FASEB
Federation of American Societies for Experimental Biology

Representing Over 130,000 Researchers

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September 13, 2021

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton:

The Federation of American Societies for Experimental Biology (FASEB) is comprised of 30 scientific societies which collectively represents and advocates for over 130,000 biological and biomedical researchers. We are writing to provide requested input to the Cures 2.0 discussion draft released for stakeholder comment. Specifically, we wish to comment on Sec. 501. Advanced Research Projects Agency for Health (ARPA-H).

The President's fiscal year 2022 budget seeks $6.5 billion for this new agency within the National Institutes of Health (NIH) to help drive transformational innovation in biomedical research and speed application and implementation of health breakthroughs. We applaud President Biden's leadership and join in support of ARPA-H's creation with the following input.

As a member of the steering committee for the Ad Hoc Group on Medical Research, FASEB supports the sentiments expressed in the coalition's July 16 letter, especially that you work with appropriators to ensure that investments in ARPA-H are balanced with robust investment in NIH-supported, foundational, investigator-initiated research that forms the bedrock of our nation's medical research ecosystem at labs across the country. As noted by the Ad Hoc Group, "There is room in this ecosystem for both advanced R&D approaches like ARPA-H and foundational science that is the core of NIH's mission, but – critically – the former depends on the latter."

Priority number one should be that ARPA-H supplements and does not supplant funding for NIH's basic fundamental research efforts. Maintaining a distinct budget line in the ARPA-H authorizing language will be necessary to achieving this goal. Firewalls or guardrails must be put in place to ensure that year-after-year NIH's basic fundamental research budget remains steady and robust when funding ARPA-H. There should be no requirement that NIH's Institutes and Centers (ICs) must provide any funds to support projects ARPA-H decides to fund as this would be counterproductive and compete with funding for NIH grants and intramural investments.

Regarding the specific questions in your request for stakeholder input, FASEB's comments are as follows:

1. What activities or areas should ARPA-H focus on? What activities or areas should ARPA-H avoid?

ARPA-H should focus on cutting-edge, high-risk projects, and transformational research to advance human health that the NIH ICs or other federal entities/programs would not fund because it is outside of their scope or priorities. ARPA-H program managers will need to understand and have access to

information about the landscape of funded government work that currently exists before funding a project to ensure that ARPA-H does not duplicate existing research.

One area where ARPA-H could make an especially meaningful contribution is in funding projects that aim to reduce health disparities. The ultimate goal is that projects could advance knowledge that will radically change the paradigm for a health condition through direct treatment or prevention that can quickly provide significant human health benefits.

Such projects could be funded for longer than three years if milestones are being met to ensure sufficient time for the kind of innovation contemplated, with a top limit of five years. A majority of the projects should be no longer than three years to ensure that ARPA-H meets its goal of accelerating research progress.

The types of grants supported by ARPA-H should not be limited to research on cancer, Alzheimer's, or diabetes but a wide variety of disease both rare and not so rare. For example, we have seen how a deadly virus for humans can spread across the globe, so it is in our interest to look beyond our borders when considering the research areas to address and prevent regression in diseases such as tuberculosis, malaria, and HIV. We should also remember vaccines have been a life saver during the COVID-19 pandemic and could be so again for other diseases, making it critical for ARPA-H to be able to support vaccine research.

2. 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?

FASEB agrees that the agency needs to operate independently and transparently. It cannot be a smaller version of NIH or be seen as an alternative place that small businesses with innovative health care ideas can access, when there is already the Small Business Administration as well as the well-funded SBIR and STTR programs. ARPA-H's staffing from top to bottom should be a model of diversity to which other agencies can reference and aspire and will help drive the core consideration of whether a project can reduce health disparities

Being located in the greater Washington, DC area would be helpful, <u>but it is not necessary for ARPA-H to be on the NIH campus.</u> Co-location with other federal agencies will facilitate information exchange and physical access to Congress and federal agency personnel.

ARPA-H should have its own legal authorities which do not overlap with the standard NIH authorities in terms of research, hiring, or funding mechanisms, all of which should instead be based on DARPA's authorities. It should have its own Health and Human Services Office of General Counsel section, separate from NIH's, since ARPA-H's General Counsel will be interpreting these DARPA-based legal authorities. In addition, we recommend that ARPA-H be exempt from Paperwork Reduction Act requirements, just like NIH, which will help it to be more nimble.

