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December 8, 2020

Joseph R. Biden, Jr.  
President-Elect  
1401 Constitution Avenue, NW  
Washington, D.C. 20230

Kamala Harris  
Vice President-Elect  
1401 Constitution Avenue, NW  
Washington, D.C. 20230

Dear President-Elect Biden and Vice President-Elect Harris:

The Association for Clinical Oncology (ASCO) extends its congratulations on your election as President and Vice President of the United States. With over 45,000 members, we represent the world's leading group of professionals who treat people with cancer. For over 50 years, ASCO and its affiliate, the American Society of Clinical Oncology (the Society) have been in the forefront advocating for quality treatment and services for cancer patients. We are the authoritative source for reliable information on cancer care and cancer clinical research and we have always appreciated your steady support, including your visit during the Society's 2016 Annual Meeting. We were especially honored, in turn, to help with the President-Elect's Cancer Moonshot Initiative and ASCO is eager to continue that spirit of collaboration accelerate progress as we work to address the complex issues facing oncology—and the entire healthcare system.

In addition to our translational research and clinical efforts, our organizations have long focused on ways to reduce disparities in cancer outcomes affecting racial and ethnic minorities, rural populations, people without insurance, and other disadvantaged populations. The Society recently published a policy statement that calls for more aggressive steps to achieve equity for all patients, particularly as the global SARS-COV-2 pandemic exacerbates existing disparities. Americans have lost their health insurance coverage, physician practices and hospitals have closed, and cancer screening and treatment have been interrupted. The need to ensure equitable access to high-quality cancer care and research is critical, now more than ever. In the short run, no cancer breakthrough offers as much benefit as quickly for Americans overall as would narrowing the gap in access to care and research.

Understanding the President-Elect's deep commitment to ensuring quality, equitable cancer care for every American, we urge action on the following issues at the beginning of the administration and are ready to help in any way possible:

**1. Require Medicaid coverage of routine care costs for patients on clinical trials.**

Robust clinical trial participation—representative of all patients with cancer—is vital to achieving insights that lead to progress against this disease. Clinical trials that enroll Americans in a representative manner will generate results that apply to all and will do so quickly. Currently, Medicaid serves many demographics, including ethnic minorities and women, who are currently underrepresented in clinical trials because of a fixable structural barrier. With lower participation in clinical trials from the Medicaid population, these patients do not have the opportunity to benefit from cutting-edge treatments and are not reflected in the outcome of the clinical research. And the entire research enterprise is slowed.

To this end, ASCO has worked with bipartisan champions in Congress to advance the *CLINICAL TREATMENT Act*. This legislation would require Medicaid, like Medicare and commercial insurance, to cover routine care costs for patients with life-threatening conditions on clinical trials. Medicaid insures over one-fifth of the US population and is the only major payer that is not required by federal law to cover these costs for its beneficiaries. This coverage is already assured for Medicare beneficiaries, through administrative action taken in 2000, and for patients with private health insurance by means of the Affordable Care Act. Although fifteen states plus Washington, D.C. require their Medicaid programs to cover these costs, there are still as many as 41.6 million Medicaid patients without this essential coverage.

ASCO has been encouraged to see bipartisan congressional support for the *CLINICAL TREATMENT Act*, but it is also possible to achieve this coverage through regulatory action at the Centers for Medicare and Medicaid Services (CMS). We implore President-elect Biden to implement this coverage for Medicaid enrollees, especially considering the increase in Medicaid enrollment as a result of COVID-19. This would be a win for patients seeking the best possible care, a win for equity, and a win for research!

**2. Ensure access to critical therapies for cancer patients by enacting reasonable and consensus-based drug pricing reforms.**

ASCO is deeply concerned about the impact of rising drug prices on cancer patients. ASCO members are experts in the clinical aspects of treating people with cancer, including the benefits and risks of drug regimens. We also are keenly aware of the financial impact that cancer treatment has on patients and families (“financial toxicity”). New approaches are necessary to manage cost while still sustaining innovation that is essential to progress. To that end, ASCO has recommended a series of demonstration projects designed to test varied approaches to controlling the cost of cancer drugs. These experiments should be contained

Association for Clinical Oncology

and voluntary, yielding insight about the impact of the policy change on drug pricing, while avoiding disruptions in access to care.

