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Product Liability - Biomaterials Provision

Withdrawal/Redaction Sheet
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. email	From: Sarah Rosen To: Gene Sperling, et al.; RE: Phone No's. (Partial) (1 page)	08/07/1998	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Elena Kagan
OA/Box Number: 14365

FOLDER TITLE:
Product Liability - Biomaterials Provision

2009-1006-F
db1537

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Withdrawal/Redaction Marker
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Product liability - biomaterials

Sarah Rosen
08/07/98 07:26:47 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: Biomaterials Signing

I do not know when the President will sign this bill next week (deadline is Aug. 15th), but I will be out of the office on Monday and Tuesday, so I wanted to circulate this draft signing statement and provide the background attached in case this comes up then. If you have comments, please email to both me and Jake Siewert, who will incorporate comments if necessary while I am out.

If you need to reach me, I should be page-able through signal or at 1-800-sky-page, pin #216-8036 or reachable at P6/(b)(6) If I can't be reached and you have a legal question, you also can call Fran Allegra who is helping out family in Cleveland at P6/(b)(6) or page him through the DoJ command center at 514--5000.

bioback.gr

STATEMENT OF THE PRESIDENT
August XX, 1998

I am pleased to sign today the Biomaterials Access Assurance Act of 1998, which should help to ensure the continued availability of life-saving and life-enhancing medical devices. The bill protects certain raw materials and parts suppliers from liability for harm caused by a medical implant. Congress heard significant evidence that these biomaterials suppliers are increasingly unwilling to sell their goods to implant manufacturers. Although these suppliers have never been found liable, they fear that their costs to defend themselves, if dragged into litigation over the medical device, would far outweigh the profits they would earn from supplying the raw materials. But without those materials, Americans would have to live without the heart valves, jaw implants, artificial hips, and other medical devices (including many not yet imagined) that can help the victims of disease and injury stay alive or improve the quality of their lives.

This bill is an appropriate limitation on tort liability, because there has been a showing of an important need -- maintaining the supply of biomaterials -- and the law is narrowly crafted to accomplish that objective. This bill addresses concerns that I raised, when I vetoed the product liability bill in 1996, about that bill's biomaterials provision. Changes made in this bill ensure that no plaintiff will be unable to recover the full amount of the damages she was awarded, because a supplier, whose negligence or intentionally tortious behavior was a cause of the plaintiff's harm, was protected from liability under this bill. As narrowed in this way, this bill represents a limited and balanced response to a demonstrated need and merits

signature.

Message Sent To:

Gene B. Sperling/OPD/EOP
David W. Beier/OVP @ OVP
Charles W. Burson/OVP @ OVP
John Podesta/WHO/EOP
Bruce R. Lindsey/WHO/EOP
Peter G. Jacoby/WHO/EOP
Sally Katzen/OPD/EOP
Shannon Mason/OPD/EOP
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Barbara Chow/OMB/EOP
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Jonathan A. Kaplan/OPD/EOP

BACKGROUND ON BIOMATERIALS

August 7, 1998

What are biomaterials?

"Biomaterials" are raw materials or component parts used in the manufacture of an implant -- a device placed in the body or in contact with bodily fluids or internal human tissue (e.g., joint replacements, pacemakers). Examples of biomaterials include the resin used in artificial heart values and Teflon once used in jaw implants.

What is the problem?

Suppliers of raw materials and component parts are increasingly unwilling to sell their goods to implant manufacturers out of fear of being dragged into costly litigation over the medical devices. Under current law, the suppliers have rarely if ever been found liable; however, they can be brought into the litigation. Some suppliers have spent considerable sums defending themselves. The suppliers argue that the potential litigation costs faced so dwarf the profits from these sales that the suppliers are better off refusing to sell to the manufacturers of these goods, since sales of the materials for use in medical devises are generally only a small portion of the overall market for these materials.

During Congressional hearings, industry representatives gave as an example the total global revenues in 1992 for polyacetol resin (used in artificial heart values) for all medical applications was only $214.50. In another story, a supplier alleged that a nickel's worth of Teflon in a jaw implant caused the supplier to incur $40 million in court costs. Several studies suggest that these problems are not isolated. Suppliers argue that without protection from liability, biomaterials would be unavailable leading to the unavailability of lifesaving and life-enhancing medical devices.

What does the Biomaterials bill do?

Under the biomaterials title of the bill, raw material and component part suppliers could not be liable for harm and could obtain an expeditious ruling on a motion to dismiss or for summary judgement if the generic raw material or component part supplied met contractual specifications and if the supplier could not be classified as either a manufacturer or a seller of the implant. The provision would immunize most biomaterials suppliers from suits for deficiencies in the design or testing of a medical device or for inadequate warnings with respect to that device.

What was the Administration's position on biomaterials?

On May 2, 1996, the President vetoed product liability legislation that contained an early version of the biomaterial provisions. While generally supportive of the legislation's purpose, the President said that he could not support provisions that protected suppliers when they knew or should have known that the material they were supplying was unsuitable for the purpose intended. Amendments were added to address our concerns. Under a new impleader section in this bill, once a final judgment had been rendered in a claimant's action against a manufacturer, a court could bring back into the case a supplier whose negligence or intentionally tortious conduct was a cause of the harm, if the manufacturer's liability should be reduced because of that negligence or intentionally tortious conduct or the manufacturer is insolvent. The White House remained concerned that the impleader rule was still too restrictive. However, Senator Lieberman agreed to drop the most limiting provision -- a requirement for "clear and convincing" evidence demonstrating that the supplier's negligence caused the claimant's injuries.

What was the "Baxter amendment"?

The Baxter amendment is not included in this bill. It was incorporated in a version of the biomaterials title of the broader product liability bill when it came to the Senate Floor early this summer. However, when the stand-alone biomaterials bill moved this year, Baxter was not added.

The Baxter amendment would have broadened the definition of "implant" to include IVS and catheters.

Specifically, implant would include: "containers and their related products to be used to collect fluids or tissue from the body or to infuse or otherwise introduce fluids or tissue into the body in conjunction with a medical device [that is intended by the manufacturer of the device (1) to be placed into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days; or (2) to remain in contact with bodily fluids or internal human tissue through a surgically produced opening for any period of time]."

By broadening the definition of implant, the amendment would broaden the protection from liability to those who supply raw materials or component parts for use in the manufacture of such IVS and catheters.

The Administration has been told that the goal of the Baxter amendment is to address concern of the Baxter Healthcare Corporation that their regular supplier of raw materials was purchased by a larger company which is concerned about potential liability, will no longer enter into long-term contracts to supply the plastics materials, and may eventually be unwilling to supply the material at all. If so, the company would need to retool and reengineer its plants at great expense to use the other materials available that might be adapted for this use. **The Administration**

expressly asked whether there had been any litigation involving the biomaterials that would be covered by the bill and was told that there had been none.

What has the Administration said on the Baxter amendment?

On May 1, 1998, in a private letter to Senators Gorton and Rockefeller, which does not appear to be in the public domain, Gene Sperling and Bruce Lindsey wrote:

"We are not prepared to expand the biomaterials provision to cover raw materials and component parts of IVS (intervenous apparatuses) and catheters, which are unlike the medical implants covered by the provisions where only a few hundred are used each year, materials suppliers face a demonstrated litigation threat, and there is a current danger of product unavailability."

Thereafter, when the product liability bill came to the Senate floor in a version that incorporated the Baxter amendment, the White House confirmed publicly that Senator Lott had been told that the President would not veto that bill over the inclusion of the Baxter amendment.

Product liability – biomaterials

From: Ingrid M. Schroeder on 07/27/98 05:38:53 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Elena Kagan/OPD/EOP, Laura Emmett/WHO/EOP
Subject: URGENT - Biomats. SAP

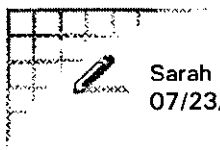
Attached is the rewrite of the HR 872 - Biomats SAP. This version has been approved by Podesta, Sperling, Katzen, and Lindsey. Please let me know ASAP if you have any comments. Thanks

"The Administration supports House passage of H.R. 872 in the form of the manager's amendment. The bill would protect certain biomaterials suppliers from liability for harm caused by an implant. In vetoing legislation that included a separate biomaterials title in 1996, the President expressed general support for the goals of the biomaterials bill, but objected to the language because it would protect from liability even those suppliers who knew or should have known that the materials, as implanted, would cause injury. The bill before the House does not protect those suppliers whose negligence or intentionally tortious conduct was a cause of the harm, if the manufacturer's liability should be reduced because of that negligence or intentionally tortious conduct or if the manufacturer is insolvent. This bill is narrowly crafted to address the demonstrated problem that the supply of life-saving and life-enhancing bodily implants is threated by the refusal of suppliers of raw materials and component parts to provide their parts and materials because their potential costs defending against liability claims exceed their profits from sale of the parts and materials."

Message Sent To:

Christopher C. Jennings/OPD/EOP
Peter G. Jacoby/WHO/EOP
John E. Thompson/OMB/EOP
David J. Haun/OMB/EOP
Steven D. Aitken/OMB/EOP
Marc Garufi/OMB/EOP
Richard J. Turman/OMB/EOP
Ellen J. Balis/OMB/EOP

Product Liab - Biomaterials



Sarah Rosen
07/23/98 01:06:29 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: See the distribution list at the bottom of this message
Subject: Movement on Biomaterials Bill

Note: Reply requested by COB Friday, if possible. House floor action possible next Tuesday.

The House may take up a stand-alone biomaterials bill on the suspension calendar next Tuesday or the following Tuesday. Senator Lieberman's office tells me that the Senator hopes to have the Senate take up the House version directly, thus avoiding a conference. As a result, Senator Lieberman wants to make sure that the Administration is comfortable with the version that will be adopted by the House and asked us for any comments.

Before the House Commerce and Judiciary Committees reported out their stand-alone biomaterials bill, majority and minority staff, along representatives of the Health Industry Manufacturers Association (the principal biomaterials bill proponent) and the Association of Trial Lawyers of America made significant, technical drafting changes to the Senate version. Senator Lieberman's office has asked us to review those changes and let them know whether or not we would object to the bill as rewritten. (Note: The House bill does not include the Baxter amendment.)

Fran Allegra (DoJ) and I have closely reviewed the rewrite. The changes clearly are motivated by an intent to clarify and improve the drafting of the biomaterials provision and almost all are changes to which we are indifferent or which we consider technical improvements.

Two changes are substantive but seem reasonable. The first would authorize the court to stay proceedings while the Secretary of HHS considers a petition to declare that the supplier was required to register the implant with the Secretary or include it on a list of devices filed with the Secretary, and thus can be found liable as a manufacturer notwithstanding the protection in the bill. As a practical matter, a court would be likely issue such a stay. This change just provides clear authority. (In addition, at our request on behalf of HHS, the time provided for the Secretary to make that declaration has been extended from 45 to 120 days.)

The second change limits the liability protection provided by the bill by allowing a supplier to be held liable as a seller, not only where the supplier acts expressly as a seller, but also where its acts effectively as a seller, but by closing in escrow and acting under contract with the manufacturer, avoid legal status as a seller. This provision was added by House counsel because of fear that biomaterials suppliers, who are also sellers, would find creative ways to avoid liability. HIMA reluctantly agreed to the change.

There were a few changes that raised new technical drafting issues. We provided the Hill staff with a list and they have tentatively agreed to all our further edits, subject to final review. We should hear back shortly. The staff plan to offer an amendment, including the technical changes we requested, as the bill is brought up on the suspension calendar next Tuesday or the Tuesday thereafter.

We have **not** said that the Administration supports this biomaterials bill, although last week we told Senator Lieberman that we would not object if biomaterials moved separately, so long as Senator Rockefeller did not object. (He has said that he does not.) When it comes up on the House floor, we will be asked to say officially whether we support this biomaterials bill. I assume that, if all our technical concerns are met, the answer is yes (or at least we have no objection), but please let me know **by close of business Friday** your views.

If you would like to receive a copy of the House bill, please let me know.

Thank you.

Message Sent To:

Gene B. Sperling/OPD/EOP
Sally Katzen/OPD/EOP
John Podesta/WHO/EOP
Bruce R. Lindsey/WHO/EOP
Charles W. Burson/OVP @ OVP
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Chris

Message Copied To:

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Jessica L. Gibson/WHO/EOP
Marjorie Tarmey/WHO/EOP
Theodore Wartell/OMB/EOP
Patricia E. Romani/OMB/EOP
Jonathan A. Kaplan/OPD/EOP
Jake Siewert/OPD/EOP

Product liability - biomaterials

DRAFT – NOT FOR RELEASE

July 27, 1998
(House)

H.R. 872 - Biomaterials Access Assurance Act of 1998
(Gekas (R) Pennsylvania and 133 cosponsors)

The Administration supports House passage of H.R. 872 in the form of the manager's amendment which would protect certain biomaterials supplier from liability for harm caused by an implant. This protection would not apply to suppliers: (1) who are registered manufacturers of the implant; (2) who are sellers of the implant and who held title to the implant at the time of sale (or is related by common ownership or control to such a seller); (3) who furnish raw materials or components that fail to meet applicable contractual requirements or specifications; or (4) whose negligence or intentionally tortious conduct was a cause of the harm, if the manufacturer's liability should be reduced because of that negligence or intentionally tortious conduct or the manufacturer is insolvent.

* * * * * * *

AMENDMENT IN THE NATURE OF A SUBSTITURE FOR H.R. 872 OFFERED BY MR. GEKAS

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE

This Act may be cited as the "Biomaterials Access Assurance Act of 1997".

SEC. 2. FINDINGS.

