111TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPORT
111–328

AMERICAN MEDICAL ISOTOPES PRODUCTION ACT OF 2009

NOVEMBER 4, 2009.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WAXMAN, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 3276]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3276) to promote the production of molybdenum-99 in the United States for medical isotope production, and to condition and phase out the export of highly enriched uranium for the production of medical isotopes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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89–006

AMENDMENT

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "American Medical Isotopes Production Act of 2009".

SEC. 2. FINDINGS.

Congress finds the following:

(1) Molybdenum-99 is a critical medical isotope whose decay product technecium-99m is used in approximately two-thirds of all diagnostic medical isotope procedures in the United States, or 16 million medical procedures annually, including for the detection of cancer, heart disease, and thyroid disease, investigating the operation of the brain and kidney, imaging stress fractures, and tracking cancer stages.

(2) Molybdenum-99 has a half-life of 66 hours, and decays at a rate of approximately one percent per hour after production. As such, molybdenum-99 cannot be stockpiled. Instead, molybdenum-99 production must be scheduled to meet the projected demand and any interruption of the supply chain from production, to processing, packaging, distribution, and use can disrupt patient care.

(3) There are no facilities within the United States that are dedicated to the production of molybdenum-99 for medical uses. The United States must import molybdenum-99 from foreign production facilities, and is dependent upon the continued operation of these foreign facilities for millions of critical medical procedures annually.

(4) Most reactors in the world which produce molybdenum-99 utilize highly enriched uranium, which can also be used in the construction of nuclear weapons. In January 2009, the National Academy of Sciences encouraged molybdenum-99 producers to convert from highly enriched uranium to low enriched uranium, and found that there are "no technical reasons that adequate quantities cannot be produced from LEU targets in the future" and that "a 7-10 year phase-out period would likely allow enough time for all current HEU-based producers to convert".

(5) The 51-year-old National Research Universal reactor in Canada, which is responsible for producing approximately sixty percent of United States demand for molybdenum-99 under normal conditions, was shut down unexpectedly May 14, 2009, after the discovery of a leak of radioactive water. It is unclear whether the National Research Universal reactor will be able to resume production of molybdenum-99.

(6) The United States currently faces an acute shortage of molybdenum-99 and its decay product technetium-99m due to technical problems which have seriously interrupted operations of foreign nuclear reactors producing molybdenum-99.

(7) As a result of the critical shortage of molybdenum-99, patient care in the United States is suffering. Medical procedures requiring technetium-99 are being rationed or delayed, and alternative treatments which are less effective, more costly, and may result in increased radiation doses to patients are being substituted in lieu of technetium-99.

(8) The radioactive isotope molybdenum-99 and its decay product technetium-99m are critical to the health care of Americans, and the continued availability of these isotopes, in a reliable and affordable manner, is in the interest of the United States.

(9) The United States should move expeditiously to ensure that an adequate and reliable supply of molybdenum-99 can be produced in the United States, without the use of highly enriched uranium.

(10) Other important medical isotopes, including iodine-131 and xenon-133, can be produced as byproducts of the molybdenum-99 fission production process. In January 2009, the National Academy of Sciences concluded that these important medical isotopes "will be sufficiently available if Mo-99 is available". The coproduction of medically useful isotopes such as iodine-131 and xenon-133 is an important benefit of establishing molybdenum-99 production in the United States without the use of highly enriched uranium, and these coproduced isotopes should also be available for necessary medical uses.

(11) The United States should accelerate its efforts to convert nuclear reactors worldwide away from the use of highly enriched uranium, which can be used in nuclear weapons, to low enriched uranium. Converting nuclear reactors away from the use of highly enriched uranium is a critically important element of United States efforts to prevent nuclear terrorism, and supports the goal an-

nounced in Prague by President Barack Obama on April 5, 2009, to create "a new international effort to secure all vulnerable nuclear material around the world within four years".

(12) The United States is engaged in an effort to convert civilian nuclear test and research reactors from highly enriched uranium fuel to low enriched uranium fuel through the Global Threat Reduction Initiative. As of September 2009, this program has successfully converted 17 reactors in the United States to low enriched uranium fuel, some of which are capable of producing molybdenum-99 for medical uses.

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.

(3) EXEMPTION.—An existing reactor fueled with highly enriched uranium shall not be disqualified from the program if the Secretary of Energy determines that—

(A) there is no alternative nuclear reactor fuel, enriched in the isotope U-235 to less than 20 percent, that can be used in that reactor;

(B) the reactor operator has provided assurances that, whenever an alternative nuclear reactor fuel, enriched in the isotope U-235 to less than 20 percent, can be used in that reactor, it will use that alternative in lieu of highly enriched uranium; and

(C) the reactor operator has provided a current report on the status of its efforts to convert the reactor to an alternative nuclear reactor fuel enriched in the isotope U-235 to less than 20 percent, and an anticipated schedule for completion of conversion.

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary of Energy for carrying out the program under paragraph (1) $163,000,000 for the period encompassing fiscal years 2010 through 2014.

(b) DEVELOPMENT ASSISTANCE.—The Secretary of Energy shall establish a program to provide assistance for—

(1) the development of fuels, targets, and processes for domestic molybdenum-99 production that do not use highly enriched uranium; and

(2) commercial operations using the fuels, targets, and processes described in paragraph (1).

