

113<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4374

To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to adopt and implement a standard identification protocol for use in the tracking and procurement of biological implants by the Department of Veterans Affairs, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 2, 2014

Mr. ROE of Tennessee introduced the following bill; which was referred to the Committee on Veterans' Affairs

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## A BILL

To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to adopt and implement a standard identification protocol for use in the tracking and procurement of biological implants by the Department of Veterans Affairs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Biological Implant  
5 Tracking and Veteran Safety Act of 2014”.

1 **SEC. 2. IDENTIFICATION AND TRACKING OF BIOLOGICAL**  
2 **IMPLANTS USED IN DEPARTMENT OF VET-**  
3 **ERANS AFFAIRS MEDICAL FACILITIES.**

4 (a) IN GENERAL.—Subchapter II of chapter 73 of  
5 title 38, United States Code, is amended by adding at the  
6 end the following new section:

7 **“§ 7330B. Identification and tracking of biological im-**  
8 **plants**

9 “(a) STANDARD IDENTIFICATION SYSTEM FOR BIO-  
10 LOGICAL IMPLANTS.—The Secretary shall adopt the  
11 unique device identification system developed for medical  
12 devices by the Food and Drug Administration pursuant  
13 to section 519(f) of the Federal Food, Drug, and Cosmetic  
14 Act (21 U.S.C. 360i(f)), or implement a comparable  
15 standard identification system, for use in identifying bio-  
16 logical implants intended for use in medical procedures  
17 conducted in medical facilities of the Department.

18 “(b) BIOLOGICAL IMPLANT TRACKING SYSTEM.—(1)  
19 The Secretary shall implement a system for tracking the  
20 biological implants referred to in subsection (a) from  
21 donor to implantation. Such system shall be compatible  
22 with the identification system adopted or implemented  
23 under subsection (a).

24 “(2) The Secretary shall implement inventory con-  
25 trols compatible with the tracking system implemented  
26 under paragraph (1) so that all patients who have re-

1 ceived, in a medical facility of the Department, a biological  
2 implant subject to a recall by the Food and Drug Adminis-  
3 tration can be notified of the recall, if based on the evalua-  
4 tion of appropriate medical personnel of the Department  
5 of the risks and benefits, the Secretary determines such  
6 notification is appropriate.

7 “(c) CONSISTENCY WITH FOOD AND DRUG ADMINIS-  
8 TRATION REGULATIONS.—To the extent that a conflict  
9 arises between this section and a provision of the Federal  
10 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)  
11 or sections 351 or 361 of the Public Health Service Act  
12 (42 U.S.C. 262) (including any regulations issued under  
13 such Acts), the provision the Federal Food, Drug, and  
14 Cosmetic Act or Public Health Service Act (including any  
15 regulations issued under such Acts) shall apply.

16 “(d) DEFINITION OF BIOLOGICAL IMPLANT.—In this  
17 section, the term ‘biological implant’ means any human  
18 cell, tissue, or cellular or tissue-based product—

19 “(1) under the meaning given the term ‘human  
20 cells’ in section 1271.3 of title 21, Code of Federal  
21 Regulations, or any successor regulation; or

22 “(2) that is regulated as a device under subpart  
23 A of part 801 of title 21, Code of Federal Regula-  
24 tions, or any successor regulation.”.

1 (b) CLERICAL AMENDMENT.—The table of sections  
2 at the beginning of such chapter is amended by adding  
3 at the end of the items relating to such subchapter the  
4 following new item:

“7330B. Identification and tracking of biological implants.”.

5 (c) IMPLEMENTATION DEADLINES.—

6 (1) STANDARD IDENTIFICATION SYSTEM.—

7 (A) IN GENERAL.—With respect to biologi-  
8 cal implants described in paragraph (1) of sub-  
9 section (d) of section 7330B of title 38, United  
10 States Code, as added by subsection (a), the  
11 Secretary of Veterans Affairs shall adopt or im-  
12 plement a standard identification system for bi-  
13 ological implants, as required by subsection (a)  
14 of such section, by not later than the date that  
15 is 180 days after the date of the enactment of  
16 this Act.

17 (B) IMPLANTS REGULATED AS DEVICES.—  
18 With respect to biological implants described in  
19 paragraph (2) of subsection (d) of such section,  
20 the Secretary of Veterans Affairs shall adopt or  
21 implement such standard identification system  
22 in compliance with the compliance dates estab-  
23 lished by the Food and Drug Administration  
24 pursuant to section 519(f) of the Federal Food,  
25 Drug, and Cosmetic Act (21 U.S.C. 360i(f)).

1           (2) TRACKING SYSTEM.—The Secretary of Vet-  
2           erans Affairs shall implement the biological implant  
3           tracking system required by subsection (b) of section  
4           7330B, as added by subsection (a), by not later than  
5           the date that is 180 days after the date of the enact-  
6           ment of this Act.

7           (d) REPORTING REQUIREMENT.—If the biological  
8           implant tracking system required by subsection (b) of such  
9           section is not operational by the date that is 180 days  
10          after the date of the enactment of this Act, the Secretary  
11          of Veterans Affairs shall provide to the Committees on  
12          Veterans' Affairs of the Senate and House of Representa-  
13          tives a written explanation for each month until such time  
14          as the system is operational. Each such explanation shall  
15          describe each impediment to the implementation of the  
16          system, steps being taken to remediate each such impedi-  
17          ment, and target dates for a solution to each such impedi-  
18          ment.