The Congress finds that—

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

(2) a continued supply of raw materials and component parts is necessary for the invention, development, improvement, and maintenance of the supply of the devices;

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

(A) move in interstate commerce;

(B) are not designed or manufactured specifically for use in medical devices; and

(C) come in contact with internal human tissue;

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

(5) because small quantities of the raw materials and component parts are used for medical devices, sales of raw materials and component parts for medical devices constitute an extremely small portion of the overall market for the raw materials and component parts;

(6) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) manufacturers of medical devices are required to demonstrate that the medical devices are safe and effective, including demonstrating that the products are properly designed and have adequate warnings or instructions;

(7) notwithstanding the fact that raw materials and component parts suppliers do not design, produce, or test a final medical device, the suppliers have been the subject of actions alleging inadequate—

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

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

(8) even though suppliers of raw materials and component parts have very rarely been held liable in such actions, such suppliers have ceased supplying certain raw materials and component parts for use in medical devices for a number of reasons, including concerns about the costs of such litigation;

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

(10) because other suppliers of the raw materials and component parts in foreign nations are refusing to sell raw materials or component parts for use in manufacturing certain medical devices in the United States, the prospects for development of new sources of supply for the full range of threatened raw materials and component parts for medical devices are remote;

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

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

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

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

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

(14) because medical devices and the raw materials and component parts used in their manufacture move in interstate commerce, a shortage of such raw materials and component parts affects interstate commerce;

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

(A) to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices; and

(B) to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs;

(16) the several States and their courts are the primary architects and regulators of our tort system; Congress, however, must, in certain circumstances involving the national interest, address tort issues, and a threatened shortage of raw materials and component parts for life-saving medical devices is one such circumstance; and

(17) the protections set forth in this Act are needed to assure the continued supply of materials for life-saving medical devices; however, negligent suppliers should not be protected.

SEC. 3. DEFINITIONS.

As used in this Act:

(1) BIOMATERIALS SUPPLIER.—

(A) IN GENERAL.—The term "biomaterials supplier" means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant.

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

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

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

(2) CLAIMANT.—

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

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

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

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

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

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

(II) the essence of the transaction is the furnishing of judgment, skill, or services;

(ii) a person acting in the capacity of a manufacturer, seller, or biomaterials supplier; or

(iii) a person alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel, except that—

(I) neither the exclusion provided by this clause nor any other provision of this Act may be construed as a finding that silicone gel (or any other

form of silicone) may or may not cause harm; and

(II) the existence of the exclusion under this clause may not be disclosed to a jury in any civil action or other proceeding, and except as necessary to establish the applicability of this Act, otherwise be presented in any civil action or other proceeding.

(3) COMPONENT PART.—

(A) IN GENERAL.—The term "component part" means a manufactured piece of an implant.

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

(i) has significant non-implant applications; and

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

(4) HARM.—

(A) GENERAL.—The term "harm" means—

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

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

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

(B) EXCLUSION.—The term does not include any commercial loss or loss of or damage to an implant.

(5) IMPLANT.—The term "implant" means—

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

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

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

(B) suture materials used in implant procedures.

(6) MANUFACTURER.—The term "manufacturer" means any person who, with respect to an implant—

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

(B) is required—

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

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

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

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

(A) has a generic use; and

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

(9) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(10) SELLER.—

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

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

(i) a seller or lessor of real property;

(ii) a provider of professional services, in any case in which the sale or use of an implant is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who acts in only a financial capacity with respect to the sale of an implant.

SEC. 4. GENERAL REQUIREMENTS; APPLICABILITY; PREEMPTION.

(a) GENERAL REQUIREMENTS.—

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

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

(b) APPLICABILITY.—

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

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

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

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

(c) SCOPE OF PREEMPTION.—

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

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

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

(1) to affect any defense available to a defendant under any other provisions of Federal or State law in an action alleging harm caused by an implant; or

(2) to create a cause of action or Federal court jurisdiction pursuant to section 1331 or 1337 of title

28, United States Code, that otherwise would not exist under applicable Federal or State law.

SEC. 5. LIABILITY OF BIOMATERIALS SUPPLIERS.

(a) IN GENERAL.—

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

(2) LIABILITY.—A biomaterials supplier that—

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

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

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

(b) LIABILITY AS MANUFACTURER.—

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

(2) GROUNDS FOR LIABILITY.—The biomaterials supplier may be considered the manufacturer of

the implant that allegedly caused harm to a claimant only if the biomaterials supplier—

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

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

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

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

(ii) include the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C.

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

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

(3) ADMINISTRATIVE PROCEDURES.—

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

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

(B) DOCKETING AND FINAL DECISION.—Immediately upon receipt of a petition filed

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

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

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

(1) the biomaterials supplier—

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

(i) the manufacture of the implant; and

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

(B) subsequently resold the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the requirements described in paragraph (1), if a court

deciding a motion to dismiss in accordance with section 6(c)(3)(B)(ii) finds, on the basis of affidavits submitted in accordance with section 6, that it is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) LIABILITY FOR VIOLATING CONTRACTUAL REQUIREMENTS OR SPECIFICATIONS.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the claimant in an action shows, by a preponderance of the evidence, that—

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

(A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for delivery of the product; or

(B) failed to meet any specifications that were—

(i) provided to the biomaterials supplier and not expressly repudiated by the

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

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

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

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

(iii) included in the submissions for purposes of premarket approval or review by the Secretary under section 510, 513, 515, or 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360, 360c, 360e, or 360j), and received clearance from the Secretary if such specifications were provided by the manufacturer to the biomaterials supplier and were not expressly repudiated by the biomaterials supplier prior to the acceptance by the manu-

facturer of delivery of the raw materials or component parts; and

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

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

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

(1) the defendant is a biomaterials supplier; and

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

(i) section 5(b), be considered to be a manufacturer of the implant that is subject to such section; or

(ii) section 5(c), be considered to be a seller of the implant that allegedly caused harm to the claimant; or

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

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

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

(1) the manufacturer is subject to service of process solely in a jurisdiction in which the biomaterials supplier is not domiciled or subject to a service of process; or

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

(c) PROCEEDING ON MOTION TO DISMISS.—The following rules shall apply to any proceeding on a motion to dismiss filed under this section:

(1) AFFIDAVITS RELATING TO LISTING AND DECLARATIONS.—

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

(B) RESPONSE TO MOTION TO DISMISS.—In response to the motion to dismiss, the claim-

ant may submit an affidavit demonstrating that—

(i) the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 5(b)(2)(B); or

(ii) the defendant who filed the motion to dismiss is a seller of the implant who is liable under section 5(c).

(2) EFFECT OF MOTION TO DISMISS ON DISCOVERY.—

(A) IN GENERAL.—If a defendant files a motion to dismiss under paragraph (1) or (2) of subsection (a), no discovery shall be permitted in connection to the action that is the subject of the motion, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss in accordance with the affidavits submitted by the parties in accordance with this section.

(B) DISCOVERY.—If a defendant files a motion to dismiss under subsection (a)(2)(B)(i) on the grounds that the biomaterials supplier

did not furnish raw materials or component parts in violation of contractual requirements or specifications, the court may permit discovery, as ordered by the court. The discovery conducted pursuant to this subparagraph shall be limited to issues that are directly relevant to—

(i) the pending motion to dismiss; or

(ii) the jurisdiction of the court.

(3) AFFIDAVITS RELATING TO STATUS OF DEFENDANT.—

(A) IN GENERAL.—Except as provided in clauses (i) and (ii) of subparagraph (B), the court shall consider a defendant to be a biomaterials supplier who is not subject to an action for harm to a claimant caused by an implant, other than an action relating to liability for a violation of contractual requirements or specifications described in section 5(d).

(B) RESPONSES TO MOTION TO DISMISS.—The court shall grant a motion to dismiss any action that asserts liability of the defendant under subsection (b) or (c) of section 5 on the grounds that the defendant is not a manufacturer subject to such section 5(b) or seller sub-

ject to section 5(c), unless the claimant submits a valid affidavit that demonstrates that—

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

(ii) with respect to a motion to dismiss contending that the defendant is not a seller, the defendant meets the applicable requirements for liability as a seller under section 5(c).

(4) BASIS OF RULING ON MOTION TO DISMISS.—

(A) IN GENERAL.—The court shall rule on a motion to dismiss filed under subsection (a) solely on the basis of the pleadings of the parties made pursuant to this section and any affidavits submitted by the parties pursuant to this section.

(B) MOTION FOR SUMMARY JUDGMENT.—Notwithstanding any other provision of law, if the court determines that the pleadings and affidavits made by parties pursuant to this section raise genuine issues as concerning material

facts with respect to a motion concerning contractual requirements and specifications, the court may deem the motion to dismiss to be a motion for summary judgment made pursuant to subsection (d).

(d) SUMMARY JUDGMENT.—

(1) IN GENERAL.—

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

(B) ISSUES OF MATERIAL FACT.—With respect to a finding made under subparagraph (A), the court shall consider a genuine issue of material fact to exist only if the evidence submitted by claimant would be sufficient to allow a reasonable jury to reach a verdict for the claimant if the jury found the evidence to be credible.

(2) DISCOVERY MADE PRIOR TO A RULING ON A MOTION FOR SUMMARY JUDGMENT.—If, under applicable rules, the court permits discovery prior to a ruling on a motion for summary judgment made

pursuant to this subsection, such discovery shall be limited solely to establishing whether a genuine issue of material fact exists as to the applicable elements set forth in paragraphs (1) and (2) of section 5(d).

(3) DISCOVERY WITH RESPECT TO A BIOMATERIALS SUPPLIER.—A biomaterials supplier shall be subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 5(d) or the failure to establish the applicable elements of section 5(d) solely to the extent permitted by the applicable Federal or State rules for discovery against nonparties.

(e) STAY PENDING PETITION FOR DECLARATION.—If a claimant has filed a petition for a declaration pursuant to section 5(b)(3)(A) with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition. The Secretary shall complete review of any such petition within 6 weeks of receipt of the petition.

(f) DISMISSAL WITH PREJUDICE.—An order granting a motion to dismiss or for summary judgment pursuant to this section shall be entered with prejudice, except

insofar as the moving defendant may be rejoined to the action as provided in section 7.

(g) MANUFACTURER CONDUCT OF LITIGATION.—The manufacturer of an implant that is the subject of an action covered under this Act shall be permitted to conduct litigation on any motion for summary judgment or dismissal filed by a biomaterials supplier who is a defendant under this section on behalf of such supplier if the manufacturer and any other defendant in such action enter into a valid and applicable contractual agreement under which the manufacturer agrees to bear the cost of such litigation or to conduct such litigation.

SEC. 7. SUBSEQUENT IMPLEADER OF DISMISSED DEFENDANT.

(a) IMPLEADING OF DISMISSED DEFENDANT.—A court, upon motion by a manufacturer or a claimant within 90 days after entry of a final judgment in an action by the claimant against a manufacturer, and notwithstanding any otherwise applicable statute of limitations, may implead a biomaterials supplier who has been dismissed from the action pursuant to this Act if—

(1) the manufacturer has made an assertion, either in a motion or other pleading filed with the court or in an opening or closing statement at trial, or as part of a claim for contribution or indemnifica-

tion, and the court finds preliminarily, based on clear and convincing evidence contained in the record of the action, that under applicable law—

(A) the negligence of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

(B) the manufacturer's liability for damages should be reduced in whole or in part because of such negligence; or

(2) the claimant has moved to implead the supplier and the court finds preliminarily, based on clear and convincing evidence contained in the record of the action, that under applicable law—

(A) the negligence of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

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

(b) STANDARD OF LIABILITY.—A biomaterials supplier who has been impleaded into an action subject to this Act, as provided for in this section,—

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

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

(2) may be found liable to a manufacturer or a claimant only to the extent required and permitted by any applicable State or Federal law other than this Act in an action alleging harm caused by an implant.

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

SEC. 8. APPLICABILITY.

This Act shall apply to all civil actions covered under this Act that are commenced on or after the date of enactment of this Act, including any such action with respect to which the harm asserted in the action or the conduct that caused the harm occurred before the date of enactment of this Act.

Chris —

Did we ever manage to get HHS/FDA's views on this legislation?

Elena

Memorandum Product Liability – biomaterials

PETER JACOBY

8/4

Bruce
Ellen
Elena
Tracey

Please find attached a draft substitute for the current Gekas biomaterials bill. He believes that he has addressed our concerns

FYI Peter

ONE HUNDRED FIFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON THE JUDICIARY

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JULIAN EPSTEIN
MINORITY STAFF DIRECTOR

July 31, 1997

The Hon. Jerrold Nadler
Ranking Minority Member
Subcommittee on Commercial and Administrative Law
House Judiciary Committee
United States House of Representatives
2448 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Nadler:

As you know, I am committed to passage of the Biomaterials Access Assurance Act (H.R. 872). This legislation, which I introduced early this year, has attracted broad support and is vitally important to the more than 8 million Americans whose lives depend on a reliable supply of raw materials and component parts for implantable medical devices.

During our recent Subcommittee hearing on this legislation, you and other members of the Subcommittee explored President Clinton's singular concern (expressed in his veto message of last year) that the bill would protect negligent biomaterials suppliers. We have worked to address this issue and I believe that we can modify H.R. 872 to address it without compromising the bill's underlying purpose.

It is my intention to mark up this legislation in the Subcommittee shortly after we return from the August district work period. At that time, I will offer an amendment in the nature of a substitute that, in addition to making minor and technical changes, should satisfy concerns with the supplier negligence issue. I have attached a copy of the intended amendment for your review. The principal modification is provision for a new post-trial procedure, available in narrowly specified circumstances, that permits impleading a biomaterials supplier previously dismissed under the legislation if sufficient evidence has been adduced to show that the dismissed biomaterials supplier's negligence was an actual and proximate cause of harm to the claimant.