(c) URANIUM LEASE AND TAKE BACK.—The Secretary of Energy shall establish a program to make low enriched uranium available, through lease contracts, for irradiation for the production of molybdenum-99 for medical uses. The lease contracts shall provide for the Secretary to retain responsibility for the final disposition of radioactive waste created by the irradiation, processing, or purification of leased uranium. The lease contracts shall also provide for compensation in cash amounts equivalent to prevailing market rates for the sale of comparable uranium products and for compensation in cash amounts equivalent to the net present value of the cost to the Federal Government for the final disposition of such radioactive waste, provided that the discount rate used to determine the net present value of such costs shall be no greater than the average interest rate on marketable Treasury securities. With respect to the final disposition of such radioactive waste from such leased uranium, the Secretary shall not use the authorities under section 3112 of the USEC Privatization Act (42 U.S.C. 2297h–10) or section 53, 63, or 161 m. of the Atomic Energy Act of 1954 (42 U.S.C. 2073, 2093, or 2201(m)).

SEC. 4. EXPORTS.

Section 134 of the Atomic Energy Act of 1954 (42 U.S.C. 2160d(b)) is amended by striking subsections b. and c. and inserting in lieu thereof the following:

"b. Effective 7 years after the date of enactment of the American Medical Isotopes Production Act of 2009, the Commission may not issue a license for the export of highly enriched uranium from the United States for the purposes of medical isotope production.

"c. The period referred to in subsection b. may be extended for no more than four years if, no earlier than 6 years after the date of enactment of the American Medical

Isotopes Production Act of 2009, the Secretary of Energy certifies to the Committee on Energy and Commerce of the House of Representatives and the Committee on Energy and Natural Resources of the Senate that—

"(1) there is insufficient global supply of molybdenum-99 produced without the use of highly enriched uranium available to satisfy the domestic United States market; and

"(2) the export of United States-origin highly enriched uranium for the purposes of medical isotope production is the most effective temporary means to increase the supply of molybdenum-99 to the domestic United States market.

"d. At any time after the restriction of export licenses provided for in subsection b. becomes effective, if there is a critical shortage in the supply of molybdenum-99 available to satisfy the domestic United States medical isotope needs, the restriction of export licenses may be suspended for a period of no more than 12 months, if—

"(1) the Secretary of Energy certifies to the Congress that the export of United States-origin highly enriched uranium for the purposes of medical isotope production is the only effective temporary means to increase the supply of molybdenum-99 necessary to meet United States medical isotope needs during that period; and

"(2) the Congress passes a Joint Resolution approving the temporary suspension of the restriction of export licenses.

"e. As used in this section—

"(1) the term 'alternative nuclear reactor fuel or target' means a nuclear reactor fuel or target which is enriched to less than 20 percent in the isotope U-235;

"(2) the term 'highly enriched uranium' means uranium enriched to 20 percent or more in the isotope U-235;

"(3) a fuel or target 'can be used' in a nuclear research or test reactor if—

"(A) the fuel or target has been qualified by the Reduced Enrichment Research and Test Reactor Program of the Department of Energy; and

"(B) use of the fuel or target will permit the large majority of ongoing and planned experiments and isotope production to be conducted in the reactor without a large percentage increase in the total cost of operating the reactor; and

"(4) the term 'medical isotope' includes molybdenum-99, iodine-131, xenon-133, and other radioactive materials used to produce a radiopharmaceutical for diagnostic, therapeutic procedures or for research and development.".

SEC. 5. REPORT ON DISPOSITION OF EXPORTS.

Not later than 1 year after the date of the enactment of this Act, the Chairman of the Nuclear Regulatory Commission, after consulting with other relevant agencies, shall submit to the Congress a report detailing the current disposition of previous United States exports of highly enriched uranium, including—

(1) their location;

(2) whether they are irradiated;

(3) whether they have been used for the purpose stated in their export license;

(4) whether they have been used for an alternative purpose and, if so, whether such alternative purpose has been explicitly approved by the Commission;

(5) the year of export, and reimportation, if applicable;

(6) their current physical and chemical forms; and

(7) whether they are being stored in a manner which adequately protects against theft and unauthorized access.

SEC. 6. DOMESTIC MEDICAL ISOTOPE PRODUCTION.

(a) IN GENERAL.—Chapter 10 of the Atomic Energy Act of 1954 (42 U.S.C. 2131 et seq.) is amended by adding at the end the following new section:

"SEC. 112. DOMESTIC MEDICAL ISOTOPE PRODUCTION. a. The Commission may issue a license, or grant an amendment to an existing license, for the use in the United States of highly enriched uranium as a target for medical isotope production in a nuclear reactor, only if, in addition to any other requirement of this Act—

"(1) the Commission determines that—

"(A) there is no alternative medical isotope production target, enriched in the isotope U-235 to less than 20 percent, that can be used in that reactor; and

"(B) the proposed recipient of the medical isotope production target has provided assurances that, whenever an alternative medical isotope production target can be used in that reactor, it will use that alternative in lieu of highly enriched uranium; and

"(2) the Secretary of Energy has certified that the United States Government is actively supporting the development of an alternative medical isotope production target that can be used in that reactor.

"b. As used in this section—

"(1) the term 'alternative medical isotope production target' means a nuclear reactor target which is enriched to less than 20 percent of the isotope U-235;

"(2) a target 'can be used' in a nuclear research or test reactor if—

"(A) the target has been qualified by the Reduced Enrichment Research and Test Reactor Program of the Department of Energy; and

"(B) use of the target will permit the large majority of ongoing and planned experiments and isotope production to be conducted in the reactor without a large percentage increase in the total cost of operating the reactor;

"(3) the term 'highly enriched uranium' means uranium enriched to 20 percent or more in the isotope U-235; and

"(4) the term 'medical isotope' includes molybdenum-99, iodine-131, xenon-133, and other radioactive materials used to produce a radiopharmaceutical for diagnostic, therapeutic procedures or for research and development.".

