

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

*Shark-Tank: New Tests for COVID-19*

May 6, 2020

10:00 AM

106 Dirksen Senate Office Building

Purpose

*The purpose of this hearing was to develop a Shark-Tank Program under the National Institutes of Health to ensure a greater quantity of more accurate tests for COVID-19.*

Members Present

Chairman Alexander, Ranking Member Murray, Senators Enzi, Casey, Roberts, Baldwin, Collins, Murphy, Cassidy, Warren, Murkowski, Kaine, Scott, Hassan, Romney, Jones, Braun, and Rosen

Witnesses

**Francis Collins, MD, PhD**

Director, National Institutes of Health (NIH)

**Gary Disbrow, PhD**

Acting Director, Biomedical Advanced Research and Development Authority (BARDA),  
Office of the Assistant Secretary for Preparedness and Response  
United States Department of Health and Human Services

Opening Statements

**Chairman Alexander** said in April, an assisted living facility tested all of their residents, which proved to be successful to pinpoint positive cases. He stated that testing is necessary to only quarantine those who are positive for the virus rather than the greater population. Testing will also help Americans gain confidence in being able to go back to their everyday lives. This Committee will examine what needs to be done to be prepared for the next pandemic. Over the last 20 years, the last three Presidents and several Congresses, America has passed seven major laws that created the National Stockpile, created the Secretary for Preparedness, created avenues for diagnostics, strengthened the Centers for Disease Control and Prevention, and provided record funding for the NIH. The New York Times reported, "Most experts agree The United States is among the countries that is best prepared to prevent or manage such an epidemic." Chairman Alexander said that it is safe to say, everyone would have liked to be more prepared. The end of this virus will come from three things - tests, treatments, and vaccines. The Administration has a goal of 100 million doses of treatments by the summer and 300 million doses by January. The private sector has been working on serology tests to determine who has been previously infected to utilize antibodies among those who are currently infected. The FDA is taking steps to ensure the serology tests are accurate. Hospitals and labs have administered about 1.6 million tests in the past week. The need for tests will only grow when individuals resume their daily activities. This Shark Tank Program at the NIH would utilize the capacities of government in coordination with the private sector to produce millions of more tests.

**Ranking Member Murray** said that at the last hearing, she expressed her frustration at the

Administration's lack of preparedness. She wants an honest assessment on where America is on testing capacities. She wants more of a plan on how to ensure Americans can get their way of life back. She believes that the fastest and most innovative tests are not always the best option, because they might not be accurate or they may not be able to be manufactured. If tests do not become available for asymptomatic people, the spread of the virus will continue. It is going to take more than the past efforts and resources to combat the virus through testing.

### Testimony

**Dr. Collins** said that the NIH has taken an “all hands on deck” approach when harnessing innovation for diagnostics, treatment, and prevention. Trial conducted on remdesivir just recently gave results that an individual had a 31% faster time recovering than a placebo. NAIAD's human trial is going very well so far. As more information comes in, NIH has been sifting through what the actual possibilities are when combatting this virus. Therapeutics and vaccines have required unprecedented partnerships among NIH and other organizations among industry leaders, government leaders, and non-profit program management. ACTIV Public-Private Partnership is broken down in working groups based on preclinical, clinical therapeutics, clinical trial capacity, and vaccines. The Diagnostic Research Program has multiple parts. First, the National Cancer Institute is using their expertise to help with serology testing. NIH launched a COVID-19 rapid initiative called Rapid Acceleration of Diagnostics (RADx) to deploy millions of tests per week. There is an emphasis on accessibility and the ability to detect asymptomatic individuals. RADx is split up into phases. Phase 0 is the “Shark-Tank”-Like Rapid Selection Process, Phase 1 is the Validation and Risk Review, Phase 2 is the Clinical Tests, Regulatory Approval, and Scaling Up. Phase 2 is predicted to go through the end of summer/fall 2020. It is possible that tests can go straight to Phase 2 depending on where they are in development. There were 1,087 applications initiated as of May 6. The final part of the Diagnostic Research Program is the demonstration projects in underrepresented groups called RADx-UP.