I hope and trust you will find these modifications satisfactory and I also hope you will join me in approving this amendment and urging its acceptance by all Members of the Subcommittee. To that end, I would like your assurance that the amendment assuages your concerns. I look forward to hearing from you, and would welcome your partnership in protecting our nation's access to biomaterials.

Very truly yours,

GEORGE W. GEKAS
MEMBER OF CONGRESS

enclosure

[DISCUSSION DRAFT]

JULY 31, 1997

AMENDMENT TO H.R. 872

OFFERED BY MR. GEKAS

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE

This Act may be cited as the "Biomaterials Access Assurance Act of 1997".

SEC. 2. FINDINGS.

The Congress finds that—

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

(2) a continued supply of raw materials and component parts is necessary for the invention, development, improvement, and maintenance of the supply of the devices;

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

(A) move in interstate commerce;

(B) are not designed or manufactured specifically for use in medical devices; and

(C) come in contact with internal human tissue;

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

(5) because small quantities of the raw materials and component parts are used for medical devices, sales of raw materials and component parts for medical devices constitute an extremely small portion of the overall market for the raw materials and component parts;

(6) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) manufacturers of medical devices are required to demonstrate that the medical devices are safe and effective, including demonstrating that the products are properly designed and have adequate warnings or instructions;

(7) notwithstanding the fact that raw materials and component parts suppliers do not design, produce, or test a final medical device, the suppliers have been the subject of actions alleging inadequate—

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

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

(8) even though suppliers of raw materials and component parts have very rarely been held liable in such actions, such suppliers have ceased supplying certain raw materials and component parts for use in medical devices for a number of reasons, including concerns about the costs of such litigation;

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

(10) because other suppliers of the raw materials and component parts in foreign nations are refusing to sell raw materials or component parts for use in manufacturing certain medical devices in the United States, the prospects for development of new sources of supply for the full range of threatened raw materials and component parts for medical devices are remote;

(11) it is unlikely that the small market for such raw materials and component parts in the United States could support the large investment

needed to develop new suppliers of such raw materials and component parts;

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

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

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

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

(14) because medical devices and the raw materials and component parts used in their manufacture move in interstate commerce, shortage of such raw materials and component parts affects interstate commerce;

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

(A) to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices; and

(B) to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs;

(16) the several States and their courts are the primary architects and regulators of our tort system; Congress, however, must, in certain circumstances involving the national interest, address tort issues, and a threatened shortage of raw materials and component parts for life-saving medical devices is one such circumstance; and

(17) the protections set forth in this Act are needed to assure the continued supply of materials for life-saving medical devices; however, negligent suppliers should not be protected.

SEC. 3. DEFINITIONS.

As used in this Act:

(1) BIOMATERIALS SUPPLIER.—

(A) IN GENERAL.—The term "biomaterials supplier" means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant.

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

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

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

(2) CLAIMANT.—

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

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

(C) ACTION BROUGHT ON BEHALF OF A MINOR OR INCOMPETENT.—With respect to an action brought on behalf of or through a minor

or incompetent, such term includes the parent or guardian of the minor or incompetent.

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

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

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

(II) the essence of the transaction is the furnishing of judgment, skill, or services;

(ii) a person acting in the capacity of a manufacturer, seller, or biomaterials supplier; or

(iii) a person alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel, except that—

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

(II) the existence of the exclusion under this clause may not be disclosed to a jury in any civil action or other proceeding, and except as necessary to establish the applicability of this Act, otherwise be presented in any civil action or other proceeding.

(3) COMPONENT PART.—

(A) IN GENERAL.—The term "component part" means a manufactured piece of an implant.

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

(i) has significant non-implant applications; and

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

(4) HARM.—

(A) GENERAL.—The term "harm" means—

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

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

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

(B) EXCLUSION.—The term does not include any commercial loss or loss of or damage to an implant.

(5) IMPLANT.—The term "implant" means—

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

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

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

(B) suture materials used in implant procedures.

(6) MANUFACTURER.—The term "manufacturer" means any person who, with respect to an implant—

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

(B) is required—

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

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

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

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

(A) has a generic use; and

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

(9) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(10) SELLER.—

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

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

(i) a seller or lessor of real property;

(ii) a provider of professional services, in any case in which the sale or use of an implant is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who acts in only a financial capacity with respect to the sale of an implant.

SEC. 4. GENERAL REQUIREMENTS; APPLICABILITY; PREEMPTION.

(a) GENERAL REQUIREMENTS.—

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

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

(b) APPLICABILITY.—

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

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

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

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

(c) SCOPE OF PREEMPTION.—

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

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

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

(1) to affect any defense available to a defendant under any other provisions of Federal or State law in an action alleging harm caused by an implant; or

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

SEC. 5. LIABILITY OF BIOMATERIALS SUPPLIERS.

(a) IN GENERAL.—

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

(2) LIABILITY.—A biomaterials supplier that—

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

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

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

(b) LIABILITY AS MANUFACTURER.—

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

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

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

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

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

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

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

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

(3) ADMINISTRATIVE PROCEDURES.—

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

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

(B) DOCKETING AND FINAL DECISION.—Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 180 days

after the petition is filed, the Secretary shall issue a final decision on the petition.

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

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

(1) the biomaterials supplier—

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

(i) the manufacture of the implant; and

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

(B) subsequently resold the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the requirements described in paragraph (1), if a court deciding a motion to dismiss in accordance with section 6(c)(3)(B)(ii) finds, on the basis of affidavits

submitted in accordance with section 6, that it is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) LIABILITY FOR VIOLATING CONTRACTUAL REQUIREMENTS OR SPECIFICATIONS.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant only if the claimant in an action shows, by a preponderance of the evidence, that—

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

(A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for delivery of the product; or

(B) failed to meet any specifications that were—

(i) provided to the biomaterials supplier and not expressly repudiated by the biomaterials supplier prior to acceptance of

delivery of the raw materials or component parts;

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

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

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

(iii) included in the submissions for purposes of premarket approval or review by the Secretary under section 510, 513, 515, or 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S. C 360, 360c, 360e, or 360j), and received clearance from the Secretary if such specifications were provided by the manufacturer to the biomaterials supplier and were not expressly repudiated by the biomaterials supplier prior to the acceptance by the manufacturer of delivery of the raw materials or component parts; and

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

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

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

(1) the defendant is a biomaterials supplier; and

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

(i) section 5(b), be considered to be a manufacturer of the implant that is subject to such section; or

(ii) section 5(c), be considered to be a seller of the implant that allegedly caused harm to the claimant; or

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

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

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

(1) the manufacturer is subject to service of process solely in a jurisdiction in which the biomaterials supplier is not domiciled or subject to a service of process; or

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

(c) PROCEEDING ON MOTION TO DISMISS.—The following rules shall apply to any proceeding on a motion to dismiss filed under this section:

(1) AFFIDAVITS RELATING TO LISTING AND DECLARATIONS.—

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

(B) RESPONSE TO MOTION TO DISMISS.—In response to the motion to dismiss, the claimant may submit an affidavit demonstrating that—

(i) the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 5(b)(2)(B); or

(ii) the defendant who filed the motion to dismiss is a seller of the implant who is liable under section 5(c)

(2) EFFECT OF MOTION TO DISMISS ON DISCOVERY.—

(A) IN GENERAL.—If a defendant files a motion to dismiss under paragraph (1) or (2) of subsection (a), no discovery shall be permitted in connection to the action that is the subject of the motion, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss in accordance with the affidavits submitted by the parties in accordance with this section.

(B) DISCOVERY.—If a defendant files a motion to dismiss under subsection (a)(2)(B)(i) on the grounds that the biomaterials supplier did not furnish raw materials or component parts in violation of contractual requirements or

specifications, the court may permit discovery, as ordered by the court. The discovery conducted pursuant to this subparagraph shall be limited to issues that are directly relevant to—

(i) the pending motion to dismiss; or

(ii) the jurisdiction of the court.

(3) AFFIDAVITS RELATING TO STATUS OF DEFENDANT.—

(A) IN GENERAL.—Except as provided in clauses (i) and (ii) of subparagraph (B), the court shall consider a defendant to be a biomaterials supplier who is not subject to an action for harm to a claimant caused by an implant, other than an action relating to liability for a violation of contractual requirements or specifications described in section 5(d).

(B) RESPONSES TO MOTION TO DISMISS.—The court shall grant a motion to dismiss any action that asserts liability of the defendant under subsection (b) or (c) of section 5 on the grounds that the defendant is not a manufacturer subject to such section 5(b) or seller subject to section 5(c), unless the claimant submits a valid affidavit that demonstrates that—

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

(ii) with respect to a motion to dismiss contending that the defendant is not a seller, the defendant meets the applicable requirements for liability as a seller under section 5(c).

(4) BASIS OF RULING ON MOTION TO DISMISS.—

(A) IN GENERAL.—The court shall rule on a motion to dismiss filed under subsection (a) solely on the basis of the pleadings of the parties made pursuant to this section and any affidavits submitted by the parties pursuant to this section.

(B) MOTION FOR SUMMARY JUDGMENT.—Notwithstanding any other provision of law, if the court determines that the pleadings and affidavits made by parties pursuant to this section raise genuine issues as concerning material facts with respect to a motion concerning contractual requirements and specifications, the

court may deem the motion to dismiss to be a motion for summary judgment made pursuant to subsection (d).

(d) SUMMARY JUDGMENT.—

(1) IN GENERAL.—

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

(B) ISSUES OF MATERIAL FACT.—With respect to a finding made under subparagraph (A), the court shall consider a genuine issue of material fact to exist only if the evidence submitted by claimant would be sufficient to allow a reasonable jury to reach a verdict for the claimant if the jury found the evidence to be credible.

(2) DISCOVERY MADE PRIOR TO A RULING ON A MOTION FOR SUMMARY JUDGMENT.—If, under applicable rules, the court permits discovery prior to a ruling on a motion for summary judgment made pursuant to this subsection, such discovery shall be limited solely to establishing whether a genuine issue

of material fact exists as to the applicable elements set forth in paragraphs (1) and (2) of section 5(d).

(3) DISCOVERY WITH RESPECT TO A BIOMATERIALS SUPPLIER.—A biomaterials supplier shall be subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 5(d) or the failure to establish the applicable elements of section 5(d) solely to the extent permitted by the applicable Federal or State rules for discovery against nonparties.

(e) STAY PENDING PETITION FOR DECLARATION.—If a claimant has filed a petition for a declaration pursuant to section 5(b)(3)(A) with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition. The Secretary shall complete review of any such petition within 6 weeks of receipt of the petition.

(f) DISMISSAL WITH PREJUDICE.—An order granting a motion to dismiss or for summary judgment pursuant to this section shall be entered with prejudice, except insofar as the moving defendant may be rejoined to the action as provided in section 7.

(g) MANUFACTURER CONDUCT OF LITIGATION.—The manufacturer of an implant that is the subject of an action covered under this Act shall be permitted to conduct litigation on any motion for summary judgment or dismissal filed by a biomaterials supplier who is a defendant under this section on behalf of such supplier if the manufacturer and any other defendant in such action enter into a valid and applicable contractual agreement under which the manufacturer agrees to bear the cost of such litigation or to conduct such litigation.

SEC. 7. SUBSEQUENT IMPLEADER OF DISMISSED DEFENDANT.

(a) IMPLEADING OF DISMISSED DEFENDANT.—A court, upon motion by a manufacturer or a claimant within 90 days after entry of a final judgment in an action by the claimant against a manufacturer, and notwithstanding any otherwise applicable statute of limitations, may implead a biomaterials supplier who has been dismissed from the action pursuant to this Act if—

(1) the manufacturer has made an assertion, either in a motion or other pleading filed with the court or in an opening or closing statement at trial, or as part of a claim for contribution or indemnification, and the court finds preliminarily, based on

clear and convincing evidence contained in the record of the action, that under applicable law—

(A) the negligence of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

(B) the manufacturer's liability for damages should be reduced in whole or in part because of such negligence; or

(2) the claimant has moved to implead the supplier and the court finds preliminarily, based on clear and convincing evidence contained in the record of the action, that under applicable law—

(A) the negligence of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

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

(b) STANDARD OF LIABILITY.—A biomaterials supplier who has been impleaded into an action subject to this Act, as provided for in this section,—

(1) may, prior to entry of judgment on the claim against it, supplement the record of the proceeding that was developed prior to the grant of the motion for impleader under subsection (a), and

(2) may be found liable to a manufacturer or a claimant only to the extent required and permitted by any applicable State or Federal law other than this Act in an action alleging harm caused by an implant.

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

SEC. 8. APPLICABILITY.

This Act shall apply to all civil actions covered under this Act that are commenced on or after the date of enactment of this Act, including any such action with respect to which the harm asserted in the action or the conduct that caused the harm occurred before the date of enactment of this Act.

Chris - Have we ever heard our
what HHS/FDA thinks of this
bill? The attached watered-
down version comes from the
Trial Lawyers, but it looks as
it Lieberman has signed on.

