

105<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 872

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## AN ACT

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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## AN ACT

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,*

1 **SECTION 1. SHORT TITLE**

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

4 **SEC. 2. FINDINGS.**

5 The Congress finds that—

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

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

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

16 (A) move in interstate commerce;

17 (B) are not designed or manufactured spe-  
18 cifically for use in medical devices; and

19 (C) come in contact with internal human  
20 tissue;

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

23 (5) because small quantities of the raw mate-  
24 rials and component parts are used for medical de-  
25 vices, sales of raw materials and component parts  
26 for medical devices constitute an extremely small

1 portion of the overall market for the raw materials  
2 and component parts;

3 (6) under the Federal Food, Drug, and Cos-  
4 metic Act (21 U.S.C. 301 et seq.) manufacturers of  
5 medical devices are required to demonstrate that the  
6 medical devices are safe and effective, including  
7 demonstrating that the products are properly de-  
8 signed and have adequate warnings or instructions;

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

14 (A) design and testing of medical devices  
15 manufactured with materials or parts supplied  
16 by the suppliers; or

17 (B) warnings related to the use of such  
18 medical devices;

19 (8) even though suppliers of raw materials and  
20 component parts have very rarely been held liable in  
21 such actions, such suppliers have ceased supplying  
22 certain raw materials and component parts for use  
23 in medical devices for a number of reasons, includ-  
24 ing concerns about the costs of such litigation;

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; or

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

6 (14) because medical devices and the raw mate-  
7 rials and component parts used in their manufacture  
8 move in interstate commerce, a shortage of such raw  
9 materials and component parts affects interstate  
10 commerce;

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

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

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

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

1 component parts for life-saving medical devices is  
2 one such circumstance; and

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

7 **SEC. 3. DEFINITIONS.**

8 As used in this Act:

9 (1) **BIOMATERIALS SUPPLIER.**—

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

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

16 (i) has submitted master files to the  
17 Secretary for purposes of premarket ap-  
18 proval of a medical device; or

19 (ii) licenses a biomaterials supplier to  
20 produce component parts or raw materials.

21 (2) **CLAIMANT.**—

22 (A) **IN GENERAL.**—The term “claimant”  
23 means any person who brings a civil action, or  
24 on whose behalf a civil action is brought, aris-  
25 ing from harm allegedly caused directly or indi-

1           rectly by an implant, including a person other  
2           than the individual into whose body, or in con-  
3           tact with whose blood or tissue, the implant is  
4           placed, who claims to have suffered harm as a  
5           result of the implant.

6                   (B) ACTION BROUGHT ON BEHALF OF AN  
7           ESTATE.—With respect to an action brought on  
8           behalf of or through the estate of a deceased in-  
9           dividual into whose body, or in contact with  
10          whose blood or tissue the implant was placed,  
11          such term includes the decedent that is the sub-  
12          ject of the action.

13                   (C) ACTION BROUGHT ON BEHALF OF A  
14          MINOR OR INCOMPETENT.—With respect to an  
15          action brought on behalf of or through a minor  
16          or incompetent, such term includes the parent  
17          or guardian of the minor or incompetent.

18                   (D) EXCLUSIONS.—Such term does not in-  
19          clude—

20                           (i) a provider of professional health  
21                           care services in any case in which—

22                                   (I) the sale or use of an implant  
23                                   is incidental to such services; and

24                                   (II) the essence of the profes-  
25                                   sional health care services provided is



1 the furnishing of judgment, skill, or  
2 services;

3 (ii) a person acting in the capacity of  
4 a manufacturer, seller, or biomaterials sup-  
5 plier; or

6 (iii) a person alleging harm caused by  
7 either the silicone gel or the silicone enve-  
8 lope utilized in a breast implant containing  
9 silicone gel, except that—

10 (I) neither the exclusion provided  
11 by this clause nor any other provision  
12 of this Act may be construed as a  
13 finding that silicone gel (or any other  
14 form of silicone) may or may not  
15 cause harm; and

16 (II) the existence of the exclusion  
17 under this clause may not—

18 (aa) be disclosed to a jury in  
19 any civil action or other proceed-  
20 ing; and

21 (bb) except as necessary to  
22 establish the applicability of this  
23 Act, otherwise be presented in  
24 any civil action or other proceed-  
25 ing.

