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Bill allows injured patients to sue

Two S.C. lawmakers oppose measure

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Health Writer

Don Fernbach was sitting at his desk one day last June when he was jolted by a shock from inside his chest.

It was followed by another. Then another. He scrambled for the phone to call for help.

“It was like getting kicked in the chest by a horse,” said the Fort Mill accountant, “except the horse was inside trying to get out.”

A year earlier, surgeons had implanted a defibrillator in Fernbach after a cardiac arrest. And it allowed the 57-year-old father of three to go on with his life until that June morning, when it sent volts of electricity into his heart 22 times.

The defibrillator was one of 268,000 recalled in 2007 by Medtronic Inc., which said the leads were defective and linked to between five and 13 deaths.

Fernbach wanted to sue. But the U.S. Supreme Court ruled in February 2008 that manufacturers whose medical devices were approved by the U.S. Food and Drug Administration could not be sued under state law by injured patients, said his attorney, Rhett Klok of Mount Pleasant.

Now Fernbach has one other hope – the Medical Device Safety Act of 2009, which would reverse the high court's decision. Congress began hearings on the bill this month.

“If this act passes, we will have a shot at moving this case forward,” said Klok.

Medtronic and FDA concluded that the risk of removing the device was greater than the risk of malfunction. But Fernbach says there are thousands of people still living with the leads who have no protection.

“As long as victims of defective medical devices can't sue,” he said, “these companies have no impetus to do the right thing.”

Medtronic disagrees.

“We think this is an appropriate system versus regulating by litigation,” said spokesman Rob Clark. “FDA is the best arbiter in determining whether the products should be on the market.”

Furthermore, he said, litigation stifles innovation and adds to the cost of medical products.

“We have a system that has allowed medical technology to come to the marketplace,” he said, “and that has saved lives.”

But the bill's sponsors, U.S. Reps. Frank Pallone Jr., D-NJ, and Henry A. Waxman, D-CA, said the ruling denies injured patients the ability to seek compensation for injuries, medical expenses and lost wages while giving manufacturers immunity. They say the FDA has repeatedly failed to adequately protect the public from unsafe medical devices and drugs, and that in another case, the court upheld the right of a patient to sue after being harmed by a drug.

Consumers Union supports the bill. And in an editorial, the New England Journal of Medicine called for its passage, saying the court's decision was not based on what is best for public health, but a point of statutory law.

“To rely just on the FDA to know everything about the safety of these devices is naïve,” said Bill Vaughan, health policy analyst with Consumers Union. “It's a relatively small agency that has to look at the safety of about $2 trillion worth of devices. We need tough tort laws to protect consumers, because FDA can't do it by themselves.”

Fernbach said he went to Washington to tell his story to U.S. Rep. John Spratt, D-S.C., and U.S. Sen. Lindsey Graham, R-S.C., and ask them to support the bill. Their spokesmen said they have not taken a position yet.

But U.S. Rep. Bob Inglis, R-S.C., said manufacturers should take reasonable steps so their products are safe, but shouldn't have to be “guarantors” of good outcomes, or product development would be suppressed. He added that while accountability through litigation is the best argument for the bill, FDA has a “rigorous” system for approving devices, and it would drive up costs.

U.S. Sen. Jim DeMint opposes the bill for the same reasons, said his spokesman Wesley Denton.

But Inglis added that medical bills resulting from a defective product should be borne by the manufacturer, not just the replacement part. Fernbach said he and his insurer paid the $30,000 bill for the surgery to replace the device.

“It's not enough to hand a new set of wires to someone,” Inglis said. “You've got to install them, too.”

Clark said Medtronic provides the free leads and up to $1,200 of unreimbursed expenses, and that insurers take the cost of potential follow-up procedures into account.

Klok said eliminating the legal option handicaps the system of checks and balances. And Fernbach said the court's rulings don't make sense.

“I can sue a drug manufacturer for the harm a drug causes,” he said, “but I cannot sue a manufacturer of life and death medical devices.”
