

Advanced Research Projects Agency for Health (ARPA-H): Considerations for Congress

May 18, 2021

On April 9, 2021, the Office of Budget and Management (OMB) submitted President Biden’s FY2022 [discretionary budget request](#) to Congress. This “skinny” budget request proposed the creation of an Advanced Research Projects Agency for Health (ARPA-H) within the National Institutes of Health (NIH), an agency in the Department of Health and Human Services (HHS). The budget request included \$6.5 billion for ARPA-H to “drive transformational innovation in health research and speed application and implementation of health breakthroughs.” Its initial focus would include “cancer and other diseases such as diabetes and Alzheimer’s.”

While the current publicly available information on the proposal lacks specifics, ARPA-H would likely follow the model of other “ARPAs,” especially the Defense Advanced Research Projects Agency ([DARPA](#)) and the Advanced Research Projects Agency—Energy ([ARPA-E](#)). [Stakeholders](#) identify a number of “[DARPA model](#)” characteristics for ARPA-H, including a flat and nimble organizational structure, tenure-limited program managers with a high degree of autonomy to select and fund projects, and a milestone-based contract approach. In contrast, NIH relies predominantly, with some exceptions discussed below, on the scientific [peer review process](#) to award most of its funding. Some [evidence](#) suggests that this investigator-driven and consensus-based process is less likely to fund high-risk, high-reward projects.

Novel approaches outside of the traditional peer-review process have been successful at funding medical research and development (R&D). Notably, DARPA invested in [Moderna’s](#) mRNA vaccine technology—[reportedly](#) at a time when it was viewed with skepticism. The Biomedical Advanced Research and Development Authority ([BARDA](#)) has supported [medical countermeasure](#) R&D through flexible, innovation-focused R&D awards—including for Coronavirus Disease 2019 ([COVID-19](#)) [products](#).

NIH currently has programs with some DARPA model characteristics—the [Common Fund](#) for high-risk, short-term and milestone-driven innovative projects and the National Center for Advancing Translational Sciences ([NCATS](#)), which focuses on innovation in medical product development. Additionally, NIH has major drug R&D efforts involving private partners and other agencies for the diseases mentioned in the President’s request—Alzheimer’s disease, cancer, and diabetes—notably through the [Alzheimer’s disease](#)

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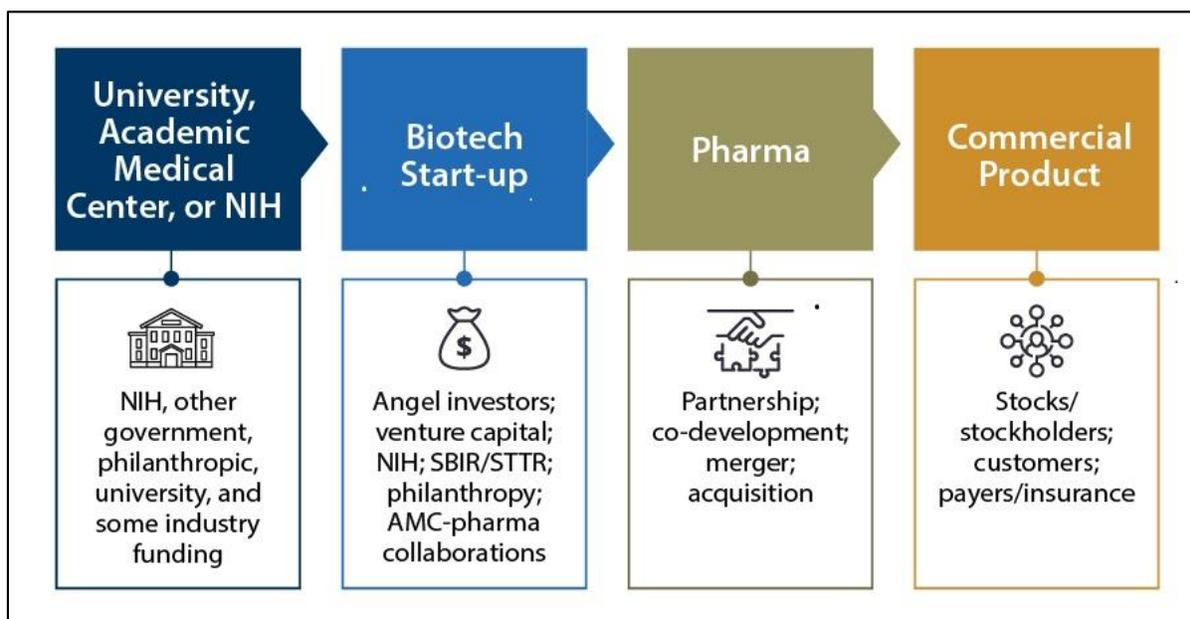
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research portfolio, the Beau Biden Cancer Moonshot Initiative, and the Accelerating Medicines Partnership (AMP). During congressional hearings, some Members have questioned if ARPA-H would replicate existing NIH efforts.

