

105TH CONGRESS  
1ST SESSION

# H. R. 872

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

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## 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

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## 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 1997”.

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 per-  
6 manently implantable within the human body;

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

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

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

15 (B) come in contact with internal human  
16 tissue;

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

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

25 (6) under the Federal Food, Drug, and Cos-  
26 metic Act (21 U.S.C. 301 et seq.), manufacturers of

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

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

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

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

15 (8) even though suppliers of raw materials and  
16 component parts have very rarely been held liable in  
17 such actions, such suppliers have ceased supplying  
18 certain raw materials and component parts for use  
19 in medical devices because the costs associated with  
20 litigation in order to ensure a favorable judgment for  
21 the suppliers far exceeds the total potential sales  
22 revenues from sales by such suppliers to the medical  
23 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 be disclosed  
9 to a jury in any civil action or other  
10 proceeding and, except as necessary to  
11 establish the applicability of this Act,  
12 otherwise be presented in any civil ac-  
13 tion or other proceeding.

14 (3) COMPONENT PART.—

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

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

21 (i) has significant non-implant appli-  
22 cations; and

23 (ii) alone, has no implant value or  
24 purpose, but when combined with other

1 component parts and materials, constitutes  
2 an implant.

3 (4) HARM.—

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

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

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

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

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

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

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

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

23 (ii) to remain in contact with bodily  
24 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 im-  
7 plant—

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)) and includes any device component  
3 of any combination product as that term is used in  
4 section 503(g) of such Act (21 U.S.C. 353(g)).

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

7 (A) has a generic use; and

8 (B) may be used in an application other  
9 than an implant.

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

12 (10) SELLER.—

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

18 (B) EXCLUSIONS.—The term does not in-  
19 clude—

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

21 (ii) a provider of professional services,  
22 in any case in which the sale or use of an  
23 implant is incidental to the transaction and  
24 the essence of the transaction is the fur-  
25 nishing of judgment, skill, or services; or

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

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

6 (a) GENERAL REQUIREMENTS.—

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

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

16 (b) APPLICABILITY.—

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

24 (2) EXCLUSION.—A civil action brought by a  
25 purchaser of a medical device for use in providing

1 professional services against a manufacturer, seller,  
2 or biomaterials supplier for loss or damage to an im-  
3 plant or for commercial loss to the purchaser—

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

6 (B) shall be governed by applicable com-  
7 mercial or contract law.

8 (c) SCOPE OF PREEMPTION.—

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

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

20 (d) STATUTORY CONSTRUCTION.—Nothing in this  
21 Act may be construed—

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

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

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

6       (a) IN GENERAL.—

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

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

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

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

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

20       (b) LIABILITY AS MANUFACTURER.—

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

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

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

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

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

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

22                         (ii) include the implant on a list of de-  
23                         vices filed with the Secretary pursuant to  
24                         section 510(j) of such Act (21 U.S.C.

1           360(j)) and the regulations issued under  
2           such section, but failed to do so; or

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

16          (3) ADMINISTRATIVE PROCEDURES.—

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

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

24                 (B) DOCKETING AND FINAL DECISION.—

25                 Immediately upon receipt of a petition filed

1           pursuant to this paragraph, the Secretary shall  
2           docket the petition. Not later than 180 days  
3           after the petition is filed, the Secretary shall  
4           issue a final decision on the petition.

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

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

14                 (1) the biomaterials supplier—

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

18                                 (i) the manufacture of the implant;

19                                 and

20                                 (ii) the entrance of the implant in the  
21                                 stream of commerce; and

22                         (B) subsequently resold the implant; or

23                 (2) the biomaterials supplier is related by com-  
24         mon ownership or control to a person meeting all the  
25         requirements described in paragraph (1), if a court

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

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

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

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

22 (B) failed to meet any specifications that  
23 were—

24 (i) provided to the biomaterials sup-  
25 plier and not expressly repudiated by the

1           biomaterials supplier prior to acceptance of  
2           delivery of the raw materials or component  
3           parts;

4                   (ii)(I) published by the biomaterials  
5           supplier;

6                   (II) provided to the manufacturer by  
7           the biomaterials supplier; or

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

14                   (iii) included in the submissions for  
15          purposes of premarket approval or review  
16          by the Secretary under section 510, 513,  
17          515, or 520 of the Federal Food, Drug,  
18          and Cosmetic Act (21 U.S.C. 360, 360e,  
19          360e, or 360j), and received clearance  
20          from the Secretary if such specifications  
21          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.

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