

BIOMATERIALS ACCESS ASSURANCE ACT OF 1998

MAY 22, 1998.—Ordered to be printed

Mr. GEKAS, from the Committee on the Judiciary,
submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 872]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill (H.R. 872) to establish rules governing product liability actions against raw materials and bulk component suppliers to medical device manufacturers, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE

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

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 non-medical 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 in-

volving 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 pre-market 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—

(aa) be disclosed to a jury in any civil action or other proceeding, and

(bb) 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) 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.
- (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 ac-

tion 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) **GROUND 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) accepted, pursuant to applicable law, by the biomaterials supplier;
- (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 accepted, pursuant to applicable law, by the biomaterials supplier;

(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 IMPEADER 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 makes a finding based on the court's independent review of the evidence contained in the record of the action, that under applicable law—

(A) the negligence or intentionally tortious conduct 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 intentionally tortious conduct; or

(2) the claimant has moved to implead the supplier and the court makes a finding based on the court's independent review of the evidence contained in the record of the action, that under applicable law—

(A) the negligence or intentionally tortious conduct 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.**—Notwithstanding any preliminary finding under subsection (a), 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.

PURPOSE AND SUMMARY

H.R. 872, the “Biomaterials Access Assurance Act of 1998” is designed to ensure American patients’ access to medical implants and devices. To foster medical device access, the bill would protect the suppliers of raw materials and component parts for such devices from much of the costs of discovery and defense in lawsuits where those suppliers would not be held liable. Litigation costs currently drive biomaterials suppliers away from the medical market, with potentially disastrous effects for ill and injured Americans.

H.R. 872 would essentially codify for biomaterials suppliers the “bulk supplier” and “learned intermediary” doctrines from the common law of torts. These doctrines generally provide that manufacturers—not suppliers of raw materials and component parts—are responsible for ensuring that products are safe.

The bill would also establish expedited procedures for dismissal of actions from which biomaterials suppliers are protected. A biomaterials supplier could be re-joined to a suit from which it was dismissed if evidence admitted in a trial between a claimant and an implant manufacturer showed that the biomaterials supplier may be liable.

BACKGROUND AND NEED FOR THE LEGISLATION

Biomaterials are the raw materials and component parts that go into medical implants and devices, which save and enhance the lives of millions of Americans. Under the bill’s definition, biomaterials have generic or non-implant uses, and they are used in a variety of nonmedical products.

The common law of torts generally gives an injured person a cause of action against manufacturers and sellers of products that cause injuries. This is based on the principle that such parties owe consumers a duty to make sure that their products are safe. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) requires manufacturers of medical devices to ensure and demonstrate that their products are safe and effective, are properly designed, and have adequate warnings or instructions.

Suppliers of biomaterials do not design, test, or produce medical devices so they are not responsible, at common law or by statute, for ensuring the safety of medical devices. Nonetheless, when a medical device is alleged to have caused harm, biomaterials suppliers are often named along with manufacturers as defendants in lawsuits alleging inadequate design and testing or inadequate warning related to use of the device.

Biomaterials suppliers are almost never held liable because of two common law doctrines, the “bulk supplier” and “learned intermediary” doctrines. They hold, in general, that the manufacturer of a component (in this context, a biomaterials supplier) is not liable for injuries caused by the component when it is incorporated into a finished product by a third party (in this case, an implant manufacturer) where the component in and of itself was not unreasonably dangerous at the time it left the component manufacturer’s

control.¹ In the same circumstances, a component manufacturer is generally not liable for failure to warn potential consumers of known or suspected finished product dangers.²

Because relatively small quantities and numbers of biomaterials are used for medical devices, sales of raw materials and component parts for medical devices often constitute an extremely small portion of the overall market for such products. For example, the quantity of polyester (PET) yarn consumed for permanent implants is about 0.002% of that consumed by other markets, the quantity of PTFE fiber consumed by the implant market is 0.3% of other markets, and the quantity of polyacetal resin consumed by the implant market is 0.00025% of other markets.³

Many biomaterials suppliers have ceased supplying raw materials and component parts for use in medical devices and implants because the costs associated with litigation far exceed the benefits of sales to the medical market. For example, based on sales of less than \$100 dollars-worth of Teflon, DuPont has been sued 651 times in 41 States over ten years, spending several million dollars successfully defending product liability suits related to another company's use of Teflon in jaw implants.⁴ In a recent study of biomaterials suppliers, all of them considered the risk of legal liability as a prominent factor in their decision whether or not to supply the medical market.⁵ Biomaterials that have been withdrawn or threatened with withdrawal from the market include fluorinated carbon, surgical stainless steel, fluoropolymers, resins and film products, silicone and silicone adhesives, polyethylene, nickel and titanium memory metals, and many others.

Continued abandonment of the medical market by biomaterials suppliers would have several probable effects. Some life-enhancing and life-saving devices could disappear from the market altogether. Other devices could disappear from the market while implant manufacturers redesign, retest, and recertify them with the Food and Drug Administration using alternative biomaterials. Whether or not any device comes off the market, the prices of medical devices for patients would rise as manufacturers pass on added costs. Already, uncertain availability of biomaterials impedes the design, testing, and marketing of new life-enhancing and life-saving implants and devices.⁶ The medical device and implant industry could

¹See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §5, cmt. a (1997) ("However expressed, these formulations recognize that component sellers who do not participate in the integration of the component into the design of the product should not be liable merely because the integration of the component causes the product to become dangerously defective."); 1 Am. Law Prod. Liab. 3d (LCP BW) §8:8 (May, 1996); *In re TMJ Implants Prods. Liab. Litig.*, 872 F. Supp. 1019, 1025-28 (D. Minn. 1995) (discussing raw material supplier and bulk supplier/learned intermediary rules).

