

116TH CONGRESS
1ST SESSION

H. R. 547

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.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 15, 2019

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

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 2019”.

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

9 “(a) STANDARD IDENTIFICATION SYSTEM FOR BIO-
10 LOGICAL IMPLANTS.—(1) The Secretary shall adopt the
11 unique device identification system developed for medical
12 devices by the Food and Drug Administration under sec-
13 tion 519(f) of the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 360i(f)), or implement a comparable standard
15 identification system, for use in identifying biological im-
16 plants intended for use in medical procedures conducted
17 in medical facilities of the Department.

18 “(2) In adopting or implementing a standard identi-
19 fication system for biological implants under paragraph
20 (1), the Secretary shall permit a vendor to use any of the
21 accredited entities identified by the Food and Drug Ad-
22 ministration as an issuing agency pursuant to section
23 830.100 of title 21, Code of Federal Regulations, or any
24 successor regulation.

25 “(b) BIOLOGICAL IMPLANT TRACKING SYSTEM.—(1)
26 The Secretary shall implement a system for tracking the

1 biological implants described in subsection (a) from
2 human donor or animal source to implantation.

3 “(2) The tracking system implemented under para-
4 graph (1) shall be compatible with the identification sys-
5 tem adopted or implemented under subsection (a).

6 “(3) The Secretary shall implement inventory con-
7 trols compatible with the tracking system implemented
8 under paragraph (1) so that all patients who have re-
9 ceived, in a medical facility of the Department, a biological
10 implant subject to a recall can be notified of the recall
11 if, based on the evaluation by appropriate medical per-
12 sonnel of the Department of the risks and benefits, the
13 Secretary determines such notification is appropriate.

14 “(c) CONSISTENCY WITH FOOD AND DRUG ADMINIS-
15 TRATION REGULATIONS.—To the extent that a conflict
16 arises between this section and a provision of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
18 or section 351 or 361 of the Public Health Service Act
19 (42 U.S.C. 262 and 264) (including any regulations issued
20 under such provisions), the provision of the Federal Food,
21 Drug, and Cosmetic Act or Public Health Service Act (in-
22 cluding any regulations issued under such provisions) shall
23 apply.

24 “(d) BIOLOGICAL IMPLANT DEFINED.—In this sec-
25 tion, the term ‘biological implant’ means any human cell,

1 tissue, or cellular or tissue-based product or animal prod-
2 uct—

3 “(1) under the meaning given the term ‘human
4 cells, tissues, or cellular or tissue-based products’ in
5 section 1271.3 of title 21, Code of Federal Regula-
6 tions, or any successor regulation; or

7 “(2) that is regulated as a device under section
8 201(h) of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 321(h)).”.

10 (b) CLERICAL AMENDMENT.—The table of sections
11 at the beginning of such chapter is amended by inserting
12 after the item relating to section 7330C the following new
13 item:

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

14 (c) IMPLEMENTATION DEADLINES.—

15 (1) STANDARD IDENTIFICATION SYSTEM.—The
16 Secretary of Veterans Affairs shall adopt or imple-
17 ment the standard identification system for biologi-
18 cal implants required by subsection (a) of section
19 7330C of title 38, United States Code, as added by
20 subsection (a), with respect to biological implants
21 described in—

22 (A) subsection (d)(1) of such section, by
23 not later than the date that is 180 days after
24 the date of the enactment of this Act; and

1 (B) subsection (d)(2) of such section, in
2 compliance with the compliance dates estab-
3 lished by the Food and Drug Administration
4 under section 519(f) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 360i(f)).

6 (2) TRACKING SYSTEM.—The Secretary of Vet-
7 erans Affairs shall implement the biological implant
8 tracking system required by section 7330C(b) of title
9 38, United States Code, as added by subsection (a),
10 by not later than the date that is 180 days after the
11 date of the enactment of this Act.

