January 12, 2016

The Vice President
Old Executive Office Building
Washington, DC 20501

Dear Mr. Vice President:

The American Society of Clinical Oncology (ASCO) is grateful for your longstanding support of cancer care and research, and we applaud your vision and commitment to a “moon shot” that will end cancer. As the national organization of nearly 40,000 physicians and other healthcare professionals specializing in cancer research, treatment and prevention, ASCO is fully engaged and prepared to support you in achieving that goal. There are many areas where your support and attention can make a tremendous difference, and we hope our constructive dialogue with your team last week is the beginning of a long-term collaboration. One immediate area for which you are uniquely positioned—and that we believe can revolutionize cancer care and research—is harnessing the potential of big data.

Nearly 1.7 million people are diagnosed with cancer each year in the United States, and the incidence of cancer is expected to grow significantly, reaching 2.3 million cases per year by 2030. The majority of cancers occur in older Americans, who are also Medicare beneficiaries. One of the most frustrating challenges we face as clinicians is that people with cancer have complex medical and other needs, yet almost all we know about cancer diagnosis, treatment, and prevention comes from a tiny subset of patients—the 3 to 5 percent who enroll in clinical trials. Clinical trials enroll relatively homogeneous patient populations, which leaves us with a lack of evidence to guide treatments for a large proportion of the other 95 to 97 percent who do not participate in, or do not qualify for studies. We thank you for your efforts to achieve stable and robust funding for federally funded research; it is critical. We believe your initiative could also focus on ways to strengthen the clinical trials infrastructure and we look forward to collaborating on that issue.

Clinical outcomes for millions of individuals with cancer are locked away in medical records and databases that, for the most part, do not communicate. By aggregating this real-life information into a common database—and making electronic health records truly interoperable—we can vastly speed
discovery and enable the possibility of personalized care for every cancer patient. Insights that have taken years to discern could happen much more quickly, helping us to understand treatments that work, those that don’t, and high impact areas where additional research is critically needed. In addition, the discoveries that your efforts support, can be returned quickly to patients and clinicians thereby democratizing data and speeding the distribution of advances. This vision is one that has been accomplished outside of medicine and we are excited by the possibility that we can accelerate learning and improve quality of care quickly using this approach.

In our meeting with your staff last week, we briefed them on a big data effort underway at ASCO, called CancerLinQ (Cancer Learning Intelligence Network for Quality). The primary purpose of CancerLinQ is to promote high quality care for every patient by quickly sharing and exchanging large amounts of data. Similar to the information-aggregating power of Google or Amazon, CancerLinQ will identify trends among millions of patients with almost every treatment, tumor type and genomic profile—and bring them to the attention of medical professionals who can translate them to improved patient care. As guardians of our patients’ health and well-being, sworn to put their interests first, we are driven solely by our mission to improve the care of cancer patients through optimal use of available treatments and rapid development of better approaches.

ASCO’s vision for CancerLinQ is to revolutionize what we know about and how we treat cancer. Providers who participate in CancerLinQ will be able to identify previously unseen patterns in patient characteristics, treatments, and outcomes that signal advances or require modifications of care plans. Cancer physicians will be able to compare the care they are giving against evidence-based guidelines. CancerLinQ will draw on a host of patient and practice data—including demographics, clinical notes, procedures, drug administration, laboratory results, and allergies, to name a few—to help patients and their physicians make medical decisions that are tailored for their unique circumstances. CancerLinQ will deliver personalized and unbiased treatment decision support at the point of care, truly enabling shared decision-making between doctors and patients. Our vision is that patients in every community and every setting, including under-resourced and rural areas, will have access to state-of-the-art information and cancer care heretofore unavailable to them.

ASCO has already made a significant investment of its own resources in making this vision a reality, working with the global software vendor SAP. However, despite the powerful combination of our commitment, our expert volunteers and the willingness of our Board of Directors to invest, the resources needed are substantial and significant roadblocks to the full operation of CancerLinQ remain. As we approach practices and health systems to share data with CancerLinQ, we have encountered challenges around intellectual property, data security, and a lack of interoperability among electronic health records. CancerLinQ is making steady progress, but we could move faster without these challenges that have slowed our ability to reach a critical mass of data—and to realize the full potential of big data in cancer. As you move forward with your moon shot we respectfully ask you to consider the following specific actions that will benefit all investigators and developers of big data initiatives:
Maximize federal support for big data initiatives. The explosion of new science, treatments and diagnostic tests make big data initiatives more important than ever so that we can quickly learn how best to apply these breakthrough treatments to the diverse U.S. population. Programs like CancerLinQ can only realize their potential if providers enroll in them. The more patient charts in the system, the greater the benefit to patients and the faster the discoveries to help inform treatment. Federal support of big data programs is needed to bolster this progress. Specifically, we ask that you:

- **Facilitate participation in big data initiatives by agencies like the Veterans Affairs Administration and the Department of Defense.** Enrolling their patients in big data programs like CancerLinQ would pave the way and provide much needed uptake of these programs. Additionally, providing incentives to institutions that receive federal funding for participation in big data initiatives would further encourage participation by the broader community.