²See 1 Am. Law Prod. Liab. 3d (LCP BW) §8:14 (May, 1996). Many courts have noted the inadvisability of extending the duty to warn, and thus liability, to component manufacturers. See, e.g., *Apperson v. E.I. Du Pont de Nemours*, 41 F.3d 1103 (7th Cir. 1994) ("[I]mposing such a duty forces the supplier to retain an expert in every finished product manufacturer's line of business.").

³Aronoff Associates, Market Study: Biomaterials Supply for Permanent Medical Implants 2 (March 1994).

⁴Letter from Ross F. Schmucki, Senior Counsel, Du Pont, to Senator Joseph I. Lieberman (July 25, 1997).

⁵Aronoff Associates, Biomaterials Availability: A Vital Health Care Industry Hangs in the Balance 10 (April 1997).

⁶See *Biomaterials Access Assurance Act: Hearing on H.R. 872 Before the Subcomm. on Commercial and Administrative Law of the House Comm. on the Judiciary*, 105th Cong. 122 (1997) (testimony of Dr. James E. Brown).

decline relative to countries where biomaterials continue to be available. American jobs in that now-vibrant industry could level off or decline. Most importantly, patients needing life-saving and life-enhancing medical implants and devices could be forced to go without and, as a result, could needlessly suffer or die.

Article I, section 8 of the Constitution gives Congress the power “To regulate Commerce with foreign Nations and among the several States.”⁷ Modern consumers are less-and-less likely to reside in the State—or even the country—where products they purchase, and the components of those products, are manufactured. Biomaterials and the medical implants and devices made from them are a good example. They are bought, sold, and transported for purchase and sale throughout the United States and the world. Many medical devices and implants, moreover, go on to be transported among the States and throughout the world in the bodies of individuals whom they have restored to health and vitality.

Though the States and their courts are the primary architects and regulators of the tort system, biomaterials suppliers can not be protected, and their participation in the medical market fostered, by reform in any one State or group of States. The susceptibility of biomaterials suppliers to extensive litigation and discovery in any State could drive them from the medical market entirely, frustrating the purposes of the bill. The Committee has heard testimony empirically illustrating the incapacity of State tort law reform to effectively apply to products that move in interstate commerce because they are bought, sold, and used in numerous jurisdictions.⁸ Leaving biomaterials suppliers susceptible to high litigation costs in any State would harm all of the United States and their citizens because medical devices and implants would be more scarce and expensive, and because the now-thriving biotechnology industry would be hobbled in its competition with firms in countries where biomaterials are more freely available.

Congress can address civil liability issues when they directly and substantially affect commerce among the States and with foreign nations. A threatened or actual shortage of raw materials and component parts for life-saving and life-enhancing medical devices, and a threatened or actual shortage of such devices, is a circumstance where the Constitution’s Commerce Clause empowers Congress to act.

The Biomaterials Access Assurance Act would generally codify for biomaterials suppliers the protections from liability found in the common law of torts. A limited protection from liability, coupled with three exceptions, cause the bill’s protections to follow the contours of the common law in most States. A biomaterials supplier would not be protected by the bill if (a) it is the manufacturer of a medical device, (b) it is the seller of a medical device, or (c) it failed to meet contractual and other specifications.

In addition, the bill would create expedited procedures for determining whether a biomaterials supplier defendant is protected by the bill. A defendant asserting such protection would file a motion to dismiss alleging that it is a biomaterials supplier not subject to

⁷U.S. CONST. art. I, § 8, Cl. 3.

⁸*Hearing on Product Liability Reform Before the House Comm. on the Judiciary*, 105th Cong. 93 (1997) (statement of Representative Tom Campbell).

any exception. The motion to dismiss in most cases would be decided on affidavits, and discovery would be limited during pendency of the motion.

The bill contains a post-trial procedure designed to retain the protections of the bill while providing for the extraordinary situation in which a dismissed biomaterials supplier should be liable. Within 90 days of entry of final judgment in the action by the claimant against the implant manufacturer, a claimant could move to implead a dismissed biomaterials supplier. A court would be authorized to grant such a motion under limited circumstances. The rulings on these motions would be preliminary because, once brought back into the proceeding, a biomaterials supplier would be entitled to supplement the record with evidence relevant to the court's ultimate finding of liability.

Some of the more prominent objections to the bill have decried cases where implant manufacturer defendants have sought bankruptcy protection, potentially denying recovery to deserving plaintiffs.⁹ Bankruptcy of an implant manufacturer creates no duty on the part of biomaterials suppliers to protect the users of implant manufacturers' products, and it does not extend liability on the part of biomaterials suppliers.¹⁰ The Biomaterials Access Assurance Act leaves in place the outcomes in cases where there is a bankrupt implant manufacturer. The bill would, however, allow actions against biomaterials suppliers related by common ownership and control to manufacturers or sellers found to lack sufficient resources to pay a likely judgment.

