

July 16, 2021

The Honorable Diana DeGette  
United States House of Representatives  
House Committee on Energy and  
Commerce  
2111 Rayburn House Office Building  
Washington, DC 20515

The Honorable Fred Upton  
United States House of Representatives  
House Committee on Energy and  
Commerce  
2183 Rayburn House Office Building  
Washington, DC 20515

**RE: AGA's Comments on ARPA-H Proposal**

Dear Representatives DeGette and Upton:

The American Gastroenterological Association (AGA) appreciates the opportunity to provide comments on the on the Cures 2.0 discussion draft with specific feedback on the development of the Advanced Research Projects Agency for Health (ARPA-H), which aims to drive transformational innovation in health research and speed application and implementation of health breakthroughs. AGA greatly supports the efforts of the Cures 2.0 Act and the goals of ARPA-H and will work with our members, policymakers, and other health care stakeholders to participate in and provide input to this important conversation.

AGA is the trusted voice of the GI community. Founded in 1897, AGA has grown to include more than 16,000 members from around the globe who are involved in all aspects of the science, practice and advancement of gastroenterology. AGA's membership contains many top thought leaders in GI research, many of whom play an instrumental role in advancing the science and practice of our profession. Please find AGA's response to the proposed questions on the development of ARPA-H below:

**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.**

DARPA is a mission-oriented agency with a focus on projects over programs. It offers a mixed-risk portfolio that combines basic research, applied research, development and demonstration across its projects.

Program managers have the technical and fiscal authority to steer efforts and are driven every day by the desire to make a transformational difference, not just incremental advances. Moreover, DARPA works within an innovation ecosystem that includes

academic, corporate, and governmental partners, which work with the agency to create new strategic opportunities and novel tactical options. This cohesive ecosystem of diverse collaborators is a nurturing environment for the creativity and innovation that DARPA is designed to cultivate.

More innovative research projects have come to fruition from this agency that would not have been considered in more traditional research settings due to the high-risk nature. DARPA's high-risk, high-reward model ensures program managers can strive to tackle some of the nation's most pressing technological issues impacting national security. With this similar model and culture implemented in ARPA-H, as demonstrated through vaccine and testing development during the COVID-19 pandemic, the scientific community could benefit greatly and see major advances across various high-impact disease areas. To truly mirror the DARPA model and culture, AGA believes ARPA-H should be housed as a separate entity outside of the National Institutes of Health (NIH).

**To ensure it has the biggest impact, on what activities or areas should ARPA-H focus? What activities or areas should ARPA-H avoid?**

For areas of focus for the agency, AGA recommends ARPA-H leaders focus on areas with a significant impact on global communities, like GI diseases and cancers, diabetes, obesity and others. Cancers of the pancreas, colon, rectum, stomach, and esophagus are impacting patients in lower age cohorts and broadening to patients in communities of color. Moreover, GI diseases, like nonalcoholic fatty liver disease (NAFLD) and inflammatory bowel disease (IBD), are increasing in similar populations and further exacerbating the health disparities that plague underserved and underinsured populations and communities of color.

Specifically, in cancer research, more work is needed to detect cancer earlier in patients. Currently, some biomarkers are aiding these efforts, but more research is necessary, especially in pancreatic and esophageal cancer, to detect and treat cancers early in a non-invasive manner. Similarly, liver diseases are also lacking a non-invasive screening mechanism.

Lastly, AGA strongly believes the agency's projects should include components on addressing health disparities, ensuring funded clinical trials are inclusive, and fostering diversity in the research workforce.

**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?**

AGA agrees with this concept and recommends that ARPA-H leadership consult with stakeholders, like AGA, when defining its scope and research strategy. More specifically, AGA asks that ARPA-H is transparent about its selection criteria and decision-making process for its broader investment goals and selection of individual research projects.

Many GI diseases and cancers have a substantial impact on various vulnerable patient populations. As a leader in the GI research community, AGA could play an integral role as an agency resource in the development of future breakthroughs.

To operate independently and transparently, AGA believes ARPA-H should be housed as a separate entity outside of the National Institutes of Health to ensure the agency is able to develop its own innovative culture, strategic plan and metrics for success without being influenced by leadership at other federal entities that do not harbor the same innovative outlook or workflow. Additionally, the agency should have the appropriate trans-agency authority to coordinate research, product development, manufacturing, distribution, and regulatory approval to expedite delivery of novel technologies to communities with high unmet need.

### **How should ARPA-H relate to, and coordinate with, existing federal entities involved in health care-related research and regulation?**

AGA recommends that ARPA-H should work independent of the NIH and other federal agencies yet should engage on at least a biannual basis with these entities to summarize key research outcomes and identify areas for future collaboration. To be innovative, the agency needs to create innovative programs with multi-disciplinary teams that include bioengineers, bioinformatics, clinical investigators, the private market, health care companies, academic institutions, and government and regulatory agencies. The goal of these programs should be to identify high risk issues and infrastructure that are not being supported by the regular NIH methods.

### **How should ARPA-H work with the private sector?**

ARPA-H should work with the private sector synergistically and view industry as a customer that bears some of the program cost sharing. Clear processes and guidelines for how intellectual property (IP) will be developed, used and improved upon should be created and agreed upon with outside entities. AGA recommends that these processes and guidelines protect IP but also bolster partnerships with the private sector.

One of the largest challenges AGA anticipates with the creation of this new agency is the differing markets between health care and defense. DARPA succeeded because there was a market for the end product, which was DOD, who worked closely with the defense industry. However, within the realm of biomedical and scientific research, it is challenging to fund the transition between academia and industry. The U.S. would need to ramp up programs, like Small Business Innovation Research (SBIR), which help products get to industry, to address this issue. Even SBIR still requires an industry partner, making this connection still problematic. This is where government intervention will be required to bridge the gap.

### **What is the appropriate funding level for ARPA-H? How do we ensure ARPA-H funding?**

**AGA recommends that ARPA-H should be funded at a substantial level at its inception to ensure programs and initiatives have the support necessary to lead with success and promote innovation. Consistent and sustainable increases in federal and private funding should be provided annually to ensure the agency can continue its mission. AGA recommends that ARPA-H funding should not impact the funding levels of other federally supported research efforts at NIH or otherwise.**

**AGA looks forward to working with the Office of Science and Technology Policy, the scientific community and policymakers as ARPA-H is developed and operationalized. If you have additional questions regarding these comments, please contact Megan Tweed, AGA's director of government affairs, at [mtweed@gastro.org](mailto:mtweed@gastro.org).**

Sincerely,



**John M. Inadomi, MD, AGAF  
President, American Gastroenterological Association**