

MEDICAL ISOTOPES

HEARING BEFORE THE COMMITTEE ON ENERGY AND NATURAL RESOURCES UNITED STATES SENATE ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

TO

RECEIVE TESTIMONY ON H.R. 3276, THE AMERICAN MEDICAL ISOTOPES
PRODUCTION ACT OF 2009

DECEMBER 3, 2009



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MEDICAL ISOTOPES

THURSDAY, DECEMBER 3, 2009

U.S. SENATE,
COMMITTEE ON ENERGY AND NATURAL RESOURCES,
Washington, DC.

The committee met, pursuant to notice, at 10:02 a.m. in room SD-366, Dirksen Senate Office Building, Hon. Jeff Bingaman, chairman, presiding.

OPENING STATEMENT OF HON. JEFF BINGAMAN, U.S. SENATOR FROM NEW MEXICO

The CHAIRMAN. OK. Why don't we get started? Let me thank the witnesses for coming to talk with us today.

Dr. Staples, I understand you used to be at Los Alamos, and we wanted to recognize that, as a former New Mexican.

Today's hearing is to receive testimony on H.R. 3276, the American Medical Isotopes Production Act of 2009, which was voted out of the House on a bipartisan basis. It addresses the recommendations of the report prepared by the National Academies of Science on the feasibility of producing medical isotopes, principally molybdenum-99 without highly enriched uranium, the principal material used in a fission-based nuclear weapon over 60 years ago and which we are urgently trying to collect around the world today.

As an incentive to limit the export of HEU, the bill authorizes a \$163 million program to work with industry to convert existing HEU-fueled reactors capable of producing isotopes, as well as other alternate methods such as accelerators.

If this bill becomes law, I hope that the department places an emphasis to work on the needs of industry to make this transition because, ultimately, it is the industry that will produce the isotopes that we need.

Let me call on Senator Murkowski for any statement she would like to make, and then we will hear from the witnesses.

[The joint prepared statement of Mr. Markey and Mr. Upton follows:]

JOINT PREPARED STATEMENT OF HON. EDWARD J. MARKEY, U.S. REPRESENTATIVE FROM MASSACHUSETTS, AND HON. FRED UPTON, U.S. REPRESENTATIVE FROM MICHIGAN

Chairman Bingaman, Ranking Member Murkowski, and Members of the Committee, thank you very much for holding this important hearing on H.R. 3276, the American Medical Isotopes Production Act of 2009. We deeply appreciate that the Senate Energy and Natural Resources Committee has taken up this bill, which we wrote and passed through the House of Representatives to solve the crisis in nuclear medicine.

The American Medical Isotopes Production Act will safeguard Americans' healthcare and our national security. By helping to establish production of critical medical isotopes here at home, the American Medical Isotopes Production Act will end our dependence on aging nuclear reactors outside of our borders. And by responsibly ending the export of weapons-usable highly enriched uranium for medical isotope production, this bill will give a much-needed boost to U.S. efforts to permanently convert all reactors away from the unnecessary and dangerous use of bomb-quality material.

The United States is facing a crisis in nuclear medicine. We face a severe shortage of a crucial radioactive isotope, molybdenum-99, which is required for nearly 50,000 medical procedures each day, usually to produce a detailed image, such as a cancer or bone scan. The shortage of this isotope, which usually costs only \$10 of a multi-thousand dollar procedure, is threatening the healthcare of millions of Americans.

Worst of all, the United States does not currently produce any of the isotope in question domestically. Instead, we are entirely dependent on a handful of foreign nuclear reactors, most of which are several decades old, some of which are literally falling apart, and which rely upon weapons-usable highly enriched uranium for their operation.

In May, the 51-year old Canadian NRU reactor broke down. It is not yet clear whether the reactor will ever operate again. And in mid-July, the 47-year old HFR reactor in The Netherlands was taken off-line for maintenance for one month.

Together, these two reactors usually produce the entire isotope supply for the United States. While the nation was able to secure a small supply during this time from other reactors, Americans' health care suffered as a result.

This bipartisan bill will solve the medical isotope crisis by authorizing \$163 million for the Department of Energy to evaluate and support projects in the private sector or at universities to develop domestic sources of the most critical medical isotopes. This is necessary because we currently face a daunting supply shortage, caused by technical problems at the aging foreign reactors upon which we are reliant. With a robust and reliable domestic production capacity the 50,000 daily procedures which normally occur in this country, including for cancer scans and bone and brain imaging, will be secure.

In addition, the nuclear nonproliferation benefits of this bill are significant and timely.

Shockingly, United States still allows for nuclear weapons-grade highly enriched uranium to be exported to other countries for medical isotope production. This 1950s-era policy simply does not work in a post-9/11 world; it is dangerous and unnecessary and must come to an end. We simply cannot afford to have additional nuclear weapons materials in circulation—when we know that terrorists would like nothing more than to steal or buy such dangerous materials.

Fortunately, according to the National Academy of Sciences, there are no technical or economic reasons why medical isotopes cannot be produced with low enriched uranium.

Currently, nuclear medicine is practiced mostly in the most developed countries, like the United States. But that is changing. And as more countries practice more nuclear medicine, more medical isotopes will need to be produced. For many years, there has been strong bipartisan agreement that weapons-usable nuclear material must be secured throughout the world. It is very much in the national security interests of the United States that the future growth of nuclear medicine internationally does not increase the use of highly enriched uranium. By sending the strongest possible signal that the United States will not use highly enriched uranium itself, and by setting a deadline for the end of U.S. exports of this dangerous material, H.R. 3276 will help ensure that the new medical isotope production around the world will be consistent with international security.

By sending a clear signal that the United States will no longer export this dangerous material, H.R. 3276 will accelerate U.S. efforts to convert reactors around the world from highly-enriched to low-enriched uranium. In fact, this has already begun, as the Department of Energy testified before our Subcommittee in September that all the medical isotope production reactors around the world which still use highly enriched uranium have approached DOE to ask for assistance in converting to low-enriched uranium in the past few months.

We are proud that this bill has the support of a wide variety of stakeholders, including the unanimous support of industry and the nuclear medical community, and nuclear nonproliferation advocates. It has been endorsed by the Society for Nuclear Medicine, the American College of Radiology, the American Society for Radiation Oncology, the American College of Cardiology, the American Society of Nuclear Cardiology, the American Association of Physicists in Medicine, the Health Physics Society, the Council on Radionuclides and Radiopharmaceuticals, Lantheus Medical

Imaging, Covidien, Astellas Pharma US, Babcock and Wilcox, GE Hitachi, the University of Missouri, the Nuclear Threat Initiative, the Union of Concerned Scientists, Physicians for Social Responsibility, and the Nonproliferation Policy Education Center.

The professional medical societies which have endorsed H.R. 3276 represent more than 100,000 physicians, nurses, scientists, pharmacists, and technicians who provide nuclear medicine every day in the United States. Their important assistance in the development of this bill, and their strong support for the legislation, give us extraordinary confidence that H.R. 3276 represents the best possible path forward to establish a robust domestic supply of medical isotopes while reducing the quantity of dangerous weapons-usable uranium in use.

We are also very proud that this bill is a strongly bipartisan one. We have worked together, across the aisle, for months to craft a robust solution to the medical isotopes crisis. H.R. 3276 followed regular order in the House, with a legislative hearing in our Subcommittee, votes in both the Subcommittee and the full Energy and Commerce Committee, and finally passed the House in a bipartisan. We worked with our colleagues on a bipartisan basis to address all concerns which were raised, and we are very pleased that the bill which passed the House won overwhelming support.

Finally, we are pleased that we were able to craft this bill to not only solve the medical isotope crisis and strengthen national security, but also to do so with full budget neutrality, according to the Congressional Budget Office.

This bill will help assure that America has a reliable domestic source of the radioisotopes needed for life-saving medical procedures and will close a dangerous loophole in our nation's nonproliferation policy by phasing out exports of highly enriched uranium. We thank you again for your attention to this crucial issue, and stand ready to assist in any way as you proceed.

STATEMENT OF HON. LISA MURKOWSKI, U.S. SENATOR FROM ALASKA

Senator MURKOWSKI. Thank you, Mr. Chairman.

I appreciate you holding the hearing. We are engaged in great detail on the floor right now with healthcare reform. This particular issue certainly is not generating as much of the headlines when we think about health issues. But I have learned a great deal just in preparing for this hearing, and we recognize the direct impact that this issue has on thousands of Americans every day.

We recognize that our hospitals and pharmacies are facing a shortage of molybdenum-99, the parent product of a number of medical isotopes and perhaps most importantly, the technetium-99m, which is used in more than 16 million medical procedures each year, over 40,000 each day.

I think we recognize that here in Congress there is not much that we can do in the immediate term to address the shortage because we rely entirely upon foreign sources for these isotopes. The foreign reactors we have been reliant upon to produce the Mo-99 are aging and are either shut down for repairs or scheduled to shut down next year.

I think we recognize that this committee has held many, many hearings about our dependence on foreign sources of oil. At least we have some level of domestic production for now. But when it comes to the medical isotopes, the U.S. uses half of the world's supply of the technetium-99m while producing none here at home. When we talk about energy independence and energy self-sufficiency, I think we also need to push that further into the discussion in terms of our reliance on the medical isotopes that so many Americans depend upon.

The bill before the committee certainly seeks to help promote domestic production of the Mo-99. This is a worthy goal. It is also tar-

geted at the potential proliferation of highly enriched uranium. While I am not as convinced that the exportation of a few grams of HEU for medical isotope production is a tremendous proliferation concern, I am supportive of the bill's intent to utilize the low-enriched uranium for targets and for fuel.

What the bill does not do, however, is provide a near-term solution to the shortage that we are experiencing today or the even greater shortage that we could experience next year. So I look at this and think it is more important that we get the policy right rather than try to rush something into law.

How long it will take to get domestic production facilities up and operating given the environmental, the siting issues, the NRC licensing hurdles, these are significant questions. Does the hard cut-off date on HEU exports realistically match up with the timeline for domestic production? Will Congress and the administration support long-term funding for this program to keep it on track during that timeline?

These are some of the questions that I hope we will be able to have some discussion on this morning. I appreciate your being here, and you, Mr. Chairman, for calling the hearing.

The CHAIRMAN. Thank you.

Why don't I introduce the three witnesses, and then we will hear from each of them.

Mr. Parrish Staples is the Director of European and African Threat Reduction at the Department of Energy in the NNSA. We appreciate you being here.

Mr. Kevin Crowley is the Director of Nuclear and Radiation Studies Board with the National Research Council of the National Academies here in Washington.

Mr. Roy Brown is the Federal Affairs Senior Director with the Council on Radionuclides and Radiopharmaceuticals in St. Louis.

Thank you all for being here.

Dr. Staples, why don't you go ahead? If each of you could take 5 or 6 minutes and tell us the main things we need to know on this subject, and then we will have some questions.

STATEMENT OF PARRISH STAPLES, DIRECTOR, OFFICE OF EUROPEAN AND AFRICAN THREAT REDUCTION, GLOBAL THREAT REDUCTION INITIATIVE, NATIONAL NUCLEAR SECURITY ADMINISTRATION, DEPARTMENT OF ENERGY

Mr. STAPLES. Thank you.

Chairman Bingaman, Ranking Member Murkowski, and other members, thank you for the opportunity to testify about the National Nuclear Security Administration's, NNSA's, efforts to minimize and, where possible, eliminate the use of highly enriched uranium, HEU, in the production of molybdenum-99, which is known as Mo-99.

My testimony will describe the benefits of the proposed American Medical Isotopes Production Act of 2009 and our efforts to accelerate the establishment of a domestic commercial supply of Mo-99 without using HEU.

Now, as you just mentioned, Mo-99 is the parent isotope of technetium-99m, which is the actual radioisotope that is used in over 40,000 diagnostic medical procedures every day in the United

States. Interruptions in production, expected to continue through 2010, place patient lives at risk if the diagnostic tests cannot be performed. Currently, the United States depends on foreign producers that use HEU targets in their production process.

The American Medical Isotopes Production Act of 2009 will provide the long-term authorization to enable the development of a reliable domestic supply of Mo-99 and further global HEU minimization efforts by ensuring that new domestic sources of Mo-99 are non HEU-based. We have been significantly aided by the National Academies report confirming that the production of Mo-99 without the use of HEU is both technically and economically feasible and that there are “no technical reasons that adequate quantities of medical isotopes cannot be produced” without the use of HEU.

Now, to address the longer-term production of Mo-99, NNSA is implementing projects to accelerate the establishment of a domestic commercial supply of Mo-99 without HEU. To prevent a single point of failure, NNSA is intending to demonstrate the feasibility of production with commercial entities on four independent technical pathways. These include LEU fission target technology, LEU solution reactor technology, neutron capture technology, and accelerator-based technology.

The goal is for each technology pathway to be independently and commercially successful, and therefore, our approach is technology neutral. NNSA intends to follow through on this program by requesting the necessary funds to implement these projects with the potential commercial Mo-99 producers whose projects are in the most advanced stages of development.

The goal is to accelerate the efforts to produce in adequate quantities for the needs of the U.S. medical community by the end of 2013. This strategy will help to diversify and stabilize the Mo-99 supply.

Now to accomplish this, we must overcome the technical complexity that is involved in extracting and processing the final medical product at a steady state and on a commercial scale to meet FDA standards for human consumption. This is a complex endeavor and experienced commercial-scale producers with new projects have experienced delays or, in fact, have failed as they have grappled with the problems of bringing new facilities into operation.

We must learn from their difficulties and maintain our focus on the demonstration of commercial-scale Mo-999 production by those few entities that are the most advanced under our technology-neutral process in order to succeed.

Now I thank Senator Bingaman and the committee for your continued leadership in supporting this legislation that will provide national visibility to address this critical medical need and important nonproliferation goal.

I would be pleased to answer any questions you have at the appropriate time.

Thank you.

[The prepared statement of Mr. Staples follows:]

PREPARED STATEMENT OF PARRISH STAPLES, DIRECTOR, OFFICE OF EUROPEAN AND
AFRICAN THREAT REDUCTION, GLOBAL THREAT REDUCTION INITIATIVE, NATIONAL
NUCLEAR SECURITY ADMINISTRATION, DEPARTMENT OF ENERGY

Chairman Bingaman, Ranking Member Murkowski, and Committee Members, thank you for the opportunity to testify about the National Nuclear Security Administration's (NNSA's) efforts to minimize and, where possible, eliminate the use of highly enriched uranium (HEU) in civilian nuclear applications, including in the production of medical radioisotopes. My testimony will include a description of the benefits of the proposed *American Medical Isotopes Production Act of 2009*, the NNSA's effort to mitigate the impact of the current and anticipated shortages of the medical isotope Molybdenum-99 (Mo-99), and the efforts to accelerate the establishment of a domestic commercial supply of Mo-99 without using HEU.

As described in Section 2 of the *American Medical Isotopes Production Act of 2009*, Mo-99 is the parent isotope of Technetium-99m, which is used in approximately 50,000 diagnostic medical isotope procedures every day in the United States. It has a very short half life and therefore cannot be stockpiled. It must be produced on a continuous basis to meet the needs of the medical community, and any interruptions in production can place patients' health at risk if diagnostic tests cannot be performed. Currently, the United States depends entirely on foreign producers for all of its Mo-99, and these producers use highly enriched uranium (HEU) targets to produce this vital medical isotope.

Historically, Mo-99 production processes have utilized the same form of HEU that can be used to produce nuclear weapons and nuclear explosive devices. Under-scoring the global recognition of the grave threat posed by HEU falling into the wrong hands, including the risk of terrorists or rogue states acquiring such material, new technical advances in Mo-99 production processes—just as in other civilian applications—are demonstrating that HEU is no longer required. Provisions of this legislation, in particular Section 2, paragraph (11) are aligned with the NNSA's mission to convert or assist in the conversion of research reactors worldwide from the use of HEU-based to LEU fuels and to convert medical isotope production from HEU to non-HEU based production.

The *American Medical Isotopes Production Act of 2009* under review by this committee would provide a long-term authorization to address this critical medical need by developing a domestic source of Mo-99 as well as furthering global HEU minimization efforts by ensuring that new domestic supplies of Mo-99 are non HEU-based. The proposed legislation will greatly promote the reliable supply of Mo-99 to hospitals throughout our country and will ultimately ensure the level of patient care that our citizens require.

The Mo-99 shortages over the last few years are due to both unforeseen and required maintenance to the aging reactors around the world that provide the global supply. In May 2009, the fragile supply chain for Mo-99 was significantly threatened by the unexpected shutdown of the primary supplier for the U.S. due to a serious maintenance concern. In 2010, this unexpected supply interruption will be exacerbated by the required scheduled maintenance of the second largest global supplier. The Office of Science and Technology Policy of the Executive Office of the President is directing an Inter-agency working group, which includes NNSA and other Department of Energy offices, to investigate options to focus on near-term efforts to increase the supply to the U.S. during periods when the major suppliers will be out of operation, and prior to the development of new longer-term production capabilities. The current Mo-99 shortages are being mitigated as effectively as possible in the near-term through industry-wide communication, scheduling and more efficient use of available Mo-99 supplies, the application of alternate diagnostic technologies and increased production from all of the global producers. Near-term production and the significant amount of attention focused to address this problem needs to be carefully balanced with other efforts to ensure the development of a long-term reliable supply of non-HEU based Mo-99. With appropriate Congressional support, the long-term options could be readily achievable and available for steady state production with the objective to create a consistent supply of the medical isotope to health care providers.

The National Academies published a report on January 14, 2009 confirming that the production of Mo-99 without the use of HEU is both technically and economically feasible. It was the National Academies' determination that there are "no technical reasons that adequate quantities [of medical isotopes] cannot be produced" without the use of HEU, and furthermore, that "... the greatest single threat to supply reliability is the approaching obsolescence of the aging reactors that large-scale producers utilize to irradiate HEU target to obtain Mo-99." The report posi-

tively supports HEU minimization by establishing that it is feasible for global producers to convert to LEU, and identifying the risk to the domestic supply reliability.