HEARINGS

In the 105th Congress, the Committee's Subcommittee on Commercial and Administrative Law held a hearing dealing with H.R. 872 on June 12, 1997. Testimony was received from eleven witnesses, representing themselves and five organizations, with additional material submitted by two organizations. The witnesses were Neil Kahanovitz, M.D., Founder, Center for Patient Advocacy; Rita Bergmann of Clarksburg, Maryland; Randy Markey of Newton, Massachusetts; Stephen D. Kaiser of Baltimore, Maryland; Donald P. Doty of Minnetonka, Minnesota; Kenneth M. Kent, M.D., Director, Washington Cardiology Center; Ronald J. Greene, Esq., Wilmer, Cutler & Pickering, representing the Health Industry Manufacturers Association; Dr. James E. Brown, Vice President for Biopharmaceutical and Implant R&D, Alza Corporation; Dane A. Miller, Ph.D., President and CEO, BioMet, Inc.; Jorge Ramirez, Ph.D., Sales and Marketing Manager, Hostalen GUR Americas, Hoechst Corporation; and Professor Mark McLaughlin Hager, Washington College of the Law, American University. The House Commerce Committee's Subcommittee on Telecommunications, Trade, and Consumer Protection also held a hearing on the subject of biomaterials access on April 8, 1997. A version of the bill has been reported by the Senate Committee on Commerce, Science, and Transportation as a title of S. 648. Several versions of biomaterials access

⁹Federal bankruptcy law generally protects debtors from proceedings and judgments against them. See 11 U.S.C. § 362.

¹⁰See, e.g., *In re TMJ Implants Prods. Liab. Litig.*, 872 F. Supp. 1019 (D. Minn. 1995).

legislation were introduced in the 104th Congress, including H.R. 753, introduced by Mr. Gekas, S. 303, and S. 565, the latter of which was reported by the Senate Committee on Commerce, Science, and Transportation. H.R. 753 was the basis of the biomaterials access title in H.R. 956, the Common Sense Legal Standards Reform Act, which passed both the House and Senate. Mr. Gekas re-introduced biomaterials access legislation as H.R. 3468 after President Clinton vetoed H.R. 956.

COMMITTEE CONSIDERATION

On September 11, 1997, the Subcommittee on Commercial and Administrative Law met in open session and ordered reported the bill H.R. 872, as amended, by voice vote, a quorum being present. On April 1, 1998, the Committee met in open session and ordered reported favorably the bill H.R. 872 as amended by voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

In compliance with clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Committee reports that the findings and recommendations of the Committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT FINDINGS

No findings or recommendations of the Committee on Government Reform and Oversight were received as referred to in clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives.

NEW BUDGET AUTHORITY AND TAX EXPENDITURES

Clause 2(l)(3)(B) of House Rule XI is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

In compliance with clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, the Committee sets forth, with respect to the bill, H.R. 872, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 403 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, April 13 1998.

Hon. HENRY J. HYDE,
*Chairman, Committee on the Judiciary,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 872, the Biomaterials Access Assurance Act of 1998.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Susanne S. Mehlman (for federal costs), who can be reached at 226–2860, and Pepper Santalucia (for the state and local impact), who can be reached at 225–3220.

Sincerely,

JUNE E. O'NEILL, *Director*.

Enclosure.

cc: Hon. John Conyers, Jr.,
Ranking Minority Member.

H.R. 872—Biomaterials Access Assurance Act of 1998

CBO estimates that enacting this bill would have no significant impact on the federal budget. Because the bill would not affect direct spending or receipts, pay-as-you-go procedures would not apply.

Under H.R. 872, suppliers of biomaterials (raw materials used to make medical implants and devices) would not be liable in federal or state courts for harm to a claimant caused by a medical implant or device unless the generic raw material used in the medical implant or device violated contract specifications or the biomaterials supplier could be classified as either a manufacturer or seller of the medical implant or device. In addition, implementing H.R. 872 would create expedited court procedures for determining whether a supplier of biomaterials is protected from liability.

While some product liability cases are tried in federal court, the majority of such cases are handled in state courts. Based on information from the Administrative Office of the United States Courts, CBO estimates that enacting this bill would have no significant impact on the number of cases that would be referred to federal courts. Thus, we estimate that enacting H.R. 872 would have no significant impact on the federal budget.

The bill contains intergovernmental mandates as defined in the Unfunded Mandates Reform Act of 1995 (UMRA) because it would preempt state tort laws and would establish new court procedures for determining whether a supplier of biomaterials is protected from liability. States could initially incur some costs in adjusting to the new procedures. Based on information from the National Center for State Courts about the number of product liability cases heard in state courts, CBO estimates that those costs would be well below the threshold established in the law (\$50 million in 1996, adjusted annually for inflation). In the longer run, states could realize net savings if this bill were to discourage potential plaintiffs from filing suits against suppliers of biomaterials. This bill would impose no new private-sector mandates as defined in UMRA.

The CBO staff contacts for this estimate are Susanne S. Mehlman (for federal costs), who can be reached at 226–2860, and Pepper Santalucia (for the state and local impact), who can be reached at 225–3220. This estimate was approved by Robert A. Sunshine, Deputy Assistant Director for Budget Analysis.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to Rule XI, clause 2(1)(4) of the Rules of the House of Representatives, the Committee finds the authority for this legislation in Article I, section 8 of the Constitution.

SECTION-BY-SECTION ANALYSIS

Sec. 1. Short Title.

