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2D SESSION

H. R. 5092

To establish rules governing product liability actions against raw materials and bulk component suppliers to medical device manufacturers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 23, 1994

Mr. PASTOR (for himself, Mr. KYL, Mr. BOEHLERT, Mr. CANADY, Mrs. MEEK, Mr. SERRANO, and Mr. MCCLOSKEY) introduced the following bill; which was referred jointly to the Committees on the Judiciary and Energy and Commerce

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A BILL

To establish rules governing product liability actions against raw materials and bulk component suppliers to medical device manufacturers, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Biomaterials Access Assurance Act of 1994''.

SEC. 2. FINDINGS.

Congress finds and declares the following:

(1) Every year millions of Americans depend on the availability of life-saving or life-enhancing permanently implantable medical devices.

(2) A continued supply of raw materials and component parts is necessary to the invention, development, improvement and maintenance of the supply of such devices.

(3) Most of these devices are made with raw materials and component parts that are not designed or manufactured specifically for use in implantable devices, but which have uses in a variety of nonmedical products as well.

(4) Small quantities of these raw materials and component parts are used, so that sales of raw materials and component parts for medical devices are an extremely small portion of the overall market for such raw materials and medical devices.

(5) Manufacturers of medical devices are required under the Federal Food, Drug, and Cosmetic Act to demonstrate that their products are safe and effective, including being properly designed and having adequate warnings or instructions, and existing tort law requires manufacturers of medical devices to ensure they are properly designed and have adequate warnings.

(6) Notwithstanding the fact that raw materials and component parts suppliers do not design, produce, or test the final implant, they have been sued in cases alleging inadequate design and testing of, or warnings related to the use of, permanently implanted medical devices.

(7) Even though raw materials and component parts suppliers have almost never been held liable in such suits, because the cost of litigating such suites to a favorable judgment far exceeds the total potential sales of such raw materials and component parts to the medical device industry, raw materials and component parts suppliers have begun to cease supplying such raw materials and component parts for use in permanently implanted medical devices.

(8) The unavailability of raw materials and component parts will, unless alternate sources of supply can be found, lead to unavailability of life-saving and life-enhancing medical devices.

(9) The prospects for development of new sources of supply for the full range of threatened raw materials and component parts are remote, as other suppliers around the world are refusing to sell raw materials or component parts for use in manufacturing permanently implantable medical devices

in the United States, and it is unlikely that such a small market could support the large investment needed to develop new suppliers and attempts to do so will raise the cost of medical devices.

(10) Courts that have considered the issue have generally found that raw materials and component part suppliers do not have a duty to evaluate the safety and efficacy of the use of a raw material or component part in a medical device, and also do not have a duty to warn concerning the safety and effectiveness of a medical device.

(11) Attempts to impose such duties will cause more harm than good by driving raw materials and component part suppliers to cease supplying manufacturers of permanently implantable medical devices.

(12) In order to safeguard the availability of a wide variety of life-saving and life-enhancing medical devices, immediate action is needed to clarify the permissible bases of liability for suppliers of raw materials and component parts used in the manufacture of permanently implantable medical devices and to provide expeditious procedures to dispose of unwarranted suits against those suppliers so as to minimize litigation costs.

SEC. 3. DEFINITIONS.

As used in this Act, the term—

(1) ''biomaterials supplier'' means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant, and includes persons that have submitted master files to the Food and Drug Administration for purposes of pre-market approval of medical devices, but does not include a manufacturer or seller of an implant;

(2) ''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, and includes persons other than the individual into whose body, or in contact with whose blood or tissue, the implant is placed, if such person claims to have suffered harm; if such an action is brought through or on behalf of an estate, the term includes the claimant's decedent, or if it is brought through or on behalf of a minor or incompetent, the term includes the claimant's parent or guardian; the term does not include—

(A) 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

(B) a manufacturer, seller, or biomaterials supplier;

(3) ''component part'' means a manufactured piece of an implant and includes a manufactured piece that has significant nonimplant applications and that by itself has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant;

(4) ''harm'' means any 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; the term does not include commercial loss or loss of or damage to an implant itself;

(5) ''implant'' means a medical device that (A) is placed into a surgically or naturally formed or existing cavity of the body or which contacts blood or internal human tissue; and (B) which (i) is intended by the manufacturer to remain in contact with the body or internal tissue of the humans continuously for a period of thirty days or more, or (ii) has label-

ing which does not contraindicate implantation or contact for thirty days or more;

(6) ''manufacturer'' means any person who, with respect to any particular 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 an implant; and

(B) is required under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), and the regulations issued thereunder, to register with the Secretary of Health and Human Services and to include the implant on a list of devices filed with the Secretary pursuant to section 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)), and the regulations issued thereunder;

(7) ''medical device'' means a medical device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h));

(8) ''qualified specialist'' means a person who is qualified by knowledge, skill, experience, training, or education in the specialty areas that are the subject of the action;

(9) ''raw material'' means a substance or product that has a generic use and that may be used in applications other than implants; and

(10) ''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; the term does not include—

(A) a seller or lessor of real property;

(B) 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

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

SEC. 4. APPLICABILITY; PREEMPTION.

