

103^D CONGRESS
2^D SESSION

S. 2215

To establish rules governing product liability actions against raw materials and bulk component suppliers to medical device manufacturers, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 20 (legislative day, JUNE 7), 1994

Mr. BYRD (for Mr. LIEBERMAN) (for himself and Mr. DURENBERGER) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

A BILL

To establish rules governing product liability actions against raw materials and bulk component suppliers to medical device manufacturers, 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 “Biomaterials Access
5 Assurance Act of 1994.”

6 **SEC. 2. FINDINGS.**

7 Congress finds and declares the following:

1 (1) Every year millions of Americans depend on
2 the availability of life-saving or life-enhancing per-
3 manently implantable medical devices;

4 (2) A continued supply of raw materials and
5 component parts is necessary to the invention, devel-
6 opment, improvement and maintenance of the supply
7 of such devices;

8 (3) Most of these devices are made with raw
9 materials and component parts that are not designed
10 or manufactured specifically for use in implantable
11 devices, but which have uses in a variety of
12 nonmedical products as well;

13 (4) Small quantities of these raw materials and
14 component parts are used, so that sales of raw ma-
15 terials and component parts for medical devices are
16 an extremely small portion of the overall market for
17 such raw materials and medical devices;

18 (5) Manufacturers of medical devices are re-
19 quired under the Federal Food Drug and Cosmetics
20 Act to demonstrate that their products are safe and
21 effective, including being properly designed and hav-
22 ing adequate warnings or instructions, and existing
23 tort law requires manufacturers of medical devices
24 to ensure they are properly designed and have ade-
25 quate warnings;

1 (6) Notwithstanding the fact that raw materials
2 and component parts suppliers do not design,
3 produce, or test the final implant, they have been
4 sued in cases alleging inadequate design and testing
5 of, or warnings related to the use of, permanently
6 implanted medical devices;

7 (7) Even though raw materials and component
8 parts suppliers have almost never been held liable in
9 such suits, because the cost of litigating such suites
10 to a favorable judgment far exceeds the total poten-
11 tial sales of such raw materials and component parts
12 to the medical device industry, raw materials and
13 component parts suppliers have begun to cease sup-
14 plying such raw materials and component parts for
15 use in permanently implanted medical devices;

16 (8) The unavailability of raw materials and
17 component parts will, unless alternate sources of
18 supply can be found, lead to unavailability of life-
19 saving and life-enhancing medical devices;

20 (9) The prospects for development of new
21 sources of supply for the full range of threatened
22 raw materials and component parts are remote, as
23 other suppliers around the world are refusing to sell
24 raw materials or component parts for use in manu-
25 facturing permanently implantable medical devices

1 in the United States, and it is unlikely that such a
2 small market could support the large investment
3 needed to develop new suppliers and attempts to do
4 so will raise the cost of medical devices;

5 (10) Courts that have considered the issue have
6 generally found that raw materials and component
7 part suppliers do not have a duty to evaluate the
8 safety and efficacy of the use of a raw material or
9 component part in a medical device, and also do not
10 have a duty to warn concerning the safety and effec-
11 tiveness of a medical device;

12 (11) Attempts to impose such duties will cause
13 more harm than good by driving raw materials and
14 component part suppliers to cease supplying manu-
15 facturers of permanently implantable medical de-
16 vices;

17 (12) In order to safeguard the availability of a
18 wide variety of life-saving and life-enhancing medical
19 devices, immediate action is needed to clarify the
20 permissible bases of liability for suppliers of raw ma-
21 terials and component parts used in the manufac-
22 ture of permanently implantable medical devices and
23 to provide expeditious procedures to dispose of un-
24 warranted suits against those suppliers so as to min-
25 imize litigation costs.

