

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 3276
OFFERED BY MR. MARKEY OF MASSACHUSETTS**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “American Medical Iso-
3 topes Production Act of 2009”.

4 SEC. 2. FINDINGS.

5 Congress finds the following:

6 (1) Molybdenum-99 is a critical medical isotope
7 whose decay product technecium-99m is used in ap-
8 proximately two-thirds of all diagnostic medical iso-
9 tope procedures in the United States, or 16 million
10 medical procedures annually, including for the detec-
11 tion of cancer, heart disease, and thyroid disease, in-
12 vestigating the operation of the brain and kidney,
13 imaging stress fractures, and tracking cancer stages.

14 (2) Molybdenum-99 has a half-life of 66 hours,
15 and decays at a rate of approximately one percent
16 per hour after production. As such, molybdenum-99
17 cannot be stockpiled. Instead, molybdenum-99 pro-
18 duction must be scheduled to meet the projected de-

1 mand and any interruption of the supply chain from
2 production, to processing, packaging, distribution,
3 and use can disrupt patient care.

4 (3) There are no facilities within the United
5 States that are dedicated to the production of mo-
6 lybdenum-99 for medical uses. The United States
7 must import molybdenum-99 from foreign produc-
8 tion facilities, and is dependent upon the continued
9 operation of these foreign facilities for millions of
10 critical medical procedures annually.

11 (4) Most reactors in the world which produce
12 molybdenum-99 utilize highly enriched uranium,
13 which can also be used in the construction of nuclear
14 weapons. In January 2009, the National Academy of
15 Sciences encouraged molybdenum-99 producers to
16 convert from highly enriched uranium to low en-
17 riched uranium, and found that there are “no tech-
18 nical reasons that adequate quantities cannot be
19 produced from LEU targets in the future” and that
20 “a 7-10 year phase-out period would likely allow
21 enough time for all current HEU-based producers to
22 convert”.

23 (5) The 51-year-old National Research Uni-
24 versal reactor in Canada, which is responsible for
25 producing approximately sixty percent of United

1 States demand for molybdenum-99 under normal
2 conditions, was shut down unexpectedly May 14,
3 2009, after the discovery of a leak of radioactive
4 water. It is unclear whether the National Research
5 Universal reactor will be able to resume production
6 of molybdenum-99.

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

12 (7) As a result of the critical shortage of molyb-
13 denum-99, patient care in the United States is suf-
14 fering. Medical procedures requiring technetium-99
15 are being rationed or delayed, and alternative treat-
16 ments which are less effective, more costly, and may
17 result in increased radiation doses to patients are
18 being substituted in lieu of technetium-99.

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

24 (9) The United States should move expedi-
25 tiously to ensure that an adequate and reliable sup-

1 ply of molybdenum-99 can be produced in the
2 United States, without the use of highly enriched
3 uranium.

4 (10) Other important medical isotopes, includ-
5 ing iodine-131 and xenon-133, can be produced as
6 byproducts of the molybdenum-99 fission production
7 process. In January 2009, the National Academy of
8 Sciences concluded that these important medical iso-
9 topes “will be sufficiently available if Mo-99 is avail-
10 able”. The coproduction of medically useful isotopes
11 such as iodine-131 and xenon-133 is an important
12 benefit of establishing molybdenum-99 production in
13 the United States without the use of highly enriched
14 uranium, and these coproduced isotopes should also
15 be available for necessary medical uses.

16 (11) The United States should accelerate its ef-
17 forts to convert nuclear reactors worldwide away
18 from the use of highly enriched uranium, which can
19 be used in nuclear weapons, to low enriched ura-
20 nium. Converting nuclear reactors away from the
21 use of highly enriched uranium is a critically impor-
22 tant element of United States efforts to prevent nu-
23 clear terrorism, and supports the goal announced in
24 Prague by President Barack Obama on April 5,
25 2009, to create “a new international effort to secure

1 all vulnerable nuclear material around the world
2 within four years”.

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

12 **SEC. 3. IMPROVING THE RELIABILITY OF DOMESTIC MED-**
13 **ICAL ISOTOPE SUPPLY.**

14 (a) **MEDICAL ISOTOPE DEVELOPMENT PROJECTS.—**

15 (1) **IN GENERAL.—**The Secretary of Energy
16 shall establish a program to evaluate and support
17 projects for the production in the United States,
18 without the use of highly enriched uranium, of sig-
19 nificant quantities of molybdenum-99 for medical
20 uses.

21 (2) **CRITERIA.—**Projects shall be judged against
22 the following primary criteria:

23 (A) The length of time necessary for the
24 proposed project to begin production of molyb-

1 denum-99 for medical uses within the United
2 States.