To address the longer-term production of Mo-99, NNSA is developing projects to accelerate the establishment of domestic commercial sources of Mo-99 without HEU. To prevent the single point of failure scenario facing today's U.S. Mo-99 supply, NNSA is helping demonstrate the feasibility of non-HEU based Mo-99 production by working with commercial entities and national laboratories on four technology pathways. These include: LEU fission technology; LEU solution reactor technology; neutron capture technology; and accelerator technology. The goal is for each technology to be commercially successful, and NNSA's approach is technology neutral. NNSA is working with the one commercial partner in each of the four areas whose projects on Mo-99 are most advanced for that technical pathway. NNSA also makes available the technical expertise of the U.S. national laboratories gained over many years in the non-HEU based Mo-99 production technologies. The commercialization of these different non-HEU based technologies supports the strategy to diversify the Mo-99 supply and move away from reliance on a sole technology and a limited number of facilities, as is the case with today's foreign producers.

NNSA is planning to spend approximately \$20 million in FY 2010 to establish these technologies. Funding would come from within the Global Threat Reduction Initiative budget.

As with any major technology initiative, there are challenges that could affect the acceleration of these technologies that must be addressed. We must overcome the technical difficulty involved in extracting the final medical product and processing it into a form that meets Food and Drug Administration (FDA) standards, and doing so steady-state on a commercial scale suitable to meet the needs of the medical community. The production of this valuable commodity is a complex endeavor and lessons learned from two experienced commercial-scale producers that have initiated recent projects to construct new production capabilities must be considered to minimize difficulties as we proceed. There are many research reactor operators globally that contend they can produce Mo-99, but we must not underestimate the difficulties to be overcome in the process to provide material at the standards required and on a scale to satisfy global demand. We must maintain our focus on supporting the demonstration of commercial scale Mo-99 production by those few specific entities that are most advanced under the technology-neutral process we have developed. We share the goals of this bill and look forward to working with you to ensure the accomplishment of nuclear threat reduction activities and the development of a reliable supply of medical isotopes to the public, while ensuring greater Presidential flexibility.

This legislation will provide the national visibility necessary to address this critical medical need as rapidly as possible and will also achieve important non-proliferation goals. I thank Senator Bingaman and the Committee for your continued leadership by supporting this legislation.

The CHAIRMAN. Thank you very much.

Mr. Crowley, why don't you go right ahead?

STATEMENT OF KEVIN D. CROWLEY, PH.D., SENIOR BOARD DIRECTOR, NUCLEAR AND RADIATION STUDIES BOARD, NATIONAL RESEARCH COUNCIL, THE NATIONAL ACADEMIES

Mr. CROWLEY. All right. Thank you very much.

I would like to use my few minutes just to highlight some key points from my written testimony, which is in the record.

As you know, section 630 of the Energy Policy Act of 2005 included a mandate for a National Academy of Sciences study to assess the feasibility of producing medical isotopes without the use of highly enriched uranium. We completed that study in late 2008. We issued our report, which is entitled "Medical Isotope Production Without Highly Enriched Uranium," in January 2009. Our report focuses on the production of the medical isotope molybdenum-99, which I will use the short-hand Mo-99. There are a lot of terms in this business that are very hard to pronounce.

The Mo-99 is used in over two-thirds of all diagnostic medical isotope procedures in the United States. There are five key mes-

sages from our report, and I just would like to briefly summarize those for you.

First, we found no technical barriers to the large-scale production of Mo-99 without highly enriched uranium. Second, we estimated that the average cost increase to convert Mo-99 production from highly enriched uranium to low-enriched uranium would likely be less than 10 percent for most current producers. Such a cost increase would result in trivial increases in prices for typical medical isotope procedures.

Third, we estimated that the U.S. demand for Mo-99 is likely to grow at rates of 3 to 5 percent per year over the next 5 years, assuming, of course, that adequate supplies of this isotope are available. Domestic growth will likely continue over the longer term as the U.S. population ages. Global demand could grow even more rapidly, especially in developing countries.

Fourth, we noted that Mo-99 supply disruptions are impacting the continuity of patient care in the United States and elsewhere. Supply reliability will continue to be a serious problem until new supply capacity is brought online.

Fifth, our report identified several steps that medical isotope producers, the Department of Energy, and others could take to improve the feasibility of conversion to low-enriched uranium. Some of these steps are already being taken, as noted in my written statement.

The American Medical Isotopes Production Act of 2009 would also implement some of the steps identified in our report. Most notably, the legislation seeks to address the supply reliability by providing incentives for the development of domestic supplies of Mo-99 for medical use. Development of domestic supplies could help alleviate global shortages and insulate the United States from future supply disruptions.

The legislation also sends a clear signal of Congress's intention to phaseout the use of highly enriched uranium for medical isotope production. This could provide a powerful near-term incentive for conversion. The legislation's proposed phase-out period of 7 years, with an additional 4 years if needed, is largely consistent with our report's suggested phase-out period of 7 to 10 years.

The legislation's authorization of a fixed appropriation to support conversion is consistent with our report's suggestion that Congress provide temporary financial incentives to promote conversion to low-enriched uranium and development of domestic supplies.

The legislation would also empower the Secretary of Energy to provide assistance on the development of fuels, targets, and processes for domestic production of Mo-99. This is consistent with our report's suggestion that the Department of Energy make the considerable technical expertise of its national laboratory system available to assist producers with conversion-related research and development.

Then, finally, the uranium lease and take back provision in the legislation was not discussed in our report. However, such a provision could serve to promote domestic production by allowing producers to sidestep the regulatory uncertainties associated with waste classification and disposition. These uncertainties were identified in our report as potential roadblocks to domestic production.

Thank you for the opportunity to testify, and I look forward to our questions and discussion period.

[The prepared statement of Mr. Crowley follows:]

PREPARED STATEMENT OF KEVIN D. CROWLEY, PH.D., SENIOR BOARD DIRECTOR, NUCLEAR AND RADIATION STUDIES BOARD, NATIONAL RESEARCH COUNCIL, THE NATIONAL ACADEMIES

Good morning Chairman Bingaman and members of the committee, my name is Kevin Crowley, and I am the director of the National Research Council's Nuclear and Radiation Studies Board.¹ I also directed the National Research Council study entitled Medical Isotope Production without Highly Enriched Uranium, which is the subject of my testimony today. This report was completed in late 2008 and released to the public in January 2009.

My testimony will address the following three topics: the origin of our medical isotopes study; study charges and principal report findings; and comments on H.R. 3276 in light of those findings.

STUDY ORIGIN

The mandate for this National Research Council study came from Section 630 of the Energy Policy Act of 2005 (Public Law 109-58). Section 630 directed the Secretary of Energy to enter into an arrangement with the National Academy of Sciences for a study on the elimination of highly enriched uranium (HEU²) from reactor fuel, reactor targets, and medical isotope production facilities. Our study focused on the production and use of molybdenum 99 because its decay product, technetium 99m, is used in over twothirds of all diagnostic medical isotope procedures in the United States. Our report concluded that the production of molybdenum 99 in quantities sufficient to meet current healthcare needs would ensure that other reactor-produced medical isotopes (such as iodine and xenon) would also be available in sufficient quantities.

The congressional mandate for our study 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 reactor fuels and targets, 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 Belgium, Canada, France, Germany, and the Netherlands for medical isotope production.

STUDY CHARGES AND PRINCIPAL FINDINGS

Our study had five charges, the first four of which were specified in the 2005 Act; the last charge was negotiated with the study sponsor, the National Nuclear Security Administration, to assist it in achieving its mandate to minimize HEU use in civilian applications. The study charges and some principal findings are summarized below.

Charge 1: Determine the feasibility of procuring supplies of medical isotopes from commercial sources that do not use HEU. We found that, at the present time, there are not sufficient quantities of medical isotopes produced without HEU to meet U.S. domestic needs. However, we also found no technical reason that adequate quantities could not be produced using low enriched uranium (LEU³) targets. Our report noted that Argentina and Australia are now producing molybdenum 99 with LEU targets. These countries are producing primarily for domestic and regional needs, but they are exploring opportunities to become global suppliers.

Charge 2: Determine the current and projected demand and availability of medical isotopes in regular current domestic use. We found that the U.S. de-

¹The 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. The Nuclear and Radiation Studies Board is responsible for oversight of National Research Council studies on safety and security of nuclear materials and waste.

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

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

mand for molybdenum 99 is about 5,000-7,000 6-day curies per week,⁴ which is about half of the global demand for this isotope. We also found that domestic demand for this isotope is likely to grow at rates of 3-5 percent per year over the next 5 years, and that growth will likely continue over the longer term as the U.S. population ages. The global demand for this isotope could grow even more rapidly in the years ahead as nuclear medicine technologies find more widespread application, especially in developing countries. Robust international growth could impact future domestic molybdenum 99 supply, availability, and price because the United States does not produce this isotope for medical use.

Global molybdenum 99 production is insufficient to meet current demand owing to the recent shutdowns of two reactors: The NRU Reactor in Canada and HFR in the Netherlands. These reactors are 52 and 48 years old, respectively, and are likely nearing the ends of their operating lifetimes. The supply disruptions arising from these reactor shutdowns are impacting the availability of molybdenum 99 for medical use and the continuity of patient care in the United States and elsewhere. Supply reliability is likely to continue to be a serious problem for the United States until new supply capacity is brought online.

Charge 3: Determine the 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 facilities. 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 LEU. Our report found that DOE has made substantial progress in converting reactor fuel and targets through the GTRI. We recommended that DOE determine the feasibility of converting 78 HEU-fueled research and test reactors that are currently out of scope of the GTRI program, and also that DOE increase its focus on eliminating the HEU wastes that result from medical isotope production.

Our report notes that molybdenum 99 producers have been slow to adopt the LEU-based production processes that have been developed by DOE and others. This is likely because producers have no good business reason for converting to LEU-based production: they would realize little or no direct revenue benefit from conversion, as conversion would not enhance product quality, nor would it reduce the production costs. In fact, we saw no evidence during our study that large-scale producers were doing the necessary research and development work to support conversion to LEU-based production.

Charge 4: Determine the potential cost differential in medical isotope production in reactors and target processing facilities if the products were derived from production systems that do not involve fuels and targets with HEU. We 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 given a sufficiently long amortization period. This finding was based on a conservative present value cost analysis at three steps in the molybdenum 99/technetium 99m supply chain: production of molybdenum 99, production of technetium generators, and delivery of technetium 99m doses. In fact, we concluded that a 10 percent increase in price at any of these three points in the supply chain would result in a trivial (< 1 percent) increase in the price of a typical medical isotope procedure.

Charge 5: Identify additional steps that could be taken by DOE and medical isotope producers to improve the feasibility of conversion to LEU-based isotope production processes. We identified additional steps that could be taken by DOE and others to improve the feasibility of conversion of medical isotope production. We specifically suggested that:

- 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.
- The Food and Drug Administration (FDA) should work with industry and technical experts to ensure that there is a common understanding of likely FDA re-

⁴A 6-day curie is a measure of the quantity of molybdenum 99 present 6 days after it leaves a producer's facility. Time calibration is necessary because the quantity of molybdenum 99 decreases by about 1 percent per hour as a result of radioactive decay.

quirements for obtaining regulatory approvals for the medical use of LEU-based molybdenum 99/technetium 99m.

- 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.

Notable progress has been made in implementing these suggestions since our report was published: DOE has offered technical assistance to medical isotope producers; the FDA acted promptly to approve the domestic sale of radiopharmaceuticals containing technetium 99m from Australia and South Africa; Mallinckrodt and Babcock and Wilcox have announced a partnership to produce molybdenum 99 using an LEU solution reactor; and the South African producer NTP recently announced that it would convert its medical isotope production process to LEU targets.

COMMENTS ON H.R. 3276

The American Medical Isotopes Production Act of 2009 is responsive to many of the findings from our report. Notably, the legislation seeks to address the chronic supply reliability problem by providing incentives for the development of domestic supplies of molybdenum 99 for medical use. Development of a domestic supply of molybdenum 99 could help alleviate current global shortages and insulate the United States from future supply disruptions. It could also help to ensure the continued availability of this workhorse isotope to meet future domestic demand if, as expected, the global demand for this isotope continues to grow.

The legislation sends a clear policy signal of Congress' intention to phase out HEU for medical isotope production; this signal could provide a powerful near-term incentive for conversion. The legislation's proposed phase-out period of 7 years, with an additional 4 years if needed, is largely consistent with our report's suggested phase-out period of 7-10 years. We judged that 7-10 years would be sufficient for producers to make an orderly conversion to LEU-based production. This judgment was based on previous experiences with conversion and our understanding of regulatory processes.

The legislation's authorization of appropriations to develop a domestic supply capacity for medical isotope production is consistent with our report's suggestion that Congress provide temporary financial incentives for conversion to LEU-based production and development of domestic supplies. Our report notes 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."

The uranium lease and take back provision in the legislation was not specifically identified as an incentive in our report. However, it could serve to promote domestic production by allowing producers to sidestep the regulatory uncertainties associated with waste classification and disposition.

Finally, the legislation would empower the Secretary of Energy to provide assistance for the development of fuels, targets, and processes for domestic production of molybdenum 99. This is consistent with our report's suggestion that the Department of Energy make the technical expertise of the DOE national laboratory system available to assist producers with conversion-related research and development.

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

The CHAIRMAN. Thank you very much.
Mr. Brown.

STATEMENT OF ROY BROWN, FEDERAL AFFAIRS SENIOR DIRECTOR, COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS (CORAR), ST. LOUIS, MO

Mr. BROWN. Good morning, Mr. Chairman, Ms. Murkowski, members of the committee, and staff. My name is Roy Brown, and I am Senior Director of Federal Affairs for the Council on Radionuclides and Radiopharmaceuticals, or CORAR.

I am here today to testify on the American Medical Isotopes Act of 2009 on behalf of CORAR and to answer questions from the committee.

CORAR supports H.R. 3276 and the provisions contained in the legislation. We believe this legislation will provide important funding, waste disposal, and regulatory support to help establish reliable medical isotope production in the U.S.

This legislation is an important step toward a reliable source of these medical radionuclides for our patients and will contribute to enhancing supply well into the future. More than 40,000 patients each day in the U.S. rely on technetium-99m to provide detection of heart disease or for early detection and staging of cancer, all of which can reduce healthcare cost and improve the quality of life.

As a supporter of H.R. 3276, 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 the U.S. patients.

First, Section 3(c) 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 generated.

The waste will be produced at new medical isotope production facilities. It is critically important DOE accepts this radioactive waste at reasonable prices. This will help assure new medical isotope production facilities can be built and operated effectively.

Second, 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 FDA, the DOT, the EPA, as well as State and local regulatory agencies. We are concerned that acceptance of money from DOE for the development of medical isotope capability under this legislation may trigger duplicative National Environmental Policy Act 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. We would like to see a provision in the legislation for any Federal money spent on the development of medical isotopes not be burdened by duplicative regulatory constraints.

Third, several groups are working on the development of new types of isotope production reactors or have plans to convert existing reactors for more efficient 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 language in Section 104 of the Atomic Energy Act due to their production focus and lack of research being conducted there. 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 Atomic Energy Act.

CORAR would like to see H.R. 3276 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 licensing of these reactors under Section 104 of the AEA. If assistance of this type

could be included in this legislation, it would help expedite the licensing of these new reactors and bring these new sources of Mo-99 to market more quickly.

Last, CORAR is aware of several promising efforts to develop new medical isotope production techniques. We believe these efforts are worthy of funding from this legislation. We also feel the American public can best be served by developing several efforts concurrently rather than backing only one or two of these efforts.

Given the legislation's intent to broadly serve American patients, funding should be directed to projects which stand the best chance of producing commercially meaningful quantities of medical isotopes. 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 decisionmaking process for these projects.

Thank you for the opportunity to testify here today. CORAR supports 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 crisis for the benefit of the American patients.

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

[The prepared statement of Mr. Brown follows:]

PREPARED STATEMENT OF ROY BROWN, FEDERAL AFFAIRS SENIOR DIRECTOR,
COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS (CORAR), ST. LOUIS, MO

CORAR¹ (Council on Radionuclides and Radiopharmaceuticals) supports H.R. 3276 and the provisions contained in the legislation. We believe this legislation will provide important funding, waste disposal and regulatory support to help establish reliable medical isotope production in the United States. The current medical isotope crisis has affected thousands of American patients who rely on these products every day for diagnosis, treatment planning and treatment. CORAR supports H.R. 3276 because it is an important step towards a stable source of these medical radionuclides for our patients and will contribute to enhancing supply well into the future.

As a supporter of H.R. 3276, CORAR would like to highlight a few issues for the committee's consideration to ensure that the bill will accomplish its goals and serve the medical needs of US patients:

- Assure DOE accepts radioactive waste generated as a result of medical isotope production at reasonable prices.
- Develop a regulatory framework in which the funding from the legislation can be distributed to worthwhile efforts without triggering duplicative regulatory reviews.
- Direct the Nuclear Regulatory Commission to develop a regulatory space to allow for the licensing of new medical isotope production reactors that do not have to be licensed as power reactors.
- Direct DOE to develop a process for the fair and technology-neutral administration of funds created in this legislation with appropriate input from industry.

CORAR would like to continue working with staff to determine the best way to address these concerns for the benefit of American patients.

¹ 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. Several of CORAR's members are the primary processors of Mo-99, or are manufacturers of Tc-99m generators which use Mo-99.

