



MEMORANDUM

February 7, 2022

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on “ARPA-H: The Next Frontier of Biomedical Research”

On **Tuesday, February 8, 2022, at 10:30 a.m. (EST), in the John D. Dingell Room, 2123 of the Rayburn House Office Building, and via Cisco WebEx online video conferencing**, the Subcommittee on Health will hold a hearing entitled, “ARPA-H: The Next Frontier of Biomedical Research.”

I. ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH

A. Background and Objectives of ARPA-H

The American biomedical research enterprise is supported by the world’s leading academic institutions, scientists, and commercial industries.¹ The development of vaccines to respond to the coronavirus disease of 2019 (COVID-19) pandemic is an example of America’s biomedical research leadership. Developing multiple vaccines within one year to effectively prevent serious illness and death from COVID-19 infection was unprecedented.² Prior to the COVID-19 pandemic, the fastest timeline for the development of any vaccine from viral sampling to approval was four years.³ This outcome was made possible by significant federal investment and collaboration with the private sector.⁴ For example, years of fundamental research on related coronaviruses that caused severe acute respiratory syndrome (SARS) and

¹ White House Office of Science and Technology Policy, *Advanced Research Project Agency for Health (ARPA-H): Concept Paper* (June 2021) (www.whitehouse.gov/wp-content/uploads/2021/06/ARPA-H-Concept-Paper.pdf).

² Philip Ball, *The Lightning-Fast Quest for COVID Vaccines — and What It Means for Other Diseases*, *Nature* (Dec. 18, 2020) (doi.org/10.1038/d41586-020-03626-1).

³ *Id.*

⁴ *Id.*

Middle East respiratory syndrome (MERS), funded by the National Institutes of Health (NIH) and biotechnology companies, played a major role in the development of COVID-19 vaccines.^{5, 6}

However, not all research projects receive the same level of investment and urgency. Barriers and gaps exist within the public and private biomedical research ecosystem, which can lead to the stalling or failure of innovative projects.⁷ Universities, nonprofits, and government agencies – predominantly NIH – lead fundamental research that investigates theoretical questions and builds the basic knowledge of molecular and cellular processes that underlie health and disease.^{8, 9} Meanwhile, the commercial sector is focused on research, development, and marketing of products that provide a medical benefit to patients and also generate revenue to recoup investment and produce a profit over a short period.¹⁰ The priorities of the academic and commercial sectors may result in ideas not being pursued that are considered too high-risk, have a significant cost, or where the potential commercial market would not support the cost, among other reasons.¹¹

To address this research gap, President Biden proposed the creation of a new entity, the Advanced Research Projects Agency for Health (ARPA-H) as a part of his fiscal year (FY) 2022 budget request.¹² The proposed mission of ARPA-H is “to make pivotal investments in breakthrough technologies and broadly applicable platforms, capabilities, resources, and solutions that have the potential to transform important areas of medicine and health for the benefit of all patients and that cannot readily be accomplished through traditional research or commercial activity.”¹³ Examples of potential ARPA-H projects include messenger ribonucleic acid (mRNA) vaccines that prevent most cancers, patient-specific immunotherapies that decrease current treatment costs, or wearables to regulate blood pressure and blood sugar.¹⁴ Stakeholders that have participated in a series of ARPA-H listening sessions hosted by the White House Office of Science and Technology Policy (OSTP) have also advocated for ARPA-H to take on

⁵ *Id.*

⁶ Amber Dance, *Coronavirus Vaccines Get a Biotech Boost*, *Nature* (July 21, 2020) (doi.org/10.1038/d41586-020-02154-2).

⁷ Francis S. Collins et al., *ARPA-H: Accelerating Biomedical Breakthroughs*, *Science*, 373 (July 9, 2021) (doi.org/10.1126/science.abj8547).

⁸ *Id.*

⁹ *Fundamental Research*, ScienceDirect (Oct.14, 2021) (www.sciencedirect.com/topics/social-sciences/fundamental-research).

¹⁰ *See* note 1.

¹¹ *Id.*

¹² The White House, *Budget of the U.S. Government: Fiscal Year 2022* (2021) (www.whitehouse.gov/wp-content/uploads/2021/05/budget_fy22.pdf).

¹³ *See* note 1.

¹⁴ *Id.*

projects related to information technology, data sharing and treatment platforms, artificial intelligence and machine-learning algorithms, and health equity, among others.¹⁵

B. ARPA-H Model and Structure

ARPA-H is inspired by and builds on the model of the Defense Advanced Research Projects Agency (DARPA).¹⁶ DARPA was launched in 1958 with the goal of making pivotal investments in breakthrough technologies for national security.¹⁷ Some of DARPA's important achievements have included the development of the internet, stealth aircraft, miniaturized Global Positioning System technologies, flat-screen displays, and more.¹⁸ With respect to structure, DARPA consists of six technical offices and approximately 200 employees, including 100 program managers who oversee about 250 projects.¹⁹ These program managers are given the resources and authority to select a portfolio of projects to pursue and achieve a clearly defined goal.²⁰ Program managers report to technical office directors, who oversee hiring and program execution.²¹ There are key features of DARPA that have facilitated its success and that are being considered in the design of ARPA-H, including its flexible hiring authorities.²² Additionally, DARPA's authorities to administer contracts, grants, cooperative agreements, and other transaction authority allow for more flexible contractual arrangements between the federal government and certain third parties.²³

An important distinction between the proposed ARPA-H and DARPA is DARPA's service to a single customer, the Department of Defense (DoD).²⁴ The biomedical research

¹⁵ The White House, *White House Office of Science and Technology Policy & National Institutes of Health Listening Sessions for ARPA-H: Summary Report* (Sept. 2021) (www.whitehouse.gov/wp-content/uploads/2021/09/093021-ARPA-H-Listening-Session-Summary_Final.pdf).