ASCO is alarmed by the Trump administration's recent move to control drug prices using a mandatory, nationwide demonstration project (mis-labeled an "experiment") testing a "most favored nation" approach to drug pricing and reimbursement. This interim final rule skirts the opportunity for public comment normally required through the advance notice and comment rulemaking process. The rule subjects every provider and patient to this "test" with no control group or other mechanisms to understand the policy's impact on either pricing of drugs or the ability of patients to receive appropriate therapies. Indeed, the administration's own analysis estimates that this policy change will either reduce access or cause almost 20% of patients to forego care by the third year of, and continuing until the end of, the seven-year demonstration project.<sup>1</sup> Patients with cancer often need very specific treatment to comport with evidence-based care goals and obtain optimal outcomes. That the rule plans for and achieves part of its savings by limiting or restricting access to care for nearly one in five patients is unconscionable and unacceptable.

Responsible, comprehensive drug pricing reform should be a top priority for this nation and ASCO stands ready to work with the President-Elect toward that goal. We urge the incoming administration to reverse the interim final rule and work with ASCO and other stakeholders toward reform that can achieve the dual goals of lowering prices and guaranteeing cancer patients the therapies they need.

### **3. Protect the sanctity of doctor-patient decision making by reining in inappropriate utilization management protocols.**

ASCO remains committed to working with the Administration and Congress to lower the overall cost of health care in our country. While there are several avenues to achieve this, many payers have resorted to potentially harmful utilization management tools to drive down the cost of care. Two utilization management tools are especially concerning for patients with cancer: step therapy and prior authorization.

ASCO was concerned to see the Trump Administration increase use of step therapy in Medicare Advantage (MA) plans, especially for Part B drugs. Step therapy ("fail first") policies—which require a plan-preferred drug to fail before patients may receive the drug recommended by their physician—are generally inappropriate for use in oncology treatment and can lead to disease progression and/or irreversible damage to a patient's health.<sup>2</sup> Step therapy policies also

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<sup>1</sup> Table 11, MFN IFR

<sup>2</sup> In fact, one study found that patients with breast cancer who experienced a delay of three months or more had a 12 percent lower 5-year survival rate than patients with shorter or no delays

undermine the doctor-patient relationship by requiring medication that contradicts what the provider has determined to be in the best interest of the patient.

ASCO strongly encourages President-elect Biden to reverse use of step therapy in Medicare Advantage plans, and to work with Congress and stakeholders on alternative solutions to lower cost while ensuring Medicare beneficiaries have access to the life-saving treatments they need.

Similarly, cancer care providers have cited prior authorization as a significant practice pressure and source of treatment delay. Most drugs and services gain approval after a mandated request for prior authorization, meaning the process is primarily a factor in delaying care and consuming provider resources—with no appreciable difference in savings. Cancer is a disease in which every treatment day lost can make a difference in outcome. Delays in care are particularly harmful for patients with cancer because they can lead to serious complications and irreversible disease progression.<sup>3</sup>

ASCO has joined other groups in the medical community to support the *Improving Seniors' Timely Access to Care Act*, bipartisan legislation that would help protect patients from unnecessary delays in care by streamlining and standardizing prior authorization under the Medicare Advantage program, providing much-needed oversight and transparency of health insurance for America's seniors. One-third of all Medicare beneficiaries are enrolled in Medicare Advantage plans, and nearly four out of five MA enrollees are in plans that require prior authorization for some services. The Centers for Medicare and Medicaid Services (CMS) could implement these patient protections and oversight through regulatory action. ASCO calls on President-elect Biden to work with physician and patient communities to ensure Americans are protected from delays in care due to prior authorization requirements.