I. INTRODUCTION

Mo-99 and Tc-99m play an important role in healthcare. The use of medical radio-nuclides is very important today—these compounds help provide early detection and treatment of diseases which can reduce health care costs and improve quality of life. There are more than 100 different nuclear medicine procedures in use today, of which more than 16 million nuclear medicine procedures performed each year in the U.S. Of these, 41,000 use Tc-99m each day. Roughly 95% of the medical radio-nuclides used in nuclear medicine are produced using HEU targets in nuclear reactors. The majority of nuclear medicine procedures are for diagnostic imaging, but there are also many therapeutic nuclear medicine treatments including Non-Hodg-kin's Lymphoma, Liver Cancer, and Thyroid Cancer and for bone pain palliation related to Prostate Cancer.

Over the last few decades more than 90% of the Mo-99, (Iodine) I-131, I-125 and (Xenon) Xe-133 that was used in the U.S. came primarily from just two government owned reactors. Those two reactors are the NRU reactor operated by AECL in Chalk River, Ontario, Canada and the HFR reactor operated by NRG on behalf of the European Union in Petten, The Netherlands. Until recently, these two reactors had been extremely reliable. However, NRU and HFR were commissioned in 1957 and 1961, respectively. The age of these reactors has led to age-related operating problems. NRU has been shut down since May while repairs are being made to the reactor vessel and is not expected to be back on-line until early 2010. HFR was recently shut down for a month for routine maintenance and is scheduled to be shut down again in early 2010 for several months while repairs are made to its cooling lines. These planned and unplanned shutdowns have created the current shortage of Mo-99. Both of these reactors operate with Low Enriched Uranium (LEU) fuel and HEU targets.

Currently, many efforts are underway to alleviate the Mo-99 shortage, which can reach crisis proportions when both reactors are out of service. These efforts are coming from governments, industry, and professional societies around the world. CORAR believes the primary focus of this new legislation should be to address the need for a longer term and sustainable solution to this problem. It should also provide a framework so that similar crises can be avoided in the future. CORAR has identified six needs that any long term solution should address or solve, including:

- Appropriate site security
- Reactor and isotope processing in proximity to each other
- Disposal path for the processing radioactive by-products must be defined and approved
- The manufacturing and processing sites should have good access to a well developed transportation network
- The reactor operation must use both LEU fuel and targets
- Knowledgeable and empathetic regulatory environment

II. DISCUSSION OF SPECIFIC ISSUES

CORAR is supportive of this legislation. We feel with some minor modifications and assistance from the Senate this bill can be extremely effective in creating additional medical isotope capacity. These issues are elaborated below.

DOE Disposal of Medical Isotope Waste

The production of medical isotopes generates Class A and Class B low level radioactive waste, and transuranic waste. Currently Mo-99 and other medical isotopes are being produced outside the U.S. and the local governments assist these facility operators in the disposal of that waste. For some radioactive waste in the U.S., there is currently no disposal pathway available. DOE has waste disposal facilities for all types of radioactive waste, but it is only available to the DOE. The legislation appropriately has a provision (Sec 3, (c)) for waste acceptance by the DOE. Our industry has worked with the DOE for many years, and as such we are aware of non-competitively high prices DOE charges for certain services and work performed for others. What we seek is an understanding that the DOE will accept radioactive waste at reasonable prices. We seek your guidance in assuring this happens, as unreasonable disposal charges would inhibit implementation of this legislation's goals.

Avoiding Duplicative Regulatory Review

For example, we are concerned 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. If NEPA is triggered and the DOE is required to complete Environmental Impact Statements (EIS) and/or Environmental Assessments (EA), it will cause significant delays in the development of

these facilities which is counterproductive to the intent of the legislation. We feel the development of EAs and EISs is not necessary because of other regulatory controls these facilities will be under. Any new reactor funded under this legislation will be required to be licensed by the NRC. The NRC has a comprehensive regulatory framework for protection of the environment, workers and the public. This regulatory framework will adequately fulfill the intent of the NEPA and will protect the environment. Any new production facility receiving funding under this legislation will be licensed by the NRC or equivalent Agreement State agency. The NRC and the Agreement States also have the material program regulatory framework to protect the environment, workers and the public. Various aspects and operations of these facilities will also be regulated by the Food & Drug Administration, Department of Transportation and the Environmental Protection Agency, as well as state and local regulatory agencies. With these various levels of regulatory oversight, we do not believe the NEPA will offer any more protection of the environment. We would like to see a provision in the legislation for any federal money spent on the development of medical isotopes to be exempt from the requirements of NEPA.

NRC Licensing of New Isotope Production Reactors

Several groups are working on the development of new types of isotope production reactors which fall into a licensing gap at the NRC. These new types of reactors are being built in the U.S. and will utilize LEU fuel. 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. At the time the AEA was written, the use of these types of reactors for the production of medical isotopes was not envisioned. 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. Consequently, these types of reactors fall into a licensing gap for the NRC. CORAR would like to see H.R. 3276 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.

Distribution of Funds Under this Legislation

CORAR believes NNSA at DOE is the logical administrator of funds identified in this legislation. NNSA has been closely involved in the development of LEU-based medical isotope production for many years. CORAR is aware of several promising efforts to develop new medical isotope capacity. We believe these efforts are worthy of funding from this legislation. We also feel the American public can best be served by developing several efforts concurrently rather than only backing one or two of these efforts. CORAR positively notes that the legislation does not limit the number of projects eligible for funding support provided the projects meet the legislation's criteria related to ability to meet the legislation's deadlines, capacity to fulfill domestic Mo-99 demand and cost. For example, given the legislation's intent to broadly serve American patients, funding should be directed to projects which stand a good chance of producing commercially meaningful quantities of medical isotopes. 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 decision-making process for these projects. The best process will be one that is technology-neutral and does not pre-judge these development efforts.

III. OTHER IMPORTANT MEDICAL RADIONUCLIDES

There are other medical radionuclides which are very important to nuclear medicine. Many of these radionuclides are used in therapeutic procedures for the treatment of cancer and other illnesses. Although their number of procedures do not come close to the annual usage of Tc-99m, they are also very important. These radionuclides can be produced in a fission reaction such as Mo-99, or they can be produced through neutron activation. The same reactors that produce Mo-99 also produce these other radionuclides including I-131, I-125, Xe-133. These radionuclides are used in diagnostic and therapeutic procedures and are being examined for use in exciting new products for nuclear medicine. It is important to remember these other radionuclides play an important role in the practice of nuclear medicine and should be included in the overall approach to assuring a reliable supply for critical medical radioisotopes.

IV. CONCLUSION

The current worldwide shortage of Mo-99 has illustrated the fragility of supply and the need for additional medical radionuclide production. CORAR is supportive of H.R. 3276 and increasing the capacity for medical radionuclides in the U.S. We believe several key issues still need to be addressed in the legislation to assure it will provide the best environment to develop additional medical isotope production capacity.

By assuring DOE accepts all radioactive waste generated as a result of medical isotope production at reasonable rates, the new production facilities being developed will be economically viable.

Developing a regulatory framework in which the funding from this legislation can be distributed to worthwhile efforts without triggering duplicative regulatory reviews, such as National Environmental Policy Act (NEPA), will assure the new facilities will come on-line more quickly without compromising the environment or protection of workers or the public.

Directing the Nuclear Regulatory Commission to develop a regulatory space to allow for the licensing of new medical isotope production reactors that do not have to be licensed as power reactors will bring these facilities on-line more quickly, and at a lower cost. Reactors dedicated solely to medical isotope production were not envisioned when the Atomic Energy Act was first written in 1954.

Directing DOE to develop a process for technology-neutral administration of funds created in this legislation with appropriate input from industry will help assure the fair and most productive use of these funds. CORAR believes it is prudent to back several alternative technologies capable of producing significant quantities and multiple reactor sites in order to avoid a repeat of the current availability and capacity issues.

As H.R. 3276 moves forward, CORAR hopes to continue to work with the Committee and staff to ensure both a swift and long term solution to the medical isotope crisis. Thank you for the consideration of our perspective. CORAR looks forward to working with you toward the enactment of this legislation.

The CHAIRMAN. Thank you very much. Thank all of you for your testimony.

Let me just ask a few questions. First, Dr. Staples, what are the potential reactors here in the U.S. that might be used for LEU-based medical isotope production?

Mr. STAPLES. Generally, large-scale quantities of LEU target-based Mo-99 production require a research reactor that operates on a steady state with a short operating cycle and can dedicate operating time to Mo-99 production. Typically, the current international producers have a minimum of 10 megawatts of power for production.

So I would actually like to take the question for the record so that I can actually convey this list to you properly. It actually does have the list of reactors in the U.S. and internationally that are producing isotope.

[The information referred to follows:]

The attached chart entitled "Research Reactor Capability" includes the research reactors at U.S. universities, U.S. Government facilities, and major foreign producers and potential producers, with the associated power levels. It should be noted there are three main considerations that are helpful when examining this chart.

First, research reactors require high levels of neutron flux to produce medical isotopes efficiently. The six major producers (denoted in the chart by asterisks) have significantly higher thermal power than any of the U.S. university reactors. To a first approximation, production capacity for fission target-based production of radioisotopes scales with reactor power.

Second, utilizing the U.S. Government facilities for medical isotope production would be technically challenging, expensive, and would impact other important missions of those facilities. The U.S. Interagency Working Group led by the Office of Science and Technology Policy (OSTP) evaluated the potential use of two U.S. Government reactors (ATR and HFIR) for irradiation of Highly Enriched Uranium (HEU) targets to alleviate the short-term shortage. However, the analysis of these alternatives has shown them to be very expensive, technically challenging and, de-

spite the effort that would be entailed, providing only a small fraction of the U.S. demand for Mo-99. These reactors also provide critical services to other customers, including national security missions that may be hindered if the facilities were devoted to Mo-99 production.

Finally, NNSA's efforts to establish a reliable non-HEU domestic source of Mo-99 in the long-term have eliminated U.S. Government facilities or its contractor facilities as possible providers since the intent is to establish a commercially viable market. To that end, it would be inappropriate for the U.S. Government organizations to compete with these commercial entities.

Research Reactor Capability – Power in Megawatts (MW)					
U.S. University research reactors [†]		Foreign reactors producing (*) or expressing some intent to produce Mo-99		U.S. Government research reactors [‡]	
Univ. of Missouri – Columbia	10 MW	NRU – Canada *	135 MW	ATR – Idaho National Lab	250 MW
Massachusetts Institute of Technology	5 MW	HFR- Netherlands *	50 MW	HFIR-Oak Ridge National Lab	85 MW
University of California – Davis	2 MW	BR2 – Belgium *	100 MW	NBSR - National Institute of Standards and Technology	20 MW
Rhode Island Nuclear Science Center	2 MW	OSIRIS – France *	70 MW		
Oregon State University	1 MW	SAFARI – South Africa *	20 MW		
University of Texas – Austin	1 MW	OPAL – Australia *	20 MW		
University of Massachusetts - Lowell	1 MW	MARIA – Poland	30 MW		
North Carolina State University	1 MW	ETTR-2 – Egypt	22 MW		
Pennsylvania State University	1 MW	Pitesti – Romania	14 MW		
Texas A&M University	1 MW	BRR- Hungary	10 MW		
Washington State University	1 MW	REZ – Czech Republic	10 MW		
University of Wisconsin	1 MW				
* Current Global Producer [†] Capacity to produce Mo-99 in commercial quantities scale with the power grading of the reactor facility. [‡] Utilizing U.S. government facilities for Mo-99 production would be technically challenging, expensive, and would impact the other important functions of the facilities. In addition, USG facilities are not being considered for long-term Mo-99 production as it would be inappropriate for USG to compete with commercial entities.					

But to quickly answer your question, there are several larger reactors in the U.S. that can operate. There are some DOE facilities, which we would not necessarily consider a DOE facility to be a primary source of irradiation for this production because of the non-commercial nature of those facilities, which would be the HFIR reactor at Oak Ridge National Laboratory. The ATR reactor is also a large research reactor that is located at Idaho National Laboratory, and then we have several university reactors, such as the University of Missouri, which is a 10-megawatt facility. Massachusetts Institute of Technology is a 5-megawatt facility.

Then there are a number of other facilities that have anywhere from 1 to 2 megawatts of operating power but are probably on the small side for regular large-scale commercial production.

The CHAIRMAN. All right. Dr. Crowley, I think you mentioned in your testimony the use of accelerators rather than reactors to produce these isotopes. Do you think that accelerators can produce the volume of Mo-99 that is required here in this country?

Mr. CROWLEY. The short answer to your question is no, and let me explain why the answer is no. The reason that reactors are used to produce Mo-99 is that they provide very high fluxes of neutrons. If you imagine a postage stamp, which is about between half an inch and an inch on a side, if you put that postage stamp into the reactor, every second about 100 trillion neutrons would go through that postage stamp. So that is a very high flux of neutrons, which is what you need to fission the uranium-235 to produce the Mo-99.

You don't get those sorts of high fluxes with accelerators. You would have to build a lot of accelerators. It would be very expensive to get an equivalent production.

The other advantage of the reactors over the accelerators is that the reactors tend to be multipurpose, multiuse facilities. So you can be producing Mo-99, but at the same time, you can be irradiating other materials and you can be conducting scientific experiments. With an accelerator, it would be a dedicated facility simply to produce Mo-99.

The estimates that I have heard for accelerator-based production of Mo-99 would be on the order of hundreds of 6-day curies per week. Six-day curies is the measure that we typically use of Mo-999 quantity. The current U.S. demand is between 5,000 and 7,000, 6-day curies per week. So an accelerator could produce hundreds of curies, but we demand thousands of curies per week.

The CHAIRMAN. All right. Let me ask you, Mr. Brown, in your testimony you indicate that the department's fuel takeback charges could be unreasonable. What is the mechanism that you would propose to ensure that these charges are reasonable while still having the industry bear the burden that is called for in the legislation to pay for the ultimate disposal?

Is there some way to accomplish both of those objectives?

Mr. BROWN. Our industry has quite a bit of experience working with the DOE and the national labs. Our experience has been that quite often charges working with the national lab are much, much higher than you would normally pay on a commercial basis, often several times higher, 3 to 4 times higher than the actual cost of that.

So we are concerned about paying more than commercially available rates for disposing of this waste. We realize that some of this waste there currently is no disposal. So to compare a commercial price for waste you can't get rid of anywhere else is difficult, but we would expect something on the order of what we would pay commercial charges for.

The CHAIRMAN. OK. Why don't I stop with that and call on Senator Murkowski?

Senator MURKOWSKI. Thank you, Mr. Chairman.

Several of you, actually I think all of you have mentioned the importance of the legislation being technology neutral in making sure that we are not favoring reactors over accelerators or other neutron-capture technology.

Mr. Brown, you mentioned that certain types of these production reactors fall within this “licensing gap” because they are not research or power reactors and have suggested that perhaps we might need some clarification to spell out whether or not it is a production reactor.

If we do that, do we then edge up against the concern that the legislation is not technology neutral? I guess a broader question to the panel would be how important is it to ensure that it is technology neutral?

Mr. BROWN. Our specific concern about the NRC licensing gap is based on the fact that when the Atomic Energy Act was written in 1954, it really wasn’t envisioned that there would be reactors that are out there producing medical isotopes that were not commercial reactors and they are not research reactors.

So that the difficulty we are in is some of these new reactors that are being considered, the NRC is coming back and saying we think they can be licensed under Section 103, which is the section of the Atomic Energy Act that deals with commercial reactors, commercial nuclear power reactors. However, these reactors for medical isotope production are inherently safe, and we don’t feel that they should be licensed under that with the more stringent requirements of a nuclear power reactor.

So the problem of the licensing gap is a little bit different. So we are just hoping that some of the provisions that are usually used for research reactors can be applied to these new medical isotope reactors.

Senator MURKOWSKI. Can somebody provide a clear understanding in terms of what our options in the United States may be for meeting the demand for the medical isotopes next year and recognizing what is happening with the facility in Canada? What are our options?

I mean, if you are a physician, do you have to defer non-emergency procedures? What happens? Any of you may respond.

Mr. STAPLES. Yes, I will take that question first. In 2 weeks, we are going to a meeting with the Organization for Economic and Co-operative Development Nuclear Energy Alliance, where a high-level working group of the current producers will try to optimize their schedules for production.

In terms of 2010—and actually, again, I will take some of this question for the record so that I can convey this chart to you. These are two very important visuals that we have to demonstrate the message. But from this chart, what you can see is that the red line of 12,000, 6-day curies is the normal demand. This is the projected supply cycle for next year. You can see there are several significant gaps.

[The information referred to follows:]

The attached graph* illustrates our best estimate of what the projected global Molybdenum-99 (Mo-99) supply availability could be in 2010, assuming the worst-case scenario that the Canadian NRU reactor does not resume operations as expected in the first quarter of 2010. Atomic Energy of Canada Limited has committed to returning the NRU to service as quickly as safely possible and the latest projected date to return to operation is by the first calendar quarter of 2010, but that is no means guaranteed. If the NRU returns to operation as expected, the expected supply shortage in the last three quarters of 2010 would largely, but not entirely, be resolved. This graph and the associated supply estimate is also highly speculative regarding the supply of medical isotopes; it is likely that in practice the shape of the curve will be different as production schedules and market forces cause adjustments.

Senator MURKOWSKI. What creates those significant gaps?

Mr. STAPLES. The operating schedule of the current producers, and they do not have any ability to operate continuously. They have regular refueling and maintenance operations that they need to undergo. This chart is actually produced assuming that the Canadian reactor does not come back into production. If the Canadian reactor comes back in operations in the first quarter, as the Canadian government is currently stating and aiming for, there will not be a supply issue in 2010.

Senator MURKOWSKI. So you will meet that red line?

Mr. STAPLES. We will be able to meet that red line if the Canada's NRU resumes operation.

Senator MURKOWSKI. Do we know when the Canadians will be able to make a decision?

Mr. STAPLES. We do not. The latest information we had, and we expect an update at the meeting in 2 weeks, will be at the first quarter of 2010.