1 (3) COMPONENT PART.—

2 (A) IN GENERAL.—The term “component  
3 part” means a manufactured piece of an im-  
4 plant.

5 (B) CERTAIN COMPONENTS.—Such term  
6 includes a manufactured piece of an implant  
7 that—

8 (i) has significant non-implant appli-  
9 cations; and

10 (ii) alone, has no implant value or  
11 purpose, but when combined with other  
12 component parts and materials, constitutes  
13 an implant.

14 (4) HARM.—

15 (A) IN GENERAL.—The term “harm”  
16 means—

17 (i) any injury to or damage suffered  
18 by an individual;

19 (ii) any illness, disease, or death of  
20 that individual resulting from that injury  
21 or damage; and

22 (iii) any loss to that individual or any  
23 other individual resulting from that injury  
24 or damage.

1 (B) EXCLUSION.—The term does not in-  
2 clude any commercial loss or loss of or damage  
3 to an implant.

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

5 (A) a medical device that is intended by  
6 the manufacturer of the device—

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

10 (ii) to remain in contact with bodily  
11 fluids or internal human tissue through a  
12 surgically produced opening for a period of  
13 less than 30 days; and

14 (B) suture materials used in implant pro-  
15 cedures.

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

19 (A) is engaged in the manufacture, prepa-  
20 ration, propagation, compounding, or processing  
21 (as defined in section 510(a)(1) of the Federal  
22 Food, Drug, and Cosmetic Act (21 U.S.C.  
23 360(a)(1)) of the implant; and

24 (B) is required—

1 (i) to register with the Secretary pur-  
2 suant to section 510 of the Federal Food,  
3 Drug, and Cosmetic Act (21 U.S.C. 360)  
4 and the regulations issued under such sec-  
5 tion; and

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

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

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

19 (A) has a generic use; and

20 (B) may be used in an application other  
21 than an implant.

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

24 (10) SELLER.—

1 (A) IN GENERAL.—The term “seller”  
2 means a person who, in the course of a business  
3 conducted for that purpose, sells, distributes,  
4 leases, packages, labels, or otherwise places an  
5 implant in the stream of commerce.

6 (B) EXCLUSIONS.—The term does not in-  
7 clude—

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

9 (ii) a provider of professional health  
10 care services in any case in which—

11 (I) the sale or use of the implant  
12 is incidental to such services; and

13 (II) the essence of the profes-  
14 sional health care services provided is  
15 the furnishing of judgment, skill, or  
16 services; or

17 (iii) any person who acts in only a fi-  
18 nancial capacity with respect to the sale of  
19 an implant.

20 **SEC. 4. GENERAL REQUIREMENTS; APPLICABILITY; PRE-**  
21 **EMPTION.**

22 (a) GENERAL REQUIREMENTS.—

23 (1) IN GENERAL.—In any civil action covered  
24 by this Act, a biomaterials supplier may—

1 (A) raise any exclusion from liability set  
2 forth in section 5; and

3 (B) make a motion for dismissal or for  
4 summary judgment as set forth in section 6.

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

10 (b) APPLICABILITY.—

11 (1) IN GENERAL.—Except as provided in para-  
12 graph (2), this Act applies to any civil action  
13 brought by a claimant, whether in a Federal or  
14 State court, on the basis of any legal theory, for  
15 harm allegedly caused, directly or indirectly, by an  
16 implant.

17 (2) EXCLUSION.—A civil action brought by a  
18 purchaser of a medical device, purchased for use in  
19 providing professional health care services, for loss  
20 or damage to an implant or for commercial loss to  
21 the purchaser—

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

24 (B) shall be governed by applicable com-  
25 mercial or contract law.

1 (c) SCOPE OF PREEMPTION.—

2 (1) IN GENERAL.—This Act supersedes any  
3 State law regarding recovery for harm caused by an  
4 implant and any rule of procedure applicable to a  
5 civil action to recover damages for such harm only  
6 to the extent that this Act establishes a rule of law  
7 applicable to the recovery of such damages.

