

104TH CONGRESS
1ST SESSION

H. R. 753

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

JANUARY 31, 1995

Mr. GEKAS (for himself, Mr. PASTOR, Mr. COBURN, Mr. RAMSTAD, Mr. COX of California, and Mr. BILBRAY) 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

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Biomaterials Access
5 Assurance Act of 1995”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

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

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

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

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

13 (B) come in contact with internal human
14 tissue;

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

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

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

1 medical devices are safe and effective, including
2 demonstrating that the products are properly de-
3 signed and have adequate warnings or instructions;

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

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

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

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

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

1 ability of lifesaving and life-enhancing medical
2 devices;

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

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

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

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

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

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

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

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

12 (A) to clarify the permissible bases of li-
13 ability for suppliers of raw materials and com-
14 ponent parts for medical devices; and

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

19 **SEC. 3. DEFINITIONS.**

20 As used in this Act:

21 (1) BIOMATERIALS SUPPLIER.—

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

1 (B) PERSONS INCLUDED.—Such term in-
2 cludes any person who—

3 (i) has submitted master files to the
4 Secretary for purposes of premarket ap-
5 proval of a medical device; or

6 (ii) licenses a biomaterials supplier to
7 produce component parts or raw materials.

8 (2) CLAIMANT.—

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

18 (B) ACTION BROUGHT ON BEHALF OF AN
19 ESTATE.—With respect to an action brought on
20 behalf or through the estate of an individual
21 into whose body, or in contact with whose blood
22 or tissue the implant is placed, such term in-
23 cludes the decedent that is the subject of the
24 action.

1 (C) ACTION BROUGHT ON BEHALF OF A
2 MINOR.—With respect to an action brought on
3 behalf or through a minor, such term includes
4 the parent or guardian of the minor.

5 (D) EXCLUSIONS.—Such term does not
6 include—

7 (i) a provider of professional services,
8 in any case in which—

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

11 (II) the essence of the trans-
12 action is the furnishing of judgment,
13 skill, or services; or

14 (ii) a manufacturer, seller, or
15 biomaterials supplier.

16 (3) COMPONENT PART.—

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

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

23 (i) has significant nonimplant applications;
24 and

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

4 (4) HARM.—

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

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

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

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

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

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

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

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

24 (ii) to remain in contact with bodily
25 fluids or internal human tissue through a

1 surgically produced opening for a period of
2 less than 30 days; and

3 (B) suture materials used in implant pro-
4 cedures.

5 (6) MANUFACTURER.—The term “manufac-
6 turer” means any person who, with respect to an
7 implant—

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

13 (B) is required—

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

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

24 (7) MEDICAL DEVICE.—The term “medical de-
25 vice” means a device, as defined in section 201(h)

1 of the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 321(h)).

3 (8) QUALIFIED SPECIALIST.—With respect to
4 an action, the term “qualified specialist” means a
5 person who is qualified by knowledge, skill, experi-
6 ence, training, or education in the specialty area
7 that is the subject of the action.

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

10 (A) has a generic use; and

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

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

15 (11) SELLER.—

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

21 (B) EXCLUSIONS.—The term does not
22 include—

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

24 (ii) a provider of professional services,

25 in any case in which the sale or use of an

1 implant is incidental to the transaction and
2 the essence of the transaction is the fur-
3 nishing of judgment, skill, or services; or

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

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

9 (a) GENERAL REQUIREMENTS.—

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

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

19 (b) APPLICABILITY.—

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

1 plier, on the basis of any legal theory, for harm al-
2 legedly caused by an implant.

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

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

10 (B) shall be governed by applicable com-
11 mercial or contract law.

12 (c) SCOPE OF PREEMPTION.—

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

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

24 (d) STATUTORY CONSTRUCTION.—Nothing in this
25 Act may be construed—

1 (1) to affect any defense available to a defend-
2 ant under any other provisions of Federal or State
3 law in an action alleging harm caused by an im-
4 plant; or

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

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

10 (a) IN GENERAL.—

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

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

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

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

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

24 (b) LIABILITY AS MANUFACTURER.—

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

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

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

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

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

23 (i) register with the Secretary under sec-
24 tion 510 of such Act (21 U.S.C. 360), and the

1 regulations issued under such section, but failed
2 to do so; or

3 (ii) include the implant on a list of devices
4 filed with the Secretary pursuant to section
5 510(j) of such Act (21 U.S.C. 360(j)) and the
6 regulations issued under such section, but failed
7 to do so.

