

caught just 25.1 million salmon. Under State management we caught 218 million salmon in 1995.

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

UNANIMOUS CONSENT AGREEMENT—CONFERENCE REPORT TO ACCOMPANY H.R. 4059

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 materials and bulk component 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 claims of damage 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 would permit 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 bill's 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 are 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 nor 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 judgement 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 marketplace 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 three specific 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 claim-

ant 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. Second, 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 supplier 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 the full amount of its damages 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, hydrocephalic 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