
Federal control would again be a disaster for the resources and those that depend on it.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that immediately following the vote on the conference report to accompany H.R. 629, the Texas compact, previously ordered to occur when the Senate reconvenes following the August recess, the Senate turn to consideration of the conference report to accompany H.R. 4059, the military construction appropriations bill.

I further ask unanimous consent that the conference report be considered as having been read; further, the Senate immediately proceed to a vote on the adoption of the conference report without any intervening action or debate.

The PRESIDING OFFICER. Without objection, it is so ordered.

BIOMATERIALS ACCESS ASSURANCE ACT OF 1997

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of H.R. 872, which is at the desk.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

A bill (H.R. 872) to establish rules governing product liability actions against raw material or component part suppliers to medical device manufacturers, and for other purposes.

The PRESIDING OFFICER. Is there objection to the immediate consideration of the bill?

There being no objection, the Senate proceeded to consider the bill.

Mr. MCCAin. Mr. President, the effort to pass legislation dealing with biomaterials has been a long fight. I want to thank Senator Lieberman, and Congressman Gekas for their extraordinary leadership and hard work on the issue. It has been a great privilege and honor working with them over the past several years to gain passage of this vital legislation.

I want to stress to my colleagues the importance of passing the Biomaterial Access Assurance Act. Over seven million lives depend upon an ample and reliable supply of medical devices and implants, such as pace makers and brain shunts.

Unfortunately, the supply of these life-saving products is in serious danger. Those who provide the raw materials from which medical implants are fashioned have been dragged into costly litigation over the safety of the components supplied from the finished product. This is the case even though such suppliers are not involved in the design, manufacture or sale of the implant. Many suppliers are unwilling to expose themselves to this enormous and undue risk. This bill will extend appropriate protection to raw material suppliers, while assuring that medical implant manufacturers will remain liable for damages caused by their products. It permits suppliers of biomaterials to be quickly dismissed from a lawsuit if they did not manufacture or sell the implant and if they met the contract specifications for the biomaterial.

Mr. President, as my colleagues are aware, the bare provisions do not extend to suppliers of silicone gel and silicone envelopes used in silicone gel breast implants.

I want to be quite clear this “ carve-out” as it’s been called, is intended to have no effect on tort cases related to breast implants. The question of whether and to what degree silicone breast implants are hazardous is a determination that must be made by scientific experts. The question of whether and to what degree raw material suppliers or are not liable is a determination that the courts must render.

Determining the safety or efficacy of a medical device is not the function of the Senate and the United States Congress. This is not our role and nothing in this legislation should be construed otherwise. So the exemption should not be interpreted as a judgment about silicone breast implants.

Our goal in this regard remains simply to ensure that this legislation draws no conclusion about and has no impact upon pending suits.

Finally, I would like to mention that this exemption should not be considered an invitation for additional carve-outs or exemptions for other raw material or component part suppliers.

I do not wish to see suppliers, who trusting in the protections of this act, return to the medical device manufacturing market, only to find themselves again targeted as deep pockets in tort actions, and thereby threaten the supply of life saving products. I appreciate the opportunity to make this very important point about a bill vital to public health.

This is an important piece of legislation and it will make a great difference to millions of Americans.

Mr. President, I would now like to enter into a colloquy with the distinguished Senator from Wisconsin regarding several aspects of this legislation.

Mr. FEINGOLD. Mr. President, I rise to express my concern regarding three provisions of the Biomaterials Access Assurance Act of 1998. Although I have broader concerns with the bill including federalism issues, consumer protection issues, and evidentiary issues, I would like clarification from one of the sponsors of the bill, Senator Mccain, on the below points.

First, Section 7(a) the language reads that only “after entry of a final judgment in an action by the claimant against a manufacturer” can a claimant attempt to implead a biomaterials supplier. I am concerned that this could be interpreted to mean that the manufacturer must lose the underlying suit before the claimant may implead the supplier. Is this correct?

Mr. MCCAin. No. Although I do not believe that the situation you pose could happen very often—specifically that a supplier could be liable when the manufacturer is not—the language should be interpreted to mean that the claimant could bring a motion to implead the supplier whether or not the manufacturer is found liable in the underlying case, as long as the judgment is final.

