National Health Council
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July 16, 2021

The Honorable Fred Upton        The Honorable Diana DeGette
U.S. House of Representatives  U.S. House of Representatives
Washington, DC 20515            Washington, DC 20515

Dear Representatives Upton and DeGette:

On behalf of the National Health Council, I am happy to respond to your Request for Information (RFI) on the creation of the Advanced Research Projects Agency for Health (ARPA-H). We are grateful for your continued leadership in crafting a path forward for advancing health research in a way that supports patients.

Created by and for patient organizations 100 years ago, the National Health Council (NHC) brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care. Made up of more than 140 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic drug, and payer organizations.

The NHC shares your desire to both increase investment in health research and to "drive transformational innovation in health research and speed application and implementation of health breakthroughs." To meet the goals of creating breakthroughs that will best benefit people with chronic conditions, ARPA-H must have the correct structure, staff, partners, and mission. Our comments focus on ensuring that the new ARPA-H prioritizes timeliness, high risk/high reward solutions, patient engagement, partnerships with the private sector and other Federal agencies.

Also importantly, we appreciate and support the funding requested in the President's budget proposal and will continue to work to ensure that this funding is available and not provided at the expense of other federal research efforts. Your work to create authorizing language to support this funding request is greatly appreciated. Our responses below to your specific questions will help assure ARPA-H best delivers needed treatments and cures.

**Question: In calling for the creation of ARPA-H, President Biden has cited the success of the Defense Advanced Research Projects Agency (DARPA) and expressed his belief that ARPA-H should be similar. Please provide specific details on which aspects of DARPA ARPA-H should replicate and why this would lead to similar success.**

The NHC appreciates DARPA's approach toward innovation, operating culture, partnering, contracting, outcomes-orientation, and funding mechanisms. One of the aspects of DARPA that ARPA-H should adopt is focusing on high-risk, high-reward research. This sets DARPA apart from other research entities and would be necessary for ARPA-H to differentiate itself from traditional NIH research. Another aspect of DARPA to replicate is bringing in staff from outside the government and for only a specific, short time period. This allows DARPA to attract creative thinkers from the private sector that often have a very different approach from Federal scientists or traditional academic researchers. The finite time period is important to move quickly to achieving individual projects goals and help drive the speed of actual research translation. It will also refresh ARPA-H regularly with fresh ideas.

Finally, while this RFI asks about aspects of DARPA, we also encourage application of best practices from the Advanced Research Projects Agency-Energy (ARPA-E). While DARPA research is primarily geared toward creating ideas that will be utilized by the Department of Defense, ARPA-E funds projects that are intended to be translated to applications in both the public and private sectors, just as ARPA-H would. We recommend consideration of ARPA-E's technology-transfer and commercialization efforts as potential best practices for ARPA-H.

**Question: To ensure it has the biggest impact, on what activities or areas should ARPA-H focus? What activities or areas should ARPA-H avoid?**

As in all Federal health-related activities, the NHC believes it is critical to prioritize those activities identified by patients as those with the most significant impact on their health and lives. We recommend that input be sought from a wide variety of patient stakeholders to ensure the research agenda meets as broad a spectrum of patient needs as possible. For instance, there is a needed balance between research into solutions for widespread diseases such as cancer and Alzheimer's, and attention to potential breakthroughs for less prevalent and rare diseases. Some specific areas of focus for ARPA-H that should be prioritized include breakthrough technologies, increasing system capabilities, and platforms that accelerate innovations in health and medical-product development across disease states.

One approach that will help make sure ARPA-H's work is meeting the needs of patients is to focus on pre-competitive collaborations with patients, for such activities as endpoint identification and measure qualification to capture the impacts patients report as important and meaningful.

As noted in response to the subsequent question about private sector relationships, all ARPA-H-funded research should have an end goal of commercialization with dedicated staff and resources to achieve that goal. A key component of promoting and implementing transformational innovation is supporting the "last mile" of research by translating a medical discovery into delivered care. ARPA-H must include support for this type of investigation in its research programs to ensure that their discoveries become scalable, accessible, equitable, and create high-value care for patients while improving resiliency and capacity in health systems.

**Question: Some assert ARPA-H's ability to operate independently and transparently will be essential to its success. Do you agree? If so, what is the best way to design ARPA-H in order to accomplish this?**

The NHC agrees that ARPA-H must be structured in such a way that fosters a unique culture of innovation, entrepreneurship, and "big picture" thinking that will lead to transformative breakthroughs in how we treat and ultimately cure the most burdensome and intractable diseases. Given the urgency of its mission and potential to transform health, ARPA-H must be focused on implementation, rapid translation, and efficacy as priorities, while adhering to the highest levels of scientific standards and integrity. ARPA-H should ensure that diverse voices are part of its leadership, staff, supported research, and community outreach, and should provide for open and transparent processes for all stakeholders to inform and shape research priorities.

**Question: How should ARPA-H relate to, and coordinate with, existing federal entities involved in health care-related research and regulation?**

ARPA-H should build upon basic science funded by NIH Institutes. Another important federal entity for coordination is the Centers for Medicare and Medicaid (CMS). ARPA-H activities should be carefully coordinated with payers and CMS to assure they are prepared to leverage the information and technology ARPA-H provides to ensure coverage is not a barrier to putting innovative therapies into patient's hands. Finally, the Food and Drug Administration (FDA) must also be a critical partner working with ARPA-H to speed the translation to approved, licensed, or cleared therapies.

**Question: What is the best way to ensure ARPA-H has a mission, culture, organizational leadership, mode of operation, expectations, and success metrics that are different than the status quo?**

There are effective lessons on patient engagement from the Patient-Centered Outcomes Research Institute (PCORI) and the FDA that should be foundational to ARPA-H from its inception. One of the greatest successes of PCORI has been its mission to involve patients and patient organizations in its governance and in every portion of its research and dissemination agendas. ARPA-H similarly has an opportunity to make patient engagement a key feature from its founding.

Other important ways of ensuring the appropriate culture include fostering and rewarding an innovative environment and extensively tapping staff with a background in the private and nonprofit sectors.

**Question: How should ARPA-H work with the private sector?**

We recommend that patient groups, private sector, nonprofit research sector, and private payers have a significant role in prioritizing projects, reviewing results, and partnering in dissemination. ARPA-H research must also draw from the best of private and public sector thinking, with private sector expertise being utilized in strategic ways.

Every ARPA-H-funded project should have a goal of commercialization and a plan to get there, which must involve private industry as a partner. As previously noted, lessons learned from ARPA-E's tech transfer and commercialization efforts could be informative.

**Question: What is the appropriate funding level for ARPA-H? How do we ensure ARPA-H funding does not come at the expense of traditional funding for the National Institutes of Health?**

Support for ARPA-H should be authorized at a level consistent with mission and funding levels needed for success. We support the President's proposed FY 22 $6.5 billion budget request. Public-private partnerships should be encouraged to increase the capacity of ARPA-H as well. Funding for ARPA-H needs to be predictable and support ongoing work. Finally, ARPA-H funding should not be at the cost of existing federal research funding at NIH Institutes and other federal efforts.

**Conclusion**

We appreciate the opportunity to provide additional input on these critical issues. Please do not hesitate to contact Eric Gascho, Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,
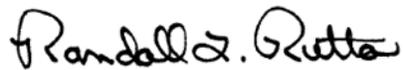
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