

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Hearing Titled Shark Tank: New Tests for COVID-19

Witness appearing before the
Senate Health, Education, Labor and Pensions Committee

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Good morning, Chairman Alexander, Ranking Member Murray and distinguished members of this committee. It is an honor to appear before you today. I want to thank you for your sustained commitment to the National Institutes of Health (NIH) which has enabled us to be at the forefront of action in this time of a national public health crisis. I am grateful to have this opportunity to address how we at the NIH and our funded scientists across the country are harnessing innovation to prevent, diagnose, and treat the novel coronavirus currently plaguing our nation.

When the genetic sequence of SARS-CoV-2, the virus that causes COVID-19 was first released on January 10, 2020, NIH worked quickly to identify possible therapeutic agents and to begin developing a fast-track vaccine. Just one month later, the National Institute of Allergy and Infectious Diseases (NIAID) launched a clinical trial on the Gilead drug remdesivir at sites across the nation, which reported preliminary results just last week, showing that patients who received remdesivir had a 31 percent faster time to recovery than those who received placebo. This is a landmark – the first rigorous demonstration of efficacy of a treatment for COVID-19.

And on March 16th, just 63 days after receiving the viral genome sequence, NIAID completed all pre-clinical evaluation of a vaccine candidate and the first human patient was dosed in a Phase I trial.

As more information has poured in from scientists and patients all over the world, we have been sifting and sorting, looking for the best ideas, and funding everything from basic biology to clinical trials -- while closely watching private sector efforts and seeking ways to collaborate. It soon became apparent that the biomedical research world is fully charged up to tackle the COVID-19 challenge, but what was needed was coordination of that vast community.

On April 17th, NIH announced the start of an unprecedented partnership with 16 biopharmaceutical companies, academic experts, and government partners that now include the Centers for Disease Control and Prevention (CDC), the Biomedical Advanced Research Development Authority (BARDA), the Food and Drug Administration (FDA), the Department of Veterans Affairs (VA), and the Department of Defense (DoD). The partnership is called ACTIV – Accelerating COVID-19 Therapeutic Interventions and Vaccines. That initiative has moved quickly to accelerate progress by conducting a scientific review of the approximately 170 therapeutic compounds and more than 50 vaccine candidates already identified. Another ACTIV Working Group is hard at work to ensure the maximum clinical trials capacity is assembled, in order to test the highest priority candidates and standardize the evaluation methods to help FDA review.

I must say a word about our industry partners here. Within two weeks, they embraced this partnership and made an unprecedented commitment. They agreed to abide by a prioritization of therapeutic candidates, no matter who owns them, and indicated their willingness to contribute their clinical trial capacity irrespective of their potential for profit. It is a partnership in the truest sense of the word.

But there's more. The most recent endeavor of our COVID-19 effort is an initiative called Rapid Acceleration of Diagnostics, or RADx, which NIH launched just last week.

Most current testing for the virus depends on detection of the viral RNA, using a polymerase chain reaction or PCR. A PCR test takes a small code of DNA or RNA and amplifies it millions of times over so that it can be detected. This amplification process is time consuming, requires a thermal cycling machine available only in laboratory settings, and needs personnel who know how to run the test and troubleshoot problems.

RADx seeks to expand the range of diagnostic technologies to include novel approaches that can rapidly expand access to testing. RADx is engaging every scientist from the basement to the boardroom in an effort to improve current tests and advance completely new technologies. As America moves back into public spaces but seeks to avoid increased infections with COVID-19, tests must be accessible, ideally to people at the point of care to make it easier for everyone to get tested. We need tests that do not require hours or days to determine results. The new types of tests need to be sensitive enough to flag asymptomatic individuals who have just become infected but may not know it. They must be reliable and have a user-friendly design, must utilize various types of samples (nasal swabs, saliva, blood, exhaled breath, etc.), and ideally should be able to integrate with mobile devices to process and show results and transmit data seamlessly. Above all, tests need to be accessible to everyone who needs them.

Such tests sound like science fiction but are scientifically possible. One category we will pursue actively is called viral antigen testing. Antigen testing detects a part of the protein capsule of the virus itself and not its genetic code. This doesn't require PCR, and allows for immediate detection if the virus is present in the body. With time and effort, antigen tests can be modified to be done at home which would allow for easier and more frequent testing. They have traditionally been more difficult to develop to a sufficient level of accuracy, but that is where RADx comes in.

The RADx solicitation for applications was just announced last week, and proposals may be submitted on a rolling basis. The RADx technology assessment and potential scale up process will occur in three phases. Phase 0 is a rapid evaluation of the technology by clinical, technical, business, regulatory, and manufacturing experts. Expert review boards covering scientific,

clinical, regulatory and business domains will rapidly evaluate technology proposals to find gems with promise for COVID-19.

Promising early stage technologies will initially move to Phase I, where NIH will make a modest award of funds while simultaneously supporting that inventor or company with technical and clinical experts to address any scientific or business weaknesses identified in the review. Already well-developed technologies may go directly to Phase II, where support will be provided for scale-up of tests for validation, meeting regulatory requirements, and support manufacture and distribution. We are also interested in approaches that can substantially increase throughput and accessibility of laboratory-based tests. While the ultimate goal of RADx is to develop and deploy of point-of-care tests, lab-based approaches can also be supported as intermediate solutions.

The goal is to help make millions of accurate and easy-to-use tests per week available to all Americans by the end of summer 2020, and even more in time for the flu season. To be completely honest, this is an ambitious goal. The scientific and logistical challenges are truly daunting. But I remain optimistic because of the track record of American ingenuity. At NIH, we believe that putting the best minds in the world together is the only way to meet the challenge and bring this virus under control.

Thank you again for this opportunity to testify. I look forward to your questions.