

have been working on for a couple of Congresses: the Biomaterials Access Assurance Act.

The Biomaterials bill is the response to a crisis affecting more than 7 million patients 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. These patients are at risk of losing access to the devices because many suppliers are refusing to sell biomaterial device manufacturers the raw materials and component parts that are necessary to make the devices. The reason: 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 the raw materials for use in implantable devices. Although not a single biomaterials supplier has ultimately been held liable so far, the actual and potential costs of defending lawsuits has caused them to leave this market. A study by Aronoff Associates 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.

The Biomaterials title of the Product Liability bill responds to this crisis by allowing most suppliers of raw materials and component parts for implantable medical devices to gain early dismissal from lawsuits. At the same time, by allowing plaintiffs to bring those suppliers back into a lawsuit in the rare case that the other defendants are bankrupt or otherwise judgment proof, it ensures that plaintiffs won't be left without compensation for their injuries if they can prove a supplier was at fault. Mr. President, I have a summary of the bill here, and I ask unanimous consent that it be printed after this statement in the RECORD.

I will have a lot more to say about the Biomaterials provisions and the entire bill when we return from recess. For now, let me just once again congratulate Senator GORTON, Senator ROCKEFELLER and the President for their success in forging this compromise bill. I urge my colleagues to support it.

There being no objection, the summary was ordered to be printed in the RECORD, as follows:

SUMMARY OF BIOMATERIALS ACCESS ASSURANCE ACT

Title II of the Product Liability Reform Act of 1998 contains the provisions of the Lieberman-McCain Biomaterials Access Assurance Act.

Need For The Biomaterials Bill: The Biomaterials bill responds to a looming crisis affecting more than 7 million patients annually who rely on implantable life-saving or life-enhancing medical devices such as pace-

makers, heart valves, artificial blood vessels, hydrocephalic shunts, and hip and knee joints. These patients are at risk of losing access to the devices because many suppliers are refusing to sell biomaterial device manufacturers the raw materials and component parts that are necessary to make the devices. The reason: suppliers no longer want to risk having to pay enormous legal fees to defend against meritless product liability suits when those legal fees far exceed any profit they make from supplying the raw materials for use in implantable devices. Although not a single biomaterials supplier has thus far been held liable, the actual and potential costs of defending lawsuits has caused them to leave this market. A study by Aronoff Associates 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 rely on implantable devices may no longer have access to them.

What The Bill Does: To alleviate these problems, the Biomaterials bill would do two things. First, with an important exception noted below, the bill would immunize suppliers of raw materials and component parts from product liability suits, unless (a) the supplier also manufactured the implant alleged to have caused harm; (b) the supplier sold the implant alleged to have caused harm; or (c) the supplier furnished raw materials or component parts that failed to meet applicable contractual requirements or specifications. Second, the bill would provide raw materials and component parts suppliers with a mechanism for making that immunity meaningful by obtaining early dismissal from lawsuits.

What The Bill Does Not Do: The bill does not keep injured plaintiffs from gaining compensation for their injuries. First, it leaves lawsuits against those involved in the design, manufacture or sale of medical devices untouched. Second, it provides a fallback rule if the manufacturer or other responsible party is bankrupt or judgment-proof. In such cases, a plaintiff may bring the raw materials supplier back into a lawsuit if a court concludes that evidence exists to warrant holding the supplier liable. Finally, the bill does not cover lawsuits involving silicone gel breast implants.

THE VERY BAD DEBT BOXSCORE

Mr. HELMS. Mr. President, at the close of business yesterday, Thursday, June 25, 1998, the federal debt stood at \$5,504,168,372,205.11 (Five trillion, five hundred four billion, one hundred sixty-eight million, three hundred seventy-two thousand, two hundred five dollars and eleven cents).

One year ago, June 25, 1997, the federal debt stood at \$5,339,644,000,000 (Five trillion, three hundred thirty-nine billion, six hundred forty-four million).

Five years ago, June 25, 1993, the federal debt stood at \$4,305,269,000,000

(Four trillion, three hundred five billion, two hundred sixty-nine million).

Twenty-five years ago, June 25, 1973, the federal debt stood at \$452,652,000,000 (Four hundred fifty-two billion, six hundred fifty-two million) which reflects a debt increase of more than \$5 trillion—\$5,051,516,372,205.11 (Five trillion, fifty-one billion, five hundred sixteen million, three hundred seventy-two thousand, two hundred five dollars and eleven cents) during the past 25 years.

