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June 19, 2015

The Honorable John Boehner  
Speaker  
US House of Representatives  
H-232, The Capitol  
Washington, DC 20515

The Honorable Nancy Pelosi  
Minority Leader  
US House of Representatives  
H-204, The Capitol  
Washington, DC 20515

**RE: 21<sup>st</sup> Century Cures Act (H.R. 6)**

Dear Speaker Boehner and Minority Leader Pelosi:

On behalf of the more than 35,000 members of the American Society of Clinical Oncology (ASCO), we commend the work of the US House of Representatives Committee on Energy and Commerce on its 21<sup>st</sup> Century Cures Act (H.R. 6). ASCO applauds the bipartisan effort put forth by the Committee in developing this comprehensive legislation and appreciates the continued openness to stakeholder feedback. As the advances coming out of the recent ASCO 2015 Annual Meeting demonstrate, it is more important than ever to realize the potential that big data and precision medicine have to offer in new treatments to patients. Many provisions in H.R. 6 will help move toward rapid development and dissemination of these important advances.

The Committee clearly recognizes that big data holds the promise of new treatments for cancer patients when it allows us to learn from every patient. The provisions related to big data in H.R. 6 such as those that address health data for research purposes under the Common Rule and HIPAA will help realize that goal.

ASCO shares that vision and is encouraged that many of the provisions in the Cures legislation would help foster advancements like ASCO's CancerLinQ™, a cutting-edge health information technology (HIT) platform that will revolutionize how we care for people with cancer. By enabling us to learn from each of the millions of individual patients living with cancer nationwide, CancerLinQ will improve the quality and value of cancer care for all by providing real-time quality feedback to providers, clinical decision support, and powerful analytical tools that will reveal previously unseen patterns in patient characteristics, treatments

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and outcomes that can lead to improvements in care. ASCO applauds the Committee's foresight that rapid learning data systems such as CancerLinQ have the ability to improve the pace of progress and quality of treatment for patients.

Additionally, provisions in this legislation will begin to reduce the number of practical and functional barriers that make it difficult for qualified clinical data registries to access health information for the purpose of gathering insights and improving quality care. We appreciate your recognition of the problem of information blocking in this provision, however big data systems such as ASCO's CancerLinQ will be unable to fully utilize their potential to improve patient care if information blocking is not quickly and adequately addressed.

The interoperability of Electronic Health Records (EHRs) is the foundation of a future where cures are developed faster through data sharing. It cannot be overstated that the current lack of interoperability is a major impediment to fully recognizing the potential of HIT. ASCO thanks the Committee for its efforts to move towards interoperable EHRs in H.R. 6, however, we remain concerned about the impact that decertifying EHRs could have on physician practice. Many oncologists have already expended significant resources in their existing EHR with the promise of interoperability. EHR vendors should not be allowed to pass the cost of new standards on to practices that may not be able to bear the additional outlay. ASCO encourages Congress to consider additional bill language or report language meet interoperability standards.

In addition to improving the potential for big data to accelerate cures, H.R. 6 would advance precision medicine, strengthen the NIH and FDA, and promote data sharing. ASCO supports those efforts and enthusiastically endorses the following provisions in particular:

- **Providing mandatory funding for the NIH and FDA.** These funds amount to a small step to make up for years of stagnant funding that has eroded spending power at the NIH and move towards a fully resourced FDA.
- **Investing in the future** biomedical research workforce through the Innovation Fund's focus on young scientists.
- **Furthering the development of precision medicine,** shaping the future of treatment for cancer patients through the Innovation Fund.
- **Requiring use of centralized IRBs** will greatly accelerate the pace of clinical trials research in the United States.
- **Easing restrictions on and burdensome paperwork of federal employee attendance at scientific meetings.** This attendance is vital to ensuring the most knowledgeable workforce at NIH and FDA.
- **Encouraging data standardization,** such as the requirements for ClinicalTrials.gov.
- **Refining Sunshine Act provisions** to ensure necessary access to Continuing Medical Education and peer-reviewed journals.
- **Patient-focused drug development** that uses vital input from and experience data from patients to create a full risk-benefit analysis of any new treatment.

- **Transparency requirements for expanded access** for drug companies to make public information about their expanded access plans after phase 2 and phase 3. This transparency will ease the process for patients and providers to obtain access to promising new treatments.

Again, ASCO thanks the House Energy & Commerce Committee for developing H.R. 6, the 21<sup>st</sup> Century Cures Act. We encourage you to pass H.R. 6 in the House and work with leaders in the Senate towards enactment of this important legislation. If you have any questions or would like assistance from ASCO on any issue involving the development of new treatments for individuals with cancer, please do not hesitate to contact Amanda Schwartz at (571) 483-1647 or [Amanda.Schwartz@asco.org](mailto:Amanda.Schwartz@asco.org).

Sincerely,

A handwritten signature in black ink, reading "Richard L. Schilsky MD". The signature is fluid and cursive, with the "MD" at the end.

Richard L. Schilsky, MD, FASCO  
Chief Medical Officer  
American Society of Clinical Oncology