Now the question that you asked regarding if there is a supply disruption, there really honestly is little that we can do other than knowing what the current production schedule looks like, such that doctors can adjust diagnostic tests and procedures or use alternate diagnostic methods to determine the treatments that might be appropriate.

Senator MURKOWSKI. The alternate diagnostic methods are not as efficient or accurate. I am assuming there is good reason that the demand exists?

Mr. STAPLES. That is correct. I am not a medical professional, and I would actually defer to Mr. Brown to fully answer that question.

Senator MURKOWSKI. I am trying to understand, your graph from a distance looks very problematic if in fact we have no control over this, since we are not producing anything in this country. We are at the mercy of those who are producing, Canada and others.

As a Nation that consumes 50 percent of these isotopes, what options do we have, if any? I would like to understand what we are going to anticipate next year if, in fact, Canada is not able to come into the supply cycle like we would hope.

Mr. STAPLES. OK. In addition to adjusting and looking at alternate treatments and trying to optimize their current production schedule, which this chart shows an optimized production schedule. This is not what the producers were originally planning to produce in 2010.

* Graph has been retained in committee files.

We have adjusted this to minimize the number of gaps that are in this chart because the medical community does state that they would prefer a regular diminished supply rather than an irregular large supply. So we have tried to smooth over the——

Senator MURKOWSKI. But this looks somewhat jagged.

Mr. STAPLES. It was worse.

Senator MURKOWSKI. There is some irregularity. It was worse?

Mr. STAPLES. It was worse.

Senator MURKOWSKI. OK.

Mr. STAPLES. It is as best as it can be, given the requirements and demands of operating the production reactors. In addition, we have worked under the direction of the OSTP, Office of Science and Technology Policy of the President, with the Department of Energy's Office of Science, our Canadian colleagues, and, in fact, the entire interagency to try to determine if there are any short-term production options.

We are still under the evaluation phase within the Department of Energy to determine if there are some short-term production options. However, they are extremely difficult to implement from a technical basis, and they are extremely expensive to implement because the only reliable facility that we can use for manufacture of the isotope is to use a U.S.-based reactor and to separate the medical isotope at the facility in Canada.

So it would require regular transportation of irradiated targets from the U.S. to Canada and separations in the Canadian facility for subsequent distribution to the United States.

Senator MURKOWSKI. We don't have the ability or the capability to do any of the separation here?

Mr. STAPLES. We do not, not in the timeframe necessary at the commercial scale necessary with FDA approval. That is the difficulty. It is not always just having the neutrons to make the isotope. The actual difficulty in this process is actually being able to separate the isotope out of the targets and turn it into a commodity that is approved by the FDA for human consumption. That really is the difficult part of this process.

Senator MURKOWSKI. Thank you, Mr. Chairman. My time is expired.

The CHAIRMAN. Senator Burr.

Senator BURR. Thank you, Mr. Chairman. Thank you and the ranking member for holding what I think is a very important hearing.

I would like to thank our witnesses today for their expertise. During the debate in 2005 on the Energy Policy Act, I fought for a provision to allow us to export highly enriched uranium for the purposes of us getting the medical isotopes we need in the marketplace, and I say this for my colleagues.

They include the treatment, diagnostic treatment for heart disease, cancer, lymphoma, Graves' disease, cold infection in AIDS, Parkinson's disease, Alzheimer's disease, epilepsy, renal kidney failure, bone infections. The one thing that this tool provides us is the ability to go to one diagnostic tool and to have conclusive evidence of where the problem is versus to run multiple diagnostic tools as you home in on what the problem might be.

So at this particular time, as we are debating healthcare, this is an absolutely crucial component of how you save money in the overall healthcare system, and that is why Mr. Brown I think is right to focus on a reasonable price. I am not sure you can pull a number out of the sky except to say here is what the commercial market offers today and here is what the cost is.

Now if you put together a matrix that raises the cost three and four times, two things happen. One, you raise the cost of healthcare. But two, you put in jeopardy a provider, be that Medicare or private sector insurer or out of pocket, of the system saying this isn't cost effective. We would rather do the other four tests because they come up cheaper than this one. Yet under that scenario, you might not conclude with finality what the problem actually is.

So refresh me, Mr. Brown, are radioisotopes used in contrast imaging?

Mr. BROWN. No. Contrast imaging uses nonradioactive drugs.

Senator BURR. OK. I couldn't remember. But contrast imaging was a great example of how the Federal Government looks at the advancement of technology and doesn't recognize that reimbursement plays a large role in whether, in fact, we incorporate these in the everyday use of medicine.

When contrast imaging came onboard, Centers for Medicare and Medicaid Services, in an effort to reimburse for this new technology, decided they would double the reimbursement for noncontrast imaging to make up for the shortfall for contrast. Every hospital administrator the next day told the areas of the hospital they would only do noncontrast imaging from that point forward because the benefit was they got a reimbursement that was double.

So I think we fool ourselves if we don't believe that reimbursements do play a part in how providers ultimately will use diagnostic tools, and this would be one of them as well.

Let me turn, if I could, to Dr. Staples for a minute. I agree with you that the quicker we can move to domestic production, the sooner we can mitigate some of the nuclear proliferation concerns, which is what we fought for the last few years. You mentioned that you are working with the industry on four technology pathways.

Does the NNSA have all the regulatory tools that you believe are necessary to effectively and efficiently commercialize those paths?

Mr. STAPLES. I believe we do, and I think that is the strength of this legislation is that it would actually give the recognition through the interagency in the authorization to ensure that, as the interagency, we come together with the FDA, the NRC, the EPA to ensure that all of the regulatory requirements and obligations that are necessary to implement this technology would actually be implemented in as timely, expedient manner as possible to meet the needs of the medical community.

Senator BURR. If, in fact, you—when this is passed—find that you don't have all the tools, will you come back to us and share what you need?

Mr. STAPLES. Absolutely. That is where I think that this legislation gives the recognition to this important issue, and that is actually where we appreciate this legislation, that it brings the high-level attention to resolve this issue. As you know, this has been a longstanding nonproliferation issue. Really, with the result of the

National Academies study coming out recently, it gave us the tool to accomplish the nonproliferation point of this bill.

But then, recently, with the collapse of the current production industry, it also gives us the ability to move forward rapidly and as expediently as possible to resolve the medical crisis that is looming for the community also.

Senator BURR. I appreciate your chart, and I hope my colleagues realize that that chart really does demonstrate how vulnerable we are to not having the resources to provide the best level of care and diagnostic tools.

Mr. Crowley, with your study now complete, you looked at several questions, including what the Department of Energy and medical isotope producers could do to transition from HEU-to LEU-based isotope production. The National Academy of Science recommends Congress provide clear policy directions to phase out the exportation of HEUs and encourage domestic production of LEU isotopes. Do you believe H.R. 3276 successfully achieves that goal?

Mr. CROWLEY. The answer to that is yes. As I mentioned in my oral testimony, we had suggested that a 7- to 10-year phase-out period for export of HEU would provide a very clear policy signal to producers that they needed to move to LEU production. The legislation has a 7- to 11-year phase-out. So I think that is very consistent with the recommendation in our report.

Senator BURR. Great. Great. I thank the chair.

The CHAIRMAN. Senator Murkowski, did you have additional questions?

Senator MURKOWSKI. Very quickly, Mr. Chairman, and this is probably best directed to you, Dr. Crowley. The National Academies have estimated that it would take between 9 to 13 years for the construction of a new reactor at a site that doesn't have a processing facility and assuming a 6- to 6-year construction period.

Are these time estimates consistent with past licensing with new reactors and new chemical processing facilities. Then, more specifically, when was the last time that the NRC licensed a new research reactor?

Mr. CROWLEY. I will have to—

Senator MURKOWSKI. It has obviously been some time.

Mr. CROWLEY. Yes. As it turns out, the 1960s were a very good decade for building research reactors, and if you look at a lot of the research reactors that are currently in use today, they were built in the 1960s, early to mid 1960s. The exception is NRU, which was built in the late 1950s. But if you would like to put that question to me in a follow-up, I can get you an answer to that.

Let me go back to your initial question, though, about construction of new reactors. The 9- to 13-year estimate was actually based on our observations of what it had taken in the past to build reactors, and that time period starts from a conception that says, gee, we would like to build a research reactor to the time that you turn on the switch.

The actual construction time can be shorter than 9 to 13 years. As an example, the NRG, which is the operator of the HFR reactor in the Netherlands, which is one of the major producers in Europe, is proposing to build a replacement reactor for HFR called the

PALLAS reactor. They are to the point now where they are ready to select a design, and they believe that they can be online by 2016.

So to the point where they are almost ready to turn dirt or to have a conceptual design to the time that they are ready to turn on the switch is considerably less than 9 to 13 years.

Senator MURKOWSKI. Do you know when the last time was that the NRC licensed a new isotope processing center, facility?

Mr. CROWLEY. I do not, but I could certainly get that answer for you as a follow-up.

Senator MURKOWSKI. One last question to you, Dr. Staples. We have talked about the objective. You have discussed NNSA's objective for future Mo-99 production, and that is to establish this domestic supply.

Now I also understand that domestic supply does not necessarily mean domestic supplier. So the question to you is whether or not you are aware of any medical isotope producers in the world who are either privately financed and not subsidized by a foreign government? Are there any?

Mr. STAPLES. The last part of that question actually is very difficult to answer, and I think that is maybe best embodied in the National Academies report in terms of the difficulties they had determining the economic situation. But, no, at this point in time, I am not aware of any facility that is producing that is not subsidized to some extent by their respective governments because almost all of the facilities are operated as State-owned or government-owned research reactor facilities.

So, in some extent, their fuels, disposition of radioactive waste are all subsidized, to the best of my knowledge. But we will follow up as a question for the record to verify.

[The information referred to follows:]

All major global producers are in some way subsidized by their respective governments. Chapter 3 of the National Academies report Medical Isotope Production without Highly Enriched Uranium states, "All of the organizations that currently produce Mo-99 utilize government-owned research or test reactors to irradiate targets, and some use government-owned facilities for target processing and Mo-99 recovery." Our assumption is that the operations of the government-owned facilities are funded at least partially by the respective governments of each major producer.

Senator MURKOWSKI. Considering the objective within the NNSA for our domestic production, how can we ensure that we have a domestic supply when we do not have a domestic supplier?

Mr. STAPLES. Yes, that is actually—I would like to come back and complete that answer, and it also goes back to the earlier question you were asking about the reliability of supply in this chart. What brought it up to this level that is demonstrated here is all of the foreign producers are in the process of increasing their production capacity and have been operating at above normal production capacities for a period of time and expect to do that through 2010.

Now we are having discussion to some extent or another with all of the current producers regarding conversion to LEU. I believe that they have embodied the importance or embraced the importance of conversion to LEU, and they are trying to work with us to convert to LEU production.

In addition, when we describe the difference between commercial domestic supply versus supplier, we are trying to work to ensure

that we have a reliable diverse supply. We have gotten into this crisis we have because we essentially have a single point of failure and one basic technology, and it is through aging infrastructure.

So developing a diverse supply, whether it is domestic or international based, will ensure that we can receive this important commodity coming into the medical community here in the United States. In fact, we ensure reliable global supply by doing that.

Senator MURKOWSKI. The reliability issue, of course, is key. When we talk about secure energy supplies, we know that, today we may be getting oil from Venezuela and they may be our friends and providing to us, but tomorrow, they may wake up on the other side of the bed and decide that they don't want to do that.

In terms of reliability of supply, how much of a consideration is this as you are looking to achieve the goals that you are setting out in terms of our domestic sources of supply?

Mr. STAPLES. I would say it is very important. Currently, we are working or we would intend to work that we would develop four independent technologies, each capable of supplying up to 50 percent of the U.S. demand. Obviously, in theory, that means that if each of these are successful, we could supply the global requirement for this isotope.

In reality, these are difficult technologies to implement. We don't necessarily expect them to be completely successful, such the final endpoint will be somewhere between having an oversupply located domestically versus having some supply that would come into the global market from both U.S.-based and foreign-based entities that are producing.

So I think diversity is very important and part of our consideration as we move forward.

Senator MURKOWSKI. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Burr, do you have any other questions?

We thank all of you very much. It has been very informative, and we will try to move ahead with the legislation.

Thank you. That will conclude our hearing.

[Whereupon, at 10:46 a.m., the hearing was adjourned.]

APPENDIXES

APPENDIX I

Responses to Additional Questions

RESPONSES OF PARRISH STAPLES TO QUESTIONS FROM SENATOR MURKOWSKI

Question 1. Dr. Staples, the legislation we are considering calls for a ban on the exportation of Highly Enriched Uranium for the purpose of medical isotope production after seven years, with the possibility for a four year extension.

a. Where does the United States currently export HEU to for medical isotope production?

Answer. The United States exports HEU to Canada for the production of targets, which are for Mo-99 production. The U.S. also exports HEU to Belgium for use as fuel in the BR-2 research reactor which has multiple functions, including the production of Mo-99.

b. Where do the other reactors that provide the United States with Mo-99 get their Highly Enriched Uranium?

Answer. The other global producers do not share information on the origin of the HEU used for the production of Mo-99 medical isotopes.

c. Are those reactors considering converting to using LEU targets?

Answer. The reactors that irradiate targets for Mo-99 production can convert to irradiating targets of LEU with few, if any, modifications. Conversion would mainly affect the processing facilities where the isotope is extracted from the targets. All global producers of Mo-99 have demonstrated or communicated a willingness to convert to LEU. In addition, the National Academies report *Medical Isotope Production without Highly Enriched Uranium* confirms that converting Mo-99 production to LEU is technically and economically feasible.

The conversion project for South Africa's Mo-99 processing facility, operated by NTP Radioisotopes, is in the demonstration phase and is currently in discussions to receive regulatory approvals to export LEU-based Mo-99 to the United States.

Belgium's Mo-99 processing facility, operated by the Institute for Radioelements (IRE), announced an intent to initiate in 2010 a new project aimed at conversion to LEU.

The Netherlands' Mo-99 processing facility operated by the Nuclear Research and Consultancy Group (NRG) has received government approval to construct a new facility that will operate only with LEU fuel and targets.

It is unclear whether the Canadian Mo-99 processing facility operated by Atomic Energy of Canada Limited (AECL) will convert to LEU. However, in the November 20, 2009 report from Canada's Expert Review Panel on proposals of alternatives for future Canadian Mo-99 production, the panel recommended that any new investment to produce Mo-99 in Canada should not use HEU.

Question 2. The NRU reactor in Canada is currently licensed to operate until October 2011, with the possibility for an extension until 2016.

a. After 2016, and possibly much earlier, do you expect Canada to continue to produce Mo-99?

Answer. Canada is currently evaluating whether to extend the license to operate the NRU beyond 2011. In the November 20, 2009 report from Canada's Expert Review Panel on proposals of alternatives for future Canadian Mo-99 production, the panel recommended that any new investment to produce Mo-99 in Canada should

not use HEU. We are not aware of any Canadian decisions yet on whether it will continue to produce Mo-99 beyond 2016.

b. Do you consider HEU exports to Canada to be a proliferation risk?

Answer. Canada meets and goes beyond the IAEA Guidelines on the Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC 225/Rev 4), and thus we consider that such material in Canada is protected in accordance with the currently-accepted international standards. The Nuclear Regulatory Commission has issued export licenses of HEU to Canada, after determining that the proposed export is not inimical to the common defense and security of the United States. Nevertheless, U.S. policy aims to eliminate the use of HEU in civilian applications to the greatest extent feasible, so as to further reduce any risk of such materials falling into the wrong hands.

Question 3. If conditions relating to the supply of Mo-99 are the same six years down the road as they are today, would it be your analysis that the requirements provided in the legislation for an extension of the exportation of HEU are met and the extension should be granted?

Answer. If conditions relating to the supply of and need for Mo-99 are the same six years down the road as they are today, the United States would be experiencing what most in the medical community currently consider a critical shortfall of supply. If H.R. 3276 is enacted as it is written today, and if HEU exports were halted for Mo-99 production while the United States experiences a critical shortfall of supply, the Secretary of Energy would decide whether to certify to Congress, in accordance with the provisions of the legislation, that there is an insufficient supply of Mo-99, and that the temporary export of HEU is required to increase the supply to the U.S. market. Because the Department would make a comprehensive and thorough analysis of the market and the need for medical isotopes, we cannot speculate on whether an analysis of a medical isotope shortage similar to what the United States is experiencing today would result in such a certification from the Secretary.

Question 4. Is there any legal authority contained in the American Medical Isotope Production Act that you do not already have?

Answer. DOE has been utilizing existing appropriations and authorities to support the development of commercial isotope production technologies. The *American Medical Isotopes Production Act of 2009* (H.R. 3276) would provide long-term authorization for funding for this effort and, as a result, demonstrate U.S. leadership and commitment to address the objectives of minimizing the commercial use of HEU in the production of medical isotopes and of promoting the establishment of a reliable domestic isotope production capability. H.R. 3276 would also support our HEU minimization policy by creating a set of deadlines and criteria on the further export of HEU for medical isotope production, although greater Presidential flexibility is desired in this respect.

Question 5. At current world production levels, how long would it take to accumulate enough of the radioactive waste product that is left over after Mo-99 is extracted from the HEU targets to build a nuclear weapon?

Answer. The National Academies report *Medical Isotope Production without Highly Enriched Uranium* states that approximately 50 kg/year of fresh HEU is utilized for medical isotope production among all of the global producers. Since the burn up is negligible, about 97% of the original HEU is still present in the waste, and its enrichment in the U-235 isotope remains close to the original enrichment, which for most producers is above 90%. The International Atomic Energy Agency defines a "significant quantity" of HEU with respect to producing a nuclear explosive device as 25 kgs of contained U-235. This means the wastes attributed to global medical isotope production accumulate one IAEA "significant quantity" of HEU every six or seven months.

