Oral Testimony

of

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on behalf of

Council on Radionuclides and Radiopharmaceuticals (CORAR)

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Committee on Energy and Natural Resources

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Good morning Mr. Chairman, Ms. Murkowski, members of the Committee and staff.

My name is Roy Brown and I am the Senior Director of Federal Affairs for the Council on Radionuclides & Radiopharmaceuticals, or CORAR[1]. I am representing CORAR here today to testify on behalf of the American Medical Isotopes Act of 2011 and to answer questions from the Committee.

CORAR testified before both the Senate and House during the last Congress in support of the proposed predecessor legislation, H.R. 3276. Thus, we support S. 99 and the provisions contained in the legislation. We believe this legislation will provide critical funding, assurance of, and the regulatory framework necessary to help establish reliable medical isotope production capabilities in the United States. This legislation is an important step towards a reliable source of medical radionuclides for our patients and will contribute to enhancing supply well into the future. In U.S. hospitals and clinics, Tc-99m (produced from Mo-99) is administered to more than 40,000 patients each day in the detection and staging of cancer, detection of heart disease, detection of thyroid disease, study of brain and kidney function, and imaging of stress fractures. Thousands of other nuclear medicine procedures are conducted every day in the U.S. with radionuclides, such as I-131, I-125, Y-90 and Xe-133, in the diagnoses and treatment of diseases. These nuclear medicine procedures not only improve the quality of life, but they save lives. A self-sustaining domestic supply of radionuclides used in nuclear medicine would ensure our patients receive the necessary care while reducing our health care costs.

[1] The Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) is comprised of companies which produce products utilizing many different radionuclides. CORAR members include the major manufacturers and distributors of radiopharmaceuticals, radioactive sources, and research radionuclides used in the U.S. for diagnostic and therapeutic medical applications and for industrial, environmental and biomedical research and quality control.

As a supporter of S. 99, CORAR would like to highlight four specific issues for the Committee's consideration to ensure that the bill will accomplish its goals and serve the needs of U.S. patients:

1. Section 3c of the legislation contains an important provision requiring DOE to accept waste created by the production of medical isotopes from the DOE-leased uranium. This provision is important because currently there is no disposal pathway available in the U.S. for the types of radioactive waste that will be generated in the production of Mo-99 and other medical isotopes. It is critically important to the objective of this legislation that DOE accepts such radioactive waste at reasonable prices. These prices should be similar to what we would expect to pay for commercial disposal, if a commercial waste disposal facility were available. This will help assure new medical isotope production facilities can be built and operated effectively.

2. The NRC has a comprehensive regulatory framework for protection of the environment, workers and the public. Any new reactor or production facility receiving funding under this legislation will be licensed by the NRC or equivalent Agreement State agency. Various aspects and operations of these facilities will also be regulated by the Food & Drug Administration (FDA), Department of Transportation (DOT) and the Environmental Protection Agency (EPA), as well as state and local regulatory agencies. We are concerned that the acceptance of money from DOE for the development of medical isotope capability under this legislation may trigger duplicative National Environmental Policy Act (NEPA) reviews. With these various levels of regulatory oversight, we do not believe NEPA will offer any more protection of the environment than that already provided by NRC, FDA, DOT and others. Triggering of NEPA by one of these new production facilities could serious delay the project and significantly increase its cost. We would like to see a provision in the legislation that any federal money spent on the development of medical isotopes to be exempt from the requirements of NEPA.

3. Several groups are working on the development of new types of isotope production reactors or have plans to utilize existing reactors for production of medical isotopes. Some of these reactors may fall into a licensing gap at the NRC. These new reactors do not meet the definition of a research reactor under the language in Section 104 of the Atomic Energy Act (AEA), due to their production focus and lack of research being conducted. These types of reactors also do not have the inherent risk or security concerns of large commercial nuclear power reactors which are licensed under Section 103 of the AEA. CORAR would like to see S. 99 either revise Section 104 of the AEA to recognize these types of reactors for the production of medical isotopes or direct the NRC to permit the licensing of these reactors under Section 104 of the AEA. If assistance of this type could be included in the legislation, it would help expedite the licensing of these new reactors and bring these new sources of Mo-99 to market more quickly.

4. CORAR is aware of several promising efforts to develop new medical isotope production technologies. DOE/NNSA has already awarded cooperative grants to a number of projects based on different technological approaches. Given the legislation's intent to broadly serve American patients, future funding should be directed to the project or projects which stand the best chance of producing commercially meaningful quantities of medical isotopes within the time frame envisaged in this legislation. We also would like to see the process by which DOE awards development money, fully vetted through a rulemaking or some other process where our industry and other interested parties can review and comment on DOE's proposed evaluation criteria and decision-making process for such projects.

Thank you for the opportunity to testify here today. CORAR is supportive of this legislation, and hopes to continue to work with the Committee and staff to ensure both a swift and long term solution to the medical isotope supply crisis for the benefit of American patients.

I would be happy to answer any questions the Committee may have.