July 30, 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,

Thank you for the opportunity to comment on the 21st Century Cures 2.0 (Cures 2.0) discussion draft. The organizations below represent millions of patients confronting serious health conditions across multiple diseases that understand the importance of capturing and incorporating patients' perspectives, preferences, and priorities in the development of safe and effective treatments. We applaud the newly proposed language included in Title II, Section 204, Patient Experience Data, Subsection (b), Collection, Submission, and Use of Data and urge this language remain, in its entirety, in the final Cures 2.0 legislation.

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 patients. The Food and Drug Administration (FDA), too, acknowledges that patient experience data provide unique insights that contribute to important patient preference information for identifying relevant clinical trial endpoints to ultimately inform medical product development that best meet patients' needs. Notwithstanding the consensus by Congress, the FDA, patient advocacy organizations, and other stakeholders on the importance of PED, there is no imperative to ensure that PED is consistently collected, submitted, and used in the drug development process as intended.

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.

Embracing required processes for the consistent collection, use, and sharing of meaningful 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. 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.

On behalf of the patients and caregivers we represent, we express our full support for the new subsection (b) of Title II, Section 204, Patient Experience Data, and urge that this language be included in the Cures 2.0 final legislation. Should you have any questions, please reach out to Phylicia Woods, Executive Director, Cancer Policy Institute at the Cancer Support Community at pwoods@cancersupportcommunity.org.

Sincerely,

Cancer Support Community
Academy of Oncology Nurse & Patient Navigators (AONN)
American Kidney Fund
Arthritis Foundation
Association of Oncology Social Work (AOSW)
Brem Foundation to Defeat Breast Cancer
CancerCare
Cancer and Careers
Child Neurology Foundation

Children's Cancer Cause
Colorectal Cancer Alliance
EveryLife Foundation for Rare Diseases
Fight Colorectal Cancer
GO2 Foundation for Lung Cancer
Hemophilia Federation of America
Leukemia and Lymphoma Society
National Alliance on Mental Illness (NAMI)
National Eczema Association
National Hemophilia Foundation
National Kidney Foundation
National Multiple Sclerosis Society
Ovarian Cancer Research Alliance (OCRA)
Sick Cells
Susan G. Komen
The AIDS Institute
UsAgainstAlzheimer's