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

7 (C) The cost of the proposed project.

8 (3) EXEMPTION.—An existing reactor fueled
9 with highly enriched uranium shall not be disquali-
10 fied from the program if the Secretary of Energy de-
11 termines that—

12 (A) there is no alternative nuclear reactor
13 fuel, enriched in the isotope U-235 to less than
14 20 percent, that can be used in that reactor;

15 (B) the reactor operator has provided as-
16 surances that, whenever an alternative nuclear
17 reactor fuel, enriched in the isotope U-235 to
18 less than 20 percent, can be used in that reac-
19 tor, it will use that alternative in lieu of highly
20 enriched uranium; and

21 (C) the reactor operator has provided a
22 current report on the status of its efforts to
23 convert the reactor to an alternative nuclear re-
24 actor fuel enriched in the isotope U-235 to less

1 than 20 percent, and an anticipated schedule
2 for completion of conversion.

3 (4) AUTHORIZATION OF APPROPRIATIONS.—

4 There are authorized to be appropriated to the Sec-
5 retary of Energy for carrying out the program under
6 paragraph (1) \$163,000,000 for fiscal years 2010
7 through 2014.

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

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

14 (2) commercial operations using the fuels, tar-
15 gets, and processes described in paragraph (1).

16 (c) URANIUM LEASE AND TAKE BACK.—The Sec-
17 retary of Energy shall establish a program to make low
18 enriched uranium available, through lease contracts, for
19 irradiation for the production of molybdenum-99 for med-
20 ical uses. The lease contracts shall provide for the Sec-
21 retary to retain responsibility for the final disposition of
22 radioactive waste created by the irradiation, processing,
23 or purification of leased uranium.

1 **SEC. 4. EXPORTS.**

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

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

10 “c. The period referred to in subsection b. may be
11 extended for no more than four years if, no earlier than
12 6 years after the date of enactment of the Act, the Sec-
13 retary of Energy certifies to the appropriate Congressional
14 committees that—

15 “(1) there is insufficient global supply of molyb-
16 denum-99 produced without the use of highly en-
17 riched uranium available to satisfy the domestic
18 United States market, and

19 “(2) the export of United States-origin highly
20 enriched uranium for the purposes of medical iso-
21 tope production is the most effective temporary
22 means to increase the supply of molybdenum-99 to
23 the domestic United States market.

24 “d. At any time after the restriction of export licenses
25 provided for in subsection b. becomes effective, if there
26 is a critical shortage in the supply of molybdenum-99

1 available to satisfy the domestic United States medical iso-
2 tope needs, the restriction of export licenses may be sus-
3 pended for a period of no more than 12 months, if—

4 “(1) the Secretary of Energy certifies to the
5 Congress that the export of United States-origin
6 highly enriched uranium for the purposes of medical
7 isotope production is the only effective temporary
8 means to increase the supply of molybdenum-99 nec-
9 essary to meet United States medical isotope needs
10 during that period; and

11 “(2) the Congress passes a Joint Resolution ap-
12 proving the temporary suspension of the restriction
13 of export licenses.

14 “e. As used in this section—

15 “(1) the term ‘alternative nuclear reactor fuel
16 or target’ means a nuclear reactor fuel or target
17 which is enriched to less than 20 percent in the iso-
18 tope U-235;

19 “(2) the term ‘highly enriched uranium’ means
20 uranium enriched to 20 percent or more in the iso-
21 tope U-235;

22 “(3) a fuel or target ‘can be used’ in a nuclear
23 research or test reactor if—

24 “(A) the fuel or target has been qualified
25 by the Reduced Enrichment Research and Test

1 Reactor Program of the Department of Energy;
2 and

3 “(B) use of the fuel or target will permit
4 the large majority of ongoing and planned ex-
5 periments and isotope production to be con-
6 ducted in the reactor without a large percentage
7 increase in the total cost of operating the reac-
8 tor; and

9 “(4) the term ‘medical isotope’ includes molyb-
10 denum-99, iodine-131, xenon-133, and other radio-
11 active materials used to produce a radiopharma-
12 ceutical for diagnostic, therapeutic procedures or for
13 research and development.”.

