CANCER SUPPORT COMMUNITY
COMMUNITY IS STRONGER THAN CANCER

July 16, 2021

The Honorable Diana DeGette
United States House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
United States House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton,

The Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to cancer patients, survivors, and their loved ones, applauds your continued leadership and commitment to patients and caregivers. As the largest provider of social and emotional support services for people impacted by cancer, CSC has a unique understanding of the cancer patient experience. In addition to our direct services, our Research and Training Institute and Cancer Policy Institute are industry leaders in advancing the evidence base and promoting patient-centered public policies.

Over the last 50 years, we have seen remarkable advancements in cancer research and innovation. We appreciate the opportunity to comment on the 21st Century Cures 2.0 (Cures 2.0) discussion draft and to respond to the request for information on the Advanced Research Projects Agency for Health (ARPA-H).

Patient Experience Data

Passage of the *21st Century Cures Act*, as amended by the *Food and Drug Reauthorization Act of 2017* (FDARA), recognized and elevated the importance of patient experience data (PED), which goes beyond the physical symptoms or side effects of a disease, therapy, or clinical investigation, to also address the psychosocial concerns, needs, and preferences of cancer patients. The inclusion of Title II, Section 204 in the discussion draft requiring the collection, submission, and use of PED in clinical trials will prove instrumental in ensuring that patients and caregivers' experiences assume their rightful, intended, and critical role in the drug development process.

PED is defined in Title III, Section 3001 of the 21st Century Cures Act (Pub. L. 114-255), as amended by section 605 of the 2017 FDARA (Pub. L. 115-52), as "data that: (1) are collected by any person (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and (2) are intended to provide information about patients' experiences with a disease or condition including (A) the impact (including physical and psychosocial impacts) of such disease or condition, or a related therapy or clinical investigation on patients' lives, and (B) patient preferences with respect to treatment of such disease or condition."
The new subsection (b) of Title II, Section 204 in Cures 2.0 will help actualize the intent behind the 21st Century Cures Act and the 2017 FDARA. Specifically, the new subsection provides a clear and consistent mechanism to enable patient experience data to best inform the drug development process by:

- requiring drug manufacturers/sponsors to collect and report on patient experience data as part of the clinical trial;
- requiring FDA to fully consider all patient experience data collected during the clinical trial; and
- requiring reporting of patient experience data in a transparent manner that is uniform, meaningful and informative to patients and providers.

Consistent collection, use, and sharing of meaningful PED will encourage increased participation in trials generally and enhance diversity among trial participants specifically, lead to greater trial adherence and retention, improve the shared decision-making process by better informing patients, caregivers, and providers about which treatment pathways may be best, and help inform future clinical trial design. The importance of collecting, using, and sharing PED that encompasses patients' psychosocial well-being is illustrated by The Institute of Medicine concluding in 2008 that comprehensive cancer care must include psychosocial care. Fully embracing PED in clinical trials advises patients, caregivers, providers, and trial sponsors about the investigation's impact on the whole person – information that helps to inform each of the above-mentioned stakeholders whether on treatment decisions, care obligations, or trial design – now and in future. On behalf of the cancer patients and caregivers we serve, as well as patients and caregivers across all diseases, inclusion of this PED language, in its entirety, in Cures 2.0 modernizes innovation in a manner that is truly patient-centered.

Moreover, the grants provided in Title III, Section 302 to further build the science of innovative clinical trial design and patient experience will help drive the successful and beneficial application and incorporation of patient experience in clinical trials. Similarly, allowing for the use of patient registries in Section 309 to fulfill post-approval study requirements to confirm clinical benefit of a therapy, acknowledges and embraces the value of PED directly captured by patients and their caregivers. We are grateful for the inclusion of this language and ask that the language be expanded to also allow patient registries to confirm the psychosocial benefits provided by a therapy.

Advanced Research Projects Agency for Health (ARPA-H)

CSC appreciates the opportunity to respond to the request for information on ARPA-H. We are excited about the visions set forth for ARPA-H and believe it will provide an unprecedented opportunity to accelerate research to innovative, breakthrough technologies and treatments for people with cancer and other diseases, giving much needed hope for a brighter future.

