

104TH CONGRESS  
2D SESSION

# H. R. 3468

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

MAY 16, 1996

Mr. GEKAS (for himself, Mr. PASTOR, Mr. HASTERT, Mr. HAYWORTH, Mr. UPTON, Mr. BERMAN, Mr. ROHRABACHER, Mr. CUNNINGHAM, Mr. BREWSTER, Mr. GUTKNECHT, Mr. STUMP, Mr. BILBRAY, Mr. EHLERS, Mr. HOBSON, Mrs. JOHNSON of Connecticut, Mr. SERRANO, Mr. BURR, Mr. ROYCE, Mr. CELEMENT, Mr. BLUTE, Mr. SCHIFF, Mr. FORBES, Mr. ZIMMER, Mr. BUYER, Mrs. KELLY, and Mr. STENHOLM) 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 1996”.

1 **SEC. 2. FINDINGS.**

2 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  
6 permanently 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  
21 devices, 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  
26 Cosmetic Act (21 U.S.C. 301 et seq.), manufactur-

1       ers of medical devices are required to demonstrate  
2       that the medical devices are safe and effective, in-  
3       cluding demonstrating that the products are prop-  
4       erly designed and have adequate warnings or in-  
5       structions;

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

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  
15              medical 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  
20              in medical devices because the costs associated with  
21              litigation in order to ensure a favorable judgment for  
22              the suppliers far exceeds the total potential sales  
23              revenues from sales by such suppliers to the medical  
24              device industry;

1           (9) unless alternate sources of supply can be  
2 found, the unavailability of raw materials and  
3 component parts for medical devices will lead to  
4 unavailability of lifesaving and life-enhancing medi-  
5 cal devices;

6           (10) because other suppliers of the raw  
7 materials and component parts in foreign nations  
8 are refusing to sell raw materials or component  
9 parts for use in manufacturing certain medical de-  
10 vices in the United States, the prospects for develop-  
11 ment of new sources of supply for the full range of  
12 threatened raw materials and component parts for  
13 medical devices 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  
11 medical 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  
16 liability for suppliers of raw materials and  
17 component parts for medical devices; and

18 (B) to provide expeditious procedures to  
19 dispose of unwarranted suits against the  
20 suppliers in such manner as to minimize litiga-  
21 tion 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  
3 indirectly supplies a component part or raw  
4 material for use in the manufacture of an im-  
5 plant.

6 (B) PERSONS INCLUDED.—Such term  
7 includes any person who—

8 (i) has submitted master files to the  
9 Secretary for purposes of premarket  
10 approval of a medical device; or

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

13 (2) CLAIMANT.—

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

23 (B) ACTION BROUGHT ON BEHALF OF AN  
24 ESTATE.—With respect to an action brought on  
25 behalf of or through the estate of an individual

1 into whose body, or in contact with whose blood  
2 or tissue the implant is placed, such term  
3 includes the decedent that is the subject of the  
4 action.

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

10 (D) EXCLUSIONS.—Such term does not  
11 include—

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

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

16 (II) the essence of the  
17 transaction is the furnishing of judg-  
18 ment, skill, or services; or

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

22 (3) COMPONENT PART.—

23 (A) IN GENERAL.—The term “component  
24 part” means a manufactured piece of an im-  
25 plant.

1 (B) CERTAIN COMPONENTS.—Such term  
2 includes a manufactured piece of an implant  
3 that—

4 (i) has significant non-implant appli-  
5 cations; and

6 (ii) alone, has no implant value or  
7 purpose, but when combined with other  
8 component parts and materials, constitutes  
9 an implant.

10 (4) HARM.—

11 (A) IN GENERAL.—The term “harm”  
12 means—

13 (i) any injury to or damage suffered  
14 by an individual;

15 (ii) any illness, disease, or death of  
16 that individual resulting from that injury  
17 or damage; and

18 (iii) any loss to that individual or any  
19 other individual resulting from that injury  
20 or damage.

21 (B) EXCLUSION.—The term does not  
22 include any commercial loss or loss of or dam-  
23 age to an implant.

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

1 (A) a medical device that is intended by  
2 the manufacturer of the device—

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

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

10 (B) suture materials used in implant  
11 procedures.