8 (3) ADMINISTRATIVE PROCEDURES.—

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

13 (i) notice to the affected persons; and

14 (ii) an opportunity for an informal
15 hearing.

16 (B) DOCKETING AND FINAL DECISION.—

17 Immediately upon receipt of a petition filed
18 pursuant to this paragraph, the Secretary shall
19 docket the petition. Not later than 180 days
20 after the petition is filed, the Secretary shall
21 issue a final decision on the petition.

22 (C) APPLICABILITY OF STATUTE OF LIM-
23 TATIONS.—Any applicable statute of limitations
24 shall toll during the period during which a

1 claimant has filed a petition with the Secretary
2 under this paragraph.

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

7 (1) held title to the implant that allegedly
8 caused harm to the claimant as a result of purchas-
9 ing the implant after—

10 (A) the manufacture of the implant; and

11 (B) the entrance of the implant in the
12 stream of commerce; and

13 (2) subsequently resold the implant.

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

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

22 (A) did not constitute the product de-
23 scribed in the contract between the biomaterials
24 supplier and the person who contracted for de-
25 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)(I) 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

24 (II) have received clearance from the
25 Secretary,

1 if such specifications were provided by the man-
2 ufacturer to the biomaterials supplier and were
3 not expressly repudiated by the biomaterials
4 supplier prior to the acceptance by the manu-
5 facturer of delivery of the raw materials or
6 component parts; and

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

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

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

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

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

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

23 (ii) section 5(c), be considered to be a sell-
24 er of the implant that allegedly caused harm to
25 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) PROCEDURAL REQUIREMENTS.—

8 (1) IN GENERAL.—The procedural requirements
9 described in paragraphs (2) and (3) shall apply to
10 any action by a claimant against a biomaterials sup-
11 plier that is subject to this Act.

12 (2) MANUFACTURER OF IMPLANT SHALL BE
13 NAMED A PARTY.—The claimant shall be required to
14 name the manufacturer of the implant as a party to
15 the action, unless—

16 (A) the manufacturer is subject to service
17 of process solely in a jurisdiction in which the
18 biomaterials supplier is not domiciled or subject
19 to a service of process; or

20 (B) an action against the manufacturer is
21 barred by applicable law.

22 (3) AFFIDAVIT.—At the time the claimant
23 brings an action against a biomaterials supplier the
24 claimant shall be required to submit an affidavit
25 that—

1 (A) declares that the claimant has con-
2 sulted and reviewed the facts of the action with
3 a qualified specialist, whose qualifications the
4 claimant shall disclose;

5 (B) includes a written determination by a
6 qualified specialist that the raw materials or
7 component parts actually used in the manufac-
8 ture of the implant of the claimant were raw
9 materials or component parts described in sec-
10 tion 5(d)(1), together with a statement of the
11 basis for such a determination;

12 (C) includes a written determination by a
13 qualified specialist that, after a review of the
14 medical record and other relevant material, the
15 raw material or component part supplied by the
16 biomaterials supplier and actually used in the
17 manufacture of the implant was a cause of the
18 harm alleged by claimant, together with a state-
19 ment of the basis for the determination; and

20 (D) states that, on the basis of review and
21 consultation of the qualified specialist, the
22 claimant (or the attorney of the claimant) has
23 concluded that there is a reasonable and meri-
24 torious cause for the filing of the action against
25 the biomaterials supplier.

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

4 (1) AFFIDAVITS RELATING TO LISTING AND
5 DECLARATIONS.—

6 (A) IN GENERAL.—The defendant in the
7 action may submit an affidavit demonstrating
8 that defendant has not included the implant on
9 a list, if any, filed with the Secretary pursuant
10 to section 510(j) of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 360(j)).

12 (B) RESPONSE TO MOTION TO DISMISS.—
13 In response to the motion to dismiss, the claim-
14 ant may submit an affidavit demonstrating
15 that—

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

21 (ii) the defendant who filed the mo-
22 tion to dismiss is a seller of the implant
23 who is liable under section 5(c).

24 (2) EFFECT OF MOTION TO DISMISS ON DIS-
25 COVERY.—

1 (A) IN GENERAL.—If a defendant files a
2 motion to dismiss under paragraph (1) or (3) of
3 subsection (a), no discovery shall be permitted
4 in connection to the action that is the subject
5 of the motion, other than discovery necessary to
6 determine a motion to dismiss for lack of juris-
7 diction, until such time as the court rules on
8 the motion to dismiss in accordance with the af-
9 fidavits submitted by the parties in accordance
10 with this section.