12 (d) REPORTING REQUIREMENT.—

13 (1) IN GENERAL.—If the biological implant
14 tracking system required by section 7330C(b) of title
15 38, United States Code, as added by subsection (a),
16 is not operational by the date that is 180 days after
17 the date of the enactment of this Act, the Secretary
18 of Veterans Affairs shall submit to the Committee
19 on Veterans' Affairs of the Senate and the Com-
20 mittee on Veterans' Affairs of the House of Rep-
21 resentatives a report explaining why the system is
22 not operational for each month until such time as
23 the system is operational.

1 (2) ELEMENTS.—Each report submitted under
2 paragraph (1) shall include a description of the fol-
3 lowing:

4 (A) Each impediment to the implementa-
5 tion of the system described in such paragraph.

6 (B) Steps being taken to remediate each
7 such impediment.

8 (C) Target dates for a solution to each
9 such impediment.

10 **SEC. 3. PROCUREMENT OF BIOLOGICAL IMPLANTS USED IN**
11 **DEPARTMENT OF VETERANS AFFAIRS MED-**
12 **ICAL FACILITIES.**

13 (a) PROCUREMENT.—

14 (1) IN GENERAL.—Subchapter II of chapter 81
15 of title 38, United States Code, is amended by add-
16 ing at the end the following new section:

17 **“§ 8129. Procurement of biological implants**

18 “(a) IN GENERAL.—(1) The Secretary may procure
19 biological implants of human origin only from vendors that
20 meet the following conditions:

21 “(A) The vendor uses the standard identifica-
22 tion system adopted or implemented by the Sec-
23 retary under section 7330C(a) of this title and has
24 safeguards to ensure that a distinct identifier has

1 been in place at each step of distribution of each bio-
2 logical implant from its donor.

3 “(B) The vendor is registered as required by
4 the Food and Drug Administration under subpart B
5 of part 1271 of title 21, Code of Federal Regula-
6 tions, or any successor regulation, and in the case of
7 a vendor that uses a tissue distribution intermediary
8 or a tissue processor, the vendor provides assurances
9 that the tissue distribution intermediary or tissue
10 processor is registered as required by the Food and
11 Drug Administration.

12 “(C) The vendor ensures that donor eligibility
13 determinations and such other records as the Sec-
14 retary may require accompany each biological im-
15 plant at all times, regardless of the country of origin
16 of the donor of the biological material.

17 “(D) The vendor agrees to cooperate with all
18 biological implant recalls conducted on the initiative
19 of the vendor, on the initiative of the original prod-
20 uct manufacturer used by the vendor, by the request
21 of the Food and Drug Administration, or by a statu-
22 tory order of the Food and Drug Administration.

23 “(E) The vendor agrees to notify the Secretary
24 of any adverse event or reaction report it provides
25 to the Food and Drug Administration, as required

1 by sections 1271.3 and 1271.350 of title 21, Code
2 of Federal Regulations, or any successor regulation,
3 or any warning letter from the Food and Drug Ad-
4 ministration issued to the vendor or a tissue proc-
5 essor or tissue distribution intermediary used by the
6 vendor by not later than 60 days after the vendor
7 receives such report or warning letter.

8 “(F) The vendor agrees to retain all records as-
9 sociated with the procurement of a biological implant
10 by the Department for at least 10 years after the
11 date of the procurement of the biological implant.

12 “(G) The vendor provides assurances that the
13 biological implants provided by the vendor are ac-
14 quired only from tissue processors that maintain ac-
15 tive accreditation with the American Association of
16 Tissue Banks or a similar national accreditation spe-
17 cific to biological implants.

18 “(2) The Secretary may procure biological implants
19 of nonhuman origin only from vendors that meet the fol-
20 lowing conditions:

21 “(A) The vendor uses the standard identifica-
22 tion system adopted or implemented by the Sec-
23 retary under section 7330C(a) of this title.

24 “(B) The vendor is registered as an establish-
25 ment as required by the Food and Drug Administra-

1 tion under sections 807.20 and 807.40 of title 21,
2 Code of Federal Regulations, or any successor regu-
3 lation (or is not required to register pursuant to sec-
4 tion 807.65(a) of such title, or any successor regula-
5 tion), and in the case of a vendor that is not the
6 original product manufacturer of such implants, the
7 vendor provides assurances that the original product
8 manufacturer is registered as required by the Food
9 and Drug Administration (or is not required to reg-
10 ister).