Section 1 entitles the Act the “Biomaterials Access Assurance Act.”

Sec. 2. Findings.

Section 2 contains findings upon which the Act is based.

Sec. 3. Definitions.

Section 3 defines key terms used in the Act.

A “biomaterials supplier” is a supplier of a component part or raw material used in the manufacture of an implant. This includes any person who has submitted master files¹¹ to the Secretary of Health and Human Services for purposes of pre-market approval of a medical device or who licenses a biomaterials supplier to produce component parts or raw materials.

A “claimant” is a person bringing a civil action, claiming to have suffered harm from an implant. The definition includes a decedent on whose behalf the estate brings an action and the parent or guardian bringing an action on behalf of a minor or incompetent. The definition excludes providers of professional health care services, persons acting in the capacity of a manufacturer, seller, or biomaterials supplier, and persons bringing such actions alleging harm caused by a silicone breast implant.

The latter exclusion was not based on a determination that silicone gel or any other form of silicone causes or may cause adverse health effects. Because of the controversy surrounding the use of silicone breast implants, in 1992 the FDA placed certain restrictions on their use pending further study. Since the imposition of these restrictions, Congress has taken testimony which reveals results of several major studies that have found no significant connection between silicone gel breast implants and connective tissue disease. The FDA has acknowledged the value of these studies in congressional hearings, but the FDA’s interpretation of the scientific evidence is not yet fully settled. Congress continues to encourage the FDA to pursue a sound scientific conclusion.

The Act specifically prohibits the silicone-gel breast implant exclusion from being used to imply that Congress has made a finding regarding the health effects of silicone or silicone implants. Even the existence of this exclusion shall not be disclosed to a jury in a civil action or other proceeding. It shall not be presented in any type of proceeding except as necessary, if necessary, to establish the applicability of the Act. This would only happen in the unlikely

¹¹A “master file” is a reference source submitted to the Food and Drug Administration, which may contain detailed information on a specific manufacturing facility, process, methodology, or component used in the manufacture, processing, or packaging of a medical device. See 21 C.F.R. § 814.3.

event that a defendant in a breast implant case were to assert one of the defenses the Act provides.

A “component part” is a manufactured piece of an implant. By definition, a component part has significant non-implant applications and has no implant value on its own.

“Harm” is injury to or damage suffered by an individual; any illness, disease, or death of that individual resulting from that injury or damage; and any loss to that individual or any other individual resulting from that injury or damage. It is not commercial loss or damage to an implant.

An “implant” is a medical device intended by its manufacturer to be placed into a surgically or naturally formed or existing cavity of the body for at least thirty days; or to remain in contact with bodily fluids or internal human tissue through a surgically produced opening for a period of less than thirty days; and suture materials used in implant procedures.

A “manufacturer” is a person (a) engaged in manufacture, preparation, propagation, compounding, or processing, as defined in § 510(a)(1) of the Federal Food, Drug, and Cosmetic Act, of an implant and (b) required to register with the Secretary pursuant to § 510 of that Act and include the implant on a list of devices filed with the Secretary pursuant to § 510(j) of that Act.

A “medical device” is a device, as defined in § 201 of the Federal Food, Drug, and Cosmetic Act, and includes any device component of any combination product as that term is used in § 503(g) of that Act.

A “raw material” is a substance or product that has generic and non-implant uses. While “raw material” and “component part” are defined separately in this section of the Act, they are treated identically, just as they are at common law.¹² When either a raw material or a component part is incorporated into a final product, the producer of that final product generally owes the product’s users a duty of care. The supplier of the raw material or component part does not. Furthermore, there is no sound distinction between raw materials and component parts. For example, a substance that is highly manufactured to achieve specific molecular or chemical properties, though not formed into the shape it would take in a medical implant or device, straddles the divide between raw material and component part. Whether and when it moves from raw material to component part could fall at nearly any point in the manufacturing process. Advances in biotechnology may take advantage of both the chemical and mechanical properties of substances. A distinction between raw materials and component parts would confuse and confound the application of this Act to such innovations. As long as commerce follows the current model of purchase and sale among identifiable parties, however, suppliers of raw materials and component parts will be distinguishable from manufacturers and sellers of medical implants and devices.

The “Secretary” is the Secretary of Health and Human Services.

A “seller” is a person who sells, distributes, leases, packages, labels, or places an implant in the stream of commerce, but is not

¹²The Restatement treats raw materials as a subset of component parts. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 5, cmt. c (“Product components include raw materials.”).

a seller of real property, a provider of professional services, or a person acting in a financial capacity with respect to the sale of an implant.

Sec. 4. General Requirements; Applicability; Preemption.

This section makes the scope of the Act explicit. The Act provides a narrow, statutory defense to liability for biomaterials suppliers in actions brought by claimants alleging harm from a medical device or implant, and the means for asserting that defense. The Act applies to all civil actions in State or Federal court, brought against a manufacturer, seller, or biomaterials supplier for harm allegedly caused by an implant, as each of those terms are defined in the Act. It does not apply to loss of, or damage to, an implant, or to commercial loss to the purchaser. Nor is it intended to restrict any rights other persons may have to sue biomaterials suppliers under a variety of State law theories. The Act does not affect the scope of a biomaterials supplier's liability to such persons under existing State common law doctrines. As a result, an implant manufacturer may sue a supplier for breach of warranty or contract violations, if such claims exist under State law, without regard to the provisions of this Act.