Question 6. I understand that the NNSA's objective for future Mo-99 production is to establish a domestic supply of 3,000 6-day curies per week. I also understand that domestic supply does not necessarily mean domestic supplier.

a. Are you aware of any medical isotope producer in the world who is privately financed and not subsidized by a foreign government?

b. Do you believe a foreign government subsidized business entity would or could guarantee a supply of medical isotopes to the United States if there were a shortage in its country of domicile?

c. If not, how would it be possible to ensure a domestic supply that is not from a domestic supplier?

Answer. All major global producers of Mo-99 are in some way subsidized by their respective governments. Chapter 3 of the National Academies report *Medical Isotope Production without Highly Enriched Uranium* states "All of the organizations that

currently produce Mo-99 utilize government-owned research or test reactors to irradiate targets, and some use government-owned facilities for target processing and Mo-99 recovery.” In addition, the European Commission’s Preliminary Report on the Supply of Radioisotopes, page 54, released on October 30, 2009, states: “All the major producers of radioisotopes use research reactors that have been partly or totally built with government funding.”

NNSA is unaware of any mechanism whereby a foreign government subsidized business entity would or could guarantee a supply to the United States if there were a shortage in its country of domicile.

H.R. 3276 would promote the establishment of a domestic production infrastructure capable of providing enough Mo-99 medical isotopes to meet domestic needs. To date, NNSA’s support for the production of medical isotopes has focused on developing reliable sources of Mo-99 within the United States. This support does not limit the United States from continuing to import foreign supplies of Mo-99.

It is also important to note that if H.R. 3276 is enacted, NNSA would continue its work to assist foreign Mo-99 medical isotope producers in converting from the use of HEU to LEU. These conversion efforts have the dual-benefit of HEU minimization and increased diversification of supplies of non-HEU-based Mo-99 available for the U.S. and global markets.

Question 7. Is there a situation in which the lack of supply of Molybdenum-99 would force the NNSA to consider using DOE-owned reactors for production of Molybdenum-99? What are the procedures and processes that would be utilized by the NNSA for making such a recommendation? What are the criteria that would be used for such a recommendation in terms of Molybdenum-99 supply? Does the NNSA have the authority to require the production of Molybdenum-99 from DOE-owned nuclear reactors?

Answer. In response to the recent shutdown of the NRU reactor, the United States and Canada reviewed alternatives for producing Mo-99 in the short-term. The Canada-U.S. Bilateral Working Group on Backup Arrangements for the Supply of Mo-99 was established and chartered to evaluate alternatives for short-term production using some DOE and some Canadian facilities. The criteria for the evaluation included such considerations as yield, cost, time impact on displaced projects, and operational requirements.

The Canada-U.S. Bilateral Working Group on Backup Arrangements for the Supply of Mo-99 submitted its results to the Governments of the United States and Canada for consideration in September 2009. In the United States, the information was reviewed by the Administration for a determination on next steps, including whether to utilize a DOE-owned facility for Mo-99 production. Faced with similar circumstances in the future, the process could be handled in a similar way by establishing a working group to evaluate alternatives with similar criteria for review by decision makers.

Question 8. You indicated that an interagency process would be utilized to streamline the regulatory process for development and licensing of facilities for Molybdenum-99 production.

a. Have the lines of responsibility for licensing activities been established?

Answer. The lines of responsibility among agencies for licensing activities are well established and will not differ from routine procedures.

b. If so, what are the responsibilities for each agency involved in the process including DOE, the NRC, and the FDA?

Answer. NRC is responsible for licensing commercial entities that engage in the production or utilization of nuclear materials. FDA is responsible for ensuring that radioactive medical products are safe for human recipients. DOE would support the development of domestic commercial capabilities to produce Mo-99 without the use of HEU by providing financial and technical resources.

RESPONSES OF PARRISH STAPLES TO QUESTIONS FROM SENATOR CANTWELL

Question 1. I share your concern about the global shortage of Molybdenum-99 and our nation’s lack of domestic production and am encouraged by provisions in the American Medical Isotope Production Act. I am particularly supportive of its effort to decrease our reliance on foreign production of Mo-99 and reduce the threat of Highly Enriched Uranium (HEU) falling into the wrong hands by transitioning to domestic production of Mo-99 fueled by Low Enriched Uranium (LEU). However, even if this bill were enacted today, the transition to LEU would take several years. What is the Department of Energy doing in the meantime to speed this transition? Are there any US research reactors that have already converted to LEU fuel that are capable of producing Mo-99?

Question 2. If yes, would these reactors be able to achieve commercial production by 2013, the commercial capacity goal expressed by the National Nuclear Security Administration?

Question 3. What steps are currently being taken by the Department of Energy and the National Nuclear Security Administration to spur domestic production of Mo-99? How is the NNSA taking advantage of reactors that have already converted to LEU?

Answers 1–3. All U.S. research reactors that use HEU have demonstrated or communicated a willingness to convert to LEU fuel. In addition, the National Academies report *Medical Isotope Production without Highly Enriched Uranium* confirms that converting Mo-99 production to LEU is technically and economically feasible.

For all U.S. university research reactors that can be converted using existing LEU fuels, NNSA's Global Threat Reduction Program completed the conversions two years ahead of schedule in September 2009. New LEU fuels are currently being developed to convert the remaining U.S. research reactors, which are expected to convert to LEU fuel by 2016.

There are research reactors in the United States that operate on LEU and HEU fuel that can produce Mo-99. However, the LEU fueled research reactors operate at much lower power level relative to the current global producers, and these facilities are not likely to be able to achieve large-scale commercial production. The HEU-fueled research reactors do not have the necessary infrastructure or programmatic mission to readily produce Mo-99 for the domestic commercial market. The largest global producers nominally operate at the following power levels: the NRU in Canada operates at 135 MW, the BR-2 in Belgium operates at 100 MW, the HFR in The Netherlands operates at 50 MW and the SAFARI-I in South Africa operates at 20 MW. The global reactors that produce large-scale quantities of Mo-99 operate at much higher power levels than the LEU-fueled research reactors in the United States.

Beyond having the power level necessary for producing neutrons for Mo-99 production, large-scale commercial production also requires a complex chemistry process to create the product that meets FDA standards.

NNSA has executed two cooperative agreements with commercial entities seeking to develop domestic commercial Mo-99 production capability. NNSA is in the process of establishing two more commercial partnerships. Each commercial entity is pursuing a different technical pathway toward commercial isotope production. Two pathways involve the use of reactors utilizing LEU fuel, and two pathways involve neutron capture and accelerator technology. Of the pathways that use a reactor for Mo-99 production, the reactor must operate consistent with U.S. HEU minimization policy by using LEU fuel, or have committed to convert to LEU fuel once an appropriate LEU fuel is developed and commercially available.

RESPONSES OF PARRISH STAPLES TO QUESTIONS FROM SENATOR RISCH

Question 1. What are the national security and economic benefits to domestically producing medical isotopes? Is there a concern that U.S. leadership in medical technologies would be adversely impacted by not pursuing domestic production?

Answer. One of NNSA's objectives is to minimize the commercial use of HEU in the global production of medical isotopes as the primary national security non-proliferation benefit. The additional benefits are largely economic. In view of the current and projected shortages from foreign suppliers, there is significant advantage for U.S. companies to provide Mo-99 to the U.S. market. Producing Mo-99 domestically will also increase the efficiency of its use, given the short half-life of the isotope and the time required for transport. Domestic production will also help ensure a reliable supply of this critical medical isotope to patients in the United States. NNSA cannot comment on U.S. leadership in medical technologies.

Question 2. Can you describe the waste streams that result from accelerator and both LEU and HEU reactor produced isotopes and discuss the disposal and proliferation concerns present with each particular method?

Answer. Wastes generated from the accelerator-based Mo-99 production technology under consideration does not pose a proliferation concern because there is no uranium present in the waste stream.

Wastes generated from the LEU-based Mo-99 production technologies under consideration do not pose a proliferation concern because HEU would not be present in the waste stream. There is a disposition pathway in the U.S. for Class A radioactive waste, but some States do not have access to disposal facilities for their Class B or C radioactive waste. The Department of Energy is early in the process of developing disposal capacity for Greater than Class C radioactive waste.

Wastes generated from HEU-based Mo-99 production technology presents a proliferation concern because HEU is present in the waste stream. According to the National Academies Report *Medical Isotope Production without Highly Enriched Uranium*, most process wastes from global Mo-99 producers are in a liquid or solid form and are either stored at producers' sites or transported to offsite storage facilities. Disposition pathways for HEU-based Mo-99 wastes in the United States have not been identified, in part because future Mo-99 production in the United States would not use HEU.

RESPONSES OF PARRISH STAPLES TO QUESTIONS FROM SENATOR WYDEN

Question 1. Please provide a copy of the 1996 Record of Decision for Mo-99 concerning production at the Sandia National Laboratory (SNL) Annular Core Research Reactor (ACRR).

Answer. The Record of Decision is provided as an insert of the record.* The information follows.

Question 2. Provide a detailed description of the capital investments and support costs incurred by the Department and SNL for implementing the Mo-99 production ROD.

Answer. Department of Energy's Office of Nuclear Energy (NE) provided \$12.6 million in FY 1998 and \$8.5 million in FY 1999 to the Sandia and Los Alamos national laboratories to accomplish this program. Additionally, \$1.08 million of carry-over funding from FY 1997 was available to support the project, for a total of \$22.18 million. On July 30th, 1999, NE directed that the Medical Isotope Program as described in the Project Execution Plan be closed out.

Question 3. Please provide a copy of the Department's 1999 Expression of Interest (EOI) for utilization of the SNL Mo-99 capacity and copies of all responses to EOI.

Answer. While we were unable to locate copies of responses to the EOI, I would like to provide the EOI and associated instructions as an insert for the record.** The information follows.

Question 4. Provide an explanation of the Department's 2007 decision to modify the ACRR core configuration and remove Mo-99 production capacity and all related decision documents.

Answer. In April 1999, DOE's Office of Defense Programs (DP) recognized an immediate need to conduct a limited-term test campaign on specific weapon components: the ACRR represented the best facility available to meet the technical and schedule testing requirements of this campaign. The ACRR had been transferred to DOE-NE, which was reconfiguring the ACRR and associated facilities for the production of various isotopes. However, schedule delays and cost overruns presented a window of opportunity for DP to conduct its weapon tests without impacting the overall isotope program schedule. So, NE and DP signed an agreement governing the reconfiguration of the ACRR from the isotope production configuration to the pulse-testing configuration and authorizing its temporary use in FY 2000 for pulse testing-activities.

In July 1999, in conjunction with unsuccessful efforts to privatize Mo-99 production and after careful consideration, the administration terminated the Mo-99 project. Specifically, an increase in the world's production capacity with the pending start-up of new reactors in Canada, Maple 1 and 2, negated the urgency of establishing an emergency backup capability in the United States. (The Maple projects were subsequently terminated on May 19, 2008.) The ACRR and associated Hot Cell Facility were transferred back from NE to DP in FY 2006 for DP's mission-related work. No nuclear materials were placed into the hot cells, and some of the Mo-99 production equipment was transferred to other national laboratories for use in their production of other isotopes.

Question 5. Provide a detailed description of the costs associated with modification of the ACRR core and disposition of fuel elements and related components.

Answer. As of September 30, 1999, project costs associated with the modification of the ACRR totaled \$21.1 million, with a further \$560,000 committed for work during FY 2000 to complete hot cell facility (HCF) modifications, for a project total of \$21.7 million. This total was \$405,000 below the project execution plan budget estimate of \$22.1 million. These costs do not include disposition of fuel elements which are still located at ACRR and associated adjacent facilities.

Question 6. To what extent are the Department's ongoing efforts to restore domestic production capability of Mo-99 cost shared with the private sector and identify the levels of funding and sources provided to date by the private sector, if any?

* Document has been retained in committee files.

** Information has been retained in committee files.

Answer. Section 988 of the Energy Policy Act of 2005 establishes guidance for the U.S. Department of Energy's cost-sharing requirements for demonstration and commercial application activities. This guidance is a 50 percent cost share for demonstration and commercial application activities.

NNSA's support to commercial entities under cooperative agreements requires a 50 percent cost share commitment, with a funding limit for the NNSA share. Some commercial partners have opted to contribute more funding to their projects than the 50 percent share. The funding and sources provided to date by the private sector are proprietary information, but NNSA has committed \$5.627 million to date.

Question 7. The Department of Energy has testified in support of H.R. 3276 which would authorize \$163 million for establishment of a program "to evaluate and support projects for the production in the United States, without the use of highly enriched uranium, of significant quantities of molybdenum-99 for medical uses." The legislation does not specify any cost share for private sector participants. Does the Department envision that this program would, in fact, be cost-shared and if so to what extent?

Answer. NNSA's four projects are intended to be demonstrated with commercial entities under cooperative agreements that have a 50/50% cost share requirement. If H.R. 3276 were enacted, the Department envisions that the program would continue to be implemented based on a 50/50% cost-share arrangement.

Question 8. Does the Department object to inclusion of a legislative requirement clarifying that the program to evaluate and support domestic Mo-99 production should be cost-shared?

Answer. No, the Department does not object.

RESPONSES OF KEVIN D. CROWLEY TO QUESTIONS FROM SENATOR MURKOWSKI

Question 1. Dr. Crowley, the National Academies report suggests that it is technically feasible that adequate quantities of medical isotopes can be produced from LEU targets. Could you describe what the options are, and whether LEU target designs from other countries could be used here in the United States?

Answer. There are two primary options for producing medical isotopes using low enriched uranium (LEU). The first option is to irradiate LEU targets in research and test reactors. These reactors have high-power-density cores that produce high neutron fluxes—typically on the order of 100 trillion to 1000 trillion neutrons per square centimeter per second. The irradiation of LEU targets with neutrons induces fission of the uranium 235 that is contained in the target material. Approximately 6 percent of these fissions produce molybdenum 99. After irradiation, the targets are removed from the reactor and chemically processed to recover molybdenum. There are several operating research and test reactors in the United States that could, in principle, be used to irradiate LEU targets for molybdenum 99 production. However, reactor schedules and operations might have to be modified and target processing facilities would have to be constructed to enable commercial-scale production.

The second option is to irradiate LEU in solution reactors. The LEU is dissolved in an acidic solution that serves as both the reactor fuel and target; the irradiation of uranium 235 in the solution produces molybdenum 99 just as in a research and test reactor. The solution is periodically drawn off and the molybdenum 99 is chemically separated and recovered. Solution reactor production of molybdenum 99 is a relatively new concept; to my knowledge it has only been demonstrated at scale in Russia. There are no operating solution reactors in the United States.

There are other potential options for producing molybdenum 99. These include neutron activation of molybdenum 98 in reactors and accelerator-based production involving uranium 235 fission, uranium 238 photo fission, photon-induced conversion of molybdenum 100, and the direct production of technetium 99m from molybdenum 100. Our study concluded that, at present, these options are not capable of producing sufficient molybdenum 99 to meet a substantial fraction of U.S. demand. However, one or more of these options might be suitable for meeting demand in smaller countries.

To date, two LEU target designs have been developed for use in molybdenum 99 production. Argentina designed and is using an LEU-aluminum alloy target for commercial production of molybdenum 99; that target is also being used for commercial production in Australia. Argonne National Laboratory has led the development of a uranium metal foil target that has been test irradiated in Argentina, Australia, Indonesia, and the United States.

Either of these target designs could be used to produce molybdenum 99 in the United States. However, some technical development would be required to adapt these targets to specific reactors and processing facilities.

Question 2. Dr. Crowley, your testimony notes that Mo-99 producers have no good business reason to convert to LEU-based production.

a. Why should we expect these businesses to pony up the millions of dollars to convert to a process that requires more uranium for the targets, but doesn't enhance quality or reduce costs?

b. Who should bear the burden of conversion costs—industry or government?

Answer. The answers to these questions can be found in Chapter 10 of our medical isotopes report: "There are currently no financial or competitive reasons for industry to convert to LEU-based production. The only reason for conversion is to support HEU minimization goals. One could argue that private industry should not be expected to shoulder the entire cost of obtaining this benefit, but that governments should also bear part of this burden." Our report suggested that the federal government could encourage conversion by providing technical assistance, temporary financial incentives, and consistent policy signals. Many of our suggestions have been embodied in HR 3276.

There is an instructive parallel between conversion of targets for medical isotope production and conversion of fuel for research and test reactors. The Reduced Enrichment for Research and Test Reactors (RERTR) Program was initiated by the Department of Energy (DOE) in 1978 to develop, test, and qualify LEU fuels for research and test reactors. DOE offers several incentives to research and test reactor owners/operators to ease the burden of conversion from HEU to LEU fuels. These incentives include technical assistance to develop and qualify LEU fuel, financial assistance to purchase the first LEU replacement core, and take back of HEU reactor fuel. These incentives appear to be an effective tool for conversion of research reactors to LEU fuel.

Question 3. The National Academies report concluded that the potential cost difference for Mo-99 produced from LEU would cost no more than 10% more than that produced from HEU. The recent shortages in Mo-99 have seen significant increases in cost for the isotope thereby making the concerns for cost of switching from HEU to LEU production moot. However, who is financially benefitting from the increased cost—the foreign-government owned reactors, or the supplier industry?

Answer. Pricing agreements between molybdenum 99 producers and reactor owners/operators and between molybdenum 99 producers and isotope buyers are generally proprietary, so it is not possible to provide a revenue breakdown; however, I can offer a personal opinion based on my understanding of the medical isotope production business. Molybdenum 99 production is subject to the same supply-demand economics that govern the sale of many other commodities. Producers can charge more for this isotope when demand exceeds supply, especially over extended time periods. Isotope buyers who have long-term purchasing agreements with molybdenum 99 producers may be protected from large price increases, but this would not be the case for buyers who purchase molybdenum 99 on the spot market.