HONORING THE PHILLIPS, SWONS, AND YOUNTS ON THEIR 30TH WEDDING ANNIVERSARIES

Mr. ASHCROFT. Mr. President, families are the cornerstone of America. The data are undeniable: Individuals from strong families contribute to the society. In an era when nearly half of all couples married today will see their union dissolve into divorce, I believe it is both instructive and important to honor those who have taken the commitment of "till death us do part" seriously, demonstrating successfully the timeless principles of love, honor, and fidelity. These characteristics make our country strong.

For these important reasons, I rise today along with the senior Senator from Missouri, Senator BOND, to honor Kathy and John Phillips, Alma and Larry Swon, and Kathy and Mike Yount of Mexico, Missouri, who on July 3, 1998, will celebrate their 30th wedding anniversaries. Many things have changed in the 30 years these couples have been married, but the values, principles, and commitment these marriages demonstrate are timeless.

My wife, Janet, and I had the privilege of celebrating our 30th wedding anniversary just one year ago. I can attest, like these fine couples, to the remarkable love and appreciation that has grown out of my own marriage. As these couples gather together in Mexico on July 3, surrounded by friends and family, it will be apparent that the lasting legacy of these marriages will be the time, energy, and resources invested in their children, church, and community.

The Phillips, Swons, and Younts exemplify the highest commitment to relentless dedication and sacrifice. Their commitment to the principles and values of their marriages deserve to be saluted and recognized.

PATIENTS' BILL OF RIGHTS

Mr. KENNEDY. Mr. President, upon our return in July, it is my hope that the Senate will turn to full and open debate of patient protection legislation at the earliest appropriate time. The American people are concerned about the state of our health care system. Earlier this month, a survey by the Pew Research Center showed HMO regulation at the top of the list of issues important to individuals and the country.

We have a proposal, the Patients' Bill of Rights (S. 1890), which would restore confidence in our system. A critical provision in our bill would allow patients who receive their benefits through their employer to hold their plans accountable for medical or coverage decisions that result in injury or death. Currently, approximately 123 million Americans are precluded from seeking any meaningful redress when they are permanently disabled or when they lose a loved one because of insurance company abuses that put profits ahead of patients.

Patients who purchase in the individual market can hold their plans accountable. Patients enrolled in plans that serve state or local employees can hold their plans accountable. But people insured through ERISA covered plans cannot. No industry deserves to be exempt from liability for their actions. Last week, William Welch, a reporter with USA Today, wrote an article that eloquently outlines this issue and how it affects families across the country. I ask unanimous consent that this article be printed in the RECORD.

There being no objection, the article was ordered to be printed in the RECORD, as follows:

[From the USA Today, June 19-21, 1998]

1974 PENSIONS LAW SPARKS POLITICAL FIRE

(By William M. Welch)

WASHINGTON—When a doctor's mistake causes death or injury to the patient, a malpractice suit frequently follows. But what if fault lies with a managed care plan that denies treatment?

Chances of a successful suit for damages are slim, many Americans are finding, because a federal law makes it practically impossible to collect from an employer-provided health care plan.

As more people get into health maintenance organizations and other types of managed-care plans, that 25-year old law has become an election-year issue. Both parties propose regulating managed-care plans and making HMOs more accountable. Knocking down legal barriers to suits has emerged as the most contentious issue in the debate.

"The American public doesn't realize that the managed-care industry is the only industry in the country that has a congressionally mandated shield from liability," says Rep. Charlie Norwood, R-Ga., a dentist who is sponsoring one of several bills that would open the door to suits against health plans. "I want these accountants to think twice before they overrule the physician who says your child needs to go to the hospital."

Sen. Edward M. Kennedy, D-Mass., is sponsoring a similar version in the Senate and vows to attach it to spending bills or other must-pass legislation, perhaps as early as next week. "We will use whatever parliamentary means," he says, "because the American people expect it."

The bills would remove the barrier to suits by changing a federal law that says decisions made by employer-provided health plans in most cases cannot be the subject of suits in state courts. It also greatly limits potential awards in federal courts.

Norwood and Kennedy say the change would instantly make healthcare plan managers more accountable for their decisions about coverage and put authority for treatment decisions back in the hands of doctors.

