

BIOMATERIALS ACCESS
ASSURANCE ACT OF 1997

Mr. GEKAS. Mr. Speaker, I ask unanimous consent to take from the Speaker's table 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, and ask for its immediate consideration.

The Clerk read the title of the bill.

The SPEAKER pro tempore (Mr. LAHOOD). Is there objection to the request of the gentleman from Pennsylvania?

Ms. LOFGREN. Reserving the right to object, Mr. Speaker, and I will not object, but I do want to say how pleased I am and so many of us on this side of the aisle are to have this wonderful success this evening. We worked hard, we gained consensus on a bipartisan basis, opponents have come together for the good of the country, and I think it is really the way the legislative process should work. I want to thank the gentleman for his efforts. It has been really a privilege to work on this, and I know that this will help many in our country who need the medicine and need the implantables, and they will now be able to get them.

So, as I say, I reserve the right to object, but I do not object.

Mr. GEKAS. Mr. Speaker, will the gentlewoman yield?

Ms. LOFGREN. I yield to the gentleman from Pennsylvania.

Mr. GEKAS. Mr. Speaker, I thank the gentlewoman not just for yielding this time to me, but for the continuous effort that she has expended in promoting the final moments which we are enjoying of the passage of this bill.

As the gentlewoman knows, some 7 million fellow Americans are at this very moment living better lives because of the medical devices which have been developed over the years and which were in danger of being stopped dead in their tracks by the lack of the flow of materials, basic materials needed in their manufacture. So this bill will go a long way in guaranteeing to the people who look forward to these medical devices in the near and far future.

We also want to put on the record the fact that the administration has nodded its head and given advanced approval of the bill so the prospects for its being signed into law are excellent.

Mr. BILBRAY. Mr. Speaker, will the gentlewoman yield?

Ms. LOFGREN. I yield to the gentleman from California.

Mr. BILBRAY. Mr. Speaker, I would just like to thank the gentleman from Pennsylvania (Mr. GEKAS) for this important piece of legislation. As my colleagues know, we asked the gentleman to take on this cause, and let me just say I would like to thank the gentleman from Pennsylvania and the gentlewoman from California for the cooperative effort for those who need the implants and the biomaterials here,

that we are talking about here today. And let me just say I would like to sort of congratulate my colleagues in the name of Titus, the young man who depends on shunts to be able to stay alive every day and was basically concerned that because of liability and the problems of liability, the biomaterials that make those shunts to keep him alive could be restricted from his position so that he could continue the happy life and the very active life.

If my colleagues met Titus, they would know what I mean. He is one of my constituents, is a young man that I look forward to watching him grow up and become prosperous, and with this kind of legislation, Mr. Speaker, I want to thank my colleagues in the name of Titus and for all the children and all the citizens in America that will be served by those biomaterials that might have been denied to people who desperately need them for life and limb.

Ms. LOFGREN. Reclaiming my time, Mr. Speaker, I would like to say that this bill is a very fair accommodation that will provide the relief necessary to keep materials in the marketplace, yet provides an opportunity should judicial relief be required to be made available.

So it strikes the exact right balance, I am proud to be associated with it, and as we have all noted at the Committee on the Judiciary, we believe that this measure should not be expanded in any way. We have got it where it needs to be, we all agree, and I am glad that we stand firm in that across the aisle.

Mr. GEKAS. Mr. Speaker, will the gentlewoman yield further?

Ms. LOFGREN. I yield to the gentleman from Pennsylvania.

Mr. GEKAS. Mr. Speaker, I am glad that the gentleman from California (Mr. BILBRAY) brought up the name of little Titus. He actually came with me at one point and sat on my knee as we both testified jointly before the relevant committee in the subcommittee of the Committee on Commerce, and I must say that he carried the day with the poignancy of the need of the special device which carries his life forward, and so he with young Tara Ransom it was, Tara Ransom also a child who needs this continuation of the medical device syndrome to survive, also testified, and thus we have a nationwide effort, shall we say, that has brought us to this moment.

Mr. BURR of North Carolina. Mr. Speaker, would the gentlewoman yield?

Ms. LOFGREN. I yield to the gentleman from North Carolina.

Mr. BURR of North Carolina. Mr. Speaker, I wanted to rise in support of H.R. 872, the Biomaterials Access Assurance Act.

