



December 16, 2019

Representative Diana DeGette
2111 Rayburn House Office Building
Washington, DC 20515

Representative Fred Upton
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton,

The Children's Cancer Cause (CCC), established in 1999, was founded to ensure the needs and perspectives of children with cancer and survivors are integrated into federal health care, research and cancer policy. Below we suggest three categories of provisions affecting the child cancer community for "Cures 2.0" inclusion: survivorship, clinical trials, and pediatric cancer drug shortages.

Survivorship

Americans are living longer with cancer, resulting in larger numbers of cancer survivors in the United States. The nation's 500,000 pediatric survivors of cancer are uniquely affected because of late effects of cancer treatment. Over 80% of childhood cancer survivors will have at least one severe, disabling, or life-threatening late effect of their disease or treatment by the time they reach 45 years of age. At the conclusion of active treatment, survivors should receive information that includes a summary of their treatment, potential risk for late effects that are associated with their treatment, and recommendations for follow up care. Obtaining follow-up care for survivors of childhood cancer has been deemed a long-term and ongoing health care challenge by the Institute of Medicine and the President's Cancer Panel. We believe this issue can be addressed in multiple ways below.

Digital Technology

Most childhood cancer patients are treated at major medical institutions, often far from their homes. After completing their treatment, patients and their families return to their communities, where access to follow-up care is limited. We believe there is promise in the utilization of telemedicine in cancer care to address this problem.

- *Telehealth coverage.* We support further utilization of digital records and telemedicine visits for 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. Providers could use digital records, such as portals and phone applications to access a comprehensive care summary and follow-up plan for children that have completed their primary cancer care.

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 interoperability is a major issue,

and success on this topic has eluded policymakers for years. Nevertheless, it remains a critical element of a successful telehealth program.

- *ONC study.* Health care information is increasingly provided to patients through a digital platform that includes portals and other means of communication. To reiterate, pediatric cancer records of care and care plans are a critical and sometimes missing component of care. We believe better data about digital platforms for pediatric survivorship care planning is needed.

Every year the Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) submits a mandated report to Congress on health IT progress, specifically examining the hi-tech era and the future of health IT. This annual report is submitted in accordance to the law set forth by section 3001(C)(6) of the Public Health Services Act and Section 13113(A) of the HITECH Act. We recommend that CURES require next year's annual report to evaluate the state of digital platforms for pediatric survivorship care with a focus on integrating existing models such as the Passport for Care model.

Data Collection

Adequate information about pediatric cancer survivorship and late effects resources and coverage is limited. Data limitations and longitudinal information gaps exist in the following key areas:

- The way children with cancer are insured under Medicaid, group health plans or other mechanisms both for their active cancer care and survivorship care.
- The number of children with cancer who receive survivorship care planning, what kind of planning, for how long, and related outcomes.
- Tracking could begin with Medicaid as a first step.

Clinical Trials

In recent years, FDA has taken steps to modernize enrollment criteria for cancer clinical trials. In guidance documents, the agency has addressed several areas important to the pediatric and adolescent community such as 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. We applaud the efforts of FDA to modernize guidance on enrollment criteria. We recommend that CURES 2.0 legislation further improve the clinical trial process by addressing several existing barriers.

- CURES 2.0 should 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. Medicaid is the only major payer that is not required to provide this coverage as they do not require state programs to provide coverage for the routine costs of clinical trials participation. However, Medicaid insures nearly one-fifth of the U.S. population, as well as a third of childhood cancer patients, and the absence of a federal requirement limits pediatric patient access to cancer treatments that are often the best clinical option.

Medicaid is a primary source of coverage for many children with cancer. Failure to address the coverage barrier that Medicaid pediatric patients face imposes access, clinical and financial burdens that could affect overall care. We urge the inclusion of the CLINICAL TREATMENT Act in CURES 2.0 legislation, as it will remove one financial barrier to participation of Medicaid recipients in trials.

- A second issue involves additional financial barriers -- beyond those related to third-party payment for routine patient care costs -- to clinical trials participation. We ask that CURES 2.0 address the burden of incidental costs of clinical trials participation, including transportation, lodging, and food costs. Pediatric care often requires family members traveling long distances for their child's treatment, taking leaves of absence or quitting their jobs and inflicting additional financial stress. CCC urges financial support for a family caregiver as a component of clinical trial participation. We recommend these elements be considered during the Cures 2.0 discussion to strengthen the standards for clinical trials and enhance participation. The National Institutes of Health (NIH), and particularly the National Cancer Institute (NCI), should be charged with testing models of caregiver support in coordination with the Centers for Medicare and Medicaid Services (CMS)

Pediatric Cancer Drug Shortages

Pediatric cancer patients recently faced a disturbing shortage of the chemotherapy drug, vincristine -- an essential component in the treatment of most childhood cancers, including leukemias, lymphoma, brain tumors, bone tumors, neuroblastoma, Wilms tumor, and rhabdomyosarcoma. A vincristine shortage represented a true crisis with no alternative or recommended substitution for the drug. The current shortage of Vincristine has its roots in two specific events: a quality control issue and departure of a manufacturer from the market.

We support legislative action on this issue, within CURES 2.0, to address the multi-faceted challenges associated with drug shortages. In this regard, we support the Mitigating Emergency Drug Shortages (MEDS) Act (S. 2723). The bill calls for FDA to speed facility inspections and application reviews for generic drugs in short supply, make bulk drug manufacturers disclose supply disruptions, direct makers of life-supporting drugs to develop back up manufacturing plans and identify where drugs are made, and recommend ways Congress could incentivize manufacturers to enter the market to avert shortages.

The Children's Cause for Cancer looks forward to working with you on CURES 2.0. If you have questions or comments please contact George Dalman at gdahlman@childrenscause.org



George Dahlman, CEO
Children's Cancer Cause