May 19, 2015

Chairman Fred Upton
House Energy and Commerce Committee
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

Ranking Member Frank Pallone
House Energy and Commerce Committee
Subcommittee on Health
2125A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Ranking Member Pallone,

The American Society for Radiation Oncology (ASTRO), representing more than 10,000 radiation oncology medical professionals treating more than 1 million Americans with cancer each year, is encouraged by the potential benefits of the House Energy and Commerce Committee’s comprehensive approach in the 21st Century Cures legislation, which identifies methods to accelerate the pace of curing diseases in America. ASTRO also is working to improve the quality of cancer care to bring us closer to a cure, and therefore we urge the Committee to consider suggested improvements to the Cures’ legislation, including increased funding for radiation oncology research and other policy recommendations below.

Title I—Discovery, Subtitle A – National Institutes of Health Funding Section 1001 – National Institutes of Health Reauthorization

ASTRO commends the Committee for increasing funding for the National Institutes of Health (NIH) for precision medicine and to ensure that young scientists have a secure future in biomedical research.

As you know, Congress has demonstrated longstanding support for NIH and cancer research and ASTRO is committed to accelerating recent advances. With your support, major advances in cancer diagnosis and treatment, including radiation oncology, are happening at a faster pace than ever. ASTRO awards nearly $1 million each year to fund research as part of our overall effort to prevent, treat and cure cancer. These research awards and grants support work in radiation and cancer biology, radiation physics, comparative effectiveness research, translational research and outcomes/health services research. We are proud to do our part to support cancer research funding and applaud the Committee for recognizing and pledging to fill its irreplaceable role supporting the important work of the NIH.
Subtitle B – National Institutes of Health Planning and Administration

ASTRO was disappointed that the legislation does not include language to address funding levels for radiation therapy-related research at the National Institutes of Health (NIH) and National Cancer Institute (NCI). In a 2013 report to Congress, NIH acknowledged that less than one percent of its total budget was spent on radiation oncology specific research and just over four percent of the NCI’s budget went toward radiation oncology research. With more than half of cancer patients receiving radiation therapy as a part of their cancer treatment, the funding for radiation oncology research is not adequate to achieve new discoveries in the field. We are deeply concerned that this lack of radiation oncology research funding is resulting in promising young researchers leaving the field.

As part of Congress’ oversight duties to know how NIH research funds are allocated and to ensure that funding levels are appropriate, ASTRO urges you to include the attached language in the final legislation. We believe ensuring appropriate funding levels of research projects related to radiation oncology will create a clearer understanding of NIH’s priorities.

Title II — Development, Subtitle L – Priority Review for Breakthrough Devices Section 2201

ASTRO applauds the Committee’s commitment to require the Food and Drug Administration (FDA) to fast-track the approval process for so-called “breakthrough devices” that could have a direct impact on patient outcomes. However, we urge the Committee to include a definition of a breakthrough device, without which FDA may have difficulty in promulgating rules surrounding these types of devices.

Additionally, the draft language does not include additional appropriations for the FDA to carry out its new regulatory authority. ASTRO urges the Congress to provide appropriate funds for the agency to effectively comply with the requirements set forth in the draft legislation.

Title III, Subtitle C – Encouraging Continuing Medical Education for Physicians, Sec. 3041. Exempting From Manufacturer Transparency Reporting Certain Transfers Used for Educational Purposes

ASTRO supports the language of Section 3041, which would exempt from reporting under the Open Payments program transfers of value in the form of peer reviewed journals, journal reprints and supplements, medical conference reports and medical textbooks, which are given by manufacturers to physicians. All of these items are aimed at improving physician education and patient care and carry with them certain assurances that they will not be mere marketing materials for manufacturers. These items should be exempt from reporting, whether they are for physician use or for the physician to share with his/her patients.

Section 3041 would also exempt payments that manufacturers give in support of independent certified and/or accredited continuing education programs, such as those held by ASTRO, that ultimately fund speaker honoraria or tuition support for attendees. As a direct provider of accredited continuing educational programs and a leader in the professional and educational development for the radiation oncology community, ASTRO follows strict policies to avoid commercial influence on its educational content. ASTRO complies with the Standards for Commercial Support: Standards to Ensure Independence in CME Activities, which were promulgated by ACCME and adopted by the US continuing medical education (CME) credit systems currently named in the regulations. These standards provide
the framework for independent continuing education and distinguish rigorous continuing education from promotional sessions sponsored by manufacturers. Payments that ultimately support physicians who participate in ASTRO’s programming, whether as speakers or attendees, should not be reported under the Open Payments. For these reasons, ASTRO supports Section 3041.

Subtitle E—Local Coverage Determination Reforms

ASTRO is pleased that the Committee has included language that would increase transparency around the Local Coverage Determination (LCD) process by amending Sec. 1874A(g) of the Social Security Act to require public notification of new and revised LCDs at least 45 days prior to the effective date. ASTRO encourages the Committee to consider establishing a comment period similar to CMS’ proposed rule process to ensure that all stakeholders benefit from increased transparency.

Subtitle G—Facilitating Collaborative Research, Section 1121, Clinical Trial Data System

ASTRO commends the Committee’s intention to create a third-party scientific research sharing system for clinical trials funded by the government to ensure that the findings of those trials are available to the public. As specifics for this system are built, ASTRO encourages the Committee to ensure that all physician specialties are represented, including all three segments of oncology (radiation, medical, surgical) in the consultation. Additionally, ASTRO urges the Committee to ensure this new system is compatible with vendors and eHealth systems of radiation oncology for true integration.

ASTRO also commends your longstanding support of the radiation oncology community and cancer patients nationwide. As the Committee examines policies to offset the costs of this important legislation, we ask you to continue protecting cancer patients’ access to radiation treatment and consider using the $3.5 billion in savings achieved by legislation to close the physician self-referral law’s loophole.

In conclusion, ASTRO supports the Committee’s work on these very important issues and urges inclusion of the above policy recommendations. Thank you for your work on behalf of the health of Americans. We welcome the opportunity to discuss these issues in detail. Please feel free to contact Shandi Barney, Congressional Relations Manager for ASTRO at 703-839-7382 or shandi.barney@astro.org if you have any questions.

Sincerely,

Laura I. Thevenot
Chief Executive Officer