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SOLVING THE MEDICAL ISOTOPE CRISIS

WEDNESDAY, SEPTEMBER 10, 2009

House of Representatives,

Subcommittee on Energy and Environment,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 2:09 p.m., in Room 2322, Rayburn House Office Building, Hon. Edward J. Markey [chairman of the subcommittee] presiding.

Present: Representatives Markey, Barrow, Upton, Shimkus, and Scalise.

Staff Present: Jeff Baran, Counsel; Matt Weiner, Special Assistant; and Peter Ketcham-Colwill, Special Assistant.

Mr. Markey. Welcome ladies and gentlemen to the Subcommittee on Energy and the Environment and our very important hearing.

Every day in the United States, thousands of people go to the hospital to be treated for life-threatening illnesses such as heart disease and cancer. But right now, due to the breakdown of a nuclear reactor in Canada, many of these critical procedures are being delayed and compromised.

The United States is facing a crisis in nuclear medicine. We face a severe shortage of a crucial radioactive isotope which is required for nearly 50,000 medical procedures every day, usually to produce a detailed image such as a cancer or a bone scan. The shortage of this isotope, which usually costs only $10 of a multi-thousand dollar procedure, is threatening the health care of millions of Americans. Worst of all, the United States does not currently produce any of the isotope 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 weapon 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. In mid July, the 47-year-old HFR reactor in the Netherlands was taken off-line for maintenance for 1 month. Together, these two reactors usually produce our entire isotope supply. While the

United States was able to secure a small supply during this time from other reactors, Americans health care suffered as a result. A recent survey of the nuclear medicine community provided sobering results. Eighty percent said their practice was impacted by the shortage. Eighty percent said they have postponed procedures. Forty-seven percent said they have cancelled procedures, and 57 percent said they had substituted alternative procedures. Unfortunately, in most cases the alternative procedures are more invasive, less effective, more costly, and pose greater radiation risk to both patients and technicians.

We don't need alternatives. We need the state of the art to be fully available again. Medical care in this country for cancer, heart disease, bone scans simply cannot be held hostage to the maintenance schedules of a 50-year-old reactor in Europe. It is absolutely vital that we act to bring a robust domestic supply of these critical medical isotopes online as soon as possible.

In order to address the crisis in nuclear medicine, I have introduced, along with my good friend, colleague and partner, Fred Upton, H.R. 3276, the American Medical Isotopes Production Act of 2009. The bill will provide the Department of Energy new authorities and resources to assist the private sector in establishing as rapidly as possible a robust medical isotope production capacity here in the United States. In addition, the bill will end the export of bomb-usable highly enriched uranium for medical isotope production in 7 to 10 years, as recommended in

a recent National Academy of Sciences report that also said there was no reason that these isotopes couldn't be made using low enriched uranium. In fact, both Argentina and Australia have started producing medical isotopes with low enriched uranium. Highly enriched uranium is nuclear bomb material, and the national security of the United States demands that we never export it again.

The Markey-Upton bill is a bipartisan bill. 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, a list of companies as well plus the Nuclear Threat Initiative, the Union of Concerned Scientists and Physicians For Social Responsibility.

I would like to ask for unanimous consent that the letters of endorsement from these organizations be entered into the record. I also would like to ask unanimous consent that members will have 5 legislative days to revise and extend their remarks and into insert extraneous material in the record.

Today's hearing will allow the subcommittee to explore this important issue and to hear the panel's views on H.R. 3276. I hope that we can all work together to address this crucial problem facing American hospitals and patients.

Now I would like to turn and recognize my good friend, the

gentleman from Michigan, Mr. Upton for his opening statement.

Mr. Upton. Thank you, Mr. Chairman. I am going to ask unanimous consent that my full statement be made part of the record.

And trying too shorten up some of the time as we are expecting votes soon, let me just make a couple of comments. We are really at a crisis. As you indicated, 16 million medical procedures in the U.S. that rely on the import of Moly-99. That's 50,000 a day. It is clear that our Nation must produce these lifesaving isotopes domestically to ensure that the public health is protected. And when I learned of this situation when you and I talked about it in July before the August break, I was delighted to partner with you to introduce legislation that I hope can move quickly.

There are a good number of organizations that are onboard. I would like to think that this hearing will catapult us into getting a bill the House very soon. And at this point, I yield back balance of my time.

Mr. Markey. Thank you. The Chair recognizes the gentleman from Illinois.

Mr. Shimkus. I will waive.

Mr. Markey. The Chair recognizes the gentleman from Louisiana.

Mr. Scalise. I will waive.

