

105TH CONGRESS
1ST SESSION

S. 364

To provide legal standards and procedures for suppliers of raw materials
and component parts for medical devices.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 26, 1997

Mr. LIEBERMAN (for himself, Mr. MCCAIN, Mr. LOTT, Mr. ASHCROFT, Mr. GORTON, Mrs. FEINSTEIN, Mr. GREGG, and Mr. FRIST) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

A BILL

To provide legal standards and procedures for suppliers of
raw materials and component parts for medical devices.

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 1997”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

8 (1) each year millions of citizens of the United
9 States depend on the availability of lifesaving or life

1 enhancing medical devices, many of which are per-
2 manently implantable within the human body;

3 (2) a continued supply of raw materials and
4 component parts is necessary for the invention, de-
5 velopment, improvement, and maintenance of the
6 supply of the devices;

7 (3) most of the medical devices are made with
8 raw materials and component parts that—

9 (A) are not designed or manufactured spe-
10 cifically for use in medical devices; and

11 (B) come in contact with internal human
12 tissue;

13 (4) the raw materials and component parts also
14 are used in a variety of nonmedical products;

15 (5) because small quantities of the raw mate-
16 rials and component parts are used for medical de-
17 vices, sales of raw materials and component parts
18 for medical devices constitute an extremely small
19 portion of the overall market for the raw materials
20 and medical devices;

21 (6) under the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 301 et seq.), manufacturers of
23 medical devices are required to demonstrate that the
24 medical devices are safe and effective, including

1 demonstrating that the products are properly de-
2 signed and have adequate warnings or instructions;

3 (7) notwithstanding the fact that raw materials
4 and component parts suppliers do not design,
5 produce, or test a final medical device, the suppliers
6 have been the subject of actions alleging inad-
7 equate—

8 (A) design and testing of medical devices
9 manufactured with materials or parts supplied
10 by the suppliers; or

11 (B) warnings related to the use of such
12 medical devices;

13 (8) even though suppliers of raw materials and
14 component parts have very rarely been held liable in
15 such actions, such suppliers have ceased supplying
16 certain raw materials and component parts for use
17 in medical devices because the costs associated with
18 litigation in order to ensure a favorable judgment for
19 the suppliers far exceeds the total potential sales
20 revenues from sales by such suppliers to the medical
21 device industry;

1 (9) unless alternate sources of supply can be
2 found, the unavailability of raw materials and com-
3 ponent parts for medical devices will lead to unavail-
4 ability of lifesaving and life-enhancing medical de-
5 vices;

6 (10) because other suppliers of the raw mate-
7 rials and component parts in foreign nations are re-
8 fusing to sell raw materials or component parts for
9 use in manufacturing certain medical devices in the
10 United States, the prospects for development of new
11 sources of supply for the full range of threatened
12 raw materials and component parts for medical de-
13 vices are remote;

14 (11) it is unlikely that the small market for
15 such raw materials and component parts in the
16 United States could support the large investment
17 needed to develop new suppliers of such raw mate-
18 rials and component parts;

19 (12) attempts to develop such new suppliers
20 would raise the cost of medical devices;

21 (13) courts that have considered the duties of
22 the suppliers of the raw materials and component
23 parts have generally found that the suppliers do not
24 have a duty—

1 (A) to evaluate the safety and efficacy of
2 the use of a raw material or component part in
3 a medical device; and

4 (B) to warn consumers concerning the
5 safety and effectiveness of a medical device;

6 (14) attempts to impose the duties referred to
7 in subparagraphs (A) and (B) of paragraph (13) on
8 suppliers of the raw materials and component parts
9 would cause more harm than good by driving the
10 suppliers to cease supplying manufacturers of medi-
11 cal devices; and

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

15 (A) to clarify the permissible bases of li-
16 ability for suppliers of raw materials and com-
17 ponent parts for medical devices; and

18 (B) to provide expeditious procedures to
19 dispose of unwarranted suits against the suppli-
20 ers in such manner as to minimize litigation
21 costs.

22 **SEC. 3. DEFINITIONS.**

23 As used in this Act:

24 (1) **BIOMATERIALS SUPPLIER.**—

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

5 (B) PERSONS INCLUDED.—Such term in-
6 cludes any person who—

7 (i) has submitted master files to the
8 Secretary for purposes of premarket ap-
9 proval of a medical device; or

10 (ii) licenses a biomaterials supplier to
11 produce component parts or raw materials.