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

13 (d) STATUTORY CONSTRUCTION.—Nothing in this  
14 Act may be construed—

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

19 (2) to create a cause of action or Federal court  
20 jurisdiction pursuant to section 1331 or 1337 of title  
21 28, United States Code, that otherwise would not  
22 exist under applicable Federal or State law.

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

24 (a) IN GENERAL.—Except as provided in section 7,  
25 a biomaterials supplier shall not be liable for harm to a

1 claimant caused by an implant unless such supplier is lia-  
2 ble—

3 (1) as a manufacturer of the implant, as pro-  
4 vided in subsection (b);

5 (2) as a seller of the implant, as provided in  
6 subsection (c); or

7 (3) for furnishing raw materials or component  
8 parts for the implant that failed to meet applicable  
9 contractual requirements or specifications, as pro-  
10 vided in subsection (d).

11 (b) LIABILITY AS MANUFACTURER.—

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

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

21 (A)(i) registered or was required to reg-  
22 ister with the Secretary pursuant to section 510  
23 of the Federal Food, Drug, and Cosmetic Act  
24 (21 U.S.C. 360) and the regulations issued  
25 under such section; and



1 (ii) included or was required to include the  
2 implant on a list of devices filed with the Sec-  
3 retary pursuant to section 510(j) of such Act  
4 (21 U.S.C. 360(j)) and the regulations issued  
5 under such section;

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

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

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

20 (C) is related by common ownership or  
21 control to a person meeting all the requirements  
22 described in subparagraph (A) or (B), if the  
23 court deciding a motion to dismiss in accord-  
24 ance with section 6(c)(3)(B)(i) finds, on the  
25 basis of affidavits submitted in accordance with

1 section 6, that it is necessary to impose liability  
2 on the biomaterials supplier as a manufacturer  
3 because the related manufacturer meeting the  
4 requirements of subparagraph (A) or (B) lacks  
5 sufficient financial resources to satisfy any  
6 judgment that the court feels it is likely to  
7 enter should the claimant prevail.

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 120 days  
20 after the petition is filed, the Secretary shall  
21 issue a final decision on the petition.

22 (C) APPLICABILITY OF STATUTE OF LIMI-  
23 TATIONS.—Any applicable statute of limitations  
24 shall toll during the period from the time a  
25 claimant files a petition with the Secretary

1 under this paragraph until such time as either  
2 (i) the Secretary issues a final decision on the  
3 petition, or (ii) the petition is withdrawn.

4 (D) STAY PENDING PETITION FOR DEC-  
5 LARATION.—If a claimant has filed a petition  
6 for a declaration with respect to a defendant,  
7 and the Secretary has not issued a final deci-  
8 sion on the petition, the court shall stay all pro-  
9 ceedings with respect to that defendant until  
10 such time as the Secretary has issued a final  
11 decision on the petition.

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 only if—

16 (1) the biomaterials supplier—

17 (A) held title to the implant and then  
18 acted as a seller of the implant after its initial  
19 sale by the manufacturer; or

20 (B) acted under contract as a seller to ar-  
21 range for the transfer of the implant directly to  
22 the claimant after the initial sale by the manu-  
23 facturer of the implant; or

24 (2) the biomaterials supplier is related by com-  
25 mon ownership or control to a person meeting all the

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

11 (d) LIABILITY FOR FAILURE TO MEET APPLICABLE  
12 CONTRACTUAL REQUIREMENTS OR SPECIFICATIONS.—A  
13 biomaterials supplier may, to the extent required and per-  
14 mitted by any other applicable law, be liable for harm to  
15 a claimant caused by an implant if the claimant in an ac-  
16 tion shows, by a preponderance of the evidence, that—

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

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

24 (B) failed to meet any specifications that  
25 were—

- 1 (i) accepted, pursuant to applicable  
2 law, by the biomaterials supplier;
- 3 (ii) published by the biomaterials sup-  
4 plier;
- 5 (iii) provided by the biomaterials sup-  
6 plier to the person who contracted for such  
7 product;
- 8 (iv) 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 (v) 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 accepted, pursuant to applicable law,  
22 by the biomaterials supplier; and
- 23 (2) such failure to meet applicable contractual  
24 requirements or specifications was an actual and  
25 proximate cause of the harm to the claimant.

