NATIONAL COALITION FOR CANCER SURVIVORSHIP

The power of survivorship. The promise of quality care.

March 27, 2015

The Honorable Fred Upton
Chairman
Energy & Commerce Committee
United States House of Representatives
Washington, DC 20515

The Honorable Diana DeGette
United States House of Representatives
Washington, DC 20515

Dear Chairman Upton and Representative DeGette:

The National Coalition for Cancer Survivorship is dedicated to improving the quality of care and quality of life for survivors of all forms of cancer. We focus our public policy on activities that will encourage the delivery of the right treatment to the right person at the right time.

We have evaluated the 21st Century Cures discussion draft dated January 2015 for its potential impact on the delivery of patient-centered care, and we offer recommendations based on that review.

Precision Medicine

In the Energy & Commerce Committee fact-finding process and in the discussion draft, there is a great emphasis on targeted therapies, or precision medicine. We understand and generally support efforts to make the biomedical research and therapeutic development program of this country and the health care delivery system ready for the precision medicine revolution. However, we also urge that the 21st Century Cures effort reflect a goal of ensuring delivery of appropriate treatment to each patient, based on a shared decision-making process and even if the treatment is not targeted according to the patient's genetic profile.

Food and Drug Administration Review

We understand the desire to accelerate Food and Drug Administration (FDA) review so that patients receive promising new treatments at the earliest possible time. Cancer patients who have no viable treatment options remaining or who had few options at the time of diagnosis certainly hope for FDA review that eliminates all inefficiencies. However, patients also need the reassurance that drugs approved by FDA are in fact safe and effective. Speed of review is not meaningful if the drugs that are approved do not provide a meaningful benefit to patients.

Balancing speed of review and the quality and quantity of data required for approval is difficult, and we commend the committee for giving serious thought to this issue. We recommend that the committee evaluate the work of the Office of Hematology and Oncology Products for insights into the effective new of the expedited review programs, including breakthrough therapy designation, fast track, priority review, and accelerated approval. Through discriminating use of these programs, the cancer drug review office has achieved an impressive level of efficiency that might be replicated by other review offices. Because we have observed the

accomplishments related to cancer drug review – including approval of many products well in advance of their user fee dates – we are not persuaded that fundamental revisions of review processes or changes in evidence required for approval are necessary.

We do not favor the elimination of confirmatory trial requirements for those products that receive accelerated approval. Neither do we support approvals – even supplemental new drug approvals – on the basis of data summaries. Efficient review of cancer drugs is being accomplished through solid utilization of the expedited review processes, and reducing the amount of data necessary to support approval is neither necessary nor in the interest of patients who should be able to trust the safety and efficacy of new products and to have adequate data about the drugs to support informed decision-making about their treatments.

Challenges of Reviewing Drugs of the 21st Century

We anticipate that FDA will soon require more reviewers and reviewers who are well-trained to consider genetically targeted therapies. Part of the training of personnel is the ability to attend scientific and medical meetings sponsored by a wide range of organizations, including academic institutions, professional societies, research foundations, patient advocacy organizations, and regulated industries.

A staff of adequate size that is appropriately trained will be achieved only with some changes in personnel, training, and travel and meeting attendance rules. We recommend simplification of personnel procedures to reduce the length of time required to hire new reviewers. We also urge an evaluation of conflict of interest rules to ensure they protect against inappropriate conflicts but do not unreasonably prevent FDA staffers from participation in science meetings. There should also be adequate FDA resources to support necessary travel to science meetings. We stress the interaction of FDA reviewers with the scientific leaders in their field, as we consider that a critical part of continuing medical education for reviewers who will be evaluating targeted, or precision, medicines and all other products submitted to the agency.

Improving Health Care Payment and Delivery to Ensure Quality Cancer Care

We appreciate that the committee focused much of its attention on the research and development of new therapies. We recommend additional efforts to ensure that patients of the 21st century have access to new treatments in a health care system that is affordable, sustainable, and patient-centered.

To achieve the goal of the right medicine for the right patient at the right time in an age of targeted therapies, we strongly recommend that the cancer care experience begin with a cancer care planning encounter between patient and physician. The cancer care plan should facilitate and encourage shared decision-making. These elements of care will be especially critical in an age of precision medicine, when appropriate diagnosis, including genetic profiling, will be necessary to match patient and drug. In addition, patients need complete information about the benefits and risks, including treatment side effects and late and long-term effects, of all treatment options.

NCCS has consistently recommended that payment systems, whether fee-for-service or alternative systems like the proposed Oncology Care Model, provide appropriate reimbursement for a cancer care planning/shared decision-making service provided by cancer care professionals. We also recommend continuing medical education for health professionals to improve their communication skills around the topic of treatment decisions and to enhance their interactions with their patients.

One of the goals of the 21st Century Cures effort has been eliminating barriers to treatments of the 21st century. We urge that this include eliminating all barriers to full and open communication with patients about their treatment options. If patients participate with their health care providers in the consideration of all treatment options, evaluation of the benefits and risks associated with all treatments, and evaluation of their own genetic profile and the appropriateness of targeted therapies, they will have made significant progress toward an assurance that they will receive the right treatment at the right time.

These important patient goals will be achieved by payment systems that value the interaction between patient and physician to properly target treatment and that foster the coordination of active treatment and symptom management.

We appreciate the opportunity to comment on the 21st Century Cures initiative. We will continue to monitor the work of the committee and comment on additional questions and issues you pose for public comment.

Sincerely,

Shelley Fuld Nasso
Chief Executive Officer