



Written Testimony

**Senate Committee on Health, Education,
Labor and Pensions**

Shark Tank: New Tests for COVID-19

Statement of

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Chairman Alexander, Ranking Member Murray, and distinguished Members of the Committee, thank you for the opportunity to testify today on our efforts to develop appropriate and effective medical countermeasures to prevent infection and test and treat those with or suspected of having COVID-19. I am Dr. Gary Disbrow, Deputy Assistant Secretary and Acting Director of the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services (HHS or Department). Today, I will provide a brief overview of the current response structure and then provide detail on BARDA's role in developing countermeasures and diagnostics to aid in the overall response.

As you all know, the federal government has been monitoring the spread and threat of the severe acute respiratory syndrome coronavirus, SARS-CoV2, the virus that causes COVID-19 – since last December when cases began emerging in the City of Wuhan, Hunan province in China. COVID-19 is a new disease, caused by a novel (or new) coronavirus that has not previously been seen in humans. Immediately after the virus was detected, various HHS agencies to include the Centers for Disease Control and Prevention (CDC), the Assistant Secretary for Preparedness and Response (ASPR), the National Institute of Allergy and Infectious Diseases (NIAID) along with several other components of the National Institutes of Health, and the Food and Drug Administration (FDA) began coordinating and leveraging tools and resources to respond to COVID-19. Specifically, these agencies began implementing efforts to prevent and slow the spread of the disease, assisting repatriated Americans, protecting the supply of food, drugs, and devices, and developing diagnostics, therapeutics, and vaccines.

ASPR's Role in Response

ASPR's mission is to save lives and protect Americans from 21st century health security threats. During past response operations, ASPR has led, on behalf of HHS, Emergency Support Function #8: Public Health and Medical Services, under the National Response Framework. This means ASPR serves as the primary coordinator for public health information and deployment of assets to support the health components of a response.

For the current COVID-19 pandemic response, ASPR is participating in 14 Task Forces comprised of subject matter experts that are operating under the Federal response structure. ASPR has subject matter experts leading and/or serving on a number of the task force groups, including the Supply Chain Task Force, the Medical Countermeasures Task Force, the Healthcare Resilience Task Force, Laboratory Diagnostics Task Force, and the Data and Analysis Task Force to name a few. The purpose and goal of the various Task Forces is to explore policy issues, identify gaps in capabilities, and identify solutions to aid in the response. The Task Force structure supports streamlined communication across the Federal Government and expedites implementation of identified solutions as and when needed.

The Biomedical Advanced Research and Development Authority's Role in Medical Countermeasure Development

Outside of the current FEMA response structure, ASPR's BARDA continues to support the innovation, advanced research, development, manufacturing capacity improvements, and acquisition of medical countermeasures (MCM) (e.g., vaccines, medicines, diagnostics, and other necessary medical supplies). Since late January, BARDA has been collaborating with

counterparts across the government, under the Medical Countermeasure Task Force, to continue to identify potential candidates and accelerate their advanced development.

Even before initial COVID supplemental funds were made available on March 6, 2020, BARDA initiated investments utilizing annual funding to quickly evaluate existing partnerships to determine those that had promising candidates and immediately made investments in vaccines, therapeutics, and diagnostics. Supporting this strategy, ASPR hosted an interagency call with industry on January 30, 2020, to inform external stakeholders of the high level strategy to pursue development of vaccines, therapeutics, and diagnostics. Over 1,500 attendees participated in the call. Shortly after the industry call, BARDA established the MCM Portal for Coronavirus, or Portal. This Portal which is accessible by NIH, CDC, FDA, the Department of Defense (DoD), and BARDA, ensures U.S. Government partners are able to stay current with the rapidly evolving landscape of promising, emerging technologies. Information and proposals from industry are submitted to the portal and then reviewed and prioritized by BARDA and interagency colleagues. After the initial review “CoronaWatch” meetings are scheduled. CoronaWatch is a unique tool that BARDA utilizes to ensure that those technologies that are ranked as highly relevant by interagency partners can be further evaluated and considered for funding across the U.S. Government. During the CoronaWatch meeting, BARDA and interagency experts discuss the specific proposal with the submitter, review data and other supporting information, and provide technical input for future submission for potential funding. As of May 1, 2020, over 2,590 applications have been submitted via the Portal and over 250 CoronaWatch meetings have been held with companies that were ranked at the highest priority level for the interagency, 99 of these for diagnostics.

