

November 5, 2014

The Honorable Dianne Feinstein Chairman Subcommittee on Energy and Water Development Committee on Appropriations **United States Senate** Washington, DC 20510

The Honorable Lamar Alexander **Ranking Member** Subcommittee on Energy and Water Development Committee on Appropriations United States Senate Washington, DC 20510

Dear Chairman Feinstein and Ranking Member Alexander,

I am writing on behalf of the American Society for Radiation Oncology (ASTRO) to express our concerns with Section 402 of the draft FY2015 Senate Energy and Water Development Appropriations Bill. ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapy. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients have access to the safest, most effective treatments.

ASTRO supports the Subcommittee's continued efforts to improve the security of radioisotopes used in health care, as well as other industries such as manufacturing, aerospace and the oil and gas industry. However, we are concerned that Section 402 would upset the delicate balance between securing radioactive materials while providing access to their remarkable capacity to help diagnose and treat cancer. Indeed, ASTRO believes the draft language in Section 402 goes too far and would limit patient access to safe, high-quality cancer treatment.

The radioisotopes identified in Section 402 are commonly used to treat inoperable brain tumors, cervical cancer, prostate cancer and breast cancer, among other diseases. Requiring their phase out within 15 years, when there are no other alternate technologies on the horizon, is seriously ill advised. By restricting access to these technologies, patients will be denied access to technologies proven to treat cancer and other diseases in a cost-effective manner. Additionally, decreasing access to these technologies would impact both clinical and translational research, ultimately limiting the development of enhanced treatment options and cures for patients.

Section 402 would require licensees to conduct feasibility studies in order to renew a license, or request a new one. This requirement will put an undue burden on those licensees; as such studies are expensive and time consuming. Many licensees may determine that the time and expense to conduct such a study would not be realistic, and would therefore decide not to renew a license or apply for a new one, thereby limiting patient access to critical care.

We believe that research on alternate technologies should not be done by the National Nuclear Security Administration (NNSA), but rather by those agencies who have the proper infrastructure to do so, such as the National Institutes of Health (NIH) and the National Cancer Institute (NCI). The NIH and NCI are central

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

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foundations for cancer research activities in the United States. Congress has recognized their critical work by their long-standing support for the role they have played in major innovations in the fight against cancer.

ASTRO supports strong policies to secure and protect radiological material from misuse. Safety and regulatory oversight of radiological sources is provided cooperatively by the Nuclear Regulatory Commission (NRC) and 37 Agreement States, which maintain the authority to license and inspect radiological materials. Most recently, the NRC updated its security regulations for radiation sources under 10 CFR Part 37, addressing many of the same issues identified in Section 402. The difference, however, is that the changes to Part 37 were subjected to extensive public review and comment, whereas the security requirements dictated by the NNSA were not. Licensees should be allowed to implement and evaluate the current requirements of Part 37 before being required to implement additional requirements.

Finally, Section 402 would require the NRC to discard its established regulatory framework in favor of mandatory security standards established by NNSA Global Threat Reduction Initiative (GTRI) for "High Risk Radiological Material." ASTRO supports security requirements for all radiation sources and believes that enhanced security should only be applied to higher risk materials classified as Category 1 or 2 by the International Atomic Energy Agency (IAEA). We are concerned that the language as written would set a harmful precedent, wherein an independent regulatory agency (the NRC) is essentially forced to reject its own standards and criteria in favor of those developed by a cabinet department (the Department of Energy and NNSA). We strongly urge the Subcommittee to work with the appropriate authorizing committees to ensure that NRC's authority is not in any way subordinated to NNSA or any other executive branch agency.

ASTRO appreciates Congress' attention to these important issues, and we look forward to serving as a resource to help ensure the secure use of radioactive isotopes in cancer treatment. Should you have any questions on the items addressed in this comment letter, please contact Dave Adler, director of advocacy, at (703) 839-7362 or <u>davea@astro.org</u>.

Sincerely,

aura Thevenot

Laura I. Thevenot Chief Executive Officer

CC: The Honorable Harry Reid, Senate Majority Leader The Honorable Mitch McConnell, Senate Minority Leader The Honorable John Boehner, Speaker of the House The Honorable Nancy Pelosi, House Minority Leader The Honorable Barbara Mikulski, Chairman, Senate Committee on Appropriations The Honorable Richard Shelby, Ranking Member, Senate Committee on Appropriations The Honorable Barbara Boxer, Chairman, Senate Committee on Environment and Public Works The Honorable David Vitter, Ranking Member, Senate Committee on Environment and Public Works The Honorable Harold Rogers, Chairman, House Committee on Appropriations The Honorable Nita Lowey, Ranking Member, House Committee on Appropriations The Honorable Mike Simpson, Chairman, House Subcommittee on Energy and Water Development, House Committee on Appropriations The Honorable Marcy Kaptur, Ranking Member, Subcommittee on Energy and Water Development, House Committee on Appropriations The Honorable Fred Upton, Chairman, House Committee on Energy and Commerce The Honorable Henry Waxman, Ranking Member, House Committee on Energy and Commerce