(a) APPLICABILITY.—This Act applies to any civil action brought by a claimant, whether in State or Federal court, against a manufacturer, seller, or biomaterials supplier, or against licensors of biomaterials suppliers, on any theory, for harm caused by an implant. 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

itself or for commercial loss to the purchaser is not subject to this Act and shall be governed by applicable commercial or contract law.

(b) SCOPE OF PREEMPTION.—This Act supersedes any State law regarding recovery for harm caused by an implant only to the extent that this Act establishes a rule of law applicable to any such recovery. Any issue arising under this Act that is not governed by any such rule of law shall be governed by applicable State or Federal law.

(c) EFFECT ON OTHER LAWS.—Nothing in this Act shall be construed to—

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

(2) 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 State or Federal law.

SEC. 5. ACTIONS AGAINST BIOMATERIALS SUPPLIERS.

(a)(1) Except as provided in subsection (b) of this Act, no claimant may bring an action for harm caused by an implant against a person, who has not registered with the Secretary of Health and Human Services, pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act, and the regulations issued thereunder, and in-

cluded the implant on a list of devices filed with the Secretary pursuant to section 510(j) of the Federal Food, Drug, and Cosmetic Act and the regulations issued thereunder.

(2) Notwithstanding subparagraph (1), a claimant may bring an action, other than as provided in subsection (b) of this Act, against a person who, with respect to claimant's implant, is the subject of a declaration issued by the Secretary under section 6(a) of this Act, or is a seller of the implant that allegedly caused harm to the claimant.

(b) No claimant may bring an action for harm caused by an implant against a biomaterials supplier, and no biomaterials supplier shall be liable for harm to a claimant caused by an implant, unless the claimant shows, by a preponderance of the evidence, that—

(1) the raw materials or component parts delivered by the biomaterials supplier either were not the product described in the contract between the biomaterials supplier and the person who contracted for delivery of the product, or failed to meet any specifications that were—

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

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

(B) published by the biomaterials supplier, provided to the manufacturer by the biomaterials supplier, or contained in a master file submitted by the biomaterials supplier to the Food and Drug Administration, and currently maintained by the biomaterials supplier, for purposes of pre-market approval of medical devices; or

(C)(i) included in the manufacturer's submissions for purposes of pre-market approval or review by the Food and Drug Administration under sections 510, 513, 515, or 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360, 360c, 360e, or 360j) that have received clearance from the Food and Drug Administration;

(ii) that were provided by the manufacturer to the biomaterials supplier and not expressly repudiated by the biomaterials supplier prior to the manufacturer's acceptance of delivery of the raw materials or component parts; and

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

(c) No claimant may bring an action for harm caused by an implant against a person who licenses a biomaterials supplier to produce raw materials or component parts.

(d) The applicable statute of limitations shall be tolled during any period in which claimant has filed a petition with the Secretary of Health and Human Services under section 6 of this Act.

SEC. 6. REVIEW BY THE SECRETARY OF NON-REGISTRATION.

(a) The Secretary may, on its own motion or upon petition by any person, after notice to the affected persons and affording an opportunity for an informal hearing, issue a declaration that a person, with respect to the implant that allegedly caused claimant's harm—

(1) should have registered with the Secretary under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), and the regulations issued thereunder, but failed to do so, or

(2) should have included the implant on a list of devices filed with the Secretary pursuant to section 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)), but failed to do so.

(b) Any petition filed pursuant to subsection (a) shall be immediately docketed by the Secretary, and the Secretary shall issue a final decision within 180 days of the filing of the petition.

SEC. 7. PROCEDURES FOR ACTIONS AGAINST A BIOMATERIALS SUPPLIER.

(a) IN GENERAL.—The procedural requirements set forth in subsection (b) shall apply to any action by a claimant against a biomaterials supplier.

(b) PROCEDURAL REQUIREMENTS.—

(1) A claimant may not bring an action against a biomaterials supplier unless the manufacturer of the implant is named as a party, except if the manufacturer is subject to service of process in no jurisdiction in which the biomaterials supplier or is also subject to service of process or unless litigation against the manufacturer is barred by applicable law.

(2) No action may be brought by any claimant against a biomaterials supplier unless, at the time the claimant brings the action, the claimant submits an affidavit—

(A) declaring that the claimant has consulted and reviewed the facts of the action with

qualified specialists, whose qualifications the claimant shall disclose;

(B) including a written determination by a qualified specialist that the raw materials or component parts actually used in the manufacture of claimant's implant were raw materials or component parts described in section 5(b)(1), together with a statement of the basis for such a determination;

(C) including a written determination by a qualified specialist that, after a review of the medical record and other relevant material, the raw material or component part supplied by the biomaterials supplier and actually used in the manufacture of claimant's implant was a cause of claimant's harm, together with a statement of the basis for the determination; and

(D) on the basis of the qualified specialists' review and consultation, that the claimant (or the claimant's attorney) has concluded that there is a reasonable and meritorious cause for the filing of the action against the biomaterials supplier.

(c) DISMISSAL.—

(1) In any action subject to this Act, a defendant may, at any time at which a motion to dismiss may be filed under applicable law, move to dismiss the action on the grounds that the defendant is a biomaterials supplier and—

(A) claimant has failed to satisfy the conditions in section 5(a) that would permit claimant to bring an action against defendant;

(B) defendant was not a seller of the implant which allegedly caused harm to the claimant; or

(C) claimant has failed to comply with the provisions of subsection (b).

(2) Defendant may submit affidavits demonstrating that defendant has not included the implant on a list, if any, filed with the Secretary pursuant to section 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Claimant may, in response to such a motion, submit affidavits demonstrating that the Secretary has, with respect to the defendant and the implant that allegedly caused claimant's harm, issued a declaration pursuant to section 6(a) of this Act, or that defendant was a seller of the implant.

(3) No discovery shall be permitted against the defendant who has filed a motion to dismiss under subparagraph (1), other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until the court has ruled on the motion to dismiss filed pursuant to subsection (1).

(4) A defendant shall conclusively be deemed to be a biomaterials supplier and not to be subject to suit except pursuant to section 5(b) of this Act, and a motion to dismiss under subsections (c)(1)(A) or (c)(1)(B) shall be granted, unless the claimant submits valid affidavits demonstrating—

(A) with respect to a motion under subsection (c)(1)(A), that the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 6(a) of this Act; or

(B) with respect to a motion under subsection (c)(1)(B), that the biomaterials supplier was a seller which held title to the implant as a result or purchasing or selling the implant after the implant was manufactured and entered the stream of commerce.

(5) The court shall rule on the motion to dismiss filed under subsection (c) solely on the basis of the pleadings and any affidavits, including affidavits submitted under paragraph (2). If the pleadings and affidavits raise genuine issues as to material facts with respect to a motion under (c)(1)(C), the motion may be treated as a motion for summary judgment pursuant to subsection (d) of this section.

(d) SUMMARY JUDGMENT.—

(1) A biomaterials supplier shall be entitled to entry of judgment without trial if there is no genuine issue as to any material fact as to each element set forth in section 5(b). A genuine issue of material fact shall exist only if the evidence submitted by claimant, if found by a jury to be credible, would be sufficient to allow a reasonable jury to reach a verdict for the claimant.

(2) In the event that the court, under applicable rules, may permit discovery prior to ruling on a motion for summary judgment, such discovery shall be limited solely to establishing whether a genuine issue of material fact exists.

(e) A biomaterials supplier shall be subject to discovery in connection with a motion under subsection (c) or

(d) solely to the extent permitted by the applicable State or Federal rules for discovery against nonparties.

(f) In the event claimant has filed a petition for a declaration pursuant to section 6(a) with respect to a defendant, and the Secretary has not issued a final decision thereon, the court shall stay all proceedings with respect to that defendant until the Secretary has issued a final decision.

(g) The manufacturer of the implant shall be permitted to file and conduct the proceeding on any motion filed pursuant to subsection (c) or (d) if the manufacturer and the other defendant(s) have entered into a valid and applicable contractual agreement in which the manufacturer agrees to bear the cost of or to conduct such proceeding.

(h) The court shall require the claimant to compensate the biomaterials supplier (or a manufacturer appearing in lieu of a supplier pursuant to subsection (g)) for attorney fees and costs, if the claimant named or joined the biomaterials supplier, but the court found the claim against the biomaterials supplier to be without merit and frivolous.

SEC. 8. EFFECTIVE DATE.

This Act shall take effect on the date of its enactment and shall apply to all civil actions pursuant to this Act

commenced on or after such date, including any action in which the harm or the conduct which caused the harm occurred before the effective date of this Act.

SEC. 9. SEVERABILITY.

If any provision of this Act, or the application of such provision to any person or circumstances is held to be unconstitutional, the remainder of this Act and application of the provisions of such to any person or circumstance shall not be affected thereby.

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