12 (2) CLAIMANT.—

13 (A) IN GENERAL.—The term “claimant”
14 means any person who brings a civil action, or
15 on whose behalf a civil action is brought, aris-
16 ing from harm allegedly caused directly or indi-
17 rectly by an implant, including a person other
18 than the individual into whose body, or in con-
19 tact with whose blood or tissue, the implant is
20 placed, who claims to have suffered harm as a
21 result of the implant.

22 (B) ACTION BROUGHT ON BEHALF OF AN
23 ESTATE.—With respect to an action brought on
24 behalf of or through the estate of an individual
25 into whose body, or in contact with whose blood

1 or tissue the implant is placed, such term in-
2 cludes the decedent that is the subject of the
3 action.

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

9 (D) EXCLUSIONS.—Such term does not in-
10 clude—

11 (i) a provider of professional health
12 care services, in any case in which—

13 (I) the sale or use of an implant
14 is incidental to the transaction; and

15 (II) the essence of the trans-
16 action is the furnishing of judgment,
17 skill, or services;

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

21 (iii) a person alleging harm caused by
22 either the silicone gel or the silicone enve-
23 lope utilized in a breast implant containing
24 silicone gel, except that—

1 (I) neither the exclusion provided
 2 by this clause nor any other provision
 3 of this Act may be construed as a
 4 finding that silicone gel (or any other
 5 form of silicone) may or may not
 6 cause harm; and

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

9 (aa) be disclosed to a jury in
 10 any civil action or other proceed-
 11 ing; and

12 (bb) except as necessary to
 13 establish the applicability of this
 14 Act, otherwise be presented in
 15 any civil action or other proceed-
 16 ing.

17 (3) COMPONENT PART.—

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

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

24 (i) has significant non-implant appli-
 25 cations; and

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

5 (4) HARM.—

6 (A) IN GENERAL.—The term “harm”
7 means—

8 (i) any injury to or damage suffered
9 by an individual;

10 (ii) any illness, disease, or death of
11 that individual resulting from that injury
12 or damage; and

13 (iii) any loss to that individual or any
14 other individual resulting from that injury
15 or damage.

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

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

20 (A) a medical device that is intended by
21 the manufacturer of the device—

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

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

5 (B) suture materials used in implant pro-
6 cedures.

7 (6) MANUFACTURER.—The term “manufac-
8 turer” means any person who, with respect to an im-
9 plant—

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

15 (B) is required—

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

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

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

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

9 (A) has a generic use; and

10 (B) may be used in an application other
11 than an implant.

12 (9) SECRETARY.—The term “Secretary” means
13 the Secretary of Health and Human Services.

14 (10) SELLER.—

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

20 (B) EXCLUSIONS.—The term does not in-
21 clude—

22 (i) a seller or lessor of real property;

23 (ii) a provider of professional services,

24 in any case in which the sale or use of an
25 implant is incidental to the transaction and

1 the essence of the transaction is the fur-
2 nishing of judgment, skill, or services; or

3 (iii) any person who acts in only a fi-
4 nancial capacity with respect to the sale of
5 an implant.

6 **SEC. 4. GENERAL REQUIREMENTS; APPLICABILITY; PRE-**
7 **EMPTION.**

8 (a) GENERAL REQUIREMENTS.—

9 (1) IN GENERAL.—In any civil action covered
10 by this Act, a biomaterials supplier may raise any
11 defense set forth in section 5.

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

18 (b) APPLICABILITY.—

19 (1) IN GENERAL.—Except as provided in para-
20 graph (2), notwithstanding any other provision of
21 law, this Act applies to any civil action brought by
22 a claimant, whether in a Federal or State court,
23 against a manufacturer, seller, or biomaterials sup-
24 plier, on the basis of any legal theory, for harm al-
25 legedly caused by an implant.

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

6 (A) shall not be considered an action that
7 is subject to this Act; and

8 (B) shall be governed by applicable com-
9 mercial or contract law.

10 (c) SCOPE OF PREEMPTION.—

11 (1) IN GENERAL.—This Act supersedes any
12 State law regarding recovery for harm caused by an
13 implant and any rule of procedure applicable to a
14 civil action to recover damages for such harm only
15 to the extent that this Act establishes a rule of law
16 applicable to the recovery of such damages.

17 (2) APPLICABILITY OF OTHER LAWS.—Any
18 issue that arises under this Act and that is not gov-
19 erned by a rule of law applicable to the recovery of
20 damages described in paragraph (1) shall be gov-
21 erned by applicable Federal or State law.