Mr. FEINGOLD. Finally, I am concerned that there would not be a sufficient introduction of evidence demonstrating the liability of the supplier in the underlying suit against the manufacturer for the court to make an independent determination that the manufacturer was an actual and proximate cause of the harm for purposes of the impleader motion as required in Sections 7(1)(A) and 7(2)(A) of the bill.

Mr. MCCAin. Under current FDA regulations and under current tort law, the manufacturer is responsible for the entire product they produce, including defects in the raw materials. Therefore, the claimant may enter evidence in the underlying action against the manufacturer regarding defect in the biomaterials used.

Mr. FEINGOLD. Finally, I am concerned that in a case where the manufacturer has gone bankrupt, the claimant will be unable to recover from the liable party. Does your bill address this issue?

Mr. MCCAin. Yes it does. Section 7(a)(2)(B) provides that in a case where the claimant is unlikely to recover from the manufacturer, if the other requirements of Section 7 are satisfied, the claimant can bring an action against the supplier. This covers bankruptcy and other scenarios where the manufacturer cannot satisfy an adverse judgment.

Mr. FEINGOLD. Senator Mccain, I thank the Senator for addressing my concerns.

Mr. LIEBERMAN. Mr. President, I rise in strong support of the bill we are about to take up and vote upon, the Biomaterials Access Assurance Act. I am proud to have co-sponsored the Senate version of this bill with Senator Mccain. We have worked together on this bill for a number of years now, and it is quite gratifying to see it now about to move toward enactment.

Mr. President, the Biomaterials bill is the response to a crisis affecting more than 7 million Americans annually who rely on implantable life-saving or life-enhancing medical devices—things like pacemakers, heart valves, artificial blood vessels, hydrophalpic shunts and hip and knee joints. They are at risk of losing access to the devices because many companies that supply the raw materials and component parts that go into the devices are
refusing to sell them to device manufacturers. Why? Because suppliers no longer want to risk having to pay enormous legal fees to defend against product liability suits when those legal fees far exceed any profit they make from supplying raw materials for use in implantable devices.

Let me emphasize that I am speaking here about—and the bill addresses—the suppliers of raw materials and component parts—not about the companies that make the medical devices themselves. The materials these suppliers sell—things like resins and yarns—are basically generic materials that they sell for a variety of uses in many, many different products. Their sales to device manufacturers usually make up only a very small part of their markets—often less than one percent. As a result—and because of the small amount of the materials that go into the implants—many of these suppliers make very little money from supplying implant manufacturers. Just as importantly, these suppliers generally have nothing to do with the design, manufacture or sale of the product.

But despite the fact that the general public has nothing to do with making the product, because of the common practice of suing everyone involved in any way with a product when something goes wrong, these suppliers sometimes get brought into lawsuits claiming problems with the implants. One company, for example, was hauled into 651 lawsuits involving 1,605 implant recipients based on a total of 5 cents worth of that company’s product in each implant. In other words, in exchange for selling less than $100 of its product, this supplier received a bill for perhaps millions of dollars of legal fees it spent in its ultimately successful effort to defend against these lawsuits.

The results from such experiences should not surprise anyone. Even though not a single biomaterials supplier has ultimately been held liable so far—let me say that again: Not a single biomaterials supplier has ultimately been held liable so far—the message nevertheless is clear for any rational business. Why would any business stay in a market that yields them little profit, but exposes them to huge legal costs? An April 1997 study of this issue found that 75 percent of suppliers surveyed were not willing to sell their raw materials to implant manufacturers under current conditions. That study predicts that unless this trend is reversed, patients whose lives depend on implantable devices may no longer have access to them.

What is at stake here, let me be clear, is not protecting suppliers from liability and not even just making raw materials available to the manufacturers of medical devices. Those things in and of themselves might be enough to bring me here. What is at stake is the health and lives of millions of Americans who depend on medical devices for their every day survival. What is at stake are the lives of children with hydrocephalus who rely on brain shunts to keep fluid from accumulating around their brains. What is at stake are the lives of adults whose hearts would stop beating without implanted automatic defibrillators. What is at stake are the tens of thousands of individuals who need cardiac pacemakers because their hearts no longer generate enough of an electrical pulse to get their heart to beat. Without implants, none of these individuals could survive.

What we must do something soon to deal with this problem. We simply cannot allow the current situation to continue to put at risk the millions of Americans who owe their health to medical devices.

Senator McCain, and I and the bill’s sponsors in the House have crafted what we think is a reasonable response to this problem. Our bill would do two things. First, with an important exception I’ll talk about in a minute, the bill would eliminate all product liability suits, unless the supplier falls into one of three categories: (1) the supplier also manufactured the implant alleged to have caused harm; (2) the supplier furnished raw materials or component parts that failed to meet applicable contractual requirements or specifications; or (3) the supplier furnished raw materials or component parts that failed to meet applicable contractual requirements or specifications.

Second, the bill would provide suppliers with a mechanism for making that immunity meaningful by obtaining early dismissal from lawsuits. By guaranteeing suppliers in advance that they will not face needless litigation costs, this bill should spur suppliers to remain in or come back to the biomaterials market, and so ensure that people who need implantable medical devices will still have access to them.

Now, it is important to emphasize that in granting suppliers immunity, we would not be depriving anyone injured by a defective implantable medical device of the right to compensation for their injuries. Injured parties still will have their full rights against anyone involved in the design, manufacture or sale of an implant, and they can sue implant manufacturers, or any other allegedly responsible party, and collect for their injuries from them if that party is at fault.

We also have added a new provision to this version of the bill, one that resulted from lengthy negotiations with representatives of the implant manufacturers, the American Trial Lawyers Association—ATLA—the White House and others. This provision responds to concerns that the previous version of the bill would have left injured implant recipients without a means of seeking compensation if the manufacturer or other responsible party is bankrupt or unable to pay judgment. As the new bill is now drafted, the bill provides that in such cases, a plaintiff may bring the raw materials supplier back into a lawsuit after judgment if a court concludes that evidence exists to warrant holding the supplier liable.

Finally, let me add that the bill does not cover lawsuits involving silicone gel breast implants.

In short, Mr. President, the Biomaterials Bill is—and I think it is—engaging in hyperbole when I say this—potentially a matter of life and death for the millions of Americans who rely on implantable medical devices to survive. This bill would make sure that implant manufacturers still have access to the raw materials they need for their products, while at the same time ensuring that those injured by implants are able to get compensation for injuries caused by defective implants. This is a good bill, and I urge my colleagues to support it.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the bill be considered read a third time and passed; that the motion to reconsider be laid upon the table; and that any statements relating to the bill be placed at the appropriate place in the RECORD.

THE PRESIDING OFFICER. Without objection, it is so ordered.

The bill (H.R. 872) was considered read the third time and passed.

IDENTITY THEFT AND ASSUMPTION DETERRENCE ACT OF 1998

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 460, S. 512.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

A bill (S. 512) to amend chapter 47 of title 18, United States Code, relating to identity fraud, and for other purposes.

The PRESIDING OFFICER. Is there objection to the immediate consideration of the bill?

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on the Judiciary, with an amendment to strike all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Identity Theft and Assumption Deterrence Act of 1998”.

SEC. 2. IDENTITY THEFT.

(a) Establishment of Offense.—Section 1028(a) of title 18, United States Code, is amended—

(1) in paragraph (5), by striking “or” at the end;

(2) in paragraph (6), by adding “or” at the end;

(3) in the flush matter following paragraph (6), by striking “or attempts to do so,”; and

(4) by inserting after paragraph (6) the following—

“(7) knowingly possesses, transfers, or uses, without lawful authority, a means of identification of another person with the intent to commit, or attempts to commit, any unlawful activity that constitutes a violation of Federal law, or that constitutes a felony under any applicable State or local law;”.

(b) Penalties.—Section 1028(b) of title 18, United States Code, is amended—

(1) in paragraph (1)—