November 14, 2022

The Honorable Charles Schumer
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Nancy Pelosi
Speaker
United States House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Republican Leader
United States Senate
Washington, DC 20510

The Honorable Kevin McCarthy
Republican Leader
United States Senate
Washington, DC 20515

Dear Majority Leader Schumer, Speaker Pelosi, Leader McConnell, and Leader McCarthy:

As Congress begins consideration of the year-end package, the American Cancer Society Cancer Action Network (ACS CAN) urges you to support legislative improvements that will address the needs of millions of cancer patients, survivors, and those at risk of a cancer diagnosis. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

We want to work with you and members in both chambers to ensure that any year-end package includes the follow priorities for cancer patients:

National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) Funding

Research is central to breakthroughs in cancer treatment. In fact, a record number of Americans are surviving cancer today due to previous research investments. We are moving forward on finding successful treatments for several cancers and increasing federal dollars for this critical work will make a difference in the lives of millions of Americans.

The National Institutes of Health (NIH) and the National Cancer Institute (NCI) are the foundation of our national cancer research program and support research in every state. The Centers for Disease Control and Prevention's cancer programs also play a critical role in bringing cancer prevention to communities. Because of past bipartisan investment, these entities are making remarkable progress in every area of discovery to improve cancer prevention, early detection, treatment, and care. However, our nation's cancer burden requires sustained increases in federal investment to continue to bring new discoveries to cancer patients. Currently, the National Cancer Institute is unable to fund hundreds of high-quality research applications every year. Without continued increases in funding, we risk losing a generation of young investigators, slowing progress and threatening Americans' survival and the country's competitive edge.

To save more lives from cancer, we urge you to include a **$4.1 billion** funding increase for the National Institutes of Health with an additional **$853 million** for cancer research at the National Cancer Institute. We also urge you to include **$462.6 million** for the Centers for Disease Control and Prevention's (CDC) cancer programs, including **$225 million** for the National Breast and Cervical Cancer Early Detection Program.

Medicare Multi-Cancer Early Detection Screening Coverage Act (MCED)

ACS CAN strongly supports inclusion of H.R. 1946/S.1873, the Medicare Multi-Cancer Early Detection Screening Coverage Act in the year-end package. This legislation has strong bi-partisan and bi-cameral support. In 2022 alone, there will be an estimated 1.9 million new cancer diagnoses.[1] For many, their diagnosis will come at a later stage when it is harder and more expensive to treat or perhaps even fatal. For example, only 6 percent of individuals diagnosed with late-stage lung cancer survive 5 years after their diagnosis. The inclusion of the MCED Act holds promise to change this reality.

By combining the latest advances in genomic sequencing and computing power, published data indicate multi-cancer early detection tests have shown the ability to detect many cancers from a simple blood draw.[2] These new tools could dramatically expand the benefits of early detection to more cancers, and expand detection's reach to more settings of care, enabling earlier treatment for a wider range of cancers. First, however, there must be a pathway to Medicare coverage. The MCED Act is not a mandate for coverage; however, this bill will empower Medicare, upon approval by the FDA and when these tests have been shown to have clinical benefit, to consider coverage determination for multi-cancer tests - something the current statute does not allow. This bill could directly address long-standing health care disparities for low-income people and ethnic minorities by ensuring equitable access.

Diversity in Clinical Trials (DIVERSE Trials Act)

Clinical trials are key to advancing new standards of care that can improve survival and quality of life for people with cancer. Numerous clinical trial diversity provisions were included in Title V of the House-passed FDA user fee reauthorization (H.R. 7667), and we encourage their inclusion in the year-end package. These provisions require diversity plans for clinical studies, guidance on decentralized trials, efforts to learn from the flexibilities offered during the COVID public health emergency and increased diversity reporting.

In addition to these previously passed provisions, we also urge the inclusion of the bipartisan Diversifying Investigations Via Equitable Research Studies for Everyone (DIVERSE) Trials Act (H.R. 5030/S. 2706). This bill works to promote equitable access to trials by bringing trials to patients where possible as well as enabling sponsors to provide support to patients for added non-medical costs - like travel - through the creation of a safe harbor. Offering financial support for ancillary costs associated with trials has been shown to increase overall enrollment and may also increase participation from underrepresented groups.[3]

---

[1] https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2022.html#:~:text=The%20Facts%20%26%20Figures%20annual%20report,deaths%20in%20the%20United%20States.)