**Dr. Disbrow** said BARDA has led their own initiatives to address COVID-19. They are working with interagency partners. They engage innovative stakeholders, establish partnerships, develop countermeasures and bring them forward for the American people to help save lives. The Medical Countermeasures Task Force was created to address therapeutics, vaccines, and diagnostics. BARDA can leverage and rapidly expand partnerships to push candidates forward to the review, testing, and approval phase. BARDA is collaborating with NIH on two new efforts - the integration of efforts established by Dr. Collins under the accelerating COVID-19 therapeutic interventions of vaccines and the RADx Program. BARDA will provide subject matter expertise as needed. The recent Supplemental Aid will and has enabled this work to continue.

### Questions and Answers

**Chairman Alexander** asked if existing technology will produce the needed number of tests, or if new technology needed. **Dr. Collins** said he believes both are needed. Existing technology can be used further, but most of these technologies are in labs and not in a “point-of-care,” and new technology will help with that front. **Chairman Alexander** asked

what to tell university presidents and principals who would like to go to school in August as far as the availability of tests. **Dr. Collins** said that it is the goal to have tests so that individual communities can assess the risks of bringing people back. **Chairman Alexander** asked about manufacturing the tests once tests that are accurate and inexpensive have been identified from the “Shark-Tank” process. **Dr. Collins** said the review board consists of experts who are looking at the potential and then once the potential has been established, the manufacturing process is then determined. **Dr. Disbrow** said it is a seamless transition, and BARDA has experience in bringing together engineers with the funding that is available.

**Ranking Member Murray** asked if, in order to ensure that there is enough testing to begin safely re-opening, the National Strategic Plan on Testing that was released by the Administration should include specific numeric targets for capacities and projections of shortages. **Dr. Collins** said that he believes this is something that the COVID-19 Task Force can determine. **Ranking Member Murray** asked both witnesses if they can commit to prioritizing public health and never give in to political favors. **Dr. Collins** and **Dr. Disbrow** said yes.

**Sen. Enzi** asked how the agency’s role is different in RADx and active partnerships and operations. **Dr. Collins** said that much can be gained from partnerships. Different expertise can provide more and better solutions. RADx is more of a bottom-up partnership because more of the ideas are coming from small businesses. **Sen. Enzi** asked if BARDA or NIH have primary authority for advance development or manufacturing for a scale-up. **Dr. Collins** said that NIH is really good at getting early ideas to get started. BARDA steps in when they are ready for a real-commercialization scale-up. **Dr. Disbrow** said this is not the first partnership between BARDA and NIH, and he is optimistic about this.

**Sen. Casey** asked about the limitations that lack of personal protective equipment (PPE) has posed on healthcare workers and if Dr. Disbrow will commit to work on being better prepared in the future. **Dr. Disbrow** said yes. **Sen. Casey** asked if peer-reviewed, scientific evidence should be what America implements in the policy in response to the pandemic. **Dr. Collins** said yes, he has built his entire career on science and real facts.

**Sen. Roberts** asked about getting rapid tests that identify the individuals that are infected to protect others. **Dr. Collins** said that is what the RADx Program is intended to accomplish.

**Sen. Baldwin** asked the witnesses to describe what associated supplies will be needed to use the tests that are produced by RADX. **Dr. Collins** said that each test will require different supporting supplies and that is something that will be reviewed as tests are approved. **Sen. Baldwin** asked if it would be helpful to know what sort of facilities and institutions will need testing and when, so that gaps can be identified and then tests that can fill those gaps. **Dr. Collins** said they want to understand the needs out there from multiple institutions, particularly in places that are vulnerable. They are aware that testing is not equally accessible. The demonstration projects will hopefully address that issue.

**Sen. Collins** asked how NIH will ensure that America has the capacity to manufacture and scale-up these innovations of medication in the US. **Dr. Disbrow** said the pandemic has highlighted the vulnerabilities in the supply chain for PPE and medical ingredients. BARDA is currently evaluating multiple programs to address this issue. Manufacturing is a long process, so the raw materials need to be acquired now to help with the scale-up. **Sen. Collins** asked what more can Congress be doing to tap in under the Defense Production Act so that when NIH and BARDA does get a “winner” in treatment, and the scale-up is supported. **Dr. Collins** said that with any new technologies, everyone must look at the resources that will come short. Being proactive is necessary to not be caught by surprise again.