22 (d) STATUTORY CONSTRUCTION.—Nothing in this
23 Act may be construed—

24 (1) to affect any defense available to a defend-
25 ant under any other provisions of Federal or State

1 law in an action alleging harm caused by an im-
2 plant; or

3 (2) to create a cause of action or Federal court
4 jurisdiction pursuant to section 1331 or 1337 of title
5 28, United States Code, that otherwise would not
6 exist under applicable Federal or State law.

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

8 (a) IN GENERAL.—

9 (1) EXCLUSION FROM LIABILITY.—Except as
10 provided in paragraph (2), a biomaterials supplier
11 shall not be liable for harm to a claimant caused by
12 an implant.

13 (2) LIABILITY.—A biomaterials supplier that—

14 (A) is a manufacturer may be liable for
15 harm to a claimant described in subsection (b);

16 (B) is a seller may be liable for harm to
17 a claimant described in subsection (c); and

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

22 (b) LIABILITY AS MANUFACTURER.—

23 (1) IN GENERAL.—A biomaterials supplier may,
24 to the extent required and permitted by any other
25 applicable law, be liable for harm to a claimant

1 caused by an implant if the biomaterials supplier is
2 the manufacturer of the implant.

3 (2) GROUNDS FOR LIABILITY.—The biomate-
4 rials supplier may be considered the manufacturer of
5 the implant that allegedly caused harm to a claimant
6 only if the biomaterials supplier—

7 (A)(i) has registered with the Secretary
8 pursuant to section 510 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 360) and
10 the regulations issued under such section; and

11 (ii) included the implant on a list of de-
12 vices filed with the Secretary pursuant to sec-
13 tion 510(j) of such Act (21 U.S.C. 360(j)) and
14 the regulations issued under such section;

15 (B) is the subject of a declaration issued
16 by the Secretary pursuant to paragraph (3)
17 that states that the supplier, with respect to the
18 implant that allegedly caused harm to the
19 claimant, was required to—

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

24 (ii) include the implant on a list of de-
25 vices filed with the Secretary pursuant to

1 section 510(j) of such Act (21 U.S.C.
2 360(j)) and the regulations issued under
3 such section, but failed to do so; or

4 (C) is related by common ownership or
5 control to a person meeting all the requirements
6 described in subparagraph (A) or (B), if the
7 court deciding a motion to dismiss in accord-
8 ance with section 6(c)(3)(B)(i) finds, on the
9 basis of affidavits submitted in accordance with
10 section 6, that it is necessary to impose liability
11 on the biomaterials supplier as a manufacturer
12 because the related manufacturer meeting the
13 requirements of subparagraph (A) or (B) lacks
14 sufficient financial resources to satisfy any
15 judgment that the court feels it is likely to
16 enter should the claimant prevail.

17 (3) ADMINISTRATIVE PROCEDURES.—

18 (A) IN GENERAL.—The Secretary may
19 issue a declaration described in paragraph
20 (2)(B) on the motion of the Secretary or on pe-
21 tition by any person, after providing—

22 (i) notice to the affected persons; and
23 (ii) an opportunity for an informal
24 hearing.

1 (B) DOCKETING AND FINAL DECISION.—
2 Immediately upon receipt of a petition filed
3 pursuant to this paragraph, the Secretary shall
4 docket the petition. Not later than 180 days
5 after the petition is filed, the Secretary shall
6 issue a final decision on the petition.

7 (C) APPLICABILITY OF STATUTE OF LIMITATIONS.—Any applicable statute of limitations
8 shall toll during the period during which a
9 claimant has filed a petition with the Secretary
10 under this paragraph.

12 (c) LIABILITY AS SELLER.—A biomaterials supplier
13 may, to the extent required and permitted by any other
14 applicable law, be liable as a seller for harm to a claimant
15 caused by an implant if—

16 (1) the biomaterials supplier—

17 (A) held title to the implant that allegedly
18 caused harm to the claimant as a result of pur-
19 chasing the implant after—

20 (i) the manufacture of the implant;

21 and

22 (ii) the entrance of the implant in the
23 stream of commerce; and

24 (B) subsequently resold the implant; or

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

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

19 (1) the raw materials or component parts deliv-
20 ered by the biomaterials supplier either—

21 (A) did not constitute the product de-
22 scribed in the contract between the biomaterials
23 supplier and the person who contracted for de-
24 livery of the product; or