1 **SEC. 3. DEFINITIONS.**

2 As used in this Act, the term—

3 (1) “biomaterials supplier” means an entity
4 that directly or indirectly supplies a component part
5 or raw material for use in the manufacture of an im-
6 plant, and includes persons that have submitted
7 master files to the Food and Drug Administration
8 for purposes of pre-market approval of medical de-
9 vices, but does not include a manufacturer or seller
10 of an implant;

11 (2) “claimant” means any person who brings a
12 civil action, or on whose behalf a civil action is
13 brought, arising from harm allegedly caused directly
14 or indirectly by an implant, and includes persons
15 other than the individual into whose body, or in con-
16 tact with whose blood or tissue, the implant is
17 placed, if such person claims to have suffered harm;
18 if such an action is brought through or on behalf of
19 an estate, the term includes the claimant’s decedent,
20 or if it is brought through or on behalf of a minor
21 or incompetent, the term includes the claimant’s
22 parent or guardian; the term does not include

23 (A) a provider of professional services in
24 any case in which the sale or use of an implant
25 is incidental to the transaction and the essence

1 of the transaction is the furnishing of judg-
2 ment, skill, or services; or

3 (B) a manufacturer, seller, or biomaterials
4 supplier.

5 (3) “component part” means a manufactured
6 piece of an implant and includes a manufactured
7 piece that has significant nonimplant applications
8 and that by itself has no implant value or purpose,
9 but when combined with other component parts and
10 materials, constitutes an implant;

11 (4) “harm” means any injury to or damage suf-
12 fered by an individual, any illness, disease, or death
13 of that individual resulting from that injury or dam-
14 age, and any loss to that individual or any other in-
15 dividual resulting from that injury or damage; the
16 term does not include commercial loss or loss of or
17 damage to an implant itself;

18 (5) “implant” means a medical device that (A)
19 is placed into a surgically or naturally formed or ex-
20 isting cavity of the body or which contacts blood or
21 internal human tissue; and (B) which (i) is intended
22 by the manufacturer to remain in contact with the
23 body or internal tissue of the humans continuously
24 for a period of thirty days or more, or (ii) has label-

1 ing which does not contraindicate implantation or
2 contact for thirty days or more;

3 (6) “manufacturer” means any person who,
4 with respect to any particular implant—

5 (A) is engaged in the manufacture, prepa-
6 ration, propagation, compounding, or process-
7 ing, as defined in Section 510(a)(1) of the Fed-
8 eral Food, Drug and Cosmetics Act (21 U.S.C.
9 360(a)(1)), of an implant; and

10 (B) is required under Section 510 of the
11 Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 360), and the regulations issued there-
13 under, to register with the Secretary of Health
14 and Human Services and to include the implant
15 on a list of devices filed with the Secretary pur-
16 suant to Section 510(j) of the Federal Food,
17 Drug and Cosmetic Act (21 U.S.C. 360(j)), and
18 the regulations issued thereunder;

19 (7) “medical device” means a medical device as
20 defined in §201(h) of the Federal Food, Drug and
21 Cosmetic Act (21 U.S.C. §321(h));

22 (8) “qualified specialist” means a person who is
23 qualified by knowledge, skill, experience, training, or
24 education in the specialty areas that are the subject
25 of the action;

1 (9) “raw material” means a substance or prod-
2 uct that has a generic use and that may be used in
3 applications other than implants;

4 (10) “seller” means a person who, in the course
5 of a business conducted for that purpose, sells, dis-
6 tributes, leases, packages, labels, or otherwise places
7 an implant in the stream of commerce; the term
8 does not include—

9 (A) a seller or lessor of real property;

10 (B) a provider of professional services in
11 any case in which the sale or use of an implant
12 is incidental to the transaction and the essence
13 of the transaction is the furnishing of judg-
14 ment, skill, or services; or

15 (C) any person who acts in only a financial
16 capacity with respect to the sale of an implant.

17 **SEC. 4. APPLICABILITY; PREEMPTION.**

18 (a) **APPLICABILITY.**—This Act applies to any civil ac-
19 tion brought by a claimant, whether in State or Federal
20 court, against a manufacturer, seller, or biomaterials sup-
21 plier, or against licensors of biomaterials suppliers, on any
22 theory, for harm caused by an implant. A civil action
23 brought by a purchaser of a medical device for use in pro-
24 viding professional services against a manufacturer, seller,
25 or biomaterials supplier for loss or damage to an implant

1 itself or for commercial loss to the purchaser is not subject
2 to this Act and shall be governed by applicable commercial
3 or contract law.