ARPA-H could potentially expand NIH's role helping researchers and companies overcome barriers (e.g., lack of capital) to the commercialization of biomedical discoveries. **Figure 1** depicts a generalized process for funding and commercializing pharmaceutical drugs. Some recent economics research indicates that pharmaceutical firms may underinvest in novel innovation, which may justify establishing ARPA-H. However, the Congressional Budget Office (CBO) has noted a risk of federal funding displacing private sector investments in pharmaceutical R&D.

Figure 1. Common Process and Funding Sources for Transitioning a Discovery into a Pharmaceutical Drug



Source: Adapted by CRS from Jeffrey Cummings, Carl Reiber, and Parvesh Kumar, "The Price of Progress: Funding and Financing Alzheimer's Disease Drug Development," *Alzheimer's & Dementia: Translational Research & Clinical Interventions*, vol. 4 (2018), p. 3337.

Notes: Figure represents a generalized process that may not apply to every pharmaceutical drug. Abbreviations: SBIR/STTR = Small Business Innovation Research/Small Business Technology Transfer programs; AMC= Academic Medical Center; Biotech Start-Up = small biotechnology companies; Pharma = large pharmaceutical companies and large- and medium-sized biotechnology companies.

DARPA's primary mission is national security, and its primary customer is the Department of Defense. As such, the agency does not have to consider commercialization—though DARPA investments do sometimes lead to commercial technologies (e.g., autonomous vehicles). ARPA-H would fund biomedical R&D and technologies that would transition primarily to the largely private health care sector, which is influenced by public and private health insurance and coverage, as well as patient and provider acceptance and uptake. Many ARPA-H-supported technologies would require preclinical and clinical testing to support Food and Drug Administration (FDA) approval.

Clinical trials (i.e., testing in humans) follow a process designed to limit exposure to potentially unsafe or ineffective products and can take over 10 years to complete. Some studies suggest that issues with clinical trials, such as trial design or barriers to participation, also pose key challenges for developing new drugs for Alzheimer's disease and cancers. Additionally, the acting FDA Commissioner and other stakeholders

have called for greater federal clinical trial coordination and infrastructure based on experience with COVID-19 R&D. ARPA-H could potentially aid in developing innovative [technologies](#) used in clinical trials (e.g., devices to measure patient outcomes) or by expanding NIH's role in [supporting clinical trials](#). However, clinical trial infrastructure programs may be more akin to NIH's existing [clinical trial networks](#) or BARDA's [clinical studies network](#).

As Congress examines the ARPA-H proposal and the role of the federal government in the commercialization of biomedical products, it may consider the following options:

- Establishing a new ARPA-H entity either within NIH or within HHS, in addition to existing programs.
- Consolidating existing related programs (e.g., the Common Fund) into a new ARPA-H.
- Expanding upon existing efforts instead of establishing ARPA-H.
- Taking no action.

If Congress decides to create ARPA-H, it may consider a number of questions:

- Are some of the goals of ARPA-H more appropriately accomplished through other policy options (e.g., tax incentives to encourage private investment)?
- How should ARPA-H determine its priorities? Are cancer, diabetes, and Alzheimer's disease the appropriate initial focus areas for ARPA-H, especially given existing NIH efforts?
- How should ARPA-H consider implementation and access to medical products and drugs? For example, cost, manufacturing capacity, provider training needs, and complex clinical administration have affected access to cancer [CAR-T therapy](#).
- Is the proposed \$6.5 billion budget appropriate? That amount would place ARPA-H among the top-funded NIH [Institutes and Centers \(IC\)](#) and potentially affect the agency's long-standing [emphasis on basic research](#).
- What are the appropriate metrics for measuring the success of ARPA-H?

Establishing a new entity may overcome existing institutional or cultural barriers to innovative approaches to biomedical R&D. At the same time, any new entity may need to coordinate with existing programs to avoid duplication. Congress may also consider whether to incorporate or align ARPA-H with other legislative proposals, such as the NIH innovation provisions in H.R. 3.

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