Mr. Markey. That is great. We will recognize our very

distinguished panel. Our first witness is Dr. Parrish Staples, director of the Office of European and African Threat Reduction at the National Nuclear Security Administration of the Department of Energy. Dr. Staples has played a leading role within the Department of Energy to help solve the medical isotopes crisis. In addition, his office is responsible for implementing the Department of Energy's efforts to reduce the use of highly enriched uranium around the world including in the production of medical isotopes.

STATEMENTS OF PARRISH STAPLES, DIRECTOR, EUROPEAN AND AFRICAN THREAT REDUCTION, OFFICE OF GLOBAL THREAT REDUCTION, NATIONAL NUCLEAR SECURITY ADMINISTRATION, UNITED STATES DEPARTMENT OF ENERGY; STEVEN LARSON, M.D., CHIEF, NUCLEAR MEDICINE SERVICE, DEPARTMENT OF RADIOLOGY, MEMORIAL SLOAN-KETTERING CANCER CENTER, VICE-CHAIRMAN, COMMITTEE ON MEDICAL ISOTOPE PRODUCTION WITHOUT HIGHLY ENRICHED URANIUM, NATIONAL ACADEMY OF SCIENCES; AND MICHAEL DUFFY, VICE PRESIDENT AND GENERAL COUNSEL, LANTHEUR MEDICAL IMAGING, MEMBER OF THE BOARD, COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS

Mr. Markey. We welcome you, Dr. Staples. Whenever you're ready please, again.

STATEMENT OF PARRISH STAPLES

Dr. Staples. Thank you, Chairman Markey, Ranking Member Upton, and the subcommittee members. Thank you for the opportunity to testify on the National Nuclear Security Administration's Global Threat Reduction Initiative's role in minimizing, and to the extent possible, eliminating the use of highly enriched uranium in civilian nuclear applications including in the production medical radioisotopes. As part of my testimony, I will briefly describe recent efforts to mitigate the impact of the current and anticipated shortages of the medical isotope moly-99 and discuss in more detail our efforts to accelerate the establishment of a domestic commercial supply of moly-99 that does not use highly enriched uranium.

Finally, I will highlight how the proposed American Medical Isotopes Production Act of 2009 can greatly help to advance our progress on the dual U.S. policy priorities to, one, establish a secure supply of this critical medical isotope for U.S. citizens, and two, to minimize the civilian use of proliferation-sensitive highly enriched uranium around the globe.

First, section 2 of the American Medical Isotope Production Act of 2009 very appropriately and succinctly covers the history, the use of moly-99, the decay product technecium-99 nine, the issues surrounding the current medical isotope production industry, the current acute shortage of moly-99 within the medical community, and the critical importance that this isotope provides

to the health care of Americans on a daily basis. And most importantly, it also covers the state of the art technology regarding conversion to low enriched uranium.

Very important to us, on January 14, 2009, the National Academy published a report confirming that the production of moly-99 without the use of highly enriched uranium is both technically and economically feasible. In addition to the National Academy's determination that there are no technical reasons that adequate quantities of medical isotope cannot be produced without the use of HEU, the National Academy also stated that the single greatest threat to the supply reliability is the approaching obsolescence of the aging reactors that current large-scale producers utilize to irradiate HEU targets to obtain moly-99. The findings of this report unambiguously support the consistency of HEU minimization policies with the full-scale production of medical isotopes while highlighting the fragile nature of the current supply chain due to the age of the foreign moly-99 production facilities.

Now, with our mission to reduce and eliminate the use of HEU in civilian applications NNSA has been working for many years to convert research reactors from the use of HEU to LEU fuel. We agree with the language in the proposed legislation which makes clear that the U.S. should accelerate its effort to convert HEU research reactors worldwide from the use of HEU. In fact, this acceleration is already underway at NNSA.

We and the Global Threat Reduction Initiative have significantly accelerated our efforts over the past several years and to date have converted 57 highly enriched uranium fuel research reactors globally from the use of HEU to LEU fuels. Through GTRI efforts, another seven HEU research reactors have been verified to shut down prior to their conversion. These activities have resulted in more than 320 kilograms of HEU no longer being used annually for reactor operations.

In addition, NNSA has also been working with both existing and potential moly-99 producers for several years to convert or develop their moly-99 production processes to utilize nonHEU-based technologies. NNSA provides technical expertise on a nonproprietary basis to all existing and potential producers to assist in converting and developing their moly-99 production processes in accordance with the U.S. HEU minimization policy. Through these efforts NNSA has established longstanding relationships with current and future moly-99 suppliers and we are uniquely suited to accelerate efforts to establish a reliable domestic supply without the use of HEU. Due to the current lack of global production capacity of moly-99 by industry, we are actively engaging in discussions with all current and possible producers to best determine how to rapidly transform the industry into a diverse, stable, commercial supply network that will not use HEU for production of this vital medical isotope.