The molybdenum 99 supplied to the United States is produced in multipurpose reactors that are owned and/or operated by foreign governments. The owners/operators of these reactors have long-term arrangements with medical isotope producers and others to provide irradiation services. The costs for these irradiation services are usually unrelated to molybdenum 99 prices unless the reactor owner/operator has a revenue sharing agreement with the molybdenum 99 producer.

Consequently, when a molybdenum 99 producer pays a fixed price for irradiation services and can charge more for the molybdenum 99 it produces it would realize a financial benefit. However, molybdenum 99 producers sometimes incur additional expenses to maintain a reliable supply system, so not all of the additional revenue would necessarily be realized as profit.

RESPONSE OF KEVIN D. CROWLEY TO QUESTION FROM SENATOR CANTWELL

Question 1. In your written testimony you mentioned a study you recently directed: Medical Isotope Production without Highly Enriched Uranium. The American Medical Isotope Production Act, as currently written, would not provide for a full conversion to LEU-based domestic production for 7-11 years. In carrying out this study, did you arrive at new suggestions or guidance regarding the ways the US can use research reactors that have already converted to LEU fuels and are capable of producing Mo-99?

Answer. Our report specifically examined the feasibility of producing molybdenum 99 in the Missouri University Research Reactor. This reactor is currently fueled with HEU but will be converted to LEU as soon as a suitable replacement fuel becomes available. (Conversion is scheduled for fiscal year 2014.) Commercial-scale production of molybdenum 99 in the Missouri reactor using LEU targets appears

to be technically feasible, but target processing facilities would need to be constructed.

Our report also examined the feasibility of producing molybdenum 99 in solution reactors that use LEU dissolved in an acid solution as both the fuel and target material. Babcock & Wilcox has announced a partnership with Mallinckrodt to construct such a reactor in the United States. This type of reactor has never been licensed by the U.S. Nuclear Regulatory Commission, and some licensing uncertainties must be resolved before a reactor could be constructed in the United States. The Babcock and Wilcox solution reactor has very low power and is designed to operate at atmospheric pressure and below the boiling point of water. Consequently, it appears unlikely that safety issues would be a significant impediment to licensing.

There are other research reactors in the United States that could potentially be used for medical isotope production, but these were not specifically examined in our report. A reactor that is used to produce molybdenum 99 at commercial scale must meet several requirements: it must have sufficient space in the reactor core or reflector region to accommodate LEU targets without interfering with other reactor uses; a sufficiently high power to provide the necessary neutron fluxes; a reliable operating schedule to allow 24/7 production, except during planned maintenance outages; and access to ancillary facilities for handling and processing irradiated targets. To my knowledge, no research reactors in the United States currently meet all of these requirements.

RESPONSES OF KEVIN D. CROWLEY TO QUESTIONS FROM SENATOR RISCH

Question 1. Please list the current domestic sources of moly-99 isotopes, the non-domestic sources and the percentage of our imports from each source. Additionally, please list the potential domestic sources for such isotopes from both reactor and accelerator technologies.

Answer. At present there are no domestic sources of molybdenum 99 for medical use. Until early 2009, the United States received about 60 percent of the molybdenum 99 used for medical purposes from Canada (AECL/MDS Nordion) and 40 percent from the Netherlands (Mallinckrodt). However, production from Canada was halted in May 2009 when a heavy water leak was discovered in the Canadian NRU Reactor. Since that time, the United States has received molybdenum 99 primarily from Mallinckrodt in the Netherlands and NTP Radioisotopes in South Africa. Additionally, arrangements have been made to supply molybdenum 99 to the United States from Australia (ANSTO), although it is not clear that this producer is shipping commercial quantities at present. The quantities of molybdenum 99 supplied to the United States by these organizations are considered to be proprietary and are not publicly available.

I am aware of two U.S.-based organizations that propose to supply molybdenum 99 to the domestic market: the Missouri University Research Reactor and Babcock & Wilcox, the latter using a solution reactor. Each of these organizations could probably produce enough molybdenum 99 to supply at least a third or more of U.S. needs, assuming that financing can be arranged to construct the necessary facilities. At this point in time, accelerator production of molybdenum 99 is unlikely to produce large supplies unless multiple facilities are constructed. It is not at all clear whether accelerator production would be cost competitive with reactor-based production.

Question 2. What is the current US demand, and how much of that demand could be met through the potential accelerator sites listed above?

Answer. Under normal supply conditions, the demand for molybdenum 99 in the United States is between 5000 and 7000 6-day curies per week. Our study did not attempt to estimate how much of that demand could be met through accelerator production. Multiple accelerators likely would be required to produce quantities of molybdenum 99 to be competitive with reactors; the cost of construction and operation of multiple accelerators would have to be analyzed to determine if a business case could be made for molybdenum 99 production.

RESPONSES OF ROY BROWN TO QUESTIONS FROM SENATOR MURKOWSKI

Question 1. Does CORAR believe that the bill's language is technology neutral in supporting an LEU-based domestic production capacity, or does it favor reactors over accelerators or neutron capture technology?

Answer. CORAR believes the DOE should remain technology-neutral during their selection process for dispersal of funds for the development of domestic medical isotope projects. We believe the bill as written is technology-neutral to both reactor and accelerator processes.

Question 2. Waste disposal.—If DOE were not required to take back the radioactive waste from a future domestic Mo-99 isotope process what are the industry's options? Has the industry determined what it believes a reasonable price for DOE to charge for waste disposal would be?

Answer. In the U.S. currently there are no disposal facilities for Class B or Class C radioactive waste. For that reason we strongly feel DOE should make their already available sites for disposal of these types of waste, and all waste generated as a result of medical isotope production from the use of DOE leased uranium available. Unless this is done, the producers of these medical isotopes using DOE leased uranium will have nowhere to dispose of this waste. The industry does not have a target price in mind for the disposal of this waste at DOE facilities. As previously stated by CORAR, we are concerned that the price DOE may set for this waste disposal, could be unreasonably high, which would hamper development of U.S. medical isotope production. We have seen DOE add allocations and other additional charges to fees for other services we have received from them. We wanted to assure that these "up charges" are not added to the waste disposal fees. We suggest that the price for this waste disposal be developed in conjunction with the National Academy of Sciences and/or DOE's Nuclear Science Advisory Committee on Isotopes. The NAS is sensitive to the costs associated with production of medical isotopes in the U.S. as a result of their report on the production of Mo-99 using LEU, and the NSACI has nuclear medicine experts from the industry that would be sensitive to waste disposal prices that may inhibit development of U.S. produced medical isotopes.

Question 3. Environmental studies.—I agree that having both DOE and NRC conduct separate environmental studies of proposed production and processing facilities is duplicative, costly, and unnecessarily delays the process. Am I correct in understanding that CORAR's preference is for the environmental review to fall with the NRC instead of DOE?

Answer. Our hope is to avoid unnecessary duplicative regulatory constraints. We feel the NRC licensing process for any new reactor facility and any new processing facility will adequately address any environmental concerns.

Question 4. What is the current level of interest by industry to provide for domestic production of Mo-99? I understand that Babcock and Wilcox have a solution reactor design they are working on, and the University of Missouri is interested in converting their research reactor to LEU use. What other possibilities are out there?

Answer. In addition to the B & W/Covidien and MURR efforts stated in your question, we are aware of several other efforts in the U.S. in various stages of development. They include the following:

UCDavis	Use of the McClellan reactor
University of Washington	Use of their research reactor
Sandia National Lab	Construction of a new Fuel Pin reactor
Iotron	Use of an accelerator for the production of Mo-99
Puerto Rico	Construction of a new reactor
Oak Ridge National Lab	Use of the HFR at ORNL by a private consortium
Idaho State University/Positron	Use of an accelerator for the production of Mo-99

We are also aware of several other efforts underway in the U.S., that may not be as far along as these listed. There are also other efforts underway in Canada and Europe. There are other possibilities with the ATR at Idaho Falls National Lab, and the ACRR at Sandia National Lab. There are several impediments which would have to be overcome before these reactors could be used. Some of these impediments are physical attributes of the reactor and some are operational.

RESPONSES OF ROY BROWN TO QUESTIONS FROM SENATOR WYDEN

Question 1. Your testimony on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR) supports enactment of H.R. 3276 to create a program to establish medical isotope production in the United States. When the U.S. Department of Energy created just such capacity at the Annular Core Research Reactor (ACRR) at Sandia at a cost of as much as \$50 million, the U.S. radiopharmaceutical industry chose not to support that capacity. Why should the Federal Government spend an additional \$163 million to develop a domestic supply and what assurance can the industry provide that it will utilize the resulting facilities?

Answer. In the 1990's when DOE offered to retrofit the ACRR in order to produce Mo-99 the industry was an active supporter and financial contributor to that effort.

However, the DOE was unable to finish that project, and then tried to privatize it. Unfortunately the financial stipulations placed on that privatization effort made it unattractive and non-viable financially; Several tens of millions of dollars would have been required to finish the ACRR effort at that time. After that failed ACRR effort the industry pursued other options. Specifically, Mallinckrodt decided to invest in its own Mo-99 processing operation in The Netherlands and Nordion contracted with AECL to construct the now moth-balled MAPLE reactors.

With the MAPLE reactors no longer supported by the Canadian Government and not likely to ever become operational and with other foreign reactors rapidly aging and failing, the industry is strongly supportive of the \$163 million contained in the AMIPA. This will be instrumental in accelerating a new, domestic Mo-99 production capacity. We feel strongly that this funding must result in project investments that are fully vetted, including input from industry. Funding of projects that lack credibility and only support theoretical research in isotope production will not help develop a U.S. supply of Moly-99 and ensuring that US patients have access to important procedures using medical isotopes.

Question 2. If the Federal Government were to proceed with the proposed program to develop multiple domestic isotope supply options as proposed in H.R. 3276, why shouldn't the industry be required to enter into binding agreements to utilize those facilities?

Answer. There are two generator manufacturers in the U.S. Both of those manufacturers have expressed strong interest in a U.S.-based Mo-99 production sources. However, both of these companies are also pursuing other options to increase worldwide capacity for medical isotopes to meet short-and medium-term needs of U.S. patients. The cost of each proposed U.S.-based medical isotope production option must be examined carefully to assure they will be able to provide isotopes at reasonable prices. The generator manufacturers are committed to providing our patients with reliable and cost effective medical isotopes. If these new U.S. production capabilities yield reliable and cost effective Mo-99, the manufacturers will be willing/ready to enter into agreements with those groups. Until the necessary factors are clearly known, entry into binding agreements would be irresponsible, and would not be in the best interest of our patients or in containing the cost of healthcare.

The solution to the long term isotope supply problem is rooted in the maintenance of a global, competitive market for the production and sale of Mo-99. The proposed domestic production solutions will fill a gap in the current global Mo-99 supply chain as its legacy assets continue to age. The domestic solutions that prevail will be well positioned as the most reliable and cost effective source of supply given the age and geographic proximity of the competing suppliers. Market dynamics and the existence of diverse supply options will mitigate reliability and pricing related risks to the benefit of the industry and healthcare system. Positioning these new domestic sources of supply in the competitive marketplace vs. the alternative of proactive binding supply agreements is the best approach for the industry and the payers.

Question 3. To what extent is the industry willing to share the costs of implementing the proposed domestic isotope production program?

Answer. Please note that these two manufacturers are already incurring significant additional costs to at least partially mitigate impact on US patients of the ongoing crisis in Moly-99 supply. Moreover, the two generator manufacturers will have significant costs qualifying and these new suppliers of medical isotopes and gaining FDA approval for use of their Mo-99. It costs roughly \$1 million to add each new supplier of isotopes. The complex process includes the need to produce generators in validation batches with isotopes from the new supplier. These validation generators need to be tested with the "cold kits" containing drugs that are commonly combined with Tc-99m. These tests demonstrate that the Tc-99m from the new Mo-99 reacts with the cold kits as expected and meets all of the FDA specifications for these kits. Data are collected from several validation batches of generators, then that data is submitted to the FDA for review as a supplement to the manufacturers' New Drug Application (NDA) for their Tc-99m generators. The FDA reviews this data, and if found acceptable, grants permission for use of the Mo-99 from the new supplier. As previously stated, this is an expensive and time consuming effort. Each additional Mo-99 supplier a generator manufacturer wishes to add requires a repeat of this process. In addition to those validation and approval investments, the manufacturers may choose to also share in the Mo-99 facility development costs. This depends, in part, on the facility's perceived chances of becoming a reliable and cost efficient supplier, as previously discussed. While this funding represents a welcome means to help projects with a domestic production agenda to become a commercial reality, it is important to note that significant additional funding will be required from industry and other private and public sources. In addition, we encourage DOE decision-makers to consider funding those projects with the highest probability of

success that will work within the model of the current supply chain. Otherwise, the more funds disbursed to low probability alternatives will mean less funding availability for higher probability shorter timeline projects.

Question 4. In aggregate, what is the annual revenue to the radiopharmaceutical industry in the U.S. from the sale of isotopes, including Mo-99 and derivatives, currently and projected over the next five, ten, and fifteen years?

Answer. Such an estimate is very difficult to make for the reasons outlined below. The best source of information is probably Arlington Medical Resources Inc. (AMR). Aggregate revenue will be difficult to estimate because of Mo-99 per curie pricing uncertainty, which itself is a function, at least in part, of available future supply. Perhaps doses administered is a metric more easily predicted, but that may also be a function of available supply and Mo-99 price.

APPENDIX II
Additional Material Submitted for the Record

U.S. SENATE,
STATE OF MISSOURI,
Washington, DC, December 11, 2009.

Hon. JEFF BINGAMAN,
Chairman, U.S. Senate Committee on Energy and Natural Resources, Washington, DC.

Hon. LISA MURKOWSKI,
Ranking Member, U.S. Senate Committee on Energy and Natural Resources, Washington, DC.

DEAR CHAIRMAN BINGAMAN AND RANKING MEMBER MURKOWSKI, The Energy and Natural Resources Committee recently took testimony on H.R. 3276, the American Medical Isotopes Production Act of 2009. I support the goals of H.R. 3276 to promote U.S. domestic production of medical isotopes and phase out the current process necessary to provide raw materials for the production of medical isotopes. However, H.R. 3276 fails to address fundamental issues necessary to ensure that cancer patients moving forward are guaranteed to receive the medicine they need to diagnose and treat their illnesses.

Every year, millions of American patients depend upon medicine derived from medical isotopes to diagnose and treat cancer, heart disease and other serious ailments. Doctors use medical isotopes to treat Non-Hodgkin's Lymphoma and thyroid cancer. Patients also depend upon medical isotopes for bone scans that assess the spread of cancer up to 18 months earlier than traditional x-ray. Medical isotopes also allow for the evaluation of kidney function and heart conditions. Thus, any proposal to block the flow of raw materials currently needed to produce medical isotopes, as does H.R. 3276, represents a serious threat to the health and treatment of U.S. patients.

While H.R. 3276 includes a legally binding cut-off date to stop the flow of raw materials necessary to produce medical isotopes, the bill provides no guarantee that U.S. patients will continue to receive their medicine and medical treatment. According to a report by the National Academies of Science, there "are not sufficient quantities of medical isotopes available" to meet U.S. domestic needs from the new processes H.R. 3276 envisions to supply medical isotopes. Conversion to a new medical isotope production process will require tens of millions of dollars and up to 13 years. Even a short period where patients cannot get the medicine they need could have grave health consequences.

Let me be clear that I support finding new ways to produce medical isotopes, especially from domestic sources. However, I am unaware of any type of comprehensive planning or documentation that describes in detail exactly who is expected to supply medical isotopes in sufficient quantities to meet the needs of U.S. medical patients without disruption, from what locations, how much this will cost to build or upgrade production facilities, who will provide precise levels of funding, from which sources, in which years, and with what assurances to reflect that the funding either exists or is on the way.

I am gratified that all of the parties involved seem to be operating in good faith with the best intentions of seeing the process move forward. However, authority to create a program or the authorization to provide funding is not the same as the administration requesting sufficient funding as part of their annual budget, the Appropriations Committee actually appropriating such sums, or the administration actually spending such sums. Likewise, an administration agreeing to provide some level of funding is not the same as reaching agreement on funding and construction plans with private parties in the number and to the degree necessary to ensure supply of U.S. domestic needs without disruption or shortfall.

The hearing by the Committee shows that you are engaged in this issue and willing to ask thoughtful questions of the process. My staff is fully prepared to engage in any efforts with your staff to improve H.R. 3276. However, you should know that I will use the options available to me as a Senator to prevent consideration of this bill on the floor before these issues are resolved. Thank you in advance for your attention to this matter.

Sincerely,

CHRISTOPHER S. BOND,
U.S. Senator.

ECONOMIC DEVELOPMENT CORPORATION OF LEA COUNTY,
Hobbs, NM, December 1, 2009.

Hon. CHAIRMAN BINGAMAN,
Hon. RANKING MEMBER MURKOWSKI,
Senate Energy and Natural Resources Committee, Senate Dirksen Room 304, Washington, DC.

DEAR CHAIRMAN BINGAMAN AND RANKING MEMBER MURKOWSKI: We are writing you today to express our support for H.R. 3276 the American Medical Isotopes Production Act of 2009. We believe that there is a very real need in this country for reestablishing the domestic production of medical isotopes and we feel that Lea County is well positioned to be a part of the answer to that need.

Given our history as a resource for the nation's energy needs, Lea County is well positioned to host a complete production facility that includes a dedicated, purpose-built reactor and separations and generator production complex. Our proximity to the National Enrichment Facility and Waste Control Specialists, experience in obtaining permitting and licensure for a NRC regulated facility, and understanding and support of the local community and region for nuclear projects creates an excellent opportunity to build a long-term successful solution for medical isotope production. As a strategy for the production of molybdenum-99 is being solidified, we would encourage decision makers to consider a long-term, full spectrum, dedicated, community initiated project to be a viable solution for the US. Further, we believe that domestic medical isotope production can be achieved without the use of highly enriched uranium with its attendant proliferation and security concerns.