Opponents say it would bring a flood of expensive lawsuits and lead to higher health

insurance costs for average Americans. In the House of Representatives, Majority Leader Dick Armey, R-Texas, is a leading opponent. He says the change would "drive up premiums and drive down coverage by letting trial lawyers sue health plans for malpractice."

MY CHILD WAS CHEATED

Advocates of changing the federal law point to people like Bill Beaver of Pollock Pines, Calif. Beaver, 52, says his HMO misdiagnosed a brain tumor for two years, then told him his condition was inoperable and hopeless. He cashed in a retirement account to visit specialists at Johns Hopkins University Hospital in Baltimore. They began radiation treatment.

The tumor receded, and Beaver is alive three years later. The HMO refused to pay for the treatment at Johns Hopkins. He wanted to sue but was told federal law would make it impossible for him to win.

"When I needed support, my HMO gave me the door," Beaver says, "Unless HMOs are forced to give quality care, they will continue to deny costly treatments that can prolong or in my case even save a life."

Melody Louise Johnson of Norco, Calif., died at age 16 of cystic fibrosis, a genetic disease that attacks the lungs. Her mother, Terry Johnson, says the family's HMO delayed their request for referral to specialists and overruled the specialists once she saw them. The family has sued, and their HMO is citing the federal law in seeking dismissal.

"I don't want another parent to have to go through what I went through," she says. "It is devastating enough to have a child with this disease. . . . My child was cheated."

Privacy laws prevent health-care companies from commenting on individual cases, says Richard Smith, vice president of the American Association of Health Plans, whose members include the nation's major HMOs and managed-care plans.

"It is nearly impossible for the plans that are being accused to respond," Smith says. "I think that most people understand there's often more than one side to a story."

SUPPORT FOR CHANGE

Armed with stories like these, supporters of change have tapped strong chords of unhappiness with managed care among voters.

More than half the House, including members in both parties, has signed on as supporters of Norwood's bill. House and Senate Democratic leaders have introduced similar bills. President Clinton has called for passage of the legislation, and Congress is expected to act this year.

A poll released this week by the Pew Research Center found that 69% say the debate over HMO regulation is very important, and 60% said it was very important to them personally.

Senate GOP leaders and Armey in the House have blocked the bills, although some Republicans are calling for action. House Speaker Newt Gingrich, R-Ga., has named a task force of GOP lawmakers to come up with a more limited bill. But he rejected their initial attempt.

The issue is already being used by Democrats in House and Senate campaigns in states as diverse as North Carolina and Montana. Some GOP lawmakers worry that their leaders are handing a powerful issue to Democrats that threatens their 11-vote House majority.

"In my opinion this will be one of the top two or three issues in this fall campaign," says Rep. Greg Ganske, R-Iowa, a physician. "We will only see legislation passed when it becomes apparent to the Republican leadership that they could lose their majority based on this issue."

WHY SUITS ARE BARRED

The obstacle to suits is a 1974 law, the Employee Retirement Income Security Act, or

ERISA. It was designed to protect pensions and simplify rules for employers by preempting state regulation of benefit plans and covering them with a single federal law.

Many experts say the law was never intended to shield health care decisions from malpractice suits, but court interpretations and the changing nature of the U.S. health care system have had that effect. Because of the law, managed-care plans can argue that they are extensions of employer-provided benefit plans and thus protected from state laws and regulations on health insurance.

The law also makes it relatively futile to sue in federal court. It prohibits plaintiffs from seeking punitive or compensatory damages. They can sue only to recover the cost of the procedure that was denied.

A decade ago, when HMOs and managed care covered relatively few Americans, denial of coverage meant an insurance company didn't pay a bill after treatment, and the law wasn't a big issue. But there has been a revolution in the way health care is provided, and now 138 million people, or three-quarters of Americans with private health insurance, rely on managed-care plans.

Those plans limit costs by tightly controlling access to many types of care. Decisions authorizing or denying care may be made by claims clerks and managers. For patients in those plans, denial of coverage can mean they don't see the doctor or specialist they want or don't get a medical procedure their doctor recommended. They may not even be informed of expensive treatments or clinical trials that hold promise for life-threatening illnesses such as cancer. A health plan can limit the options its doctors discuss with patients.

"In non-managed care, it's not an issue because the physician makes the decision and is accountable," says Dr. Thomas Reardon, president of the American Medical Association. "It's when you have a third party second-guessing the physician that this becomes a problem."