1 (B) failed to meet any specifications that
2 were—

3 (i) provided to the biomaterials sup-
4 plier and not expressly repudiated by the
5 biomaterials supplier prior to acceptance of
6 delivery of the raw materials or component
7 parts;

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

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

12 (III) contained in a master file that
13 was submitted by the biomaterials supplier
14 to the Secretary and that is currently
15 maintained by the biomaterials supplier for
16 purposes of premarket approval of medical
17 devices; or

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

1 biomaterials supplier and were not ex-
 2 pressly repudiated by the biomaterials sup-
 3 plier prior to the acceptance by the manu-
 4 facturer of delivery of the raw materials or
 5 component parts; and

6 (2) such conduct was an actual and proximate
 7 cause of the harm to the claimant.

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

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

15 (1) the defendant is a biomaterials supplier;
 16 and

17 (2)(A) the defendant should not, for the pur-
 18 poses of—

19 (i) section 5(b), be considered to be a man-
 20 ufacturer of the implant that is subject to such
 21 section; or

22 (ii) section 5(c), be considered to be a sell-
 23 er of the implant that allegedly caused harm to
 24 the claimant; or

1 (B)(i) the claimant has failed to establish, pur-
 2 suant to section 5(d), that the supplier furnished
 3 raw materials or component parts in violation of
 4 contractual requirements or specifications; or

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

7 (b) MANUFACTURER OF IMPLANT SHALL BE NAMED
 8 A PARTY.—The claimant shall be required to name the
 9 manufacturer of the implant as a party to the action, un-
 10 less—

11 (1) the manufacturer is subject to service of
 12 process solely in a jurisdiction in which the biomate-
 13 rials supplier is not domiciled or subject to a service
 14 of process; or

15 (2) an action against the manufacturer is
 16 barred by applicable law.

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

20 (1) AFFIDAVITS RELATING TO LISTING AND
 21 DECLARATIONS.—

22 (A) IN GENERAL.—The defendant in the
 23 action may submit an affidavit demonstrating
 24 that defendant has not included the implant on
 25 a list, if any, filed with the Secretary pursuant

1 to section 510(j) of the Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 360(j)).

3 (B) RESPONSE TO MOTION TO DISMISS.—

4 In response to the motion to dismiss, the claim-
5 ant may submit an affidavit demonstrating
6 that—

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

11 or

12 (ii) the defendant who filed the mo-
13 tion to dismiss is a seller of the implant
14 who is liable under section 5(c).

15 (2) EFFECT OF MOTION TO DISMISS ON DIS-
16 COVERY.—

17 (A) IN GENERAL.—If a defendant files a
18 motion to dismiss under paragraph (1) or (2) of
19 subsection (a), no discovery shall be permitted
20 in connection to the action that is the subject
21 of the motion, other than discovery necessary to
22 determine a motion to dismiss for lack of juris-
23 diction, until such time as the court rules on

1 the motion to dismiss in accordance with the af-
2 fidavits submitted by the parties in accordance
3 with this section.

4 (B) DISCOVERY.—If a defendant files a
5 motion to dismiss under subsection (a)(2)(B)(i)
6 on the grounds that the biomaterials supplier
7 did not furnish raw materials or component
8 parts in violation of contractual requirements or
9 specifications, the court may permit discovery,
10 as ordered by the court. The discovery con-
11 ducted pursuant to this subparagraph shall be
12 limited to issues that are directly relevant to—

13 (i) the pending motion to dismiss; or

14 (ii) the jurisdiction of the court.

15 (3) AFFIDAVITS RELATING STATUS OF DEFEND-
16 ANT.—

17 (A) IN GENERAL.—Except as provided in
18 clauses (i) and (ii) of subparagraph (B), the
19 court shall consider a defendant to be a bio-
20 materials supplier who is not subject to an ac-
21 tion for harm to a claimant caused by an im-
22 plant, other than an action relating to liability
23 for a violation of contractual requirements or
24 specifications described in subsection (d).

1 (B) RESPONSES TO MOTION TO DISMISS.—

2 The court shall grant a motion to dismiss any
3 action that asserts liability of the defendant
4 under subsection (b) or (c) of section 5 on the
5 grounds that the defendant is not a manufac-
6 turer subject to such section 5(b) or seller sub-
7 ject to section 5(c), unless the claimant submits
8 a valid affidavit that demonstrates that—

9 (i) with respect to a motion to dismiss
10 contending the defendant is not a manu-
11 facturer, the defendant meets the applica-
12 ble requirements for liability as a manufac-
13 turer under section 5(b); or

14 (ii) with respect to a motion to dis-
15 miss contending that the defendant is not
16 a seller, the defendant meets the applicable
17 requirements for liability as a seller under
18 section 5(c).