From Ballentine/
Patton Boggs

Elena

File: Product Liability-biomaterial
pumice

Proposed Biomaterials Supplier Liability Consensus

The attached proposed compromise biomaterials supplier liability bill is a modified version of the biomaterials language found in S. 5. This version includes an exception for claims for harm allegedly caused by breast implants. The bill also includes the following changes:

1. **Negligent Supplier Compromise.** Clearly the most important change deals with the potential of a negligent supplier. The President stated in his veto statement that "[biomaterials liability] protections must be clearly limited to non-negligent suppliers" (*Statement of the President, May 2, 1996*). The problem is how to reconcile this important concern of the President and of many Members of Congress with the core goal of the legislation, which is to relieve biomaterial suppliers from the up-front costs of litigation, even when the suppliers are ultimately dismissed from the action. The proposed solution to this problem is found in section 7 of the bill. Biomaterial suppliers may be dismissed from a case pursuant to the procedures set up in the original legislation. However, if in the ongoing litigation between the manufacturer and the seller, either the manufacturer makes the claim that its liability should be limited because the now-dismissed supplier was at fault for the claimants' harm, or compelling evidence otherwise arises that the supplier was in fact at fault and caused the harm, then the supplier may be brought back into the action as a party.

2. **Protecting Suppliers from All Claims.** If a manufacturer brings a claim against a supplier for harm caused by the materials supplied, then the supplier should be similarly protected by the provisions of the bill -- as if the claim were brought by an individual. Thus, the definition of "claimant" is expanded to include a manufacturer, and the definition of "harm" is expanded to include pecuniary harm.

3. **Component Parts.** This bill limits its scope to suppliers of raw materials and does not extend to "component parts".

4. **Tightening Manufacturer Exception.** The original bill purports to extend liability to suppliers if they were also "manufacturers", but it limits the term "manufacturer" to entities that have registered with the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act. If a manufacturer violated that Act by failing to register, they should not reap gains from that transgression. Therefore, the proposed bill changes the language "has registered" to "has or should have registered". Similarly, the language -- "included the implant on a list of devices filed with the Secretary" has been changed to "included or should have included".

5. **Secretary's Role.** The Secretary is not required to respond to a petition filed pursuant to this Act (asking the Secretary to verify if a company is a medical device manufacturer).

The proposed bill makes it mandatory on the Secretary to respond and that the Secretary respond within six weeks. This latter point is especially important since the litigation can be stayed pending the response of the Secretary.

6. **Level of Proof Required.** The claimant might not be in a position, after only limited discovery, to prove that a contractual violation by a supplier was "an actual and proximate cause" of the claimant's harm. We are not certain on how to address this problem, but have added the word "likely" before "an actual and proximate cause of the harm".

7. **Dismissal of Party, Not "Action".** At several points the bill refers to the dismissal of the "action" upon the supplier satisfying the terms of the Act. The "action" is not dismissed, only the "claims" against that defendant are dismissed.

8. **Quasi-Judicial Proceeding.** The attached bill eliminates the odd and ambiguous provision in the original bill which seems to have the manufacturer instead of the court conducting some quasi-judicial proceeding on a motion for summary judgment.

9. **Loser Pays.** This bill eliminates the loser pays provision in the original bill.

#266507

S.___

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

IN THE SENATE OF THE UNITED STATES

_____ __ (legislative day, _____ _), 1997

Mr. Lieberman (for himself, Mr. Breaux, _____, . . .) introduced the following bill; which was read twice and placed on the calendar.

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

DISCUSSION DRAFT ONLY

SEC. 1. SHORT TITLE

This title may be cited as the "Biomaterials Access Improvement Act of 1997."

SEC. 2. FINDINGS

Congress finds that --

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

(2) a continued supply of raw materials is necessary for the invention, development, improvement, and maintenance of the supply of the devices;

(3) most of the medical devices are made with raw materials that --

(A) are not designed or manufactured specifically for use in medical devices; and

(B) come in contact with internal human tissue

(4) the raw materials also are used in a variety of nonmedical products;

(5) because small quantities of the raw materials are used for medical devices, sales of raw materials for medical devices constitute an extremely small portion of the overall market for the raw materials and medical devices;

(6) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), manufacturers of medical devices are required to demonstrate that the medical devices are safe and effective, including demonstrating that the products are properly designed and have adequate warnings or instructions;

(7) notwithstanding the fact that raw materials suppliers do not design, produce, or test a final medical device, the suppliers have been the subject of actions alleging inadequate design and testing of medical devices manufactured with materials or parts supplied by the suppliers, and inadequate warnings related to the use of such medical devices;

(8) for a number of reasons, including concerns about the costs of such litigation, some such suppliers have ceased supplying certain raw materials for use in medical devices;

(9) unless alternate sources of supply can be found, the unavailability of raw materials for medical devices could lead to unavailability of lifesaving and life-enhancing medical devices;

(10) because other suppliers of the raw materials in foreign nations are refusing to sell raw materials for use in manufacturing certain medical devices in the United States, the prospects for development of new sources of supply for the full range of threatened raw materials for medical devices are remote;

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

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

(13) courts that have considered the duties of the suppliers of the raw materials have generally found that the suppliers do not have a duty --

(A) to evaluate the safety and efficacy of the use of a raw material in a medical device; and

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

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

(A) to clarify the permissible bases of liability for suppliers of raw materials for medical devices; and

(B) to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs.

SEC. 3. DEFINITIONS.

As used in this title:

(1) BIOMATERIALS SUPPLIER. --

(A) IN GENERAL. -- The term "biomaterials supplier" means an entity that directly or indirectly supplies a raw material for use in the manufacture of an implant.

(B) PERSONS INCLUDED. -- Such term includes any person who --

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

(ii) licenses a biomaterials supplier to produce raw materials.

(2) CLAIMANT. --

(A) IN GENERAL. -- The term "claimant" means any entity or person who brings a civil action, or on whose behalf a civil action is brought, arising from harm allegedly caused directly or indirectly by an implant, including a person or entity other than the individual into whose body, or in contact with whose blood or tissue, the implant is placed, such as a manufacturer, who claims to have suffered or to have been held responsible for harm from an implant or as a result of the raw materials supplied for such implant.

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

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

(D) EXCLUSIONS. -- Such term does not include --

(i) a provider of professional health care services, in any case in which --

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

(II) the essence of the transaction is the furnishing of judgment, skill, or services;

(ii) a person alleging harm caused by a breast implant.

(3) HARM. --

(A) IN GENERAL. -- The term "harm" means --

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

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

(iii) any loss to that individual or any other individual resulting from that injury or damage; or

(B) COMMERCIAL LOSS. -- "Harm" also includes any commercial loss, including lost profits, loss of or damage to an implant, or other liability incurred as a result of an implant.

(4) IMPLANT. -- The term "implant" means --

(A) a medical device that is intended by the manufacturer of the device --

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

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

(B) suture materials used in implant procedures.

(5) MANUFACTURER. -- The term "manufacturer" means any person who, with respect to an implant --

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

(B) is required --

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

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

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

(7) RAW MATERIAL. -- The term "raw material" means a substance or product that --

(A) has a generic use; and

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

(8) SECRETARY. -- The term "Secretary" means the Secretary of Health and Human Services.

(9) SELLER. --

(A) IN GENERAL. -- The term "seller" means a person who, in the course of a business conducted for that purpose, sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce.

(B) EXCLUSIONS. -- The term does not include --

(i) a seller or lessor of real property;

(ii) a provider of professional services, in any case in which the sale or use of an implant is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who acts in only a financial capacity with respect to the sale of an implant.

SEC. 4. GENERAL REQUIREMENTS; APPLICABILITY; PREEMPTION.

(a) GENERAL REQUIREMENTS. --

(1) IN GENERAL. -- In any civil action covered by this title, a biomaterials supplier may raise any defense set forth in section 5.

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

(b) APPLICABILITY. --

(1) IN GENERAL. -- Except as provided in paragraph (2), notwithstanding any other provision of law, this title applies to any civil action brought by a claimant, whether in a Federal or State court, against a manufacturer, seller, or biomaterials supplier, on the basis of any legal theory, for harm allegedly caused by an implant or by the raw materials or component parts used in such implant.

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

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

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

(c) SCOPE OF PREEMPTION. --

(1) IN GENERAL. -- This title supersedes any State law regarding recovery for harm caused by an implant and any rule of procedure applicable to a civil action to

recover damages for such harm only to the extent that this title establishes a rule of law applicable to the recovery of such damages.

(2) APPLICABILITY OF OTHER LAWS. -- Any issue that arises under this title and that is not governed by a rule of law applicable to the recovery of damages described in paragraph (1) shall be governed by applicable Federal or State law.

(d) STATUTORY CONSTRUCTION. -- Nothing in this title may be construed to create a cause of action or Federal court jurisdiction pursuant to section 1331 or 1337 of title 23, United States Code, that otherwise would not exist under applicable Federal or State law.

SEC. 5. LIABILITY OF BIOMATERIALS SUPPLIERS.

(a) IN GENERAL. --

(1) EXCLUSION FROM LIABILITY. -- Except as provided in paragraph (2) and subsection (e), a biomaterials supplier shall not be liable for harm to a claimant caused by an implant.

(2) LIABILITY. -- A biomaterials supplier that --

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

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

(C) furnishes raw materials that fail to meet applicable contractual requirements or specifications may be liable for a harm to a claimant described in subsection (d).

(b) LIABILITY AS MANUFACTURER --

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

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

(A)

(i) has or should have registered with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act 121 U.S.C. 360 and the regulations issued under such section; and

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

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

(i) register with the Secretary under section 510 of such Act (21 U.S.C. 350), and the regulations issued under such section, but failed to do so; or

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

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

(3) ADMINISTRATIVE PROCEDURES. --

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

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

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

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

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

(1) the biomaterials supplier--

(A) held title to the implant that allegedly caused harm to the claimant as a result of purchasing the implant after--

(i) the manufacture of the implant and

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

(B) subsequently resold the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the requirements described in paragraph (1), if a court deciding a motion to dismiss in accordance with section 6(c)(3)(B)(ii) finds on the basis of affidavits submitted in accordance with section 6 that is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) LIABILITY FOR VIOLATING CONTRACTUAL REQUIREMENTS OR SPECIFICATIONS. -- A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant, if the claimant in an action shows, by a preponderance of the evidence, that-

(1) the raw materials or component parts delivered by the biomaterials supplier either--

(A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for delivery of the product; or

(B) failed to meet any specifications that were --

(i) provided to the biomaterials supplier and not expressly repudiated by the biomaterials supplier prior to acceptance of delivery of the raw materials or component parts;

(ii)

(I) published by the biomaterials supplier;

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

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

(iii) included in the submissions for purposes of premarket approval or review by the Secretary under section 510, 513 515, or 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S. C 360, 360c, 360e, or 360j), and received clearance from the Secretary if such specifications were provided by the manufacturer to the biomaterials supplier and were not expressly repudiated by the biomaterials supplier prior to the acceptance by the manufacturer of delivery of the raw materials or component parts; and

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

(e) LIABILITY AFTER IMPLEADER. -- A biomaterials supplier who has been impleaded into an action subject to this Act, as provided for in Section 7, may be found liable for harm caused by an implant according to any applicable state or federal law, notwithstanding any other provision of this Act.

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

(a) MOTION TO DISMISS. -- In any action that is subject to this title, a biomaterials supplier who is a defendant in such action may, at any time during which a motion to dismiss may be filed under an applicable law, move to dismiss the claims against it on the grounds that --

(1) the defendant is a biomaterials supplier; and

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

(i) section 5(b), be considered to be a manufacturer of the implant that is subject to such section; or

(ii) section 5(c), be considered to be a seller of the implant that allegedly caused harm to the claimant;

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

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

(b) PROCEEDING ON MOTION TO DISMISS. -- The following rules shall apply to any proceeding on a motion to dismiss filed under this section:

(1) AFFIDAVITS RELATING TO LISTING AND DECLARATIONS. --

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

(B) RESPONSE TO MOTION TO DISMISS. -- In response to the motion to dismiss, the claimant may submit an affidavit demonstrating that--

(i) the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 5(b)(2)(B); or

(ii) the defendant who filed the motion to dismiss is a seller of the implant who is liable under section 5(c)

(2) EFFECT OF MOTION TO DISMISS ON DISCOVERY. --

(A) IN GENERAL. -- If a defendant files a motion to dismiss under paragraph (1) or (2) of subsection (a), no discovery shall be permitted connection to the action that is subject of the motion, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss in accordance with the affidavits submitted the parties in accordance with section.

(B) DISCOVERY. -- If a defendant files a motion to dismiss under subsection (a)(B)(i) on the grounds that the biomaterials supplier did not furnish raw materials or component parts in violation of contractual requirements or specifications, the court may permit discovery, as ordered by the court. The discovery conducted pursuant to this subparagraph shall be limited to issues that are directly relevant to--

(i) the pending motion to dismiss; or

(ii) the jurisdiction of the court.

(3) AFFIDAVITS RELATING TO STATUS OF DEFENDANT. --

(A) IN GENERAL. -- Except as provided in clauses (i) and (ii) of subparagraph (B), the court shall consider a defendant to be a biomaterials supplier who is not subject to an action for harm to a claimant caused by an implant, other than an action relating to liability for a violation of contractual requirements or specifications described in subsection (d).

(B) RESPONSES TO MOTION TO DISMISS. -- The court shall grant a motion to dismiss any claim that asserts liability of the defendant under subsection (b) or (c) of section 5 on the grounds that the defendant is not a

manufacturer subject to such section 5(b) or seller subject to section 5(c), unless the claimant submits a valid affidavit that demonstrates that--

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

(ii) with respect to a motion to dismiss contending that the defendant is not a seller, the defendant meets the applicable requirements for liability as a seller under section 5(c).