In addition, BARDA continues to encourage applications to its two primary funding solicitations. To date, there has been 128 submissions under BARDA's Broad Agency Announcement (BAA) and 275 submissions under our Easy BAA (EZ BAA). The EZ BAA was established in 2018 to advance early-stage innovative approaches to health security, with the ability to make awards in as few as 12 days.

Leveraging the funds provided in the first COVID-19 supplemental, the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Public Law 116-123), awards have already been made to promising candidates to date. Specifically, BARDA has made investments in three vaccine candidates, 8 therapeutic programs and 19 diagnostic programs. BARDA's COVID-19 portfolio is rapidly expanding, with daily awards and updates. For the most up-to-date information, please visit

<https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx>.

BARDA has a track record of success in delivering effective countermeasures in response to public health emergencies. Past successes include the 2009 H1N1 influenza pandemic, Ebola outbreaks in 2014-2016 in West Africa and in 2018 the Democratic Republic of the Congo, as well as Zika in 2015. For these past response operations as well as the current response to COVID-19, Congress has provided emergency supplemental funding to support medical countermeasure development. For the current COVID-19 response, BARDA reviewed investments with Regeneron, Janssen, Sanofi Pasteur, and Genentech, all of which have previously shown success in the successful development of both prophylactic and therapeutic

medical countermeasures for emerging infectious diseases. BARDA's leveraging of these existing partnerships and established platforms may help shave months off the development timelines for medical countermeasures and has been made possible because of flexible authorities and prior investment into these platforms.

Beyond medical countermeasure development, BARDA is also supporting efforts to strengthen domestic manufacturing capacity. Several years ago, BARDA established the Centers for Innovation in Advanced Development and Manufacturing (CIADMs). While these CIADMs provided such benefits as training opportunities for current and future industry and government scientists who engage in advanced development and manufacturing of medical countermeasures, there is great potential that they will aid the response to COVID-19 by supporting manufacturing as products are identified. Specifically, Janssen, a Johnson & Johnson company, has identified a lead candidate using their AdVac system. They have signed a partnering agreement with the BARDA CIADM at Emergent BioSolutions to help manufacture their vaccine.

The focus of today's Hearing is diagnostics. To support the anticipated need for expanded diagnostic capacity, BARDA initially invested in molecular tests to identify individuals who were infected with COVID-19. These tests specifically look for the virus RNA in respiratory samples. In March, BARDA invested in adding SARS-CoV-2 assays to systems that are routinely used in the commercial and clinical diagnostic space to rapidly expand high throughput capacity (Hologic, Luminex, DiaSorin, Cepheid). BARDA also invested in near patient/hospital based molecular diagnostics (Qiagen, GeneMark, Cepheid, Vela, Luminex). Finally, BARDA has supported hand-held and point of care molecular diagnostics (Mesa BioTech, Cue,

Cepheid). The latter, point-of-care diagnostics are “sample-to-answer” systems that do not require the separate extraction reagents required by other systems that have been in short supply. BARDA’s efforts have helped ensure the availability of diagnostic testing in the United States. In the last 6 weeks, 2 million diagnostic tests have been shipped by BARDA-funded test developers for use domestically and we expect our partners to continue to increase production and scale. As the pandemic has progressed, the need to develop antigen or antibody/serological tests is now the emphasis. These types of tests will allow for identification of individuals who were infected and now have antibodies against the virus. BARDA’s investments include antibody/serological based tests (DiaSoren, InBios, Nanomix, Hememix) and antigen tests (OraSure, Nanomix, Hememix). BARDA has and will continue to work closely with interagency partners (FDA, CDC, NIH/NIAID, DoD) and with the Laboratory Diagnostics Task Force to help address existing and emerging technical and operational challenges related to COVID-19 diagnostics. BARDA is also currently supporting the Serology Project Team established by HHS to address the research, technical, and operational issues and gaps for utilization of antibody tests.

BARDA is proud to partner with the new NIH effort, Rapid Acceleration of Diagnostics (RADx). BARDA will provide subject matter expertise to review applications, evaluate potential candidates, and support development teams as they are assembled. NIH’s initiative and BARDA’s efforts are complimentary and will ensure RADx is as successful as possible to expedite development of new countermeasures. As products are developed, BARDA stands ready to aid in the manufacturing as needed, through established partnerships.

Conclusion

Since its inception, BARDA has entered over 300 industry partnerships, attained 13 years of clinical product development experience, and helped partners achieve 54 FDA approvals.

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.

Thank you for passing the recent supplemental appropriations that will aid our overall response efforts. We could not do our job without your partnership and support.

Thank you for your time and I look forward to discussing how we can continue to work together on this important issue.