19       **SEC. 3. PROCUREMENT OF BIOLOGICAL IMPLANTS USED IN**  
20                       **DEPARTMENT OF VETERANS AFFAIRS MED-**  
21                       **ICAL FACILITIES.**

22          (a) PROCUREMENT.—

23               (1) IN GENERAL.—Subchapter II of chapter 81  
24               of such title is amended by adding at the end the  
25               following new section:

1 **“§ 8129. Procurement of biological implants**

2 “(a) IN GENERAL.—(1) The Secretary may procure  
3 biological implants only from vendors that meet the fol-  
4 lowing conditions:

5 “(A) The vendor uses the standard identifica-  
6 tion system adopted or implemented by the Sec-  
7 retary under section 7330B(a) of this title and has  
8 safeguards to ensure that a production identifier has  
9 been in place at each step of distribution of each bio-  
10 logical implant from its donor.

11 “(B) The vendor is registered with the Food  
12 and Drug Administration under subpart B of part  
13 1271 of title 21, Code of Federal Regulations, or  
14 any successor regulation, and in the case of a vendor  
15 that uses tissue distribution intermediaries, the ven-  
16 dor uses only tissue distribution intermediaries that  
17 are appropriately registered with the Food and Drug  
18 Administration.

19 “(C) The vendor ensures that donor eligibility  
20 determinations and such other records as the Sec-  
21 retary may require accompany each biological im-  
22 plant at all times, regardless of the country of origin  
23 of the donor of the biological material.

24 “(D) The vendor consents to periodic inspec-  
25 tions and audits by the Department of Veterans Af-

1       fairs regarding the accuracy of records and the han-  
2       dling of products.

3               “(E) The vendor agrees to cooperate with all bi-  
4       ological implant recalls conducted on the vendor’s  
5       own initiative, by the request of the Food and Drug  
6       Administration, or by a statutory order of the Food  
7       and Drug Administration.

8               “(F) The vendor agrees to provide to the Sec-  
9       retary any adverse event report or warning letter of  
10      the Food and Drug Administration issued to the  
11      vendor by not later than 30 days after the vendor  
12      receives such report or warning letter.

13              “(G) The vendor agrees to retain all records as-  
14      sociated with the procurement of a biological implant  
15      by the Department for at least five years after the  
16      date of the procurement of the biological implant.

17              “(H) The vendor maintains active accreditation  
18      with the American Association of Tissue Banks or a  
19      similar national accreditation specific to biological  
20      implants.

21              “(2) The Secretary shall procure biological implants  
22      under the Federal Supply Schedules of the General Serv-  
23      ices Administration, unless such implants are not available  
24      under such Schedules. For biological implants listed on  
25      the Federal Supply Schedules, the Secretary shall accom-

1 modate reasonable vendor requests to undertake outreach  
2 efforts to educate medical professionals of the Department  
3 about the use and efficacy of such biological implants.

4 “(3) Section 8123 of this title shall not apply to the  
5 procurement of biological implants.

6 “(4) In the case of biological implants that are un-  
7 available for procurement under the Federal Supply  
8 Schedules, the Secretary shall procure such implants using  
9 competitive procedures in accordance with applicable law  
10 and the Federal Acquisition Regulation.

11 “(b) PENALTIES.—In addition to any applicable pen-  
12 alty under any other provision of law, any procurement  
13 employee of the Department who is found responsible for  
14 a biological implant procurement transaction with intent  
15 to avoid or with reckless disregard of the requirements of  
16 this section shall be ineligible to hold a certificate of ap-  
17 pointment as a contracting officer or to serve as the rep-  
18 resentative of an ordering officer, contracting officer, or  
19 purchase card holder.

20 “(c) DEFINITIONS.—In this section:

21 “(1) The term ‘biological implant’ shall have  
22 the meaning given such term in section 7330B(d) of  
23 this title.

24 “(2) The term ‘production identifier’ means a  
25 distinct identification code that—



1           “(A) relates a biological implant to the  
2 donor of the implant and to all records per-  
3 taining to the implant;

4           “(B) includes information designed to fa-  
5 cilitate effective tracking, using the distinct  
6 identification code, from the donor to the recipi-  
7 ent and from the recipient to the donor; and

8           “(C) satisfies the requirements of sub-  
9 section (c) of section 1271.290 of title 21, Code  
10 of Federal Regulations, or any successor regula-  
11 tion.”.

12           (2) CLERICAL AMENDMENT.—The table of sec-  
13 tions at the beginning of such chapter is amended  
14 by adding at the end of the items relating to such  
15 subchapter the following new item:

“8129. Procurement of biological implants.”.

16           (b) EFFECTIVE DATE.—Section 8129 of title 38,  
17 United States Code, as added by subsection (a), shall take  
18 effect on the date that is 180 days after the date on which  
19 the tracking system required under subsection (b) of sec-  
20 tion 7330B of such title, as added by section 2(a) is imple-  
21 mented.

22           (c) SPECIAL RULE FOR CRYOPRESERVED PROD-  
23 UCTS.—During the three-year period beginning on the ef-  
24 fective date of section 8129 of title 38, United States  
25 Code, as added by subsection (a), biological implants pro-

1 duced and labeled before that date may be procured by  
2 the Department of Veterans Affairs without relabeling  
3 under the standard identification system adopted or imple-  
4 mented under section 7330B of such title, as added by  
5 section 2(a).

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