(4) BASIS OF RULING ON MOTION TO DISMISS. --

(A) IN GENERAL. -- The court shall rule on a motion to dismiss filed under subsection (a) solely on the basis of the pleadings of the parties made pursuant to this section and any affidavits submitted by the parties pursuant to this section.

(B) MOTION FOR SUMMARY JUDGMENT.--Notwithstanding any other provision of law, if the court determines that the pleadings and affidavits made by parties pursuant to this section raise genuine issues as concerning material facts with respect to a motion concerning contractual requirements and specifications, the court may deem the motion to dismiss to be a motion for summary judgment made pursuant to subsection (c).

(c) SUMMARY JUDGMENT. --

(1) IN GENERAL. --

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

(B) ISSUES OF MATERIAL FACT. -- With respect to a finding made under subparagraph (A), the court shall consider a genuine issue of material fact to exist only if the evidence submitted by claimant would be sufficient to allow a reasonable jury to reach a verdict for the claimant if the jury found the evidence to be credible.

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

(3) DISCOVERY WITH RESPECT TO A BIOMATERIALS SUPPLIER. -- A biomaterials supplier shall be subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 5(d) or the failure to establish the applicable elements of section 5(d) solely to the extent permitted by the applicable Federal or State rules for discovery against nonparties.

(d) STAY PENDING PETITION FOR DECLARATION. -- If a claimant has filed a petition for a declaration pursuant to section 5(b)(3)(A) with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition. The Secretary shall, however, complete review of such petitions within six weeks of receipt of the petition.

(e) DISMISSAL WITHOUT PREJUDICE. -- A motion to dismiss or for summary judgment granted pursuant to this Section shall be entered without prejudice, but only insofar as the moving defendant may be rejoined to the action as provided in Section 7.

SEC. 7. SUBSEQUENT IMPLEADER OF DISMISSED DEFENDANT.

(a) IMPLEADING OF DISMISSED DEFENDANT. -- A court, upon motion or its own recognizance, and notwithstanding any otherwise applicable statute of limitations, shall implead a biomaterials supplier who has been dismissed from the action pursuant to this Act if the court finds that --

(1) Any other defendant not dismissed pursuant to this Act subsequently makes or pursues a claim that the negligence of the dismissed biomaterials supplier in whole or in part caused claimant's harm, or that that defendant's liability should be reduced in whole or in part because of the negligent acts or omissions of the dismissed biomaterials supplier defendant; or

(2) The claimant has made a compelling showing that --

(A) its harm was caused in whole or in part by the negligent acts or omissions of the dismissed biomaterials supplier, and

(B) the claimant is unlikely to recover the full amount of its damages from the remaining defendants.

(b) DISCOVERY.-- Nothing in this section shall give a claimant or any other party the right to get discovery from a biomaterials supplier defendant beyond that allowed under Section 6.

SEC. 8. APPLICABILITY

This Act shall apply to all civil actions covered under this Act that are commenced after the date of enactment.

252429

File/ Product liability - biomaterials

cc: Chris Jennings
Chris - We need an evaluation of this issue by HHS. Please call me on it ASAP. Thanks. Elena
cc: Bruce R.

Public Citizen

DOUBTS ABOUT THE "BIOMATERIALS SHORTAGE"

Public Citizen opposes the Biomaterials Access Assurance Act of 1997, legislation that is contained in S. 648 -- the Product Liability Reform Act of 1997. Immunity for biomaterial suppliers would remove an important financial incentive for them to properly research and test their products, as well as to warn manufacturers or the public if they suspect that their components are being used in an unsafe manner. While we all want access to life-saving medical devices, we also want biomaterial suppliers to sell the safest materials possible. Granting immunity to major corporations like Dow Chemical and DuPont, with records of wrongdoing in many other areas, is not an acceptable health and safety risk.

The bill's exemptions, such as for suppliers that violate contractual specifications, are far too limited to protect public health and safety. They do not cover situations where companies suspect that their biomaterials, as implanted, could cause serious injury or death, but do not warn the public. We agree with President Clinton, in vetoing last year's products liability bill, that such suppliers "should not receive any protection from suit."

In its campaign to obtain immunity for biomaterial suppliers, the Health Industry Manufacturers Association (HIMA) has often exaggerated facts about litigation in this area. For example, in the case of silastic shunts used for hydrocephalus (water on the brain), witnesses at an April 8, 1997 hearing before a Senate Commerce subcommittee confirmed that neither the manufacturers, nor the biomaterial suppliers, of hydrocephalic shunts have ever been sued. A review of case filings reveals two lawsuits involving defective shunts. Both were against physicians for failing to diagnose shunt malfunction, which resulted in serious mental incapacity for the patients.

In addition, assuming that biomaterial suppliers do pull out of the business, there is absolutely no guarantee that this legislation would get them back. Indeed, we have heard through members of the media that DuPont, for one, is saying privately that they will not come back into the biomaterials market even if this legislation passes.

Public Citizen's Survey Of Medical Device Manufacturers

HIMA has distributed a list of 84 medical devices that it calls "potentially affected permanent implants" due to current shortages of biomaterials. According to HIMA, this list was compiled by a HIMA staff person who called around to manufacturers who are HIMA members, and asked them what medical devices might be affected.

In response to this list, Public Citizen conducted a review of the 1997 Medical Device Register, published by *Medical Economics,* which lists every medical device registered with the FDA. The purpose of this review was to determine how manufacturers were still producing the 84 devices said to be threatened.

The survey reveals that there are still several, and often numerous manufacturers of most every permanent implant on HIMA's list. This survey is attached. (We recognize that in some cases, manufacturers of a particular device all may rely on a single biomaterials supplier, whose withdraw from the market might impact all manufacturers of that device.)

HIMA's List of Potentially Affected Permanent Implants (due to alleged biomaterials embargo)	**Number of Current Permanent Implant Manufacturers (as reported in 1997 Medical Device Register)***
ACETABULAR CUPS	Category: "prosthesis, hip, acetabular": 7
ANNULOPLASTY RING	3
AORTIC/CORONARY LOCATORS	No category listed. No manufacturer could identify it.
ARTIFICIAL PANCREAS	No category listed.
BATTERIES • Defibrillator	No category listed. According to one defibrillator manufacturer, batteries for defibrillators are made by Panasonic and are common industrial grade batteries. There are 19 manufacturers of battery-powered defibrillators.
• Pacemaker	No category "pacemakers, battery-powered." 1 pacemaker battery manufacturer listed.
BONE CEMENT	4
BREAST IMPLANTS	10

* **How this research was conducted:** Where HIMA's description of a medical device did not correspond to a particular listing in the Medical Device Register, calls were made to manufacturers of similar devices, or to other experts, to determine other names under which the device might be listed. Devices that could not be identified are so indicated.

HIMA's List of Potentially Affected Permanent Implants (due to alleged biomaterials embargo)	**Number of Current Permanent Implant Manufacturers (as reported in 1997 Medical Device Register)***
CARDIAC MATERIALS	
• Fabrics	No category listed. No manufacturer could identify it.
• Felts	1
• Mesh	8
• Patches (vascular repair)	6
CATHETERS	
• CAPD	Category: "Catheter, angioplasty": 22
• Central Venous	16
• Chest	No category listed. According to catheter manufacturers, there is no catheter category specifically for chests. Several types of catheters are used in the chest area.
• Intra-Skomal Corneal Ring	No category listed.
• Peritoneal Dialysis	7
• Other	There are over 50 categories of catheters listed.
CATHETER INTRODUCER KITS	Category: "introducer, catheter": 59
CEMENT SPACERS	No category listed. No manufacturer could identify it.
CLIPS	
• Aneurysm	10
• Ligation	3
• Vena Cava	6

HIMA's List of Potentially Affected Permanent Implants (due to alleged biomaterials embargo)	**Number of Current Permanent Implant Manufacturers (as reported in 1997 Medical Device Register)***
COCHLEAR IMPLANT	2
CONTRACEPTIVE	No category listed. According to Planned Parenthood of Washington, D.C., there are no contraceptive devices with silicone as their main component.
DEFIBRILLATORS	27
EMBOLIC DEVICE	2
FREKOTE LUBRICANT (general)	No category listed. No manufacturer could identify it.
GENERATORS • Defibrillator pulse • Pacemaker pulse • Other	According to defibrillator and pacemaker manufacturers, pulse generators are components of each defibrillator and pacemaker. There are 27 defibrillator and 23 pacemaker manufacturers listed. Over 90 generator manufacturers listed.
GRAFTS • A-V Access • Intra-aortic • Valve • Vascular	No categories listed. 8
IMPLANTABLE PUMPS	Category: "pump, infusion, implantable": 9
IMPOTENCE IMPLANT	Category: "penile implant": 4
INCONTINENCE IMPLANT	No category listed. No manufacturer could identify it.

HIMA's List of Potentially Affected Permanent Implants (due to alleged biomaterials embargo)	**Number of Current Permanent Implant Manufacturers (as reported in 1997 Medical Device Register)***
INTRAOCULAR LENS	25
LEADS • Cardio • Defibrillator • Pacemaker • Vagus Nerve	One category listed: "lead, pacemaker": 27
LEAD ADAPTORS	12
LEAD CONNECTORS	No category listed. According to a lead adapter manufacturer, lead connectors come packaged with pacemakers and adapters, and are also sold separately with leads, pacemakers, headers and connector blocks.
MOLDED COMPONENTS (Catheters, etc.)	No listed category. No manufacturer could identify it.
NASAL BUTTON	6
ORBITAL IMPLANT	4
ORTHOPEDICS • Finger Prosthesis • Fracture Fixation Device • Hip Joint • Knee Joint • Partial/Total Ossicular Replacement • Plug (hip fracture stem) • Shoulder Joint	 8 No category listed. Category: "prothesis, hip": 18 Category: "prothesis, knee": 18 4 No category listed. Category: "prothesis, shoulder": 9

HIMA's List of Potentially Affected Permanent Implants (due to alleged biomaterials embargo)	Number of Current Permanent Implant Manufacturers (as reported in 1997 Medical Device Register)*
ORTHOPEDICS (continued)	
• Spinal Systems	No category listed.
• Tibia Insert	4
PACEMAKERS	23
PATELLAR BUTTONS	Category: "button, surgical": 4
PENILE IMPLANT	4
PLEDGETS	5
PORTS • Infusion • Injection • Osteoport • Vascular access • Other	Only category listed: "ports, vascular": 17
PROSTHETIC HEART VALVES	6
SHEETING (Scar tissue prevention lining)	Category: "sheeting, silicone": 16
SHUNTS	
• CNS	No category listed.
• Dialysis	No category listed.
• Hydrocephalus	4
• Peritoneal	2
• Other	12

HIMA's List of Potentially Affected Permanent Implants (due to alleged biomaterials embargo)	**Number of Current Permanent Implant Manufacturers (as reported in 1997 Medical Device Register)***
STIMULATORS • Bone Growth Implant • Functional Electrical • Neuro (& Accessories)	 2 23 14
SUTURES	Categories: "polybutester," "polyester," or "polypropylene": 13
TUBES • Myringotomy • Otological Ventilation • Vent	Category: "tubes, myringotomy": 2. According to myringotomy tube manufacturer, otological ventilation and vent tubes are the same as myringotomy tubes, used for ear surgery drainage.
UMBILICAL TAPE	6
VALVED CONDUITS	No category listed. No manufacturer could identify it.
VASCULAR ACCESS DEVICE	Category: "hemostasis, vascular device": 2
VASCULAR STENTS	4

Product liability - biomaterials provision

DRAFT 2

SUMMARY OF PROPOSED BILL ON BIOMATERIALS SUPPLIER LIABILITY

The attached draft of a proposed bill on biomaterials supplier liability would offer substantive legal protections to the biomaterials suppliers of raw materials for medical implants, including various procedures for the expedited dismissal of civil actions brought against biomaterials suppliers. In contrast to other legislative proposals on biomaterials supplier liability, this bill would not apply to: (1) lawsuits involving breast implants; (2) the biomaterials suppliers of "components"; (3) the biomaterials suppliers of "defective" raw materials; and (4) those biomaterials suppliers who breach their duty to warn buyers or users about the risks associated with a particular use of the raw materials. Moreover, this proposed bill would apply to business claimants seeking to recover from biomaterials suppliers and would effectuate two way preemption.

BIOMATERIALS ACCESS ASSURANCE

SEC. 201. SHORT TITLE.

This title may be cited as the "Biomaterials Access Assurance Act of 1996".

SEC. 202. FINDINGS.

Congress finds that—

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

(2) a continued supply of raw materials and component parts is necessary for the invention, development, improvement, and maintenance of the supply of the devices;

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

(A) are not designed or manufactured specifically for use in medical devices; and

(B) come in contact with internal human tissue;

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

(5) because small quantities of the raw materials and component parts are used for medical devices, sales of raw materials and component parts for medical devices constitute an extremely small portion of the overall market for the raw materials and medical devices;

(6) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), manufacturers of medical devices are required to demonstrate that the medical devices are safe and ef-

fective, including demonstrating that the products are properly designed and have adequate warnings or instructions;

(7) notwithstanding the fact that raw materials and component parts suppliers do not design, produce, or test a final medical device, the suppliers have been the subject of actions alleging inadequate—

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

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

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

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

(10) because other suppliers of the raw materials and component parts in foreign nations are refusing to sell raw materials or component parts for use in manufacturing certain medical devices in the United States, the prospects for development of new sources of supply for the full range of threatened raw materials and component parts for medical devices are remote;

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

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

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

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

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

(14) attempts to impose the duties referred to in subparagraphs (A) and (B) of paragraph (13) on suppliers of the raw materials and component parts would cause more harm than good by driving the suppliers to cease supplying manufacturers of medical devices; and

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

(A) to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices; and

(B) to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs.

