THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE of the ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Testimony before the
House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

Hearing Titled
U.S. Role in Global COVID-19 Vaccine Equity

Gary Disbrow, Ph.D.
Deputy Assistant Secretary for Preparedness and Response, Director of the Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response

November 17, 2021

Chairwoman DeLauro, Ranking Member Cole, and distinguished Members of the Committee, thank you for the opportunity to testify today on our efforts to develop, manufacture, and procure safe and effective COVID-19 vaccines. I am grateful for this opportunity to address this Committee and appreciate your continued support for the ongoing response efforts. I want to start by thanking the Biomedical Advanced Research and Development Authority (BARDA) team for their tireless efforts over the last 21 months to develop critical medical countermeasures to address COVID-19.

***Update on ASPR's COVID-19 Response Effort***

The response to the COVID-19 pandemic has required an unprecedented whole of government approach. Secretary Becerra continues to direct the Office of the Assistant Secretary for Preparedness and Response (ASPR) to lead the ongoing coordination of the COVID-19 response across the Department of Health and Human Services (HHS). ASPR programs are working to directly support elements of the response.

Starting with my office, BARDA, in collaboration and partnership with the Countermeasures Acceleration Group (CAG), continues to leverage the supplemental appropriations provided by Congress to support the development of vaccines, therapeutics, and diagnostics to end the COVID-19 pandemic. To date, BARDA has awarded contracts for 77 medical countermeasure projects to aid the COVID-19 response. All of these contract awards are listed on medicalcountermeasures.gov in detail and include 15 therapeutics, 55 diagnostics, and seven vaccine candidates. Notably, BARDA has placed 1.5 billion doses of vaccine under contract (including a combination of adult primary, booster, and pediatric doses), purchased over 4.88 million doses of monoclonal antibodies, and shipped more than 144 million diagnostic kits.

ASPR has also leveraged the authorities delegated to the Secretary under the Defense Production Act (DPA) to issue 62 priority ratings for United States Government (USG) contracts for health resources, eight priority ratings for USG contracts for industrial expansion, three ratings for non-USG contracts to support the production of resins for both diagnostics and infusion pumps, and the manufacture of closed suction catheters for treatment of patients with COVID-19—all to ensure that private sector partners making life-saving products are able to acquire the raw materials, components, and products requisite to deliver for the response.

Also under the DPA, ASPR is strengthening the industrial base to secure and develop domestic capacity, retool and expand industry machinery, scale production facilities, train workforces, and ultimately supplying the marketplace with products the US needs to contain further pandemic waves. ASPR continues to use critical funding to invest in expanding domestic manufacturing including investments of: $250M in manufacturing PPE; $268M in manufacturing of testing consumables; $14.8M in vaccine raw material manufacturing; $160M in fill finish capacity; $65M in vaccine vial manufacturing; $168M in manufacturing capacity for at home and point of care tests; and, $53.8M in testing raw materials, with additional funds going out the door every day. Each of these domestic manufacturing initiatives meets current, as well as future, COVID-19 needs and seeks to create or sustain high-value domestic jobs.

***Biomedical Advanced Research and Development Authority Investments and Programs***

ASPR's BARDA continues to support the innovation, advanced research and development, manufacturing capacity improvements, and acquisition of medical countermeasures (e.g., vaccines, medicines, diagnostics, and other necessary medical supplies). Since late January 2020, BARDA has been collaborating with counterparts across the government to continue to identify potential COVID-19 countermeasure candidates and accelerate their advanced development. Even before initial COVID supplemental funds were made available on March 6, 2020, BARDA initiated investments utilizing advanced research and development funding as well as pandemic influenza funding to quickly evaluate existing partnerships to determine promising candidates that could be pivoted to address COVID-19 and immediately made investments in vaccines, therapeutics, and diagnostics.

Beginning in February 2020, BARDA made a series of initial investments targeting a diverse combination of proven platform technologies suitable for rapid development of vaccines and therapeutics. The investments were made as funding became available, and prior to standing up the interagency Operation Warp Speed (OWS, since renamed the Countermeasures Acceleration Group -- CAG) effort. The small initial investments used annual appropriations and existing contract options that BARDA had established specifically for pandemic preparedness, including BARDA's programs in influenza and Ebola. Technology leveraged from these programs for the Federal COVID-19 Response included:

- Sanofi Pasteur's recombinant protein technology and GlaxoSmithKline's (GSK) adjuvants;
- Merck's recombinant vesicular stomatitis virus (rVSV) technology, first supported by BARDA as part of the now FDA-licensed Ebola vaccine ERVEBO;
- Janssen's adenovirus 26 (Ad26) technology that BARDA supported to develop their Ebola vaccine that is licensed in the European Union (EU);
- Regeneron's monoclonal antibody therapeutic technology utilizing their platform that led to the first FDA-approved Ebola therapeutic.

Using the funds provided by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123) signed into law March 6, 2020, BARDA invested $1.256B in the advanced research and development of Moderna's mRNA-1273 vaccine candidate, supporting clinical trials and manufacturing scale up and validation. Moderna's COVID-19 vaccine was based on their mRNA platform technology, a platform BARDA had been supporting since 2015 for Zika vaccine development and scale up. This collaboration enabled non-clinical development and advancement of the vaccine candidate into expanded clinical studies, support through FDA authorization and expansion of vaccine production in the United States in preparation for large scale production as soon as the vaccine met regulatory requirements.