While the protections of the Act are intended to follow the contours of the common law in most states, they may not in every case, and the Act preempts State law to the extent it establishes a rule of law applicable to the recovery of damages. The Act does not affect any defense available under other provisions of law to a defendant in an action where harm caused by an implant is alleged. Other law, including, but not limited to, jurisdiction, rules of evidence, and jury trial rights, is unaffected by the Act.

Note also that, following a successful impleader under section 7 of the Act, any preemption of the rule of law applicable to the recovery of damages would be nullified. If a party is re-joined to a case under section 7, other applicable law is fully reinstated as to that party.

Sec. 5. Liability of Biomaterials Suppliers.

This section supplies the standard of liability for biomaterials suppliers, other than those re-joined to a case under section 7, and makes three exceptions that take a party otherwise fitting the definition of a biomaterials supplier out from under the protections of the Act.

A biomaterials supplier is not liable for harm to a claimant caused by an implant unless it is (a) a manufacturer, (b) a seller, or (c) a furnisher of raw materials that fails to meet contractual requirements or specifications, as discussed below.

A biomaterials supplier may be liable as a manufacturer if it registered, or if it should have registered, as such with the Secretary under the Federal Food, Drug and Cosmetic Act. It also may be liable if it listed, or if it should have listed, the implant with the Secretary pursuant to that Act. It may be liable if the Secretary declares that it was required either to register or to list the implant under federal law, but failed to do so. A biomaterials supplier may also be liable if it is related by common ownership or control to a

person, meeting either requirement above, that is found by a court to lack sufficient resources to pay a likely judgment.

A biomaterials supplier may be liable as a seller if it held title to the implant after the implant's manufacture and entry into the stream of commerce and if it subsequently resold the implant. It may also be liable if it is related by common ownership or control to a person meeting the above requirement if that person is found by a court to lack sufficient resources to pay a likely judgment.

A biomaterials supplier may be liable, having violated contractual requirements or specifications, if that violation was an actual and proximate cause of harm. A violation of contractual requirements or specifications occurs if the raw material or component parts did not constitute the product described in the contract, or if the biomaterials supplier failed to meet specifications that were (a) accepted by it under applicable law, (b) published by the biomaterials supplier, (c) provided to the manufacturer by the supplier, or (d) submitted by the supplier to the Secretary pursuant to the pre-market approval process. While making clear that a biomaterials supplier may be liable if it failed to meet the terms of a contract or certain administrative filings, these provisions do not place any requirement on a biomaterials supplier to ensure that its products meet the specialized requirements of medical applications; this must be done by implant manufacturers and sellers.

The Act allows claimants to petition the Secretary and, if warranted, receive a declaration that a biomaterials supplier should have registered with the Secretary or listed an implant under the Federal Food, Drug and Cosmetic Act. The Act sets forth the procedures the Secretary must follow in deciding whether to issue a declaration. In light of the Secretary's expertise and in the interest of consistent interpretations of law and regulation, the Committee encourages courts to defer to a declaration issued by the Secretary regarding registration or listing requirements. In passing these provisions, the Committee contemplated currently issued registration and listing requirements. Changes to the registration and listing requirements after the Act is passed should not make otherwise bona fide biomaterials suppliers susceptible to suit as manufacturers.

The Act allows 180 days for the Secretary to decide on the petition. So that claims can be promptly adjudicated, this time is shortened elsewhere in the Act if an action is stayed due to pendency of a petition. Any statute of limitations is tolled while the Secretary considers whether to issue a declaration. This is intended to eliminate the incentive to file suit against a biomaterials supplier while a petition is pending. The Committee encourages potential claimants to refrain from filing an action against a biomaterials supplier on the theory that the supplier may be liable as a manufacturer until a declaration that the biomaterials supplier should have registered has been issued by the Secretary.

Sec. 6. Procedures for Dismissal of Civil Actions Against Biomaterials Suppliers.

This section lays out the procedure to be used for ruling on a motion to dismiss under the Act. It narrowly circumscribes discovery during pendency of such a motion so that a presumptively pro-

tected biomaterials supplier is subject to discovery only on issues salient to the motion until the court rules.

A supplier may file a motion to dismiss on the grounds that it is a biomaterials supplier and that it is not considered to be a manufacturer; that it is not a seller; and that it has not failed to meet specifications. The claimant must name the manufacturer of the implant as a party unless jurisdiction over the manufacturer is not available or the claimant can not proceed against the manufacturer because of applicable law or rules of practice. A biomaterials supplier may file a motion to dismiss on the ground that the claimant has failed to name the manufacturer of the implant as a party.

The defendant and claimant may file affidavits regarding certain issues in the dismissal motion. If the court permits discovery while the motion to dismiss is pending, it is limited to the issues salient to the motion, and to jurisdiction of the court.

In an action other than one based on failure to meet specifications, the court shall grant the motion to dismiss unless the claimant demonstrates by affidavit that the supplier is a manufacturer or seller. The court shall make its determination based solely on the pleadings and affidavits, and may treat the motion as a motion for summary judgment.

If the claimant has petitioned the Secretary for a declaration, and if the Secretary's decision on the petition has not been issued, the court shall stay proceedings for which the declaration is needed until the Secretary has issued a final decision on the petition. When a proceeding is stayed, the Secretary must issue a decision on the petition within six weeks of the date the petition was received.