There should also be transparency and accountability to the stakeholder community to understand why certain projects were selected for ARPA-H funding. Maintaining an up-to-date system for public access to information about ARPA-H funded projects will be necessary. Since ARPA-H project proposals will not

undergo a traditional peer review process, it is essential to communicate the merits of funded projects and the risks for failure to ensure continued funding for the agency. To ensure the agency does not perpetuate inequality, we also urge adoption of practices to improve preparedness of Early-Stage Investigators and historically excluded groups to pursue ARPA-H funds.

As part of the transparency effort, data generated from terminated and successful ARPA-H funded projects must be made available in a useable format. By doing so other researchers, industry, and academia can benefit from what is learned through these grants.

FASEB also suggests that ARPA-H hold an innovation conference similar to what ARPA-E does to bring together participants from across the country and around the globe such as industry, academia, scientific societies, health care organizations, and government (state, local and tribal) to meet and discuss the most pressing issues in the healthcare ecosystem and brainstorm future opportunities for ARPA-H to consider.

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

We understand the culture of ARPA-H will be different from that of NIH. However, there still needs to be some level of coordination with NIH and other federal agencies that work in the health care space. The Director of ARPA-H should not report to the NIH Director, who will have a different universe of constituents and priorities. Instead, we recommend possibly having the ARPA-H Director report to the Office of Science and Technology Policy or the head of the Department of Health and Human Services.

There should be a mechanism that allows ARPA-H to coordinate with existing federal entities. That could be done through the current Office of Science and Technology Policy with a liaison from each relevant federal agency that is working directly on health care matters.

Employees from other federal agencies that support research that impacts health including use of machine learning and AI at the National Science Foundation, computing at the Department of Energy Office of Science, and behavioral sciences should have a voice in informing ARPA-H activities. In addition, ARPA-H should regularly solicit input from stakeholders in health care, scientific organizations, foundations, industry, and patient groups.

Regulatory and business pathways should be considered as part of any project selected by ARPA-H so that successful results can move with a sense of urgency to application rather than being hindered by costs and regulatory barriers.

4. 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?

Establishing the culture of an organization begins at the top. Therefore, the first director of ARPA-H will be critical to creating a culture where people are eager to have the opportunity to work at ARPA-H as a program manager or longer as operational staff. If the director is successful, ARPA-H will be one of the best places to work in the government when it comes to biomedical advancements. A successful ARPA-H director must have demonstrated unconventional thinking, possess a level of gravitas, create a sense of

urgency, understand not only how researchers think but how industry operates, be skilled at building partnerships, willing to build champions to protect the organization in the long run, possess demonstrated ability to sell a concept widely, and keep and maintain bipartisan Congressional support. Success can be measured by weighted factors not limited to the following:

- Out of the box thinking;
- Impact of the project to change the health paradigm by creating a new process or line of research;
- Impact on health disparities;
- Data generated is downloaded, utilized, and cited by others;
- Is in an area of research industry has not demonstrated a willingness to fund such as the creation of new antibiotics;
- Did the project utilize data generated by other sources such as health care organizations?;
- Was there diversity in any trials that took place?;
- Was there diversity among those funded by ARPA-H ?; and
- Impact of a project beyond the traditional healthcare system.

ARPA-H must also have the hiring flexibility to engage innovators who are not necessarily scientists themselves but can assemble a team that will drive results regardless of the educational and career trajectory of the team members.

Project managers must have clear and enforceable milestones; have the ability to adjust projects as needed; and be encouraged to end projects that cannot meet milestones.

Termination of projects will not be seen as a failure, but as a way to shift resources to other promising projects.

5. How should ARPA-H work with the private sector?

When selecting projects to fund, ARPA-H should encourage applications from teams of scientists from academia and the private sector working together to achieve research goals. The private sector can bring different perspectives when it comes to actual production, marketing, and distribution of any new breakthrough that emerges from the process.

The private sector should also be a source of program managers hired for ARPA-H. Individuals from the private sector should be included in any request for information, stakeholder engagement, annual meetings, etc. of ARPA-H.

6. 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?

Its funding should be seen by appropriators as supporting not only NIH, but other federal agencies such as the Centers for Disease Control and Prevention, the Food and Drug Administration (FDA), and the Department of Veterans Affairs (VA). FDA and VA both fall outside of the jurisdiction of the House Appropriation's Labor, Health and Human Services, Education and Related subcommittee. Given that the agency is likely to have a cross-functional impact across several functional accounts in the federal

budget and federal agencies benefiting from its work will fall under several appropriations subcommittees, policymakers will need to think creatively about the various sources of funding for ARPA-H.

We look forward to working with you and your staff as the specifics of ARPA-H are further developed and the appropriations process advances. Thank you for considering our views.

Sincerely,

Patricia L. Morris, MS, PhD
FASEB President