In order to provide the most robust array of solutions for this critical need we believe the current legislation should be amended to allow for the use of a dedicated and single purpose production system instead of only a short-term potentially make-shift solution. While expediency is a factor to consider, equal or greater weight should be given to the overall strategic quality of the proposed molybdenum-99 production system. Dedicated and purpose-built production systems will ensure the long-term strategic needs of the US are met, rather than relying on stop-gap measures. We also believe that the current legislation does not give merit or consideration to the waste management practice for a proposed production system. While the waste burden is not particularly great with most molybdenum-99 production systems, given the general challenges of radioactive waste management facing our country, we feel it would be prudent if the legislative criteria included a factor that considered waste type and volume, waste disposal pathway, and waste management practices. Finally we would like to see the legislation include criteria that considers the degree of local stakeholder community support.

In August 2009, the Society of Nuclear Medicine polled its members and 80 percent reported their medical practice or facility had been negatively impacted by the medical isotope shortage. Lea County would like to help meet this critical need. Included with this letter is some draft amendment language we hope you will consider as this legislation moves forward.

Thank you,

JOHNNY COPE,
Energy Committee, Chairman.

DRAFT LANGUAGE

SEC. 3. IMPROVING THE RELIABILITY OF DOMESTIC MEDICAL ISOTOPE SUPPLY

(a) Medical Isotope Development Projects—

(1) IN GENERAL—The Secretary of Energy shall establish a program to evaluate and support projects for the production in the United States, without the use of highly enriched uranium, of significant quantities of molybdenum-99 for medical uses.

(2) CRITERIA—Projects shall be judged on their overall strategic qualities to meet U.S. needs and interests, and against the following primary criteria:

(A) The length of time necessary for the proposed project to begin production of molybdenum-99 for medical uses within the United States.

(B) The capability of the proposed project to produce a significant percentage of United States demand for molybdenum-99 for medical uses.

(C) The cost of the proposed project.

(D) The likelihood for securing regulatory approval and licensing of the proposed project.

(E) The strategic quality of the proposed project to meet long-term capacity and reserve needs, including the degree to which the proposed project is dedicated and purpose built for molybdenum-99 production,

(F) The overall waste management plan and fate of the waste burden for the proposed project.

(G) The degree of local community support for the proposed project.

SNM,
Reston, VA, November 24, 2009.

Hon. JEFF BINGAMAN,
Chairman, Senate Committee on Energy and Natural Resources, U.S. Senate, 703 Hart Senate Office Building, Washington, DC.

Hon. LISA MURKOWSKI,
Ranking Member, Senate Committee on Energy and Natural Resources, U.S. Senate, 709 Hart Senate Office Building, Washington, DC.

DEAR CHAIRMAN BINGAMAN AND RANKING MEMBER MURKOWSKI: The Society of Nuclear Medicine¹ (SNM)—an international scientific and medical organization dedicated to raising public awareness about what molecular imaging is and how it can help provide patients with the best health care possible—appreciates the Committee on Energy and Natural Resources’ consideration of the *American Medical Isotopes Production Act of 2009 (HR. 3276)*. The *American Medical Isotopes Production Act* would help to ensure a domestic supply of the important isotope Molybdenum-99 (Mo-99) within the US and to curtail the use of highly-enriched uranium (HEU) in radionuclide production as a non-proliferation strategy to deter terrorism. As you know, Mo-99 decays into Technetium-99m (Tc-99m), which is used in approximately 16 million nuclear medicine procedures each year in the US. Recent disruptions in the supply of Mo-99 have highlighted the urgent need to ensure a domestic supply for the US. The *American Medical Isotope Production Act* will help patients who rely on medical imaging for the treatment and diagnosis of many common cancers by authorizing funding and providing a clear road map to create a domestic supply of Mo-99 while also allowing a responsible timeline and safeguards for the transfer of HEU to low enriched uranium (LEU); therefore, SNM endorses the *American Medical Isotope Production Act of 2009*.

Tc-99m is used 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. In addition to pinpointing the underlying cause of disease, physicians can actually see how a disease is affecting other functions in the body. Imaging with Tc-99m is an important part of patient care. As you may be aware, SNM, along with thousands of nuclear medicine physicians in the US, have, over the course of the last two years, been disturbed about supply interruptions of Mo-99 from foreign vendors and the lack of a reliable supplier of Mo-99 in the US. Due to these recent shutdowns in Canada, numerous nuclear medicine professionals across the country have delayed or had to cancel imaging procedures. Because Mo-99 is produced through the fission of uranium and has a half-life of 66 hours, it cannot be produced and stored for long periods of time. Unlike traditional pharmaceuticals, which are dispensed by pharmacists or sold over-the-counter, nuclear reactors produce radioactive isotopes that are processed and provided to hospitals and

¹ SNM is an international scientific and medical organization dedicated to raising public awareness about what molecular imaging is and how it can help provide patients with the best health care possible. SNM members specialize in molecular imaging, a vital element of today’s medical practice that adds an additional dimension to diagnosis, changing the way common and devastating diseases are understood and treated. SNM’s more than 17,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings and leading advocacy on key issues that affect molecular imaging and therapy research and practice. For more information, visit www.snm.org.

other nuclear medicine facilities based on demand. Any disruption to the supply chain can wreak havoc on patient access to important medical imaging procedures.

In order to ensure that patient needs are not compromised, a continuous reliable supply of medical radioisotopes is essential. Currently there are no facilities in the US that are dedicated to manufacturing Mo-99 for Mo-99/Tc-99m generators. The United States must develop domestic capabilities to produce Mo-99, and not rely solely on foreign suppliers. In addition, forcing a change from HEU to LEU must be done with adequate time made available for the research and development needed for the transition period. There also must be consideration of economic and environmental factors to prevent, first and foremost, putting patients at risk because of delays in production of much needed radionuclides, such as Technetium-99m (Tc-99m) which is made from Mo-99. With one of the major facilities in The Netherlands scheduled for a maintenance shutdown while the Canadian facilities are still not functional will produce an even more acute shortage in the first half of 2010 making this need for this legislation and funding to address the shortage more urgent.

This legislation will help address the needs of patients by promoting the production of Mo-99 in the United States. We thank you for your efforts and look forward to continuing to work with you on this important issue.

Sincerely,

MICHAEL GRAHAM, PH.D., M.D.,
President.

AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE,
College Park, MD, December 2, 2009.

Hon. JEFF BINGAMAN,
Chair.

Hon. LISA MURKOWSKI,
Ranking Member, Energy and Natural Resources Committee, 304 Dirksen Senate Office Building, U.S. Senate, Washington, DC.

DEAR SENATORS BINGAMAN AND MURKOWSKI: The American Association of Physicists in Medicine (AAPM)¹—an association whose mission is to advance the application of physics in medicine and biology for the benefit of all patients—urges the Senate Energy and Natural Resources Committee to give full support to and take timely action on H.R.3276, the *American Medical Isotope Production Act of 2009*.

AAPM remains concerned that the recent disruptions in the supply of Molybdenum-99 (Mo-99) have resulted in medical professionals across the country delaying or canceling imaging procedures. Although there may be alternatives to certain diagnostic procedures using Technetium-99m (Tc-99m) (including substitution of other isotopes for Tc-99m, and some computed tomography (CT) and invasive angiography procedures), clinicians routinely choose the most accurate, most useful and most dose-efficient imaging technique. These disruptions in access to the radioactive isotope have highlighted the urgent need to ensure a domestic supply for the United States. It is a disservice to patients to deny them access to the most appropriate study due solely to the non-availability of Tc-99m in the United States.

In order to ensure that patient needs are not compromised, a continuous reliable supply of medical radioisotopes is essential. Currently there are no facilities in the United States that are dedicated to manufacturing Mo-99 for Mo-99/Tc-99m generators. The United States must develop domestic capabilities to produce Mo-99, and not rely solely on foreign suppliers. In addition, forcing a change from HEU to LEU must be done within an adequate time period to allow for the research and development needed for the transition period. There also must be consideration of economic and environmental factors to, first and foremost, prevent putting patients at risk

¹The American Association of Physicists in Medicine's (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 7,000 medical physicists.

because of delays in production of much needed radionuclides, such as Tc-99m which is made from Mo-99.

A national effort to address these concerns requires (1) a commitment by the administration to have a coordinated inter-agency program with the specific responsibility to achieve reliable domestic independence in the production of Mo-99, (2) continued appropriations by Congress to provide the financial investment needed by the administration's program, and (3) support of the Congress through authorizing legislation that will serve as the basis for the continuation of the administration's program until its goals are achieved.

The Obama administration has made a commitment to achieve domestic independence in the production of Mo-99. The AAPM believes the initiative being led by the National Nuclear Security Administration through the Global Threat Reduction Initiative with oversight and interagency coordination by the Office of Science and Technology Policy has the capability to achieve the establishment of a reliable domestic production of Mo-99 within the next ten years. The Congress has appropriated sufficient support for fiscal year 2010. The remaining task is to obtain congressional support through authorizing legislation that will serve as the support and basis for the administration's program into the future.

AAPM believes that the *American Medical Isotope Production Act of 2009* will help patients who rely on medical imaging for the treatment and diagnosis of many common cancers by authorizing funding and providing a clear road map to create a domestic supply of Mo-99 while also allowing a responsible timeline and safeguards for the transfer of HEU to low enriched uranium (LEU); therefore, AAPM endorses the *American Medical Isotope Production Act of 2009*.

We thank you for your efforts and look forward to continuing to work with you on this important issue.

Sincerely,

MARYELLEN L. GIGER, PH.D., FAAPM, FAIMBE.

COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS, INC.,
Moraga, CA, January 18, 2010.

DEAR CHAIRMAN BINGAMAN AND SENATOR MURKOWSKI, CORAR¹ strongly supports H.R. 3276, the American Medical Isotopes Act of 2009, and we are eager to work with you going forward in the passage of this bill. Accordingly, CORAR provides our thoughts on the issues raised by Senator Bond in his letter to you dated December 11.

Senator Bond raised an important question on appropriations legislation in support of the bill. H.R. 3276 makes the case for the authorization of \$163 million for the development of domestic medical isotope production but appropriations legislation is necessary. We recognize that H.R. 3276 has two goals: The elimination of HEU use in the production of medical isotopes and, equally important, creation of a reliable domestic supply of medical isotopes. We stand ready to work with you on securing the necessary appropriations. Meanwhile, we note that the Department of Energy spent several million last year targeted at securing a domestic supply of medical isotopes. In addition, the DOE has demonstrated its and the Administration's good faith by allocating already budgeted funds for use in its Cooperative Agreement program, also targeting the same goals. CORAR is hopeful that these positive signs will bode well for the necessary appropriations legislation.

Senator Bond also expressed his concern that: "H.R. 3276 fails to address fundamental issues necessary to ensure that cancer patients moving forward are guaranteed to receive the medicine they need to diagnose and treat their illnesses." CORAR shares his goal to provide patients a reliable and robust supply of medical isotopes for detection of heart disease or the early detection, staging and treatment of cancer, all of which can reduce health care costs and improve patients' quality of life. We believe this legislation will go far in establishing domestic production of Mo-99 and other critical medical isotopes. This U.S. production will also increase worldwide capacity of these isotopes, providing the desired redundancy of a continuous isotope supply when one or more reactors go down for maintenance. There are several efforts already underway that look very promising. These efforts have benefitted from DOE involvement and guidance.

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.

Senator Bond wrote: "Even a short period where patients cannot get the medicine they need could have consequences." He raised this in the context of the cut-off date for the export of highly-enriched uranium (HEU). CORAR shares that concern, but believes the mandatory deadline included in HR 3276 is critical to ensure that proposed medical isotope projects will be aggressively pursued and funded. As a result, CORAR does not support modifying the deadline contained in HR 3276. However, CORAR encourages the committee to maintain ongoing oversight of medical isotope supply to ensure that patients' medical isotope needs are not restricted in 2020.

Senator Bond noted apprehension about the lack of "any type of comprehensive planning or documentation that describes in detail exactly who is expected to supply medical isotopes in sufficient quantities to meet the needs of the U.S. patients without disruption. . . ." CORAR remains technology-neutral as to new supplies of medical isotopes, but is aware of several potentially viable initiatives that are in progress. The lack of specificity in HR 3276 should be addressed by the DOE Merit Review Process, assembled to evaluate proposals for funding of new medical isotope production, with four distinct methods identified for the production of Mo-99 and other medical isotopes. These four areas are 1) the production of Mo-99 using conventional reactor technology with the fission of low enriched uranium (LEU) targets; 2) the production of Mo-99 utilizing solution reactors using LEU fuel; 3) the production of Mo-99 using a $(\gamma, n)^2$ reaction on Mo-100; and 4) the production of Tc-99m using a $(p, 2n)^3$ reaction on Mo-100.

There are several credible projects in place for the domestic production of Mo-99 including:

1. The use of the Missouri University Research Reactor (MURR) for the $(n, f)^4$ production of Mo-99.
2. The construction of Aqueous Homogeneous Solution Reactors by Babcock & Wilcox and Covidien for the (n, f) production of Mo-99 using LEU fuel.

There are also several other efforts being investigated using existing reactors, building new reactors or using accelerator technology. These include:

1. The use of the McClellan research reactor by the University of California-Davis for the LEU (n, f) production of Mo-99.
2. Construction of a new fuel pin type reactor proposed by Sandia National Laboratory using LEU fuel as targets, at a site to be determined.
3. Use of the existing research reactor at the University of Washington for the production of (n, f) Mo-99.
4. Use of the high flux reactor (HFR) at Oak Ridge National Laboratory for (n, f) production of Mo-99 by a private consortium.
5. Construction of a new reactor in Puerto Rico by a private firm.
6. The use of Electron Beam Accelerator technology by Iotron for the production of Mo-99 with a (γ, n) reaction on Mo-100.
7. Production of Mo-99 by the use of the accelerator at Idaho State University using a (γ, n) reaction on Mo-100.
8. Production of Tc-99m by the use of accelerators using a $(p, 2n)$ reaction on Mo-100 by Positron Corporation.

CORAR believes one or more of these efforts will be commercially successful and capable of producing a significant portion of the U.S. needs for Mo-99 and other medical isotopes, such as I-131. Further, it should minimize the global impact arising from future shutdowns of any of the major medical isotope producing facilities for maintenance, helping to prevent a repeat of the current shortage situation due to insufficient capacity worldwide.

Thank you for the opportunity to provide this information to the Committee concerning Senator Bond's letter. Please let us know if you have any questions.

Sincerely,

ROY W. BROWN,
Senior Director, Federal Affairs.

²The (γ, n) process or $^{100}\text{Mo}(\gamma, n)^{99}\text{Mo}$ is the process by which you produce Mo-99 by the bombardment of an enriched Mo-100 target with gamma rays in a high energy accelerator.

³The $(p, 2n)$ process or $^{100}\text{Mo}(p, 2n)^{99m}\text{Tc}$ is the process of producing Tc-99m directly by bombarding Mo-100 targets with protons in a low energy accelerator. In this process no Tc-99m generator is necessary since you are directly producing Tc-99m and bypassing Mo-99. Since Tc-99m has a six hour half-life, this method is only good for "local" production of Tc-99m.

⁴The (n, f) process or $^{98}\text{Mo}(n, f)^{99}\text{Mo}$ is the process of by which you fission U-235 in a reactor using neutrons. This is the process all the major producers usually use (i.e. HFR in Petten and NRU in Canada). There has also been some work done examining the fission of U-238 in a high energy accelerator.

STATEMENT OF S. ANDREW ORRELL, DIRECTOR OF NUCLEAR ENERGY PROGRAMS,
SANDIA NATIONAL LABORATORIES, ALBUQUERQUE, NM

With regard to H.R. 3276—American Medical Isotopes Production Act of 2009, we offer the following comments and suggestions:

1. Sandia National Laboratories (SNL) was tasked by the U.S. Department of Energy (DOE) in the 1990's to design a molybdenum-99 production system. SNL has a wealth of experience gained from its DOE sponsored molybdenum-99 medical isotope program in the 1990's. This unique experience includes reactor design and modifications for molybdenum-99 target irradiation, as well as separation process and facility design. These efforts were later terminated when Canada committed to the production of molybdenum-99. Regardless, the expertise still exists within SNL.

2. We support the intent of HR 3276 to promote the production of molybdenum-99 in the United States for medical isotope production, and to do so without the use of highly enriched uranium and its attendant proliferation and security concerns. We concur with the National Academy's report confirming that the production of molybdenum-99 without the use HEU is technically and economically feasible and that adequate quantities of medical isotopes can be produced without the use of HEU. However, we suggest that LEU fission target technology represents the best technology to meet the strategic needs of the U.S.

3. The Secretary of Energy criteria for evaluating and supporting projects, as written in Section 3(a)(2), tend to favor short-term and perhaps makeshift solutions using modified capabilities pressed into service, rather than long-term strategic solutions based on new-build production systems which are dedicated and purpose-built for meeting the U.S. and export demand for molybdenum-99. Though expediency is a factor to consider, greater weight should be given to the overall strategic quality of the proposed molybdenum-99 production system. Dedicated, purpose-built production systems will ensure the long-term strategic needs of the U.S. are met, rather than relying on stop-gap measures. Given the fragility of the molybdenum-99 production and supply chain, it is more important that we get the U.S. policy, for supply and LEU conversion, right rather rushed.

4. The Secretary of Energy criteria for evaluating and supporting projects, as written in Section 3(a)(2), does not give merit or consideration to the waste management practice for a proposed production system. While the waste burden is not particularly great with most molybdenum-99 production systems, given the general challenges of radioactive waste management facing the USG, it would be prudent if the Secretary's criteria included a factor that considered waste type and volume, the availability of waste disposal pathways, and waste management practices, as a consideration for providing assistance to a particular project.

