

Union Calendar No. 349

105TH CONGRESS
2^D SESSION

H. R. 872

[Report No. 105-549, Parts I and II]

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

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 27, 1997

Mr. GEKAS (for himself, Mr. BILBRAY, Mr. BRYANT, Mr. BURR of North Carolina, Mr. BUYER, Mr. CUNNINGHAM, Ms. DUNN, Mr. EHLERS, Mr. ENGLISH of Pennsylvania, Ms. ESHOO, Mr. GALLEGLY, Mr. GREENWOOD, Mr. GUTKNECHT, Mr. HASTERT, Mr. HAYWORTH, Mrs. KELLY, Mr. KIND, Mr. LUTHER, Mr. MCCOLLUM, Mr. MCINTOSH, Mr. PASTOR, Mr. RAMSTAD, Mr. ROHRABACHER, Mr. SABO, Mr. SCHIFF, Mr. SENSENBRENNER, Mr. STUMP, and Mr. VENTO) introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

MAY 22, 1998

Reported from the Committee on the Judiciary with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

MAY 22, 1998

Referral to the Committee on Commerce extended for a period ending not later than July 14, 1998

JULY 14, 1998

Additional sponsors: Mr. BARCIA, Mr. CLEMENT, Mr. COBURN, Mr. COX of California, Mr. CRANE, Mr. HORN, Mr. NORWOOD, Mr. PORTER, Mr. SALMON, Mr. SERRANO, Mr. SHAYS, Mrs. TAUSCHER, Mrs. EMERSON, Mr. HUTCHINSON, Mr. INGLIS of South Carolina, Mr. PICKERING, Mr. BUNNING, Mr. CONDIT, Mrs. CUBIN, Mr. FOX of Pennsylvania, Mr. GILLMOR, Mr. HEFNER, Mr. MCHUGH, Mr. MORAN of Virginia, Mr.

PACKARD, Mrs. ROUKEMA, Mr. DAN SCHAEFER of Colorado, Mr. SESSIONS, Mr. STENHOLM, Mr. TOWNS, Mr. BARTON of Texas, Mr. BOUCHER, Mr. DOOLEY of California, Mr. FALCOMAVAEGA, Mr. GANSKE, Mr. GOODE, Mr. KIM, Mr. LARGENT, Mr. MINGE, Mr. PASCRELL, Mr. SPRATT, Mr. CALVERT, Mr. COOK, Mr. DREIER, Mr. FAZIO of California, Mr. HOEKSTRA, Mr. OBERSTAR, Mr. PICKETT, Mr. ROYCE, Mr. SOLOMON, Mr. THORNBERRY, Mr. ROTHMAN, Mr. TORRES, Mr. BALLENGER, Mr. COBLE, Ms. CHRISTIAN-GREEN, Mr. COOKSEY, Mr. GRAHAM, Mr. HOSTETTLER, Mr. LANTOS, Mr. MCKEON, Mr. ROGAN, Ms. SANCHEZ, Mr. SHIMKUS, Mr. CAPPS, Mr. GOODLING, Mr. HOLDEN, Mr. WALSH, Mr. YOUNG of Florida, Mr. BERMAN, Mr. EDWARDS, Ms. HOOLEY of Oregon, Ms. LOFGREN, Mr. BOB SCHAFFER of Colorado, Ms. SLAUGHTER, Mr. WHITE, Mr. CAMPBELL, Ms. HARMAN, Mrs. JOHNSON of Connecticut, Mr. SHERMAN, Mr. WELDON of Pennsylvania, Mr. DAVIS of Florida, Mr. FRANKS of New Jersey, Mr. MATSUI, Mr. SNYDER, Mr. CAMP, Mr. FRELINGHUYSEN, Mr. LEWIS of California, Ms. WOOLSEY, Mr. PAPPAS, Mrs. NORTHUP, Ms. PELOSI, Mr. QUINN, Mr. SMITH of New Jersey, Mr. WELDON of Florida, Mr. FARR of California, Mr. SAXTON, Mr. STEARNS, Mr. ANDREWS, Mr. LOBIONDO, Mr. MENENDEZ, Mr. ADAM SMITH of Washington, Mr. PALLONE, Mr. REDMOND, Mr. BILIRAKIS, Mr. STRICKLAND, Mr. PRICE of North Carolina, and Ms. WILSON

JULY 14, 1998

Reported from the Committee on Commerce with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in boldface roman]

[For text of introduced bill, see copy of bill as introduced on February 27, 1997]

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 As-*
 5 *urance Act of 1998”.*

1 **SEC. 2. FINDINGS.**

2 *The Congress finds that—*

3 *(1) each year millions of citizens of the United*
4 *States depend on the availability of lifesaving or life-*
5 *enhancing medical devices, many of which are perma-*
6 *nently implantable within the human body;*

7 *(2) a continued supply of raw materials and*
8 *component parts is necessary for the invention, devel-*
9 *opment, improvement, and maintenance of the supply*
10 *of the devices;*

11 *(3) most of the medical devices are made with*
12 *raw materials and component parts that—*

13 *(A) move in interstate commerce;*

14 *(B) are not designed or manufactured spe-*
15 *cifically for use in medical devices; and*

16 *(C) come in contact with internal human*
17 *tissue;*

18 *(4) the raw materials and component parts also*
19 *are used in a variety of nonmedical products;*

20 *(5) because small quantities of the raw materials*
21 *and component parts are used for medical devices,*
22 *sales of raw materials and component parts for medi-*
23 *cal devices constitute an extremely small portion of*
24 *the overall market for the raw materials and compo-*
25 *nent parts;*

1 (6) under the Federal Food, Drug, and Cosmetic
2 *Act (21 U.S.C. 301 et seq.) manufacturers of medical*
3 *devices are required to demonstrate that the medical*
4 *devices are safe and effective, including demonstrating*
5 *that the products are properly designed and have ade-*
6 *quate warnings or instructions;*

7 (7) notwithstanding the fact that raw materials
8 *and component parts suppliers do not design,*
9 *produce, or test a final medical device, the suppliers*
10 *have been the subject of actions alleging inadequate—*

11 (A) design and testing of medical devices
12 *manufactured with materials or parts supplied*
13 *by the suppliers; or*

14 (B) warnings related to the use of such med-
15 *ical devices;*

16 (8) even though suppliers of raw materials and
17 *component parts have very rarely been held liable in*
18 *such actions, such suppliers have ceased supplying*
19 *certain raw materials and component parts for use in*
20 *medical devices for a number of reasons, including*
21 *concerns about the costs of such litigation;*

22 (9) unless alternate sources of supply can be
23 *found, the unavailability of raw materials and com-*
24 *ponent parts for medical devices will lead to unavail-*

1 *ability of lifesaving and life-enhancing medical de-*
2 *vices;*

3 *(10) because other suppliers of the raw materials*
4 *and component parts in foreign nations are refusing*
5 *to sell raw materials or component parts for use in*
6 *manufacturing certain medical devices in the United*
7 *States, the prospects for development of new sources of*
8 *supply for the full range of threatened raw materials*
9 *and component parts for medical devices are remote;*

10 *(11) it is unlikely that the small market for such*
11 *raw materials and component parts in the United*
12 *States could support the large investment needed to*
13 *develop new suppliers of such raw materials and com-*
14 *ponent parts;*

15 *(12) attempts to develop such new suppliers*
16 *would raise the cost of medical devices;*

17 *(13) courts that have considered the duties of the*
18 *suppliers of the raw materials and component parts*
19 *have generally found that the suppliers do not have*
20 *a duty—*

21 *(A) to evaluate the safety and efficacy of the*
22 *use of a raw material or component part in a*
23 *medical device; and*

24 *(B) to warn consumers concerning the safe-*
25 *ty and effectiveness of a medical device;*

1 (14) because medical devices and the raw mate-
2 rials and component parts used in their manufacture
3 move in interstate commerce, a shortage of such raw
4 materials and component parts affects interstate com-
5 merce;

6 (15) in order to safeguard the availability of a
7 wide variety of lifesaving and life-enhancing medical
8 devices, immediate action is needed—

9 (A) to clarify the permissible bases of liabil-
10 ity for suppliers of raw materials and compo-
11 nent parts for medical devices; and

12 (B) to provide expeditious procedures to dis-
13 pose of unwarranted suits against the suppliers
14 in such manner as to minimize litigation costs;

15 (16) the several States and their courts are the
16 primary architects and regulators of our tort system;
17 Congress, however, must, in certain circumstances in-
18 volving the national interest, address tort issues, and
19 a threatened shortage of raw materials and compo-
20 nent parts for life-saving medical devices is one such
21 circumstance; and

22 (17) the protections set forth in this Act are
23 needed to assure the continued supply of materials for
24 life-saving medical devices; however, negligent suppli-
25 ers should not be protected.