Given the market dynamics with the current supply shortage,

we fully expect that the 7-year timeframe referenced in the American Medical Isotopes Production Act of 2009 is more than adequate to ensure that a sufficient supply of nonHEU moly-99 can be available to the medical community. Further we believe that the development of new producers or the conversion of existing producers to low enriched uranium can be accomplished with no impact upon the current supply availability. In fact, through the current acute supply shortage of this critical medical isotope and the associated market dynamics with the focus of the American Medical Isotopes Production Act of 2009 on this issue, we believe that we can ensure the successful development of a diverse, reliable supply of moly-99 to the medical community that will also help to accomplish an important and longstanding nuclear nonproliferation mission.

Now, the United States has approached the moly-99 supply problem by --

Mr. Markey. If you could summarize please, Dr. Staples.

Dr. Staples. I would just go to my closing paragraph then. The American Medical Isotope Production Act of 2009 is crucial of ensuring the success of our efforts to accelerate development of a domestic supply of moly-99 nine without the use of HEU. This legislation will accelerate greatly and enhance the development of reliable supply of this isotope for the use in the U.S. medical community and further support U.S. objectives to reduce the use of proliferation-sensitive HEU in civilian applications.

I thank the subcommittee and Chairman Markey, in particular, for your continued leadership on such a crucial nuclear energy and civil nuclear application issue, and we stand ready to answer questions.

Mr. Markey. Thank you, sir.

[The prepared statement of Dr. Staples follows:]

******** INSERT 1-1 ********

Mr. Markey. Our second witness is Dr. Steven Larson the Chair of the Nuclear Medicine Service, Department of Radiology at the Memorial Sloan-Kettering Cancer Institute. Whenever you are ready, please begin.

STATEMENT OF STEVEN LARSON, M.D.

Dr. Larson. Good afternoon, chairman and members of the committee. My name is Steven Larson, and I am chief of nuclear medicine, as you have heard at Memorial Sloan-Kettering Cancer Institute in New York. I also served as vice chair of the National Research Council's Committee on medical isotope production without highly enriched uranium. I was asked to testify today regarding the report from the study, but first I want to offer some personal observations as a practicing nuclear medicine physician.

I am the director of a large nuclear medicine clinic at Memorial Sloan-Kettering Cancer Center. For most of the summer like other nuclear medicine clinics in the northeast, we have seen a reduction of 20 to 25 percent in the optimum amount of technetium for clinical use. Now, technetium 99m, as you have heard, is by far the most common clinical isotope and a bellwether for nuclear medicine isotope supplied health care. This reduction supply has negatively impacted our ability to efficiently deliver

nuclear medicine-based care to patients.

Furthermore, medical isotope providers are telling us to expect continued shortages of technician 99m during 2009 and beyond, and they are warning about the possibility of even deeper reductions in technetium 99m availability. Clearly we are in the need of a more reliable supply of medical isotope for American health care.

Let me turn to the National Research Council's study on medical isotope production without highly enriched uranium. The mandate for this study came from section 630 of the Energy Policy Act of 2005. Our study was completed in late 2008, and the final report was issued in January, 2009. It focused primarily on the use of HEU for the production of medical isotope molybdenum 99.

Briefly, some key findings. Adequate quantities of medical isotopes to meet U.S. demands could be produced without HEU. A report found that an 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. Reliability of medical isotope supply is a significant problem now and likely to be a problem for the foreseeable future with demand close to total capacity for production and with little margin for additional production capacity in the event of an interruption of supply.

On the other hand demand for nuclear medicine services are stable with likely growth rates of utilization of 3 to 5 percent

per year.

Several steps could be taken by the U.S. Government and others to improve the feasibility of eliminating the use of HEU for medical isotope production. I note that H.R. 3276 legislatively enshrines several of these steps. It authorizes the Department of Energy to provide technical assistance to producers who wish to convert to production without HEU. It provides financial assistance to develop a domestic isotope production capacity, and it provides for a 7-year phaseout period for HEU exports for medical isotope production.

When I began work on this study I was skeptical about the economic feasibility of conversion to LEU-based medical isotope production and the potential impact that that might have on conversion or supply reliability. But based on the information I received during this National Research Council study, I now believe that if medical isotope producers have the will to convert that, they can do so without undue costs. My opinion is based on the observations we made during the site visits to the medical isotope production facilities in Argentina and Australia and discussion with technical experts about conversion. Under modest circumstances and without elaborate additional infrastructure, Argentina was able to convert to LEU-based production in less than 2 years and for less than a million dollars in supplies and facilities modification.

