

Statement of

# The Honorable Patrick Leahy

United States Senator  
Vermont  
September 12, 2007

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Chairman, Senate Judiciary Committee  
Hearing on "Regulatory Preemption:  
Are Federal Agencies Usurping Congressional and State Authority"  
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Today the Committee focuses on a little-known abuse of Executive authority that threatens devastating consequences for American consumers. Diana Levine was a successful musician in Vermont. She and her husband performed and recorded children's music. A few years ago, she sought medical treatment at a local clinic for nausea and was injected with an antihistamine. A subsequent infection resulted in gangrene and, tragically, Diana had to have her arm amputated.

She filed a common law negligence claim at her local courthouse against the drug's manufacturer. A jury awarded her \$2.4 million in economic damages and \$5 million in non-economic damages for her life-altering injuries. The drug company defendant appealed. The Vermont Supreme Court upheld the verdict and judgment upon review.

This tragic case demonstrates how our civil justice system can work. It also reveals a practice by this Administration to usurp laws through federal regulations at the expense of consumers. In this case, the drug company has not accepted the jury findings and decisions of the Vermont courts. Instead, it is seeking review from the United States Supreme Court because it argues that federal regulation of the drug's label should prevent even the filing of the suit for these injuries.

In this case, the Vermont Supreme Court held that the FDA labeling rules create only minimum requirements, and that the rules are not intended to and do not immunize drug companies from liability. I agree with the Vermont Supreme Court. But I fear that some on the United States Supreme Court will follow the lead of the Bush Administration and try to throw Diana out of court -- just as it did Lilly Ledbetter last year in a terribly cramped legal opinion written by Justice Alito that prevented redress for employment discrimination.

Diana's story illustrates how an obscure legal theory called "implied preemption" is being invoked to shield corporations from culpability and prevent injured Americans from obtaining redress for their injuries.

Today's hearing will examine the Bush Administration's efforts to assist corporations in this effort and override State laws that protect Americans. Just yesterday, a judge appointed by this President struck down a New York City law requiring fast food supposedly conflicted with federal regulations. Ironically, President Bush once told a group of governors that the role of the federal government is "not to impose its will on states and local communities . . . it's to empower the states and people and local communities to be able to realize the vast potential of this country." That rhetoric rings hollow when the record shows clearly his Administration's attempt to grant corporate defendants blanket civil immunity by aggressively preempting State law in the course of issuing administrative regulations.

In addition to concerns about the Administration's actions threatening principles of federalism, Senator Specter and I joined to voice our concern about how the Administration's efforts in this regard violate powers assigned to Congress. On November 17, 2005, we wrote to the National Highway Transportation Safety Administration about a proposed agency rule on "roof crush standards" that sought to preempt numerous State laws, and ultimately weaken consumer

protections for Americans. Senator Specter and I pointed out in our letter that it appeared the federal agency was plainly acting beyond the authority granted to it by Congress in the Transportation Equity Act. Unfortunately, the federal agency's response did nothing to address our questions about its authority to override State laws that may compensate motorists critically injured in car accidents. Those roof crush regulations are just one example of at least a dozen issued by the Consumer Product Safety Commission, the Department of Homeland Security, the Federal Drug Administration and other federal agencies that are being used to shield drug and other product manufacturers from liability without congressional action.

The Administration's concerted effort to thwart effective consumer protection and to remove the incentive to improve safety beyond the minimum standards set by regulatory agencies reminds me of its politicizing of the Justice Department. Just as we have witnessed improper political considerations undermine our federal law enforcement agency for partisan gain, we are now witnessing agency rulemaking turned into a mechanism to immunize powerful corporations at the expense of ordinary Americans. Rather than issuing regulations based on facts and science to benefit the American people, the process has apparently been hijacked. The intended result of this politically-motivated version of rulemaking not only slams the local courthouse door shut on injured victims but it prevents State law, State regulators and State courts from protecting their citizens.

Our nation's civil justice system serves not only to compensate those who have been injured by misconduct but to deter future misconduct. For hundreds of years that system has provided an effective incentive for manufacturers to improve safety. That is now being threatened by this aggressive legal theory. As several of today's witnesses suggest, when this Administration could not get Congress to legislate its anti-consumer agenda, it acted unilaterally through its executive agencies.

Principles of federalism and the separation of powers are crucial to our constitutional democracy. When one branch begins to encroach upon the constitutional responsibilities of another, this should concern not just members of Congress, but all Americans. When this Administration attempts to override the efforts of State authorities to provide meaningful health and safety and consumer protections, all Americans are more vulnerable. I am glad to have a distinguished panel of witnesses today to shed some light on this important issue.

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