Testimony of

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without Highly Enriched Uranium

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Good morning, Mr. Chairman and members of the Committee. My name is Steven M. Larson and I am the Donna and Benjamin M. Rosen Chair and Chief of Nuclear Medicine Service of the Department of Radiology at Memorial Sloan Kettering Cancer Center, New York, New York. I also served as vice chair of the National Research Council's (NRC's)[1] Committee on "Medical Isotope Production without Highly Enriched Uranium." I was asked to testify today regarding the findings and recommendations of this report.

First, if I may, I wish to offer some personal observations, as a practicing nuclear medicine physician with long experience, regarding the timeliness and importance of H.R. 3276 to the field of nuclear medicine and its importance to medical care. I am the director of a large nuclear medicine clinic at Memorial Sloan-Kettering Cancer Center in New York City. We have one of the larger clinical practices in the United States, and typically we see between 110 to 120 patients per day, of which two thirds require diagnostic procedures that utilize technetium 99m when this isotope is available. However, the recent and unplanned shutdown of the NRU reactor at Chalk River in Canada has disrupted supplies of this important isotope to our clinic and to other hospitals in the northeastern United States. For most of the summer, our clinic has seen a reduction of between 20% and 25% in the amount of technetium 99m available for clinical use. Furthermore, medical isotope providers are telling us to expect continued shortages of technetium 99m during 2009 and beyond, and they are warning about the possibility of even deeper reductions in technetium 99m availability on the near horizon,

[1] The National Research Council is the operating arm of the National Academy of Sciences, National Academy of Engineering, and the Institute of Medicine of the National Academies, chartered by Congress in 1863 to advise the government on matters of science and technology.

since continued U.S. supply is dependent on old Canadian and European reactors whose operational life expectancies are unpredictable.

We accommodated to this new reality by reducing the dose for bone scans, delaying patient care, particularly for ventilation and perfusion scans, and switching to other less optimal isotopes such as thallium 201. In addition, we have also begun to perform more procedures using rubidium 82 and a PET/CT scanner, even though the economics are not as favorable in our setting.

At present, we have the acute exacerbation of a chronic problem with technetium 99m supplies that is the result of an unhealthy dependency on reactors in other countries whose operational life expectancy is unpredictable. To make matters worse, continued operation of these reactors depends on the willingness of foreign governments in Canada, Europe, and South Africa to provide subsidies and in some cases modify their reactor operations to continue medical isotope production for the needs of our citizens.

In my personal opinion, technetium 99m will continue to be the workhorse radiopharmaceutical for patient care in the United States for the foreseeable future, especially for cardiac and oncology applications. I personally support the objectives of the proposed legislation, H.R. 3276. The development of a reliable domestic supply of technetium 99m is good public policy.

Let me now turn to the key relevant findings and recommendations from the NRC report "Medical Isotope Production without Highly Enriched Uranium." The mandate for this report came from Section 630 of the Energy Policy Act of 2005. The Secretary of Energy was directed to contract with the National Academies for a study on the

elimination of highly enriched uranium (HEU[2]) from reactor fuel, reactor targets, and the production of medical isotopes. The study request arose because of a conflict between the Energy Policy Act of 1992, which created increasing pressure to phase out U.S. exports of HEU for medical isotope production, and the Energy Policy Act of 2005, which sought to increase the reliability of medical isotope supply by lifting the requirements of the 1992 Act for HEU exports to Canada, the Netherlands, Belgium, France, and Germany for medical isotope production. The balance between the dual objectives of securing HEU and providing a reliable supply of medical isotopes drove much of the discussion and work of the NRC committee. H.R. 3672 appears to be inspired by similar concerns.

Our study was completed in late 2008 and the final report was issued in January 2009. It focuses primarily on the use of HEU for the production of the medical isotope molybdenum 99, because its decay product, technetium 99m, is by far the most common clinical isotope and a bellwether for nuclear medicine isotope supply to healthcare. Our report concluded that the production of sufficient quantities of molybdenum 99 would ensure that other reactor-produced medical isotopes would also be available in sufficient quantities to meet healthcare needs.

The study had five specific charges, which I have paraphrased here:

1. Determine feasibility of procuring supplies of medical isotopes from commercial sources that do not use HEU.

[2] HEU is defined as uranium enriched in the isotope uranium 235 to levels greater than or equal to 20%. The United States supplies most of the HEU that is used to produce medical isotopes.

2. Determine current and projected demand and availability of medical isotopes in regular and current domestic use.
3. Determine progress being made by the Department of Energy and others to eliminate all use of HEU in reactor fuel, reactor targets, and medical isotope production.
4. Determine the potential cost differential in medical isotope production in the reactors and target processing facilities if the products were derived from the production systems that do not involve fuels and targets with HEU.
5. Identify additional steps that could be taken by DOE and medical isotope producers to improve feasibility of conversion of HEU based to LEU based processes.

