October 20, 2021

Senator Patrick Leahy
Chair
Senate Appropriations Committee
U.S. Senate
Washington, DC 20510

Senator Richard Shelby
Ranking Member
Senate Appropriations Committee
U.S. Senate
Washington, DC 20510

Representative Rosa DeLauro
Chair
House Appropriations Committee
Washington, DC 20515

Representative Kay Granger
Ranking Member
House Appropriations Committee
Washington, DC 20515

Dear Chairs Leahy and DeLauro & Ranking Members Shelby and Granger:

The American Society for Cell Biology (ASCB) is a professional society of more than 7,000 basic biomedical scientists in all 50 states, many of whom are supported by funding through the U.S. National Institutes of Health (NIH). We have a number of questions and concerns regarding the proposed creation of ARPA-H. Overall, we believe that the current system of federal research funding, while always open to improvements, has fueled unprecedented innovation, new therapy development, and job creation in the U.S. biomedical and biotech sectors in the past 40 years, and is still the “gold standard” in these sectors worldwide. Indeed, the NIH is a critical driver of the economy and public health innovation in the United States.

Our main concern is that ARPA-H will fundamentally alter the character of the NIH, which is a huge “success story” in the United States. We fear that ARPA-H, as currently described, would jeopardize this basic research engine that has been unrivaled internationally, as well as jeopardize the incredible progress in translating this work to advance progress for public health in the United States and throughout the world. Recent advances in treating cancer, hepatitis C, and the incredibly rapid development of the vaccine against SARS-CoV2 are all testaments to the success of the NIH. Given these and many other successes, altering the NIH system should be conducted with care.
Specifically, we are writing to express the following concerns that we believe have not been addressed in the material or in various briefings and discussions.

A major concern is that the initial white paper calling for the formation of ARPA-H, and in public presentations by ARPA-H advocates, promotes the narrative that the current government-funded biomedical research agencies “do not work.” We utterly reject this narrative. While we remain entirely open to innovations that improve government-funded biomedical research, we wish to emphasize two long-standing strengths of the current system:

a. NIH- and National Science Foundation (NSF)-funded laboratories are highly valued by commercial biomedical entities, and have largely become the basic research wings of these entities. The long-term, basic studies by our laboratories continue to reveal unexpected results of direct impact commercially, that are rapidly implemented by industry. There are multiple examples of this rapid translation, in the form of the many start-up biotech companies founded each year. A particularly clear example, though, is vaccine development during the COVID pandemic, in which an NIH-trained and funded researcher rapidly adapted over a decade of fundamental research to provide the foundation for all major vaccines in the United States (National Geographic, December 31 2020). It is this fundamental research that served as the foundation for all future COVID-19 advances, including later advances made by DARPA.

Other examples include the use of the immune system to fight cancer (Nobel Prize 2018) and the treatment of hepatitis C (Nobel Prize 2020). Both of these Nobel prizes went to NIH-funded researchers and grew out of their basic research programs. In this light, statements such as the following “whereas most NIH proposals are ‘curiosity-driven,’ ARPA-H ideas would be largely ‘use-driven’ research - that is, research directed at solving a practical problem” from the White House ARPA-H-FAQ (https://tinyurl.com/White-House-ARPA-H-FAQ, pg 2) paint a false picture of the relationship between NIH-funded researchers and industry. While adapting the system to allow more rapid implementation of discoveries by government-funded laboratories themselves is a good thing, it cannot be done at the expense of basic research, which provides sustainable, long-term benefit to the U.S. economy.

b. U.S. government-sponsored research labs conduct the vital job of training the next generation of scientists. Given the emphasis on the need for STEM training in the United States, policy proposals that compromise this training are inherently damaging to long-term U.S. interests.

A second concern is that the available literature on ARPA-H provides no information on training. As stated above, a major role of government-funded biomedical research is to train the next generation of scientists, in order to maintain the sustained track record of innovation from which the biomedical and pharmaceutical industry has benefited. Since academic laboratories (involved in training) are likely recipients of ARPA-H funds, we are concerned that
there is no description currently of what would happen to trainee support if ARPA-H contracts to a given laboratory are terminated. Such situations would be detrimental to the training and career development of young scientists in ARPA-H funded labs, particularly those from traditionally under-represented groups, for whom disruption of training can have disastrous consequences. To this end, we strongly recommend that ARPA-H develop a Training Impact Statement that addresses how its establishment will impact issues related to training and developing the next generation of scientists.

We are also concerned about how “success” of ARPA-H will be assessed. Measuring return on investment is particularly difficult in the biomedical sciences, since it can be years or decades before the impact of basic research discoveries are fully appreciated. It would be helpful to understand what short- and long-term metrics will be used to evaluate the success of ARPA-H.

A final concern is with the selection process for the Program Director of ARPA-H. From currently available information, the Program Director of ARPA-H will have broad-ranging powers including choosing which projects to fund and which to terminate. Given these broad powers, clear rationale and specific criteria for selection are needed.

A strong case can be made that the productivity of the NIH, dollar-for-dollar, is significantly higher than the same investment in industry, or investments in other countries. A large part of that success can be attributed to how the system is organized: The core is individual investigator-initiated research grants as opposed to a large centralized program that is directed from above. The individual investigators are willing to take large risks to make large gains. Often a large-centralized program is much more conservative and reticent to take large risks. Yes, some individual projects may fail. The risk of failure is necessary to take to make large gains. The uncertain success of many small NIH grants provides the critical seeds to run the U.S. pharmaceutical industry. The National Center for the Advancement of Translational Sciences (NCATS), under the leadership of Francis Collins, has facilitated many individual investigators in advancing their work to a stage where we can evaluate their clinical impact. The new ARPA-H will have decisions set by program officers who will be doing a top-down direction rather than a direction set by scientists who are active in their fields. A top-down approach jeopardizes the success of American science and its position as the world leader in biomedical research.

We look forward to working with you on this important issue.

Sincerely,

Holly Goodson
Chair, ASCB Public Policy Committee
University of Notre Dame

Simon Atkinson, University of Kansas
Henry Higgs, Dartmouth College
Jason MacGurn, Vanderbilt University

Dyche Mullins, University of California, San Francisco
Sanford Simon, Rockefeller University