SEC. 203. DEFINITIONS.

As used in this title:

(1) BIOMATERIALS SUPPLIER.—

(A) IN GENERAL.—The term "biomaterials supplier" means an entity that directly or indirectly supplies ~~a component part or~~ raw material for use in the manufacture of an implant.

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

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

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

(2) CLAIMANT.—

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

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

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

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

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

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

(II) the essence of the transaction is the furnishing of judgment, skill, or services; ~~or~~

(ii) a person acting in the capacity of a manufacturer, seller, or biomaterials supplier; ~~or~~

(iii) a person alleging harm caused by a breast implant.

~~(3) COMPONENT PART.—~~

~~(A) IN GENERAL.—The term "component part" means manufactured piece of an implant.~~

~~(B) CERTAIN COMPONENTS.—Such term includes manufactured piece of an implant that—~~

~~(i) has significant noninplant applications; and~~

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

(4) HARM.—

(A) IN GENERAL.—The term "harm" means—

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

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

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

~~(B) EXCLUSION.—The term does not include any commercial loss or loss of or damage to an implant.~~

(B) COMMERCIAL LOSS.--The term includes any commercial loss or loss of or damage to an implant.

(6) IMPLANT.—The term "implant" means—

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

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

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

(B) suture materials used in implant procedures.

(7) MANUFACTURER.—The term "manufacturer" means any person who, with respect to an implant—

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

(B) is required—

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

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

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

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

(A) has a generic use; and

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

(9) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(10) SELLER.—

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

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

(i) a seller or lessor of real property;

(ii) a provider of professional services, in any case in which the sale or use of an implant is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who acts in only a financial capacity with respect to the sale of an implant.

SEC. 204. GENERAL REQUIREMENTS; APPLICABILITY; PREEMPTION.

(a) GENERAL REQUIREMENTS.—

(1) IN GENERAL.—In any civil action covered by this title, a biomaterials supplier may raise any defense set forth in section 205.

(2) PROCEDURES.—Notwithstanding any other provision of law, the Federal or State court in which a civil action covered by this title is pending shall, in connection with a motion for dismissal or judgment based on a defense described in paragraph (1), use the procedures set forth in section 206.

(b) APPLICABILITY.—

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

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

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

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

(c) SCOPE OF PREEMPTION.—

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

(2) APPLICABILITY OF OTHER LAWS.—Any issue that arises under this title and that is not governed by a rule of law applicable to the recovery of damages described in paragraph (1) shall be governed by applicable Federal or State law.

(d) STATUTORY CONSTRUCTION.—Nothing in this title may be construed—

~~*(1) to affect any defense available to a defendant under any other provision of Federal or State law in an action alleging harm caused by an implant; or*~~

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

SEC. 205. LIABILITY OF BIOMATERIALS SUPPLIERS.

(a) IN GENERAL.—

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

(2) LIABILITY.—A biomaterials supplier that—

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

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

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

(b) LIABILITY AS MANUFACTURER.—

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

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

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

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

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

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

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

(C) is related by common ownership or control to a person meeting all the requirements described in subparagraph (A) or (B), if the court deciding a motion to dismiss in accordance with section 206(c)(3)(B)(i) finds, on the basis of affidavits submitted in accordance with section 206, that it is necessary to impose liability on the biomaterials supplier as a manufacturer because the related manufacturer meeting the requirements of subparagraph (A) or (B) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(3) ADMINISTRATIVE PROCEDURES.—

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

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

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

(D) knows, or through reasonable inquiry could have known:

(i) of the application to which the raw material is to be put; (ii) of the risks attendant to such use; and (iii) that the buyer or user of the raw material is ignorant of such risks, but failed to warn such buyer or user of such risks, may be liable for harm to a claimant described in subsection (e); and

(E) furnishes raw materials that are defective may be liable for harm to a claimant as described in subsection (f).

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

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

(1) the biomaterials supplier—

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

(i) the manufacture of the implant; and

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

(B) subsequently resold the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the requirements described in paragraph (1), if a court deciding a motion to dismiss in accordance with section 206(c)(3)(B)(ii) finds, on the basis of affidavits submitted in accordance with section 206, that it is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) LIABILITY FOR VIOLATING CONTRACTUAL REQUIREMENTS OR SPECIFICATIONS.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant, if the claimant in an action shows, by a preponderance of the evidence, that—

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

(A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for delivery of the product; or

(B) failed to meet any specifications that were—

(i) provided to the biomaterials supplier and not expressly repudiated by the biomaterials supplier prior to acceptance of delivery of the raw materials or component parts;

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

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

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

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

biomaterials supplier and were not expressly repudiated by the biomaterials supplier prior to the acceptance by the manufacturer of delivery of the raw materials or component parts; and

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

SEC. 206. PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS AGAINST BIOMATERIALS SUPPLIERS.

(a) MOTION TO DISMISS.—In any action that is subject to this title, a biomaterials supplier who is a defendant in such action may, at any time during which a motion to dismiss may be filed under an applicable law, move to dismiss the action against it on the grounds that—

(1) the defendant is a biomaterials supplier; and

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

(i) section 205(b), be considered to be a manufacturer of the implant that is subject to such section; or

(ii) section 205(c), be considered to be a seller of the implant that allegedly caused harm to the claimant; ~~or~~

(B)(i) the claimant has failed to establish, pursuant to section 205(d), that the supplier furnished raw materials or component parts in violation of contractual requirements or specifications; or

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

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

~~(1) the manufacturer is subject to service of process solely in a jurisdiction in which the biomaterials supplier is not domiciled or subject to a service of process; or~~

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

b (c) PROCEEDING ON MOTION TO DISMISS.—The following rules shall apply to any proceeding on a motion to dismiss filed under this section:

(1) AFFIDAVITS RELATING TO LISTING AND DECLARATIONS.—

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

(B) RESPONSE TO MOTION TO DISMISS.—In response to the motion to dismiss, the claimant may submit an affidavit demonstrating that—

(i) the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 205(b)(2)(B); or

(ii) the defendant who filed the motion to dismiss is a seller of the implant who is liable under section 205(c).

(2) EFFECT OF MOTION TO DISMISS ON DISCOVERY.—

(e) LIABILITY FOR FAILURE TO WARN.--A biomaterials supplier may, to the extent required or permitted by any other applicable law, be liable for harm caused by an implant if the biomaterials supplier--

(1) knew, or through reasonable inquiry could have known:

(A) of the application to which the raw material was to be put;

(B) of the risks attendant to such use; and

(C) that the buyer or user of the raw material was ignorant of such risks; and

(2) failed to warn such buyer or user of such risks.

(f) LIABILITY FOR DEFECTIVE MATERIAL.-- A biomaterials supplier may, to the extent permitted by any other applicable law, be liable for harm caused by an implant if the harm was in whole or in part caused by a defect in the raw material supplied by the biomaterials supplier.

(iii) section 205(e), be found to have failed to warn the buyer or user of the raw material of its known risks;

(iv) section 205(f), be found to have supplied defective material; or

(A) IN GENERAL.—If a defendant files a motion to dismiss under paragraph (1) or (2) of subsection (a), no discovery shall be permitted in connection to the action that is the subject of the motion, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss in accordance with the affidavits submitted by the parties in accordance with this section.

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

(i) the pending motion to dismiss; or

(ii) the jurisdiction of the court.

(3) AFFIDAVITS RELATING STATUS OF DEFENDANT.—

(A) IN GENERAL.—Except as provided in clauses (i) and (ii) of subparagraph (B), the court shall consider a defendant to be a biomaterials supplier who is not subject to an action for harm to a claimant caused by an implant, other than an action relating to liability for a violation of contractual requirements or specifications described in subsection (d).

(B) RESPONSES TO MOTION TO DISMISS.—The court shall grant a motion to dismiss any action that asserts liability of the defendant under subsection (b) or (c) of section 205 on the grounds that the defendant is not a manufacturer subject to such section 205(b) or seller subject to section 205(c), unless the claimant submits a valid affidavit that demonstrates that—

(i) with respect to a motion to dismiss contending the defendant is not a manufacturer, the defendant meets the applicable requirements for liability as a manufacturer under section 205(b); or

(ii) with respect to a motion to dismiss contending that the defendant is not a seller, the defendant meets the applicable requirements for liability as a seller under section 205(c).

(4) BASIS OF RULING ON MOTION TO DISMISS.—

(A) IN GENERAL.—The court shall rule on a motion to dismiss filed under subsection (a) solely on the basis of the pleadings of the parties made pursuant to this section and any affidavits submitted by the parties pursuant to this section.

(B) MOTION FOR SUMMARY JUDGMENT.—Notwithstanding any other provision of law, if the court determines that the pleadings and affidavits made by parties pursuant to this section raise genuine issues as concerning material facts with respect to a motion concerning contractual requirements and specifications, the court may deem the mo-

tion to dismiss to be a motion for summary judgment made pursuant to subsection (d).

(f) SUMMARY JUDGMENT.—

(1) IN GENERAL.—

(A) BASIS FOR ENTRY OF JUDGMENT.—A biomaterials supplier shall be entitled to entry of judgment without trial if the court finds there is no genuine issue as concerning any material fact for each applicable element set forth in paragraphs (1) and (2) of section 205(d).

(B) ISSUES OF MATERIAL FACT.—With respect to a finding made under subparagraph (A), the court shall consider a genuine issue of material fact to exist only if the evidence submitted by claimant would be sufficient to allow a reasonable jury to reach a verdict for the claimant if the jury found the evidence to be credible.

(2) DISCOVERY MADE PRIOR TO A RULING ON A MOTION FOR SUMMARY JUDGMENT.—If, under applicable rules, the court permits discovery prior to a ruling on a motion for summary judgment made pursuant to this subsection, such discovery shall be limited solely to establishing whether a genuine issue of material fact exists as to the applicable elements set forth in paragraphs (1) and (2) of section 205(d).

(3) DISCOVERY WITH RESPECT TO A BIOMATERIALS SUPPLIER.—A biomaterials supplier shall be subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 205(d) or the failure to establish the applicable elements of section 205(d) solely to the extent permitted by the applicable Federal or State rules for discovery against nonparties.

(g) STAY PENDING PETITION FOR DECLARATION.—If a claimant has filed a petition for a declaration pursuant to section 205(b)(3)(A) with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition.

~~(h) MANUFACTURER CONDUCT OF PROCEEDING.—The manufacturer of an implant that is the subject of an action covered under this title shall be permitted to file and conduct a proceeding on any motion for summary judgment or dismissal filed by a biomaterials supplier who is a defendant under this section if the manufacturer and any other defendant in such action enter into a valid and applicable contractual agreement under which the manufacturer agrees to bear the cost of such proceeding or to conduct such proceeding.~~

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

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

(2) the court found the claim against the biomaterials supplier ~~to be without merit and frivolous.~~ →

was clearly without merit and frivolous at the time the claim was brought.

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Product Liability –
biomaterials provision

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HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

JAMES S. BENSON

EXECUTIVE VICE PRESIDENT, TECHNOLOGY AND REGULATORY AFFAIRS

April 17, 1997

Mr. Bruce Lindsey
Assistant to the President and Deputy Counsel
The White House
Second Floor, West Wing
Washington, D.C. 20500

Dear Bruce:

At our March 10 meeting during which we discussed the need to act quickly to enact legislation ensuring continued access to biomaterials and components, you expressed a desire for more background on the FDA process. In particular, you sought assurances that the process was sufficiently rigorous so that with passage of the Biomaterials Access Assurance Act, the public could be certain that all materials, components, and implantable devices were safe and efficacious. As promised, I am enclosing a description of the FDA device review and approval process with emphasis on how it addresses the safety, quality, and purity of materials and components.

We appreciate your understanding of the legal implications of expanding the bill to include "willfully negligent" suppliers, which as you know, could have the unintended effect of allowing discovery each time such allegations were lodged. The legal and other costs associated with discovery are among the very reasons suppliers of materials and components are leaving the implantable medical device market.

As the enclosed analysis describes, the FDA review process specifically addresses the concerns raised by ATLA regarding the hypothetically willfully negligent supplier. At each and every step, the FDA process ensures the safety, quality, and purity of the materials and components that are used in the manufacture of implantable devices. In short, the Food, Drug and Cosmetics Act holds device manufacturers responsible for demonstrating the safety and efficacy of the materials and components, and, more important, the device as a whole.

Frankly, we believe the hypothetical situation of a "willfully negligent supplier" is impossible since the supplier is simply responding to extremely detailed material or component specifications developed by the device manufacturer. Should a problem with the materials or components occur, it would either prove to be the fault of the device manufacturer in the development of their specifications, or a failure of the supplier to live up to the specifications.

[illegible]

In either case, the proposed biomaterials legislation would hold the appropriate party responsible for damages. In the first case, the manufacturer would clearly be at fault. In the second, the legislation clearly covers suppliers who fail to meet contract specifications.

Finally, even if the supplier were to make representations about the safety of its materials or components, the supplier cannot reasonably know how the manufacturer will process or apply the materials and components in a particular device. For these reasons, the FDA requires the manufacturer to do its own safety and bench testing of materials and components as they will be processed and used in the device. For example, lithium is highly toxic and yet lithium batteries are preferred for implantable devices because of their superior longevity as a reliable power source. When encased in a hermetically sealed canister, such as a pacemaker, a lithium battery's toxic qualities are negated and more important, help eliminate the need for an invasive operation to replace a device simply because its power source has lapsed.