5. A new molybdenum-99 production system capability will likely require local community support for new or adapted reactor and separations operations. Regulatory approvals for reactor operations in densely populated metropolitan areas can be controversial. Community support for any nuclear operation can at times prove to be difficult to secure, and could lead to substantial delays affecting the start of production. How long it will take to get domestic production facilities licensed, constructed and operating, given the potential for delay due to environmental or siting concerns, or NRC licensing hurdles for novel technologies, are significant factors to consider. Several potential delays are mitigated with strong local community support. Thus, it is suggested that the Secretary's criteria should include a factor that considers the degree of local stakeholder community support.

6. Recognizing the legislation empowers the Secretary of Energy to provide financial assistance in the development of fuels, targets and processes for domestic production of molybdenum-99, we concur with the notion that funding should be directed to those projects which stand the best chance of producing commercially meaningful quantities of medical isotopes, rather than striving for technical neutrality. While other technologies are conceivable, only LEU fission target technology has the potential to efficiently balance the demands for license feasibility and production capacity at predictable costs and timeframes.

7. Given the issues noted in items 3, 4, 5 and 6 above, we recommend the language in the Senate version of the American Medical Isotopes Production Act of 2009 be modified to include Secretary criteria designed to give merit to projects that represent an overall strategic quality solution to US needs, and that:

- a. are designed as dedicated and purpose-built production systems for meeting the full capacity (with reserve) of U.S. demand,
- b. have addressed the management and fate of the waste burden, and,
- c. have demonstrated community support for hosting such facilities.

Suggested draft language for Section 3 is provided below.

If the Senate Energy and Natural Resources Committee needs any additional information or technical expertise regarding medical isotopes and their production, SNL stands ready to assist the Committee in any way possible. Thank you for providing SNL with an opportunity to express its views regarding H.R. 3276 and we greatly appreciate your consideration of our recommendations.

Sandia National Laboratories is a multiprogram laboratory operated by Sandia Corporation, an autonomous Lockheed Martin company, for the U.S. Department of Energy's National Nuclear Security Administration. With main facilities in Albuquerque, N.M., and Livermore, Calif., Sandia has major R&D responsibilities in national security, energy and environmental technologies, and economic competitiveness.

As written:

SEC. 3. IMPROVING THE RELIABILITY OF DOMESTIC MEDICAL ISOTOPE SUPPLY.

(a) Medical Isotope Development Projects—

(1) IN GENERAL—The Secretary of Energy shall establish a program to evaluate and support projects for the production in the United States, without the use of highly enriched uranium, of significant quantities of molybdenum-99 for medical uses.

(2) CRITERIA—Projects shall be judged against the following primary criteria:

(A) The length of time necessary for the proposed project to begin production of molybdenum-99 for medical uses within the United States.

(B) The capability of the proposed project to produce a significant percentage of United States demand for molybdenum-99 for medical uses.

(C) The cost of the proposed project.

Proposed:

SEC. 3. IMPROVING THE RELIABILITY OF DOMESTIC MEDICAL ISOTOPE SUPPLY.

(a) Medical Isotope Development Projects—

(1) IN GENERAL—The Secretary of Energy shall establish a program to evaluate and support projects for the production in the United States, without the use of highly enriched uranium, of significant quantities of molybdenum-99 for medical uses.

(2) CRITERIA—Projects shall be judged on their overall strategic qualities to meet U.S. needs and interests, and against the following primary criteria:

(A) The length of time necessary for the proposed project to begin production of molybdenum-99 for medical uses within the United States.

(B) The capability of the proposed project to produce a significant percentage of United States demand for molybdenum-99 for medical uses.

(C) The cost of the proposed project.

(D) The likelihood for securing regulatory approval and licensing of the proposed project.

(E) The strategic quality of the proposed project to meet long-term capacity and reserve needs, including the degree to which the proposed project is dedicated and purpose built for molybdenum-99 production,

(F) The overall waste management plan and fate of the waste burden for the proposed project.

(G) The degree of local community support for the proposed project.

ASTELLAS US LLC,
Deerfield, IL, November 30, 2009.

Hon. JEFF BINGAMAN,
U.S. Senate, 703 Senate Hart Office Building, Washington, DC.

Hon. LISA MURKOWSKI,
U.S. Senate, 709 Senate Hart Office Building, Washington, DC.

Re: American Medical Isotope Production Act of 2009

DEAR CHAIRMAN BINGAMAN AND RANKING MEMBER MURKOWSKI: On behalf of Astellas Pharma US, Inc. (Astellas), I am writing in strong support of the American Medical Isotope Production Act of 2009 recently passed by the House of Representatives. Astellas believes that this legislation is critical to ensuring a sufficient supply of radioisotopes used in life-saving medical tests and procedures. We appreciate the Senate Energy Committee's consideration of this legislation and look forward to the Committee's December 3rd hearing to examine this important issue.

Astellas is among the top 20 global research-based pharmaceutical companies, and is a recognized leader in the area of pharmacologic stress agents for nuclear imaging. In North America, our headquarters are located in Deerfield, IL; our research and development facilities are located in Santa Monica, CA, Skokie, IL, and Durham, NC; and we have a production and distribution facility in Norman, OK.

Two Astellas products, Lexiscan® and Adenoscan®, are cardiac stress agents used with Technetium-99m (Tc-99m) in radionuclide myocardial perfusion imaging (MPI). MPI is a key noninvasive test used to assess blood flow in the heart and to diagnose and manage patients at risk for a heart attack. The inability of doctors to perform MPI due to a lack of Tc-99m would result in greater numbers of invasive procedures, and put patients at risk while increasing the costs of care dramatically.

You have recognized the significant problems with current foreign sources of radioisotopes, and the real threat that necessary medical procedures could be unavailable to American patients—with dire consequences. Your leadership on this issue and this legislation will ensure that the United States controls its own destiny with radioisotope production, and that future crises in patient access to necessary medical care are averted.

We also support the legislation's phase-out of highly enriched uranium exports, given the safeguards in the legislation for its temporary continued use during a period of insufficient supply of molybdenum-99. This time period for transition from highly-enriched uranium to low enriched uranium will ensure that patient access to medical radioisotopes remains uninterrupted in the future.

Again, we thank you for your leadership on this effort of vital importance to patients and providers. We are committed to working with you and others in ensuring the availability of a stable supply of radioisotopes for patients.

Sincerely,

MICHAEL J. RUGGIERO,
Senior Director, Govt. Policy and External Affairs.

HEALTH PHYSICS SOCIETY,
McLean, VA, November 30, 2009.

Hon. JEFF BINGAMAN,
Chair.

Hon. LISA MURKOWSKI,
Ranking Member, Energy and Natural Resources Committee, 304 Dirksen Senate Office Building, U.S. Senate, Washington, DC.

DEAR SENATORS BINGAMAN AND MURKOWSKI: On behalf of the Health Physics Society (HPS), I urge the Senate Energy and Natural Resources Committee to give full support to and take timely action on H.R.3276, the "American Medical Isotope Production Act of 2009."

The Health Physics Society, a nonprofit scientific organization of approximately 5000 radiation safety professionals, has joined with eight other professional organizations in a coalition to address two concerns of national importance: (1) an inherent need for reliable domestic suppliers of Molybdenum-99 (Mo-99); and, (2) efforts to curtail the use of high-enriched uranium (HEU) in radionuclide production as a non-proliferation strategy and to deter terrorism. A discussion of these concerns with recommendations for action by the United States is contained in a white paper by the coalition of professional organizations titled "Reliable Domestic & Global Supplier of Molybdenum-99 (Mo-99) and Switch from Highly Enriched Uranium (HEU) to Low-Enriched Uranium (LEU) to Produce Mo-99." The white paper is accessible at http://hps.org/documents/isotopes_white-paper_multiorganization.pdf.

A national effort to address these concerns requires (1) a commitment by the administration to have a coordinated inter-agency program with the specific responsibility to achieve reliable domestic independence in the production of Mo-99, (2) continued appropriations by Congress to provide the financial investment needed by the administration's program, and (3) support of the Congress through authorizing legislation that will serve as the basis for the continuation of the administration's program until its goals are achieved.

The Obama administration has made a commitment to achieve domestic independence in the production of Mo-99. The HPS believes the initiative being led by the National Nuclear Security Administration through the Global Threat Reduction Initiative with oversight and interagency coordination by the Office of Science and Technology Policy has the capability to achieve the establishment of a reliable domestic production of Mo-99 within the next ten years. The Congress has appropriated sufficient support for fiscal year 2010. The remaining task is to obtain congressional support through authorizing legislation that will serve as the support and basis for the administration's program into the future.

The HPS believes H.R.3276 provides the needed congressional support for the administration's program.

We understand there may be some concern about the provisions in H.R.3276 for imposing a ban on export of HEU at a fixed time in the future. HPS's interest in the issue of domestic production of radioisotopes is related to the radiation safety implications of the issue, including the implications of exporting HEU for this purpose. In 2005, the HPS did not support the inclusion of an HEU export ban provision in the Energy Policy Act of 2005. The HPS felt that the controls under which HEU was exported were rigorous enough to make the export acceptably safe when compared to the prospect of not having a supply of Mo-99. This position was influenced by the lack of any administration program or congressional support for a program dedicated to the domestic production of radioisotopes. The HPS still considers the controls for export of HEU for production of radioisotopes to be rigorous enough to make the risk of diversion for terrorism, or other malicious use of the HEU to be speculative. However, we feel that with appropriate congressional support, the initiative to establish reliable domestic production of Mo-99 will be successful within the next ten years, making the need to export HEU unnecessary. Therefore, we feel the export ban provisions will prove to be extraneous and, therefore, do not form a basis for not supporting H.R.3276.

I hope this letter is helpful in your considered deliberation of action on H.R.3276. Please do not hesitate to contact me if you have any questions about this letter or HPS support for H.R.3276.

Sincerely,

HOWARD W. DICKSON, CHP,
President.

December 3, 2009.

Hon. JEFF BINGAMAN,
Chair.

Hon. LISA MURKOWSKI,
Ranking Minority Member, Energy and Natural Resources Committee, U.S. Senate,
Washington, DC.

DEAR SENATORS, We are writing to express our strong support for H.R. 3276, the "American Medical Isotopes Production Act of 2009," which was passed in the House of Representatives in November of this year by an overwhelming 400-17 vote, and to urge the Senate to approve a counterpart bill as soon as possible. We believe that the bill strikes the right balance between the acute need to develop a highly reliable, domestic supply of molybdenum-99, and the crucial policy objective of working to eliminate the use of nuclear bomb-usable highly enriched uranium (HEU) in the production process as soon as feasible.

As the text of H.R. 3276 indicates, U.S. patients are already experiencing supply interruptions of molybdenum-99 as a result of their reliance on aging, foreign production facilities that have been subject to prolonged, safety-related shutdowns. While the United States is contemplating emergency measures to deal with the isotope crisis in the shortterm, it is equally important to ensure that a credible strategy is in place to avoid recurrence of the problem in the long-term. We are confident that the bill will effectively support such a strategy, and acknowledge the endorsement of H.R. 3276 by major U.S. nuclear medicine professional associations. We also appreciate that H.R. 3276 responsibly promotes efforts to eliminate the use of HEU in medical isotope production—including eventually ending the current U.S. practice

of exporting HEU for this purpose—while providing safeguards to ensure that such efforts will never interfere with the availability of an affordable supply of these isotopes for U.S. patients.

We commend you and the entire Committee for receiving testimony today on this important legislation, which not only will have positive benefits for millions of U.S. patients, but also will help to reduce the threat of nuclear terrorism that imperils us all.

Sincerely,

EDWIN S. LYMAN,
*Senior Staff Scientist, Global Security Program,
Union of Concerned Scientists.*

FRANK VON HIPPEL,
*Professor of Public and International Affairs, Princeton University,
Co-chair, International Panel on Fissile Materials.*

HENRY SOKOLSKI,
*Executive Director,
Nonproliferation Policy Education Center.*

SHARON SQUASSONI,
*Senior Associate, Nonproliferation Program,
Carnegie Endowment for International Peace.*

ALAN J. KUPERMAN,
*Associate Professor, and Director of Nuclear Proliferation Prevention Program,
University of Texas at Austin.*

MICHELE BOYD,
*Director, Safe Energy Program,
Physicians for Social Responsibility.*

STATEMENT OF LLOYD SCOTT, CHIEF EXECUTIVE OFFICER AND CHAIRMAN, IOTRON INDUSTRIES CANADA INC., PORT COQUITLAM, BC

Chairman Bingaman, Ranking Member Senator Murkowski, and members of the Committee, thank you for the opportunity to submit for the record the testimony of Iotron Industries Canada Inc. (Iotron). Iotron strongly supports enactment of H.R. 3276 and commends the House of Representatives for passing the bill by an overwhelming bipartisan vote. Iotron also greatly appreciates this Committee's prompt attention to the critical shortage of the medical isotope Molybdenum 99 (Moly-99), and related nuclear non-proliferation issues.

Iotron believes that our proven, commercial Electron Beam accelerator technology can be used to produce Moly-99 in an economic and timely manner. We are eager to be part of the solution to the ongoing Moly-99 supply crisis. Iotron strongly supports clarifications that H.R. 3276 does not favor any particular technology to receive funding as a Medical Isotope Development Project. Instead, the Department of Energy (DOE) should be required to make funding decisions in a technology neutral manner, supporting isotope projects that best meet the criteria in the bill, regardless of the technology used. Iotron is not seeking favorable treatment, only fair competition.

IOTRON BACKGROUND

Iotron is a private corporation headquartered in Vancouver, British Columbia. Iotron provides advanced irradiation services to industry using its IMPELA Electron Beam accelerator technology acquired from Atomic Energy of Canada Limited (AECL) in 2001. These services include the sterilization of medical devices and molecular modification to various products, including gemstones and semiconductor materials. Iotron is a mature company, incorporated in 1989.

If Iotron has the opportunity to compete for the financial support authorized by H.R. 3276, it would seek seed funding for an accelerator project or projects located in the United States and managed by a U.S. subsidiary. Iotron has not entered into any partnerships to pursue this endeavor to date, but it is open to collaborating with others if appropriate.

IOTRON'S ACCELERATOR TECHNOLOGY

Iotron's Electron Beam accelerator technology can be used to produce medical isotopes such as Moly-99. The technical viability of this production route was demonstrated more than 10 years ago at a number of research institutes. To make production possible on a commercial scale requires the use of high-power and high-en-

ergy electron beam accelerators. We propose to use the IMPELA® technology developed by AECL and owned by Iotron. IMPELA is a unique technology regarded as the first commercial electron beam accelerator capable of generating both high-energy and high-power levels and has won several awards, including the R&D 100 Award. This accelerator technology is entirely conventional and is proven to be effective in a commercial environment, with simple servicing requirements and high uptime and reliability.

The photonuclear process uses high-energy photons generated in a photo-converter to drive the nuclear transmutation of stable Moly-100 to the radioisotope Moly-99. The photons are created when the electron beam is slowed in a photo-converter creating so-called Bremsstrahlung (braking radiation). Such converters are routinely employed on commercial electron beam accelerators used to sterilize some medical goods and foodstuffs. In the photonuclear process these photons irradiate a molybdenum target to create Moly-99 by the (gamma,n) reaction.

BENEFITS OF ACCELERATOR PRODUCTION OF MOLY-99

There are many benefits to using an accelerator for producing Moly-99 and other medical isotopes compared with other methods. First, the capital and operating costs of using a reactor for this purpose are avoided. Neither high-enriched nor low-enriched uranium is needed for an accelerator process to produce Moly-99 since it is not based on fission of uranium. In addition, the time necessary to move from the design and development phase to construction and production, including regulatory approvals, is relatively short for an accelerator-based solution; we estimate some two to three years.

Other benefits are that the accelerator production of Moly-99 generates minimal radioactive waste compared to the current fission method. Such wastes require disposal at considerable cost. In addition, the use of a number of accelerators located at various locations provides the redundancy to assure a constant supply while reducing transportation problems and inherent decay loss of the isotopes.

IMPROVEMENTS TO H.R. 3276

The text of H.R. 3276 does not bar DOE from providing financial assistance to a project using accelerator technology to produce Moly-99. However, the bill text refers repeatedly and specifically to reactors and does not mention accelerators or any other non-reactor technology. In addition, the phrase “Medical Isotope Development Projects” is not defined. Therefore, the current legislative text could potentially be misconstrued by DOE to imply a Congressional preference for reactor solutions to the Moly-99 shortage.

Iotron is grateful to the authors of H.R. 3276 for the following language that was included in the House Committee Report, which specifically addresses the need for a level playing field for all potential technologies considered by DOE for funding support. The Committee Report states:

The Committee recognizes that there are a variety of potential technological options for the production of molybdenum-99. The Committee emphasizes that H.R. 3276 does not favor any particular technology to receive funding as a medical isotope development project. Instead, it is the intent of the Committee that the Department of Energy support molybdenum-99 production projects in a technology neutral manner, choosing to assist those projects that best meet the criteria in section 3(a)(2) of H.R. 3276.

This report language is excellent and squarely addresses Iotron’s concern. However, Iotron respectfully requests that when this Committee acts on H.R. 3276 that it include the “technology neutral” requirement for DOE funding in the legislative text, not only in the Senate Committee Report.

Iotron also recommends that the criteria in Section 3(a)(2) of H.R. 3276 for the evaluation of Medical Isotope Development Projects could be improved with the additional clarification that “waste disposal” costs must be considered when estimating project costs. These costs are likely to be substantial for certain Moly-99 production technologies and must be factored into any DOE cost estimate and comparison.

CONCLUSION

Iotron again thanks the Committee for the opportunity to file testimony for the record regarding H.R. 3276. If the Committee has any questions regarding our testimony or related matters, please do not hesitate to contact us.

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