4 (b) SCOPE OF PREEMPTION.—This Act supersedes
5 any State law regarding recovery for harm caused by an
6 implant only to the extent that this Act establishes a rule
7 of law applicable to any such recovery. Any issue arising
8 under this Act that is not governed by any such rule of
9 law shall be governed by applicable State or Federal law.

10 (c) EFFECT ON OTHER LAWS.—Nothing in this Act
11 shall be construed to—

12 (1) affect any defense available under other
13 provisions of State or Federal law to a defendant in
14 an action alleging harm caused by an implant; or

15 (2) create a cause of action or Federal court ju-
16 risdiction pursuant to 28 U.S.C. 1331 or 1337 that
17 otherwise would not exist under applicable State or
18 Federal law.

19 **SEC. 5. ACTIONS AGAINST BIOMATERIALS SUPPLIERS.**

20 (a)(1) Except as provided in subsection (b) of this
21 Act, no claimant may bring an action for harm caused
22 by an implant against a person, who has not registered
23 with the Secretary of Health and Human Services, pursu-
24 ant to section 510 of the Federal Food, Drug and Cosmet-
25 ics Act, and the regulations issued thereunder, and in-

1 cluded the implant on a list of devices filed with the Sec-
2 retary pursuant to Section 510(j) of the Federal Food,
3 Drug and Cosmetics Act and the regulations issued there-
4 under.

5 (2) Notwithstanding subparagraph (1), a claimant
6 may bring an action, other than as provided in subsection
7 (b) of this Act, against a person who, with respect to
8 claimant's implant, is the subject of a declaration issued
9 by the Secretary under section 6(a) of this Act, or is a
10 seller of the implant that allegedly caused harm to the
11 claimant.

12 (b) No claimant may bring an action for harm caused
13 by an implant against a biomaterials supplier, and no
14 biomaterials supplier shall be liable for harm to a claimant
15 caused by an implant, unless the claimant shows, by a pre-
16 ponderance of the evidence, that—

17 (1) the raw materials or component parts deliv-
18 ered by the biomaterials supplier either were not the
19 product described in the contract between the
20 biomaterials supplier and the person who contracted
21 for delivery of the product, or failed to meet any
22 specifications that were—

23 (A) provided to the biomaterials supplier
24 and not expressly repudiated by the

1 biomaterials supplier prior to acceptance of de-
2 livery of the raw materials or component parts;

3 (B) published by the biomaterials supplier,
4 provided to the manufacturer by the
5 biomaterials supplier, or contained in a master
6 file submitted by the biomaterials supplier to
7 the Food and Drug Administration, and cur-
8 rently maintained by the biomaterials supplier,
9 for purposes of pre-market approval of medical
10 devices; or

11 (C)(i) included in the manufacturer's sub-
12 missions for purposes of pre-market approval or
13 review by the Food and Drug Administration
14 under section 510, 513, 515, or 520 of the Fed-
15 eral Food, Drug and Cosmetic Act (21 U.S.
16 Code §§ 360, 360c, 360e, or 360j) that have re-
17 ceived clearance from the Food and Drug Ad-
18 ministration, (ii) that were provided by the
19 manufacturer to the biomaterials supplier and
20 not expressly repudiated by the biomaterials
21 supplier prior to the manufacturer's acceptance
22 of delivery of the raw materials or component
23 parts; and

24 (2) such conduct was an actual and proximate
25 cause of the claimant's harm.

1 (c) No claimant may bring an action for harm caused
2 by an implant against a person who licenses a biomaterials
3 supplier to produce raw materials or component parts.

4 (d) The applicable statute of limitations shall be
5 tolled during any period in which claimant has filed a peti-
6 tion with the Secretary of Health and Human Services
7 under section 6 of this Act.

