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ONE HUNDRED ELEVENTH CONGRESS

# Congress of the United States

## House of Representatives

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### Opening Statement of Rep. Henry A. Waxman Chairman, Committee on Energy and Commerce H.R. 1346, The Medical Device Safety Act of 2009 Subcommittee on Health May 12, 2009

This morning, the Subcommittee will hear testimony on an issue that affects all of us: the legal liability of manufacturers that produce dangerous medical devices.

Until February of last year, when Americans were injured by defective medical devices, they had a remedy. In most states, they were able to sue the manufacturer of that product for damages in state court. In fact, the only way patients can obtain compensation is to bring a lawsuit under state law.

In February 2008, the Supreme Court dramatically altered this landscape. The Court ruled that, so long as FDA has approved a medical device, patients injured by that device can no longer seek compensation to help them deal with their permanent disabilities, their inability to work, and their costly medical procedures.

Ironically, the decision applies only to the most dangerous and most complex devices. The kind of devices that, when they malfunction, often result in death or severe physical impairment.

This decision has already had a devastating impact. Over 1,400 cases brought by injured patients, have been thrown out. Countless other lawsuits will never be brought.

In the wake of the Court's decision, it doesn't matter how badly a defective device harmed a patient. It doesn't matter how egregious the device manufacturer's conduct was in marketing a defective device. Patients now have no recourse and no ability to be compensated for their injuries.

The Court's decision was bad for Americans in another way too. It has destroyed one of the most powerful incentives for safety — the possibility of liability.

We know that some device companies have hidden and manipulated important safety data. Some have failed to report serious adverse events. And some have failed to disclose known defects.

Yet, under the Court's decision, even if a company withholds information about potentially fatal defects from physicians, patients, or the FDA, it is still immune from any liability for its actions.

In the absence of liability, all the financial incentives will point medical device companies in the wrong direction. Tragically, the end result is that these abusive practices will undoubtedly multiply.

Some would counter: FDA will be there to protect against these abuses. FDA approved these devices, so why should we have juries second-guessing FDA's expert judgment?

As a result of chronic underfunding and weak leadership, FDA's ability to protect the public has plummeted. FDA's own Science Board issued a report saying that the agency is so starved of resources that "American lives are at risk."

But even if we were to get FDA every penny it needs, there would still be a compelling need for our system of state liability laws. That's because we operate on a model that relies on industry to innovate, research, develop, and market their medical products. FDA is not the one playing this role. So the device companies themselves will always know more about their products than the FDA.

And here's another problem: The clinical trials upon which FDA relies to approve drugs or devices are often too small to detect less frequent risks. Some risks can only be detected when the drug or medical device is used in the population at large. Without the risk of liability, companies would have little incentive to give FDA timely reports about these dangers. We have seen such risks arise, over and over, with devices and drugs. And, over and over, we've seen companies fail to disclose such risks to patients and physicians. Yet preemption gives companies a free pass on any safety problems discovered after approval.

All the resources in the world will not change the nature of this system. Congress needs to enact the Medical Device Safety Act of 2009 to correct this dangerous situation.

Let me briefly address another argument that is often made against the bill: that the bill will somehow destroy medical device innovation.

Keep in mind that patients have long had the ability to bring product liability cases under state tort law for all types of consumer products, including medical devices. That is, until the Supreme Court's decision last year. Until last year, medical device manufacturers had always operated with the knowledge that they might have to deal with lawsuits over injuries caused by their products — and, over the years, thankfully for all of us, device innovation has flourished.

The Medical Device Safety Act does nothing more than to simply return things to the status quo before last year's Court decision.

I am grateful to our witnesses for being with us today to discuss this issue, and I look forward to their testimony.