September 6, 2016

The Vice President
Old Executive Office Building
Washington, DC 20501

Re: Request for Recommendation of Immediate Actions for the National Cancer Moonshot

Dear Mr. Vice President,

Thank you for the invitation to submit our ideas for “quick wins” that could be made toward the National Cancer Moonshot during the remainder of your term in the White House. We were honored to have you speak at the American Society of Clinical Oncology (ASCO) Annual Meeting in June to share your vision to accelerate the pace of cancer research — and we welcome the opportunity to identify ways the Administration could make strides toward realizing that vision in the immediate future.

In addition to the recommendations we have made previously, ASCO sees several areas where you and the Cancer Moonshot Task Force can take immediate and practical steps that would have a profound impact on our ability to conduct research, better understand cancer, and get closer to a cure.

Expand Access to Clinical Trials
Currently, patients with low socio-economic status, older adults, and ethnic and racial minority groups are underrepresented in clinical trials. A significant barrier to participation for many patients is that, unlike Medicare and private insurers, Medicaid is not required by federal law to cover routine care costs incurred by patients in clinical trials. While this may have been an oversight, addressing this issue would immediately impact the ability of tens of thousands of Americans to enroll in clinical trials.

Thankfully, there’s a clear path forward. The Clinton Administration issued an Executive Order to provide Medicare coverage for routine coverage of clinical trials. We would urge President Obama to use that same authority to preserve that same right for Medicaid patients.
Similarly, Medicare’s national clinical trials coverage policy requires researchers to prove “therapeutic intent” and determining benefit to patients is a central aim and question of any clinical trial. Nevertheless, this requirement has been used to deny coverage of routine patient costs in phase I trials, which form the foundation for progress in more effective treatments. President Obama should issue an Executive Order affirming that all phase I trials in cancer meet Medicare’s coverage requirement for “therapeutic intent.”

**Invest in Pragmatic Trials**

Pragmatic trials are designed to evaluate the efficacy of an intervention in real-world conditions and to produce results that are generalizable to routine clinical care. Industry funded only nine pragmatic clinical trials between 1996 and 2010 – but funded thousands of traditional efficacy trials during that same time period. Increasing public investment in pragmatic, multi-stakeholder clinical trials that are more integrated with existing clinical practice standards would bring immediate gains. This investment would enable more clinicians to be familiar with the research process and expand patients’ participation in clinical research.

One such example of this is ASCO’s Targeted Agent and Profiling Utilization Registry (TAPUR) Study. The TAPUR study is evaluating molecularly targeted cancer drugs and collecting data on clinical outcomes to learn about additional uses of these drugs outside of indications already approved by the FDA. TAPUR is a study grounded in real-world clinical practice – relying on physician judgement, collecting clinical outcomes as monitored in routine practice, and enabling participation of patients who are more reflective of cancer patients overall.

**Streamline Reporting and Reduce Administrative Burdens**

You made a passionate call for teamwork and coordination at ASCO’s Annual Meeting. We heard you and we agree this collaboration is necessary to speed the pace of progress. The siloed nature of our own federal agencies often creates additional hurdles and costs for cancer researchers as well. Several areas where small changes would result in immediate and meaningful improvements for researchers include:

- **Standardize Reporting.** Each federal agency that funds research uses different terminology for reporting adverse events. This creates an added and unnecessary administrative burden on researchers for something that has no scientific or safety purpose. In fact, this practice is self-defeating because it makes it more difficult for regulators and investigators to compare adverse events across clinical trials. We’d propose a quick and easy fix: all federal agencies that fund research should adopt the FDA terminology. Similarly, your Cancer Moonshot Task Force could create a single, centralized, and universally-required portal for sponsors to report adverse events to further alleviate this burden.

- **Centralize Coverage Analyses.** For trials conducted across multiple sites, each site conducts its own independent coverage analysis to identify routine patient care costs that should be covered by insurance. This costs the research system
$600,000 for each multisite clinical trial it opens. That money could be much better spent on actual research. The NCI recently started to develop national coverage analysis reports for each of the trials that it opens so that research sites can use the analysis to submit insurance claims. All federally-funded clinical trials should follow this standardized approach.

We applaud the Administration for its commitment to the National Cancer Moonshot, and wish to help in whatever way can. It is in the spirit of your vision that we offer the above recommendations. From ASCO’s perspective, taking these steps would result rapidly accelerating the pace of cancer research and improving the lives of cancer patients and survivors immediately and indefinitely.

Most Respectfully,

Daniel F. Hayes, MD, FASCO
President
American Society of Clinical Oncology