8 **SEC. 6. REVIEW BY THE SECRETARY OF NON-REGISTRA-**
9 **TION.**

10 (a) The Secretary may, on its own motion or upon
11 petition by any person, after notice to the affected persons
12 and affording an opportunity for an informal hearing,
13 issue a declaration that a person, with respect to the im-
14 plant that allegedly caused claimant's harm,

15 (1) should have registered with the Secretary
16 under Section 510 of the Federal Food, Drug and
17 Cosmetics Act (21 U.S.C. 360), and the regulations
18 issued thereunder, but failed to do so, or

19 (2) should have included the implant on a list
20 of devices filed with the Secretary pursuant to Sec-
21 tion 510(j) of the Federal Food, Drug and Cosmetic
22 Act (21 U.S.C. 360(j)), but failed to do so.

23 (b) Any petition filed pursuant to subsection (a) shall
24 be immediately docketed by the Secretary, and the Sec-

1 retary shall issue a final decision within 180 days of the
2 filing of the petition.

3 **SEC. 7. PROCEDURES FOR ACTIONS AGAINST A**
4 **BIOMATERIALS SUPPLIER.**

5 (a) IN GENERAL.—The procedural requirements set
6 forth in subsection (b) shall apply to any action by a
7 claimant against a biomaterials supplier.

8 (b) PROCEDURAL REQUIREMENTS.—

9 (1) A claimant may not bring an action against
10 a biomaterials supplier unless the manufacturer of
11 the implant is named as a party, except if the manu-
12 facturer is subject to service of process in no juris-
13 diction in which the biomaterials supplier or is also
14 subject to service of process or unless litigation
15 against the manufacturer is barred by applicable
16 law.

17 (2) No action may be brought by any claimant
18 against a biomaterials supplier unless, at the time
19 the claimant brings the action, the claimant submits
20 an affidavit—

21 (A) declaring that the claimant has con-
22 sulted and reviewed the facts of the action with
23 qualified specialists, whose qualifications the
24 claimant shall disclose;

1 (B) including a written determination by a
2 qualified specialist that the raw materials or
3 component parts actually used in the manufac-
4 ture of claimant's implant were raw materials
5 or component parts described in section 5(b)(1),
6 together with a statement of the basis for such
7 a determination;

8 (C) including a written determination by a
9 qualified specialist that, after a review of the
10 medical record and other relevant material, the
11 raw material or component part supplied by the
12 biomaterials supplier and actually used in the
13 manufacture of claimant's implant was a cause
14 of claimant's harm, together with a statement
15 of the basis for the determination;

16 (D) on the basis of the qualified special-
17 ists' review and consultation, that the claimant
18 (or the claimant's attorney) has concluded that
19 there is a reasonable and meritorious cause for
20 the filing of the action against the biomaterials
21 supplier.

22 (c) DISMISSAL.—

23 (1) In any action subject to this Act, a defend-
24 ant may, at any time at which a motion to dismiss
25 may be filed under applicable law, move to dismiss

1 the action on the grounds that the defendant is a
2 biomaterials supplier and—

3 (A) claimant has failed to satisfy the con-
4 ditions in section 5(a) that would permit claim-
5 ant to bring an action against defendant;

6 (B) defendant was not a seller of the im-
7 plant which allegedly caused harm to the claim-
8 ant; or

9 (C) claimant has failed to comply with the
10 provisions of subsection (b).

11 (2) Defendant may submit affidavits dem-
12 onstrating that defendant has not included the im-
13 plant on a list, if any, filed with the Secretary pur-
14 suant to section 510(j) of the Federal Food, Drug
15 and Cosmetic Act (21 U.S.C. 360). Claimant may,
16 in response to such a motion, submit affidavits dem-
17 onstrating that the Secretary has, with respect to
18 the defendant and the implant that allegedly caused
19 claimant's harm, issued a declaration pursuant to
20 section 6(a) of this Act, or that defendant was a
21 seller of the implant.