¹⁶ Congressional Research Service, *Advanced Research Agency for Health (ARPA-H): Potential Questions for Consideration* (Sept. 23, 2021) (www.crs.gov/Reports/R46901?source=search&guid=c6ee36775a9c4ed8a9239b678b393e61&index=0).

¹⁷ Defense Advanced Research Projects Agency, *About DARPA* (www.darpa.mil/about-us/about-darpa) (accessed Jan. 30, 2022).

¹⁸ Defense Advanced Research Projects Agency, *Innovation at DARPA* (July 2016) (www.darpa.mil/attachments/DARPA_Innovation_2016.pdf).

¹⁹ *See* note 17.

²⁰ *Id.*

²¹ *Id.*

²² Defense Advanced Research Projects Agency, *Contracting Managing* (www.darpa.mil/work-with-us/contract-management) (accessed Jan. 30, 2022).

²³ *Id.*

²⁴ *See* note 1.

system involves numerous stakeholders, including patients, hospitals, physicians and other providers, pharmaceutical companies, and insurers, all of which are subject to different and often complex regulatory requirements.²⁵ For these reasons, the structure of APRA-H is intended to take into account the unique complexities of biomedical research.

The Administration has proposed that ARPA-H be housed within NIH.²⁶ Placing ARPA-H within NIH is intended to facilitate scientific collaboration and productivity while avoiding duplication of scientific and administrative activities.²⁷ Regardless of agency placement, the Administration's proposal emphasizes that ARPA-H be designed to foster a distinct culture, organization, authority, and leadership separate from any existing NIH institute.²⁸ Critics of placing ARPA-H within NIH argue that the traditional leadership and culture will not allow for independence and autonomy.²⁹

Under the Administration's proposal, ARPA-H would be led by a director limited to a five-year term, subject to a single extension of five years.³⁰ This director would oversee a diverse cohort of program managers, subject to a three year appointment with up to one renewal of two to three years, who develop and manage programs, actively engage with their project performers, apply metrics and milestones, and monitor progress.³¹ Projects taken on by ARPA-H will be time-limited with goals, benchmarks, and accountability.³² This approach is distinct from the traditional peer-review model that NIH Institutes and Centers follow, which requires an initial peer review and second level of council review, both of which are subject to additional administrative requirements of the Federal Advisory Committee Act.³³ Although this process is important to supporting basic research, some argue it is less likely to fund and execute high-risk, high-reward projects.³⁴

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *See* note 1.

²⁹ *See* note 16.

³⁰ *See* note 1.

³¹ The White House, *ARPA-H Frequently Asked Questions* (Sept. 29, 2021) (www.whitehouse.gov/wp-content/uploads/2021/09/092921-ARPA-H-FAQ.pdf).

³² *Id.*

³³ National Institutes of Health, *NIH Peer Review: Grants and Cooperative Agreements* (grants.nih.gov/grants/peerreview22713webv2.pdf) (accessed Jan. 30, 2021).

³⁴ *See* note 16.

C. Key Authorities and Funding

The Administration has also called for ARPA-H to be granted certain authorities to support its ability to operate with more flexibility than traditional federal research agencies.³⁵ In order to recruit technical experts from the private sector for a term of limited government service, the Administration has requested hiring authorities that will permit the hiring of individuals outside of the typical civil service hiring system which will allow for rapid processing and a competitive wage scale.³⁶ The Administration has also requested flexible funding authorities for ARPA-H to allow for funding distribution over multiple years, support more long-term projects, and promote competitive activity among scientific and industry players.³⁷ If ARPA-H were placed within NIH, the Administration has requested exemptions from the traditional peer-review processes, which can take up to 18 months to complete.³⁸ To carry out these authorities and establish ARPA-H, the President's FY 2022 budget requested \$6.5 billion.³⁹

II. CONGRESSIONAL ACTION

Multiple pieces of legislation have been introduced to establish ARPA-H. H.R. 4502, a FY 2022 appropriations measure, passed the House on July 29, 2021 and included \$3 billion for ARPA-H in a new account at NIH through September 30, 2024, contingent on the passage of authorizing legislation.⁴⁰ On October 25, 2021, Senator Murray (D-WA) introduced S. 3062, the Departments of Labor, Health and Human Services, and Education, and Related Appropriations Act, 2022, which includes \$2.4 billion for ARPA-H through September 30, 2024, and also contingent on authorizing legislation.⁴¹

Two authorization bills have been introduced in the House of Representatives: H.R. 5585, the "ARPA-H Act," introduced by Rep. Eshoo (D-CA) on October 15, 2021, and H.R. 6000, the "CURES 2.0 Act," introduced by Rep. DeGette (D-CO) on November 11, 2021.^{42, 43} Both bills include language authorizing ARPA-H; establishing goals for the new agency; outlining activities and processes; defining the role and authorities of the director and program managers and authorizing personnel hiring; funding awards, cooperative agreements, and other

³⁵ See note 1.

³⁶ *Id.*

³⁷ *Id.*

³⁸ See note 16.

³⁹ See note 12.

⁴⁰ See note 16.

⁴¹ S. 3062.

⁴² H.R. 5585.

⁴³ H.R. 6000.

transactions; implementing advisory committees; creating reporting requirements; and authorizing funding.⁴⁴

III. WITNESSES

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⁴⁴ See notes 41 and 42.