**Sen. Murphy** asked if the US should also join the Coalitions for Epidemic Preparedness Innovations (CEPI) like other countries while also leading our own effort in developing a vaccine. **Dr. Collins** said he was President of CEPI, formerly. He believes that there are still connections in indirect ways to continue development of a vaccine. However, this is a global crisis and America should approach it globally. **Sen. Murphy** asked if outside industry groups have too much sway inside the Dr. Bright operation. **Dr. Disbrow** said that all proposals have to go through scientific review by interagency partners. He is confident in the way that BARDA makes investment decisions.

**Sen. Cassidy** asked about the RADx-UP program and how to apply for it. **Dr. Collins** said that this program is still in the formative process. **Sen. Cassidy** asked about having certainty prior to making policy decisions on the usefulness of antibody testing. **Dr. Collins** said COVID-19 is something people can recover from, but this virus can mutate. However, it does not mutate like influenza. There are still a lot of unanswered questions to make policy decisions.

**Sen. Warren** asked if the federal government is running drug manufacturing factories across the country with government employees inside and on the production line. **Dr. Disbrow** said no, BARDA partners with companies and they form a public-private partnership to help develop life-saving medical countermeasures. **Sen. Warren** asked if a vaccine is accomplished, what other basic medical supplies are needed to actually produce and administer these treatments. **Dr. Collins** said that this would be something that would vary depending on what the vaccine looked like. It is too early to say for certain.

**Sen. Murkowski** asked what the NIH is doing for places like Alaska who do not have the resources to even come back from a “hard hit” of COVID-19. **Dr. Collins** said that “Shark Tank” is aiming to give everyone a test that has a quick turnover time to detect the virus before it gets to the “hard hit” phase.

**Sen. Kaine** asked why, from March 3 to today, the South Korean death toll has gone from 28 to 265 and the US death toll has gone from 9 to 74,665. **Dr. Collins** said South Korea did figure out the testing and distancing thing rapidly. Unfortunately, the US is still figuring it out.

**Sen. Scott** asked about RADx prospects and getting vulnerable populations in rural America that have the pre-existing conditions that make it significantly harder to recover from COVID-19 to participate in this program. **Dr. Collins** said that the purpose of the RADx-UP program is to relieve some of the burden to get access to testing. **Sen. Scott** asked about CRISPR and gene editing technology to advance more testing and new types of testing. **Dr. Collins** said CRISPR is a great way to identify a little bit of a virus somewhere in a biological sample. A number of the applications so far use CRISPR.

**Sen. Hassan** asked what steps NIH is taking to ensure quality and quantity of these new testing capabilities. **Dr. Collins** said the technology has to be validated against gold standards of sensitivity and specificity.

**Sen. Romney** asked what the probability was that a vaccine will be generally available for the American public by the end of the year. **Dr. Disbrow** said he is not in the position to make that call. **Sen. Romney** asked what is wrong with the Abbott machine and making this machine available to businesses. **Dr. Collins** said that it requires a machine, which is limited, expensive, and it has about a 15% false negative rate.

**Sen. Jones** asked what can be done to make these vulnerable populations less vulnerable, not just in terms of the pandemic. **Dr. Collins** said the demonstrations are intended to change the dynamic by introducing more tests and treatments.

**Sen. Braun** asked which tests and treatments of South Korea are similar to the ones that America has. **Dr. Collins** said the ones that companies like LabCorp has where it is done in a central lab. **Sen. Braun** asked about the witnesses' opinions on the work people are doing to accomplish this testing solution. **Dr. Collins** said that he believes people have been putting in the energy in response to the virus.

**Sen. Rosen** asked if any studies have been discussed to track the individuals who have antibodies, and if the "Shark-Tank" will include antibody tests. She also asked what the NIH is doing to prevent the unintended consequences from the competitive nature of a "Shark-Tank." **Dr. Collins** said that tracking is important and the program called "All of Us" has been implemented and helped with that. The commercial market has done a pretty good job at pushing out antibody tests, so there is a less of a need for this kind of testing. Unintended consequences will be monitored as technologies are reviewed.