12 (6) MANUFACTURER.—The term  
13 “manufacturer” means any person who, with respect  
14 to an implant—

15 (A) is engaged in the manufacture,  
16 preparation, propagation, compounding, or  
17 processing (as defined in section 510(a)(1)) of  
18 the Federal Food, Drug, and Cosmetic Act (21  
19 U.S.C. 360(a)(1)) of the implant; and

20 (B) is required—

21 (i) to register with the Secretary  
22 pursuant to section 510 of the Federal  
23 Food, Drug, and Cosmetic Act (21 U.S.C.  
24 360) and the regulations issued under such  
25 section; and

1 (ii) to include the implant on a list of  
2 devices filed with the Secretary pursuant  
3 to section 510(j) of such Act (21 U.S.C.  
4 360(j)) and the regulations issued under  
5 such section.

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

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

14 (A) has a generic use; and

15 (B) may be used in an application other  
16 than an implant.

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

19 (10) SELLER.—

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

1 (B) EXCLUSIONS.—The term does not  
2 include—

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

4 (ii) a provider of professional services,

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

6 implant is incidental to the transaction and

7 the essence of the transaction is the

8 furnishing of judgment, skill, or services;

9 or

10 (iii) any person who acts in only a

11 financial capacity with respect to the sale

12 of an implant.

13 **SEC. 4. GENERAL REQUIREMENTS; APPLICABILITY; PRE-**  
14 **EMPTION.**

15 (a) GENERAL REQUIREMENTS.—

16 (1) IN GENERAL.—In any civil action covered

17 by this Act, a biomaterials supplier may raise any

18 defense set forth in section 5.

19 (2) PROCEDURES.—Notwithstanding any other

20 provision of law, the Federal or State court in which

21 a civil action covered by this Act is pending shall, in

22 connection with a motion for dismissal or judgment

23 based on a defense described in paragraph (1), use

24 the procedures set forth in section 6.

25 (b) APPLICABILITY.—

1           (1) IN GENERAL.—Except as provided in  
2 paragraph (2), notwithstanding any other provision  
3 of law, this Act applies to any civil action brought  
4 by a claimant, whether in a Federal or State court,  
5 against a manufacturer, seller, or biomaterials  
6 supplier, on the basis of any legal theory, for harm  
7 allegedly caused by an implant.

8           (2) EXCLUSION.—A civil action brought by a  
9 purchaser of a medical device for use in providing  
10 professional services against a manufacturer, seller,  
11 or biomaterials supplier for loss or damage to an  
12 implant or for commercial loss to the purchaser—

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

15                   (B) shall be governed by applicable  
16 commercial or contract law.

17 (c) SCOPE OF PREEMPTION.—

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

24           (2) APPLICABILITY OF OTHER LAWS.—Any  
25 issue that arises under this Act and that is not

1 governed by a rule of law applicable to the recovery  
2 of damages described in paragraph (1) shall be gov-  
3 erned by applicable Federal or State law.

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

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

10 (2) to create a cause of action or Federal court  
11 jurisdiction pursuant to section 1331 or 1337 of title  
12 28, United States Code, that otherwise would not  
13 exist under applicable Federal or State law.

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

15 (a) IN GENERAL.—

16 (1) EXCLUSION FROM LIABILITY.—Except as  
17 provided in paragraph (2), a biomaterials supplier  
18 shall not be liable for harm to a claimant caused by  
19 an implant.

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

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

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

1 (C) furnishes raw materials or component  
2 parts that fail to meet applicable contractual  
3 requirements or specifications may be liable for  
4 a harm to a claimant described in subsection  
5 (d).