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

3 (a) MOTION TO DISMISS.—A defendant may, at any  
4 time during which a motion to dismiss may be filed under  
5 applicable law, move to dismiss an action against it on  
6 the grounds that the defendant is a biomaterials supplier  
7 and one or more of the following:

8 (1) The defendant is not liable as a manufac-  
9 turer, as provided in section 5(b).

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

12 (3) The defendant is not liable for furnishing  
13 raw materials or component parts for the implant  
14 that failed to meet applicable contractual require-  
15 ments or specifications, as provided in section 5(d).

16 (4) The claimant did not name the manufac-  
17 turer as a party to the action, as provided in sub-  
18 section (b).

19 (b) MANUFACTURER OF IMPLANT SHALL BE NAMED  
20 A PARTY.—In any civil action covered by this Act, the  
21 claimant shall be required to name the manufacturer of  
22 the implant as a party to the action, unless—

23 (1) the manufacturer is subject to service of  
24 process solely in a jurisdiction in which the biomate-  
25 rials supplier is not domiciled or subject to a service  
26 of process; or

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

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

6           (1) EFFECT OF MOTION TO DISMISS ON DIS-  
7           COVERY.—

8           (A) IN GENERAL.—Except as provided in  
9           subparagraph (B), if a defendant files a motion  
10          to dismiss under subsection (a), no discovery  
11          shall be permitted in connection with the action  
12          that is the subject of the motion, other than  
13          discovery necessary to determine a motion to  
14          dismiss for lack of jurisdiction, until such time  
15          as the court rules on the motion to dismiss.

16          (B) DISCOVERY.—If a defendant files a  
17          motion to dismiss under subsection (a)(3) on  
18          the grounds that it did not furnish raw mate-  
19          rials or component parts for the implant that  
20          failed to meet applicable contractual require-  
21          ments or specifications, the court may permit  
22          discovery limited to issues that are directly rel-  
23          evant to—

24                       (i) the pending motion to dismiss; or

25                       (ii) the jurisdiction of the court.

1 (2) AFFIDAVITS.—

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

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

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

19 or

20 (ii) the defendant is a seller of the im-  
21 plant who is liable under section 5(c).

22 (3) BASIS OF RULING ON MOTION TO DIS-  
23 MISS.—The court shall rule on a motion to dismiss  
24 filed under subsection (a) solely on the basis of the  
25 pleadings and affidavits of the parties made pursu-



1 ant to this subsection. The court shall grant a mo-  
2 tion to dismiss filed under subsection (a)—

3 (A) unless the claimant submits a valid af-  
4 fidavit that demonstrates that the defendant is  
5 not a biomaterials supplier;

6 (B) unless the court determines, to the ex-  
7 tent raised in the pleadings and affidavits, that  
8 one or more of the following apply:

9 (i) the defendant may be liable as a  
10 manufacturer, as provided in section 5(b);

11 (ii) the defendant may be liable as a  
12 seller, as provided in section 5(c); or

13 (iii) the defendant may be liable for  
14 furnishing raw materials or component  
15 parts for the implant that failed to meet  
16 applicable contractual requirements or  
17 specifications, as provided in section 5(d);

18 or

19 (C) if the claimant did not name the man-  
20 ufacturer as a party to the action, as provided  
21 in subsection (b).

22 (4) TREATMENT OF MOTION AS MOTION FOR  
23 SUMMARY JUDGMENT.—The court may treat a mo-  
24 tion to dismiss as a motion for summary judgment  
25 subject to subsection (d) in order to determine

1 whether the pleadings and affidavits, in connection  
2 with such action, raise genuine issues of material  
3 fact concerning whether the defendant furnished raw  
4 materials or component parts of the implant that  
5 failed to meet applicable contractual requirements or  
6 specifications as provided in section 5(d).

