

Hearing Titled Shark Tank: New Tests for COVID-19

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

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On April 17<sup>th</sup>, 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 and Development Authority (BARDA), the Food and Drug Administration (FDA), the Department of Veterans Affairs (VA), and 0 0 1 442.39t792 re c5f932u0vAio0 g 0 G [(a)4(t now )] TJ ET Q q 0.000

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 widespread 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 type 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.

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 point-of-