The Argentina process is now being implemented in Australia

and the Australian company, ANSTO, hopes to begin exporting small quantities of molybdenum 99 to the United States in the near future.

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

Mr. Markey. Thank you so much, Dr. Larson.

[The prepared statement of Dr. Larson follows:]

******** INSERT 1-2 ********

Mr. Markey. And our final witness is Michael Duffy, vice president and general counsel of Lantheus Medical Imaging, one of only two U.S. manufacturers of these type of generators. Welcome, sir.

STATEMENT OF MICHAEL DUFFY

Mr. Duffy. Good afternoon, Mr. Chairman, Mr. Upton, members of the committee, staff. I am here today to testify on behalf of the bill on behalf of both Lantheus and CARAR, the Council on Radionuclides and Radiopharmaceuticals. Lantheus endorses H.R. 3276. We strongly support the committee's efforts to promote the protection of moly in the United States for medical isotope applications. We have been a worldwide leader in diagnostic medical imaging for the past 50 years. Lantheus is the home to leading diagnostic imaging brands, including the Technelite generator which I have for those who want to take a look, and this is what actually causes the -- the radioactive salient is put through here. It comes out here and is mixed with a powder and becomes the injection which is injected into the patient.

So what's so important about these imaging agents, these radionuclides? They allow a clinician to have a functional view of an organ like the heart more than just a mere anatomical image. Instead, a picture from the outside looking in, they allow the

physician to see what is inside projecting out, for example, blood flow, heart function, tissue health. These are extremely helpful and important in the diagnosis and treatment of disease. The moly supply crisis is a chronic crisis resulting from an aging supply infrastructure and a market failure to attract sufficient replacement capacity. As Chairman Markey said, the crisis has become acute because of the ongoing shutdown in Canada at the NRU reactor and the an ongoing repairs in the Netherlands at the HFR reactor. Although Lantheus has had access to moly supply from the major moly-producing reactors around the world, because of this crisis, we have not been fully able to meet our customers' needs and we are having to ration the generators on a weekly basis.

Approximately a third of the moly manufactured outside of North America decays before it reaches our manufacturing facility in Massachusetts. Some of the old hands at Lantheus refer to this as buying ice on a warm day. Lantheus believes that a robust U.S. supply of moly is an important U.S. policy for reasons of accessible and affordable health care, efficient waste management, and nuclear nonproliferation.

As a result of the moly supply crisis, important diagnostic procedures are being postponed or cancelled. Clinicians are turning to older nuclear isotopes with potentially less diagnostic certainty and more patient risk. Clinicians may even be foregoing nuclear medicine entirely, opting instead for more invasive, more expensive, higher risk surgical procedures. Lantheus believes

that the private sector should have a major role in the resolution of this issue. However, we also believe there is a strong role for government to play. The U.S. Government's financial support of multiple projects with appropriate investment risk profiles will be the best way to develop a robust domestic supply of moly. And as a matter of health care policy, medical imaging procedures that rely on moly-derived imaging agents can improve patient outcomes and reduce costs. Strategic investments to help develop a domestic supply of moly should pay large dividends for both U.S. patients and U.S. taxpayers.

Wearing my CORAR hat now, CORAR supports 3276 and increasing capacity for medical isotopes in the United States. CORAR has two concerns about the bill. First, how do we ensure a full supply of moly if we get to the 7 to 10-year period and we don't yet have sufficient commercial quantities of domestically-produced LEU available? Second, CORAR would like the bill to contain specific language that would direct the Nuclear Regulatory Commission to allow the new aqueous homogenous reactors which have been recently proposed to be properly licensed as research reactors. CORAR believes the bill provides good support to bring new and alternative supplies to moly online quickly and believes it is prudent to back several alternative technologies and multiple reactor sites in order to avoid a repeat of the current availability in capacity issues.

In sum, as H.R. 3276 moves forward, both Lantheus and CORAR

hope to continue to work with the committee and staff to ensure both a swift and long-term solution to the moly crisis.

Thank you for the consideration of our perspectives. We look forward to working with you moving forward and I would be glad to answer any questions.

[The prepared statement of Mr. Duffy follows:]

******** INSERT 1-3 ********

Mr. Markey. They have called four roll calls on the House floor. There are 10 minutes left to go before we have to go to that roll call. Let me recognize the gentleman from Michigan, Mr. Upton.

Mr. Upton. Thanks.