6 (b) LIABILITY AS MANUFACTURER.—

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

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

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

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

24 (B) is the subject of a declaration issued  
25 by the Secretary pursuant to paragraph (3)

1 that states that the supplier, with respect to the  
2 implant that allegedly caused harm to the  
3 claimant, was required to—

4 (i) register with the Secretary under  
5 section 510 of such Act (21 U.S.C. 360),  
6 and the regulations issued under such  
7 section, but failed to do so; or

8 (ii) include the implant on a list of  
9 devices filed with the Secretary pursuant  
10 to section 510(j) of such Act (21 U.S.C.  
11 360(j)) and the regulations issued under  
12 such section, but failed to do so; or

13 (C) is related by common ownership or  
14 control to a person meeting all the requirements  
15 described in subparagraph (A) or (B), if the  
16 court deciding a motion to dismiss in ac-  
17 cordance with section 6(c)(3)(B)(i) finds, on  
18 the basis of affidavits submitted in accordance  
19 with section 6, that it is necessary to impose  
20 liability on the biomaterials supplier as a  
21 manufacturer because the related manufacturer  
22 meeting the requirements of subparagraph (A)  
23 or (B) lacks sufficient financial resources to  
24 satisfy any judgment that the court feels it is  
25 likely to enter should the claimant prevail.

1 (3) ADMINISTRATIVE PROCEDURES.—

2 (A) IN GENERAL.—The Secretary may  
3 issue a declaration described in paragraph  
4 (2)(B) on the motion of the Secretary or on  
5 petition by any person, after providing—

6 (i) notice to the affected persons; and  
7 (ii) an opportunity for an informal  
8 hearing.

9 (B) DOCKETING AND FINAL DECISION.—

10 Immediately upon receipt of a petition filed  
11 pursuant to this paragraph, the Secretary shall  
12 docket the petition. Not later than 180 days  
13 after the petition is filed, the Secretary shall  
14 issue a final decision on the petition.

15 (C) APPLICABILITY OF STATUTE OF LIMITATIONS.—Any applicable statute of limitations  
16 shall toll during the period during which a  
17 claimant has filed a petition with the Secretary  
18 under this paragraph.

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

24 (1) the biomaterials supplier—

1 (A) held title to the implant that allegedly  
2 caused harm to the claimant as a result of  
3 purchasing the implant after—

4 (i) the manufacture of the implant;

5 and

6 (ii) the entrance of the implant in the  
7 stream of commerce; and

8 (B) subsequently resold the implant; or

9 (2) the biomaterials supplier is related by  
10 common ownership or control to a person meeting  
11 all the requirements described in paragraph (1), if a  
12 court deciding a motion to dismiss in accordance  
13 with section 6(c)(3)(B)(ii) finds, on the basis of affi-  
14 davits submitted in accordance with section 6, that  
15 it is necessary to impose liability on the biomaterials  
16 supplier as a seller because the related seller meet-  
17 ing the requirements of paragraph (1) lacks suffi-  
18 cient financial resources to satisfy any judgment  
19 that the court feels it is likely to enter should the  
20 claimant prevail.

21 (d) LIABILITY FOR VIOLATING CONTRACTUAL RE-  
22 QUIREMENTS OR SPECIFICATIONS.—A biomaterials  
23 supplier may, to the extent required and permitted by any  
24 other applicable law, be liable for harm to a claimant

1 caused by an implant, if the claimant in an action shows,  
2 by a preponderance of the evidence, that—

3 (1) the raw materials or component parts  
4 delivered by the biomaterials supplier either—

5 (A) did not constitute the product  
6 described in the contract between the biomate-  
7 rials supplier and the person who contracted for  
8 delivery of the product; or

9 (B) failed to meet any specifications that  
10 were—

11 (i) provided to the biomaterials  
12 supplier and not expressly repudiated by  
13 the biomaterials supplier prior to accept-  
14 ance of delivery of the raw materials or  
15 component parts;

16 (ii)(I) published by the biomaterials  
17 supplier;

18 (II) provided to the manufacturer by  
19 the biomaterials supplier; or

20 (III) contained in a master file that  
21 was submitted by the biomaterials supplier  
22 to the Secretary and that is currently  
23 maintained by the biomaterials supplier for  
24 purposes of premarket approval of medical  
25 devices; or

1 (iii) included in the submissions for  
2 purposes of premarket approval or review  
3 by the Secretary under section 510, 513,  
4 515, or 520 of the Federal Food, Drug,  
5 and Cosmetic Act (21 U.S.C. 360, 360e,  
6 360e, or 360j), and received clearance  
7 from the Secretary if such specifications  
8 were provided by the manufacturer to the  
9 biomaterials supplier and were not ex-  
10 pressly repudiated by the biomaterials sup-  
11 plier prior to the acceptance by the manu-  
12 facturer of delivery of the raw materials or  
13 component parts; and

