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March 30, 2020

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

The Honorable Steny Hoyer
Majority Leader
United States House of Representatives
Washington, DC 20515

The Honorable Kevin McCarthy Minority Leader United States House of Representatives Washington, DC 20515 The Honorable Mitch McConnell Majority Leader United States Senate Washington, DC 20510

The Honorable Charles E. Schumer Minority Leader United States Senate Washington, DC 20510

Dear Speaker Pelosi, House Majority Leader Hoyer, House Minority Leader McCarthy, Senate Majority Leader McConnell, and Senate Minority Leader Schumer:

As members of the Board of Directors of the American Association for Cancer Research (AACR), on behalf of the more than 47,000 laboratory, translational, and clinical researchers; physicians and other healthcare professionals; population scientists; and patient advocates who constitute our national and international membership, we applaud your tireless efforts to address the COVID-19 national health emergency, which include your recent passage of the historic \$2 trillion "Coronavirus Aid, Relief, and Economic Security Act" (the "relief, recovery, and stimulus" bill) to address the economic fallout from the COVID-19 pandemic and provide vital emergency funding for hospitals and other essential elements of our nation's healthcare infrastructure.

Cancer researchers are at the forefront of biomedical research in the development of molecular diagnostics and therapeutics, and there is a convergence of coronavirus biology with cancer research that will have clinical importance. As the first and largest organization dedicated to the prevention and cure of all cancers through research and patient care, the AACR has the ability to marshal its members' expertise and broad experience to aid the national COVID-19 response. The scientific and clinical knowledge of AACR members positions us to contribute in a major way to the deployment of resources and the advancement of research to overcome this pandemic. Time is of the essence, and we call on you and your colleagues in Congress to move swiftly forward to take the following steps to alleviate the COVID-19 public health emergency, while also ensuring patients with cancer are protected and the cancer workforce remains vibrant.

A Global Call to Action to Conquer COVID-19

Urge President Trump to use his powers to immediately and fully implement the Defense Production Act (DPA) to direct industries to accelerate the manufacture of all the crucial medical equipment desperately needed to protect our frontline healthcare providers and to save the lives of those suffering from COVID-19. It is absolutely critical that we equip our healthcare providers currently entrenched in a "medical war zone" with the personal protective equipment (PPE) that is necessary to keep them, their families, and others safe, such as surgical and N95 masks, gloves, gowns and face shields. In addition, we implore you to take steps that provide critically ill patients with access to advanced life support systems, such as ventilators and ECMO devices. To this end, we strongly support the Medical Supply Chain Emergency Act, which was introduced on Monday, March 23, 2020, by Senators Chris Murphy (D-Connecticut) and Brian Schatz (D-Hawaii), as it calls on President Trump to use his powers to fully implement the DPA and produce 500 million masks as well as 200,000 ventilators and other desperately needed supplies including nasal swabs.

Implement widespread testing of symptomatic individuals immediately, as well as asymptomatic individuals who have been exposed to infection or those in high-risk patient groups such as patients with cancer.

Testing and tracking the novel coronavirus are vital measures to understanding the spread of COVID-19 in our communities, which will allow us to better isolate identified cases and contain the infection clusters that are present. Overly restrictive testing criteria, such as testing only those who had contact with an already infected individual or traveled to a specific foreign country, will not allow us to adequately assess and combat this rapidly advancing health crisis. Our healthcare providers should be able to access testing because they are on the front lines combatting this pandemic and are at increased risk of contracting and spreading this virus. It is also crucial to recognize that cancer treatment leaves many patients with compromised immune systems, placing them at increased risk for a severe, life-threatening case of COVID-19. Therefore, patients with cancer should be tested for COVID-19 whenever their oncologists or other healthcare providers deem it appropriate. Testing alone is not sufficient; a deidentified, national central database should be established immediately to track novel coronavirus positive cases and those who are antibody positive, i.e., who have been exposed to the virus and developed immunity.

Continue a nationwide social distancing policy for as long as necessary to reduce COVID-19 disease incidence and overall death toll, effectively protecting our frontline healthcare providers. Pulling back or even pausing our social distancing efforts prematurely would likely result in tens of thousands of additional cases and overwhelm our healthcare system. It is imperative that current social distancing policies be extended as required to end this national emergency.

Uphold the rigorous, science-based approach of the U.S. Food and Drug Administration (FDA) in its approval of all COVID-19 therapies. It is essential that the administration protect the agency's high standards of safety and efficacy when approving COVID-19 therapies. We appreciate the rapid issue of guidance to industry, "Coronavirus (COVID-19) Update: FDA Issues Guidance for Conducting Clinical Trials," which prioritizes the safety of patients enrolled in clinical trials and provides insight into how to move forward with clinical trials already underway. The agency should continue to be open to well-designed, collaborative, innovative clinical trial strategies that will expedite the prevention, detection, and treatment of COVID-19.

Encourage the use of the FDA's expanded access program, sometimes referred to as "compassionate use," as the primary pathway for patients to access investigational medical products and urge the agency to immediately deploy a COVID-19 focused version of Project Facilitate. Project Facilitate is an innovative, common sense, single point of contact program that helps healthcare providers navigate expanded access for oncology therapeutics administered by the FDA Oncology Center of Excellence. Importantly, expanded access allows us to learn from the experience of every patient treated with investigational drugs, knowledge that will be vital for the conquest of COVID-19.

