February 4, 2022

The Honorable Patty Murray
154 Russell Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
217 Russell Senate Office Building
Washington, DC 20510

Dear Chairwoman Murray and Ranking Member Burr,

The Association for Clinical Oncology (ASCO) applauds your bipartisan commitment to strengthening our nation's healthcare system. ASCO represents nearly 45,000 clinical oncologists, researchers, and other oncology professionals who treat and study patients with cancer across the country. We are pleased to submit the following comments in response to the *Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act),* which contains important provisions that would not only improve the nation's public health and medical preparedness systems, but improve the U.S. healthcare system more broadly.

Title II: Improving Public Health Preparedness and Response Capacity

ASCO applauds the inclusion of provisions to address disparities in healthcare by creating grant programs to support evidence-based projects that aim to address social determinants of health (SDOH) in **Section 201 in the draft**. ASCO's 'COVID-19 Road to Recovery Report: Learning from the COVID-19 Experience to Improve Clinical Research and Cancer Care' addresses opportunities to make cancer care and research more accessible to and equitable for patients in every community by applying lessons learned in the response to the COVID-19 pandemic and includes specific recommendations regarding SDOH.

ASCO's 2020 report outlines the mitigation measures that health care institutions, practices, and workers put into place in order to protect patients during the pandemic and resulting public health emergency, and to prevent disruptions in care. The report includes specific recommendations about the importance of data collection to better understand the impact of COVID-19 on screening, treatment and outcomes for patients with cancer and highlighted the importance of ensuring COVID-19 registries collect data on SDOH.

ASCO applauds you for including **Section 213**, which aims to create modern, standardized, and interoperable healthcare data systems. The lack of standardized

data capture, reporting, and metrics continues to be a significant challenge in our pursuit of equity. Cancer disparities research has been limited by a lack of comprehensive, consistent data on factors that impact disparities in cancer care and patient outcomes, including a patient's social status and demographics, community and lifestyle factors, and biology and genetics. Widespread variation in data collection methodologies has also compromised the utility of select data sets for disparities research. Having a recognized standard set of demographic questions and variables would demonstrably benefit stakeholders' ability to document, understand, and begin to address systemic inequities.

ASCO has also endorsed *the Social Determinants Accelerator Act* (S. 2986/H.R. 2503), which would create the Social Determinants Accelerator Interagency Council tasked with distributing grants for social determinants accelerator plans, allowing communities to tackle SDOH more effectively by improving data collection and coordination of services.

Title IV: Modernizing and Strengthening the Supply Chain for Vital Medical Products

During the pandemic, healthcare providers struggled to obtain medications and supplies essential to patient care, including the sedatives necessary to mechanically ventilate patients, personal protective equipment (PPE) such as gloves and masks, and ancillary devices and supplies, such as syringes and swabs. ASCO strongly supports **Sections 402, 404, and 408** of the bill, which would take considerable steps towards shoring up our Strategic National Stockpile by conducting an assessment on product vulnerabilities, issuing guidance on how to access the strategic national stockpile and regular reporting on stockpile depletion.

Title V: Enhancing Development and Combating Shortages of Medical Products

ASCO is especially pleased to see the inclusion of **Section 502**, aiming to modernize clinical trials through decentralization, the use of digital health technologies, and innovative clinical trial design. While the COVID-19 pandemic accelerated the need for clinical trials in which patients could participate at or close to home, researchers have long endeavored to make clinical trials more convenient for participants. The decentralized approach could open the door to clinical trials for a much broader array of participants, such as those who live hours from a trial site or do not have the ability to make repeated visits to the trial site due to work or caregiving schedules. Decentralized trials have several potential benefits including reduced patient and sponsor burden and increased accrual and retention of a more diverse trial population and reduce exposure to COVID-19 for vulnerable patient populations.

ASCO has endorsed the *Diversifying Investigations Via Equitable Research Studies for Everyone (DIVERSE) Trials Act* (H.R. 5030/S. 2706), which would make it easier for all patients to participate in clinical trials while removing barriers that are known to keep certain racial and ethnic groups, older adults, rural residents, and those with limited incomes from being appropriately represented. The legislation would permit individuals to receive financial support for the non-medical costs associated with their participation in clinical trials, by creating a statutory safe harbor for clinical trial sponsors to use in reimbursing such costs. Additionally, the bill would allow trial sponsors to provide individuals with the technology necessary for them to participate remotely in clinical trials and would require the Department of HHS to issue guidance on decentralized clinical trials.

Finally, ASCO is supportive of several provisions aimed at mitigating drug and device shortages. Specifically, **Sections 505, 511, 512, 515, 516, and 517.**

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Drug shortages are an ongoing public health concern in the United States. Over the last several years, natural disasters, quality problems, manufacturer consolidation, and other issues have disrupted pharmaceutical manufacturing and have left the U.S. healthcare system on the brink of a significant public health crisis multiple times. The COVID-19 public health emergency further underscored the vulnerability of our nation's healthcare supply chain. In June 2020, ASCO sent a letter to Congressional leadership urging swift action to address drug shortages, specifically recommending that Congress:

- Require that manufacturers be more transparent with the Food and Drug Administration about potential drug shortages
- Require manufacturer transparency around their sources of raw material–such as active pharmaceutical ingredients (API)–including which state and country the API come from
- Require manufacturers of critical medications and supplies to develop a reasonable contingency plan in the event of a production interruption or shut down
- Create requirements for supply chain resiliency, including multiple manufacturing sites for important drugs and multiple suppliers of API for the same drug
- Create incentives for manufacturers to increase production when drug shortages occur

The provisions noted above within the *PREVENT Pandemics Act* would take a necessary first step towards mitigating these ongoing disruptions and shortages.

Advanced Research Projects Agency for Health

ASCO is eager to work with Congress and the Administration on the proposed Advanced Research Projects Agency for Health (ARPA-H), which has the potential to transform and improve medicine and health by funding bold, high-risk projects that could create new capabilities and that require large-scale, sustained coordination. As you finalize the text of this package and may consider the addition of ARPA-H authorization language, we encourage you to solicit further input from stakeholders. ASCO has established a set of broad principles for consideration in the creation of ARPA-H and look forward to continuing the conversation on the proposed agency.

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ASCO looks forward to working with you as you craft final language and advance this important legislative package. Should you have any questions on the response to the discussion draft please do not hesitate to contact Kristin Stuart at Kristin.Stuart@asco.org.

Sincerely,

Howard "Skip" Burris, MD, FASCO

Chair of the Board
Association for Clinical Oncology