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

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

18 (a) MOTION TO DISMISS.—In any action that is  
19 subject to this Act, a biomaterials supplier who is a de-  
20 fendant in such action may, at any time during which a  
21 motion to dismiss may be filed under an applicable law,  
22 move to dismiss the action against it on the grounds  
23 that—

24 (1) the defendant is a biomaterials supplier;  
25 and

1           (2)(A) the defendant should not, for the  
2 purposes of—

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

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

9           (B)(i) the claimant has failed to establish,  
10 pursuant to section 5(d), that the supplier furnished  
11 raw materials or component parts in violation of  
12 contractual requirements or specifications; or

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

15           (b) MANUFACTURER OF IMPLANT SHALL BE NAMED  
16 A PARTY.—The claimant shall be required to name the  
17 manufacturer of the implant as a party to the action,  
18 unless—

19           (1) the manufacturer is subject to service of  
20 process solely in a jurisdiction in which the biomate-  
21 rials supplier is not domiciled or subject to a service  
22 of process; or

23           (2) an action against the manufacturer is  
24 barred by applicable law.

1 (c) PROCEEDING ON MOTION TO DISMISS.—The  
2 following 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  
18 allegedly caused harm to the claimant, is-  
19 sued a declaration pursuant to section  
20 5(b)(2)(B); or

21 (ii) the defendant who filed the  
22 motion 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 (2) 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  
7 jurisdiction, until such time as the court rules  
8 on the motion to dismiss in accordance with the  
9 affidavits submitted by the parties in accord-  
10 ance with this section.

11           (B) DISCOVERY.—If a defendant files a  
12 motion to dismiss under subsection (a)(2)(B)(i)  
13 on the grounds that the biomaterials supplier  
14 did not furnish raw materials or component  
15 parts in violation of contractual requirements or  
16 specifications, the court may permit discovery,  
17 as ordered by the court. The discovery con-  
18 ducted pursuant to this subparagraph shall be  
19 limited 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 bio-  
2 materials supplier who is not subject to an ac-  
3 tion for harm to a claimant caused by an  
4 implant, other than an action relating to liabil-  
5 ity for a violation of contractual requirements  
6 or 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  
12 manufacturer subject to such section 5(b) or  
13 seller subject to section 5(c), unless the claim-  
14 ant submits a valid affidavit that demonstrates  
15 that—

16 (i) with respect to a motion to dismiss  
17 contending the defendant is not a  
18 manufacturer, the defendant meets the  
19 applicable requirements for liability as a  
20 manufacturer under section 5(b); or

21 (ii) with respect to a motion to  
22 dismiss contending that the defendant is  
23 not a seller, the defendant meets the appli-  
24 cable requirements for liability as a seller  
25 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  
7 affidavits submitted by the parties pursuant to  
8 this 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  
13 section raise genuine issues as concerning mate-  
14 rial facts with respect to a motion concerning  
15 contractual 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

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

3 (B) ISSUES OF MATERIAL FACT.—With  
4 respect 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  
7 submitted by claimant would be sufficient to  
8 allow a reasonable jury to reach a verdict for  
9 the claimant if the jury found the evidence to  
10 be credible.

11 (2) DISCOVERY MADE PRIOR TO A RULING ON  
12 A MOTION FOR SUMMARY JUDGMENT.—If, under  
13 applicable rules, the court permits discovery prior to  
14 a 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 as to the applicable elements  
18 set forth in paragraphs (1) and (2) of section 5(d).

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

1 ly to the extent permitted by the applicable Federal  
2 or State rules for discovery against nonparties.

3 (e) STAY PENDING PETITION FOR DECLARATION.—

4 If a claimant has filed a petition for a declaration  
5 pursuant to section 5(b)(3)(A) with respect to a defend-  
6 ant, and the Secretary has not issued a final decision on  
7 the petition, the court shall stay all proceedings with re-  
8 spect to that defendant until such time as the Secretary  
9 has issued a 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  
18 manufacturer agrees to bear the cost of such proceeding  
19 or to 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 biomate-  
25 rials supplier; and

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

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