11 (B) DISCOVERY.—If a defendant files a
12 motion to dismiss under subsection (a)(2) on
13 the grounds that the biomaterials supplier did
14 not furnish raw materials or component parts
15 in violation of contractual requirements or spec-
16 ifications, the court may permit discovery, as
17 ordered by the court. The discovery conducted
18 pursuant to this subparagraph shall be limited
19 to issues that are directly relevant to—

20 (i) the pending motion to dismiss; or

21 (ii) the jurisdiction of the court.

22 (3) AFFIDAVITS RELATING STATUS OF DEFEND-
23 ANT.—

24 (A) IN GENERAL.—Except as provided in
25 clauses (i) and (ii) of subparagraph (B), the

1 court shall consider a defendant to be a
2 biomaterials supplier who is not subject to an
3 action for harm to a claimant caused by an im-
4 plant, other than an action relating to liability
5 for a violation of contractual requirements or
6 specifications described in subsection (d).

7 (B) RESPONSES TO MOTION TO DISMISS.—

8 The court shall grant a motion to dismiss any
9 action that asserts liability of the defendant
10 under subsection (b) or (c) of section 5 on the
11 grounds that the defendant is not a manufac-
12 turer subject to such subsection 5(b) or seller
13 subject to subsection 5(c), unless the claimant
14 submits a valid affidavit that demonstrates
15 that—

16 (i) with respect to a motion to dismiss con-
17 tending the defendant is not a manufacturer,
18 the defendant meets the applicable require-
19 ments for liability as a manufacturer under sec-
20 tion 5(b); or

21 (ii) with respect to a motion to dismiss
22 contending that the defendant is not a seller,
23 the defendant meets the applicable require-
24 ments for liability as a seller under section 5(c).

1 (4) BASIS OF RULING ON MOTION TO DIS-
2 MISS.—

3 (A) IN GENERAL.—The court shall rule on
4 a motion to dismiss filed under subsection (a)
5 solely on the basis of the pleadings of the par-
6 ties made pursuant to this section and any affi-
7 davits submitted by the parties pursuant to this
8 section.

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

19 (d) SUMMARY JUDGMENT.—

20 (1) IN GENERAL.—

21 (A) BASIS FOR ENTRY OF JUDGMENT.—A
22 biomaterials supplier shall be entitled to entry
23 of judgment without trial if the court finds
24 there is no genuine issue as concerning any ma-

1 terial fact for each applicable element set forth
2 in paragraphs (1) and (2) of section 5(d).

3 (B) ISSUES OF MATERIAL FACT.—With re-
4 spect to a finding made under subparagraph
5 (A), the court shall consider a genuine issue of
6 material fact to exist only if the evidence sub-
7 mitted by claimant would be sufficient to allow
8 a reasonable jury to reach a verdict for the
9 claimant if the jury found the evidence to be
10 credible.

11 (2) DISCOVERY MADE PRIOR TO A RULING ON
12 A MOTION FOR SUMMARY JUDGMENT.—If, under ap-
13 plicable rules, the court permits discovery prior to a
14 ruling on a motion for summary judgment made
15 pursuant to this subsection, such discovery shall be
16 limited solely to establishing whether a genuine issue
17 of material fact exists.

18 (3) DISCOVERY WITH RESPECT TO A
19 BIOMATERIALS SUPPLIER.—A biomaterials supplier
20 shall be subject to discovery in connection with a
21 motion seeking dismissal or summary judgment on
22 the basis of the inapplicability of section 5(d) or the
23 failure to establish the applicable elements of section
24 5(d) solely to the extent permitted by the applicable

1 Federal or State rules for discovery against
2 nonparties.

3 (e) STAY PENDING PETITION FOR DECLARATION.—

4 If a claimant has filed a petition for a declaration pursu-
5 ant to section 5(b) with respect to a defendant, and the
6 Secretary has not issued a final decision on the petition,
7 the court shall stay all proceedings with respect to that
8 defendant until such time as the Secretary has issued a
9 final decision on the petition.

10 (f) MANUFACTURER CONDUCT OF PROCEEDING.—

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

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

24 (1) the claimant named or joined the
25 biomaterials supplier; and

1 (2) the court found the claim against the
2 biomaterials supplier to be without merit and frivo-
3 lous.

4 **SEC. 7. APPLICABILITY.**

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

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