For your interest, I am also enclosing a recent article from the *Washington Post* which speaks to the critical importance of implantable devices in our health care system as well as a recent *Washington Post* editorial that favors passage of the biomaterials legislation. You may also be interested in the findings of a recent report commissioned by HIMA (see enclosed summary) which has concluded that the biomaterials shortage is growing and must be addressed if we are to ensure American patients continued access to implantable devices.

In closing, I believe our meetings have been productive and I look forward to further discussion with you. Please don't hesitate to contact me if you have any questions about the FDA review process.

Sincerely,

James S. Benson

Enclosures

cc: Elena Kagan

FDA DEVICE REVIEW AND APPROVAL

Note to the Reader: Vertical lines in the left margin indicate passages particularly relevant to FDA evaluation of materials and components.

INTRODUCTION

This presentation describes the regulatory requirements that medical device manufacturers must meet before they may lawfully distribute their devices in the U.S. The focus will be on how the regulatory framework that governs all aspects of device development and commercial distribution addresses safety issues related to the device's materials and components.

A clear understanding of the FDA regulatory framework—including both manufacturer and FDA responsibilities—will lead to the realization that the medical device manufacturer, and no other party, is fully responsible for demonstrating to the Agency the safety and effectiveness of the device.

1.0 MEDICAL DEVICE LEGISLATION AND REGULATION

In the 1970s, as Congress was considering granting FDA specific authority to regulate medical devices, it was clear that any new authorities would have to provide a regulatory framework that would apply to a broad range of medical technology posing a wide variety of potential risks. Recognizing that a demand for absolute safety could paralyze the practice of medicine, Congress sought a regulatory framework that would provide a *reasonable* assurance of safety and a *reasonable* assurance of effectiveness for medical devices. This standard of reasonable safety and effectiveness has, over the past two decades, proven to be a strong safeguard for the welfare of the American public.

The result of this Congressional action, the Medical Device Amendments of 1976 (MDA), established regulatory obligations—violations of which are punishable by civil or criminal penalties—that govern the manufacture and distribution of all medical devices in the U.S. The MDA established a system in which FDA classifies medical devices according to relative risk and when they were placed on the market. In addition, depending on the classification, FDA either *clears* or *approves* them for market. Under this system, all devices are described as "preamendment" and "postamendment." A "preamendment" device was commercially distributed prior to the MDA enactment date, May 28, 1976; a "postamendment" device was commercially distributed for the first time on or after May 28, 1976.

1.1 Medical Device Classification System

The MDA further subdivides medical devices into one of three device risk-related classes. The level of regulatory control is then commensurate with the risk posed by the device. There are three device classes:

- Class I - The simplest devices presenting the lowest risk. They are regulated using General Controls and limited FDA review. Examples: Tongue Depressors, Bandages.

- Class II - Present a spectrum of risk and make up the bulk of medical devices. They are regulated using Special Controls. The intensity of review and the degree of control imposed are commensurate with risk. They are *cleared* for market. Examples: Hip Protheses, Catheters, Sutures.

- Class III - Present the highest level of risk and make up the smallest number of devices. They are regulated through intense Premarket Approval scrutiny of safety and effectiveness data and are *approved* for market. FDA may also require postmarket data collection. Examples: Heart Valves, Pacemakers, Vascular Grafts (Synthetic Arteries and Veins).

1.2 Substantial Equivalence

The MDA mandated FDA to classify all preamendment devices. Classification is an intensive process, open to public participation through notice-and-comment rule making. The process evaluates the probable risk and benefit for each device to determine the appropriate level of regulatory control.

According to the MDA, all postamendment devices are automatically Class III. Formally, a device manufacturer submits either a premarket approval application (PMA) acknowledging that the device is Class III or requests a classification decision from FDA. The result of a classification decision is that the device is either ruled "substantially equivalent" to a preamendment device (i.e., it is cleared for market), or not "substantially equivalent" (i.e., a PMA is required).

The process for clearing devices through a substantial equivalence decision was described in Section 510(k) of the MDA and is generally referred to as the 510(k) process. Originally, the MDA required Class II, i.e., 510(k), devices to be compared to a preamendment device. It also mandated FDA to develop and issue performance standards for all Class II devices. However, because in most cases newer devices are the result of refinements and further development of preamendment devices, FDA cleared them based on comparison to currently marketed devices.

In 1990, Congress codified current procedure when it passed the Safe Medical Devices Act of 1990 (SMDA). Now, a 510(k) device can be compared to any legally marketed device, and Class II devices can be regulated through the use of Special Controls, which can include either FDA generated standards or voluntary consensus standards.

1.3 Preamendment Class III Devices

When the MDA was enacted, preamendment Class III devices were permitted to remain on the market. These devices had posted a long record of safe use—in some cases more than twenty years—and to do otherwise would have deprived the American public of vital medical care.

In 1990, Congress passed the Safe Medical Devices Act of 1990 (SMDA). SMDA required FDA to call for PMAs for preamendment Class III devices and set deadlines for Agency action. As a result, FDA ordered manufacturers of preamendment Class III devices to submit information for the Agency to use to decide whether to call for PMAs or downclassify the devices. FDA has subsequently called for PMAs for 41 devices and announced its intention to downclassify several others.

2.0 PREMARKET EVALUATION PROGRAM

FDA's Office of Device Evaluation (ODE) oversees the premarket evaluation of medical devices. The process is directed by a variety of internal documents (i.e., "Blue Book" memorandum) that establish policy for handling reviews to assure the comprehensiveness, depth, credibility, and integrity of all device reviews. The policies are complemented by numerous guidance documents that are publicly available. Because MDA places on the manufacturer the ultimate responsibility to produce the information or data required for device review, manufacturers use these documents to guide the preparation of their submissions for device approval or clearance. *ODE's premarket evaluation of medical devices is indisputably the most rigorous in the world.*

2.1 Safety Testing of Materials as Part of Premarket Evaluation

For many medical devices, implants in particular, materials of manufacture are critical to safety and effectiveness. Indeed, manufacturers devote considerable attention to determining the suitability of the materials and components used in their devices. Whether a specific device is being reviewed on the 510(k) pathway or the PMA pathway, FDA requires manufacturers to submit data on many materials issues, including chemical identity and purity, toxicological effects (biocompatibility), degradation, strength, susceptibility to stress, surface finish, and permeability, among others, as appropriate. Frequently these data are generated using national or international consensus standards. When data are needed but relevant standards are not available, FDA stipulates the testing requirements and criteria. FDA then reviews both the test protocols and the test data.

FDA places a high priority on the potential toxicological effects of medical devices, particularly implantable devices, using materials that come in contact with bodily fluids or tissues. Manufacturers of such devices must submit comprehensive data addressing any potential toxic

effects that might be caused by the material as used in a specific device, taking into account the manufacturing process for that device.[1]

2.2 Master Files

Under the MDA, the manufacturer is responsible for supplying all safety testing data. However, there is frequently basic proprietary information on commercial materials that materials suppliers want to hold confidential. To accommodate the device manufacturers' need to supply information to FDA, suppliers place this information into an FDA *Master File* maintained by the supplier at the Agency. The material supplier then authorizes its customers to reference the Master File in the customer's submission. This allows FDA access to the data while maintaining its confidential and proprietary nature.

Some suppliers also generate biocompatibility data that they publish in the open scientific literature. Manufacturers often use both Master File data and published data to facilitate device development. However, the information in the Master File must be supplemented with data specific to the device in question to account for the generality of the Master File data. The device manufacturer must also validate the relevance of Master File data to the manufactured device through:

- quality assurance testing of purchased raw material, and
- biocompatibility testing on material that has been subjected to the device manufacturing processes, and possibly biocompatibility testing of completed devices.

2.3 Premarket Notification [510(k)]

As described in Section 1.0, the cornerstone of MDA's regulatory system for classifying postamendment devices is Section 510(k), which requires first time device marketers to obtain FDA clearance before introducing into commerce a device intended for human use. FDA reviews Premarket Notifications, commonly referred to as a "510(k)s," and finds the device either "substantially equivalent" or "not substantially equivalent."

Equivalence here refers to a *predicate device*, a legally marketed device to which the manufacturer claims equivalence. A *substantially equivalent* ruling means the device satisfies the same standard of safety and effectiveness as the predicate device. A finding of *not substantially equivalent* retains the device as Class III and makes it subject to the Premarket Approval process (see Section 2.4).

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[1] FDA's Office of Device Evaluation (ODE) formal guidance concerning biocompatibility testing was initially described in Blue Book Memorandum G87-1, which establishes as official guidance the international standard ISO-10993, Biological Evaluation of Medical Devices Part I: Evaluation and Testing (revised in ODE Blue Book Memorandum G95-1; 01 May 95).

Since most device submissions to FDA represent incremental improvements and refinement to existing devices, as many as 98% of devices are cleared through the 510(k) process[2]. This process requires the manufacturer to supply data on design, manufacturing, and safety and effectiveness testing adequate to permit FDA to make a reasonable decision based on good science. The Agency may also request clinical data to support a submission.

Significantly, in SMDA, Congress reaffirmed its commitment to the 510(k) device review process by updating it to incorporate current FDA practice[3]. This process requires FDA to examine, in a step-wise fashion, issues directly relevant to the assessment of the safety and effectiveness of each device[4]. For any device that is an implant or that otherwise comes in contact with the body or body fluids, the 510(k) review process requires that there be an examination of the materials of manufacture and the biocompatibility of those materials.

FDA clearance of a device through the 510(k) pathway requires that the manufacturer have a good record with respect to compliance with the FDA's Current Good Manufacturing Practices regulation (CGMP) (see Section 3.0). After a device has been cleared for marketing by FDA, subsequent modifications of the device must be evaluated for the need to submit another 510(k) for the modification. The MDA requires that a 510(k) be submitted for any change or modification in the device that could significantly affect the safety or effectiveness of the device, (e.g., a significant change or modification in design, materials or components, chemical composition, energy sources, or manufacturing process[5]).

2.4 Premarket Approval (PMA)

The PMA pathway for market clearance is even more rigorous than the 510(k) pathway. When a device undergoes PMA review, additional Agency attention is given to safety and effectiveness issues, including those related to device materials. In addition to submitting safety test protocols and data, the device manufacturer must assert that all safety testing was performed in strict conformance with the Good Laboratory Practices regulation (designed to ensure that laboratory practices are consistent and appropriate leading to reliable test results) or explain the deviations. Thus the device manufacturer has even greater and more focused responsibility in assuring the validity of submitted safety data.

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[2] House Report 101-808 (101st Congress, 2d Session) accompanying House passage of H.R. 3095, the Safe Medical Devices Act of 1990 (PL 101-629).

[3] SMDA changed the 510(k) standard from equivalence to a preamendment device that was on the market prior to MDA to equivalence to a currently legally marketed device. This change reflected the realities of current FDA practice. Thus the substantial equivalence process now compares devices using current technology.

[4]The fundamental, systematic process by which FDA reviews and makes clearance decisions on 510(k)s was first documented in the ODE Blue Book Memorandum K86-3, dated June 30, 1986.

[5]The most recent guidance covering such changes is contained in ODE Blue Book Memorandum K97-1, dated January 10, 1997.

FDA approval of a device through the PMA pathway requires that the manufacturer pass an FDA pre-approval CGMP inspection (see Section 3.0). After a device has been cleared for marketing by FDA, any subsequent modification of the device must be approved by FDA prior to being implemented. Such changes include, but are not limited to:

- use of a different facility to manufacture the device;
- changes in manufacturing facilities, methods, or quality control procedures;
- changes in sterilization procedures; and
- changes in performance or design specifications, circuits, materials or components.

3.0 GOOD MANUFACTURING PRACTICES REGULATION

Since 1978, FDA has had a Current Good Manufacturing Practices (CGMP) regulation implementing authorities in MDA governing the manufacture of devices. In addition, SMDA gave FDA explicit authority to add preproduction design controls to the CGMP. In 1993, FDA proposed extensive revisions to the CGMP regulation. The agency's goals were threefold:

1. To implement the new SMDA authority;

2. To increase FDA's effectiveness in enforcing other aspects of quality assurance in the design and manufacture of devices; and

3. To harmonize its regulation with those of foreign governments and with international standards.

The Good Manufacturing Practice final rule was published in October 1996 and will go into effect June 1, 1997.

The new rule requires each manufacturer to have a comprehensive and detailed quality assurance system. The rule affects every aspect of design and manufacture of medical devices. The requirements specifically address, among other items, design controls, purchasing controls, and production and process controls. These directly affect and control the selection, qualification, and documentation of raw materials for the device being designed. Compliance with these requirements provides assurances to the manufacturer and to FDA that a selected material meets its specifications for identity and purity before being incorporated into the manufacture of the medical device.

Likewise, the new rule directly affects and controls the design and manufacture of component parts, including selection, qualification, and documentation of component manufacturers and of their quality systems, and similarly provides assurances that the component parts meet their specifications before being incorporated into the manufacture of the medical device.

One cannot overemphasize the fact that these regulations place responsibility directly on the medical device manufacturer to employ a detailed, comprehensive, integrated approach to

quality assurance for the design and manufacture of its devices. The required elements include management responsibilities, quality audits, personnel and training, design controls, document controls, purchasing controls, identification and traceability of product to facilitate corrective action, production and process controls, acceptance activities (including receiving, in-process, and finished device acceptance), a means of dealing with non-conforming product, and corrective and preventive activities. All of these elements have direct bearing on the quality and safety of materials and components used in medical devices.

3.1 Safety and Quality Assurance of Materials and Components

Several areas of the new CGMP regulation specifically address the fitness for use and consistent quality of materials and components:

- *Design Controls* - Manufacturers must have in place a system to ensure that device design is performed in an orderly, scientific manner so that design decisions can be traced, justified, and understood. Part of product design is the selection of appropriate materials and development of the necessary specifications to ensure that the chosen materials are appropriate for the intended use.

