWS supported increased manufacturing capacity for some of the vaccine candidates while they were still being tested, rather than the normal practice of waiting to scale-up until testing is complete. This is considered "at-risk," in that the government is paying to build facilities to manufacture a vaccine candidate that might not prove to be safe or effective. Vaccine candidates that received support from the federal government for vaccine development include Moderna, Janssen Pharmaceuticals, Sanofi/GSK, and Merck/IAVI, whereas the other three candidates participated in OWS through federal purchase of vaccine doses only. Production of vaccine doses simultaneously with safety and efficacy testing has helped ensure that vaccine doses are ready to deploy as soon as they have been approved for use by the Food and Drug Administration (FDA). The Pfizer/BioNTech vaccine received Emergency Use Authorization (EUA) from the FDA on December 11, 2020, and the Moderna

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IN11560

vaccine received similar approval status on December 18, 2020. Distribution of these two vaccines has thus begun according to guidelines approved by the CDC. Because OWS has purchased these vaccines, all doses are to be federally owned and 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)	Storage
Pfizer/BioNTech	mRNA[a]	$3.96B	200 million doses	2	Phase II/III (95%) EUA Issued	Ultra cold storage (-70° C)
Moderna, Inc.	mRNA	$3.1B $955M	200 million doses Development[b]	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, Inc.)	Viral Vector	$1B $456M	100 million doses Development	1	Phase III	Refrigerator (3 mos, -2° to -8° C)
Novavax, Inc.	Protein[d]	$1.6B	100 million doses	2	Phase III	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	1	Phase I	Unknown

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Note: Current as of December 22, 2020.

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

b. Only Moderna, Janssen Pharmaceuticals, Sanofi/GSK, and Merck/IAVI have received funding from the federal government to support vaccine development. Pfizer/BioNTech, AstraZeneca/Oxford University, and Novavax have participated in federal purchase of vaccine doses only.

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 is supported by BARDA, but not by OWS.

The Government Accountability Office has noted difficulty in assessing the transparency of the full supply chain and production of vaccines and ancillary supplies. Shortages of ancillary vaccination supplies that could potentially delay the vaccination campaign have also been of concern. Monitoring and addressing potential supply issues may thus be of interest to Congress as vaccines are distributed throughout the country. **Table 2** provides OWS contract awards for needles, syringes, glass vials, and vial alternatives.

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
Retractable Technologies, Inc.	$53.6 million	Expansion of manufacturing capacity to produce safety needles and syringes
Retractable Technologies, Inc.	$83.8 million	320 million needles and syringes
Marathon Medical Corp.	$27.5 million	
Duopross Meditech Corporation	$48 million	
Cardinal Health Inc.	$15 million	
Gold Coast Medical Supply, LP	$14 million	134 million safety syringes by the end of 2020 500 million safety syringes over a 12-month period (August 2020 – August 2021)
HTL STREFA Inc.	$12 million	
Quality Impact, Inc.	$9 million	
Medline Industries, Inc.	$6 million	

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Note: Current as of December 22, 2020.

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