



# THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS

## Comments of The American Association of Immunologists on the Cures 2.0 Draft Legislation

July 15, 2021

The American Association of Immunologists (AAI), the nation's largest professional association of research scientists and physicians who are dedicated to understanding the immune system through basic, translational, and clinical research, appreciates this opportunity to comment on the Cures 2.0 discussion draft. AAI thanks Representatives DeGette and Upton for their leadership in addressing not only the long-term needs of the federal scientific enterprise, but also the immediate needs caused by the ongoing COVID-19 pandemic.

AAI would like to begin by responding to the Request for Information (RFI) that was issued, which specifically solicits views on President Joe Biden's proposal to create a new agency, the Advanced Research Projects Agency for Health (ARPA-H). AAI is enthusiastic about ARPA-H's potential, which could greatly advance human immunology by supporting broad collaborations and high-risk, high-reward research. We believe, however, that any funding provided for ARPA-H must supplement, and not supplant, the regular budget of the National Institutes of Health (NIH), its parent agency, and that ARPA-H's activities must enhance, and not interfere with, NIH's historic commitment to funding basic research. In addition, NIH, as ARPA-H's parent agency, should solicit stakeholder input to help answer many outstanding questions, including whether existing NIH entities and programs, like the National Center for Advancing Translational Sciences (NCATS), will be integrated into the new agency, and which research areas will be identified and selected.

Our specific responses to the RFI questions (in blue) appear below (in black):

- In calling for the creation of ARPA-H, President Biden has cited the success of the Defense Advanced Research Projects Agency (DARPA) and expressed his belief that ARPA-H should be similar. Please provide specific details on which aspects of DARPA ARPA-H should replicate and why this would lead to similar success.
  - AAI does not have experience with DARPA and so cannot comment on exactly which aspects should be replicated within ARPA-H. AAI does know, however, that the "culture" at NIH, in which investigators receive funding only after their project proposals have been peer-reviewed, scored highly, and scrutinized by professional staff, differs significantly from the culture of DARPA. Creating a successful ARPA-H will require adapting a long-established

military-oriented program to a robust life sciences enterprise. If done right, however, AAI sees great value in encouraging a subset of researchers to pursue bold, transformational ideas that would likely not be funded by existing federal agencies.

- To ensure it has the biggest impact, on what activities or areas should ARPA-H focus? What activities or areas should ARPA-H avoid?
  - The decision regarding the activities or areas on which ARPA-H should initially focus should ultimately be made by the ARPA-H Director and the ARPA-H program managers, but only after meaningful consultation with, and appropriate consideration of, the views of a wide range of scientific stakeholders. AAI is encouraged that NIH Director Francis Collins, M.D., Ph.D., has already reached out to NIH Institute and Center Directors to solicit their feedback on projects ripe for consideration; similar conversations should be held with other federal scientific agencies.
  - Although it may be tempting to Congress to legislate specific research areas or activities, particularly in response to constituent concerns, AAI cautions against this, as it could undermine both the achievement of rapid, transformative results and the public's confidence in the scientific independence of ARPA-H.
- Some assert ARPA-H's ability to operate independently and transparently will be essential to its success. Do you agree? If so, what is the best way to design ARPA-H in order to accomplish this?
  - AAI agrees that ARPA-H must be able to operate independently and transparently in order to succeed. That independence, however, should not be construed as permission to fail to consult, or, as appropriate, collaborate or cooperate with other federal science agencies, and in particular, with NIH. One possible way to foster this exchange is to establish a Federal advisory panel, similar to the one proposed by President Biden, and chaired by the ARPA-H Director, that includes designated representatives from the nation's key scientific research agencies. AAI recommends limiting the number of political appointees who serve on this panel.
  - Meetings should be open to the public, with appropriate intellectual property protections provided (as needed).
- How should ARPA-H relate to, and coordinate with, existing federal entities involved in health care-related research and regulation?
  - See reply above.
- What is the best way to ensure ARPA-H has a mission, culture, organizational leadership, mode of operation, expectations, and success metrics that are different than the status quo?
  - ARPA-H should be given a clearly defined mission, and its culture, organizational leadership, mode of operation, expectations, and success metrics should be tailored to enable it to achieve its mission. Given the large budgets proposed by both the president (\$6.5 billion over three years) and the House Labor, Health and Human Services, Education, and Related

Agencies Appropriations Subcommittee (\$3 billion over three years), it will be especially important to establish not just success metrics but also policies and procedures that can best ensure ARPA-H's responsible stewardship of federal tax dollars.

