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 Michael C. Burgess, M.D. (R-TX)

1. ARPA-H is looking to accomplish what many private companies are already investing in. While I don't think any of us disagree that investment in research and development to find a cure for the "uncurable" diseases is important, the investment in ARPA-H is far less that what the private industry is currently investing. What could ARPA-H do that is not, or cannot, currently be accomplished at other agencies or within the private sector?

   It would be challenging for ARPA-H to accomplish that which is currently being accomplished at other agencies and in the private sector. The National Institutes of Health Extramural Grant Program invests $31 billion annually in biomedical research, representing nearly half of the over $70 billion in annual federal biomedical research expenditures. The life sciences investment community puts forth over $36 billion annually into life sciences startups.

   Despite convening 10 listening sessions with over 5,100 stakeholders, the White House Office of Science and Technology Policy has not published a list of specific scientific and medical research priorities for ARPA-H. Thus, it is unclear exactly what mission gap ARPA-H will be filling that other entities, public and private, are not already fulfilling or could otherwise be re-tasked (or otherwise incentivized with existing mechanisms) to address.

   Regardless, the principles of ARPA-H should be deployed: an independent professional staff, time-based milestones for research outcomes, and a target of revolutionary ideas. Policymakers would be well-served by empowering existing federal research programs to better execute on these principles. If we are to use taxpayer dollars for research, we should seek the projects that are "high risk, high return."

   a. What do you believe the most efficient way to structure ARPA-H would be, and what do you believe the goals of this agency should be?

   Instead of structuring ARPA-H as an independent agency (where it would incur all the structural and management costs associated thereof) or as an institute at the National Institutes of Health (and thus face similar challenges), policymakers should

consider restructuring part of pre-existing extramural grant program along the proposed aims of ARPA-H. This could either be part of each area study section funding being "partitioned" out for a more aggressive, high-risk high-return program; a repurposing of existing programs such as NCATS; or a combination of the aforementioned.

Using a DARPA-like program-manager model or FDA "professional staff reviewer" model in place of study sections could promote more rapid decision-making, increase flexibility, and allow for positive idea risk in project selection.

Such a program should invest in areas currently not being covered by other programs, focusing on high-risk, high-reward research. Accordingly, a program should not be initiated until clear medical and scientific gaps are elucidated, and policymakers ensure that there is not overlap with pre-existing public and private research efforts.

2. Our country has a long history of looking for ways to accelerate innovation. Do you agree that before committing to a fully new program, that there are reforms that can be made to other government programs intended to spur innovation, such as the Centers for Medicare and Medicaid Innovation Center?

Before funding, authorizing, and executing a new healthcare innovation program, policymakers should examine prior federal health innovation programs, characterizing success and failures. Created in 2010, the Centers for Medicare and Medicaid Innovation Center, was authorized with a $10 billion budget over a decade with a handful of statutorily-specified models with the rest left to agency discretion. After a decade of conducting experiments in health finance, the Chief Actuary of CMS has only certified four of over fifty models for national scaling,[1] with only two – the Diabetes Prevention Program[2,3] and components of the Pioneer ACO model – scaled nationally within the Medicare program.[4] Market impact of the CMS Innovation Center has been limited: despite over 16.4 million beneficiaries estimated to meet eligibility criteria for the Diabetes Prevention Program,[5] by 2019 only 200 beneficiaries had enrolled.[6] The Pioneer ACO model exhibited similar challenges during its trial period, with

[1] Berwick DM, Gilfillan R. "Reinventing the Center for Medicare and Medicaid Innovation." *JAMA* 325(13):1247-1248.
[2] *Independent experts confirm that diabetes prevention model supported by the Affordable Care Act saves money and improves health.* (2016) Retrieved from https://wayback.archive-it.org/3926/20170127185647/https:/www.hhs.gov/about/news/2016/03/23/independent-experts-confirm-diabetes-prevention-model-supported-affordable-care-act-saves-money.html
[3] Medicare Diabetes Prevention Program Expansion. Centers for Medicare & Medicaid Services (2016). Available from: https://www.cms.gov/newsroom/fact-sheets/medicare-diabetes-prevention-program-expansion
[4] Berwick, DM., Gilfillan, R. (2021) Reinventing the Center for Medicaid and Medicare Innovation. JAMA. 2021;325(13):1247–1248. doi:10.1001/jama.2021.3203
[5] Meyer H. (2021). Medicare Diabetes Prevention: Enrollment Short Of Projections. *Health Affairs (Project Hope)*, *40*(11), 1682–1687. https://doi.org/10.1377/hlthaff.2021.01292
[6] Tahir, D. (2019). Medicare diabetes prevention program helps a few hundred instead of hundreds of thousands. *Politico*. Retrieved from https://www.politico.com/news/2019/10/22/medicare-diabetes-hhs-055006

approximately one-third of providers remaining enrolled during the initial three-year performance period.[7] *The achieved (i.e. executed) value of scale CMS Innovation Center programs for taxpayers is a source of debate, albeit is likely less than the initial programmatic investment and even smaller when ignoring the opportunity cost of human capital deployed. Before undertaking any similar program for further funding biomedical innovation, a neutral third party such as the National Academy of Medicine (in consultation with relevant private sector stakeholders) should undertake a thorough assessment of the successes and failures of CMS so as to avoid repeating prior mistakes in another innovation policy arena.*

a. What are some suggestions you have for reforms to these programs, and could dollars saved from reforming these programs be reinvested in efforts like an ARPA-H?

Specifically, existing program funding focused on translational research could be redirected to this purpose. Promoting transparency and appropriateness of indirect costs at existing institutions participating in federal research would allow for identification of specific savings. Some institutions may need high indirect costs (e.g. maintenance of a BSL-4 laboratory), while others may not.

The Honorable Gus Bilirakis (R-FL)

1. Dr. Miller, Operation Warp Speed proved that with the proper agency coordination, funding, and partnership with the private sector, we can accomplish an acceleration of biomedical research and development, ultimately leading to approval of treatments – and this was done all under the existing federal agency framework. Can you tell me how you believe ARPA-H could replicate this success, if at all, instead of bogging down our existing infrastructure?

Existing as an independent agency or as part of the NIH, ARPA-H would struggle to replicate the effects of Operation Warp Speed. In record time with a focus on achieving a scientific and operational outcome – development and mass product of vaccines, therapeutics, and diagnostics – Operation Warp Speed promoted across government coordination and elimination of regulatory barriers all driven by a sense of urgency if not emergency. It is unlikely that a single agency would be able to replicate this success. Consumers would be better served by examining regulatory policy barriers to lower the cost and increase the speed of drug and device development, given the massive existing public and private infrastructure already spent on biomedical research.

[7] "Evaluation of CMMI Accountable Care Organization Initiatives: Pioneer ACO 2016 Final Report." L&M Health Policy Research 2016. Retrieved from https://innovation.cms.gov/files/reports/pioneeraco-finalevalrpt.pdf