

**Attachment—Additional Questions for the Record**

**Subcommittee on Health  
Hearing on  
"ARPA-H: The Next Frontier of Biomedical Research"  
February 8, 2022**

Admiral Brett P. Giroir, M.D., Former Assistant Secretary for Health, U.S. Department of Health and Human Services

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

1. You have one of the strongest understandings of the DARPA program. You have worked with the program both on the private research and development side, and on the administrative side while serving as the Director of the Defense Sciences Office. What did you learn about the structure of DARPA during this time and involvement with the program, and do you believe any of these qualities should be applied to ARPA-H?

**ANSWER**

The structure of ARPA-H, like that of DARPA, must be one that promotes innovation, speed, agility, and boldness without fear of failure. In order to achieve this, the organization must be small (DARPA has only ~100 technical staff), flat (few layers of command and control), and unencumbered by bureaucratic processes. The program managers and leadership should not have to answer to external officials who do not understand the culture and mission of DARPA/ARPA-H. Funding for small highly innovative proposals should be provided within weeks, and the agency must be allowed to design a balanced and risk-adjusted portfolio in order to achieve national objectives. The structure must also support frequent and transparent communication to Congress, industry, academy, NGOs, and patient advocacy support groups. My last year at DARPA as an office director, I did 113 formal briefings, and about one-quarter of those were to Members of Congress or professional staff.

**The Honorable Gus Bilirakis (R-FL)**

1. Dr. Giroir, 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?

**ANSWER**

OWS was a tremendous success, but its success was acceleration and financial de-risking of relatively standard processes based on science that was funded 8 years earlier by

DARPA. ARPA-H must be designed to innovate, perhaps radically, and then transition those innovations either to the private sector or to public-private-partnerships (like OWS) to perform the final implementation. DARPA invented the internet (ARPA-net), but DARPA did not need to implement the internet to make it successful. DARPA invented stealth, but never operationalized or weaponized the actual combat aircraft (the Air Force did that). ARPA-H will operate at a different level of innovation, far upstream in the pipeline from programs like OWS.

2. Dr. Giroir, your testimony goes at length about the key importance of program managers at DARPA, and how it could make or break ARPA-H. Can you expand on this need for regulatory flexibility, where the private sector fits into the equation, and what challenges you would foresee if we decided to add this to the existing framework of bureaucracy?

**ANSWER**

Program managers are the entrepreneurs in the public's interest. They will come from all sectors, including the private sector, academia, and other government agencies. The private sector (and academia) will be benefitted substantially by the high risk- high reward research and development fostered by ARPA-H, as it has been by DARPA. Far from it, ARPA-H must cut through the typical bureaucracies of the federal government in general, and NIH in particular. It is anti-bureaucracy by its nature.

3. Dr. Giroir, you mention in your testimony that it's important that ARPA-H's director should be "strategic, visionary, and able to recruit the best and brightest program managers...". How would this work if ARPA-H is under the umbrella of the NIH as proposed by the White House?

**ANSWER**

The ARPA-H director must report to the Secretary. For the director to report anywhere within the NIH, or be encumbered by NIH processes, would guarantee failure of the new agency.

4. Considering the NIH is limited by statute to 27 institutes and centers, how would the White House proposal ensure that ARPA-H doesn't serve as an additional layer of bureaucracy, and where would this put the work of NCATS, whose mission is to transform scientific discoveries into new treatments and cures?

**ANSWER**

ARPA-H, if positioned within NIH, could indeed become just another layer of stagnation and fail to achieve its stated mission. As former NCATS director Dr. Christopher Austin described, NCATS is important but has a different mission and focus; and its inability to innovate in the way DARPA has (or ARPA-H should) is itself a testament for why ARPA-H should not be organized within the NIH, nor report to anyone except the Secretary of HHS.