Going forward, the investments in a mRNA vaccine will support new vaccine production platforms in the future that will improve the efficiency and reduce the timeline to develop vaccines for other biodefense threats and emerging infectious diseases. Platform technologies,

such as the mRNA approach, can provide flexible and rapid response and have many advantages with potential to revolutionize the way vaccines and therapeutics are produced for known and newly emerging threats.

In order to achieve the ambitious goals set out in the American Pandemic Preparedness plan, it is critical that we apply the lessons learned from the current pandemic to continue to leverage platforms, such as the mRNA platform, to prepare against future pandemics. We must fill the gaps associated with advanced research and development, large-scale clinical trials, documented efficacy with antigen/platform combinations, and warm base manufacturing capacity. With the goal of establishing and maintaining a capability to design, test, develop, and authorize use of a vaccine within 100 days, it will be critical to advance vaccine programs through clinical development and commercial scale manufacturing towards licensure before the next pandemic. These activities are essential to demonstrate manufacturability and assess key safety and immunogenicity issues, such as the potential for immune-enhanced disease in target populations. With resources requested in the American Pandemic Preparedness plan, BARDA would coordinate with NIH/NIAID to develop prototype vaccines against the pathogens (or virus families) with greatest pandemic potential and advance up to 20 promising vaccine candidates into clinical studies and manufacturing scale-up.

BARDA would also establish US-based capability to develop and manufacture safe and effective vaccines against known or unknown pandemic pathogens within 100 days of pathogen identification that will leverage platform-based technology such as mRNA-based vaccines. Manufacturing technology platforms that could be applicable across multiple threats would be prioritized to efficiently address as many unknown threats as possible. The initial goal would be to get vaccine candidates to a point where clinical safety and immunogenicity are established, and, commercial scale manufacturing processes have been demonstrated with sufficient vaccine in final containers to respond to future disease outbreaks under an Investigational New Drug (IND) application. Vaccine candidate readiness would be leveraged to demonstrate clinical efficacy in the context of an outbreak response, such as a naturally occurring outbreak. In the absence of an outbreak or pandemic, BARDA would continue to drive these programs so that they may be viable candidates for FDA authorization via the Animal Efficacy Rule or Accelerated Approval pathways.

BARDA understands the importance of delivering lifesaving medical countermeasures quickly, especially during a pandemic, and that the logistical constraints on the current mRNA vaccines have made it challenging to deliver vaccines across the Nation and globally. In 2019, BARDA established the Beyond the Needle program within the Division of Research, Innovation, and Ventures, focused on the development of alternative technologies that aim to transform the paradigm of making vaccines and therapeutics easier to administer and more widely available, without the need for needles, syringes, vials, and cold-chain distribution burdens. Beyond the Needle supports technologies that use alternative routes of administration, such as oral, intranasal, and transdermal patch technologies that involve simplified logistics that enable easier deployment and uptake and can be administered without a trained healthcare professional. This program anticipates bringing to market the most flexible and efficacious modes of delivering emergency drugs and vaccines to more people, in more care settings, with minimal dosing, supply, and logistical requirements. Specifically, Beyond the Needle aims to overcome the

logistics burdens associated with manufacturing, storing, shipping, and distributing needles, syringes, and other ancillary supplies, and with vaccine cold-chain storage and transportation. In addition, this program aims to increase immunization compliance and make vaccines and therapeutics more widely available, especially in resource-constrained settings and during a pandemic or other public health emergency where qualified healthcare professionals are in short supply. The Beyond the Needle program currently supports six individual programs in different stages of development (preclinical to IND enabling) and ranging from oral, intranasal or solid dose formulations, to 3D printer microneedle patches to deliver vaccines.

***International Vaccine Donations***

All of the vaccine doses HHS has purchased to date were ordered for domestic use. However, international donations have been made available from amounts that have been in excess of demand once vaccines were available for use. As of November 9, 2021, of the total number of doses ordered, 433,156,393 doses have been administered domestically.

As of early November, HHS/CAG has donated over 130 million doses of vaccine that DoD purchased on behalf of the HHS to foreign countries or to COVAX. Donations by manufacturer follow:

- Moderna: 71,898,480
- J&J/Janssen: 35,628,150
- Pfizer: 19,460,040
- AstraZeneca: 3,412,900

In addition to the 3.4 million doses of AstraZeneca vaccine donated, 1.5 million doses and 2.7 million doses were made available in March to Canada and Mexico, respectively.

The Administration has pledged 500 million Pfizer COVID-19 vaccine doses to be purchased/donated internationally, on top of the 500 million previously pledged.

**Conclusion**

Thank you again for inviting me to testify before you on efforts within ASPR to support the COVID-19 response. Since its inception, BARDA has entered over 300 industry partnerships, attained 13 years of clinical product development experience, and supported 61 products that achieved FDA approvals or authorizations. BARDA's long standing expertise of accelerating the advanced research and development of candidate diagnostics, therapeutics, and vaccines through to FDA approvals, clearances, licensures and Emergency Use Authorizations, is unmatched across the government and underscores the overall capabilities that we have brought to bear on COVID-19. I look forward to answering your questions and thank you for passing the supplemental appropriations that have aided our overall response efforts. We could not do our job without your partnership and support.