A dismissal under the Act shall be entered with prejudice, except insofar as a biomaterials supplier may be re-joined to the action under section 7.

The Act permits a manufacturer to file and conduct any proceeding on behalf of a supplier if both parties have entered into a binding indemnification agreement allowing the manufacturer to do so.

Sec. 7 Subsequent Impleader of Dismissed Defendant.

Section 7 provides for the extraordinary situation where evidence admitted at the trial between the claimant and the implant manufacturer clearly shows that the dismissed biomaterials supplier may be liable under other law. The purpose of this section is to leave open the possibility of litigation against a biomaterials supplier in an extreme case so egregious as to overcome the common law limitations on supplier liability. The Committee has not found a single case that has gone to final judgment where a biomaterials supplier has been held liable. While this procedure may identify such a case, if one ever arises, courts should police its use to ensure that it does not become a routine post-trial motion. It is for extreme, unusual cases.

Upon motion, made within ninety days after entry of a final judgment in an action by the claimant against a manufacturer, a court may implead a biomaterials supplier who was dismissed pursuant to the Act. The court may do so if the manufacturer asserts in motions or arguments at trial, and the court finds preliminarily, based on its independent review of the evidence contained in the

record of the action, that, under applicable law, the biomaterials supplier's negligence or intentional tortious conduct caused the claimant's injury. Additional or novel theories of liability should not form the basis for granting the motion.

The court's review should be independent and substantive. A court should grant the impleader motion only if it finds by a preponderance of the evidence that a biomaterials supplier may be liable—not if it finds, for example, that a “reasonable jury” might view the evidence that is part of the record as sufficient to support liability. Because the biomaterials supplier will not have been represented in the trial, no finding by a jury, by general or special verdict, can dispose of any issue for purposes of the court's review.

If a court grants the motion, its finding that a biomaterials supplier may be liable is preliminary. Because it is based on evidence adduced at a trial where the biomaterials supplier will not have been represented, the court's preliminary finding may not become the law of the case, or a basis for issue preclusion or collateral estoppel. The Act gives a re-joined biomaterials supplier an opportunity to fully supplement the record. This is intended to ensure that the claimant and the biomaterials supplier reach equipoise in terms of evidence admitted, opportunity to have facts found, and arguments and motions made. A court must make every effort to see that they do.

If the court allows impleader of the biomaterials supplier, the standard of liability and legal rule determining all issues are provided by other applicable law.

Sec. 8. Applicability.

The Act does not apply to actions commenced before the date of enactment of the Act.

DISSENTING VIEWS ON H.R. 872

H.R. 872 "Biomaterials Access Assurance Act of 1998"

INTRODUCTION

We oppose the Biomaterials Access Assurance Act of 1998. While we recognize that H.R. 872 represents an improvement over predecessor versions of the legislation, we believe the legislation represents yet another misguided effort to federalize state tort law at the expense of victims.

H.R. 872 would shield the liability of biomaterials suppliers under state law to those who fail to meet contractual and other specifications where such failure is an actual and proximate cause of the harm to the claimant. The immunity is so broad that even a supplier that knew or should have known that its product would cause injury or death would be immune from suit if it can meet the foregoing requirement. The legislation also prescribes very detailed procedural mandates on state courts for the dismissal of actions against biomaterials suppliers, at the beginning stage of a suit. It provides for post-trial procedures permitting a dismissed supplier to be brought back into the action only if it can be shown that its negligence was an actual and proximate cause of harm to the claimant.

We oppose H.R. 872 because in our view there is no evidence of a shortage of life-saving medical devices, and there is no compelling reason to abrogate traditional respect for state tort law in this area. For these and the other reasons set forth herein, we dissent from H.R. 872.

1. *There is no evidence of a shortage of medical devices and current law provides appropriate safeguards for the dismissal of frivolous litigation.*

Although the purported justification to H.R. 872 is that there is an imminent shortage of life-saving medical devices and that manufacturers will soon run out of their raw materials stock piles, a comprehensive review of the 1997 Medical Device Register (published by *Medical Economics*) which lists every medical device registered with the FDA, indicates to the contrary. Among other things, the most recent Register reports that there continue to be several, and often numerous, manufacturers of almost every permanent implant that are alleged to be in short supply.¹

Notwithstanding proponents' arguments that costly lawsuits and the fear of litigation remove incentives for suppliers to make their life-saving compounds available to implant manufacturers, the record indicates that biomaterials suppliers have been sued infre-

¹U.S. Public Interest Research Group, *The "Biomaterials Shortage" Where's the Evidence* at 1.

quently, and when they are, blameless suppliers are routinely found not liable for injuries and illnesses caused by defective medical implants.²

Professor Mark Hager has also observed that a number of legal doctrines have evolved which provide protection to biomaterials suppliers from supposedly frivolous lawsuits:

A fabric of common law doctrines has effectively protected upstream suppliers from such suits. These doctrines—the bulk supplier doctrine, the sophisticated user doctrine, the component parts doctrine, and others—have been constructed by courts to protect upstream suppliers in the medical device industry and elsewhere from liability. Courts have determined that upstream liability could saddle suppliers with burdensome duties to monitor the safety of parts and materials they sell in a thousand and one different applications.³