7 (d) SUMMARY JUDGMENT.—

8 (1) IN GENERAL.—

9 (A) BASIS FOR ENTRY OF JUDGMENT.—If  
10 a motion to dismiss of a biomaterials supplier  
11 is to be treated as a motion for summary judg-  
12 ment under subsection (c)(4) or if a biomate-  
13 rials supplier moves for summary judgment, the  
14 biomaterials supplier shall be entitled to entry  
15 of judgment without trial if the court finds  
16 there is no genuine issue of material fact for  
17 each applicable element set forth in paragraphs  
18 (1) and (2) of section 5(d).

19 (B) ISSUES OF MATERIAL FACT.—With re-  
20 spect to a finding made under subparagraph  
21 (A), the court shall consider a genuine issue of  
22 material fact to exist only if the evidence sub-  
23 mitted by the claimant would be sufficient to  
24 allow a reasonable jury to reach a verdict for

1           the claimant if the jury found the evidence to  
2           be credible.

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

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

19          (e) DISMISSAL WITH PREJUDICE.—An order grant-  
20          ing a motion to dismiss or for summary judgment pursu-  
21          ant to this section shall be entered with prejudice, except  
22          insofar as the moving defendant may be rejoined to the  
23          action as provided in section 7.

24          (f) MANUFACTURER CONDUCT OF LITIGATION.—The  
25          manufacturer of an implant that is the subject of an ac-

1 tion covered under this Act shall be permitted to conduct  
2 litigation on any motion for summary judgment or dismis-  
3 sal filed by a biomaterials supplier who is a defendant  
4 under this section on behalf of such supplier if the manu-  
5 facturer and any other defendant in such action enter into  
6 a valid and applicable contractual agreement under which  
7 the manufacturer agrees to bear the cost of such litigation  
8 or to conduct such litigation.

9 **SEC. 7. SUBSEQUENT IMPLAINDER OF DISMISSED BIOMATE-**  
10 **RIALS SUPPLIER.**

11 (a) IMPEADING OF DISMISSED DEFENDANT.—A  
12 court, upon motion by a manufacturer or a claimant with-  
13 in 90 days after entry of a final judgment in an action  
14 by the claimant against a manufacturer, and notwith-  
15 standing any otherwise applicable statute of limitations,  
16 may implead a biomaterials supplier who has been dis-  
17 missed from the action pursuant to this Act if—

18 (1) the manufacturer has made an assertion, ei-  
19 ther in a motion or other pleading filed with the  
20 court or in an opening or closing statement at trial,  
21 or as part of a claim for contribution or indemnifica-  
22 tion, and the court finds based on the court's inde-  
23 pendent review of the evidence contained in the  
24 record of the action, that under applicable law—

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

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

9 (2) the claimant has moved to implead the sup-  
10 plier and the court finds, based on the court's inde-  
11 pendent review of the evidence contained in the  
12 record of the action, that under applicable law—

13 (A) the negligence or intentionally tortious  
14 conduct of the dismissed supplier was an actual  
15 and proximate cause of the harm to the claim-  
16 ant; and

17 (B) the claimant is unlikely to be able to  
18 recover the full amount of its damages from the  
19 remaining defendants.

20 (b) STANDARD OF LIABILITY.—Notwithstanding any  
21 preliminary finding under subsection (a), a biomaterials  
22 supplier who has been impleaded into an action covered  
23 by this Act, as provided for in this section—

24 (1) may, prior to entry of judgment on the  
25 claim against it, supplement the record of the pro-

1 ceeding that was developed prior to the grant of the  
2 motion for impleader under subsection (a); and

3 (2) may be found liable to a manufacturer or  
4 a claimant only to the extent required and permitted  
5 by any applicable State or Federal law other than  
6 this Act.

7 (c) DISCOVERY.—Nothing in this section shall give  
8 a claimant or any other party the right to obtain discovery  
9 from a biomaterials supplier at any time prior to grant  
10 of a motion for impleader beyond that allowed under sec-  
11 tion 6.

12 **SEC. 8. EFFECTIVE DATE.**

13 This Act shall apply to all civil actions covered under  
14 this Act that are commenced on or after the date of enact-  
15 ment of this Act, including any such action with respect  
16 to which the harm asserted in the action or the conduct  
17 that caused the harm occurred before the date of enact-  
18 ment of this Act.

Passed the House of Representatives July 30 (legis-  
lative day, July 29), 1998.

Attest:

*Clerk.*