Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
"ARPA-H: The Next Frontier of Biomedical Research"
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The Honorable Frank Pallone, Jr. (D-NJ)

1. The incredible relief provided by COVID-19 vaccines and treatments that were made possible by biomedical innovation are a testament to the importance of strengthening the biomedical ecosystem to support future medical breakthroughs.

    a. How do you see ARPA-H playing a role in improving our nation's pandemic preparedness? Are there any particular technologies or platforms that could lead to breakthroughs in our ability to prevent or respond to novel threats?

    While ARPA-H's mission should be broader than pandemic preparedness, it would be ideally situated to leverage learnings from the COVID-19 pandemic and prioritize investments that will both leave us better prepared for future public health emergencies and benefit the overall biomedical innovation ecosystem.

    - Investment should be prioritized in platform technologies (e.g., mRNA, prototype pathogens) and research infrastructure. COVID 19 shone a spotlight on the challenges in our clinical trial infrastructure, particularly the lack of ability to engage community-level providers that enable greater patient participation and those impacted disproportionately by the burden of disease. ARPA-H offers an opportunity to build an infrastructure platform to support a national community-based clinical trial network.
    - A number of high-value platforms and assets were created during the pandemic that should be sustained and made available to ARPA-H (e.g., RADx, the National COVID Cohort Collaborative data platform, NIH's Clinical Trial Capacity Inventory).
    - Collaboration, across and within sectors, was key to accelerating research and product development during the pandemic, and ARPA-H should be a platform for continued collaboration among those players.

    b. How do you envision ARPA-H working in a collaborative manner with other research agencies?

    A multi-agency and multi-stakeholder approach should be employed for setting priorities and guiding/informing projects. First, ARPA-H must ensure its work is complementary to and not duplicative of other science-funding agencies such as

DARPA, NSF, and BARDA. Second, we strongly believe that representatives of patients, including those from underserved communities, must be part of priority-setting, defining the problems most important to be solved. And finally, if ARPA-H's work is to be truly solutions-oriented, it must be actively and regularly engaged with and informed by other agencies critical to advancing solutions to patients, such as FDA and CMS.

c. In what ways can ARPA-H amplify the important work done across HHS and other federal entities working to improve health?

ARPA-H should work in close coordination with other science-funding agencies to ensure its work is not duplicative but rather addresses the types of cross-cutting challenges that other agencies cannot. Because of its focus on problem-solving and commercialization of products, it should have a strong interest in close coordination with regulatory and reimbursement agencies like FDA and CMS to ensure that the projects it funds reach their intended end-users.

d. What metrics should be used to assess the progress of ARPA-H?

In the near term, we should be looking at the agency's ability to organize quickly; attract the type of leadership and program managers who are a key to DARPA's success; get needed and appropriate authorities in place to enable its rapid and flexible operations; and prioritize problems in areas of high unmet need and low investment, to be addressed in consultation with a multi-agency, multi-stakeholder advisory group.

An important ingredient in DARPA's success is the ability to "fail fast," and failure for technical reasons is not viewed as a negative. This culture must be replicated at ARPA-H, and any metrics utilized must not create unintended consequences of penalizing "failure."

In the medium- to long term, therefore, ARPA-H should be evaluated by its ability to stimulate the development and commercialization of products and platforms that benefit the biomedical innovation ecosystem and ultimately patients—or to fail fast and apply the lessons learned to new approaches.

We also need to ensure the projects selected by ARPA-H improve the lives of populations that are historically underserved and come from marginalized minority communities.

2. When we consider DARPA, the model agency for ARPA-H, it is a unique agency that benefits from numerous special authorities. For example, DARPA is able to capitalize on flexible hiring and procurement authorities, including grants, contracts, cooperative agreements and other transaction authorities. These special authorities have in part paved the way for DARPA's success.

    a. In scenarios where ARPA-H is working with prototype technologies or companies that don't typically partner with the government, what special authorities are needed to ensure successful development of new platform technologies?

ARPA-H would certainly require Other Transaction Authority, which gives it flexibility in the contracting and procurement contracting process. It needs to have a strong focus on technology transfer and commercialization—though that would not necessarily require different authorities, just skills and prioritization. It would also require freedom from federal hiring constraints to attract the types of personnel required to manage these projects and pay them competitively.

b. How can the government ensure that technologies developed through the ARPA-H pipeline make it into the mainstream and are accessible to all who need them?

The private sector is a critical partner in this work, whether as collaborators in executing specific projects or as the recipients and amplifiers of any innovation coming out of the program. Technology transfer and commercialization will be central considerations in the policies and approach of the new agency.

Another aspect of working with the private sector could be finding ways to leverage private investment in technologies that might come out of ARPA-H. BARDA Ventures could be a potential model in this regard, or In-Q-Tel, which invests in new technologies related to national security.

3. ARPA-H would employ a high-risk, high-reward and fail fast model. ARPA-H would also collaborate with the private sector and other stakeholders to ensure that the projects it supports ultimately lead to improvements in health for patients.

a. From your perspective, what would the collaboration between ARPA-H and the private sector and other stakeholders look like?

As noted above, the private sector is a critical partner in ARPA-H's work, whether directly contracted to execute specific projects or through licensing intellectual property created at academic institutions in pursuit of its goals. Innovative products do not make it to patients without the involvement of the private sector.

We believe that ARPA-H should have a collaborative priority-setting process that involves a multi-stakeholder advisory group, including representatives of patients, to ensure that the agency is aiming its efforts at solving problems in areas of high unmet need with low investment.

The Honorable Bobby L. Rush (D-IL)

1. Last May, I was proud to introduce the LOANS for Biomedical Research Act (H.R. 3437), which would establish a BioBonds Program. The BioBonds Program is a novel approach to fund biomedical research by leveraging the significant, untapped resources of private-sector institutional investors, including pension funds.

BioBonds are a package of loans made to researchers at eligible biomedical companies and universities. Banks would package these loans and then sell them to institutional investors. BioBonds are similar in structure to green bonds, which generate hundreds of

billions of dollars in investments for climate and environmental projects. In 2020, the green bond market reached $1 trillion dollars. Investments generated by BioBonds would help advance translational research and enable promising research to progress from the lab to the patient.

In my opinion, BioBonds fits squarely in the overall directive of ARPA-H to use funds to translate scientific discoveries into technological innovations. This innovative financing mechanism is consistent with the goals and authorizing legislation for ARPA-H and could enable meaningful advancements in a wide range of diseases. To say it another way, I believe a BioBonds program, like the one established in my bill, could be operationalized within ARPA-H.

a. Ms. Krofah: Do you agree that BioBonds fit into the fast-growing ESG (or Environmental, Social, Governance) arena in which investors look not only at return, but also at public welfare, as is the case with green bonds? Why or why not?

   We agree that the BioBonds proposal for debt financing is a valuable addition to the array of options available to support biomedical innovation, engaging a broader range of investor types. In our view, this seems to fits squarely into the current interest in investing in companies that create value across the ESG spectrum. We would like to see more focus on the "Social" elements, and specifically the health-related benefits, tracked by ESG metrics. We are looking at how the Milken Institute might play a role in defining such metrics and driving their adoption.