[2] https://www.annalsofoncology.org/article/S0923-7534(20)36058-0/fulltext and https://science.sciencemag.org/content/369/6499/eabb9601

[3] Nipp, R. D., Lee, H., Powell, E., Birrer, N. E., Poles, E., Finkelstein, D., Winkfield, K., Percac-Lima, S., Chabner, B., & Moy, B. (2016). Financial Burden of Cancer Clinical Trial Participation and the Impact of a Cancer Care Equity Program. The oncologist, 21(4), 467–474. https://doi.org/10.1634/theoncologist.2015-0481

When including this legislation in the final package, we urge you to make the following modifications to the introduced version of the DIVERSE Trials Act: removal of Section 4, which would have only applied during the COVID public health emergency and therefore has limited impact; and addition of a conforming amendment in Section 5 to clarify that the proposed financial support safe harbor is for both the Civil Monetary Penalty (as currently in the legislation) as well as the Anti-kickback statutes.

Modernization of Diagnostic Test Oversight (VALID Act)

Cancer patients rely on accurate and clinically valid diagnostic tests to optimize their treatment options, and ACS CAN has long called for harmonizing and modernizing the regulatory framework. The Verifying Accurate Leading-edge IVCT Development (VALID) Act (S. 2209/ H.R. 4128) proposes to create harmonized oversight for all diagnostics with tiered requirements tied to the risk posed by a given diagnostic test. Currently, diagnostic tests undergo widely different levels of oversight depending on whether they are submitted to the FDA for review or are offered as laboratory developed tests (LDTs). This difference opens the door to the possibility that test results may vary depending on where the test is conducted, potentially leading to incorrect treatment decisions and patient harm if a test result is not valid.

The current bipartisan draft of VALID is the result of a years-long process of stakeholder engagement and represents a balance between regulatory certainty and flexibility for innovation. The VALID Act proposes a system of shared oversight where the highest risk tests are reviewed by FDA, while developers can bring low-risk tests immediately to the market. Multiple exemptions are created to ensure continued innovation and patient access, while processes like technology certification and the use of accredited third-party reviewers are envisioned as ways to ensure timely and efficient review.

Palliative Care and Hospice Education and Training Act (PCHETA)

ACS CAN also urges you to include S.4260, the Palliative Care and Hospice Education and Training Act (PCHETA) in the final package. Palliative care provides relief of pain, stress, and other debilitating symptoms of serious illness, such as cancer, cardiac disease, respiratory disease, kidney failure, Alzheimer's, AIDS, ALS, and MS. Its goal is to provide the best possible quality of life for patients and their families and can be provided starting at the point of diagnosis, alongside curative treatment, and throughout the continuum of care. By its very nature, palliative care is patient-centered care – appropriate treatments that meet patient goals. PCHETA would increase federal research funding for palliative care, including pain and symptom management, and would establish palliative care education and training programs for doctors, nurses, and other health professionals. This important legislation would also increase education among patients and providers about the availability and benefits of palliative care.

Medicaid Funding for Puerto Rico

Unlike in the states, where Medicaid funding responds to changes in health care costs and the number of people who qualify, Medicaid in Puerto Rico and the U.S. territories is partly funded through block grants, meaning this base funding does not adjust to meet growing health care costs, or increased need due to economic downturns, natural disasters, or pandemics. Unless Congress acts by December 16th the Federal Medical Assistance Percentage (FMAP) for Puerto Rico will decrease from its current 76 percent to 55 percent. This would result in more than one million residents in Puerto Rico who are currently enrolled in Medicaid experiencing deep cuts in their eligibility and benefits. We urge Congress to enact a multi-year enhanced package with a matching rate for Puerto Rico's Medicaid program to provide the island with the stability it needs to make investments in the program.

Thank you for your consideration. We look forward to working with you on the successful passage of year-end legislation that addresses the needs of cancer patients. If you have any questions or need additional information, please feel free to contact me directly or Tammy Boyd, Vice President, Federal Advocacy & Strategic Alliance at Tammy.Boyd@cancer.org.

Sincerely,

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network