14 **SEC. 5. REPORT ON DISPOSITION OF EXPORTS.**

15 Not later than 1 year after the date of the enactment
16 of this Act, the Chairman of the Nuclear Regulatory Com-
17 mission, after consulting with other relevant agencies,
18 shall submit to the Congress a report detailing the current
19 disposition of previous United States exports of highly en-
20 riched uranium, including—

- 21 (1) their location;
22 (2) whether they are irradiated;
23 (3) whether they have been used for the pur-
24 pose stated in their export license;

1 (4) whether they have been used for an alter-
2 native purpose and, if so, whether such alternative
3 purpose has been explicitly approved by the Commis-
4 sion;

5 (5) the year of export, and reimportation, if ap-
6 plicable;

7 (6) their current physical and chemical forms;
8 and

9 (7) whether they are being stored in a manner
10 which adequately protects against theft and unau-
11 thorized access.

12 **SEC. 6. DOMESTIC MEDICAL ISOTOPE PRODUCTION.**

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

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

22 “(1) the Commission determines that—

23 “(A) there is no alternative medical isotope
24 production target, enriched in the isotope U-

1 235 to less than 20 percent, that can be used
2 in that reactor; and

3 “(B) the proposed recipient of the medical
4 isotope production target has provided assur-
5 ances that, whenever an alternative medical iso-
6 tope production target can be used in that reac-
7 tor, it will use that alternative in lieu of highly
8 enriched uranium; and

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

13 “b. As used in this section—

14 “(1) the term ‘alternative medical isotope pro-
15 duction target’ means a nuclear reactor target which
16 is enriched to less than 20 percent of the isotope U-
17 235;

18 “(2) a target ‘can be used’ in a nuclear re-
19 search or test reactor if—

20 “(A) the target has been qualified by the
21 Reduced Enrichment Research and Test Reac-
22 tor Program of the Department of Energy; and

23 “(B) use of the target will permit the large
24 majority of ongoing and planned experiments
25 and isotope production to be conducted in the

1 reactor without a large percentage increase in
2 the total cost of operating the reactor;

3 “(3) the term ‘highly enriched uranium’ means
4 uranium enriched to 20 percent or more in the iso-
5 tope U-235; and

6 “(4) the term ‘medical isotope’ includes molyb-
7 denum-99, iodine-131, xenon-133, and other radio-
8 active materials used to produce a radiopharma-
9 ceutical for diagnostic, therapeutic procedures or for
10 research and development.”.

11 (b) TABLE OF CONTENTS.—The table of contents for
12 the Atomic Energy Act of 1954 is amended by inserting
13 the following new item after the item relating to section
14 111:

“Sec. 112. Domestic medical isotope production.”.

15 **SEC. 7. ANNUAL DEPARTMENT OF ENERGY REPORTS.**

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

23 (1) For medical isotope development projects—

1 (A) the names of any recipients of Depart-
2 ment of Energy support under section 3 of this
3 Act;

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

6 (C) the milestones expected to be reached
7 for each project during the year for which sup-
8 port is provided;

9 (D) how each project is expected to sup-
10 port the increased production of molybdenum-
11 99 for medical uses;

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

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

17 (2) A description of actions taken in the pre-
18 vious year by the Secretary of Energy to ensure the
19 safe disposition of radioactive waste from used mo-
20 lybdenum-99 targets.

21 **SEC. 8. NATIONAL ACADEMY OF SCIENCES REPORT.**

22 The Secretary of Energy shall enter into an arrange-
23 ment with the National Academy of Sciences to conduct
24 a study of the state of molybdenum-99 production and uti-
25 lization, to be provided to the Congress not later than 5

1 years after the date of enactment of this Act. This report
2 shall include the following:

3 (1) For molybdenum-99 production—

4 (A) a list of all facilities in the world pro-
5 ducing molybdenum-99 for medical uses, includ-
6 ing an indication of whether these facilities use
7 highly enriched uranium in any way;

8 (B) a review of international production of
9 molybdenum-99 over the previous 5 years, in-
10 cluding—

11 (i) whether any new production was
12 brought online;

13 (ii) whether any facilities halted pro-
14 duction unexpectedly; and

15 (iii) whether any facilities used for
16 production were decommissioned or other-
17 wise permanently removed from service;
18 and

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

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

6 **SEC. 9. DEFINITIONS.**

7 In this Act the following definitions apply:

8 (1) **HIGHLY ENRICHED URANIUM.**—The term
9 “highly enriched uranium” means uranium enriched
10 to 20 percent or greater in the isotope U-235.

11 (2) **LOW ENRICHED URANIUM.**—The term “low
12 enriched uranium” means uranium enriched to less
13 than 20 percent in the isotope U-235.

14 (3) **APPROPRIATE CONGRESSIONAL COMMIT-**
15 **TEES.**—The term “appropriate Congressional com-
16 mittees” means the House Committee on Energy
17 and Commerce and the Senate Committee on En-
18 ergy and Natural Resources.