22 (3) No discovery shall be permitted against the
23 defendant who has filed a motion to dismiss under
24 subparagraph (1), other than discovery necessary to
25 determine a motion to dismiss for lack of jurisdic-

1 tion, until the court has ruled on the motion to dis-
2 miss filed pursuant to subsection (1).

3 (4) A defendant shall conclusively be deemed to
4 be a biomaterials supplier and not to be subject to
5 suit except pursuant to section 5(b) of this Act, and
6 a motion to dismiss under subsections (c)(1)(A) or
7 (c)(1)(B) shall be granted, unless the claimant sub-
8 mits valid affidavits demonstrating—

9 (A) with respect to a motion under sub-
10 section (c)(1)(A), that the Secretary has, with
11 respect to the defendant and the implant that
12 allegedly caused harm to the claimant, issued a
13 declaration pursuant to section 6(a) of this Act;
14 or

15 (B) with respect to a motion under sub-
16 section (c)(1)(B), that the biomaterials supplier
17 was a seller which held title to the implant as
18 a result of purchasing or selling the implant
19 after the implant was manufactured and en-
20 tered the stream of commerce.

21 (5) The court shall rule on the motion to dis-
22 miss filed under subsection (c) solely on the basis of
23 the pleadings and any affidavits, including affidavits
24 submitted under paragraph (2). If the pleadings and
25 affidavits raise genuine issues as to material facts

1 with respect to a motion under (c)(1)(C), the motion
2 may be treated as a motion for summary judgment
3 pursuant to subsection (d) of this section.

4 (d) SUMMARY JUDGMENT.—

5 (1) A biomaterials supplier shall be entitled to
6 entry of judgment without trial if there is no genu-
7 ine issue as to any material fact as to each element
8 set forth in section 5(b). A genuine issue of material
9 fact shall exist only if the evidence submitted by
10 claimant, if found by a jury to be credible, would be
11 sufficient to allow a reasonable jury to reach a ver-
12 dict for the claimant.

13 (2) In the event that the court, under applicable
14 rules, may permit discovery prior to ruling on a mo-
15 tion for summary judgment, such discovery shall be
16 limited solely to establishing whether a genuine issue
17 of material fact exists.

18 (e) A biomaterials supplier shall be subject to discov-
19 ery in connection with a motion under subsection (c) or
20 (d) solely to the extent permitted by the applicable State
21 or Federal rules for discovery against nonparties.

22 (f) In the event claimant has filed a petition for a
23 declaration pursuant to section 6(a) with respect to a de-
24 fendant, and the Secretary has not issued a final decision
25 thereon, the court shall stay all proceedings with respect

1 to that defendant until the Secretary has issued a final
2 decision.

3 (g) The manufacturer of the implant shall be per-
4 mitted to file and conduct the proceeding on any motion
5 filed pursuant to subsection (c) or (d) if the manufacturer
6 and the other defendant(s) have entered into a valid and
7 applicable contractual agreement in which the manufac-
8 turer agrees to bear the cost of or to conduct such pro-
9 ceeding.

10 (h) The court shall require the claimant to com-
11 pensate the biomaterials supplier (or a manufacturer ap-
12 pearing in lieu of a supplier pursuant to subsection (g))
13 for attorney fees and costs, if the claimant named or
14 joined the biomaterials supplier, but the court found the
15 claim against the biomaterials supplier to be without merit
16 and frivolous.

17 **SEC. 9. EFFECTIVE DATE.**

18 This act shall take effect on the date of its enactment
19 and shall apply to all civil actions pursuant to this act
20 commenced on or after such date, including any action in
21 which the harm or the conduct which caused the harm
22 occurred before the effective date of this act.

23 **SEC. 10. SEVERABILITY.**

24 If any provision of this act, or the application of such
25 provision to any person or circumstances is held to be un-

- 1 constitutional, the remainder of this act and application
- 2 of the provisions of such to any person or circumstance
- 3 shall not be affected thereby.

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S 2215 IS—2

S 2215 IS—3