Jerry Cannon of Newcastle, Okla., learned about the limits on accountability when his wife, Phyllis, contracted leukemia. Her HMO denied the bone marrow transplant that her doctor recommended until it was too late. She died in 1992 at 46. When Cannon sued, a federal court ruled that the federal law prevented any award.

A three-judge panel of the 10th U.S. Circuit Court of Appeals upheld the ruling and said the law was clear, however wrong the result may seem. The Supreme Court refused the case.

"Although moved by the tragic circumstances of this case and the seemingly needless loss of life that resulted, we conclude the law gives us no choice," the appeals court said.

Cannon recalls taking the phone call and relaying word to his wife that the HMO wasn't going to provide the transplant she needed: "It just devastated her. She gave up after that. Oh, it was horrible. Once I got off the phone, I could see all hope leave her."

RADICAL PROPOSAL

Concerned about growing calls for change, employers, insurers and health care companies have begun an aggressive advertising and lobbying campaign against the bills. They contend that changing the law could open the door to expensive lawsuits against employers as well as health plans, drive up costs for consumers, and ultimately reduce the quality of health care.

"This kind of radical proposal to expand the current flawed medical liability system is not going to generate better medical care. It's going to generate lower quality medical care," says Smith, of the health plans association.

Kennedy and Norwood dispute the industry view and say their bills would not permit suits against employers unless they actually participated in the decisions leading to injury.

But industry groups say higher costs and the potential for suits could cause some big employers to stop offering health plans for their workers.

"There is no question, we believe, that this would cause a lot of employers to drop coverage. They just couldn't take the risk," says Dan Danner, chairman of the Health Benefits Coalition, made up of business groups organized to fight the bills.

His group has run ads in selected congressional districts attacking the bills as protecting "fat cat trial lawyers" rather than the sick. Danner says his group's spending is approaching \$2 million, and individual companies are spending more.

Fighting for the bills are consumer groups and an unusual alliance of doctors and trial lawyers, who are traditionally adversaries in malpractice cases. The lawyers have let groups with more sympathetic public images, such as doctors, wage the visible campaign while the lawyers lobby aggressively inside Congress.

THERE ARE PROBLEMS

Industry officials say their decisions are protected because they are not, strictly speaking, medical decisions. Instead, they say the decisions revolve around what treatments are or are not covered by a plan. Doctors, who are liable to lawsuits for their decisions, dismiss that claim.

"That's absurd because they are making medical decisions," says the AMA's Reardon. "They're hiding behind the facade that it is not medical, that it's a coverage decision."

Some industry officials agree that some new regulation of managed care plans is needed, short of dropping the prohibition on suits.

"There are problems with managed care," says Danner. "Hopefully the debate will focus on the best way to solve those problems without significant unintended consequences."

Advocates from Norwood to the AMA say that accountability is at the heart of the issue. Making HMOs liable for their decisions would bring dramatic change for all patients, not just those inclined to sue, they say.

"If the plans are held as accountable as I am for the medical decision-making," Reardon says, "it will benefit the patient."

ABOUT THE MANAGED-CARE BILL

Here are key provisions in a managed-care regulation bill proposed by Rep. Charlie Norwood, R-Ga.

A Democrat-sponsored bill is similar.

Gag rule. Plans may not restrict discussions between their doctors and patients, including treatment options.

Legal liability. Eliminates federal law blocking individuals from suing managed-care companies for malpractice.

Emergency care. Requires plans to pay for emergency care in most cases without prior authorization.

Information. Plans must provide information about policies and appeals procedures in a uniform and understandable manner.

Access. Plans must have enough doctors or other providers to ensure that patients have timely access to benefits.

Choice. Patients can choose a doctor or other health provider within the plan.

Appeals. An independent outside third-party appeals board must be available to hear appeals of treatment denials.

MESSAGES FROM THE PRESIDENT

Messages from the President of the United States were communicated to the Senate by Mr. Williams, one of his secretaries.

EXECUTIVE MESSAGES REFERRED

As in executive session the Presiding Officer laid before the Senate messages from the President of the United States submitting three treaties and sundry nominations which were referred to the appropriate committees.

(The nominations received today are printed at the end of the Senate proceedings.)