- *Supplier Qualification* - Manufacturers must have in place a system to document that materials and component suppliers are capable of supplying materials specified in purchasing agreements (i.e., contracts) in a continuing and reliable manner.

- *Materials Acceptance* - Manufacturers must have a system in place to ensure that incoming materials meet the manufacturer's specifications for those materials.

- *Product and Process Verification* - Manufacturers must perform appropriate tests to ensure that materials, components, final products, and the processes used in manufacturing them are appropriate and consistent.

The requirements of the new CGMP regulation also extend well beyond the product approval/clearance processes to the product's foreseeable lifetime to ensure that the manufacturer produces devices that are true to the original specifications.

4.0 POSTMARKET CONTROLS

In addition to the premarket evaluations performed before a device can be marketed, and the CGMP system that must be in place for the design and manufacture of the device, there are other responsibilities placed on medical device manufacturers to assure the safety and effectiveness of their devices. These include a variety of tracking and reporting requirements to ensure that a device manufacturer can locate certain high risk devices throughout their useful lifetimes, and for all devices to capture information on adverse events.

5.0 CONCLUSION

The MDA, SMDA, and implementing regulations and practices of FDA place responsibility exclusively on the medical device manufacturer for the safety and effectiveness of the medical devices it produces including the selection, quality and purity of materials and components. This responsibility is comprehensive and explicit, and the device manufacturer cannot delegate it. Through its premarket evaluation program, FDA examines data submitted by the device manufacturers, decides whether the assembled data supports a reasonable assurance of safety and effectiveness, and ultimately decides whether the device should be permitted access to the market. Through its inspection activities and postmarket monitoring activities, FDA requires that device manufacturers manufacture and distribute only devices having the safety and effectiveness described in their premarket evaluation submissions.

THE WASHINGTON POST by Rick Weiss (4/15pA2)

Device Outperforms Medicine In Abnormal Heartbeat Study

Doctors Suggest Patients Consider Switching Treatment

By Rick Weiss
Washington Post Staff Writer

Researchers have halted a large study that compared commonly prescribed heart drugs to an implantable device that corrects abnormal heart rhythms, saying the electrical device is clearly superior and people taking the medicines should consider switching to the device.

The three-year study, sponsored by the National Heart, Lung and Blood Institute (NHLBI), was the first to compare the two most popular approaches to treating abnormal heart rhythms, or arrhythmias, which cause an estimated 350,000 deaths every year in the United States.

Doctors said that patients taking the medicines—amiodarone (brand name Cordarone) or sotalol (brand name Betapace)—should not stop taking the drugs but should talk to their doctors about switching to the device, called an implantable cardiac defibrillator.

The defibrillator, about the size of a pack of cigarettes, is tucked surgically beneath the skin below the left collarbone and sends a rhythm-correcting shock to the heart when it detects a dangerous rhythm abnormality.

"This will literally revolutionize our initial treatment for arrhythmia patients," said Douglas Zipes, chief of cardiology at Indiana University School of Medicine and chairman of the steering committee that oversaw the study.

Zipes said the device's superiority over drugs was especially apparent during the first nine months after an initial diagnosis of arrhythmia. As a result, he said, people who have recently begun taking drugs for this problem should "maybe walk a little more quickly to their doctor."

People who have been on the drugs for two or three years may decide with their doctors not to make the change, Zipes said, although the study suggests that even after three years the device prevents more deaths than the drugs do.

The total cost of getting an implantable defibrillator, including hospital charges, is about $66,600, said Eleanor Schron, the study's project director for NHLBI. By contrast, it costs about $34,000 to get started on drug therapy; most of the costs for the drug option come from the many days of hospitalization required while an exact dose is determined for each patient.

Every year more than 20,000 Americans get defibrillators installed in their chests, Schron said, and about an equal number opt for drug therapy. The implants are given to patients with either ventricular fibrillation, an abnormal quivering of the heart, or ventricular tachycardia, an abnormally rapid heart rate—both of which can block the ability to pump blood. Both options are generally covered by insurance.

Although the current study looked only at death rates, Schron said, the NHLBI is now conducting a cost-benefit comparison to determine the total costs—or savings—that might come with a global switch from drugs to devices. A separate study will consider quality of life issues.

> *"This will literally revolutionize our initial treatment for arrhythmia patients."*
>
> — Douglas Zipes, chairman of study's steering committee

Both drugs can have serious side effects, including fatal lung problems and liver damage. Implantable defibrillators are relatively free of side effects, although they occasionally zap the heart without a good reason. "It's a mule kick in the chest," Zipes said.

In the NHLBI study, half the patients received a defibrillator and the other half were given one of the two drugs. The government stopped the trial April 7, even though it was still 200 people short of its 1,200-person enrollment goal, because an early analysis of the data showed significantly better survival rates in those who had the devices.

After one year, there were 38 percent fewer deaths in the group of patients that got defibrillators compared with the group that got a drug. After the second and third years, the defibrillator group had 25 percent fewer deaths than the medicine group.

Implantable defibrillators can be placed inside the chest in a relatively simple surgical procedure with a local anesthetic. Batteries last from three to five years, and can be changed "lickety split" under local anesthesia, Zipes said.

The NHLBI, an institute of the National Institutes of Health, announced the findings yesterday in a press release and said researchers will describe details in New Orleans early next month at a meeting of the North American Society for Pacing and Electrophysiology.

THE WASHINGTON POST Editorial (4/14pA16)

Silicone Exemption

ONE OF THE more dangerous side effects of the toxic legal-medical tangle over breast implants has been the growing skittishness it inspires among makers and suppliers of the raw material silicone, who fear, not entirely without basis, that they could somehow be drawn into liability cases based on these or other silicone devices. Were this skittishness to get too widespread, representatives of the industries that make silicone and other "biomaterials" keep warning, companies might pull out of the business of supplying them, leading to life-threatening shortages of such devices as replacement joints and shunts to drain liquid.

That argument is the basis for legislation recently introduced in both House and Senate at the urging of big biomaterials companies—not just Dow Chemical, which has been sued in connection with breast implants, but such chemical giants as DuPont—to create liability protection for the makers of biomaterials except under certain circumstances of willful harm.

You could argue that these fears are overblown, particularly in the wake of several court rulings agreeing that breast implant victims may not sue for or recover damages from Dow Chemical Co., parent company of implant maker Dow Corning Corp. and a major developer of silicone before its use in breast implants was contemplated. Still, justified or not, companies' fears of liability can set off unmanageable ripples.

What's interesting about these bills is that both include a so-called "carve-out" provision stipulating that none of the protections in the new law would apply to breast implants. This is because, as supporters of the bill agree, years of efforts to get a hearing on the biomaterials problem have gone nowhere out of fears that such liability protection could become, or simply appear to be, a back-door way of clearing the makers of breast implants.

The legislation, sponsored by Sens. Joseph Lieberman and John McCain, has been pushed with a fanfare by medical supply groups that point to new surveys of worried companies and predict disaster if the bill is not passed. Besides patching a problem, passing the measure would have an added advantage: It would take a genre of otherwise unrelated horror stories and object lessons off the table and out of the debate still raging on implants' safety and liability. Just for that, it may be worth doing. The implant fiasco has far too many extraneous matters mixed up in it already.

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KEY FINDINGS
1997 ARONOFF STUDY

Patient Access to Lifesaving Devices Is Increasingly Jeopardized

A new study, "*Biomaterials Availability: A Vital Health Care Industry Hangs in the Balance*," conducted by New York-based Aronoff Associates, reveals that at least 75 percent of suppliers of biomaterials used to make medical implants—heart valves, pacemakers, catheters, artificial blood vessels, and sutures—have banned sales to U.S. implant manufacturers. Most of those that still supply are seriously evaluating whether they should continue to do so. This change reflects a 40 percent drop in the percentage of suppliers willing to sell to the permanent implant market since 1994.

The study is an update of a similar report released three years ago by the same research group. Both studies were commissioned by HIMA to determine the impact of a biomaterials shortage on patients, doctors, and the medical device implant industry. Both focused on the same three widely-used materials: PET polyester yarn, polytetrafluoroethylene, and polyacetal resin; this study also included ultra high molecular weight polyethylene.

- The study found that the risk of legal liability was a key factor for 100 percent of suppliers in deciding whether to sell to the implant market. The perceived risk, combined with the small market size for implants—from .002 to 3 percent of the total market for these materials—is more than sufficient reason to discourage most suppliers from entering this market. It also keeps those companies currently in the market constantly reviewing whether it makes sense to *remain* in the implantable device market.

- Under current U.S. liability law, suppliers may be brought into the litigation process and potentially held liable for huge damage awards, even though they were not involved in the design, manufacture, or sale of the implant. U.S. courts have held that suppliers are not liable, yet it can cost millions of dollars to defend and win these lawsuits.

- One supplier, DuPont, who has subsequently halted sales to the implant market, spent $8 million annually over a five-year period defending and winning liability cases arising from the use of its material in a jaw implant—even though there was only a nickel's worth of the material in each implant. As the study findings suggest, the profit margin for suppliers who are sued does not justify—nor remotely cover—the cost and risk of a liability lawsuit.

- The President of Dupont, Mr. John A. Krol, has stated that if and when biomaterials legislation protecting suppliers of materials used in implants is passed, DuPont will again supply the implantable device market. Because many in the supplier community look to DuPont for leadership, passage of the Biomaterials Access Assurance Act should substantially ease the biomaterials shortage.

- According to the Aronoff study, manufacturers of implants are currently receiving their supply of biomaterials through four sources, *all of which are tenuous at best*:

  - ***Stockpiles.*** Between 67 and 75 percent of implant makers (depending on the specific material) are dependent on the use of stockpiled materials for the production of one or more products. Stockpiled materials will last as little as eight months for some products and up to ten years for others; however, this can give rise to a false sense of security. Some materials deteriorate or change sufficiently in storage so that they become useless, and accidents have occurred that destroyed stockpiled material.

  - ***Agreements that meet the "liability risk control" standards of existing supplier.*** In all cases where suppliers are willing to sell to an implant maker, it is under highly restrictive conditions—including an indemnification agreement *and* liability insurance coverage acceptable to the supplier. Liability insurance of up to $100 million for each implant has been cited by at least one supplier. All of these agreements are also under constant evaluation by the suppliers, and by their very structure, exclude smaller companies.

  - ***Alternate Suppliers.*** Some companies have made supply arrangements for key materials with alternate suppliers where an alternate supplier actually exists, and the prospective supplier is willing and legally able to supply for permanent implants. In some cases, the material may be unique and no alternate supplier may exist. In other cases, an alternate may exist, but due to a licensing agreement or other legal constraints, be unable to sell into the U.S. market for any purpose. Where an alternate exists and is willing and able to sell to U.S. manufacturers, it is under highly restrictive conditions, including indemnification agreements and liability insurance coverage acceptable to the supplier. Sales may also be restricted to companies having minimum sales of $1 billion, again, a condition which excludes small and medium-sized companies.

  - ***Work-Arounds.*** The direct customers of the materials supplier are often converters who process the materials into another form or distributors who act as middlemen in selling to the manufacturer. As needed materials have become restricted for implants, some manufacturers have obtained exactly the same materials they have used for years from these third parties—a route that

permits traceability in accord with FDA regulations. However, as suppliers become aware of such arrangements, they are discontinued.

- Stockpiles of some materials will reportedly run out in eight months, while other stockpiles may last up to ten years.

- There will be a narrowing of choices for doctors in providing the best treatment for patients as certain implant products disappear from the market. One such product documented in the study—an implant used in spinal surgery—will disappear from the market by the end of 1997. There will also be a disappearance of ancillary products and products made by small and medium-sized companies. In some cases, product lines will be acquired by large companies having the material supply to support them.

- Manufacturers have been, and will continue to divert resources away from research and development of new and innovative products towards the search for a valid replacement material for existing products.

- Advanced devices based on new or existing materials may be marketed only *outside* the U.S. to reduce the risk of mass lawsuits involving the materials supplier. This means the American public may find itself deprived of the latest generation of lifesaving devices, while patients overseas benefit from the best the U.S. implant industry has to offer.

- There are numerous cases where the liability issue has affected the supply of a wide variety of materials and components used in vital implants. Among the items used in pacemakers, heart valves, and catheters, for example, that are difficult, if not impossible to obtain, are:

  - electronic components and circuitry
  - specialty electrical wires
  - lithium used in batteries
  - films used for flexible circuitry
  - coloring agents
  - specialty glue

- Special materials developed by multinational suppliers that are not on the open market will be unavailable to most companies *large and small.* Any availability will favor large companies that can meet indemnification requirements. Products based on such materials may be restricted to non-U.S. sales.

- Research interaction between major materials producers and implant manufacturers has been virtually halted, a trend that is likely to continue due to liability fears.

- Small independent companies—that have been able to enter and compete in the market on the basis of innovative products—are crippled due to an inability to obtain materials. Start-up companies that require materials that have been restricted for implant use will be unable to enter the market as independent companies. If they do, they may be forced into joint ventures or partnerships with other companies, foreign and domestic, with the financial muscle to deliver on indemnification agreements.

- Liability factors do not appear to be a significant factor in overseas markets. While searching for, obtaining, and qualifying new materials, there will be an inevitable loss of international leadership by the U.S. medical implant industry to its foreign competitors. Overseas manufacturers do not have to meet the same conditions as U.S. manufacturers because they are not as concerned from the liability standpoint.