(b) TABLE OF CONTENTS.—The table of contents for the Atomic Energy Act of 1954 is amended in the items relating to chapter 10, by inserting at the end the following new item:

"Sec. 112. Domestic medical isotope production.".

SEC. 7. ANNUAL DEPARTMENT OF ENERGY REPORTS.

The Secretary of Energy shall report to Congress no later than one year after the date of enactment of this Act, and annually thereafter for 5 years, on Department of Energy actions to support the production in the United States, without the use of highly enriched uranium, of molybdenum-99 for medical uses. These reports shall include the following:

(1) For medical isotope development projects—

(A) the names of any recipients of Department of Energy support under section 3 of this Act;

(B) the amount of Department of Energy funding committed to each project;

(C) the milestones expected to be reached for each project during the year for which support is provided;

(D) how each project is expected to support the increased production of molybdenum-99 for medical uses;

(E) the findings of the evaluation of projects under section 3(a)(2) of this Act; and

(F) the ultimate use of any Department of Energy funds used to support projects under section 3 of this Act.

(2) A description of actions taken in the previous year by the Secretary of Energy to ensure the safe disposition of radioactive waste from used molybdenum-99 targets.

SEC. 8. NATIONAL ACADEMY OF SCIENCES REPORT.

The Secretary of Energy shall enter into an arrangement with the National Academy of Sciences to conduct a study of the state of molybdenum-99 production and utilization, to be provided to the Congress not later than 5 years after the date of enactment of this Act. This report shall include the following:

(1) For molybdenum-99 production—

(A) a list of all facilities in the world producing molybdenum-99 for medical uses, including an indication of whether these facilities use highly enriched uranium in any way;

(B) a review of international production of molybdenum-99 over the previous 5 years, including—

(i) whether any new production was brought online;

(ii) whether any facilities halted production unexpectedly; and

(iii) whether any facilities used for production were decommissioned or otherwise permanently removed from service; and

(C) an assessment of progress made in the previous 5 years toward establishing domestic production of molybdenum-99 for medical uses, including the extent to which other medical isotopes coproduced with molybdenum-99, such as iodine-131 and xenon-133, are being used for medical purposes.

(2) An assessment of the progress made by the Department of Energy and others to eliminate all worldwide use of highly enriched uranium in reactor fuel, reactor targets, and medical isotope production facilities.

SEC. 9. DEFINITIONS.

In this Act the following definitions apply:

(1) HIGHLY ENRICHED URANIUM.—The term "highly enriched uranium" means uranium enriched to 20 percent or greater in the isotope U-235.

(2) LOW ENRICHED URANIUM.—The term "low enriched uranium" means uranium enriched to less than 20 percent in the isotope U-235.

PURPOSE AND SUMMARY

H.R. 3276, the American Medical Isotopes Production Act of 2009, was introduced by Reps. Edward J. Markey (D–MA) and Fred Upton (R–MI) on July 21, 2009. The purpose of H.R. 3276 is to authorize the U.S. Department of Energy to evaluate and support projects for the domestic production of molybdenum-99, a medical isotope, without the use of highly enriched uranium. In addition, H.R. 3276 sunsets the authority of the Nuclear Regulatory Commission to issue licenses for the export of highly enriched uranium for medical isotope production.

BACKGROUND AND NEED FOR LEGISLATION

Molybdenum-99 is a critical medical isotope, and its decay product, technetium-99m, is used in approximately two-thirds of all diagnostic medical isotope procedures in the United States, or 16 million medical procedures annually. These procedures are used to detect cancer, heart disease, and thyroid disease, investigate the operation of the brain and kidney, image stress fractures, and track cancer stages.

There are no facilities within the United States that currently produce molybdenum-99 for medical uses. As a result, the United States imports molybdenum-99 from foreign production facilities and is dependent upon the continued operation of these foreign facilities for millions of critical medical procedures annually. Nearly all of the global supply of molybdenum-99 has been produced by four organizations at five reactors in Canada, the Netherlands, Belgium, France, and South Africa.

The United States currently faces an acute shortage of molybdenum-99 due to technical problems that have interrupted operations of nuclear reactors producing molybdenum-99 in Canada and the Netherlands. According to testimony received by the Committee, medical procedures requiring technetium-99 are being rationed or delayed, and alternative treatments that are less effective, more costly, and may result in increased radiation doses to patients are being substituted in lieu of technetium-99.

Most reactors that produce molybdenum-99 utilize highly enriched uranium, which has the potential to be used in the construction of nuclear weapons. In these reactors, molybdenum-99 is produced by irradiating a uranium "target" in the reactor. In a January 2009 study, the National Academy of Sciences encouraged molybdenum-99 producers to convert from highly enriched uranium to low enriched uranium, which has virtually no potential to be used in a nuclear weapon. The study found that there are "no technical reasons that adequate quantities cannot be produced from [low enriched uranium] targets in the future" and that "a 7–10 year phase-out period would likely allow enough time for all current

[highly enriched uranium]-based producers to convert."[1] Low enriched uranium-based molybdenum-99 production is already occurring in Argentina and Australia.

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.

The January 2009 report by the National Academy of Sciences found that, "other medical isotopes such as iodine-131 (I-131) and xenon-133 (Xe133) are by-products of the Mo-99 production process and will be sufficiently available if Mo–99 is available."[2] Because establishing domestic fission-based production of molybdenum-99 would necessarily result in the domestic coproduction of isotopes such as iodine-131 and xenon-133, the Committee fully expects that such coproduced isotopes will also be available for medical uses.