The bulk supplier/sophisticated user doctrine, for example, provides a supplier with immunity if the supplier sold bulk quantities of an inherently nondefective raw material to a manufacturer, who combined the material with other ingredients to produce a defective implant, and the supplier did not know that the raw material would be put to a dangerous use.⁴

The fact that the few possible negligent manufacturers are subject to potential liability through the tort system helps ensure the safety of biomaterials supplies. As Professor Andrew Popper testified at the House Commerce Subcommittee on Telecommunications, Trade and Consumer Protections Hearing on access to biomaterials:

Suppliers currently have an incentive to develop means to inspect and test products or create such opportunities in part because they are subject to liability in tort . . . Their exposure compels a critical level of caution regarding their products, a pressure that would be lost were they to be granted immunity from liability.⁵

While the FDA regulates the design of medical devices, it only regulates the raw materials and component parts on rare occasions. It is therefore important that safety standards be imposed by the suppliers on themselves and by the manufacturers on the suppliers. The current state tort system fills these regulatory gaps.

²For example, while complaints frequently cite that children suffering from hydrocephalus (water on the brain) will be unable to obtain life-saving silastic shunts because of costly litigation, a review of case filings reveals only two lawsuits involving defective shunts. Both cases were brought against physicians whose failure to diagnose shunt malfunction resulted in serious mental incapacity for the patients. See U.S. Public Interest Research Group, *The "Biomaterials Shortage" Where's the Evidence?* at 2.

³H.R. 872, *The Biomaterials Access Assurance Act of 1997: Hearing before the House Judiciary Sub-Committee on Administrative and Commercial Law*, 105th Cong., 1st Sess. (June 12, 1997) (Statement of Mark Hager at 1–2).

⁴The rationale supporting this doctrine is that downstream producers (finished product manufacturers) are in a better position than upstream suppliers (raw materials and component parts manufacturers) to convey product warnings to consumers. This is especially true when the raw materials suppliers supply in "bulk" to a host of manufacturers or where product manufacturers are so "sophisticated," such as medical device manufacturers, that they can assess the dangers of the product and properly advise the public.

⁵*Product Liability and Consumer Access to Biomaterial Products: Hearing before the House Commerce Sub-Committee on Telecommunications, Trade, and Consumer Protection*, 105th Cong., 1st Sess. (April 8, 1997) (Statement of Professor Andrew F. Popper at 17).

2. *H.R. 872 prevents adequate discovery from taking place in cases involving defective medical devices*

In a misguided and unnecessary effort to protect biomaterials suppliers from defending against most lawsuits, H.R. 872 inappropriately dismisses biomaterials suppliers at the outset of litigation, rather than after the discovery period. Although the legislation nominally allows for interpleader of negligent suppliers at the end of the case, the proposed standards provided in H.R. 872 are extremely burdensome. The supplier can be made a party to the action subsequent to dismissal, but only after a final judgment has been ordered. Thus, the case must be tried twice. Even then, the motion to implead will only be granted if the court finds that evidence contained in the record exists that the supplier was the actual and proximate cause of harm. Finally, there are many reasons why evidence may not make it into the record—for example, the court may determine certain evidence offered by the plaintiff in the initial trial to be irrelevant—and once a court renders a final decision, it is generally reluctant to reopen the case.

The net effect of these restrictive impleader rules will be to prevent victims from obtaining information leading to the determination of the biomaterials supplier's liability and to prevent victims from gathering valuable information that would strengthen the case against the device manufacturer. As a result, plaintiffs may never learn who is responsible for their injuries, and neither the public nor regulators may be alerted to product dangers.

3. *H.R. 872 abrogates our traditional respect for State tort law*

States are fully capable of enacting product liability reforms when they feel it necessary to balance the competing needs of business and consumers within their borders. Indeed over the last twenty years all states have enacted some form or another of product liability or tort law protection to benefit defendants.⁶

Unfortunately, federalizing this issue will inevitably lead to greater confusion than certainty because the federal standard will be applied and interpreted in many different contexts in federal and state courts. The Conference of Chief Justices has testified that the search for uniformity of product liability laws (through laws such as H.R. 872) will ultimately prove counterproductive:

It follows that Federal standards, however well articulated, will be applied in many different contexts and inevitably will be interpreted and implemented differently, not only by the State courts but also by the Federal courts . . . Moreover, State Supreme Courts will no longer be, as they are today, the final arbiters of their tort law . . . a legal thicket is inevitable and the burden of untangling it, if it can be untangled at all, will lie only with the Supreme Court of the United States, a court which many experts

⁶See Henry Cohen, *Fifty-State Surveys of Selected Products Liability Issues*, CRS Report for Congress (June 20, 1995).

feel is not only overburdened but also incapable of maintaining adequate uniformity in existing Federal law.⁷

We would also note that H.R. 872 sets forth elaborate rules of civil procedure with regard to motions to dismiss, discovery, summary judgment and impleader for the states to follow, disregarding state rules of civil procedure.⁸ This unprecedented intervention into state procedural rules may well violate the Tenth Amendment under the *New York v. United States*.⁹ In that 1992 case, the Supreme Court held that the federal government cannot commandeer state regulatory processes for federal purposes in a way that unduly burdens or takes away political accountability. In H.R. 872 as well, we are concerned that dictating state rules of civil procedure will unduly burden state courts and will remove the political accountability of the state legislatures.

