White House Office of Science and Technology Policy & National Institutes of Health ARPA-H Listening Session: Philanthropy and Venture Capital Organizations Wednesday, July 14, 2021 Summary

Overview

On July 14, 2021 the White House Office of Science and Technology Policy (OSTP) and the National Institutes of Health (NIH) convened a listening session to provide input into the scientific focus of the Advanced Projects Research Agency for Health (ARPA-H). As part of the 90-minute listening session, representatives from 14 foundations and venture capital companies¹ discussed scientific opportunities, approaches, challenges, and partnership strategies ARPA-H might adopt.

The meeting was introduced by Dr. Eric Lander, the Director of OSTP. Dr. Lander welcomed participants and explained the meeting goal, which was to engage participants in a discussion about potential R&D priorities and programs for ARPA-H. Dr. Lander noted that many innovative biomedical research ideas do not necessarily fit existing Federal government mechanisms for support nor companies' need for a return on investment over short time frames. He noted that these innovative ideas may not fit other existing mechanisms because they are high-risk, costly, require coordination across multiple parties, or do not match academia's incentives. In addition, projects that focus on remedying inequities or disparities in healthcare access often are not seen as ripe for commercial investment. He noted that flexible high risk, high reward efforts, such as those launched by DARPA, have historically been successful in supporting breakthrough technologies, and that having similar capabilities and approaches applied to health offers opportunities for new breakthroughs.

After Dr. Lander's introduction, participants engaged in a question and answer session, followed by two feedback sessions moderated by Dr. Lawrence Tabak, Principal Deputy Director of NIH. The first session considered critical gap areas on which ARPA-H could focus and possible approaches that should be considered or opportunities leveraged to overcome critical challenges in the market, regulatory and reimbursement environment, biomedical research enterprise, or elsewhere in the ecosystem. The second session considered systemic barriers and challenges in the biomedical research enterprise that are slowing progress and the approaches and partnership strategies an ARPA-H might employ to overcome them.

Themes

• ARPA-H can address large-scale challenges to improve health and health equity. Participants identified a range of potential scientific areas for ARPA-H to address for all patient populations, including childhood genetic disorders, antimicrobial resistance, virtual technologies for mental health screening and treatment, and immune system reprogramming to prevent disease. Participants further noted that ARPA-H should avoid technology areas that are already being considerably researched by industry and other organizations, such as wearable technologies. ARPA-H should employ landscape analyses to help avoid investing in areas that are already resourced and similarly, should deploy horizon scanning techniques to gain insight into future

¹ Bay City Capital, Chan Zuckerberg Initiative, Flagship Pioneering, Foundation for the National Institutes of Health, Bill & Melinda Gates Foundation, The Howard Hughes Medical Institute, The Kavli Foundation, MacArthur Foundation, Gordon and Betty Moore Foundation, Reagan-Udall Foundation, The Rockefeller Foundation, Schmidt Futures, Stand Up to Cancer, X PRIZE Foundation

areas of R&D. In addition, participants suggested that ARPA-H should be designed to promote patient-centered applications and health equity, through involvement of patient groups – especially from marginalized communities – and other stakeholders in the identification of priority areas.

- ARPA-H should address priorities associated with preclinical development, clinical research, and deployment of innovations in addition to fundamental challenges. Participants noted that for ARPA-H to be successful, the innovations it fosters will need to reach patients and change existing standards of care. Participants noted a range of areas in the preclinical and clinical development space where ARPA-H might develop platforms valuable to the biomedical enterprise broadly, including more accurate preclinical models (e.g., in silico approaches), rapid GMP manufacturing and bioprocess development that can help to accelerate clinical trials, and developing novel ways to generate clinical evidence that speed and democratize clinical research such as community-based virtual trials. Participants also noted that ARPA-H should foster a data sharing infrastructure (especially one that allows for application of machine learning techniques) and create incentives for data sharing that will facilitate collaboration and speed research and clinical approval of innovations.
- ARPA-H will need statutory authorities and administrative processes designed to foster flexibility, speed, and independence. Participants reiterated the need for ARPA-H to be given statutory authorities already leveraged by DARPA-like organizations, such as term appointments of program directors, contracting flexibilities, and promoting competition among performer teams. Participants also recommended that ARPA-H should be given the authority and independence to develop its own culture, with leadership drawn from the industry or the DARPA community to reinforce these distinct ways of working.
- ARPA-H should pursue novel partnership and incentive strategies to achieve its goals. Given the challenges ARPA-H is intended to address, it will need to pursue innovative partnership strategies. Government partnerships with industry and non-governmental organizations and crowdsourcing approaches were suggested as examples of these novel approaches. Participants also recommended that interdisciplinary collaborations between engineering and physical and biological sciences would be required to conceive of the novel approaches required for breakthroughs. Participants also noted that ARPA-H should pursue novel incentives. One topic of discussion concerned incentives for data-sharing and inclusiveness. In addition, participants also mentioned prizes as a form of incentive distinct from what government typically pursues as a mechanism.

Next Steps and Conclusion

The White House will continue to seek perspectives on ARPA-H from stakeholders within and outside the Federal government. This is the first of a series of listening sessions being convened by OSTP and NIH to solicit feedback from particular communities, with listening sessions targeting patient groups, industry, scientific societies, and other stakeholders scheduled in July and August. OSTP and NIH will use interagency processes to promote coordination and ensure that ARPA-H complements the priorities of NIH and other Federal research agencies. OSTP and NIH are grateful for the participation and perspectives provided by the wide variety of stakeholders in these listening sessions. Much work remains to ensure that the biomedical ecosystem is engaged in solving some of the most pressing health challenges of our time. The Administration will continue to work to ensure that the US remains a global leader in biomedical innovation for the benefit of all Americans.