LEGISLATIVE HISTORY

The Energy Policy Act of 1992 amended the Atomic Energy Act to require that the Nuclear Regulatory Commission only issue a license for the export of highly enriched uranium for the production of medical isotopes if the recipient provided assurances that it would convert to the use of low enriched uranium whenever the necessary technology was available, and that the U.S. government was actively assisting in developing such technology.

The Energy Policy Act of 2005 amended the Atomic Energy Act to allow Canada, Belgium, France, Germany, and the Netherlands to import highly enriched uranium from the United States for medical isotope production.

Additionally, the Energy Policy Act of 2005 required the National Academy of Sciences to conduct a study on the feasibility of procuring sufficient medical isotopes from commercial sources not using highly enriched uranium and to describe the current and projected domestic demand and availability of medical isotopes. The National Academy of Sciences report, which was delivered to Congress in January 2009, recommended the development of domestic sources of molybdenum-99 and concluded that the conversion of all current international producers from the use of highly enriched uranium to low enriched uranium was both technologically and economically feasible and that all such conversions likely could be completed in a period of seven to ten years.

H.R. 3276, the American Medical Isotopes Production Act of 2009, was introduced by Reps. Markey and Upton on July 21, 2009, and referred to the Committee on Energy and Commerce. The bill was subsequently referred to the Subcommittee on Energy and Environment on July 22, 2009. A legislative hearing on H.R. 3276 was held by the Subcommittee on Energy and Environment on September 9, 2009.

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[1] Medical Isotope Production Without Highly Enriched Uranium, National Academy of Sciences (January 2009).

[2] Medical Isotope Production Without Highly Enriched Uranium, National Academy of Sciences, 2.1 (January 2009).

COMMITTEE CONSIDERATION

The Subcommittee on Energy and Environment met in open markup session on Wednesday, October 14, 2009, to consider H.R. 3276. The Subcommittee agreed to favorably forward H.R. 3276, amended, to the full Committee by a voice vote.

The Committee on Energy and Commerce met in open markup session on Wednesday, October 21, 2009, to consider H.R. 3276 as approved by the Subcommittee on Energy and Environment. Subsequently, the full Committee ordered H.R. 3276 favorably reported to the House, amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the recorded votes on the motion to report legislation and amendments thereto. The Committee agreed to a motion by Mr. Waxman to order H.R. 3276 favorably reported to the House, amended, by a voice vote. There were no roll call votes on the bill or any amendments thereto during Committee consideration of the bill.

APPLICABILITY OF LAW TO THE LEGISLATIVE BRANCH

The Committee finds that H.R. 3276 does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act of 1985.

COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the findings and recommendations of the Committee are reflected in the descriptive portions of this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, H.R. 3276 contains the following general performance goals and objectives, including outcome-related goals and objectives authorized.

H.R. 3276 aims to ensure that the United States has an adequate and reliable supply of molybdenum-99 produced in the United States without the use of highly enriched uranium. The legislation also seeks to phase out the export of highly enriched uranium for use in the production of medical isotopes.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the constitutional authority for H.R. 3276 is provided in Article I, sections 3 and 18.

ADVISORY COMMITTEE STATEMENT

No advisory committees were created by H.R. 3276 within the meaning of section 5 U.S.C. App., section 5(b) of the Federal Advisory Committee Act.

UNFUNDED MANDATES STATEMENT

The Committee adopts as its own the estimates of federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

EARMARKS AND TAX AND TARIFF BENEFITS IDENTIFICATION

H.R. 3276 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9 of rule XXI of the Rules of the House of Representatives.

COMMITTEE COST ESTIMATE STATEMENT

Pursuant to clause 3(d) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the cost estimate on H.R. 3276 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the cost estimate on H.R. 3276 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act, and finds that H.R. 3276 would result in no new entitlement authority or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate on H.R. 3276 provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

OCTOBER 27, 2009.

Hon. HENRY A. WAXMAN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 3276, the American Medical Isotopes Production Act of 2009.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Megan Carroll and Kathleen Gramp.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 3276—American Medical Isotopes Production Act of 2009

Summary: H.R. 3276 would authorize funding to support projects to produce molybdenum-99, a radioactive isotope used in certain medical procedures. Assuming appropriation of the authorized amounts, CBO estimates that implementing the bill would cost $130 million over the 2010–2014 period. CBO also estimates that enacting the legislation would have a negligible net impact on di-

rect spending for any given year. The bill would not affect revenues.

H.R. 3276 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 3276 is shown in the following table. The costs of this legislation fall within budget function 270 (energy).

	By fiscal year, in millions of dollars—					
	2010	2011	2012	2013	2014	2010–2014
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Estimated Authorization Level	165	0	0	0	0	165
Estimated Outlays	12	25	30	30	33	130

Basis of estimate: H.R. 3276 would authorize the appropriation of $163 million to support projects to produce molybdenum-99, a radioactive isotope produced from uranium, for use in certain medical procedures. In addition to direct financial support for those projects, the bill would direct the Secretary of Energy to make low enriched uranium (LEU) available through lease contracts to producers of molybdenum-99. Such lease contracts would provide for the Secretary to retain financial responsibility for radioactive waste generated by the irradiation, processing, or purification of LEU.

CBO estimates that providing funding for proposed projects, completing related studies and reports, and managing radioactive waste resulting from leases of LEU would increase discretionary spending by $130 million over the 2010–2014 period. We also estimate that leasing LEU would have a negligible net impact on direct spending.

