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Part 2

BIOMATERIALS ACCESS ASSURANCE ACT OF 1998

JULY 14, 1998.—Ordered to be printed

Mr. BLILEY, from the Committee on Commerce, submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany H.R. 872]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, 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, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

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 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; or

(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, although such protections do not protect negligent suppliers.

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 a deceased individual into whose body, or in contact with whose blood or tissue the implant was 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 such services; and

(II) the essence of the professional health care services provided 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 health care services where—

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

(II) the essence of the health care services provided 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—

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

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

(2) PROCEDURES.—Notwithstanding any other provision of law, a Federal or State court in which an action covered by this Act is pending shall, in connec-

tion with a motion under section 6 or 7, use the procedures set forth in this Act.

(b) APPLICABILITY.—

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

(2) EXCLUSION.—A civil action brought by a purchaser of a medical device, where such purchaser intends to use the device in providing professional health care services, 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.—Except as provided in section 7, a biomaterials supplier shall not be liable for harm to a claimant caused by an implant unless such supplier—

(1) is a manufacturer of the implant, as provided in subsection (b);

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

(3) furnished raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, as provided 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 was required 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) included or was required 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;

(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 120 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 from the time a claimant files a petition with the Secretary under this paragraph until such time as either (i) the Secretary issues a final decision on the petition, or (ii) the petition is withdrawn.

(D) STAY PENDING PETITION FOR DECLARATION.—If a claimant has filed a petition for a declaration 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 120 days of receipt of the petition.

(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 and then acted as a seller of the implant after its initial sale by the manufacturer; or

(B) acted under contract as a seller to arrange for the transfer of the implant directly to the claimant after the initial sale by the manufacturer of 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 FAILURE TO MEET APPLICABLE 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 biomaterials supplier supplied raw materials or component parts for use in the implant that either—

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

(B) failed to meet any specifications that were—

(i) accepted, pursuant to applicable law, by the biomaterials supplier;

(ii) published by the biomaterials supplier;

(iii) provided by the biomaterials supplier to the person who contracted for such product;

(iv) 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

(v) 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; and

(2) such failure to meet applicable contractual requirements or specifications 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.—A defendant may, at any time during which a motion to dismiss may be filed under applicable law, move to dismiss an action against it on the grounds that the defendant is a biomaterials supplier and one or more of the following:

(1) The defendant is not liable as a manufacturer, as provided in section 5(b).

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

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

(4) The claimant did not name the manufacturer as a party to the action, as provided in subsection (b).

(b) MANUFACTURER OF IMPLANT SHALL BE NAMED A PARTY.—The claimant in an action brought for harm caused by an implant 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 by a defendant under this section:

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

(A) IN GENERAL.—Except as provided in subparagraph (B), if a defendant files a motion to dismiss under subsection (a), no discovery shall be permitted in connection with 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.

(B) DISCOVERY.—If a defendant files a motion to dismiss under subsection (a)(3) on the grounds that it did not furnish raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, the court may permit discovery limited to issues that are directly relevant to—

(i) the pending motion to dismiss; or

(ii) the jurisdiction of the court.

(2) AFFIDAVITS.—

(A) DEFENDANT.—A defendant may submit affidavits supporting the grounds for dismissal contained in its motion to dismiss under subsection (a). If the motion is made under subsection (a)(1), the defendant may submit an affidavit demonstrating that the 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) CLAIMANT.—In response to a motion to dismiss, the claimant may submit affidavits 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 is a seller of the implant who is liable under section 5(c).

(3) BASIS OF RULING ON MOTION TO DISMISS.—The court shall rule on a motion to dismiss filed under subsection (a) solely on the basis of the pleadings and affidavits of the parties made pursuant to this subsection. The court shall grant a motion to dismiss filed under subsection (a)—

(A) unless the claimant submits a valid affidavit that demonstrates that the defendant is not a biomaterials supplier;

(B) unless the court determines, to the extent raised in the pleadings and affidavits, that one or more of the following apply:

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

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

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

(C) if the claimant did not name the manufacturer as a party to the action, as provided in subsection (b).

(4) TREATMENT OF MOTION AS MOTION FOR SUMMARY JUDGMENT.—The court may treat a motion to dismiss as a motion for summary judgment subject to subsection (d) in order to determine whether the pleadings and affidavits, in connection with such action, raise genuine issues of material fact concerning whether the defendant furnished raw materials or component parts of the implant that failed to meet applicable contractual requirements or specifications as provided in section 5(d).

(d) SUMMARY JUDGMENT.—

(1) IN GENERAL.—

(A) BASIS FOR ENTRY OF JUDGMENT.—If a motion to dismiss of a biomaterials supplier is to be treated as a motion for summary judgment under subsection (c)(4) or if a biomaterials supplier moves for summary judgment, the biomaterials supplier shall be entitled to entry of judgment without trial if the court finds there is no genuine issue of 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 the 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 governed by section 5(d), 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) DISMISSAL WITH PREJUDICE.—Except as provided in section 7, an order granting a motion to dismiss or for summary judgment pursuant to this section shall be entered with prejudice.

(f) 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 BIOMATERIALS SUPPLIER.

(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 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 finds, 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.

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

SEC. 8. EFFECTIVE DATE.

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

H.R. 872 protects biomaterials suppliers from litigation over injuries caused by medical devices, except in unusual cases where the biomaterials supplier actually manufactured or sold the device (as opposed to just supplying the materials), or where it failed to supply the product according to contract specifications. Under current law, biomaterials suppliers are rarely found liable for harm caused by defective medical devices. However, the legal costs to defend against such claims can run into the millions of dollars. Thus, the purpose of this legislation is to keep biomaterials suppliers out of lawsuits where possible, and to minimize the time and resource costs required to obtain a dismissal when litigation occurs.

H.R. 872 is not intended in any way to impair the recovery of an injured party against the manufacturer or seller of a defective medical device. While suppliers have no legal duty to monitor, test, or provide consumer warnings regarding the products in which their supplies are used, manufacturers of consumer products (and in some instances the seller) do have a duty to take reasonable steps to make sure that their products are safe. Manufacturers of medical devices, in particular, are subject to a rigorous review process by the Food and Drug Administration (FDA) to ensure an adequate level of safety and efficacy of their products, including the materials used during production of a medical implant. This bill reflects and affirms the general common law position that the burden of responsibility for the safety of medical implants, including all of their raw materials and component parts, must fall upon the manufacturer (and in certain cases the seller) of the implant, and not the suppliers who provided their supplies according to contract specifications.

In the extraordinary case where the fraudulent conduct of a biomaterials supplier was the cause of a claimant's injury from a medical implant, a provision was added to the bill which would allow a court to bring the supplier back into the case for allocation of damages. Specifically, the bill allows a court to implead a dismissed biomaterials supplier back into a case where the negligence or intentionally tortious conduct of the dismissed supplier was an actual and proximate cause of the harm to the claimant and either the manufacturer has argued that its liability for damages should accordingly be reduced or the court finds that the claimant is un-

likely to recover its full damages from the remaining defendants. To date, however, the Committee is not aware of any court that has ever found a biomaterials supplier liable for intentional or negligent conduct.

SUMMARY

In general, H.R. 872 applies to any civil action brought by a claimant physically harmed by a medical implant. It excludes a biomaterials supplier from liability for harm to a claimant from an implant unless such supplier is a manufacturer of the implant, a seller of the implant, or failed to meet applicable contract requirements or specifications in providing its biomaterials.

A defendant can move to dismiss itself from an action on the grounds that it is a biomaterials supplier and it is not liable (1) as a manufacturer, (2) as a supplier, (3) for furnishing raw materials or component parts that failed to meet applicable contractual requirements or specifications, or (4) because the claimant did not name the manufacturer as a party to the action. No discovery is allowed in the case after such a motion to dismiss is filed, except for discovery related to jurisdictional issues and limited discovery relevant to a claim that the biomaterials supplier failed to furnish materials or parts for the implant that met applicable contractual requirements or specifications.

The court is required to rule on the motion to dismiss solely on the basis of the pleadings and any relevant affidavits submitted, granting such motion unless the claimant demonstrates that the defendant is not a biomaterials supplier, or the court determines that the defendant may be liable as a manufacturer, seller, or for failure to meet applicable contractual requirements or specifications, or because the claimant failed to name the manufacturer as a party to the action. The court may treat a motion to dismiss (regarding meeting contractual requirements and specifications) as a motion for summary judgment under certain circumstances, granting such motion if there is no genuine issue of material fact existing sufficient to allow a reasonable jury to reach a verdict for the claimant.

A manufacturer or claimant may, within 90 days after entry of a judgment, motion to implead back into the case a biomaterials supplier who had earlier been dismissed pursuant to this Act. This can only happen if (1) the manufacturer asserts and the court determines that (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 accordingly be reduced; or (2) the claimant requests and the court finds that (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 recover its full damages from the remaining defendants. A biomaterials supplier impleaded after dismissal may supplement the records of the proceeding, and may only be found liable to the extent required and permitted under applicable law.

BACKGROUND AND NEED FOR LEGISLATION

For over two decades, the Committee on Commerce has grappled with the issue of product liability reform. Historically, injuries caused by defective products gave rise to a tort action in State courts. As transportation and communications systems developed, more products crossed State boundaries, increasing the volume of interstate commerce exponentially and creating more interstate product liability claims. Products manufactured in one State are now sold in another, and may cause injury in yet a third jurisdiction. Because each State has different rules governing recovery in tort, forum shopping is encouraged, common law has developed unevenly, and manufacturers are found liable for conduct in one State that would fail to give rise to a cause of action in another.

In order to safeguard the availability of a wide variety of lifesaving and life-enhancing medical devices, the Committee has determined that immediate action is needed to address biomaterials liability. Biomaterials are component parts or raw materials supplied for the manufacture of medical implants. Almost 8 million Americans have had their lives saved or improved by implantable medical devices containing biomaterials. According to a study by Dr. Marvin S. Aronoff presented to the Committee last year, 75 percent of the suppliers of biomaterials required for implantable medical devices have banned sales to U.S. device manufacturers—a 42 percent decline in just a three year time period. One hundred percent of these suppliers have cited liability exposure as a key factor in discontinuing sales of their products to medical device manufacturers. Fourteen major biomaterials suppliers have now limited or stopped selling critical raw materials for use in implantable medical devices altogether, with many biomaterial supplies no longer available or only available from small companies with uncertain long term financial stability.

Manufacturers of many life saving medical devices are currently relying on stockpiled biomaterials which may run out before the end of 1998. Smaller manufacturers, in particular, will be increasingly unable to obtain necessary biomaterials as suppliers continue to be forced to withdraw from the market over liability concerns. For example, a primary producer of polytetrafluoroethylene (PTFE) chose to withdraw last year from supplying the permanent medical implant market, recognizing that its annual out-of-pocket costs for liability exposure were about $8 million for a single type of medical device, while the annual revenues from that market were less than $500,000. Even though in almost every case the biomaterials suppliers have been ultimately able to establish their lack of culpability, the legal fees and employee resources involved in obtaining a judgment or dismissal usually outweighed any profits to be gained from the relatively small biomaterials markets. Without legal reform, decreasing consumer access to critical biomaterials products may be inevitable.

HEARINGS

The Subcommittee on Telecommunications, Trade, and Consumer Protection held a hearing on whether our legal system is jeopardizing consumers' access to life-saving products, focusing in particular

on the need for biomaterials access assurance, on April 8, 1997. The Subcommittee received testimony from the following witnesses: The Honorable George W. Gekas, U.S. House of Representatives, Seventeenth District, Commonwealth of Pennsylvania; Belinda and Titus Simonini, private citizens; Rita Bergmann, private citizen; Karen M. Hicks, PhD., private citizen; Neil Kahanovitz, M.D., President, Center for Patient Advocacy; Ronald W. Dollens, President and CEO, Guidant Corporation; Andrew F. Popper, Professor of Law, Washington College of Law, American University; Mark A. Behrens, Senior Associate, Crowell and Moring LLP; and Marvin S. Aronoff, PhD., President, Aronoff Associates.

COMMITTEE CONSIDERATION

On June 17, 1998, the Subcommittee on Telecommunications, Trade, and Consumer Protection met in open markup session and approved H.R. 872, the Biomaterials Access Assurance Act of 1998, for Full Committee consideration, amended, by a voice vote, a quorum being present. On June 24, 1998, the Full Committee met in open markup session to consider H.R. 872 and ordered the bill reported to the House, as amended, by a voice vote, a quorum being present.

ROLLCALL VOTES

Clause 2(l)(2)(B) of rule XI of the Rules of the House of Representatives requires the Committee to list the recorded votes on the motion to report legislation and amendments thereto. There were no recorded votes taken in connection with ordering H.R. 872 reported. A motion by Mr. Bliley to order H.R. 872 reported to the House, as amended, was agreed to by a voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Committee held a legislative hearing and made findings that are reflected in this report.

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform and Oversight.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives, the Committee finds that H.R 872, the Biomaterials Access Assurance Act of 1998, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 30, 1998.

Hon. TOM BLILEY,
Chairman, Committee on Commerce,
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. Mehlmen (for federal costs) and Pepper Santalucia (for the state and local impact).

Sincerely,

JUNE E. O'NEILL, *Director.*

Enclosure.

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, H.R. 872 would establish 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 (UMRA) because it would preempt state tort laws and would establish new court procedures for determining whether a supplier of biomaterials is protected from liabil-

ity. State 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.

On April 13, 1998, CBO transmitted a cost estimate for H.R. 872, as ordered reported by the House Committee on the Judiciary on April 1, 1998. The two versions of the bill are similar and CBO estimates that both versions would have no significant impact on the federal budget.

The CBO staff contacts for this estimate are Susanne S. Mehlman (for federal costs) and Pepper Santalucia (for the state and local impact). This estimate was approved by Robert A. Sunshine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 states the short title of the bill as the "Biomaterials Access Assurance Act of 1998."

Section 2. Findings

Section 2 contains the findings setting forth the need and basis for the legislation.

Section 3. Definitions

Section 3 establishes definitions for certain terms used in the Act.

Section 4. General requirements; applicability; preemption

Section 4 sets forth the general requirements, applicability, and preemption standards for the bill. The Act applies to any civil action brought by a claimant harmed directly or indirectly by an implant. The Act does not apply to commercial loss or contract cases. The Act only preempts State law to the extent that the Act establishes a rule of law applicable to the recovery of damages for the applicable harm, and it does not preempt other available defenses or create a new cause of action or Federal jurisdiction.

Section 5. Liability of biomaterials suppliers

Section 5 excludes a biomaterials supplier from liability for harm to a claimant from an implant unless such supplier is a manufacturer of the implant, a seller of the implant, or failed to meet applicable contract requirements or specifications.

The biomaterials supplier may be liable to the extent permitted under otherwise applicable law as a seller of the implant if it (A) held title to the implant and then acted as a seller after the initial sale by the implant's manufacturer, or (B) acted under contract as a seller to arrange for the transfer of the implant to the claimant after the implant's initial sale by the manufacturer. The biomaterials supplier may also be liable as a seller if it is related by common ownership or control to someone who is liable as a seller of the implant.

The biomaterials supplier may also be liable for harm caused by an implant if the claimant shows by a preponderance of the evidence that (1) the biomaterials supplier supplied raw materials or component parts for the implant that either did not constitute the product contracted for, or failed to meet any applicable specifications accepted, published, or provided by the biomaterials supplier, contained in a master file submitted by the biomaterials supplier to the Secretary of Health and Human Services (the Secretary), or included in the submissions to the Secretary for premarket approval and accepted by the biomaterials supplier, and (2) such failure to meet applicable contractual requirements or specifications was an actual and proximate cause of the harm to the claimant.

Section 6. Procedures for dismissal of civil actions against biomaterials suppliers

Subsection (a) allows a defendant in an applicable case to motion to dismiss an action against it on the grounds that it is a biomaterials supplier and it is not liable (1) as a manufacturer, (2) as a supplier, (3) for furnishing raw materials or component parts that failed to meet applicable contractual requirements or specifications, or (4) because the claimant did not name the manufacturer as a party to the action.

Subsection (b) requires a claimant to name the manufacturer of the implant as a party to the action unless 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 if such a claim would be barred under law.

Subsection (c) sets forth the procedures for a motion to dismiss. In general, no discovery is allowed in connection with an action after a motion to dismiss is filed under this Act, except for discov-

ery related to jurisdictional issues and limited discovery relevant to a claim that the biomaterials supplier failed to furnish materials or parts for the implant that met applicable contractual requirements or specifications. The court shall rule on a motion to dismiss solely on the basis of the pleadings and any relevant affidavits submitted, granting such motion unless the claimant demonstrates that the defendant is not a biomaterials supplier, or the court determines that the defendant may be liable as a manufacturer, seller, or for failure to meet applicable contractual requirements or specifications, or because the claimant failed to name the manufacturer as a party to the action. The court may treat a motion to dismiss (regarding meeting contractual requirements and specifications) as a motion for summary judgment under certain circumstances.

Subsection (d) provides the standards for adjudicating a motion to dismiss that is treated as a motion for summary judgment, requiring the court to grant such motion if, after limited discovery based on the applicable rules for nonparties, there is no genuine issue of material fact existing sufficient to allow a reasonable jury to reach a verdict for the claimant.

Subsection (e) requires a court granting a motion to dismiss or for summary judgment to enter such motion with prejudice against the claimant.

Subsection (f) allows a manufacturer to represent a biomaterials supplier in court on a motion for dismissal or summary judgment.

Section 7. Subsequent impleader of dismissed biomaterials supplier

Section 7 allows a manufacturer or claimant within 90 days after entry of a judgment to motion to implead back into the case a biomaterials supplier who had earlier been dismissed pursuant to this Act. This can only happen if (1) the manufacturer asserts and the court determines that (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 accordingly be reduced; or (2) the claimant requests and the court finds that (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 recover its full damages from the remaining defendants. A biomaterials supplier impleaded after dismissal may supplement the records of the proceeding, and may only be found liable to the extent required and permitted under applicable law.

Section 8. Effective date

Section 8 makes the Act effective for any actions commenced after enactment.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

H.R. 872 does not amend any existing Federal statute.

ADDITIONAL VIEWS ON H.R. 872

Our support and the support of many of our colleagues on the Judiciary Committee who previously voted for H.R. 872 is contingent on one very specific understanding: that this legislation not be expanded beyond the form reported by the Commerce Committee.

Even in the legislation as reported, we have some concerns relating to the scope of its protections. While we understand the arguments made in support of this legislation as it relates to the supply of raw materials, this bill also protects the manufacturers of "component parts" of inplantable devices. Raw materials, such as silicone or polyethelene, are vastly different subject matter from components, which can be as technically diverse as batteries, tubes, wiring and pacemaker leads. Yet there is little, if any, substantiation in the legislative record by broadening H.R. 872's protections to the manufacturers of such components.

While we supported the bill moving forward, we believe liability protection for manufacturers of component parts should be carefully reviewed before this bill achieves final passage. If the provision remains in the bill, it should be construed as narrowly as possible to avoid unintended consequences of limiting liability of the makers of the manufactured pieces of such devices.

But our primary concerns arise from any potential expansion in the scope and effect of H.R. 872. We would be strongly opposed to changes in which FDA-regulated products are included within the class of biomaterials that receive special protections in this bill. Moreover, we would also oppose any effort to make H.R. 872 a vehicle for broader product liability protections in the House or in the Senate.

On June 23, 1998, we received a letter from Jim Benson, executive vice president of the Health Industry Manufacturers Association (HIMA), assuring us that it is the intention of that organization to oppose any effects to change the bill as reported or encumber it with other legislative items.

This possibility is not mere speculation. On July 9, 1998, the New York Times reported that Senate Majority Leader Lott had handwritten an amendment into the Senate version of H.R. 872 on behalf of a major medical device manufacturer, Baxter International. Baxter recently lost a $18 million lawsuit to the family of Andrina Hansen, who suffered severe brain damage because of a faulty Baxter intravenous, or IV, connector.

In 1991, Mrs. Hansen underwent surgery for a bleeding ulcer. After successful surgery, the disconnection of a postoperative IV forced air into her brain, causing a stroke. Mrs. Hansen spent four years in a nursing home as a quadriplegic before she died. When her family took legal action, all defendants settled except Baxter Healthcare, a subsidiary of Baxter International and the manufacturer of the faulty IV connector.

According to the court record, Baxter's internal memoranda documented the company's awareness that its IV connector design allowed IV tubing to slip. This defect was also the subject to almost 70 lawsuits over 20 years. Baxter also manufactured a newer, improved connector which prevented fatal incidents like Mrs. Hansen's. But Baxter never warned patients or health providers of these problems.

The proposed Senate amendment would insulate Baxter and similar undeserving manufacturers of components parts of "containers and their related products to be used to collect fluids or tissue from the body or to infuse or to otherwise introduce fluids or tissue into the body" from liability for defective and dangerous products. This would be true even is it was the component, such as Baxter's defective IV connector, and not the entire device which was the cause of injuries or deaths.

In a July 10 letter to Senate Majority Leader Lott, Alan Magazine, president, and Ronald Dollens, chairman-elect of HIMA wrote of their organization's very serious concerns about expanding [H.R. 872] to medical devices not considered during the four-year long debate on this legislation."

We take them at their word in this commitment, and we accept the assurance of our colleagues on the Commerce Committee that passage of this bill without amendment is their intention. But if that is not the case—if it is amended adversely on the House floor or becomes a vehicle for unwarranted Senate changes—then we will not support it and in fact will do all we can to see that it does not become law.

SHERROD BROWN.
EDWARD J. MARKEY.
HENRY A. WAXMAN.
DIANA DEGETTE.

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