



December 23, 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, appreciates the opportunity to provide comments on H.R. 6000, *Cures 2.0 Act* (Cures 2.0). 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.

We applaud the introduction of Cures 2.0 as it would ensure standardized patient experience data (PED) are consistently collected and considered in clinical trials, create and fund the Advanced Research Projects Agency for Health (ARPA-H) to bring about transformational innovations, and expand access to telehealth to improve the lives of patients including those impacted by cancer.

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 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. PED are intended to provide information about patients' experiences including the physical and psychosocial impact of the disease, its related therapy, or clinical investigation as well as patients' preferences regarding the treatment of their disease. 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.

Therefore, CSC supports the inclusion of Title II, Section 204 (b) of Cures 2.0 which benefits all stakeholders by facilitating a consistent process that eliminates discrepancies and promotes the full incorporation and elevation of PED in drug development and approval as Congress intended in *21st Century Cures*. Specifically, this section would achieve standardization of the collection, submission, and consideration of PED in clinical trials to ensure a therapy under investigation includes meaningful information relevant to patients' lives as well as serves as an important comparator for other investigational treatments and approved products.

PED is most meaningful when it is considered on a relative basis. To date, the sporadic, random, and selective nature of PED collected and considered has limited sponsors' and the FDA's opportunity to better understand the physical and psychosocial impact of an investigational therapy on patients and patients' preferences for treating their disease. Most importantly, the lack of standardization and consistency in the collection, submission, and review of PED has denied patients and providers access to meaningful and comparative information to better inform the patient-provider shared decision-making process to determine the most

appropriate treatment to meet a patient's needs, preferences, and priorities. Embracing a consistent process that standardizes the collection, submission, and consideration of PED will allow us to better understand and address the full range of patients' needs and concerns which will, in turn, 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.

Advanced Research Projects Agency for Health

CSC supports the creation of ARPA-H to promote transformative innovations in medicine and health, including cancer. We appreciate the need to allocate meaningful funding for the creation of ARPA-H as well as the need for continued, sustainable funding moving forward. However, we wish to impress the importance of the ARPA-H budget being separate and distinct from that of the National Institutes of Health and National Cancer Institute and in no way reducing or redirecting funding away from either agency. Similar to the importance of PED in the drug development and review process discussed above, we believe the success of ARPA-H hinges on community input and collaboration with key stakeholders in academia, industry, government, patient advocacy organizations, and others. The transformative innovations seeking to be achieved from ARPA-H must be meaningful to the patients and caregivers these discoveries seek to serve.

Telehealth

CSC applauds the inclusion of telehealth provisions in Cures 2.0 that call for the issuance and dissemination of guidance to help states overcome barriers and expand access to telehealth under Medicaid and the Children's Health Insurance Program. These telehealth provisions will improve the health and well-being of adults and children and promote a more equitable delivery of care. Specifically, the requirement to conduct a study in a minimum of 10 states and submit a report to Congress on the impact of telehealth on access, utilization, cost, and outcomes broken down by race, ethnicity, sex, age, disability status, and zip code demands action and accountability to produce a better and more equitable health care system.

Similarly, we support including the *Telehealth Modernization Act* in Section 403 of Cures 2.0 which recognizes the importance of increasing access to care to meet patients' needs. The COVID-19 pandemic highlighted the benefits of expanding access and removing burdensome and/or artificial limitations to telehealth services. Permanently removing Medicare's geographic and originating site restrictions requiring a patient to live in a rural area and be physically in a doctor's office to use telehealth services modernizes our health care system and keeps the focus on patients' health care needs and preferences. Allowing the Secretary of Health and Human Services to permanently expand the types of health care providers permitted to offer telehealth services and the types of services covered under Medicare (including tele-mental health services) will bring about even further changes that improve patients' experiences, lives, and health.

Thank you for the continued opportunity to provide comments on Cures 2.0. Should you have any questions or would like to arrange a time to discuss further, please contact Phylcia L. Woods, Executive Director of the Cancer Policy Institute at the Cancer Support Community at pwoods@cancersupportcommunity.org.

Sincerely,



Phylcia L. Woods, JD, MSW
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Cancer Support Community Headquarter