Spending subject to appropriation

CBO estimates that implementing H.R. 3276 would require appropriations totaling $165 million over the 2010–2014 period. That amount includes $163 million specifically authorized to support projects to produce molybdenum-99 and $2 million for related studies, reports, and regulatory activities. Assuming appropriation of those amounts, CBO estimates that spending would total $130 million over the 2010–2014 period, with the remaining $35 million occurring in later years. That estimate is based on information from the Department of Energy (DOE) about the types of molybdenum-99 projects that might be supported under H.R. 3276 and takes into account historical spending patterns for similar activities.

Under H.R. 3276, the federal government would be responsible for disposing of radioactive waste generated by molybdenum-99 producers who lease LEU from DOE. Because the bill would prohibit DOE from using certain existing barter authorities to obtain waste-disposal services in exchange for commercially valuable uranium owned by DOE, CBO believes that any spending to dispose of waste generated under such leases would be subject to the availability of appropriated funds. Based on information from DOE about the relatively small volume of LEU the agency anticipates would be leased under H.R. 3276, CBO expects that resulting quantities of waste would be small. While such costs would be incurred over many years and may reach significant levels over time,

CBO estimates that increased costs over the 2010–2014 period would not exceed $500,000 in any year.

Direct spending

H.R. 3276 would direct the Secretary to lease LEU to producers of molybdenum-99. Under current law, CBO estimates that sales of the material that would be leased under the bill would otherwise generate offsetting receipts totaling about $1 million annually. Because H.R. 3276 would require that lessees pay fees equivalent to the prevailing market rates for the sale of comparable uranium products, CBO estimates that any differences in receipts generated under the bill would be negligible in any given year.

The bill also would require the Secretary to charge lessees a fee to offset the net present value of DOE's anticipated costs to dispose of radioactive waste generated from leased LEU. As discussed above (under "spending subject to appropriation"), CBO expects that such costs would be small and estimates that resulting fees would not exceed $500,000 in any year.

Intergovernmental and private-sector impact: H.R. 3276 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal Costs: Megan Carroll and Kathleen Gramp; Impact on State, Local, and Tribal Governments: Ryan Miller; Impact on the Private Sector: Amy Petz.

Estimate approved by: Peter H. Fontaine, Assistant Director for Budget Analysis.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1: Short title

This section provides that the short title of the bill is the "American Medical Isotopes Production Act of 2009".

Section 2: Findings

This section makes a number of findings regarding the medical isotope molybdenum-99 and efforts to eliminate the use of highly enriched uranium, summarized below:

(1) Molybdenum-99 is a critical medical isotope used in 16 million procedures annually in the United States.

(2) Given its 66-hour half-life, molybdenum-99 cannot be stockpiled and its production must be scheduled to meet projected demand.

(3) There are currently no facilities in the United States producing molybdenum-99 for medical uses.

(4) Most reactors in the world that produce molybdenum-99 utilize highly enriched uranium, which can also be used in the construction of nuclear weapons. A January 2009 report by the National Academy of Sciences found that these reactors could all convert to the use of low enriched uranium.

(5) On May 14, 2009, the 51-year old National Research Universal reactor in Canada, which normally produces 60% of U.S. demand for molybdenum-99, shut down unexpectedly.

(6) The United States currently faces an acute shortage of molybdenum-99 and its decay product technetium-99m.

(7) The supply shortage of molybdenum-99 is causing patient care in the United States to suffer.

(8) Molybdenum-99 and technetium-99m are critical to the health care of Americans, and the continued availability of these isotopes, in a reliable and affordable manner, is in the interest of the United States.

(9) The United States should move expeditiously to ensure that an adequate and reliable supply of molybdenum-99 can be produced in the United States without the use of highly enriched uranium.

(10) Other important medical isotopes, including iodine-131 and xenon-133, can be produced as byproducts of the molybdenum-99 fission production process, and these coproduced isotopes should also be available for necessary medical uses.

(11) The United States should accelerate its efforts to convert nuclear reactors worldwide away from the use of highly enriched uranium. Doing so supports the goal announced in Prague by President Barack Obama on April 5, 2009, to create "a new international effort to secure all vulnerable material around the world within four years."

(12) As of September 2009, the 17 reactors in the United States have been converted to low enriched uranium fuel, some of which are capable of producing molybdenum-99 for medical uses.

Section 3: Improving the reliability of the domestic medical isotope supply

Subsection (a) requires the Secretary of Energy to establish a program to evaluate and support projects for the domestic production of molybdenum-99, without the use of highly enriched uranium, for medical uses. The Secretary is required to assess proposed projects against three primary criteria: the length of time necessary to begin production of molybdenum-99 for medical uses; the capability of the proposed project to produce a significant percentage of United States demand for molybdenum-99 for medical uses; and the cost of the proposed project. There are authorized to be appropriated to the Secretary for this program $163,000,000 for the period encompassing fiscal years 2010 through 2014.

An exemption provides that an existing reactor fueled with highly enriched uranium shall not be excluded from participation in the program if it is in the process of converting to the use of low enriched uranium. The purpose of this exemption is to allow all relevant technologies to be eligible for the program, provided that any highly enriched uranium conversion projects are being pursued with maximum expeditiousness.

Subsection (b) requires the Secretary of Energy to establish a program to provide assistance for the development of fuels, targets, and processes for domestic molybdenum-99 production without the use of highly enriched uranium, and for commercial operations of these fuels, targets, and processes.