Provide the telehealth digital infrastructure and technology needed to ensure continuity of care for patients with cancer. During the COVID-19 pandemic, telehealth technology will be especially valuable to enable vulnerable patients to receive some of their care at home and avoid exposure to the novel coronavirus when visiting the clinic. The survival of patients with cancer depends on the continuity of access to care. Although patients with cancer are immune-compromised and at high risk of severe COVID-19 disease, their cancer treatment cannot be interrupted indefinitely without dire health consequences. The expansion of telehealth programs will help patients with cancer by facilitating regular communication with providers and enabling access to timely information about their care. As telehealth is implemented more broadly, we urge you to incorporate patient privacy safeguards into any associated policies.

Leverage the brain trust of cancer researchers and oncology healthcare providers who are contributing to our national capacity to address COVID-19. Cancer researchers are serving the global and national interest by lending their scientific and clinical expertise to address the COVID-19 pandemic. AACR members have the ability to drastically impact current efforts in diagnostic and treatment strategies. They are already working to address coronavirus testing shortages by repurposing their laboratory space to make COVID-19 testing kits and are collecting and analyzing data on patients with cancer and COVID-19 through initiatives such as the COVID-19 and Cancer Consortium (CCC19).

Cancer researchers are able to leverage their laboratory expertise and capacity in numerous ways including to: aid in drug screening, development, and repurposing; develop antibody tests; investigate the efficacy of convalescent serum from recovered COVID-19 infected persons as treatment; and conduct vaccine research for COVID-19. Clinical cancer researchers are also well positioned to help manage aspects of care for COVID-19 patients. Through the study and use of new immunotherapies, including CAR T-cell therapies, cancer researchers have gained experience using immune-modulating therapies and managing severe immune-mediated side effects also seen in COVID-19. Serious consideration should be given to engaging cancer researchers from various disciplines, oncology healthcare providers, and laboratory professionals in a call to action to study, detect, and defeat COVID-19. The AACR is prepared to survey its constituents to identify volunteers who are willing to help conduct COVID-19 testing during this time when research laboratories are not functioning.

Impact of COVID-19 on Cancer and Medical Research

Continue your exceptional support and steadfast commitment to cancer and medical research. During the past five years, you have prioritized funding for the National Institutes of Health (NIH) to the point that the agency's budget has increased by \$11.6 billion or 39 percent. The COVID-19 pandemic highlights the importance and value of the NIH portfolio, and emphasizes that this generous support must be sustained,

even more so during this period when our nation is facing a national health emergency. The support you have shown for cancer and medical research has contributed to a substantial reduction in cancer incidence and mortality. The age-adjusted U.S. cancer death rate declined by 29 percent from 1991 to 2017, a reduction that translates into 2.9 million cancer deaths avoided. Therefore, during the fiscal year 2021 appropriations process, we will be calling on you to help make sure this scientific progress continues.

The future of cancer and medical research depends on ensuring career continuity for researchers despite the adverse influences of COVID-19. Diminished research time and output due to the COVID-19 crisis will unduly harm less-established investigators when they apply for grants. This professional uncertainty is compounded by financial insecurity, as many early-career scientists struggle with considerable student loan debt. We appreciate the support you have shown in the passage of the relief, recovery, and stimulus bill to help Americans who are struggling to repay their student loans. We ask that you consider additional measures that will encourage these vulnerable scientists to persist in their research careers, such as directing the NIH to extend the duration of grants to accommodate research disruptions caused by COVID-19 and modifying eligibility windows for special career stage designations (e.g., postdoc and early-stage investigator).

Sustain scientific innovation and progress for the benefit of patients and cancer survivors. We have serious concerns about the toll that economic stress resulting from the COVID-19 public health challenge is taking on scientific innovation. Assurances from NIH Deputy Director for Extramural Research Michael Lauer and National Cancer Institute (NCI) Director Ned Sharpless that NIH and NCI peer review and grants administration will continue as previously scheduled are encouraging. However, while a focus must be maintained on conquering COVID-19, a prolonged halting of our national cancer research efforts will slow the recent rate of progress in providing patients with new therapies for cancer. Unfortunately, the current COVID-19 crisis is resulting in cancer clinical trials grinding to a halt, and healthcare and PPE shortages have a deleterious effect on all areas of cancer research and patient care. When this global pandemic is behind us, Congress must provide the necessary resources to maximize the potential for future advances in cancer and medical research and treatment.

Promoting innovation through the dissemination of new cancer research findings among scientists and other stakeholders is at the core of the AACR mission, and rapid communication of the latest developments in science and medicine is now more important than ever. Therefore, effective immediately, the AACR is making any journal article containing information directly relevant to advancing our understanding of COVID-19 open access and available online. Further, we are already hard at work conducting web-based conferences, and we will organize sessions at our scientific meetings that address the biologic and clinical intersection of COVID-19 and cancer.

In conclusion, your leadership and support over the past several decades have ensured the development of a highly effective National Cancer Program that can now apply its unique and substantive knowledge and skills to help society defeat this virulent pathogen. We recognize the need to take action immediately to vanquish this virus that threatens the lives of millions of Americans, ravages our economy, and derails scientific progress. Otherwise, our healthcare system will fail and our most vulnerable patients, including those with cancer, will disproportionately suffer. The AACR and its members stand ready to work with you and other members of Congress to achieve the vital recommendations set forth herein. Thank you in advance for your consideration.

Sincerely,

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