19 (4) BASIS OF RULING ON MOTION TO DIS-
20 MISS.—

21 (A) IN GENERAL.—The court shall rule on
22 a motion to dismiss filed under subsection (a)

1 solely on the basis of the pleadings of the par-
2 ties made pursuant to this section and any affi-
3 davits submitted by the parties pursuant to this
4 section.

5 (B) MOTION FOR SUMMARY JUDGMENT.—
6 Notwithstanding any other provision of law, if
7 the court determines that the pleadings and af-
8 fidavits made by parties pursuant to this sec-
9 tion raise genuine issues as concerning material
10 facts with respect to a motion concerning con-
11 tractual requirements and specifications, the
12 court may deem the motion to dismiss to be a
13 motion for summary judgment made pursuant
14 to subsection (d).

15 (d) SUMMARY JUDGMENT.—

16 (1) IN GENERAL.—

17 (A) BASIS FOR ENTRY OF JUDGMENT.—A
18 biomaterials supplier shall be entitled to entry
19 of judgment without trial if the court finds
20 there is no genuine issue as concerning any ma-
21 terial fact for each applicable element set forth
22 in paragraphs (1) and (2) of section 5(d).

23 (B) ISSUES OF MATERIAL FACT.—With re-
24 spect to a finding made under subparagraph
25 (A), the court shall consider a genuine issue of

1 material fact to exist only if the evidence sub-
2 mitted by claimant would be sufficient to allow
3 a reasonable jury to reach a verdict for the
4 claimant if the jury found the evidence to be
5 credible.

6 (2) DISCOVERY MADE PRIOR TO A RULING ON
7 A MOTION FOR SUMMARY JUDGMENT.—If, under ap-
8 plicable rules, the court permits discovery prior to a
9 ruling on a motion for summary judgment made
10 pursuant to this subsection, such discovery shall be
11 limited solely to establishing whether a genuine issue
12 of material fact exists as to the applicable elements
13 set forth in paragraphs (1) and (2) of section 5(d).

14 (3) DISCOVERY WITH RESPECT TO A BIOMATE-
15 RIALS SUPPLIER.—A biomaterials supplier shall be
16 subject to discovery in connection with a motion
17 seeking dismissal or summary judgment on the basis
18 of the inapplicability of section 5(d) or the failure to
19 establish the applicable elements of section 5(d) sole-
20 ly to the extent permitted by the applicable Federal
21 or State rules for discovery against nonparties.

22 (e) STAY PENDING PETITION FOR DECLARATION.—
23 If a claimant has filed a petition for a declaration pursu-
24 ant to section 5(b)(3)(A) with respect to a defendant, and

1 the Secretary has not issued a final decision on the peti-
2 tion, the court shall stay all proceedings with respect to
3 that defendant until such time as the Secretary has issued
4 a final decision on the petition.

5 (f) MANUFACTURER CONDUCT OF PROCEEDING.—

6 The manufacturer of an implant that is the subject of an
7 action covered under this Act shall be permitted to file
8 and conduct a proceeding on any motion for summary
9 judgment or dismissal filed by a biomaterials supplier who
10 is a defendant under this section if the manufacturer and
11 any other defendant in such action enter into a valid and
12 applicable contractual agreement under which the manu-
13 facturer agrees to bear the cost of such proceeding or to
14 conduct such proceeding.

15 (g) ATTORNEY FEES.—The court shall require the
16 claimant to compensate the biomaterials supplier (or a
17 manufacturer appearing in lieu of a supplier pursuant to
18 subsection (f)) for attorney fees and costs, if—

19 (1) the claimant named or joined the biomate-
20 rials supplier; and

21 (2) the court found the claim against the bio-
22 materials supplier to be without merit and frivolous.

1 **SEC. 7. APPLICABILITY.**

2 This Act shall apply to all civil actions covered under
3 this Act that are commenced on or after the date of enact-
4 ment of this Act, including any such action with respect
5 to which the harm asserted in the action or the conduct
6 that caused the harm occurred before the date of enact-
7 ment of this Act.

○