Subsection (c) requires the Secretary of Energy to establish a program to make low enriched uranium available, through lease contracts, for the production of molybdenum-99 for medical uses. The lease contracts shall provide for the Secretary to retain responsibility for the final disposition of radioactive waste created by the irradiation, processing, or purification of leased uranium. In addi-

tion, the lease contracts will provide for compensation in cash amounts equivalent to prevailing market rates for both the low enriched uranium as well as for the disposition of the resulting waste. The Secretary shall not barter or otherwise sell or transfer uranium in exchange for services related to final disposition of any radioactive waste resulting from this program. It is the Committee's intent that, in subsection (c), the term "final disposition" shall be interpreted to include the disposal of the radioactive waste created by the irradiation, processing, or purification of leased uranium, as well as any treatment or processing necessary for such disposal. The purpose of this subsection is to provide that sufficient low enriched uranium will be available to projects, that the Department of Energy will be responsible for the disposition of radioactive waste produced, that the Department of Energy will receive full and appropriate compensation at prevailing market rates for both the uranium and the waste disposition services, and that the Department will not use its uranium barter, sale, or transfer authorities to cover any portion of the costs of the waste disposition.

Section 4: Exports

Section 4 amends section 134 of the Atomic Energy Act to require that after seven years of the date of enactment of the American Medical Isotopes Production Act of 2009, the Nuclear Regulatory Commission may not issue a license for the export of highly enriched uranium for the purposes of medical isotope production. This period can be extended by no more than four years if the Secretary of Energy certifies that there is an insufficient supply of molybdenum-99 produced without the use of highly enriched uranium available to United States patients and that the export of highly enriched uranium for the purpose of medical isotope production is the most effective temporary means to increase the supply of molybdenum-99 available to the United States. After the restriction on export licenses goes into effect, the restriction can be temporarily suspended for no more than twelve months if the Secretary of Energy certifies that the export of United States-origin highly enriched uranium for the production of medical isotopes is the only effective temporary means to increase the supply of molybdenum-99 available to the United States, and if the Congress passes a Joint Resolution approving the temporary suspension of the restriction of export licenses.

The purpose of this section is to accelerate the transition away from the use of highly enriched uranium for medical isotope production internationally. Highly enriched uranium can be used in the production of nuclear weapons, and the elimination of the use of highly enriched uranium is in the national security interests of the United States. The Department of Energy operates the Global Threat Reduction Initiative to minimize the use of highly enriched uranium around the world.

By setting a date for the end of United States exports of highly enriched uranium for medical isotope production, those remaining medical isotope producers who use highly enriched uranium will be provided with a new and effective incentive to convert their operations to low enriched uranium. The 2009 National Academy of Sciences report found that "a 7–10 year phase out period would likely allow enough time for all current [highly enriched uranium]-

based producers to convert."[3] This section provides for a flexible seven to eleven year period, providing sufficient time for conversions to occur prior to the export license restrictions becoming effective.

Section 5: Report on disposition of exports

This section requires, within one year of the date of enactment of the American Medical Isotopes Production Act of 2009, that the Nuclear Regulatory Commission report to Congress on the disposition of previous United States exports of highly enriched uranium. The Commission last reported to Congress on this subject in January 1993.

Section 6: Domestic medical isotope production

This section allows the Nuclear Regulatory Commission to issue a license for the use of highly enriched uranium as a target for medical isotope production only if there is no low enriched uranium target that will work in that reactor, the reactor operator has agreed to convert to the use of low enriched uranium targets when able, and the United States government is actively supporting the development of low enriched uranium targets for use in that reactor.

The purpose of this section is to provide flexibility to the Executive branch as it seeks to find short-term methods to increase the supply of molybdenum-99 to the United States during the current supply shortage. One option that Executive branch has considered is to temporarily irradiate existing highly enriched uranium targets in United States reactors. The Committee does not wish to preclude this option if it is the most effective short-term means to increase the supply of molybdenum-99 to the United States pending the establishment of a robust domestic production capacity. Given, however, that it would utilize highly enriched uranium, the Committee expects that in the event that this option is pursued it be done so on a strictly short-term basis, and in full compliance of the restrictions contained in section 6 of this Act.

Section 7: Annual Department of Energy reports

This section requires annual reports from the Department of Energy for 6 years on the Department's actions and progress in supporting the production of molybdenum-99 in the United States.

Section 8: National Academy of Sciences report

This section requires a study by the National Academy of Sciences on the production and utilization of molybdenum-99 and other medical isotopes coproduced with molybdenum-99 to be provided to Congress 5 years after enactment of the Act.

Section 9: Definitions

This section defines "highly enriched uranium" as uranium enriched to 20% or greater in the isotope U-235, and defines "low enriched uranium" as uranium enriched to less than 20% in the isotope U-235.

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[3] Medical Isotope Production Without Highly Enriched Uranium, National Academy of Sciences, 10.19 (January 2009).

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

ATOMIC ENERGY ACT OF 1954

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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CHAPTER 10—ATOMIC ENERGY LICENSES

* * * * * * *

SEC. 112. DOMESTIC MEDICAL ISOTOPE PRODUCTION. a. The Commission may issue a license, or grant an amendment to an existing license, for the use in the United States of highly enriched uranium as a target for medical isotope production in a nuclear reactor, only if, in addition to any other requirement of this Act—

(1) the Commission determines that—

(A) there is no alternative medical isotope production target, enriched in the isotope U-235 to less than 20 percent, that can be used in that reactor; and

(B) the proposed recipient of the medical isotope production target has provided assurances that, whenever an alternative medical isotope production target can be used in that reactor, it will use that alternative in lieu of highly enriched uranium; and

(2) the Secretary of Energy has certified that the United States Government is actively supporting the development of an alternative medical isotope production target that can be used in that reactor.

b. As used in this section—

(1) the term "alternative medical isotope production target" means a nuclear reactor target which is enriched to less than 20 percent of the isotope U-235;

(2) a target "can be used" in a nuclear research or test reactor if—

(A) the target has been qualified by the Reduced Enrichment Research and Test Reactor Program of the Department of Energy; and

(B) use of the target will permit the large majority of ongoing and planned experiments and isotope production to be conducted in the reactor without a large percentage increase in the total cost of operating the reactor;

(3) the term "highly enriched uranium" means uranium enriched to 20 percent or more in the isotope U-235; and

(4) the term "medical isotope" includes molybdenum-99, iodine-131, xenon-133, and other radioactive materials used to produce a radiopharmaceutical for diagnostic, therapeutic procedures or for research and development.

CHAPTER 11—INTERNATIONAL ACTIVITIES

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SEC. 134. FURTHER RESTRICTIONS ON EXPORTS.—

a. * * *

[b. MEDICAL ISOTOPE PRODUCTION.—

[(1) DEFINITIONS.—In this subsection:

[(A) HIGHLY ENRICHED URANIUM.—The term "highly enriched uranium" means uranium enriched to include concentration of U–235 above 20 percent.

[(B) MEDICAL ISOTOPE.—The term "medical isotope" includes Molybdenum 99, Iodine 131, Xenon 133, and other radioactive materials used to produce a radiopharmaceutical for diagnostic, therapeutic procedures or for research and development.

[(C) RADIOPHARMACEUTICAL.—The term "radiopharmaceutical" means a radioactive isotope that—

[(i) contains byproduct material combined with chemical or biological material; and

[(ii) is designed to accumulate temporarily in a part of the body for therapeutic purposes or for enabling the production of a useful image for use in a diagnosis of a medical condition.

[(D) RECIPIENT COUNTRY.—The term "recipient country" means Canada, Belgium, France, Germany, and the Netherlands.

[(2) LICENSES.—The Commission may issue a license authorizing the export (including shipment to and use at intermediate and ultimate consignees specified in the license) to a recipient country of highly enriched uranium for medical isotope production if, in addition to any other requirements of this Act (except subsection a.), the Commission determines that—

[(A) a recipient country that supplies an assurance letter to the United States Government in connection with the consideration by the Commission of the export license application has informed the United States Government that any intermediate consignees and the ultimate consignee specified in the application are required to use the highly enriched uranium solely to produce medical isotopes; and

[(B) the highly enriched uranium for medical isotope production will be irradiated only in a reactor in a recipient country that—

[(i) uses an alternative nuclear reactor fuel; or

[(ii) is the subject of an agreement with the United States Government to convert to an alternative nuclear reactor fuel when alternative nuclear reactor fuel can be used in the reactor.

[(3) REVIEW OF PHYSICAL PROTECTION REQUIREMENTS.—

[(A) IN GENERAL.—The Commission shall review the adequacy of physical protection requirements that, as of the date of an application under paragraph (2), are applicable to the transportation and storage of highly enriched uranium for medical isotope production or control of residual material after irradiation and extraction of medical isotopes.

[(B) IMPOSITION OF ADDITIONAL REQUIREMENTS.—If the Commission determines that additional physical protection requirements are necessary (including a limit on the quantity of highly enriched uranium that may be contained in a single shipment), the Commission shall impose such requirements as license conditions or through other appropriate means.

[(4) FIRST REPORT TO CONGRESS.—

[(A) NAS STUDY.—The Secretary shall enter into an arrangement with the National Academy of Sciences to conduct a study to determine—

[(i) the feasibility of procuring supplies of medical isotopes from commercial sources that do not use highly enriched uranium;

[(ii) the current and projected demand and availability of medical isotopes in regular current domestic use;

[(iii) the progress that is being made by the Department of Energy and others to eliminate all use of highly enriched uranium in reactor fuel, reactor targets, and medical isotope production facilities; and

[(iv) the potential cost differential in medical isotope production in the reactors and target processing facilities if the products were derived from production systems that do not involve fuels and targets with highly enriched uranium.

[(B) FEASIBILITY.—For the purpose of this subsection, the use of low enriched uranium to produce medical isotopes shall be determined to be feasible if—

[(i) low enriched uranium targets have been developed and demonstrated for use in the reactors and target processing facilities that produce significant quantities of medical isotopes to serve United States needs for such isotopes;

[(ii) sufficient quantities of medical isotopes are available from low enriched uranium targets and fuel to meet United States domestic needs; and

[(iii) the average anticipated total cost increase from production of medical isotopes in such facilities without use of highly enriched uranium is less than 10 percent.

[(C) REPORT BY THE SECRETARY.—Not later than 5 years after the date of enactment of the Energy Policy Act of 2005, the Secretary shall submit to Congress a report that—

[(i) contains the findings of the National Academy of Sciences made in the study under subparagraph (A); and

[(ii) discloses the existence of any commitments from commercial producers to provide domestic requirements for medical isotopes without use of highly enriched uranium consistent with the feasibility criteria described in subparagraph (B) not later than the date that is 4 years after the date of submission of the report.

[(5) SECOND REPORT TO CONGRESS.—If the study of the National Academy of Sciences determines under paragraph (4)(A)(i) that the procurement of supplies of medical isotopes from commercial sources that do not use highly enriched uranium is feasible, but the Secretary is unable to report the existence of commitments under paragraph (4)(C)(ii), not later than the date that is 6 years after the date of enactment of the Energy Policy Act of 2005, the Secretary shall submit to Congress a report that describes options for developing domestic supplies of medical isotopes in quantities that are adequate to meet domestic demand without the use of highly enriched uranium consistent with the cost increase described in paragraph (4)(B)(iii).

[(6) CERTIFICATION.—At such time as commercial facilities that do not use highly enriched uranium are capable of meeting domestic requirements for medical isotopes, within the cost increase described in paragraph (4)(B)(iii) and without impairing the reliable supply of medical isotopes for domestic utilization, the Secretary shall submit to Congress a certification to that effect.

[(7) SUNSET PROVISION.—After the Secretary submits a certification under paragraph (6), the Commission shall, by rule, terminate its review of export license applications under this subsection.

[c. As used in this section—

[(1) the term "alternative nuclear reactor fuel or target" means a nuclear reactor fuel or target which is enriched to less than 20 percent in the isotope U–235;

[(2) the term "highly enriched uranium" means uranium enriched to 20 percent or more in the isotope U–235; and

[(3) a fuel or target "can be used" in a nuclear research or test reactor if—

[(A) the fuel or target has been qualified by the Reduced Enrichment Research and Test Reactor Program of the Department of Energy, and

[(B) use of the fuel or target will permit the large majority of ongoing and planned experiments and isotope production to be conducted in the reactor without a large percentage increase in the total cost of operating the reactor.]

b. Effective 7 years after the date of enactment of the American Medical Isotopes Production Act of 2009, the Commission may not issue a license for the export of highly enriched uranium from the United States for the purposes of medical isotope production.

c. The period referred to in subsection b. may be extended for no more than four years if, no earlier than 6 years after the date of enactment of the American Medical Isotopes Production Act of 2009, the Secretary of Energy certifies to the Committee on Energy and

Commerce of the House of Representatives and the Committee on Energy and Natural Resources of the Senate that—

(1) there is insufficient global supply of molybdenum-99 produced without the use of highly enriched uranium available to satisfy the domestic United States market; and

(2) the export of United States-origin highly enriched uranium for the purposes of medical isotope production is the most effective temporary means to increase the supply of molybdenum-99 to the domestic United States market.

d. At any time after the restriction of export licenses provided for in subsection b. becomes effective, if there is a critical shortage in the supply of molybdenum-99 available to satisfy the domestic United States medical isotope needs, the restriction of export licenses may be suspended for a period of no more than 12 months, if—

(1) the Secretary of Energy certifies to the Congress that the export of United States-origin highly enriched uranium for the purposes of medical isotope production is the only effective temporary means to increase the supply of molybdenum-99 necessary to meet United States medical isotope needs during that period; and

(2) the Congress passes a Joint Resolution approving the temporary suspension of the restriction of export licenses.

e. As used in this section—

(1) the term "alternative nuclear reactor fuel or target" means a nuclear reactor fuel or target which is enriched to less than 20 percent in the isotope U-235;

(2) the term "highly enriched uranium" means uranium enriched to 20 percent or more in the isotope U-235;

(3) a fuel or target "can be used" in a nuclear research or test reactor if—

(A) the fuel or target has been qualified by the Reduced Enrichment Research and Test Reactor Program of the Department of Energy; and

(B) use of the fuel or target will permit the large majority of ongoing and planned experiments and isotope production to be conducted in the reactor without a large percentage increase in the total cost of operating the reactor; and

(4) the term "medical isotope" includes molybdenum-99, iodine-131, xenon-133, and other radioactive materials used to produce a radiopharmaceutical for diagnostic, therapeutic procedures or for research and development.

* * * * * * *

EXCHANGE OF LETTERS

November 4, 2009

The Honorable Henry A. Waxman
Chairman
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

I am writing to you concerning H.R. 3276, the American Medical Isotopes Production Act of 2009.

This bill contains provisions within the Rule X jurisdiction of the Committee on Foreign Affairs. In the interest of permitting your Committee to proceed expeditiously to floor consideration of this important bill, I am willing to waive this Committee's right to mark up this bill. I do so with the understanding that by waiving consideration of the bill, the Committee on Foreign Affairs does not waive any future jurisdictional claim over the subject matters contained in the bill which fall within its Rule X jurisdiction.

Further, I request your support for the appointment of Foreign Affairs Committee conferees during any House-Senate conference convened on this legislation. I would ask that you place this letter into the Committee Report on H.R. 3276.

I look forward to working with you as we move this important measure through the legislative process.

Sincerely,

Howard L. Berman

HOWARD L. BERMAN
Chairman

HLB:ds/gb

HENRY A. WAXMAN, CALIFORNIA
CHAIRMAN

JOE BARTON, TEXAS
RANKING MEMBER

ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

November 4, 2009

The Honorable Howard L. Berman
Chairman
House Committee on Foreign Affairs
2170 Rayburn House Office Building
Washington DC, 20515

Dear Chairman Berman:

Thank you for your letter regarding H.R. 3276, the American Medical Isotopes Production Act of 2009." I appreciate your effort to facilitate consideration of this bill.

Your letter noted that provisions of the bill implicate the jurisdiction of the Committee on Foreign Affairs. The Committee on Energy and Commerce recognizes the jurisdictional interest of the Committee on Foreign Affairs in provisions of H.R. 3276. I appreciate your agreement to forgo action on the bill, and concur that doing so does not in any way prejudice the Committee on Foreign Affairs with respect to its jurisdictional prerogatives on this bill or similar legislation in the future. I also would support your effort to seek appointment of an appropriate number of conferees to any House-Senate conference involving this legislation.

I will include our letters in the Committee report on H.R. 3276. Again, I appreciate your cooperation regarding this important legislation and I look forward to working with the Committee on Foreign Affairs as the bill moves through the legislative process.

Sincerely,

Henry A. Waxman

cc: The Honorable Nancy Pelosi, Speaker
The Honorable Steny Hoyer, Majority Leader
The Honorable John Boehner, Minority Leader
The Honorable Joe Barton
The Honorable Ileana Ros-Lehtinen
Mr. John Sullivan, Parliamentarian

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