AAI believes that funding for ARPA-H projects should be provided for longer than three years (where appropriate, and provided that milestones are being met) to ensure sufficient time for the kind of innovative, collaborative, and transformative research that is contemplated. Funding for shorter periods of time may create expectations of success that historically have generally not been possible in the life sciences.

As a new entity, ARPA-H also has the opportunity to make diversity, equity, inclusion, and accessibility (DEIA) central to its mission from day one. AAI is greatly encouraged to see that the ARPA-H concept paper developed by the White House stresses this important goal: *"Equity considerations (including race, ethnicity, gender/gender identity, sexual orientation disability, and income level) must be woven throughout the ARPA-H mission — with some projects focused directly at addressing equity and all projects considering equity in their design."*

AAI recommends regular evaluations of ARPA-H's performance on DEIA.

- [How should ARPA-H work with the private sector?](#)
  - AAI agrees that working with the private sector will be necessary in order for ARPA-H to succeed. However, special care must be taken to ensure transparency, prevent conflicts of interest, and establish an appropriate cap on funding for corporate participation.
- [What is the appropriate funding level for ARPA-H? How do we ensure ARPA-H funding does not come at the expense of traditional funding for the National Institutes of Health?](#)
  - AAI supports the appropriation of substantial funding to launch ARPA-H. However, as stated above, while AAI is enthusiastic about ARPA-H's potential, we believe that any funding provided must supplement, and not supplant, the regular NIH budget, and that this new agency must enhance, and not interfere with, NIH's historic commitment to funding basic research.

In June testimony to the Senate Labor, Health and Human Services, Education, and Related Agencies Appropriations Subcommittee, AAI recommended an overall appropriation of \$52 billion for NIH for FY 2022, including at least \$46.1 billion for the regular NIH budget, to enable the agency to fund needed research to prevent dangerous infectious diseases and treat debilitating chronic illnesses, support meritorious scientists at all career stages, and ensure a robust research enterprise that maintains U.S. preeminence in biomedical science and innovation.

Because the COVID-19 pandemic has posed difficult challenges, including lab closures and other interruptions, to many biomedical (particularly early career) scientists, NIH needs, and AAI strongly supports, an infusion of additional funding to specifically address these problems. AAI therefore greatly appreciates that the draft bill incorporates the text of the

Research Investment to Spark the Economy (RISE) Act, which would authorize supplemental relief funds for federal sciences agencies, including \$10 billion to NIH.

AAI also strongly supports many of the public health provisions included in Title I of the discussion draft. The national survey of patients with Post-Acute Sequelae of SARS-CoV-2 (PASC or Long COVID), as well as the learning collaborative on long-COVID, are wise short-term steps to ensure that the U.S. is poised to continue making progress against the significant health challenges caused by this novel virus. For the long-term, AAI agrees that it is vital to develop a national testing and response strategy for future pandemics. As the legislative text notes, this strategy must be based heavily on lessons learned from the COVID-19 pandemic, and thus AAI continues to support a holistic review of the current pandemic by a nonpartisan entity like the National Academies of Sciences, Engineering, and Medicine.

In both the short- and long-term, global success in defeating highly infectious, dangerous diseases like COVID-19 depends on our ability to quickly develop safe and effective vaccines and to facilitate both domestic and international vaccine uptake. Continued robust investment in basic biomedical research is crucial to laying the groundwork for rapid vaccine development. But vaccine acceptance and hesitancy remain major problems, and thus AAI supports the discussion draft's authorization of funds for an awareness campaign on the safety and importance of vaccines. In addition, AAI supports the authorization of funds to strengthen the Centers for Disease Control and Prevention's Immunization Information Systems.

AAI looks forward to reviewing the draft further and providing additional input.