December 16, 2019

The Honorable Diana DeGette
United States House of Representatives
House Energy and Commerce Committee
Washington, DC 20515

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

Dear Representatives DeGette and Upton,

On behalf of the Cancer Support Community (CSC) and the patients that we represent, we thank you for your leadership in the passage of 21st Century Cures Act. As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology professionals in the United States, CSC applauds your continued commitment to elevating the patient voice and truly modernize coverage and access to life saving cures. In response to your request to build upon the progress made to date, CSC urges the closing of existing gaps revealed in 21st Century Cures that have thwarted Congress’ intent to ensure that patients remain at the center of the drug development process.

The 21st Century Cures Act, as amended by the Food and Drug Reauthorization Act of 2017, recognizes the importance of patient experience data and the physical and psychosocial impacts of a disease or condition, or related therapy or clinical investigation, on patients’ lives. The 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 congruity of Congress’ expectations and the FDA’s acknowledgements, there is no imperative to fully measure and understand the patient experience in clinical trials. Therefore, we believe the best way to ensure that the full intent of Cures 1.0 is realized is for Congress to require the collection and incorporation of patient experience data in clinical trial design.

Patient experience data is defined in Title III, Section 3001 of the 21st Century Cures Act (Pub. L. 114-255), as amended by section 605 of the FDA Reauthorization Act of 2017 (Pub. L. 115-52) (FDARA), 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.”

To actualize the intent and spirit of 21st Century Cures and, importantly, to modernize the drug approval process to reflect the best interests of patients and current best practices, CSC believes that the second installment of 21st Century Cures must: 1) require drug manufacturers/sponsors to collect and report on patient experience data as part of the trial; 2) require the FDA to fully consider all patient experience data collected during the clinical trial; and 3) require discussion and reporting of patient experience data in a transparent manner that is uniform, meaningful and informative to patients and providers.

More people are living with cancer than ever before, with 38.4% of Americans expected to receive a cancer diagnosis in their lifetime (National Cancer Institute, 2018). “Many patients – from newly diagnosed to patients multiple years out from a diagnosis – experience varying levels of distress related to psychological, social, and financial concerns. High levels of distress can negatively impact patient outcomes, and alleviating distress, through screening and support, is an integral component of any cancer care plan.” (Cancer Support Community, 2017, p.8). In this context, psychosocial distress refers to an unpleasant experience of an emotional, psychological, social, or spiritual nature that interferes with the ability to cope with treatment. Such experiences vary from more common feelings of vulnerability, sadness, and fears, to invasive concerns of depression, anxiety, panic, and feeling isolated or in a spiritual crisis. Approximately 50% of all cancer patients experience moderate levels of distress (Institute of Medicine, 2008), and between one-third and one-half of cancer patients report that distress is a significant problem (Carlson, 2004).

The Institute of Medicine concluded in 2008 that comprehensive cancer care must include psychosocial care. Similarly, the American College of Surgeons Commission on Cancer (CoC) began requiring CoC-accredited institutions to screen all cancer patients for distress and refers to this practice as a critical first step to providing high-quality cancer care. Patients entering clinical trials at CoC sites are guaranteed distress screening services, yet they are not promised the same standard of care in all clinical trials. Just as a person’s blood is measured in a clinical trial, so, too, should be his or her level of distress. Psychosocial distress screening along with follow-up care is associated with an improvement in patient outcomes (quality of life and survival outcomes). CSC survey data found 93% of respondents consider quality of life very important when weighing treatment options, higher than length of life (79%), yet product labels continue to focus very little on fully measuring comprehensive quality of life metrics (Cancer Support Community, 2017). Clinical trials that incorporate patient experience data, both physical and psychosocial impacts of the disease or clinical investigation, allow us to better understand a patient’s response to each arm of the trial, as well as meet the patient’s needs and concerns – all goals of 21st Century Cures.

Distress caused or exacerbated by trial design can contribute to trial non-compliance and, ultimately, abandonment of participation – a concern with implications for both the patient and the sponsor. In addition to meeting the needs of a patient, identifying, measuring, and managing
the psychosocial impacts of the cancer or clinical investigation is an innovative opportunity for
the sponsor.

Although the 21st Century Cures Act does not currently require the collection of patient
experience data, it does require the Secretary of Health and Human Services to make public a
brief statement regarding patient experience data and related information, if any, submitted and
reviewed as part of an application. There is no clear directive on how, when, and where to make
public such a statement. In the absence of such clarity, the FDA has created a form that includes
check marks for the drug manufacturer/sponsor to complete asking what, if any, patient
experience data was submitted as part of the application, as well as a corresponding area where a
notation can be made indicating the section of review where the information was discussed, if
applicable. How the information on this form is conveyed in a manner relevant and meaningful
to patients and providers remains unclear.

CSC appreciates the proposed areas of focus set forth in Cures 2.0: digital health, coverage of
new cures and medical products, harnessing data to empower patients and improve health, and
expanding and improving family and caregiver resources. However, without first ensuring that
the patient voice and experience is meaningfully included in the drug development process and
the information is subsequently conveyed to patients and providers in a manner that allows
informed and shared decision making, these additional efforts to modernize coverage and access
to life-saving cures will not achieve their intended purpose.

CSC appreciates your consideration of our comments and we welcome the opportunity to work
with Congress to ensure that patients derive the full benefit intended by 21st Century Cures.
Please feel free to contact me at kczubaruk@cancersupportcommunity.org if we can serve as a
resource.

Sincerely,

Kim Czubaruk
Senior Director, Policy and Advocacy

References
Cancer Support Community. 2017. Insight into the patient experience: Cancer experience

Carlson, L. E., Angen, M., Cullum, J., Goodey, E., Koopmans, J., Lamont, L….& Bultz, B.D.
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21st Century Cures Act (Title III, section 3001, Pub. L. 114-255), as amended by the Food and