I have one very quick question, and that is the bill as you know has a 7- to 10-year time frame. Do you think that is long enough? Is that the right amount of time or should we look at extending that? Go ahead, Mr. Duffy, Dr. Larson too.

Mr. Duffy. The National Academies had a point of view on that, and I welcome Dr. Larson's views on that. The concern that industry has about the timeframe is one of technology and one of regulation. On the technology side can we design targets appropriately which generate commercially sustainable amounts of molybdenum and can we do this in a way that is going to pass muster with the EPA, the Nuclear Regulatory Commission, the FDA and all the other State and Federal regulatory authorities? Industry embraces the proposal, is going to work hard to try to implement it, but CORAR, in particular, is concerned that for reasons beyond its control the period may not be sufficient.

Mr. Upton. Dr. Larson.

Dr. Larson. The main report felt that after careful deliberation that it would be feasible to bring this conversion in a 7-year timeframe; however, it does depend on the actual type of

conversion that was required. If one was talking about a complete refilled new facility, it may, in fact, take a bit longer. So we can -- my feeling is that the 7 years is probably enough especially with the 3-year window that is offered. The committee does have expertise to bring to bear upon this and if you wish we can certainly review this issue and give you a more full description of it since it is such a key.

Mr. Upton. That would be great. If you would like to do that that would be great. I will yield back.

Mr. Markey. Let me just ask one question, Dr. Larson. The National Academy of Sciences report recommended that Congress set a deadline to end the export of HEU for medical isotope. The report concluded that a 7- to 10-year phaseout period would likely allow enough time for all current HEU-based producers to convert to low enriched uranium. How did you arrive at that conclusion of 7 to 10 years?

Dr. Larson. I think the conclusion was based on interviews, discussions, field trips, and reviews of time of development of new facilities. We had the opportunity to visit, for example, Australia and to observe their process and plan for this. But since this is such a key point, we certainly would be glad to provide some more detailed background on how this was arrived at.

Mr. Markey. Thank you, sir. The gentleman from Georgia.

Mr. Barrow. No questions.

Mr. Markey. Thank you.

Dr. Staples, I am going to ask you what I think is the single most important question and that is how long will it take for the U.S. industry with the help of the Department of Energy to establish a robust domestic supply without the use of HEU?

Dr. Staples. Thank you. We believe that to develop a robust supply without the use of HEU would take on the order of 5 years with the type of attention focus that this bill could bring to the industry and the issue given the acute shortage of this isotope we are currently experiencing. As a clarification, we are not just talking about conversion of existing facilities. We are talking about looking at a diverse reliable supply network that would be implemented using nonHEU, not just LEU fission target-based technologies.

Mr. Markey. Dr. Staples, is DOE working with the foreign medical isotope producers to help them convert from HEU to LEU?

Dr. Staples. In fact, yes, we are. Given the recent supply shortage, we have engaged in at least informal discussions with all current producers regarding options and process and procedure for the conversion --

Mr. Markey. Have they asked for your help in conversions?

Dr. Staples. Yes. They have solicited our help and assistance in conversions.

Mr. Markey. Have they made those requests recently?

Dr. Staples. As recently as last week, yes sir.

Mr. Markey. Great. Does there seem to be a renewed interest

in converting from HEU to LEU at this time?

Dr. Staples. Absolutely. Again, I think primarily driven by the shortage of supply in the current industry.

Mr. Markey. Would phaseout of export of HEU for medical isotope production in 7 to 10 years given the handful of foreign producers present a window of opportunity for their operations?

Dr. Staples. If I understand, we believe that the 7-year timeframe would give more than a sufficient timeframe for these facilities to work on conversion and for the development of a diverse domestic supply of moly 99 not using enriched uranium.

Mr. Markey. Does 7 to 10 years give the foreign producers adequate time to convert to LEU?

Dr. Staples. Yes.

Mr. Markey. The bill authorizes $163 million over 5 years for DOD to help establish a domestic supply. Is that the right of amount of money and is that the right amount of time?

Dr. Staples. Yes. We believe that is consistent with a program plan that we have in place where we would intend this year to place up to $10 million on programs to support the development of commercial industry and $30 million in each of the respective outyears to support the developments of domestic and/or commercial supply of isotope.

Mr. Markey. I have a group of other written questions here, and I am going to submit to you each for your response to the committee. We apologize to you. There is a whole series of roll

calls which are going to now go off and keep us for an indefinite time out on the House floor. We apologize to you for that, and with the thanks of the subcommittee and apologies because of the truncated form of the hearing, this hearing is adjourned. Thank you.

[Whereupon, at 2:42 p.m., the subcommittee was adjourned.]