11 “(C) The vendor agrees to cooperate with all bi-
12 ological implant recalls conducted on the initiative of
13 the vendor, on the initiative of the original product
14 manufacturer used by the vendor, by the request of
15 the Food and Drug Administration, or by a statu-
16 tory order of the Food and Drug Administration.

17 “(D) The vendor agrees to notify the Secretary
18 of any adverse event report it provides to the Food
19 and Drug Administration as required under part
20 803 of title 21, Code of Federal Regulations, or any
21 successor regulation, or any warning letter from the
22 Food and Drug Administration issued to the vendor
23 or the original product manufacturer used by the
24 vendor by not later than 60 days after the vendor
25 receives such report or warning letter.

1 “(E) The vendor agrees to retain all records as-
2 sociated with the procurement of a biological implant
3 by the Department for at least 10 years after the
4 date of the procurement of the biological implant.

5 “(3)(A) The Secretary shall procure biological im-
6 plants under the Federal Supply Schedules of the General
7 Services Administration unless such implants are not
8 available under such Schedules.

9 “(B) With respect to biological implants listed on the
10 Federal Supply Schedules, the Secretary shall accommo-
11 date reasonable vendor requests to undertake outreach ef-
12 forts to educate medical professionals of the Department
13 about the use and efficacy of such biological implants.

14 “(C) In the case of biological implants that are un-
15 available for procurement under the Federal Supply
16 Schedules, the Secretary shall procure such implants using
17 competitive procedures in accordance with applicable law
18 and the Federal Acquisition Regulation, including through
19 the use of a national contract.

20 “(4) In procuring biological implants under this sec-
21 tion, the Secretary shall permit a vendor to use any of
22 the accredited entities identified by the Food and Drug
23 Administration as an issuing agency pursuant to section
24 830.100 of title 21, Code of Federal Regulations, or any
25 successor regulation.

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

3 “(b) PENALTIES.—In addition to any applicable pen-
4 alty under any other provision of law, any procurement
5 employee of the Department who is found responsible for
6 a biological implant procurement transaction with intent
7 to avoid or with reckless disregard of the requirements of
8 this section shall be ineligible to hold a certificate of ap-
9 pointment as a contracting officer or to serve as the rep-
10 resentative of an ordering officer, contracting officer, or
11 purchase card holder.

12 “(c) DEFINITIONS.—In this section:

13 “(1) The term ‘biological implant’ has the
14 meaning given that term in section 7330C(d) of this
15 title.

16 “(2) The term ‘distinct identifier’ means a dis-
17 tinct identification code that—

18 “(A) relates a biological implant to the
19 human donor of the implant and to all records
20 pertaining to the implant;

21 “(B) includes information designed to fa-
22 cilitate effective tracking, using the distinct
23 identification code, from the donor to the recipi-
24 ent and from the recipient to the donor; and

1 “(C) satisfies the requirements of section
2 1271.290(e) of title 21, Code of Federal Regu-
3 lations, or any successor regulation.

4 “(3) The term ‘tissue distribution intermediary’
5 means an agency that acquires and stores human
6 tissue for further distribution and performs no other
7 tissue banking functions.

8 “(4) The term ‘tissue processor’ means an enti-
9 ty processing human tissue for use in biological im-
10 plants, including activities performed on tissue other
11 than donor screening, donor testing, tissue recovery
12 and collection functions, storage, or distribution.”.

13 (2) CLERICAL AMENDMENT.—The table of sec-
14 tions at the beginning of chapter 81 is amended by
15 inserting after the item relating to section 8128 the
16 following new item:

“8129. Procurement of biological implants.”.

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

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 effective date may be pro-
2 cured by the Department of Veterans Affairs without re-
3 labeling under the standard identification system adopted
4 or implemented under section 7330C of such title, as
5 added by section 2(a).

6 **SEC. 4. FUNDING.**

7 No additional funds are authorized to carry out the
8 requirements of this Act and the amendments made by
9 this Act. Such requirements shall be carried out using
10 amounts otherwise authorized.

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