



July 16, 2021

The Honorable Diana DeGette
U.S. House of Representatives
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
Washington, DC 20515

Re: Request for Information: 21st Century Cures 2.0 – Sec. 501 Advanced Research Projects Agency for Health

Dear Representative DeGette and Representative Upton:

The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society (the Society), supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

We are pleased at the opportunity to contribute to the 21st Century Cures 2.0 Initiative and offer the following in response to the Request for Information related to the creation of the Advanced Research Projects Agency for Health (ARPA-H):

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.

- Several aspects that make the DARPA model successful could be replicated to achieve similar success in ARPA-H and include:
 - A focus on bold transformative projects,
 - Dedicated funding,
 - Adoption of a distinctive culture, and
 - Statutory authority to engage in a wide variety of agreements and contracts and operate independently and transparently.

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

- ARPA-H is being developed to address areas of research and innovation not currently being done by the National Institutes of Health (NIH) because the areas do not fit their research funding model or by industry because of the perception that there is no financial return. It will be critical to focus on the types of projects that fall into that funding gap and not simply tackle large NIH-style projects. It will also be important to differentiate NIH projects from ARPA-H projects to ensure that solutions for the gaps identified are addressed. Projects should include not only technology improvements that advance the broader research enterprise, but also translational projects that directly yield new interventions that can benefit patients. The specific research or translational needs should be identified through a comprehensive and inclusive process that includes formal opportunities to provide input from the public and patient stakeholder groups, including stakeholders representing all aspects of the cancer community.

NIH currently has numerous initiatives that are similar to what ARPA-H might do in terms of directing funding at specific, persistent challenges. For example, NCI has funded the RAS Initiative, an effort to identify strategies to develop therapeutics targeted to the RAS pathway and the National Cancer Institute (NCI) has also funded the “Provocative Questions” Initiative intended to address therapeutic advancement bottlenecks. It would be important to not simply shift these large projects to ARPA-H, but rather identify projects that truly cannot be done by NIH (as opposed to those that could be done, but simply aren’t). To demonstrate impact in a short time frame, ARPA-H will also need to identify translational projects that yield tangible patient benefits within a matter of a few years.

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?

- The administration has proposed placing ARPA-H within NIH. ARPA-H’s ability to operate independently and transparently will be essential to its success, and steps should be taken to ensure a high degree of independence and transparency within the agency. This could include steps such as using a presidential appointee to lead ARPA-H and filling critical roles with staff from outside the NIH enterprise.

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

- To achieve its goals, ARPA-H should communicate and coordinate with existing federal entities involved in health care-related research (e.g. NIH, NCI) and regulation (e.g. The U.S. Food and Drug Administration) to identify and create new strategic opportunities in

research and product development and to leverage existing expertise. ARPA-H should complement, not compete with, other federal entities and build off their discoveries to move knowledge forward in areas where there are persistent innovation and translation gaps.

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?

- Steps should be taken to ensure ARPA-H has a distinct culture that emphasizes high-risk, high-reward transformative work on targeted issues. This could include steps such as using a presidential appointee to lead ARPA-H and filling critical roles with staff from outside the NIH enterprise. Additionally, the type of work envisioned by ARPA-H will require a wide variety of agreements and contracts therefore it should have full transactional authority - including “other transactions” authority without artificial constrictions on allowed research – and the ability to conduct product development and regulatory approval.

How should ARPA-H work with the private sector?

- As the primary translational force in biomedical research, the private sector is uniquely positioned to provide insights into the type of projects they are not engaging in, and what work would be needed to make such projects more attractive (e.g. continuing federal funding through initial stages of clinical studies).

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?

- ARPA-H should have its own dedicated funding that is adequate to ensure the agency’s infrastructure can be stood up and processes developed to issue funds and coordinate work. Once the agency is established, projects may take several years to complete, thus funding for the agency should be guaranteed for three to five years to ensure it is built on a solid foundation and is able to drive the kinds of transformational work that it is envisioned. Importantly, ARPA-H should be separately appropriated to ensure that funds are supplemental to annual NIH appropriations and do not supplant this critical, annual appropriation. NCI is currently experiencing frustratingly low paylines and it is important that this new agency doesn’t exacerbate this challenge.

Thank you again for the opportunity to contribute toward the 21st Century Cures 2.0 Initiative. Please do not hesitate to contact Keysha Brooks-Coley (Keysha.Brooks-Coley@cancer.org) if you have any questions. We look forward to continuing the discussion, and being of assistance in creating a final legislative product that meets the needs of cancer patients, survivors, and those who are helping them in the fight against the disease.



Sincerely,

A handwritten signature in black ink that reads "Lisa A. Lacasse". The signature is written in a cursive, flowing style with a long horizontal tail stroke.

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network