Exhibit 54

DARPA's Pandemic-Related Programs

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INSIGHT

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The Defense Advanced Research Projects Agency (DARPA) has contributed to the development of important military and commercial technologies, including stealth and personal electronics. DARPA's role and investments in defense-related research and development (R&D), including biological defense, has potential significance for the science and technology available to address the Coronavirus Disease 2019 (COVID-19) pandemic and any future biological threats. Advances in genome sequencing and editing, along with the application of engineering principles and computing and information sciences to the field of biology, have created opportunities to accelerate and expand the development of biotechnology products and processes. Although DARPA has invested in biological research since its establishment in 1958, in 2014 the agency created the Biological Technologies Office, which focuses specifically on the biological sciences and biotechnology.

The Biological Technologies Office currently supports a number of programs that address pandemics. Since the emergence of COVID-19, DARPA has shifted the efforts of many of these programs to focus specifically on the coronavirus pandemic. According to DARPA,

> There is currently a mismatch between the rapidity at which biological threats can emerge and proliferate and the response time for developing and deploying effective medical countermeasures.… Cognizant of the need for speed, DARPA began aggressively pursuing medical countermeasures research more than a decade ago with a focus on developing generalizable, virus-agnostic technologies that can address whatever threat emerges, rather than building a collection of one-off solutions.

Examples of current DARPA investments include the Pandemic Prevention Platform (P3) program, whose goal is to develop methods "capable of producing relevant numbers of doses against any known or previously unknown infectious threat within 60 days of identification of such a threat." Awardees of the P3 program have been applying the results of their work to COVID-19. For example, a COVID-19 antibody treatment developed with support from DARPA by AbCellera Biologics, in partnership with Eli Lilly and the National Institutes of Health (NIH) Vaccine Research Center, began human clinical trials in June 2020.

Additionally, an awardee from DARPA's Epigenetic Characterization and Observation (ECHO) program, Fluidigm, in collaboration with a consortium of medical schools, is developing an early detection test for SARS-CoV-2, the novel virus that causes COVID-19.

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Previous DARPA investments are also showing promise in combating COVID-19. For example, in 2013, the Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) program awarded grant funding to Moderna Therapeutics for the development of a new type of vaccine based on messenger RNA. The company used that technology to develop its COVID-19 vaccine, currently undergoing Phase I clinical trials in conjunction with NIH.

These DARPA programs are part of a broader biodefense effort to address threats that include naturally occurring epidemics, as well as accidental biological exposures, biowarfare, and bioterrorism. The nation's biodefense enterprise is distributed, spanning multiple departments and agencies with different missions, making preparing for and responding to a diverse and evolving set of biological threats challenging. In 2016, Congress directed the Secretaries of Health and Human Services (HHS), Defense, Homeland Security, and Agriculture to jointly develop a national biodefense strategy and associated implementation plan (P.L. 114-328, Section 1086). Issued in September 2018, the *National Biodefense Strategy* (with an implementation plan in Annex I) calls for the integration of biodefense R&D into federal planning, emphasizing the development of procedures and policies for interagency coordination of R&D efforts associated with responding to a biological incident. While the plan also calls for the sustainment of a robust national science and technology base to support biodefense, it does not articulate a need for interagency R&D planning and coordination. In 2015, the Blue Ribbon Study Panel on Biodefense, now the Bipartisan Commission on Biodefense, highlighted military-civilian collaboration in biological R&D as one of many issues that "deserve more congressional oversight."

As directed by Congress in 2016, GAO reviewed the *National Biodefense Strategy*. In February 2020, GAO found that the interagency governance and budgeting mechanisms established by the strategy represented a "promising new approach." GAO also indicated a need to "change management practices to help bridge agency cultures and missions, such as efforts to reinforce collaborative behaviors and enterprise-wide approaches." Additionally, GAO recommended the development of processes and responsibilities for joint decisionmaking.

The potential impact of DARPA-funded research in addressing the coronavirus pandemic, in addition to future biological threats, raises a number of questions:

- How does DARPA coordinate its pandemic-related programs with other federal agencies, such as NIH?
- Is DARPA effective at transitioning the results of its pandemic-related research to other federal agencies and the private sector? According to GAO, there are four factors that contribute to the successful transition of DARPA-funded research and technology: military or commercial demand for the technology; linkage to a research area where DARPA has had a sustained interest; active collaboration with the potential transition partner; and achievement of clearly defined technical goals.
- How could the commercialization of the results of DARPA's pandemic-related research be accelerated and expanded?

As it relates to biodefense R&D—especially R&D associated with preparedness,

- What changes, if any, are needed to the *National Biodefense Strategy* to improve the research, development, and commercialization of innovative biodefense technologies, including technologies that are adaptable to a range of infectious diseases, by DARPA and other federal agencies?

In its role as advisor to the Secretary of HHS, the National Biodefense Science Board (NBSB), stated that

> R&D for technologies, platforms, and systems to develop new MCM [medical countermeasures] against Disease X in 28 days from the recognition of the outbreak, which NBSB recommends as [a]

target timeline, requires new incentives, specific goals, and advanced planning within HHS (involving many stakeholders) to achieve effective capabilities.

The need for advanced planning, specific goals, and new incentives may need to go beyond HHS specific efforts requiring additional interagency planning and coordination. Congress may consider establishing a formal R&D coordination mechanism through the National Science and Technology Council similar to those associated with nanotechnology or quantum science. However, it could be considered duplicative of the roles of the existing Biodefense Steering Committee and Biodefense Coordination Team established by National Security Presidential Memorandum (NSPM)-14.

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