CANCER EARLY DETECTION ALLIANCE

August 13, 2021

The Honorable Diana DeGette
US House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
US House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton,

The undersigned members of the Cancer Early Detection Alliance (CEDA) appreciate the opportunity to provide comment on the *21st Century Cures 2.0 Discussion Draft* (Cures 2.0). We are particularly excited about the potential that this draft could have for improving the early detection of cancer.

CEDA

CEDA consists of national organizations representing a diversity of stakeholders, including patient advocacy organizations, healthcare professional societies, and industry leaders. CEDA's mission is to promote and expand access to quality, equitable early cancer detection and care, with a specific focus on reaching underserved communities and addressing racial and ethnic disparities. To this end, we seek to engage patients, providers, and other allies to promote legislation and regulation for the early detection of cancer, remove barriers to cancer care, and support and advance targeted and meaningful funding opportunities geared toward early detection.

Importance of Innovations in Cancer Early Detection

Early detection identifies cancer when it is most treatable and therefore is critical to increasing survival rates and improving outcomes for cancer patients. Detecting an individual's cancer early can help patients and their providers develop a treatment plan sooner, which can help prevent or delay cancer. The American Cancer Society estimates that in 2021, there will be nearly 1.9 million new cancer cases diagnosed and 608,570 cancer deaths in the United States.[1]

One of the most significant barriers to detecting cancer early is the lack of investment and support for the development of new technologies that would allow for timely detection without relying on the presentation of signs or symptoms of disease. Currently, the United States Preventive Services Task Force (USPSTF) recommends screening for only four cancers.

[1] American Cancer Society. *Cancer Facts and Figures 2021*. https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2021.html

However, there are over 100 different types of cancers, and unscreened cancers account for the majority of cancer-related deaths. Investing in innovation will help better detect all cancers at an earlier stage and lead to improved survival rates for cancer patients.

We appreciate that the original 21st Century Cures Act included specific, forward-thinking actions focused on cancer prevention and cures. Notably, the 21st Century Cures Act launched the Cancer Moonshot initiative. However, more can be done to advance the mission to end cancer as we know it. Not all cancers have benefitted from recent advances in diagnostic tools and treatments, and more work is needed to ensure these patients have access to life-saving technologies and care.

The recent COVID-19 public health emergency resulted in a drastic decrease in individuals getting screened for cancer. Preventive cancer screenings dropped by as much as 94% during the first four months of 2020.[2, 3] Fewer screenings led to a decrease in cancer diagnoses, but not an actual decrease in cancer incidence. The National Cancer Institute predicts almost 10,000 excess deaths over the next decade from breast and colorectal cancer alone because of pandemic-related delays in diagnosing and treating these cancers.[4]

Legislative support for advancement in innovative and breakthrough technologies for early cancer detection is even more critical at this time as many individuals delayed their routine cancer screenings due to COVID-19. We believe that now is a critical time to improve early cancer detection, and Cures 2.0 is the perfect vehicle given the legislation's history in advancing breakthrough technology. Please consider the following recommendations.

Modernizing the United States Preventive Services Task Force (USPSTF)

The USPSTF, an independent professional body, makes recommendations that directly influences coverage of preventive services, such as cancer screenings, by Medicaid, Medicare and private insurance under the Affordable Care Act (ACA). However, USPSTF is limited in its ability to quickly respond to innovations in healthcare, limiting patient access. Further, USPSTF's review and recommendation process is neither transparent nor responsive to all relevant stakeholders. For example, in 2012, USPSTF issued a recommendation against routine prostate-specific antigen (PSA)-based prostate cancer screening for healthy men without engaging urologists and other medical specialists. To ensure that USPSTF is accountable and responsive to stakeholders, including patients the process should change.

[2] https://ehrn.org/articles/delays-in-preventive-cancer-screenings-during-covid-19-pandemic/

[3] https://www.propublica.org/article/a-crisis-of-undiagnosed-cancers-is-emerging-in-the-pandemics-second-year

[4] https://www.propublica.org/article/a-crisis-of-undiagnosed-cancers-is-emerging-in-the-pandemics-second-year

The Cures 2.0 legislation presents an opportunity to modernize the USPSTF review process and make it more transparent, responsive, and facile. With Cures 2.0 calling for advancements in preventive care, it is a natural vehicle for updates to the USPSTF review and recommendation process. Specifically, Cures 2.0 should establish a more frequent review cycle that includes public input from relevant experts. Cures should also ensure that membership and stakeholder input is robust, transparent and made up of diverse stakeholders. One way to improve stakeholder engagement would be to establish a stakeholder panel of specialist clinicians who are experts in their relevant field(s).

Diversity in Clinical Trials

CEDA strongly supports the language in the draft legislation that addresses barriers to participation by historically underrepresented populations, including efforts to increase diversity in clinical trials. Diversity in trials is crucial to improving cancer early detection. Clinical trials function as a gatekeeper to bringing new medicines and diagnostic tools safely to patients and communities. Racial and ethnic minority participation in clinical trials helps researchers find better treatments and screening options for cancer by uncovering racial and ethnic differences in, for example, disease biology and therapeutic responses. Ultimately, inclusion of racial and ethnic minorities will improve cancer screening for everyone and is likely to prevent cancer among underrepresented populations. A recent study found that there is evidence of cancer screening disparities linked to lower socioeconomic status and race. Black Americans die of all cancers, combined, at a rate higher than any other racial group, and cancer is the leading cause of death among Latinos. Diversification of clinical trials for both diagnostics and therapeutics can help improve cancer diagnosis and care for everyone. As such, we are pleased to see the focus of Cures 2.0 on ensuring diversity in clinical trials.

Advanced Research Projects Agency for Health (ARPA-H)

CEDA is supportive of any effort that will lead to improved cancer screening tools. We are hopeful that ARPA-H will lead to innovations in cancer early detection research and development by accelerating the often-long grant review and approval processes at the National Institutes of Health (NIH) research grants. We have important questions about what ARPA-H will look like if housed within NIH, including how this new approach will complement and enhance efforts to improve cancer early detection.

Cancer sounds like one disease but is many with different subtypes, prognoses, treatment modalities and outcomes. Preventing, detecting, and treating cancer will require a focused and coordinated response. Through ARPA-H, the government and private sector must work together to achieve innovation in cancer diagnosis, treatment, and prevention to move from research to action. Efforts to advance cancer research will also require a coordinated effort

between governmental agencies, including the FDA, NIH, Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services (HHS). As you continue to develop the structure of ARPA-H, we recommend that you work with coalitions, such as CEDA, to ensure that the response is coordinated and focused.

Now more than ever, support for robust early cancer screening infrastructure is needed as we seek to address the impact of COVID-19 on cancer-related morbidity and mortality. We look forward to working with you as you continue to move towards the 21st Century Cures 2.0 Act. Please contact Peggy Tighe at Peggy.Tighe@PowersLaw.com or Taryn Couture at taryn.couture@powerslaw.com if you have any questions about the information provided here.

Sincerely,

CEDA

American Osteopathic Association *American Urological Association*

Colon Cancer Coalition *Freenome* *Guardant Health*

Ovarian Cancer Research Alliance *Prevent Cancer Foundation*

ZERO - The End of Prostate Cancer