4. *There is no evidence of a competitive threat from foreign biomaterials providers*

One of the principal rationales stated for the bill is American competitiveness—the need to ensure that we are not at a competitive disadvantage in our biomaterials industry as compared to other countries, as suppliers supposedly withdraw from the medical device market.¹⁰ But, the medical device industry is a thriving domestic market and as Professor Popper has testified, “a system that condemns defective products and services produced in a negligent or grossly negligent manner cannot possibly be considered destructive of our competitive posture.”¹¹

If increased foreign competitiveness was being sought by the bill's proponents, they would have accepted an amendment offered by Representative Conyers providing that the protections under H.R. 872 do not apply to a biomaterials supplier which is a foreign corporation unless it was located in the United States or was headquartered in a country whose law accords protections comparable to those that will apply in the United States with respect to biomaterials suppliers. This would have ensured that our own suppliers would be placed on at least an equal footing with foreign firms. However, the amendment was defeated by the majority.

5. *Other substantive concerns*

In addition to the above problems we have with the legislation, there are a number of other substantive concerns with H.R. 872.

⁷*Product Liability and Civil Justice Reform: Hearings before the House Comm. On the Judiciary*, 104th Cong., 1st Sess. (February 13, 1995) (Statement of the Conference of Chief Justices at 6–7).

⁸For example, in order to obtain a pre-trial dismissal, the bill specifies that a defendant may file a motion alleging that it has met the various legal requirements for dismissal, including the contractual and other product specifications. While the motion is pending, H.R. 872 limits discovery and requires that State courts rule on the motion based on the pleadings and affidavits before it. It also sets forth rules for the issuance of summary judgments and stays. Post-trial motions to implead are also subject to limited discovery and the bill provides further opportunity for the supplier to supplement the record before any trial on the merits may proceed.

⁹505 U.S. 144 (1992). See also *Printz v. United States*, 117 S.Ct. 2365 (1997) (holding unconstitutional, under the Tenth Amendment, the requirement in the Brady Handgun Violence Protection Act that local law enforcement officials conduct background checks on prospective gun purchasers).

¹⁰Sec. 2(10).

¹¹*Product Liability and Consumer Access to Biomaterial Products: Hearing before the House Commerce Sub-Committee on Telecommunications, Trade, and Consumer Protection*, 105th Cong., 1st Sess. (April 8, 1997) (Statement of Professor Andrew F. Popper at 14).

For example, immunity is so broadly written¹² that it extends to biomaterials suppliers who knew or should have known that their product would cause injury or death. President Clinton specifically addressed this issue in his veto statement of last Congress' products liability bill where he stated that "such suppliers should not receive any protection from suit."¹³ Because suppliers usually know the potential misuses of their products and are aware of the dangerous consequences associated with improper uses, they must be relied upon to take remedial action when appropriate.

H.R. 872 also improperly shields components that are intricate products themselves. While the legislation's proponents claim their motivation is to protect the availability of raw materials used in medical implants, the definition of "biomaterials" includes "components" and thus, extends the legislation's protections to manufacturers of component parts contained in implantable medical devices. Raw materials and component parts are not one and the same and should not be treated as such. No showing has been made during the hearings of any need to immunize component parts manufacturers.

It is also informative to note that H.R. 872 exempts breast implant litigants from its coverage. However, the exclusion does not take into account the thousands of medical device patients, who may suffer from a silicone induced disease, caused by such products as penile implants, hip or joint implants, and jaw implants. In our view, there is simply no policy rationale for distinguishing between these cases. While this exclusion reflects the sponsors' awareness that biomaterials may, in certain limited circumstances, cause substantial physical injury, it also indicates that the sponsors of this bill are, in essence, betting the lives and health of future generations of Americans that the silicone gel tragedy will never occur with some other biomaterial.

H.R. 872 also carves out a number of possible non-individual claimants from the liability restrictions in the bill. For example, providers of professional health care services, manufacturers, sellers and biomaterials suppliers are specifically excluded from the definition of "claimant."¹⁴ H.R. 872 further provides a "commercial loss" exception which allows doctors and others who use implants to provide professional services to sue the biomaterials supplier for commercial loss (damage to goods). Collectively, these provisions discriminate against implant recipients, the persons whose lives have been drastically affected¹⁵ by taking away their right to sue suppliers, while retaining every other possible corporate plaintiff's right to sue.

Finally, we would note there are possible market solutions to the liability concerns of biomaterials suppliers that do not require federal preemption of state liability law. For example, medical device manufacturers could indemnify suppliers against liability or could name suppliers as co-insureds on liability policies that they maintain.

¹²Sec. 5.

¹³*Message on Returning Without Approval to the House of Representatives the Common Sense Product Liability Legal Reform Act of 1996*, 32 WEEKLY COMP. PRES. DOC. 780 (May 2, 1996).

¹⁴Sec. (3)(2)(D)(I) and (2).

¹⁵Sec. 4(B)(2).

CONCLUSION

While we support appropriate safeguards to protect biomaterials suppliers from frivolous litigation, we cannot support this legislation. State common law provides numerous special defenses to suppliers. To the extent such defenses are found to be in any way to be insufficient, the remedy lies with the states, rather than with a one-size-fits-all federal fix.

H.R. 872, though improved from prior versions, continues to include numerous flaws. These include offering immunity to potentially negligent raw material and component parts suppliers; restrictive discovery and interpleader rules; burdensome procedural mandates on the states; and exclusions for potential corporate victims which discriminate against individual victims.

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