- **Work with CMS and NCI to Link Medicare-SEER data to CancerLinQ.** One of the most widely used databases by health researchers today is the Medicare-Surveillance, Epidemiology and End Results (SEER) database, which combines Medicare claims with clinical data reported by tumor registries across the United States. Operated by the National Cancer Institute, SEER currently collects and publishes cancer incidence and survival data from population-based cancer registries covering approximately 28 percent of the nation’s cancer cases. In addition to covering only selected populations, SEER data do not include clinical information from physicians’ offices, where nearly 80 percent of cancer treatment occurs. Linking Medicare claims with both SEER and CancerLinQ would provide powerful clinical information now missing from Medicare/SEER.

- **Expand Medicare’s investment in coverage with evidence development.** The explosion of potential new targeted therapies is outpacing our cumbersome and inefficient clinical research infrastructure—and slowing our ability to understand what works and what does not. Coverage with Data Development (CDD) allows Medicare to advance coverage for promising new therapies, provided physicians report clinical experience and outcomes to a central database. ASCO has used this kind of approach in its Targeted Agent and Profiling Utilization Registry (TAPUR) Study. TAPUR is a non-randomized clinical trial that aims to describe the performance (both safety
and efficacy) of commercially available, targeted anticancer drugs prescribed for treatment of patients with advanced cancer that has a potentially actionable genomic variant. The study will provide approved targeted therapies that are contributed to the program by collaborating pharmaceutical companies, catalogue the choice of genomic profiling test by clinical oncologists and learn about the utility of registry data to develop hypotheses for additional clinical trials. We believe that expanding coverage with evidence development programs would be extremely effective in advancing the Vice President’s goals. CDD initiatives, especially in the area of precision medicine, would contribute to the overall move towards big data, improve patient access to promising new treatments and technologies and speed progress toward more effective treatment.

- **Support public private partnerships** to enhance federal agencies’ efforts to speed progress toward more effective and higher quality treatment. Two examples:

  - **Clinical experts should partner with the FDA** to streamline approval of new treatments, including providing expert advice on clinical trial endpoints, off label uses of existing therapies and recommending appropriate mechanisms to acquire safety data from diverse populations who were not included in clinical trials. ASCO and others have worked well with the FDA in these areas, but more robust support for programs such as these would be extremely helpful in speeding progress and in disseminating new treatment strategies to practicing physicians.

  - **CMS should partner with professional societies to reduce administrative burden** and achieve meaningful federal reporting requirements for physician performance. Administrative burden is becoming a serious barrier to patient care. Although new Medicare payment rules announced the goal of streamlining many of the existing programs, preliminary rules—and some that will govern over the next two years—appear to worsen, not lighten, this load. Further, there is significant confusion over requirements, with different direction coming from various components of the Administration. These operational issues—although they may sound mechanical—if not addressed, will interfere with our ability to translate vision into actual patient care. This is an urgent requirement.

- **Work with Congress to enact a new, stable funding mechanism for the National Institutes of Health (NIH) in 2016.** Until the increase approved by Congress in this year’s budget, the NIH has experienced what some have called a
“long period of drought.” The appropriations process has produced an unpredictable funding roller coaster, which has caused study delays, constant re-ordering of priorities, and missed opportunities in exciting areas of science. We urge you to put the power of your office behind initiatives such as those proposed in House and Senate legislation that would establish more predictable and stable funding for this vital core of our national health research programs. It is the NIH that identifies the early promise of new therapies and provides the nation’s critical infrastructure for clinical research. Unpredictable funding represents a long-term risk to innovation and significantly impedes the faster development of cures that you seek.

Your staff rightly pointed to your unique capacity as a convener who can bring together multiple stakeholders to solve complex policy problems. To that end, we recommend two high priority areas for your consideration:

- **Convene a blue ribbon panel on interoperability.** The Congress, federal government and private stakeholders have spent over a decade trying, but failing, to attain health IT systems that are interoperable. We now face a patchwork of platforms optimized for medical billing, but not high-quality clinical care. In fact, some IT platforms are not able to share information within the same health system. (Some institutions, for example, have installed a single vendor’s system that can’t exchange information between different physical settings or buildings.) While often a multifactorial problem, it is difficult to believe, given the technology capacity of so many other industries, that the barriers to interoperability are insurmountable. As Vice President, you have a unique convening power to bring together industry, government and other stakeholders to overcome these barriers in the sharing of data.

- **Convene a multi-stakeholder panel that is charged with recommending—by October 2016—action steps and specific policies that address rising cost of drugs.** The very advances that we find so exciting, and the big data projects that can identify their optimal use, are limited in impact if patients can’t afford the treatments. Drug pricing has been the subject of increasing public scrutiny and debate this past year and the issue will become only thornier as precision therapies—often used in combination—arrive to market with monthly price tags in the tens of thousands of dollars. We are keenly aware of the financial burden cancer treatment represents for patients and families, regardless of their personal circumstances. ASCO has had a special task force focused on cost and value of care for several years. We have developed an initial decision support framework to aid in selection of high value therapy that best meets individual patient needs and are
currently working on development of a tool physicians can use in discussing options with their patients. The tool will allow patients to weigh expected benefit of treatment options with toxicities and cost, determining with their physician which course to take. Efforts like the value framework are important, but that alone will not address this problem. Unless action is taken, price tags will be as much of a barrier to effective treatment as the lack of any treatment at all.

As the national organization spanning the breadth of cancer treatment and research, ASCO hopes nothing more than for you to achieve your goal to end cancer and stands ready to assist you in that endeavor.

Most Respectfully,

Julie M. Vose, MD, MBA, FASCO
President
American Society of Clinical Oncology