MESSAGES FROM THE HOUSE RECEIVED DURING ADJOURNMENT

ENROLLED BILL SIGNED

Under the authority of the order of the Senate of January 7, 1997, the Secretary of the Senate, on June 26, during the adjournment of the Senate, received a message from the House of Representatives announcing that the Speaker has signed the following enrolled bill:

H.R. 2646. An act to amend the Internal Revenue Code of 1986 to allow tax-free expenditures from education individual retirement accounts for elementary and secondary school expenses, to increase the maximum annual amount of contributions to such accounts, and for other purposes.

The enrolled bill was signed subsequently by the President pro tempore (Mr. THURMOND).

MEASURES PLACED ON THE CALENDAR

The following bill was read the second time and placed on the calendar:

S. 2236. An act to establish legal standards and procedures for product liability litigation, and for other purposes.

The following bill was discharged from the Committee on Armed Services, and ordered placed on the calendar:

S. 2052. An act to authorize appropriations for fiscal year 1999 for intelligence and intelligence-related activities of the United States Government, the Community Management Account, and the Central Intelligence Retirement and Disability System, and for other purposes.

ENROLLED BILL PRESENTED

The Secretary of the Senate reported that on June 26, 1998, he had presented to the President of the United States, the following enrolled bill:

S. 2069. An act to permit the mineral leasing of Indian land located within the Fort Berthold Indian Reservation in any case in which there is consent from a majority interest in the parcel of land under consideration for lease.

REPORTS OF COMMITTEES

The following reports of committees were submitted:

By Mr. GORTON, from the Committee on Appropriations, without amendment:

S. 2237: An original bill making appropriations for the Defense of the Interior related agencies for the fiscal year ending September 30, 1999, and for other purposes (Rept. No. 105-227).

By Mr. MURKOWSKI, from the Committee on Energy and Natural Resources: Report to accompany the bill (S. 1683) to transfer administrative jurisdiction over part of the Lake Chelan National Recreation Area from the Secretary of the Interior to the Secretary of Agriculture for inclusion in the Wenatchee National Forest (Rept. No. 105-228).

By Mr. MURKOWSKI, from the Committee on Energy and Natural Resources with an amendment in the nature of a substitute:

S. 638: A bill to provide for the expeditious completion of the acquisition of private mineral interests within the Mount St. Helens National Volcanic Monument mandated by the 1982 Act that established the Monument, and for other purposes (Rept. No. 105-229).

S. 1403: A bill to amend the National Historic Preservation Act for purposes of establishing a national historic lighthouse preservation program (Rept. No. 105-230).

By Mr. MURKOWSKI, from the Committee on Energy and Natural Resources, without amendment:

H.R. 1439: A bill to facilitate the sale of certain land in Tahoe National Forest, in the State of California to Placer County, California (Rept. No. 105-231).

H.R. 1779: A bill to make a minor adjustment in the exterior boundary of the Devils Backbone Wilderness in the Mark Twain National Forest, Missouri, to exclude a small parcel of land containing improvements (Rept. No. 105-232).

INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second time by unanimous consent, and referred as indicated:

By Mr. GORTON:

S. 2237. An original bill making appropriations for the Defense of the Interior related agencies for the fiscal year ending September 30, 1999, and for other purposes; from the Committee on Appropriations; placed on the calendar.

By Mr. LOTT (for Mr. MCCAIN (for himself and Mr. BRYAN)):

S. 2238. A bill to reform unfair and anti-competitive practices in the professional boxing industry; to the Committee on Commerce, Science, and Transportation.

By Mr. MURKOWSKI:

S. 2239. A bill to revise the boundary of Fort Matanzas Monument and for other purposes; to the Committee on Energy and Natural Resources.

S. 2240. A bill to establish the Adams National Historical Park in the Commonwealth of Massachusetts, and for other purposes; to the Committee on Energy and Natural Resources.

S. 2241. A bill to provide for the acquisition of lands formerly occupied by the Franklin D. Roosevelt family at Hyde Park, New York, and for other purposes; to the Committee on Energy and Natural Resources.

By Mr. DEWINE (for himself, Mr. GRASSLEY, Mr. KOHL, Mr. ABRAHAM, Mr. SESSIONS, and Mr. COVERDELL):

S. 2242. A bill to amend the Controlled Substances Import and Export Act to place limitations on controlled substances brought into the United States from Canada and Mexico; to the Committee on the Judiciary.

By Mrs. HUTCHISON:

S. 2243. A bill to authorize the repayment of amounts due under a water reclamation