Biomaterials are the raw materials or component parts used by manufacturing companies to make implantable medical devices. Almost 8 million Americans have had their lives saved or improved by biomedical, including anyone using a pacemaker, a heart

valve, a hip joint, a knee joint or who have received sutures during surgery.

Last year the Committee on Commerce found that only 25 percent of the biomaterials companies are currently willing to supply implant manufacturers with necessary raw materials for production of medical devices. The other 75 percent have banned sales of their raw materials to medical implant markets in the United States. This means that in the United States my colleagues and their families may no longer be able to get the pacemaker or heart valve or knee joint, once stockpiles run out.

Why are these companies no longer willing to provide these lifesaving products? One hundred percent of the companies surveyed stated that a key factor driving them out of the American market was our out-of-control legal system that is bankrupting their operations.

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Tens of millions of dollars are being wasted on litigation cost for biomaterials suppliers to protect themselves from liability. Tens of millions of dollars that could be spent on research or making health care more affordable for the American people.

Any American who has been sued knows how the system works. Even if they are innocent, they risk going broke just to pay their legal fees to prove themselves in the case against them.

This bill does not protect the manufacturer of medical devices. They will still be liable to the injured victim for defective products. Nor does this bill protect the seller of medical devices. Consumers will still have every opportunity to get their full recoveries from the responsible parties.

This bill merely says that the entities who provide the raw materials used in medical devices, but do not manufacture or sell the device, and, therefore, are never found liable by the courts should not have to prove themselves out of the same types of litigation year after year after year.

H.R. 872 was reported unanimously out of the Committee on Commerce and has been negotiated on a bipartisan, bicameral basis with the participation and assistance of the administration.

Eight million Americans are relying on us to protect the continued supply of raw materials used for medical devices.

I urge everyone in this House to support this unanimous consent request.

Mr. MORAN of Virginia. Mr. Speaker, I rise today in support of the Biomaterial Access Assurance Act.

When companies decide to stop producing certain life-saving products because of the threat of costly litigation, we have reached the point in our society where our urge to protect smotherers our ability to heal.

Medical implants such as heart valves, joint implants, and brain shunts save or improve the lives of more than 7.5 million people every

year. The worldwide market for medical devices exceeds \$100 billion, with about half of that supplied by American firms.

Biomaterials are the raw materials, such as silicone, polyester, urethane, and polypropylene, used to make medical devices. The already small number of U.S. firms that produce these materials is shrinking, as businesses face the threat of scatter-shot lawsuits. Under U.S. product liability laws, any party involved in the creation of a product—even remote contributors—may be included in product liability litigation.

It is a troubling paradox that now, when the opportunity for technical innovation in the use of medical implants has never been greater, Americans are being robbed of the benefits of these products.

Dupont decided in 1994 to halt the supply of three materials used in medical implants because the sale of small amounts of these marginally profitable materials exposed Dupont to very expensive product liability lawsuits, even if Dupont won.

The growing fear of litigation has led 14 suppliers to cut the supply of biomaterials to the medical implant market, with many certain to follow. The uncertainty surrounding the supply of biomaterials has already caused a technological slowdown. Companies are reluctant to push forward with new product ideas they're not sure they can ever afford to insure, manufacture and market.

Suppliers of raw biomaterials (mostly small companies) who do not make or design medical devices should not be held responsible when a manufactured product allegedly malfunctions. This protection from litigation is included in the Biomaterial Access Assurance Act.

This biomaterials reform legislation will not hold the manufacturers of faulty biomaterial products harmless. The ability to sue a supplier is maintained in the legislation if the biomaterial is defective, fails to meet contractual agreements, or where the supplier is also the manufacturer.

Putting small high-tech firms that make implantable medical devices out of business is an unfortunate economic consequence of our society's litigious nature. These firms should be nurtured and supported, not run out of business because they can't afford the cost of lawsuits, the vast majority of which they win, but which nevertheless soak up valuable financial and human resources.

Opponents of product liability reform often speak of their concern for the victims of defective products. But unless we enact this legislation, we could soon have more than 7.5 million more victims—those individuals who depend on medical devices made with biomaterials.