1 **SEC. 3. DEFINITIONS.**

2 *As used in this Act:*

3 (1) *BIOMATERIALS SUPPLIER.*—

4 (A) *IN GENERAL.*—*The term “biomaterials*
5 *supplier” means an entity that directly or indi-*
6 *rectly supplies a component part or raw mate-*
7 *rial for use in the manufacture of an implant.*

8 (B) *PERSONS INCLUDED.*—*Such term in-*
9 *cludes any person who—*

10 (i) *has submitted master files to the*
11 *Secretary for purposes of premarket ap-*
12 *proval of a medical device; or*

13 (ii) *licenses a biomaterials supplier to*
14 *produce component parts or raw materials.*

15 (2) *CLAIMANT.*—

16 (A) *IN GENERAL.*—*The term “claimant”*
17 *means any person who brings a civil action, or*
18 *on whose behalf a civil action is brought, arising*
19 *from harm allegedly caused directly or indirectly*
20 *by an implant, including a person other than*
21 *the individual into whose body, or in contact*
22 *with whose blood or tissue, the implant is placed,*
23 *who claims to have suffered harm as a result of*
24 *the implant.*

25 (B) *ACTION BROUGHT ON BEHALF OF AN*
26 *ESTATE.*—*With respect to an action brought on*

1 *behalf of or through the estate of an individual*
2 *into whose body, or in contact with whose blood*
3 *or tissue the implant is placed, such term in-*
4 *cludes the decedent that is the subject of the ac-*
5 *tion.*

6 (C) *ACTION BROUGHT ON BEHALF OF A*
7 *MINOR OR INCOMPETENT.*—*With respect to an*
8 *action brought on behalf of or through a minor*
9 *or incompetent, such term includes the parent or*
10 *guardian of the minor or incompetent.*

11 (D) *EXCLUSIONS.*—*Such term does not in-*
12 *clude—*

13 (i) *a provider of professional health*
14 *care services, in any case in which—*

15 (I) *the sale or use of an implant*
16 *is incidental to the transaction; and*

17 (II) *the essence of the transaction*
18 *is the furnishing of judgment, skill, or*
19 *services;*

20 (ii) *a person acting in the capacity of*
21 *a manufacturer, seller, or biomaterials sup-*
22 *plier; or*

23 (iii) *a person alleging harm caused by*
24 *either the silicone gel or the silicone enve-*

1 *lope utilized in a breast implant containing*
2 *silicone gel, except that—*

3 *(I) neither the exclusion provided*
4 *by this clause nor any other provision*
5 *of this Act may be construed as a find-*
6 *ing that silicone gel (or any other form*
7 *of silicone) may or may not cause*
8 *harm; and*

9 *(II) the existence of the exclusion*
10 *under this clause may not—*

11 *(aa) be disclosed to a jury in*
12 *any civil action or other proceed-*
13 *ing, and*

14 *(bb) except as necessary to es-*
15 *tablish the applicability of this*
16 *Act, otherwise be presented in any*
17 *civil action or other proceeding.*

18 *(3) COMPONENT PART.—*

19 *(A) IN GENERAL.—The term “component*
20 *part” means a manufactured piece of an im-*
21 *plant.*

22 *(B) CERTAIN COMPONENTS.—Such term in-*
23 *cludes a manufactured piece of an implant*
24 *that—*

1 (i) *has significant non-implant appli-*
2 *cations; and*

3 (ii) *alone, has no implant value or*
4 *purpose, but when combined with other*
5 *component parts and materials, constitutes*
6 *an implant.*

7 (4) *HARM.—*

8 (A) *IN GENERAL.—The term “harm”*
9 *means—*

10 (i) *any injury to or damage suffered*
11 *by an individual;*

12 (ii) *any illness, disease, or death of*
13 *that individual resulting from that injury*
14 *or damage; and*

15 (iii) *any loss to that individual or any*
16 *other individual resulting from that injury*
17 *or damage.*

18 (B) *EXCLUSION.—The term does not in-*
19 *clude any commercial loss or loss of or damage*
20 *to an implant.*

21 (5) *IMPLANT.—The term “implant” means—*

22 (A) *a medical device that is intended by the*
23 *manufacturer of the device—*

1 (i) to be placed into a surgically or
2 naturally formed or existing cavity of the
3 body for a period of at least 30 days; or

4 (ii) to remain in contact with bodily
5 fluids or internal human tissue through a
6 surgically produced opening for a period of
7 less than 30 days; and

8 (B) suture materials used in implant proce-
9 dures.

10 (6) *MANUFACTURER.*—The term “manufacturer”
11 means any person who, with respect to an implant—

12 (A) is engaged in the manufacture, prepara-
13 tion, propagation, compounding, or processing
14 (as defined in section 510(a)(1) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C.
16 360(a)(1)) of the implant; and

17 (B) is required—

18 (i) to register with the Secretary pur-
19 suant to section 510 of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 360)
21 and the regulations issued under such sec-
22 tion; and

23 (ii) to include the implant on a list of
24 devices filed with the Secretary pursuant to
25 section 510(j) of such Act (21 U.S.C. 360(j))

1 *and the regulations issued under such sec-*
2 *tion.*

3 (7) *MEDICAL DEVICE.*—*The term “medical de-*
4 *vice” means a device, as defined in section 201(h) of*
5 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
6 *321(h)), and includes any device component of any*
7 *combination product as that term is used in section*
8 *503(g) of such Act (21 U.S.C. 353(g)).*

9 (8) *RAW MATERIAL.*—*The term “raw material”*
10 *means a substance or product that—*

11 (A) *has a generic use; and*

12 (B) *may be used in an application other*
13 *than an implant.*

14 (9) *SECRETARY.*—*The term “Secretary” means*
15 *the Secretary of Health and Human Services.*

16 (10) *SELLER.*—

17 (A) *IN GENERAL.*—*The term “seller” means*
18 *a person who, in the course of a business con-*
19 *ducted for that purpose, sells, distributes, leases,*
20 *packages, labels, or otherwise places an implant*
21 *in the stream of commerce.*

22 (B) *EXCLUSIONS.*—*The term does not in-*
23 *clude—*

24 (i) *a seller or lessor of real property;*

1 (ii) a provider of professional services,
2 in any case in which the sale or use of an
3 implant is incidental to the transaction and
4 the essence of the transaction is the furnish-
5 ing of judgment, skill, or services; or

6 (iii) any person who acts in only a fi-
7 nancial capacity with respect to the sale of
8 an implant.

9 **SEC. 4. GENERAL REQUIREMENTS; APPLICABILITY; PRE-**
10 **EMPTION.**

11 (a) *GENERAL REQUIREMENTS.*—

12 (1) *IN GENERAL.*—In any civil action covered by
13 this Act, a biomaterials supplier may raise any de-
14 fense set forth in section 5.

15 (2) *PROCEDURES.*—Notwithstanding any other
16 provision of law, the Federal or State court in which
17 a civil action covered by this Act is pending shall, in
18 connection with a motion for dismissal or judgment
19 based on a defense described in paragraph (1), use the
20 procedures set forth in section 6.

21 (b) *APPLICABILITY.*—

22 (1) *IN GENERAL.*—Except as provided in para-
23 graph (2), notwithstanding any other provision of
24 law, this Act applies to any civil action brought by
25 a claimant, whether in a Federal or State court,

1 *against a manufacturer, seller, or biomaterials sup-*
2 *plier, on the basis of any legal theory, for harm alleg-*
3 *edly caused by an implant.*

4 (2) *EXCLUSION.*—*A civil action brought by a*
5 *purchaser of a medical device for use in providing*
6 *professional services against a manufacturer, seller, or*
7 *biomaterials supplier for loss or damage to an im-*
8 *plant or for commercial loss to the purchaser—*

9 (A) *shall not be considered an action that*
10 *is subject to this Act; and*

11 (B) *shall be governed by applicable commer-*
12 *cial or contract law.*

13 (c) *SCOPE OF PREEMPTION.*—

14 (1) *IN GENERAL.*—*This Act supersedes any State*
15 *law regarding recovery for harm caused by an im-*
16 *plant and any rule of procedure applicable to a civil*
17 *action to recover damages for such harm only to the*
18 *extent that this Act establishes a rule of law applica-*
19 *ble to the recovery of such damages.*

20 (2) *APPLICABILITY OF OTHER LAWS.*—*Any issue*
21 *that arises under this Act and that is not governed*
22 *by a rule of law applicable to the recovery of damages*
23 *described in paragraph (1) shall be governed by ap-*
24 *licable Federal or State law.*

1 (d) *STATUTORY CONSTRUCTION.*—*Nothing in this Act*
2 *may be construed—*

3 (1) *to affect any defense available to a defendant*
4 *under any other provisions of Federal or State law in*
5 *an action alleging harm caused by an implant; or*

6 (2) *to create a cause of action or Federal court*
7 *jurisdiction pursuant to section 1331 or 1337 of title*
8 *28, United States Code, that otherwise would not exist*
9 *under applicable Federal or State law.*

10 **SEC. 5. LIABILITY OF BIOMATERIALS SUPPLIERS.**

11 (a) *IN GENERAL.*—

12 (1) *EXCLUSION FROM LIABILITY.*—*Except as*
13 *provided in paragraph (2) or section 7, a biomate-*
14 *rials supplier shall not be liable for harm to a claim-*
15 *ant caused by an implant.*

16 (2) *LIABILITY.*—*A biomaterials supplier that—*

17 (A) *is a manufacturer may be liable for*
18 *harm to a claimant described in subsection (b);*

19 (B) *is a seller may be liable for harm to a*
20 *claimant described in subsection (c); and*

21 (C) *furnishes raw materials or component*
22 *parts that fail to meet applicable contractual re-*
23 *quirements or specifications may be liable for*
24 *harm to a claimant described in subsection (d).*

25 (b) *LIABILITY AS MANUFACTURER.*—

1 (1) *IN GENERAL.*—A biomaterials supplier may,
2 to the extent required and permitted by any other ap-
3 plicable law, be liable for harm to a claimant caused
4 by an implant if the biomaterials supplier is the
5 manufacturer of the implant.

6 (2) *GROUND FOR LIABILITY.*—The biomaterials
7 supplier may be considered the manufacturer of the
8 implant that allegedly caused harm to a claimant
9 only if the biomaterials supplier—

10 (A)(i) has or should have registered with the
11 Secretary pursuant to section 510 of the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 360)
13 and the regulations issued under such section;
14 and

15 (ii) included or should have included the
16 implant on a list of devices filed with the Sec-
17 retary pursuant to section 510(j) of such Act (21
18 U.S.C. 360(j)) and the regulations issued under
19 such section;

20 (B) is the subject of a declaration issued by
21 the Secretary pursuant to paragraph (3) that
22 states that the supplier, with respect to the im-
23 plant that allegedly caused harm to the claim-
24 ant, was required to—

1 (i) register with the Secretary under
2 section 510 of such Act (21 U.S.C. 360),
3 and the regulations issued under such sec-
4 tion, but failed to do so; or

5 (ii) include the implant on a list of de-
6 vices filed with the Secretary pursuant to
7 section 510(j) of such Act (21 U.S.C. 360(j))
8 and the regulations issued under such sec-
9 tion, but failed to do so; or

10 (C) is related by common ownership or con-
11 trol to a person meeting all the requirements de-
12 scribed in subparagraph (A) or (B), if the court
13 deciding a motion to dismiss in accordance with
14 section 6(c)(3)(B)(i) finds, on the basis of affida-
15 vits submitted in accordance with section 6, that
16 it is necessary to impose liability on the bio-
17 materials supplier as a manufacturer because the
18 related manufacturer meeting the requirements
19 of subparagraph (A) or (B) lacks sufficient fi-
20 nancial resources to satisfy any judgment that
21 the court feels it is likely to enter should the
22 claimant prevail.

23 (3) ADMINISTRATIVE PROCEDURES.—

24 (A) IN GENERAL.—The Secretary may issue
25 a declaration described in paragraph (2)(B) on

1 *the motion of the Secretary or on petition by*
2 *any person, after providing—*

3 *(i) notice to the affected persons; and*

4 *(ii) an opportunity for an informal*
5 *hearing.*

6 *(B) DOCKETING AND FINAL DECISION.—Im-*
7 *mediately upon receipt of a petition filed pursu-*
8 *ant to this paragraph, the Secretary shall docket*
9 *the petition. Not later than 180 days after the*
10 *petition is filed, the Secretary shall issue a final*
11 *decision on the petition.*

12 *(C) APPLICABILITY OF STATUTE OF LIMITA-*
13 *TIONS.—Any applicable statute of limitations*
14 *shall toll during the period during which a*
15 *claimant has filed a petition with the Secretary*
16 *under this paragraph.*

17 *(c) LIABILITY AS SELLER.—A biomaterials supplier*
18 *may, to the extent required and permitted by any other ap-*
19 *plicable law, be liable as a seller for harm to a claimant*
20 *caused by an implant only if—*

21 *(1) the biomaterials supplier—*

22 *(A) held title to the implant that allegedly*
23 *caused harm to the claimant as a result of pur-*
24 *chasing the implant after—*

1 (i) *the manufacture of the implant;*

2 *and*

3 (ii) *the entrance of the implant in the*

4 *stream of commerce; and*

5 (B) *subsequently resold the implant; or*

6 (2) *the biomaterials supplier is related by com-*
7 *mon ownership or control to a person meeting all the*
8 *requirements described in paragraph (1), if a court*
9 *deciding a motion to dismiss in accordance with sec-*
10 *tion 6(c)(3)(B)(ii) finds, on the basis of affidavits*
11 *submitted in accordance with section 6, that it is nec-*
12 *essary to impose liability on the biomaterials supplier*
13 *as a seller because the related seller meeting the re-*
14 *quirements of paragraph (1) lacks sufficient financial*
15 *resources to satisfy any judgment that the court feels*
16 *it is likely to enter should the claimant prevail.*

17 (d) *LIABILITY FOR VIOLATING CONTRACTUAL RE-*
18 *QUIREMENTS OR SPECIFICATIONS.—A biomaterials sup-*
19 *plier may, to the extent required and permitted by any*
20 *other applicable law, be liable for harm to a claimant*
21 *caused by an implant if the claimant in an action shows,*
22 *by a preponderance of the evidence, that—*

23 (1) *the raw materials or component parts deliv-*
24 *ered by the biomaterials supplier either—*

1 (A) did not constitute the product described
2 in the contract between the biomaterials supplier
3 and the person who contracted for delivery of the
4 product; or

5 (B) failed to meet any specifications that
6 were—

7 (i) accepted, pursuant to applicable
8 law, by the biomaterials supplier;

9 (ii)(I) published by the biomaterials
10 supplier;

11 (II) provided to the manufacturer by
12 the biomaterials supplier; or

13 (III) contained in a master file that
14 was submitted by the biomaterials supplier
15 to the Secretary and that is currently main-
16 tained by the biomaterials supplier for pur-
17 poses of premarket approval of medical de-
18 vices; or

19 (iii) included in the submissions for
20 purposes of premarket approval or review
21 by the Secretary under section 510, 513,
22 515, or 520 of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 360, 360c, 360e, or
24 360j), and received clearance from the Sec-
25 retary if such specifications were accepted,

1 *pursuant to applicable law, by the biomate-*
2 *rials supplier; and*

3 *(2) such conduct was an actual and proximate*
4 *cause of the harm to the claimant.*

5 **SEC. 6. PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS**
6 **AGAINST BIOMATERIALS SUPPLIERS.**

7 *(a) MOTION TO DISMISS.—In any action that is sub-*
8 *ject to this Act, a biomaterials supplier who is a defendant*
9 *in such action may, at any time during which a motion*
10 *to dismiss may be filed under an applicable law, move to*
11 *dismiss the action against it on the grounds that—*

12 *(1) the defendant is a biomaterials supplier; and*

13 *(2)(A) the defendant should not, for the purposes*
14 *of—*

15 *(i) section 5(b), be considered to be a manu-*
16 *facturer of the implant that is subject to such*
17 *section; or*

18 *(ii) section 5(c), be considered to be a seller*
19 *of the implant that allegedly caused harm to the*
20 *claimant; or*

21 *(B)(i) the claimant has failed to establish, pur-*
22 *suant to section 5(d), that the supplier furnished raw*
23 *materials or component parts in violation of contrac-*
24 *tual requirements or specifications; or*

1 (ii) the claimant has failed to comply with the
2 procedural requirements of subsection (b).

3 (b) *MANUFACTURER OF IMPLANT SHALL BE NAMED*
4 *A PARTY.*—The claimant shall be required to name the
5 manufacturer of the implant as a party to the action, un-
6 less—

7 (1) the manufacturer is subject to service of proc-
8 ess solely in a jurisdiction in which the biomaterials
9 supplier is not domiciled or subject to a service of
10 process; or

11 (2) a claim against the manufacturer is barred
12 by applicable law or rule of practice.

13 (c) *PROCEEDING ON MOTION TO DISMISS.*—The fol-
14 lowing rules shall apply to any proceeding on a motion to
15 dismiss filed under this section:

16 (1) *AFFIDAVITS RELATING TO LISTING AND DEC-*
17 *LARATIONS.*—

18 (A) *IN GENERAL.*—The defendant in the ac-
19 tion may submit an affidavit demonstrating that
20 defendant has not included the implant on a list,
21 if any, filed with Secretary pursuant to section
22 510(j) of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 360(j)).

1 (B) *RESPONSE TO MOTION TO DISMISS.*—In
2 response to the motion to dismiss, the claimant
3 may submit an affidavit demonstrating that—

4 (i) the Secretary has, with respect to
5 the defendant and the implant that alleg-
6 edly caused harm to the claimant, issued a
7 declaration pursuant to section 5(b)(2)(B);
8 or

9 (ii) the defendant who filed the motion
10 to dismiss is a seller of the implant who is
11 liable under section 5(c).

12 (2) *EFFECT OF MOTION TO DISMISS ON DISCOV-*
13 *ERY.*—

14 (A) *IN GENERAL.*—If a defendant files a
15 motion to dismiss under paragraph (1) or (2) of
16 subsection (a), no discovery shall be permitted in
17 connection to the action that is the subject of the
18 motion, other than discovery necessary to deter-
19 mine a motion to dismiss for lack of jurisdiction,
20 until such time as the court rules on the motion
21 to dismiss in accordance with the affidavits sub-
22 mitted by the parties in accordance with this
23 section.

24 (B) *DISCOVERY.*—If a defendant files a mo-
25 tion to dismiss under subsection (a)(2)(B)(i) on

1 the grounds that the biomaterials supplier did
2 not furnish raw materials or component parts in
3 violation of contractual requirements or speci-
4 fications, the court may permit discovery, as or-
5 dered by the court. The discovery conducted pur-
6 suant to this subparagraph shall be limited to
7 issues that are directly relevant to—

8 (i) the pending motion to dismiss; or

9 (ii) the jurisdiction of the court.

10 (3) *AFFIDAVITS RELATING TO STATUS OF DE-*
11 *FENDANT.*—

12 (A) *IN GENERAL.*—*Except as provided in*
13 *clauses (i) and (ii) of subparagraph (B), the*
14 *court shall consider a defendant to be a biomate-*
15 *rials supplier who is not subject to an action for*
16 *harm to a claimant caused by an implant, other*
17 *than an action relating to liability for a viola-*
18 *tion of contractual requirements or specifications*
19 *described in section 5(d).*

20 (B) *RESPONSES TO MOTION TO DISMISS.*—
21 *The court shall grant a motion to dismiss any*
22 *action that asserts liability of the defendant*
23 *under subsection (b) or (c) of section 5 on the*
24 *grounds that the defendant is not a manufac-*
25 *turer subject to such section 5(b) or seller subject*

1 to section 5(c), unless the claimant submits a
2 valid affidavit that demonstrates that—

3 (i) with respect to a motion to dismiss
4 contending the defendant is not a manufac-
5 turer, the defendant meets the applicable re-
6 quirements for liability as a manufacturer
7 under section 5(b); or

8 (ii) with respect to a motion to dismiss
9 contending that the defendant is not a sell-
10 er, the defendant meets the applicable re-
11 quirements for liability as a seller under
12 section 5(c).

13 (4) BASIS OF RULING ON MOTION TO DISMISS.—

14 (A) IN GENERAL.—The court shall rule on
15 a motion to dismiss filed under subsection (a)
16 solely on the basis of the pleadings of the parties
17 made pursuant to this section and any affidavits
18 submitted by the parties pursuant to this section.

19 (B) MOTION FOR SUMMARY JUDGMENT.—
20 Notwithstanding any other provision of law, if
21 the court determines that the pleadings and affi-
22 davits made by parties pursuant to this section
23 raise genuine issues as concerning material facts
24 with respect to a motion concerning contractual
25 requirements and specifications, the court may

1 *deem the motion to dismiss to be a motion for*
2 *summary judgment made pursuant to subsection*
3 *(d).*

4 *(d) SUMMARY JUDGMENT.—*

5 *(1) IN GENERAL.—*

6 *(A) BASIS FOR ENTRY OF JUDGMENT.—A*
7 *biomaterials supplier shall be entitled to entry of*
8 *judgment without trial if the court finds there is*
9 *no genuine issue as concerning any material fact*
10 *for each applicable element set forth in para-*
11 *graphs (1) and (2) of section 5(d).*

12 *(B) ISSUES OF MATERIAL FACT.—With re-*
13 *spect to a finding made under subparagraph (A),*
14 *the court shall consider a genuine issue of mate-*
15 *rial fact to exist only if the evidence submitted*
16 *by claimant would be sufficient to allow a rea-*
17 *sonable jury to reach a verdict for the claimant*
18 *if the jury found the evidence to be credible.*

19 *(2) DISCOVERY MADE PRIOR TO A RULING ON A*
20 *MOTION FOR SUMMARY JUDGMENT.—If, under appli-*
21 *cable rules, the court permits discovery prior to a rul-*
22 *ing on a motion for summary judgment made pursu-*
23 *ant to this subsection, such discovery shall be limited*
24 *solely to establishing whether a genuine issue of mate-*

1 *rial fact exists as to the applicable elements set forth*
2 *in paragraphs (1) and (2) of section 5(d).*

3 (3) *DISCOVERY WITH RESPECT TO A BIOMATE-*
4 *RIALS SUPPLIER.—A biomaterials supplier shall be*
5 *subject to discovery in connection with a motion seek-*
6 *ing dismissal or summary judgment on the basis of*
7 *the inapplicability of section 5(d) or the failure to es-*
8 *tablish the applicable elements of section 5(d) solely*
9 *to the extent permitted by the applicable Federal or*
10 *State rules for discovery against nonparties.*

11 (e) *STAY PENDING PETITION FOR DECLARATION.—If*
12 *a claimant has filed a petition for a declaration pursuant*
13 *to section 5(b)(3)(A) with respect to a defendant, and the*
14 *Secretary has not issued a final decision on the petition,*
15 *the court shall stay all proceedings with respect to that de-*
16 *fendant until such time as the Secretary has issued a final*
17 *decision on the petition. The Secretary shall complete re-*
18 *view of any such petition within 6 weeks of receipt of the*
19 *petition.*

20 (f) *DISMISSAL WITH PREJUDICE.—An order granting*
21 *a motion to dismiss or for summary judgment pursuant*
22 *to this section shall be entered with prejudice, except insofar*
23 *as the moving defendant may be rejoined to the action as*
24 *provided in section 7.*

1 (g) *MANUFACTURER CONDUCT OF LITIGATION.*—The
2 *manufacturer of an implant that is the subject of an action*
3 *covered under this Act shall be permitted to conduct litiga-*
4 *tion on any motion for summary judgment or dismissal*
5 *filed by a biomaterials supplier who is a defendant under*
6 *this section on behalf of such supplier if the manufacturer*
7 *and any other defendant in such action enter into a valid*
8 *and applicable contractual agreement under which the*
9 *manufacturer agrees to bear the cost of such litigation or*
10 *to conduct such litigation.*

11 **SEC. 7. SUBSEQUENT IMPLAIDER OF DISMISSED DEFEND-**
12 **ANT.**

13 (a) *IMPLEADING OF DISMISSED DEFENDANT.*—A
14 *court, upon motion by a manufacturer or a claimant with-*
15 *in 90 days after entry of a final judgment in an action*
16 *by the claimant against a manufacturer, and notwithstand-*
17 *ing any otherwise applicable statute of limitations, may*
18 *implead a biomaterials supplier who has been dismissed*
19 *from the action pursuant to this Act if—*

20 (1) *the manufacturer has made an assertion, ei-*
21 *ther in a motion or other pleading filed with the*
22 *court or in an opening or closing statement at trial,*
23 *or as part of a claim for contribution or indemnifica-*
24 *tion, and the court makes a finding based on the*
25 *court's independent review of the evidence contained*

1 *in the record of the action, that under applicable*
2 *law—*

3 *(A) the negligence or intentionally tortious*
4 *conduct of the dismissed supplier was an actual*
5 *and proximate cause of the harm to the claim-*
6 *ant; and*

7 *(B) the manufacturer's liability for dam-*
8 *ages should be reduced in whole or in part be-*
9 *cause of such negligence or intentionally tortious*
10 *conduct; or*

11 *(2) the claimant has moved to implead the sup-*
12 *plier and the court makes a finding based on the*
13 *court's independent review of the evidence contained*
14 *in the record of the action, that under applicable*
15 *law—*

16 *(A) the negligence or intentionally tortious*
17 *conduct of the dismissed supplier was an actual*
18 *and proximate cause of the harm to the claim-*
19 *ant; and*

20 *(B) the claimant is unlikely to be able to re-*
21 *cover the full amount of its damages from the re-*
22 *maining defendants.*

23 *(b) STANDARD OF LIABILITY.—Notwithstanding any*
24 *preliminary finding under subsection (a), a biomaterials*

1 *supplier who has been impleaded into an action subject to*
2 *this Act, as provided for in this section—*

3 *(1) may, prior to entry of judgment on the claim*
4 *against it, supplement the record of the proceeding*
5 *that was developed prior to the grant of the motion*
6 *for impleader under subsection (a), and*

7 *(2) may be found liable to a manufacturer or a*
8 *claimant only to the extent required and permitted by*
9 *any applicable State or Federal law other than this*
10 *Act in an action alleging harm caused by an im-*
11 *plant.*

12 *(c) DISCOVERY.—Nothing in this section shall give a*
13 *claimant or any other party the right to obtain discovery*
14 *from a biomaterials supplier defendant at any time prior*
15 *to grant of a motion for impleader beyond that allowed*
16 *under section 6.*

17 **SEC. 8. APPLICABILITY.**

18 *This Act shall apply to all civil actions covered under*
19 *this Act that are commenced on or after the date of enact-*
20 *ment of this Act, including any such action with respect*
21 *to which the harm asserted in the action or the conduct*
22 *that caused the harm occurred before the date of enactment*
23 *of this Act.*

1 SECTION 1. SHORT TITLE.

2 **This Act may be cited as the “Biomaterials**
3 **Access Assurance Act of 1998”.**

4 SEC. 2. FINDINGS.

5 **The Congress finds that—**

6 (1) each year millions of citizens of
7 the United States depend on the avail-
8 ability of lifesaving or life-enhancing
9 medical devices, many of which are per-
10 manently implantable within the human
11 body;

12 (2) a continued supply of raw mate-
13 rials and component parts is necessary
14 for the invention, development, improve-
15 ment, and maintenance of the supply of
16 the devices;

17 (3) most of the medical devices are
18 made with raw materials and component
19 parts that—

20 (A) move in interstate commerce;

21 (B) are not designed or manufac-
22 tured specifically for use in medical
23 devices; and

24 (C) come in contact with internal
25 human tissue;

1 **(4) the raw materials and component**
2 **parts also are used in a variety of non-**
3 **medical products;**

4 **(5) because small quantities of the**
5 **raw materials and component parts are**
6 **used for medical devices, sales of raw ma-**
7 **terials and component parts for medical**
8 **devices constitute an extremely small**
9 **portion of the overall market for the raw**
10 **materials and component parts;**

11 **(6) under the Federal Food, Drug, and**
12 **Cosmetic Act (21 U.S.C. 301 et seq.) manu-**
13 **facturers of medical devices are required**
14 **to demonstrate that the medical devices**
15 **are safe and effective, including dem-**
16 **onstrating that the products are properly**
17 **designed and have adequate warnings or**
18 **instructions;**

19 **(7) notwithstanding the fact that raw**
20 **materials and component parts suppliers**
21 **do not design, produce, or test a final**
22 **medical device, the suppliers have been**
23 **the subject of actions alleging inad-**
24 **equat—**

1 **(A) design and testing of medical**
2 **devices manufactured with materials**
3 **or parts supplied by the suppliers; or**

4 **(B) warnings related to the use of**
5 **such medical devices;**

6 **(8) even though suppliers of raw ma-**
7 **terials and component parts have very**
8 **rarely been held liable in such actions,**
9 **such suppliers have ceased supplying cer-**
10 **tain raw materials and component parts**
11 **for use in medical devices for a number**
12 **of reasons, including concerns about the**
13 **costs of such litigation;**

14 **(9) unless alternate sources of supply**
15 **can be found, the unavailability of raw**
16 **materials and component parts for medi-**
17 **cal devices will lead to unavailability of**
18 **lifesaving and life-enhancing medical de-**
19 **vices;**

20 **(10) because other suppliers of the**
21 **raw materials and component parts in**
22 **foreign nations are refusing to sell raw**
23 **materials or component parts for use in**
24 **manufacturing certain medical devices in**
25 **the United States, the prospects for de-**

1 **velopment of new sources of supply for**
2 **the full range of threatened raw mate-**
3 **rials and component parts for medical de-**
4 **vices are remote;**

5 **(11) it is unlikely that the small mar-**
6 **ket for such raw materials and compo-**
7 **nent parts in the United States could sup-**
8 **port the large investment needed to de-**
9 **velop new suppliers of such raw mate-**
10 **rials and component parts;**

11 **(12) attempts to develop such new**
12 **suppliers would raise the cost of medical**
13 **devices;**

14 **(13) courts that have considered the**
15 **duties of the suppliers of the raw mate-**
16 **rials and component parts have generally**
17 **found that the suppliers do not have a**
18 **duty—**

19 **(A) to evaluate the safety and effi-**
20 **cacy of the use of a raw material or**
21 **component part in a medical device;**
22 **or**

23 **(B) to warn consumers concern-**
24 **ing the safety and effectiveness of a**
25 **medical device;**

1 **(14) because medical devices and the**
2 **raw materials and component parts used**
3 **in their manufacture move in interstate**
4 **commerce, a shortage of such raw mate-**
5 **rials and component parts affects inter-**
6 **state commerce;**

7 **(15) in order to safeguard the avail-**
8 **ability of a wide variety of lifesaving and**
9 **life-enhancing medical devices, imme-**
10 **diat e action is needed—**

11 **(A) to clarify the permissible**
12 **bases of liability for suppliers of raw**
13 **materials and component parts for**
14 **medical devices; and**

15 **(B) to provide expeditious proce-**
16 **dures to dispose of unwarranted suits**
17 **against the suppliers in such manner**
18 **as to minimize litigation costs;**

19 **(16) the several States and their**
20 **courts are the primary architects and**
21 **regulators of our tort system; Congress,**
22 **however, must, in certain circumstances**
23 **involving the national interest, address**
24 **tort issues, and a threatened shortage of**
25 **raw materials and component parts for**

1 **life-saving medical devices is one such**
2 **circumstance; and**

3 **(17) the protections set forth in this**
4 **Act are needed to assure the continued**
5 **supply of materials for life-saving medi-**
6 **cal devices, although such protections do**
7 **not protect negligent suppliers.**

8 **SEC. 3. DEFINITIONS.**

9 **As used in this Act:**

10 **(1) BIOMATERIALS SUPPLIER.—**

11 **(A) IN GENERAL.—The term “bio-**
12 **materials supplier” means an entity**
13 **that directly or indirectly supplies a**
14 **component part or raw material for**
15 **use in the manufacture of an implant**

16 **(B) PERSONS INCLUDED.—Such**
17 **term includes any person who—**

18 **(i) has submitted master files**
19 **to the Secretary for purposes of**
20 **premarket approval of a medical**
21 **device; or**

22 **(ii) licenses a biomaterials**
23 **supplier to produce component**
24 **parts or raw materials.**

25 **(2) CLAIMANT.—**

1 **(A) IN GENERAL.—**The term “claim-
2 **ant”** means any person who brings a
3 **civil action, or on whose behalf a civil**
4 **action is brought, arising from harm**
5 **allegedly caused directly or indirectly**
6 **by an implant, including a person**
7 **other than the individual into whose**
8 **body, or in contact with whose blood**
9 **or tissue, the implant is placed, who**
10 **claims to have suffered harm as a re-**
11 **sult of the implant.**

12 **(B) ACTION BROUGHT ON BEHALF OF**
13 **AN ESTATE.—**With respect to an action
14 **brought on behalf of or through the**
15 **estate of a deceased individual into**
16 **whose body, or in contact with whose**
17 **blood or tissue the implant was**
18 **placed, such term includes the dece-**
19 **dent that is the subject of the action.**

20 **(C) ACTION BROUGHT ON BEHALF OF**
21 **A MINOR OR INCOMPETENT.—**With re-
22 **spect to an action brought on behalf**
23 **of or through a minor or incom-**
24 **petent, such term includes the parent**

1 or guardian of the minor or incom-
2 petent.

3 (D) EXCLUSIONS.—Such term does
4 not include—

5 (i) a provider of professional
6 health care services in any case
7 in which—

8 (I) the sale or use of an
9 implant is incidental to such
10 services; and

11 (II) the essence of the pro-
12 fessional health care services
13 provided is the furnishing of
14 judgment, skill, or services;

15 (ii) a person acting in the ca-
16 pacity of a manufacturer, seller,
17 or biomaterials supplier; or

18 (iii) a person alleging harm
19 caused by either the silicone gel,
20 or the silicone envelope, utilized
21 in a breast implant containing sil-
22 icone gel, except that—

23 (I) neither the exclusion
24 provided by this clause nor
25 any other provision of this

1 **Act may be construed as a**
2 **finding that silicone gel (or**
3 **any other form of silicone)**
4 **may or may not cause harm;**
5 **and**

6 **(II) the existence of the**
7 **exclusion under this clause**
8 **may not—**

9 **(aa) be disclosed to a**
10 **jury in any civil action or**
11 **other proceeding, and**

12 **(bb) except as nec-**
13 **essary to establish the ap-**
14 **plicability of this Act, oth-**
15 **erwise be presented in**
16 **any civil action or other**
17 **proceeding.**

18 **(3) COMPONENT PART.—**

19 **(A) IN GENERAL.—The term “com-**
20 **ponent part” means a manufactured**
21 **piece of an implant.**

22 **(B) CERTAIN COMPONENTS.—Such**
23 **term includes a manufactured piece**
24 **of an implant that—**

1 **(i) has significant non-implant**
2 **applications; and**

3 **(ii) alone, has no implant**
4 **value or purpose, but when com-**
5 **bined with other component parts**
6 **and materials, constitutes an im-**
7 **plant.**

8 **(4) HARM.—**

9 **(A) IN GENERAL.—The term “harm”**
10 **means—**

11 **(i) any injury to or damage**
12 **suffered by an individual;**

13 **(ii) any illness, disease, or**
14 **death of that individual resulting**
15 **from that injury or damage; and**

16 **(iii) any loss to that individual**
17 **or any other individual resulting**
18 **from that injury or damage.**

19 **(B) EXCLUSION.—The term does**
20 **not include any commercial loss or**
21 **loss of or damage to an implant.**

22 **(5) IMPLANT.—The term “implant”**
23 **means—**

1 **(A) a medical device that is in-**
2 **tended by the manufacturer of the de-**
3 **vice—**

4 **(i) to be placed into a sur-**
5 **gically or naturally formed or ex-**
6 **isting cavity of the body for a pe-**
7 **riod of at least 30 days; or**

8 **(ii) to remain in contact with**
9 **bodily fluids or internal human**
10 **tissue through a surgically pro-**
11 **duced opening for a period of less**
12 **than 30 days; and**

13 **(B) suture materials used in im-**
14 **plant procedures.**

15 **(6) MANUFACTURER.—The term “manu-**
16 **facturer” means any person who, with re-**
17 **spect to an implant—**

18 **(A) is engaged in the manufac-**
19 **ture, preparation, propagation,**
20 **compounding, or processing (as de-**
21 **defined in section 510(a)(1) of the Fed-**
22 **eral Food, Drug, and Cosmetic Act (21**
23 **U.S.C. 360(a)(1)) of the implant; and**

24 **(B) is required—**

1 **(i) to register with the Sec-**
2 **retary pursuant to section 510 of**
3 **the Federal Food, Drug, and Cos-**
4 **metic Act (21 U.S.C. 360) and the**
5 **regulations issued under such**
6 **section; and**

7 **(ii) to include the implant on**
8 **a list of devices filed with the Sec-**
9 **retary pursuant to section 510(j)**
10 **of such Act (21 U.S.C. 360(j)) and**
11 **the regulations issued under such**
12 **section.**

13 **(7) MEDICAL DEVICE.—The term “medi-**
14 **cal device” means a device, as defined in**
15 **section 201(h) of the Federal Food, Drug,**
16 **and Cosmetic Act (21 U.S.C. 321(h)), and**
17 **includes any device component of any**
18 **combination product as that term is used**
19 **in section 503(g) of such Act (21 U.S.C.**
20 **353(g)).**

21 **(8) RAW MATERIAL.—The term “raw**
22 **material” means a substance or product**
23 **that—**

24 **(A) has a generic use; and**

1 **(B) may be used in an application**
2 **other than an implant.**

3 **(9) SECRETARY.—The term “Secretary”**
4 **means the Secretary of Health and**
5 **Human Services.**

6 **(10) SELLER.—**

7 **(A) IN GENERAL.—The term “seller”**
8 **means a person who, in the course of**
9 **a business conducted for that pur-**
10 **pose, sells, distributes, leases, pack-**
11 **ages, labels, or otherwise places an**
12 **implant in the stream of commerce.**

13 **(B) EXCLUSIONS.—The term does**
14 **not include—**

15 **(i) a seller or lessor of real**
16 **property;**

17 **(ii) a provider of professional**
18 **health care services where—**

19 **(I) the sale or use of the**
20 **implant is incidental to such**
21 **services; and**

22 **(II) the essence of the**
23 **health care services provided**
24 **is the furnishing of judgment,**
25 **skill, or services; or**

1 **(iii) any person who acts in**
2 **only a financial capacity with re-**
3 **spect to the sale of an implant.**

4 **SEC. 4. GENERAL REQUIREMENTS; APPLICABILITY; PRE-**
5 **EMPTION.**

6 **(a) GENERAL REQUIREMENTS.—**

7 **(1) IN GENERAL.—In any civil action**
8 **covered by this Act, a biomaterials sup-**
9 **plier may—**

10 **(A) raise any exclusion from li-**
11 **ability set forth in section 5; and**

12 **(B) make a motion for dismissal**
13 **or for summary judgment as set forth**
14 **in section 6.**

15 **(2) PROCEDURES.—Notwithstanding**
16 **any other provision of law, a Federal or**
17 **State court in which an action covered by**
18 **this Act is pending shall, in connection**
19 **with a motion under section 6 or 7, use**
20 **the procedures set forth in this Act.**

21 **(b) APPLICABILITY.—**

22 **(1) IN GENERAL.—Except as provided**
23 **in paragraph (2), this Act applies to any**
24 **civil action brought by a claimant, wheth-**
25 **er in a Federal or State court, on the**

1 basis of any legal theory, for harm alleg-
2 edly caused, directly or indirectly, by an
3 implant.

4 (2) EXCLUSION.—A civil action brought
5 by a purchaser of a medical device,
6 where such purchaser intends to use the
7 device in providing professional health
8 care services, for loss or damage to an
9 implant or for commercial loss to the pur-
10 chaser—

11 (A) shall not be considered an ac-
12 tion that is subject to this Act; and

13 (B) shall be governed by applica-
14 ble commercial or contract law.

15 (c) SCOPE OF PREEMPTION.—

16 (1) IN GENERAL.—This Act supersedes
17 any State law regarding recovery for
18 harm caused by an implant and any rule
19 of procedure applicable to a civil action
20 to recover damages for such harm only to
21 the extent that this Act establishes a rule
22 of law applicable to the recovery of such
23 damages.

24 (2) APPLICABILITY OF OTHER LAWS.—
25 Any issue that arises under this Act and

1 that is not governed by a rule of law ap-
2 plicable to the recovery of damages de-
3 scribed in paragraph (1) shall be gov-
4 erned by applicable Federal or State law.

5 **(d) STATUTORY CONSTRUCTION.**—Nothing in
6 this Act may be construed—

7 (1) to affect any defense available to a
8 defendant under any other provisions of
9 Federal or State law in an action alleging
10 harm caused by an implant; or

11 (2) to create a cause of action or Fed-
12 eral court jurisdiction pursuant to sec-
13 tion 1331 or 1337 of title 28, United States
14 Code, that otherwise would not exist
15 under applicable Federal or State law.

16 **SEC. 5. LIABILITY OF BIOMATERIALS SUPPLIERS.**

17 **(a) IN GENERAL.**—Except as provided in
18 section 7, a biomaterials supplier shall not be
19 liable for harm to a claimant caused by an im-
20 plant unless such supplier—

21 (1) is a manufacturer of the implant,
22 as provided in subsection (b);

23 (2) is a seller of the implant, as pro-
24 vided in subsection (c); or

1 **(3) furnished raw materials or compo-**
2 **nent parts for the implant that failed to**
3 **meet applicable contractual require-**
4 **ments or specifications, as provided in**
5 **subsection (d).**

6 **(b) LIABILITY AS MANUFACTURER.—**

7 **(1) IN GENERAL.—A biomaterials sup-**
8 **plier may, to the extent required and per-**
9 **mitted by any other applicable law, be**
10 **liable for harm to a claimant caused by**
11 **an implant if the biomaterials supplier is**
12 **the manufacturer of the implant.**

13 **(2) GROUNDS FOR LIABILITY.—The bio-**
14 **materials supplier may be considered the**
15 **manufacturer of the implant that alleg-**
16 **edly caused harm to a claimant only if**
17 **the biomaterials supplier—**

18 **(A)(i) has or was required to reg-**
19 **ister with the Secretary pursuant to**
20 **section 510 of the Federal Food, Drug,**
21 **and Cosmetic Act (21 U.S.C. 360) and**
22 **the regulations issued under such**
23 **section; and**

24 **(ii) included or was required to**
25 **include the implant on a list of de-**

