July 6, 2015

Chairman Fred Upton
House Energy and Commerce Committee
2125 Rayburn HOB
Washington, DC, 20515

Congresswoman Diana DeGette
House Energy and Commerce Committee
2322A, Rayburn HOB
Washington, DC 20515

Re: Comments on 21st Century Cures Act

Dear Chairman Upton and Congresswoman DeGette:

On behalf of the Cancer Support Community (CSC), an international nonprofit organization providing support, education and hope to over 1 million people affected by cancer each year, we would like to offer our comments on the 21st Century Cures Act. Like the earlier discussion draft, we applaud your efforts to put patients first in this legislation. We also applaud the bipartisan success of this legislation including the unanimous vote in favor of the bill in the Energy and Commerce Committee. We would like to offer our support for the underlying legislation. However, we strongly urge you to strengthen this bill by adding language to incorporate distress screening and supportive care into Clinical Trial Protocol at the National Institutes of Health (NIH). We ask that before you pass 21st Century Cures, that language be incorporated into the bill ensuring that patients are screened for psychosocial distress.

Psychosocial Distress Screening in Clinical Trials:

As was indicated in our previous comment letter in February, CSC strongly urges the Congress to improve upon the legislation by ensuring that distress screening for patients enrolled in clinical trials, and supportive care for those patients who show signs of distress, becomes a routine part of the clinical trial process. Nearly 50 percent of patients with cancer experience psychological, social, or economic distress, and that this form of distress can have a significant negative effect on the patient’s ability to complete a course of therapy. In a clinical trial context, a patient’s personal distress level can have a profound effect on the patient’s ability to participate in all protocol-mandated visits, tests, treatments, and follow-up appointments. Each time a patient is unable to adhere to the requirements of the study, or fails altogether to complete the study, the overall quality and statistical power of the study is weakened.

Research shows that if offered early, psychosocial distress screening and supportive care can provide improved outcomes and possibly longer survival for patients. Data shows that when patients participate in an every other week support group for one year they experience a reduced risk for breast cancer recurrence and a reduction in risk of dying from breast cancer if they did have a recurrence. Furthermore, of the patients in this study who died, those participating in group lived a full 1.3 years longer than their counterparts. As you continue to make progress with moving innovation forward, please consider the impact of psychosocial innovation as a part of the complete treatment paradigm.

With proper screening and intervention we can reduce distress levels by 25 percent. Moreover, it is likely that by identifying and addressing patient distress levels, we will improve each patient’s prospect for retention in the trial and his or her adherence to the protocol. Given the fact that a mere 3 percent of eligible patients enroll in an oncology clinical trial, and that patients have significantly better health outcomes when screened and treated for distress, we believe distress screening and supportive care will...
lead to more efficient use of clinical trial resources and have a positive impact on patient outcomes. In order to meaningfully advance cures in the 21st Century, we must do a far better job of recruiting and retaining patients in clinical trials. A true focus on patient-centered needs and concerns and the application of evidence-based interventions would dramatically improve participation, outcomes and satisfaction. Therefore, we strongly urge the House to pass language incorporating this screening into Clinical Trial Protocol.

**National Institutes of Health**

We would like to express our strong support for the proposed $10 billion increase in funding for medical research at the National Institutes of Health (NIH). As you know, NIH is vitally important in our work to treat cancer. In particular, the National Cancer Institute (NCI) is the principle institute for cancer research and training. The work being done at the NCI is essential in efforts to improve quality of care for patients. For more than a decade, funding for medical research has declined significantly. This proposal is a welcomed change to previous funding cuts. We applaud your bipartisan effort to increase funding for medical research at NIH.

We also appreciate the opportunity to play a role, with other patient advocacy groups, in developing a 5 year bio-medical research plan for NIH. We believe that an essential component within the Mission Priority Focus Areas must be the incorporation of distress screening and supportive care. If the goal of these focus areas is to eliminate the burden of the disease, then the inclusion of psychosocial care should be a top priority. Our research shows that this screening and care would improve quality of care for the patient therefore reducing the burden of the disease.

**Clinical Trial Registry Data Bank**

We believe that the standardization of data in the Clinical Trial Registry data bank is much needed and would improve cancer care. At CSC, research and data collection has been a top priority in working to improve care. In 2009, we opened our Research and Training Institute – the first independent Institute in the United States dedicated to psychosocial, behavioral and survivorship research and training in cancer. In 2013, we launched our Cancer Experience Registry, a database and community of nearly 8,000 people with all types of cancer and their loved ones.

As this proposal is further developed and implemented, we stand ready to offer our support and expertise to improve the data collection process for clinical trials. With the common goal of improving care for all patients, we believe we can improve the efficiency of drug discovery and development.

**Structured Risk Benefit Assessment Framework:**

As stated in our previous letter, we would like to express our support for the Structured Risk-Benefit Assessment Framework provision in the bill. CSC supports the intent of this language which would help ensure that the patient experience is considered in any risk-benefit assessment. However, we believe there is opportunity to strengthen this section of the legislation by integrating patient-focused incentives, including psychosocial distress screening and follow up care into the assessment as a patient reported outcome. The legislative language below provides a strong framework for how this patient focused care can be achieved.

Furthermore, CSC believes that the patient-centered themes outlined in the title should be a mandatory part of the assessment, management and risk-benefit review for all patients who participate in a clinical trial. This type of intervention would ensure that we are proactively assessing components of care for the whole patient that are often not a part of biomedical assessments, yet have considerable impact on the overall experience. CSC believes that the measurement and inclusion of distress-related data is essential in understanding the patient’s comprehensive needs, and should be incorporated into the clinical trials protocol. Integrating this data will not only allow us to better understand the key elements of the patient experience but also improve patient adherence to the clinical trial requirements.
**Patient Experience Data:**

We appreciate the guidance drafted in the bill related to the Patient Experience Data. However, we urge you to include both the social and emotional aspects of the disease as a part of that guidance. The benefit of psychosocial support as a part of comprehensive care has been well known and documented. Most notably, the Institute of Medicine 2008 report *Cancer Care for the Whole Patient* specifically states, “Today, it is not possible to deliver good-quality cancer care without using existing approaches, tools, and resources to address patients’ psychosocial health needs.” Including the social and emotional aspects of the disease within the Patient Experience Data will ensure that patients are getting the highest quality of care.

In June of this year, the American Society of Clinical Oncology (ASCO) released its ASCO Value Framework. The framework assesses new treatment options in comparison to older treatment options. In the framework, there is no consideration of long-term, chronic side effects as having impact to patients; despite overwhelming evidence of the challenges they pose. When asked about the omission, Dr. Lowell Schnipper, on behalf of ASCO, indicated that there is a “global deficiency” of collecting patient reported outcomes data as a part of the drug development process. Dr. Schnipper went on to state that this is a deficiency we must correct.

You have the opportunity with this legislation to correct this global deficiency by requiring that patient reported outcomes including physical and psychosocial measures are collected, reported and managed as a routine part of care.

**Methodology Workshop and Patient Feedback:**

As stated in our February letter, CSC supports the inclusion of language regarding the creation of workshops to seek feedback regarding methodological approaches. CSC fully believes there is an opportunity for patients to provide substantive feedback throughout this process. However, aligned with feedback provided to the FDA on December 4, 2015, CSC is concerned that the feedback may not be a comprehensive perspective given the inability of many to attend in person due to physical, geographic or other limitations. CSC is also concerned that local/regional bias related to access and care may contribute to limited information. CSC encourages the agencies to make a larger commitment to securing feedback by working with patient groups, community organizations and other mechanisms that allow the collection of a more comprehensive view of the patient experience.

**Food and Drug Administration**

CSC also supports the $550 million increase in funding for the Food and Drug Administration (FDA). This increased funding will ensure that the FDA has the resources needed to make the drug approval process more efficient. These changes and additional resources will give patients access to lifesaving drugs and therapies sooner. NIH Director Francis Collins recently noted that medical knowledge has outpaced gains made in treatment. We believe that additional resources are a positive step forward for drug treatment. It will help in closing the gap between the scientific advances that have been made and drug treatments.
Medicare Site-of-Service Transparency

CSC strongly believes that healthcare cost transparency continues to be a major problem for cancer patients. In March, we released our Insight into Patient Access to Care in Cancer study which found that out-of-pocket costs remain a top concern for many patients. Our survey found that Medicare was second highest form of coverage, behind employer-based coverage. Of those surveyed, nearly one-third of patients expressed high concern about out-of-pocket costs for hospital stays, medications, lab tests or scans. Over 37 percent reported being very concerned about bankrupting their families. We believe that transparency will help improve this continuing problem and will help patients financially plan for their care.

Again, thank you for your leadership and work on accelerating cures in the 21st Century. We look forward to working with you on this important effort.

Sincerely,

Kim Thiboldeaux
Chief Executive Officer

References