#### **4. Support robust funding for the National Institutes of Health and the National Cancer Institute.**

We appreciate the efforts of President-elect Biden during his tenure in the Senate and the White House to advance cancer care through investments in biomedical and cancer research. The progress that has resulted from that effort is undeniable. Between 2016 and 2017 the United States saw a 2.2 percent drop in cancer mortality; the largest single-year drop in deaths ever reported. Next year will be the 50th anniversary of the *National Cancer Act*, providing an opportunity to expand on the efforts of the Beau Biden Cancer Moonshot and renew our country's commitment to the fight against cancer. Robust, sustained, and predictable funding growth for the National Institutes of Health (NIH) and the National Cancer Institute's (NCI)

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<sup>3</sup> In a survey by the American Cancer Society Cancer Action Network (ACS CAN) one in three patients and caregivers reported delays in care because of prior authorization. In an AMA survey, 91% of respondents reported that prior authorization has a "significant or somewhat negative impact" on patient clinical outcomes.

baseline budget are critical towards advancing our nation's work towards combating, and ultimately curing, diseases like cancer.

Over the last few years, Democrats and Republicans have set aside differences to prioritize funding for the NIH. This strong commitment to scientific discovery has helped the research community continue current momentum and sustain our nation's position as the world leader in biomedical research. We are in an exciting and promising era of medical research with new discoveries leading to major improvements in the way we care for patients with cancer at an accelerating pace. The result is that patients with cancer are living longer and better than ever before. Every major medical breakthrough in cancer started with the NIH and NCI. Beyond that, renewed investment in the NIH has supported more than 476,000 jobs across the country and generated more than \$81 billion economic activity in fiscal year (FY) 2019 alone.<sup>4</sup> Continued investment in biomedical and cancer research is another win-win: it will help spur our nation's recovery in the wake of the economic consequences of the ongoing public health emergency and generate new treatments and better health for all Americans.

Despite the progress that has been made over the past half-century, cancer remains the nation's second leading cause of death, and more funding is desperately needed to meet increasing demand for research grants at the NCI. Between FY2013 and FY2018, the most recent year for which data are available, the number for Research Project Grants (R01) applications rose by 45.9 percent, the most of any Institute or Center (IC) within the NIH. During the same time period, funding for the NCI rose by just 20 percent. This extraordinary demand for grant funding at NCI reflects excitement about the possibilities for progress and innovation in cancer research, however, due to insufficient funding, the NCI is only able to fund about 11 percent of submitted applications, leaving potential breakthroughs unfunded.<sup>5</sup>

Our nation must continue this forward momentum with sustained budget growth. As President-elect Biden's Administration works on budget priorities for FY2022 and beyond, ASCO encourages robust increases in funding for the NIH and NCI.

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We recognize the challenges facing the administration during this unprecedented health care and economic crisis. ASCO stands ready to work with you toward a world where every cancer

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<sup>4</sup> NIH's Role in Sustaining the U.S. Economy: 2020 State-by-State Update. United for Medical Research. February 2020. Retrieved from: <https://www.unitedformedicalresearch.org/wp-content/uploads/2019/04/NIHs-Role-in-Sustaining-the-US-Economy-FY19-FINAL-2.13.2020.pdf>

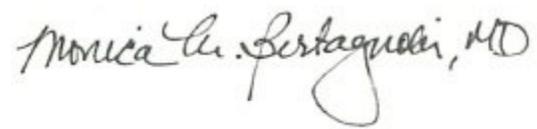
<sup>5</sup> NCI Director's Report 2018 and Plans for NCI's Fiscal Year 2019 Budget. Norman E. Sharpless, MD. Retrieved from: <https://www.cancer.gov/news-events/cancer-currents-blog/2018/sharpless-nci-fy2019-budget>

Association for Clinical Oncology

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patient has access to quality cancer care. Please call on us, our nation's cancer experts, to assist you as you move forward with your transition.

Sincerely,

A handwritten signature in black ink that reads "Monica L. Bertagnolli, MD". The signature is written in a cursive style with a large, looping 'M' and 'L'.

Monica Bertagnolli, MD, FACS, FASCO  
Chair of the Board  
Association for Clinical Oncology

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