Activities and Areas of Focus

It is essential that any and all transformational research conducted by ARPA-H to develop cures, treatments, and therapies for cancer and other diseases be patient-centered, which includes prioritizing patients' needs, concerns, and preferences – physical as well as psychosocial. Patients' experiences living with, treating, and/or managing their disease provides crucial information not otherwise traditionally captured through the research process. The *21st Century Cures Act* and FDARA amplified the importance of collecting PED. Notable stakeholders such as the Institute of Medicine, the Patient-Center Outcomes Research Institute, and the American College of Surgeons Commission on Cancer recognize psychosocial care as the standard of care in oncology. To be transformational and build off of the recognition of the importance of PED, all ARPA-H research should include requirements and mechanisms to consistently collect, consider, and report how resulting innovative technologies and treatments impact patients' physical and psychosocial well-being. Ensuring PED is fully incorporated in all ARPA-H research projects will also advance health equity by providing a diverse population of patients and providers with meaningful information to reference when selecting the most appropriate diagnostic tools and treatments.

Collaboration with existing federal entities.

While speed and independence comprise two key components of ARPA-H, the new agency would also benefit from drawing upon the lessons learned from other agencies, including the National Institutes of Health (NIH), National Cancer Institute (NCI), Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC). The successes as well as challenges experienced by these agencies will assist ARPA-H in identifying and defining both its unique role and its collective purpose in connection to existing federal entities. Collaboration with the broader public and private biomedical community will be essential to achieving breakthroughs that conquer human diseases for which, to date, there are no known cures.

Funding Structure
CSC shares the enthusiasm for the new possibilities offered to cancer patients and caregivers by the creation of ARPA-H while recognizing that innovations rest upon and develop out of prior evidence-based research. As such, we urge Congress to ensure that this new endeavor in no way reduces or redirects funding away from the NIH or NCI, both of which conduct critical basic, translational, and clinical research that help fuel discoveries in cancer prevention, detection, diagnosis, and survivorship. Meaningful and ongoing investment in these two well-established agencies is necessary to continue building a cancer research infrastructure for the future.

To this end, we believe the budget for ARPA-H should, at all times, be separate and distinct from that of the NIH and NCI, both of which must continue to receive long-term, sustained, funding increases. Of particular concern is the President's FY2022 budget for NCI which calls for an increase of only $174 million – significantly less than what NCI has said it needs in the FY22 NCI Professional Budget Proposal. As evidenced by the number of R01 grant applications to NCI increasing by 50.6 percent between FY 2013 and 2019, NCI is facing a demand for research funding far beyond that of any other Institute or Center at the NIH. This realization demands that the new ARPA-H agency be structured in a way that leverages the incredible existing scientific research programs at the NIH. Similarly, the COVID-19 pandemic has illustrated the realization and benefit of life-saving treatments derived through collaborative partnerships with the private sector. The addition of ARPA-H, with its own unique mission, culture, and organizational leadership, will likewise offer an additional partner with which to collaborate to bring about transformational innovations and health breakthroughs.

Stakeholder engagement
ARPA-H's success hinges on community input and collaboration with key stakeholders in academia, industry, government, patient advocacy, etc. The policy development process must involve robust dialogue with, and substantial input from, these key stakeholders. Patient advocacy organizations' participation in the creation, implementation, and ongoing work of ARPA-H is essential to ensure that the potential breakthrough technologies and treatments achieved by this new agency are meaningful to and advance the health of the patients and caregivers it intends to serve. Establishing from the out-set avenues for public engagement and feedback gathering (e.g., RFIs, listening sessions, advisory committees, public hearings) will help propel the success of ARPA-H.

Telehealth Modernization Act
CSC also appreciates the inclusion of the Telehealth Modernization Act within the discussion draft. The COVID-19 pandemic has highlighted the benefits of expanding telehealth access by removing Medicare's geographic and originating site restrictions. Permanently securing these flexibilities beyond the public health emergency will ensure beneficiaries continue to receive access to services that improve their health and well-being. Also allowing the Secretary of Health and Human Services (HHS) to permanently expand the types of health care providers that can offer telehealth services and the types of services that can be reimbursed under Medicare (including tele-mental health) will help enable and promote changes that positively impact the lives of patients and caregivers.

Thank you again for the opportunity to provide comments and feedback on the discussion draft for Cures 2.0 and the development of ARPA-H. Should you have any questions or would like to arrange a time to discuss further, please contact Phylicia L. Woods, Executive Director of the Cancer Policy Institute at the Cancer Support Community at pwoods@cancersupportcommunity.org.

Sincerely,
Phylicia L. Woods

Phylicia L. Woods, JD, MSW
Executive Director – Cancer Policy Institute
Cancer Support Community Headquarters