ASPET
Transforming Discoveries into Therapies

The Hon. Diana DeGette
Chair
House Energy and Commerce
Subcommittee on Oversight and Investigations
2125 Rayburn H.O.B.
U.S. House of Representatives
Washington, DC 20515

The Hon. Fred Upton
Ranking Member
House Energy and Commerce
Subcommittee on Energy
2322 Rayburn H.O.B.
U.S. House of Representatives
Washington, D.C. 20515

July 16, 2021

Dear Chairwoman DeGette and Ranking Member Upton,

The American Society for Pharmacology & Experimental Therapeutics (ASPET) appreciates the opportunity to provide feedback to the committee on its "21st Century Cures 2.0" discussion draft, which includes an authorization for President Biden's proposed Advanced Research Projects Agency for Health (ARPA-H) and the Research Investment to Spark the Economy (RISE) Act. ASPET is appreciative of, and supports investments in, the nation's research infrastructure so that the U.S. can maintain its preeminence in biomedical research. However, questions about how funding for ARPA-H will impact NIH's base budget and its existing resources and how ARPA-H will function as a distinct division of NIH need to be addressed.

ASPET is a 4,000-member scientific society whose members conduct essential basic and clinical pharmacological research and are employed by academia, government, large pharmaceutical companies, small biotech companies, and non-profit organizations. ASPET members work in a variety of different fields and their efforts help to develop new medicines and therapeutic agents to fight existing and emerging diseases.

ASPET appreciates and supports the underlying goals of ARPA-H to fund high-risk projects that speed transformational innovation in health research, but we have concerns about the proposed structure of ARPA-H as outlined in the fact sheet shared by the White House. Housing ARPA-H as a division within NIH raises concerns that ARPA-H could siphon resources from other Institutes and Centers at NIH with lower profile or more focused—though, no less important—missions. In their commentary for *Science* magazine outlining the scope of ARPA-H, NIH Director Francis Collins and White House Office of Science and Technology Policy Director Eric Lander emphasize collaboration with NIH as a feature of ARPA-H, noting the new agency will be able to "...draw on the vast range of biomedical and health knowledge, expertise, and activities at NIH." While collaborative networks, information sharing, and access to facilities at other institutions can accelerate discoveries, ARPA-H must not impede or detract from NIH's core mission or its support for basic science research. To ensure that ARPA-H does not channel resources away from NIH, ARPA-H will need a separate budget that provides robust funding for grants, personnel, facilities, and other components of research infrastructure so that ARPA-H will be able to

function as a distinct division without laying claim to resources appropriated to other NIH entities. Access to its own budget and facilities will allow ARPA-H to build on the fundamental research funded by NIH rather than diminish it.

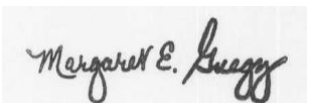
Additionally, ARPA-H's position within NIH raisies questions about how the division will maintain the independence, nimbleness, and "distinct culture" that are argued to be necessary to fulfill its mission. The plan for creating a unique culture for ARPA-H within NIH's existing structure and culture is short on details. For instance, much of the discussion of staff thus far has focused on the recruitment of empowered program managers for 3-5 year terms who will provide leadership for the new division. However, with the proposal for ARPA-H program managers to be limited to short terms, who are the career support staff that will facilitate logistics? The commentary from Drs. Collins and Lander suggests subject matter experts and managers from NIH might be candidates to fill those roles, but how would recruitment from current NIH staff be conducted to ensure ARPA-H's culture does not mimic that of NIH? Further, will ARPA-H be exempt from the numerous data collecting requirements, reporting mandates, and advisory committees that characterize work at NIH? And will similar data and reporting be required of ARPA-H's grantees? The bureaucracy that results from such extensive reporting mandates would be counterproductive to any desired acceleration from ARPA-H. However, a significant departure from these requirements raises the question of whether ARPA-H will be so distinct an entity as to be ungovernable by NIH leadership. The committee and NIH must take great care to answer these questions and reconcile these tensions.

In describing the concept for ARPA-H, the White House fact sheet identifies Alzheimer's, infectious diseases, cancer, and mRNA vaccines as areas where ARPA-H may be able to revolutionize treatment and prevention, and ASPET supports research in these areas. However, there is scant mention of substance abuse disorders in the fact sheet or in other materials promoting and describing ARPA-H. This is an unfortunate omission given the alarming toll substance abuse disorders are taking on our country. Just this week, the National Center for Health Statistics released a provisional report estimating that 93,000 Americans died of a drug overdose last year, an increase of approximately 30% over 2019. The main drivers of deaths from substance abuse—fentanyl and other synthetic opioids—continue to proliferate and infiltrate the U.S. supply of illicit drugs, and research has not kept pace in finding treatments for addiction and overdose related to these substances. An agency with a mandate to make "pivotal investments in break-through technologies" in health should prioritize revolutionary research on ideas to combat substance abuse disorders like anti-drug vaccines and the use of genotyping to design personalized treatments for addiction. In creating and promoting ARPA-H, ASPET supports the inclusion of substance abuse disorders as an area where the division will focus its disruptive efforts to generate major breakthroughs.

Lastly, ASPET is grateful to the bill's authors for including H.R. 869, the Research Investment to Spark the Economy (RISE) Act, in its discussion draft. COVID-related work stoppages and precautions that went into effect in spring 2020 shuttered labs across the country and disrupted projects that were underway before the public health emergency. While many institutions are ramping back up as safely as possible, challenges associated with the disruptions continue to linger. Several types of research—such as clinical trials and other research projects with human participants—have been slower to recover. The pandemic also disproportionately affected early career researchers, women, and minorities at a pivotal point in their career trajectories. The bipartisan RISE Act would provide $10 billion to the National Institutes of Health and $3 billion to the National Science Foundation to help restore our nation's research capacity to its pre-pandemic strength and continue efforts to diversify our biomedical research workforce.

ASPET appreciates the emphasis the administration and Congress are placing on biomedical research and public health with the FY 22 budget, the ARPA-H proposal, and the inclusion of the RISE Act in 21st Century Cures 2.0. The support these investments represent will position the U.S. to continue to enhance health, lengthen life, and reduce illness and disability. ASPET looks forward to working with the committee and providing input as it crafts this important legislation.

Respectfully,



Margaret E. Gnegy
President
ASPET