1 vices filed with the Secretary pursu-
2 ant to section 510(j) of such Act (21
3 U.S.C. 360(j)) and the regulations
4 issued under such section;

5 (B) is the subject of a declaration
6 issued by the Secretary pursuant to
7 paragraph (3) that states that the
8 supplier, with respect to the implant
9 that allegedly caused harm to the
10 claimant, was required to—

11 (i) register with the Secretary
12 under section 510 of such Act (21
13 U.S.C. 360), and the regulations
14 issued under such section, but
15 failed to do so; or

16 (ii) include the implant on a
17 list of devices filed with the Sec-
18 retary pursuant to section 510(j)
19 of such Act (21 U.S.C. 360(j)) and
20 the regulations issued under such
21 section, but failed to do so; or

22 (C) is related by common owner-
23 ship or control to a person meeting
24 all the requirements described in sub-
25 paragraph (A) or (B), if the court de-

1 **cluding a motion to dismiss in accord-**
2 **ance with section 6(c)(3)(B)(i) finds,**
3 **on the basis of affidavits submitted in**
4 **accordance with section 6, that it is**
5 **necessary to impose liability on the**
6 **biomaterials supplier as a manufac-**
7 **turer because the related manufac-**
8 **turer meeting the requirements of**
9 **subparagraph (A) or (B) lacks suffi-**
10 **cient financial resources to satisfy**
11 **any judgment that the court feels it is**
12 **likely to enter should the claimant**
13 **prevail.**

14 **(3) ADMINISTRATIVE PROCEDURES.—**

15 **(A) IN GENERAL.—The Secretary**
16 **may issue a declaration described in**
17 **paragraph (2)(B) on the motion of the**
18 **Secretary or on petition by any per-**
19 **son, after providing—**

20 **(i) notice to the affected per-**
21 **sons; and**

22 **(ii) an opportunity for an in-**
23 **formal hearing.**

24 **(B) DOCKETING AND FINAL DECI-**
25 **SION.—Immediately upon receipt of a**

1 petition filed pursuant to this para-
2 graph, the Secretary shall docket the
3 petition. Not later than 120 days after
4 the petition is filed, the Secretary
5 shall issue a final decision on the pe-
6 tition.

7 (C) APPLICABILITY OF STATUTE OF
8 LIMITATIONS.—Any applicable statute
9 of limitations shall toll during the pe-
10 riod from the time a claimant has
11 filed a petition with the Secretary
12 under this paragraph until such time
13 as the Secretary either (i) issues a
14 final decision on the petition, or (ii)
15 the petition is withdrawn.

16 (D) STAY PENDING PETITION FOR
17 DECLARATION.—If a claimant has filed
18 a petition for a declaration with re-
19 spect to a defendant, and the Sec-
20 retary has not issued a final decision
21 on the petition, the court shall stay
22 all proceedings with respect to that
23 defendant until such time as the Sec-
24 retary has issued a final decision on
25 the petition. The Secretary shall com-

1 plete review of any such petition
2 within 120 days of receipt of the peti-
3 tion.

4 **(c) LIABILITY AS SELLER.—**A biomaterials
5 supplier may, to the extent required and per-
6 mitted by any other applicable law, be liable
7 as a seller for harm to a claimant caused by
8 an implant only if—

9 **(1) the biomaterials supplier—**

10 **(A) held title to the implant and**
11 **then acted as a seller of the implant**
12 **after its initial sale by the manufac-**
13 **turer; or**

14 **(B) acted under contract as a sell-**
15 **er to arrange for the transfer of the**
16 **implant directly to the claimant after**
17 **the initial sale by the manufacturer**
18 **of the implant; or**

19 **(2) the biomaterials supplier is relat-**
20 **ed by common ownership or control to a**
21 **person meeting all the requirements de-**
22 **scribed in paragraph (1), if a court decid-**
23 **ing a motion to dismiss in accordance**
24 **with section 6(c)(3)(B)(ii) finds, on the**
25 **basis of affidavits submitted in accord-**

1 **ance with section 6, that it is necessary to**
2 **impose liability on the biomaterials sup-**
3 **plier as a seller because the related seller**
4 **meeting the requirements of paragraph**
5 **(1) lacks sufficient financial resources to**
6 **satisfy any judgment that the court feels**
7 **it is likely to enter should the claimant**
8 **prevail.**

9 **(d) LIABILITY FOR FAILURE TO MEET APPLI-**
10 **CABLE CONTRACTUAL REQUIREMENTS OR SPECI-**
11 **FICATIONS.—A biomaterials supplier may, to**
12 **the extent required and permitted by any**
13 **other applicable law, be liable for harm to a**
14 **claimant caused by an implant if the claimant**
15 **in an action shows, by a preponderance of the**
16 **evidence, that—**

17 **(1) the biomaterials supplier supplied**
18 **raw materials or component parts for use**
19 **in the implant that either—**

20 **(A) did not constitute the product**
21 **described in the contract between the**
22 **biomaterials supplier and the person**
23 **who contracted for the supplying of**
24 **the product; or**

1 **(B) failed to meet any specifica-**
2 **tions that were—**

3 **(i) accepted, pursuant to ap-**
4 **plicable law, by the biomaterials**
5 **supplier;**

6 **(ii) published by the biomate-**
7 **rials supplier;**

8 **(iii) provided by the biomate-**
9 **rials supplier to the person who**
10 **contracted for such product;**

11 **(iv) contained in a master file**
12 **that was submitted by the bio-**
13 **materials supplier to the Sec-**
14 **retary and that is currently main-**
15 **tained by the biomaterials sup-**
16 **plier for purposes of premarket**
17 **approval of medical devices; or**

18 **(v) included in the submis-**
19 **sions for purposes of premarket**
20 **approval or review by the Sec-**
21 **retary under section 510, 513, 515,**
22 **or 520 of the Federal Food, Drug,**
23 **and Cosmetic Act (21 U.S.C. 360,**
24 **360c, 360e, or 360j), and received**
25 **clearance from the Secretary if**

1 such specifications were accept-
2 ed, pursuant to applicable law, by
3 the biomaterials supplier; and

4 (2) such failure to meet applicable
5 contractual requirements or specifica-
6 tions was an actual and proximate cause
7 of the harm to the claimant.

8 **SEC. 6. PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS**
9 **AGAINST BIOMATERIALS SUPPLIERS.**

10 **(a) MOTION TO DISMISS.—A defendant may,**
11 **at any time during which a motion to dismiss**
12 **may be filed under applicable law, move to**
13 **dismiss an action against it on the grounds**
14 **that the defendant is a biomaterials supplier**
15 **and one or more of the following:**

16 (1) The defendant is not liable as a
17 manufacturer, as provided in section 5(b).

18 (2) The defendant is not liable as a
19 seller, as provided in section 5(c).

20 (3) The defendant is not liable for fur-
21 nishing raw materials or component
22 parts for the implant that failed to meet
23 applicable contractual requirements or
24 specifications, as provided in section 5(d).

1 **(4) The claimant did not name the**
2 **manufacturer as a party to the action, as**
3 **provided in subsection (b).**

4 **(b) MANUFACTURER OF IMPLANT SHALL BE**
5 **NAMED A PARTY.—The claimant in an action**
6 **brought for harm caused by an implant shall**
7 **be required to name the manufacturer of the**
8 **implant as a party to the action, unless—**

9 **(1) the manufacturer is subject to**
10 **service of process solely in a jurisdiction**
11 **in which the biomaterials supplier is not**
12 **domiciled or subject to a service of proc-**
13 **ess; or**

14 **(2) a claim against the manufacturer**
15 **is barred by applicable law or rule of**
16 **practice.**

17 **(c) PROCEEDING ON MOTION TO DISMISS.—**
18 **The following rules shall apply to any pro-**
19 **ceeding on a motion to dismiss filed by a de-**
20 **fendant under this section:**

21 **(1) EFFECT OF MOTION TO DISMISS ON**
22 **DISCOVERY.—**

23 **(A) IN GENERAL.—Except as pro-**
24 **vided in subparagraph (B), if a de-**
25 **fendant files a motion to dismiss**

1 under subsection (a), no discovery
2 shall be permitted in connection to
3 the action that is the subject of the
4 motion, other than discovery nec-
5 essary to determine a motion to dis-
6 miss for lack of jurisdiction, until
7 such time as the court rules on the
8 motion to dismiss.

9 (B) DISCOVERY.—If a defendant
10 files a motion to dismiss under sub-
11 section (a)(3) on the grounds that the
12 biomaterials supplier did not furnish
13 raw materials or component parts for
14 the implant that failed to meet appli-
15 cable contractual requirements or
16 specifications, the court may permit
17 discovery limited to issues that are
18 directly relevant to—

19 (i) the pending motion to dis-
20 miss; or

21 (ii) the jurisdiction of the
22 court.

