Opening Statement of Rep. Henry A. Waxman
Chairman, Committee on Oversight and Government Reform
Should FDA Drug and Medical Device Regulation Bar State Liability Claims?
May 14, 2008

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

Currently, when Americans are injured by any sort of defective product, they have a remedy. In most states, they can sue the manufacturer of that product for damages in state court.

Under a radical legal doctrine being advocated by the pharmaceutical and device industries and the Food and Drug Administration (FDA), this would change. Patients hurt by defective drugs and medical devices would no longer have the ability to seek compensation for their injuries. This is known as "preemption."

The result is that one of the most powerful incentives for safety — the threat of liability — would vanish.

One of our witnesses today describes the case of Joshua Oukrop, a 21-year-old college student who died in 2005 when his cardiac defibrillator malfunctioned. Joshua's device failed because of a design flaw. The manufacturer knew about this flaw at the time of Joshua's death, but neither Joshua, his physician, nor his parents did.

Three years elapsed between the time the manufacturer first learned of the defect and the time the manufacturer withdrew the defibrillator from the market. All the while, doctors continued to implant this device known to the company to be defective. Ultimately, the defect was linked to seven deaths.

In the lawsuits that followed, the manufacturer argued that it should be immune from liability because FDA had approved the defibrillator. This type of argument received a significant boost when the Supreme Court ruled earlier this year that FDA approval of complicated medical devices preempts most liability claims.

Think of the message that the manufacturer is trying to send: even if a company withholds information about potentially fatal defects from physicians, patients, or the FDA, it is still immune from liability for its actions.

This morning we will have two expert panels to help us understand the implications of this legal doctrine of preemption. We will also have a chance to question FDA about why it is now taking the side of the manufacturers on this crucial public safety issue.

For decades, FDA believed that state liability cases actually helped the agency regulate drugs and medical devices. But under the Bush Administration, FDA has reversed course. Now FDA advocates that once a product receives FDA approval, the manufacturers should be absolved of responsibility for injuries caused by their products.

This is exactly the wrong time for FDA to be saying: "Trust us."

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

But even with an FDA with more funding and better leadership, there would still be a compelling need for our system of state liability laws.

Some drug and 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.

If manufacturers face no liability, all the financial incentives will point them in the wrong direction, and these abusive practices will multiply.

And there'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.

All the resources in the world will not fix these inherent problems.

Patients who are injured by approved drugs and devices deserve compensation to help them deal with their permanent disabilities, their inability to work, and their costly medical procedures. But the only way patients can obtain compensation is to bring a lawsuit under state law.

Today we will be considering a fundamental question with high stakes for everyone in America who depends on drugs and medical devices: Should the companies that produce these products be absolved of their legal obligation to ensure the safety of their products?

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