Let me briefly summarize the key relevant findings and recommendations from the report.

With regard to charge 1, the committee found that at the present time there were not sufficient quantities of medical isotopes produced without HEU to meet U.S. domestic needs, but that the committee saw no technical reason that adequate quantities could not be produced. In fact, Argentina and Australia are now producing medical isotopes without HEU.

With regard to charge 2, the current U.S. demand for molybdenum 99 is about 5000-7000 6-day curies per week. Demand for nuclear medicine services is stable, with a likely growth rate in utilization of 3-5% per year. Technetium 99m is crucial to the nation's health care in oncology, cardiology, and neurology. Reliability of supply is a

significant problem now and likely to be a problem for the foreseeable future. Total capacity for production is very near current use, and there is little margin for additional production capacity in the event of an interruption of supply. The NRC report noted that "because current supplies of Mo-99 are produced in reactors built largely at government expense, private companies that can provide new domestic supplies of [molybdenum 99] might not choose to compete without government assistance."

With regard to charge 3, the U.S. Department of Energy (DOE) is leading the Global Threat Reduction Initiative (GTRI), which is working to convert reactor fuel and targets from HEU to low enriched uranium (LEU[3]). The report found that DOE is making considerable progress in converting reactor fuel and targets. However, much work remains to convert reactor targets for molybdenum 99 production from HEU to LEU. This is not a criticism of DOE, but rather the result of the reluctance of private-sector producers to convert. LEU targets are being used today to produce molybdenum 99 in Argentina and Australia. There is no technical reason that LEU targets could not be used by other producers.

With regard to charge 4, the report found that the anticipated average cost increase to convert to the production of medical isotopes without the use of HEU would likely be less than 10 percent for most current large-scale producers. This finding was based on a present value cost analysis at three steps in the molybdenum 99/technetium 99m supply chain: production of molybdenum 99, production of technetium generators, and

[3] LEU is uranium enriched in the isotope uranium 235 to less than 20 percent.

delivery of technetium 99m doses. This is probably the most controversial finding in the report. I will say more about this later in my testimony.

With regard to charge 5, the report identifies additional steps that could be taken by DOE and others to improve the feasibility of conversion of medical isotope production. These include the following:

- Producers should commit to conversion and announce a best-effort schedule for eliminating HEU-based production.
- DOE should make the considerable technical expertise of the national laboratory system available to assist producers with conversion-related research and development.
- The Department of State should intensify the diplomatic pressure on countries that still use HEU to induce them to convert. In particular, those countries that are partners in the GTRI have made a commitment to the minimization of HEU and should be encouraged to live up to their commitments.
- The Food and Drug Administration (FDA) should work with industry and technical experts to ensure that there is a common understanding of likely FDA requirements for obtaining regulatory approvals for the use of LEU produced Mo99 in radiopharmaceuticals.
- The U.S. Congress should provide clear and consistent policy directions concerning conversion to LEU-based molybdenum 99 production, consider a gradual phaseout of HEU exports for medical isotope production, and consider

incentives to motivate conversion and the development of domestic sources of molybdenum 99 production.

H.R. 3276 legislatively enshrines some of these steps: It authorizes DOE to provide technical assistance to producers who wish to convert, it provides financial assistance to develop a domestic production capacity, and it provides for a seven-year phase-out period for HEU exports.

As I mentioned before, the report's conversion cost analysis has proven to be controversial with some stakeholders. I can say that when I began work on the NRC study I too was skeptical about the feasibility of conversion to LEU-based medical isotope production and the potential impact of conversion on supply reliability. Based on the information I received during this NRC study I now believe that if the medical isotope producers have the will to convert they can do so without undo costs. I am not an economist or an expert accountant; instead, my opinion is based on the observations we made during site visits to medical isotope production facilities in Argentina and Australia and discussion with technical experts about conversion.

Under modest circumstances, and without elaborate additional infrastructure, Argentina was able to convert from HEU-based production to LEU-based production in less than two years and for less than a million dollars for supplies and facilities modification. The Argentina production process is now being implemented in Australia, and the Australian company ANSTO hopes to begin exporting small quantities of molybdenum 99 to the United States in the near future.

I was also initially concerned about the flexibility that FDA would have with respect to regulatory requirements for conversion. However, this concern was allayed when FDA regulators fast-tracked approval of the molybdenum 99 produced from Australia and South Africa for use in the United States. It is clear that FDA is prepared to act quickly when it receives high-quality applications from producers.

This concludes my testimony to the committee. I would be pleased to answer any questions.