23 (2) AFFIDAVITS.—

24 (A) DEFENDANT.—A defendant may
25 submit affidavits supporting the

1 grounds for dismissal contained in its
2 motion to dismiss under subsection
3 (a). If the motion is made under sub-
4 section (a)(1), the defendant may sub-
5 mit an affidavit demonstrating that
6 the defendant has not included the
7 implant on a list, if any, filed with the
8 Secretary pursuant to section 510(j)
9 of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 360(j)).

11 (B) CLAIMANT.—In response to a
12 motion to dismiss, the claimant may
13 submit affidavits demonstrating
14 that—

15 (i) the Secretary has, with re-
16 spect to the defendant and the
17 implant that allegedly caused
18 harm to the claimant, issued a
19 declaration pursuant to section
20 5(b)(2)(B); or

21 (ii) the defendant is a seller of
22 the implant who is liable under
23 section 5(c).

24 (3) BASIS OF RULING ON MOTION TO DIS-
25 MISS.—The court shall rule on a motion to

1 **dismiss filed under subsection (a) solely**
2 **on the basis of the pleadings and affida-**
3 **vits of the parties made pursuant to this**
4 **subsection. The court shall grant a mo-**
5 **tion to dismiss filed under subsection**
6 **(a)—**

7 **(A) unless the claimant submits a**
8 **valid affidavit that demonstrates that**
9 **the defendant is not a biomaterials**
10 **supplier;**

11 **(B) unless the court determines,**
12 **to the extent raised in the pleadings**
13 **and affidavits, that one or more of the**
14 **following apply:**

15 **(i) the defendant may be lia-**
16 **ble as a manufacturer, as pro-**
17 **vided in section 5(b);**

18 **(ii) the defendant may be lia-**
19 **ble as a seller, as provided in sec-**
20 **tion 5(c); or**

21 **(iii) the defendant may be lia-**
22 **ble for furnishing raw materials**
23 **or component parts for the im-**
24 **plant that failed to meet applica-**
25 **ble contractual requirements or**

1 specifications, as provided in sec-
2 tion 5(d); or

3 (C) if the claimant did not name
4 the manufacturer as a party to the ac-
5 tion, as provided in subsection (b).

6 (4) TREATMENT OF MOTION AS MOTION
7 FOR SUMMARY JUDGMENT.—The court may
8 deem a motion to dismiss as a motion for
9 summary judgment subject to subsection
10 (d) in order to determine whether the
11 pleadings and affidavits, in connection
12 with such action, raise genuine issues of
13 material fact concerning whether the de-
14 fendant furnished raw materials or com-
15 ponent parts of the implant that failed to
16 meet applicable contractual require-
17 ments or specifications as provided in
18 section 5(d).

19 (d) SUMMARY JUDGMENT.—

20 (1) IN GENERAL.—

21 (A) BASIS FOR ENTRY OF JUDG-
22 MENT.—If a motion to dismiss of a bio-
23 materials supplier is to be treated as
24 a motion for summary judgment
25 under subsection (c)(4) or if a bio-

1 materials supplier moves for sum-
2 mary judgment, the biomaterials sup-
3 plier shall be entitled to entry of
4 judgment without trial if the court
5 finds there is no genuine issue of ma-
6 terial fact for each applicable element
7 set forth in paragraphs (1) and (2) of
8 section 5(d).

9 (B) ISSUES OF MATERIAL FACT.—

10 With respect to a finding made under
11 subparagraph (A), the court shall con-
12 sider a genuine issue of material fact
13 to exist only if the evidence submit-
14 ted by claimant would be sufficient to
15 allow a reasonable jury to reach a
16 verdict for the claimant if the jury
17 found the evidence to be credible.

18 (2) DISCOVERY MADE PRIOR TO A RULING
19 ON A MOTION FOR SUMMARY JUDGMENT.—If,
20 under applicable rules, the court permits
21 discovery prior to a ruling on a motion
22 for summary judgment governed by sec-
23 tion 5(d), such discovery shall be limited
24 solely to establishing whether a genuine
25 issue of material fact exists as to the ap-

1 **plicable elements set forth in paragraphs**
2 **(1) and (2) of section 5(d).**

3 **(3) DISCOVERY WITH RESPECT TO A BIO-**
4 **MATERIALS SUPPLIER.—A biomaterials sup-**
5 **plier shall be subject to discovery in con-**
6 **nection with a motion seeking dismissal**
7 **or summary judgment on the basis of the**
8 **inapplicability of section 5(d) or the fail-**
9 **ure to establish the applicable elements**
10 **of section 5(d) solely to the extent per-**
11 **mitted by the applicable Federal or State**
12 **rules for discovery against nonparties.**

13 **(e) DISMISSAL WITH PREJUDICE.—Except as**
14 **provided in section 7, an order granting a mo-**
15 **tion to dismiss or for summary judgment pur-**
16 **suant to this section shall be entered with**
17 **prejudice.**

18 **(f) MANUFACTURER CONDUCT OF LITIGA-**
19 **TION.—The manufacturer of an implant that is**
20 **the subject of an action covered under this**
21 **Act shall be permitted to conduct litigation on**
22 **any motion for summary judgment or dismis-**
23 **sal filed by a biomaterials supplier who is a**
24 **defendant under this section on behalf of**
25 **such supplier if the manufacturer and any**

1 other defendant in such action enter into a
2 valid and applicable contractual agreement
3 under which the manufacturer agrees to bear
4 the cost of such litigation or to conduct such
5 litigation.

6 SEC. 7. SUBSEQUENT IMPLAID OF DISMISSED BIOMATE-
7 RIALS SUPPLIER.

8 (a) IMPLAIDING OF DISMISSED DEFENDANT.—
9 A court, upon motion by a manufacturer or a
10 claimant within 90 days after entry of a final
11 judgment in an action by the claimant against
12 a manufacturer, and notwithstanding any
13 otherwise applicable statute of limitations,
14 may implead a biomaterials supplier who has
15 been dismissed from the action pursuant to
16 this Act if—

17 (1) the manufacturer has made an as-
18 sertion, either in a motion or other plead-
19 ing filed with the court or in an opening
20 or closing statement at trial, or as part of
21 a claim for contribution or indemnifica-
22 tion, and the court finds based on the
23 court's independent review of the evi-
24 dence contained in the record of the ac-
25 tion, that under applicable law—

1 **(A) the negligence or inten-**
2 **tionally tortious conduct of the dis-**
3 **missed supplier was an actual and**
4 **proximate cause of the harm to the**
5 **claimant; and**

6 **(B) the manufacturer's liability**
7 **for damages should be reduced in**
8 **whole or in part because of such neg-**
9 **ligence or intentionally tortious con-**
10 **duct; or**

11 **(2) the claimant has moved to im-**
12 **plead the supplier and the court makes a**
13 **finding based on the court's independent**
14 **review of the evidence contained in the**
15 **record of the action, that under applica-**
16 **ble law—**

17 **(A) the negligence or inten-**
18 **tionally tortious conduct of the dis-**
19 **missed supplier was an actual and**
20 **proximate cause of the harm to the**
21 **claimant; and**

22 **(B) the claimant is unlikely to be**
23 **able to recover the full amount of its**
24 **damages from the remaining defend-**
25 **ants.**

1 **(b) STANDARD OF LIABILITY.—Notwith-**
2 **standing any preliminary finding under sub-**
3 **section (a), a biomaterials supplier who has**
4 **been impleaded into an action subject to this**
5 **Act, as provided for in this section—**

6 **(1) may, prior to entry of judgment on**
7 **the claim against it, supplement the**
8 **record of the proceeding that was devel-**
9 **oped prior to the grant of the motion for**
10 **impleader under subsection (a), and**

11 **(2) may be found liable to a manufac-**
12 **turer or a claimant only to the extent re-**
13 **quired and permitted by any applicable**
14 **State or Federal law other than this Act.**

15 **(c) DISCOVERY.—Nothing in this section**
16 **shall give a claimant or any other party the**
17 **right to obtain discovery from a biomaterials**
18 **supplier at any time prior to grant of a motion**
19 **for impleader beyond that allowed under sec-**
20 **tion 6.**

21 **SEC. 8. EFFECTIVE DATE.**

22 **This Act shall apply to all civil actions**
23 **covered under this Act that are commenced**
24 **on or after the date of enactment of this Act,**
25 **including any such action with respect to**

1 which the harm asserted in the action or the
2 conduct that caused the harm occurred be-
3 fore the date of enactment of this Act.

Union Calendar No. 349

105TH CONGRESS
2^D SESSION

H. R. 872

[Report No. 105-549, Parts I and II]

A BILL

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

Reported from the Committee on Commerce with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed