

CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS
ADDRESSING PUBLIC POLICY ISSUES IN CANCER

December 16, 2019

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

The Honorable Fred Upton
United States House of Representatives
Washington, DC 20515

Dear Representatives DeGette and Upton:

The undersigned cancer organizations appreciate the opportunity to comment on the Cures 2.0 effort, which you describe as “an effort to modernize coverage and access to life-saving cures in the United States and across the globe.”

Some of our organizations have the word “cures” in our names, and all of us share a dedication to finding and making cancer cures accessible to Americans. Until we have cures for all cancers, our mission must also include providing the best possible care to people with cancer, boosting the quality of care they receive and the quality of life they experience after a cancer diagnosis. In our comments below, we embrace this expansive view of cures and quality care.

Improving Coverage of Innovative Therapies

Cancer patients have been the beneficiaries of groundbreaking new therapies, including immunotherapies and personalized approaches to treatment. These treatments may be complex in their administration and be accompanied by significant treatment side effects, yet their benefits may be truly life-saving. The challenges to coverage and payment for these therapies have in some cases been significant.

One solution, of course, is to take steps to ensure that coverage and payment occur as soon as possible after Food and Drug Administration (FDA) approval. While this is an important goal, it is inadequate. It does not address many other issues, including the significant cost-sharing that patients may confront when they receive groundbreaking new therapies, the concrete and specific challenges associated with receiving some new therapies, and the management of the side effects of treatment.

We urge that there be consideration of new models for covering and reimbursing for groundbreaking new therapies that address the issues we identify above. We also appreciate that the health care system will be taxed by the cost of these new therapies, so we need to be sure that the therapies are delivered to those who will benefit from them and that the therapies

are delivered in a way to maximize their benefits (including through management of side effects of treatment, when necessary).

The collection and utilization of real-world evidence regarding new therapies are important to informing clinicians and payers about the utilization of new therapies and to providing data over time that will support off-label uses of new therapies (and labeling expansion).

Development and Utilization of Real -World Evidence

In the years since enactment of the 21st Century Cures Act, the Food and Drug Administration (FDA) has advanced a number of initiatives related to the collection and utilization of real-world evidence. The agency has published guidance documents that provide the industry and all other stakeholders advice about submission of real-world evidence to the agency for use in regulatory decisions. The agency is also providing guidance to all stakeholders, in a process that is still ongoing, about the collection of patient experience data so that it may also be submitted to and used by the agency.

We applaud these efforts, as we think that real-world evidence will inform the utilization of new therapies and coverage and payment determinations, as we discuss above. Despite the progress that has been made in setting the standards for collection and utilization of real-world evidence, there remains the challenge of who will bear the responsibility for collection of real world data and how these efforts will be financed. In addition, although FDA has addressed real-world evidence issues, there is no comparable advice about real-world data collection and utilization from payers, both public and private.

We recommend that the Cures 2.0 effort give serious consideration to strategies for collection of real-world evidence. Should such collection be the responsibility of clinicians, working with data managers, or is such data collection more appropriately a post-marketing requirement for sponsors of new products? Nonprofit patient organizations believe that they can play a role in the real-world data collection effort, especially with collection of quality-of-life data, but in most cases lack the resources and infrastructure for analysis of real-world data. We also recommend that the Cures 2.0 effort consider those federal agencies that might be engaged in real-world data collection or that might fund such efforts through grants.

Modernizing Clinical Trials

In recent years, FDA has taken steps to modernize enrollment criteria for cancer clinical trials. In guidance documents, the agency has addressed the minimum age for enrollment of pediatric patients in trials, enrollment of those with brain metastases, the enrollment of those with prior malignancies or organ dysfunction, and the enrollment of adolescents in adult trials. This work has been informed by cancer community efforts led by the American Society of Clinical Oncology and Friends of Cancer Research. The agency has also released a guidance document addressing the enrollment of male breast cancer patients in trials. In addition to these cancer-specific efforts, the agency released a 2019 guidance that addresses the matter of achieving diversity in clinical trial populations.

We applaud the efforts of FDA and our cancer community colleagues to modernize guidance on enrollment criteria. We now encourage all stakeholders to consider how the revised and modernized enrollment criteria can have an impact, by being utilized by clinical trial sponsors as aggressively as possible. The standards for clinical trial enrollment that FDA has articulated would result in more diverse trial enrollees than has been past practice and also a clinical trial population that will yield better answers about the benefits of the investigational agent. However, this more diverse trial population will only happen if trial sponsors honor the standards. We encourage you to consider steps to ensure utilization of recently revised enrollment criteria, revised to encourage diversity in trials and a clinical trials population more reflective of those who may use the investigational agent when approved.

We also recommend that CURES 2.0 legislation include the CLINICAL TREATMENT Act (HR 913), which would require payment for routine patient care costs for Medicaid recipients who are enrolled in clinical trials. Some Medicaid programs provide coverage for routine patient care costs for trial enrollees, but other state programs do not or do not have a clear policy. We urge the inclusion of the CLINICAL TREATMENT Act in legislation you develop, as it will remove one financial barrier to participation of Medicaid recipients in trials.

Several patient advocacy organizations are engaged in wide-ranging activities to remove additional financial barriers -- beyond those related to third-party payment for routine patient care costs -- to clinical trials participation. Among other actions, they are seeking to address the burden of incidental costs of clinical trials participation, including transportation, lodging, and food costs. Some are seeking to support a caregiver for the clinical trial participant, so that the trial enrollee receives caregiver support and completes the trial. We urge that the activities of these nonprofits be considered during the Cures 2.0 discussion, as some of these efforts to support clinical trial enrollees might be appropriate as standards for clinical trials. This might be an area for testing by the National Institutes of Health (NIH).

Using Digital Technology to Improve Cancer Care

We believe there is promise in the utilization of telemedicine in cancer care. Two specific uses are the use of telemedicine in the management of treatment side effects and in the delivery of survivorship care. The ongoing Medicare demonstration project for cancer care, the Oncology Care Model, has seen a reduction in emergency department visits and hospitalizations for management of treatment side effects, in part the result of 24/7 access to a provider who has access to electronic medical records. We suggest that telemedicine visits might build on the 24/7 access to providers that is an element of the Oncology Care Model, although of course we recommend these visits not only in the Oncology Care Model context.

There is also promise in the utilization of telemedicine visits for survivorship care. Survivorship care includes in part the monitoring of possible late and long-term effects of treatment and follow-up care when necessary. Telemedicine visits could be an element of the monitoring of treatment side effects.

To advance the utilization of telemedicine in cancer care, several policy steps will be necessary. These include appropriate and adequate payment for providers who supply telemedicine services, training of professionals in delivery of telemedicine services, and interoperability of electronic health systems. We realize that our final point about interoperability is a major issue, and success on this topic has eluded policymakers for years. It is still a necessary element of a successful telehealth program.

We urge consideration of the telehealth efforts at the Veterans Administration as the CURES 2.0 team considers expansion of telehealth in new therapeutic areas.

Supporting Families and Caregivers to Improve Cancer Care

The cancer community uses the term “survivor” to refer not only to a person diagnosed with cancer but also their families, friends, and caregivers. We have embraced this terminology because cancer affects not only the person diagnosed but the entire family and the patient’s network of friends. We underscore the language we have traditionally used to stress our keen interest in policy initiatives that will support caregivers who are in turn supporting Americans diagnosed with cancer.

There is strong literature on the financial toxicities of cancer, and that literature makes clear that the financial burdens of cancer relate to the cost of care but also to the fact that some people with cancer are unable to work during or after treatment or are able to work only a limited amount of time. And there are many elements of cancer care that are not covered by third-party payers. These patients depend on family and friend caregivers, who may as a result encounter their own financial toxicities.

We urge that the consideration of caregiver issues be undertaken with a wide lens. We are aware of previous legislative efforts to provide respite services for caregivers, in programs that were publicly funded and provided limited terms of respite care. These are a solid – but modest -- element of a broad effort to support caregivers.

We mention above some ongoing efforts in the private sector to provide financial support to caregivers to patients who are enrolled in clinical trials. We urge that the benefits and the financial costs of these efforts be evaluated, as part of a broad look at ways to support caregivers.

As the baby boom generation ages, the incidence of cancer will increase. This demographic trend raises a serious question about who will take care of these cancer survivors. We know that there are inadequate numbers of cancer care professionals to meet the needs of the baby boom. There is a parallel problem with family and friend caregivers.

We appreciate the opportunity to offer initial ideas regarding your effort to advance a CURES 2.0 package. We look forward to working with you on this initiative.

Sincerely,

Cancer Leadership Council

American Society for Radiation Oncology
American Society of Clinical Oncology
CancerCare
Children's Cancer Cause
Fight Colorectal Cancer
International Myeloma Foundation
LUNgevity Foundation
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Ovarian Cancer Research Alliance
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen