

move to bring to a close debate on the pending committee substitute amendment to S. 534, the solid waste disposal bill.

John H. Chafee, Bob Dole, Bob Smith, Jim Jeffords, Hank Brown, Kit Bond, Orrin Hatch, Spencer Abraham, Jon Kyl, Larry E. Craig, Kay Bailey Hutchison, Trent Lott, R.F. Bennett, Pete V. Domenici, Dirk Kempthorne, Jesse Helms.

MORNING BUSINESS

(During today's session of the Senate, the following morning business was transacted:)

PRODUCT LIABILITY FAIRNESS ACT

Mr. DODD. Mr. President, today the Senate passed the Product Liability Fairness Act, which I have cosponsored, by an overwhelming vote of 61-37. For those of us who have been working on this issue for a long time—my involvement dates back to 1985—this is an historic day. With passage of this balanced measure, we have taken a huge step toward improving the product liability system for everyone—for the injured people who need fast and fair compensation, for consumers who need quality products to choose from, for those American businesses who are at the cutting edge of international competition, and for workers who depend on a strong economy to support their families.

I commend Senator ROCKEFELLER and Senator GORTON, and their staffs, for their heroic efforts on this measure. From drafting the legislation, to skillfully guiding it through a lengthy debate on the Senate floor, they have worked extremely effectively. Their success is reflected in the broad bipartisan coalition that supported the bill.

I also commend Senator LIEBERMAN, my colleague from my home State of Connecticut. He authored an important section on biomaterials. That provision is designed to ensure that manufacturers of life-saving and life-enhancing medical devices have access to raw materials. In recent years, the supply of raw materials has been threatened by litigation. This is a critical problem, and I commend Senator LIEBERMAN for crafting a promising solution.

Of course, like any compromise, this bill will not please everyone in all respects. I had drafted, for example, an amendment providing a different approach to punitive damages. Under my amendment, the jury would determine whether punitive damages are appropriate, and the judge, guided by certain factors, would determine the amount. That procedure, in my view, offers a better approach to punitive damages than one which provides limits, or caps. Senators ROCKEFELLER and GORTON incorporated some aspects of my proposal in the final provision, and I appreciate their efforts on this difficult issue.

The final version of this bill does not contain a provision that I have sup-

ported in the past—the Government standards defense. One aspect of that defense, related to approval of drugs and medical devices by the Food and Drug Administration, was passed by voice vote in the House and will, I understand, be considered in conference. I ask unanimous consent that a number of letters supporting this provision be printed in the RECORD at the end of my remarks. As these letters point out, inappropriate punitive damages have convinced many corporate researchers to avoid the search for safer and more effective drugs.

Once again, I commend my colleagues, particularly Senators ROCKEFELLER and GORTON, for their bipartisan efforts on the Product Liability Fairness Act.

There being no objection, the letters were ordered to be printed in the RECORD, as follows:

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA,
Washington, DC, April 25, 1995.

Hon. CHRISTOPHER J. DODD,
U.S. Senate,
Washington, DC

DEAR SENATOR DODD: As a physician volunteer, I treat AIDS patients at the Whitman-Walker Clinic. The suffering that I see—and the threat of an ever-wider epidemic—convince me that the greatest gift anyone could give to society would be an AIDS vaccine. If I were the chairman of a philanthropic foundation, I would invest every dollar in vaccine research.

However, if I were CEO of a pharmaceutical company, knowing that the investment in my company represented the retirement and college savings of many of my stockholders, I wouldn't touch AIDS vaccine research with a ten-foot pole—until the liability issue has been successfully addressed.

Even the safest, most widely accepted vaccines entail risks—and potentially bankrupting liability burdens. Childhood vaccines are available in adequate supply only because Congress passed the Childhood Vaccine Compensation Act. This came about only because several manufacturers got out of the business of manufacturing childhood vaccines due to liability concerns—raising fears of a dangerous scarcity.

In 1975, a man who got polio after changing his baby's diaper sued the manufacturer of the Sabin polio vaccine, which the baby had received. The risk of polio transmission was known, but small—about 1 in 1 million. Nevertheless, the jury awarded punitive damages. The award was later reversed, but only by the narrowest possible margin. The very fact that such a widely acclaimed health advance could expose a manufacturer to punitive damages would certainly give pause to any manufacturer considering research on an AIDS vaccine—which entails special liability risks.

With a preventive AIDS vaccine, people who are vaccinated will probably turn HIV positive—with all the social stigma and threat of job loss or insurance loss that this involves. There is a risk that a very small number of people will get AIDS from the vaccine. Additionally, there is the risk that the vaccine won't "take" in all cases and that some people who think they are protected may engage in risky behavior and come down with AIDS. All of these eventualities could result in lawsuits.

In the case of therapeutic vaccines for people who already have the disease, it would be very difficult to distinguish the symptoms of AIDS from any side-effects of the vaccine.

And people with AIDS, prodded by unscrupulous lawyers, might easily be tempted to sue vaccine manufacturers.

Unless the liability threat is alleviated—at least by exempting manufacturers of FDA-approved products from punitive damages—developing an AIDS vaccine is decidedly a "no-win" proposition. This is outrageous, unfair, tragic—but true.

Sincerely,

JOHN D. SIEGFRIED, M.D.

MAY 2, 1995.

Hon. CHRISTOPHER J. DODD,
U.S. Senate,
Washington, DC.

DEAR SENATOR DODD: We are writing to ask that you vote in favor of a proposal that we believe will have a positive effect on research and development of new medicines and medical devices. American innovation is in trouble in the courts particularly in the high risk areas of reproductive health. Liability fears have caused the withdrawal of new drugs and medical devices that the Food and Drug Administration (FDA) considers safe and effective. We understand that when S. 565, the "Product Liability Fairness Act of 1995" is considered on the Senate floor, an amendment will be offered that would prevent juries from second-guessing the FDA's scientific decisions that a drug is safe insofar as punitive damages are concerned.

The proposed FDA-approval defense to punitive damages would establish a defense to punitive damages in tort actions involving drugs or devices approved by the FDA and subject to FDA regulation. The defense would apply only to punitive damages, and would not be available to a manufacturer that has withheld or misrepresented information to the FDA, including all required post-approval disclosure of unexpected adverse effects.

In the past twenty years, most companies have halted U.S. research on contraceptives and drugs to combat infertility and morning sickness. As a case in point, Bendectin, a morning-sickness drug, was removed from the market by its manufacturer in 1984 after more than 2,000 lawsuits were filed claiming it caused birth defects. Merrell Dow has spent over \$100 million defending those suits and is still doing so. Even though almost every court which has looked at the issue has determined that there is no scientific evidence to support the contention that the drug causes birth defects, and even though Bendectin is still approved by the FDA for use in pregnancy, no manufacturer will risk making a morning sickness drug.

The 1970s brought more litigation over oral contraceptives than any other drug. In the early 1970s, there were 13 companies doing research and development on contraceptives. Eight of these were American. Today there are only two major U.S. companies doing such research. In 1990, a distinguished panel of scientists put together by the National Academy of Sciences noted that due to fear of lawsuits, the United States is decades behind Europe and other countries in the contraceptive choices it offers women.

In early 1994, because it had spent tens of millions of dollars defending against suits by people claiming injury from temporomandibular joint implants, DuPont announced it would no longer make polymers available to the medical device industry in the United States. These polymers are used in artificial hearts, pacemakers, catheters, hip and knee prostheses, and a host of other implantable devices. We have not even begun to feel the full impact of that decision.

The Senate is taking advantage of an unprecedented opportunity to fix a flawed product liability system. We ask that you include