I must admit to a certain personal interest in this subject. There is a medical implant, a small brain shunt, in my daughter Dorothy's head that serves as a relief valve so that the pressure from any fluid buildup from cancer growth can be relieved. I don't even know the name of the company that supplied the materials for the brain shunt. Yet I'm told by her doctors that our current short-sighted product liability laws may force the company that helped save my daughter's life to forego supplying any more such low-cost shunts.

In 1994, when Dorothy was diagnosed with brain cancer, her doctors gave her 50/50 odds of reaching her fifth birthday. Dorothy turned six last month, and will attend first grade in

September. Her ongoing recovery is attributable to many factors, the shunt in her hand being only one. And yet the supplier of the material that forms that shunt might pull its product off the domestic medical device market, if it hasn't already, because of the looming danger of financial ruin posed by potential product liability lawsuits.

We can protect biomaterials suppliers, and provide a better quality life for the recipients of medical devices, by passing this bill.

Mr. MARKEY. Mr. Speaker, I rise in support of H.R. 872, the "Biomaterials Access Assurance Act."

Modern medical science has produced true miracles, and we want to encourage continued innovation in this area. We all want to assure that those who suffer from injury or illness can get access to the treatments and technologies needed to treat or cure them. At the same time, however, we must recognize that consumers deserve protection from defective or unsafe medical devices or drugs. Since that the FDA cannot always be safely relied upon to prevent dangerous or unsafe drugs or medical devices from reaching the market, consumers currently depend on our system of tort law to compensate them for the harm caused by such products and to create incentives for product and materials manufacturers and suppliers to undertake rigorous product testing, issue appropriate warnings, and obtain sufficient insurance or indemnification to guard against litigation risks.

While I am generally skeptical about the notion of carving an entire class of persons out of tort liability, I agree that we should assure that patients can obtain access to critically needed medical devices. The House today is presented with a more narrow and limited biomaterials bill, which represents a significant improvement over previous incarnations and minimizes the prospect that injured consumers would be unable to obtain appropriate redress and compensation. Specifically, the bill before us today addresses the three concerns I had raised about legislating in this area in the Subcommittee's oversight hearing last year. First, it is a free-standing biomaterials bill, and not part of a broader product liability reform effort. Second, the so-called "English Rule" of the original bill has been dropped, which would have forced losing litigants to pay litigation costs. Third, and most importantly, an effort has been made in the impleading provisions of the bill to address the concerns I raised in the hearing regarding the need to assure that fraudulent suppliers could be held liable for their actions.

These are all positive changes, and in light of their adoption I intend to support this legislation today. I do wish to note, for the record, however, that I continue to have some concerns about the extension of the bill to cover manufacturers of component parts in addition to raw material suppliers. While I 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 implantable devices. Raw materials, such as silicone or polyethylene, 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 for broadening H.R. 872's protections to the manufacturers of such components. While I, the gentleman from

California (Mr. Waxman) and others on this side of the aisle support the bill moving forward, we believe liability protection for manufacturers of component parts should be very 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. I hope that we can work in conference to address these concerns.

In addition, I am concerned about reports that an effort may be underway to use this biomaterials bill as a vehicle to get into conference on a broader product liability legislation, or to broaden the scope of the bill to cover other medical devices. I want to caution strongly against either course of action. My support is contingent on one very specific understanding: that this legislation not be expanded beyond the form reported by the Commerce Committee.

I would, for example, be strongly opposed to changes in which FDA-regulated products are included within the class of biomaterials that receive special protections in this bill. 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 efforts to change the bill as reported or encumber it with other legislative items. I commend HIMA for taking this stance.

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 of 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 underserving manufacturers of component 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 if 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."

I take HIMA at their word in this commitment, and commend them for making it. I also accept the assurances 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 this bill is amended adversely or becomes a vehicle for unwarranted Senate changes—then I will not support it and in fact will do all I can to see that it does not become law.

In its present form, however, this is a limited bill that I think the Members can and should support. Thank you, Mr. Speaker, and I yield back the balance of my time.

Mr. CUNNINGHAM. Mr. Speaker, I rise today in support of the Biomaterials Access Assurance Act. I want to thank my colleague, Mr. GEKAS, and the Committee Chairmen, Mr. HYDE and Mr. BLILEY, for bringing this important legislation forward.

This legislation seeks to alleviate a critical shortage of biomaterials available to our nation's medical device manufacturers. Biomaterials are the raw materials and component parts that go into life-saving and life-enhancing medical implants and devices. These devices include heart valves, prosthetics, brain shunts, and many other devices that provide an unmeasurable benefit to the lives of millions of Americans. Our citizens can only continue to enjoy these benefits if the biomaterials that go into such devices remain available.

This legislation will ensure that patients have access to the biomaterials and medical devices that they need. Over the last several years, I have met with researchers and doctors who manufacture medical devices. Each time we meet they stress the importance of this legislation and show another area of critical shortage in biomaterials which could prevent them from making the medical devices which save lives.

I have also met with parents and children who suffer from diseases which require these important medical devices. One of these young men is Titus Simonini, 5, who suffers from Hydrocephalus, a condition in which spinal fluid is blocked and builds up in the brain, often causing brain damage, paralysis and death. Titus' condition is treated through the implantation of silastic shunts, a silicon-coated device that regulates the fluid and prevents the buildup in the brain. These shunts are manufactured by only two small suppliers in the entire country. Without this legislation we are approaching the day when children like Titus won't have these products that make their lives possible.

The Biomaterials Access Assurance Act protects biomaterials suppliers from the litigation that swarms to them whenever they sell to the medical device market, even though they take no part in the design, testing, or sales of medical devices. The Biomaterials Access Assurance Act gives biomaterials suppliers a quick exit from lawsuits in which they would not be found liable anyway.

With regards to this important issue, it is equally important to stress what this bill does not do. The bill does not protect anyone who is involved in the design, testing, manufacture, or sale of medical implants. The bill also does not allow biomaterials suppliers to be neg-

ligent or fraudulent in their sale of materials to the medical market. As everyone knows, medical implants are intricately designed and rigorously tested in the FDA approval process. The specifications and tolerances of the materials that go into these devices are very precise and very narrow. If a biomaterials supplier fails to meet contractual specifications or specifications given to the Food and Drug Administration in the premarket approval process, the protections of this bill evaporate.

Now, these are narrow, technical points that should not detract from the main focus of this legislation. The threat to biomaterials access is a problem on which Congress must take action. With the protections of this legislation material suppliers will continue to provide important components for medical devices that help Americans live healthier and more productive lives. I encourage all of my colleagues to support this important legislation.

Mr. BERMAN. Mr. Speaker, I rise in strong support of H.R. 872, the Biomaterial Access Assurance Act.

I believe a persuasive case has been made that many medical device manufacturers face a shortage of raw materials and component parts as a result of their suppliers' exposure to tort claims. It troubles me that consumers could be denied access to life-saving and life-enhancing products, and it is for this reason that I have long engaged in efforts to seek a legislative solution to the problem.

The manufacturers who have made the most compelling case to me are people I have known for years in my own state of California. Many of them are small companies who depend for critical supplies on corporate giants. Because of their deep pockets, these suppliers are almost invariably brought in as co-defendants in lawsuits brought against device manufacturers. Because the device manufacturers are often an inconsequential segment of the market for their raw materials and components, the suppliers have increasingly refused to sell to them.

This is the problem we need to solve. But as strongly as I feel about our responsibility to act, I did not embrace this bill as originally introduced. I felt that it was wrong to completely shield the supplier who may have a degree of culpability for a faulty device.

That is why I was heartened that further efforts were made to improve the bill in committee, by spelling out means by which the supplier, though initially dismissed, can be brought back into the lawsuit.

I believe the appropriate balance has now been struck between consumer protection from faulty devices and consumer access to life-saving and life-enhancing devices. For that reason, I enthusiastically support the bill we have before us today.

I am compelled to make one further statement. I emphatically believe the case has been made for H.R. 872 in the form in which it is presented to us today. I do not believe the case has been made for an expansion of the bill beyond its present countours.

To be more precise, I am well aware that efforts have been made to expand the scope of the bill to include devices that do not fit the term "implant" as defined in the bill, thereby sweeping in devices and materials used outside of the body.

I want to be very clear that I will withdraw my support for this bill if along the way it is expanded beyond its present terms either by

broadening its scope or enrolling it into a broader product liability bill. Today's floor consideration has long been sought by myself and other supporters of this bill. But it would be snatching defeat from the jaws of victory than for anyone to alter the careful balance achieved by this bill.

I profoundly hope that we can pass this bill today and have it quickly taken up by the other body, so that the millions of Americans who depend on life-saving and life-enhancing medical devices can be assured that they can continue to rely on the products of America's peerless medical technology industry.

Ms. LOFGREN. Mr. Speaker, I withdraw my reservation of objection.

The SPEAKER pro tempore (Mr. LAHOOD). Is there objection to the request of the gentleman from Pennsylvania?

There was no objection.

The Clerk read the bill, as follows:

H.R. 872

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 1997".

SEC. 2. FINDINGS.

The Congress finds that—

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

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

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

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

(B) come in contact with internal human tissue;

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

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

(6) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), manufacturers of medical devices are required to demonstrate that the medical devices are safe and 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 because the costs associated with litigation in order to ensure a favorable judgment for the suppliers far exceeds the total potential sales revenues from sales by such suppliers to the medical device industry;

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

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

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

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

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

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

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

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

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

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

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

SEC. 3. DEFINITIONS.

As used in this Act:

(1) **BIOMATERIALS SUPPLIER.**—

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

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

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

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

(2) **CLAIMANT.**—

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

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

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

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

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

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

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

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

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

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

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

(3) **COMPONENT PART.**—

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

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

(i) has significant non-implant applications; and

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

(4) **HARM.**—

(A) **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 action to recover damages for such harm only to the extent that this Act establishes a rule of law applicable to the recovery of such damages.

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

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

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

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

SEC. 5. LIABILITY OF BIOMATERIALS SUPPLIERS.

(a) **IN GENERAL.**—

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

(2) LIABILITY.—A biomaterials supplier that—

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

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

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

(b) LIABILITY AS MANUFACTURER.—

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

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

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

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

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

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

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

(C) is related by common ownership or control to a person meeting all the requirements described in subparagraph (A) or (B), if the court deciding a motion to dismiss in accordance with section 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 if—

(1) the biomaterials supplier—

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

(i) the manufacture of the implant; and

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

(B) subsequently resold the implant; or

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

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

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

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

(B) failed to meet any specifications that were—

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

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

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

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

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

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

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

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

(1) the defendant is a biomaterials supplier; and

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

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

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

(B)(i) the claimant has failed to establish, pursuant to section 5(d), that the supplier

furnished raw materials or component parts in violation of contractual requirements or specifications; or

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

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

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

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

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

(1) AFFIDAVITS RELATING TO LISTING AND DECLARATIONS.—

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

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

(i) the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 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 STATUS OF DEFENDANT.—

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

(B) RESPONSES TO MOTION TO DISMISS.—The court shall grant a motion to dismiss any action that asserts liability of the defendant under subsection (b) or (c) of section 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 concerning 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.

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

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

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

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

AMENDMENT IN THE NATURE OF A SUBSTITUTE OFFERED BY MR. GEKAS

Mr. GEKAS. Mr. Speaker, I offer an amendment in the nature of a substitute.

The Clerk read as follows:

Amendment in the nature of a substitute offered by Mr. GEKAS:

Strike out all after the enacting clause, and insert the following:

SECTION 1. SHORT TITLE

This Act may be cited as the "Biomaterials Access Assurance Act of 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 in any case in which—

(I) the sale or use of the 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; 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 connection 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, purchased for use 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 is liable—

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

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

(3) for furnishing 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) registered 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.

(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.**—In any civil action covered by this Act, 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 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.**—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.

(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 IMPEALER OF DISMISSED BIOMATERIALS SUPPLIER.

(a) **IMPEALING 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 covered by 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.

Mr. GEKAS (during the reading). Mr. Speaker, I ask unanimous consent that the amendment be considered as read and printed in the RECORD.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Pennsylvania?

There was no objection.

The SPEAKER pro tempore. The question is on the amendment in the nature of a substitute offered by the gentleman from Pennsylvania (Mr. GEKAS).

The amendment in the nature of a substitute was agreed to.

The bill was ordered to be engrossed and read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table

GENERAL LEAVE

Mr. GEKAS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks on H.R. 872, the bill just passed.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Pennsylvania?

There was no objection.

TERRY SANFORD COMMEMORATION ACT OF 1998

Mr. KIM. Mr. Speaker, I ask unanimous consent for the immediate con-

sideration of the bill (H.R. 3982) to designate the Federal building located at 310 New Bern Avenue in Raleigh, North Carolina, as the "Terry Sanford Federal Building."

The Clerk read the title of the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from California?

Mr. TRAFICANT. Mr. Speaker, reserving the right to object, I would ask the gentleman from California (Mr. KIM) to explain this bill.

Mr. KIM. Mr. Speaker, will the gentleman yield?

Mr. TRAFICANT. I yield to the gentleman from California.

Mr. KIM. Mr. Speaker, I thank the gentleman for yielding to me.

Mr. Speaker, H.R. 3982 designates the Federal building located in Raleigh, North Carolina as the "Terry Sanford Federal Building."

Senator Sanford was successful in many pursuits. He was the founder of three law firms and held positions on the boards of numerous universities and colleges and corporations in the technology industry. Senator Sanford was also president of Duke University from 1969 to 1984 and continued as president emeritus from 1995 until his passing in 1998.

However, in addition to his pursuits in private sector, Senator Sanford also was a dedicated public servant. From 1950 to 1953, he served on the North Carolina State Ports Authority. In 1953, he was elected to the North Carolina State Senate and served until 1955.

In 1961, he was elected Governor of North Carolina for a term, returning to private practice in 1965. After several years out of public office, Senator Sanford returned in 1986 with a successful bid to the United States Senate where he served North Carolina until 1993.

This is a fitting tribute to a dedicated public servant. I support the bill as amended and urge my colleagues to support it.

Mr. TRAFICANT. Mr. Speaker, further reserving my right to object, I yield to the gentleman from North Carolina (Mr. ETHERIDGE).

Mr. ETHERIDGE. Mr. Speaker, I thank the gentleman for yielding.

Mr. Speaker, I am honored to have this opportunity to honor the life and memory of a truly great American, Terry Sanford. I want to thank the gentlemen from California and from Ohio for his support in legislation which is so important to the Sanford family and really to all the people whose lives that he touched.

I want to thank the chairman and ranking member of the Committee on Transportation and Infrastructure, the House majority leader, and the minority leader in their efforts in getting this legislation scheduled for consideration.

Terry Sanford learned growing up that hard work reaps rewards, that boldness is a requirement of leadership, and that possibilities exist that are only bound by the size of one's imagination.

He also learned that there is character in service, and serve he did, as you have already heard, as an FBI agent, keeping our streets safe from crime; as a paratrooper in World War II where he was decorated for his acts of valor; as a member of the North Carolina Senate, representing the values we hold dear in public service, and perhaps more importantly as governor of the State of North Carolina, for which he received the appropriate title of the education governor.

It is fitting that Harvard University named him as one of this country's 10 most effective governors during this whole century. His leadership continued after he left the governor's mansion, as we have already heard this evening, serving as president of Duke University and later as a United States Senator.

Through his life, he fought to improve education, promote racial healing, eradicate poverty, promote economic development and help his fellow man. Terry Sanford was more than a great and admired politician. He was one of the most accomplished Americans of our time. His North Carolina values and visionary leadership brought us through some of the most difficult challenges that our State faced. This gesture is the least we should do for a man who allowed us to view the world from his broad shoulders.

(Mr. ETHERIDGE asked and was given permission to revise and extend his remarks.)

(Mr. ETHERIDGE addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

(Mr. TRAFICANT asked and was given permission to revise and extend his remarks.)

Mr. TRAFICANT. Further reserving the right to object, Mr. Speaker, Terry Sanford's leadership and diligence led Harvard University to name him as one of the most effective governors of the 20th Century. His service in the United States Senate is distinguished by hard work and loyalty to the interests of his constituents.

Duke University has benefited from his tenure as president. With wisdom and vision, he guided the university into becoming a leader in the field of medicine and law. I am proud to join in passing this bill to name this Federal building in his honor.

Mr. Speaker, I withdraw my reservation of objection.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from California?

There was no objection.

The Clerk read the bill, as follows:

H.R. 3982

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 "Terry Sanford Commemoration Act of 1998".

SEC. 2. FINDINGS.

Congress makes the following findings: