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Trial Lawyers Association

Talking Points on: Federal Preemption

Introduction. Thwarted on many fronts, the “tort reformers” have stealthily implemented a new tactic towards shutting down courthouse doors through federal preemption. Preemption measures defy Congress and trump states’ rights. The preemption creep has adversely affected our safety in many ways, even involving threats of terrorism.

While Congress is expressly granted power under the Constitution to enact federal laws that supersede state laws, federal regulatory agency bureaucrats and courts have taken the unprecedented step of creating rules that preempt state law and state tort remedies. This practice, called preemption, usurps the authority of Congress, state legislatures, and state courts and is harmful to American consumers. Agencies seeking preemption are doing so without Congressional or constitutional authority.

Five Top Talking Points on the Dangers of Preemption

1. Eliminates accountability for corporate negligence involving dangerous products.
2. Endangers public safety and security, including even terrorist threats.
3. Doubles the danger of a disempowered bureaucracy—not only have they abdicated regulatory responsibility, but they are taking away civil justice rights as a last resort to protect public safety.
4. Violates constitutional reservation of rights for the states and steals away Congressional power.
5. While the Medtronic case is limited to medical devices, what’s next? Drugs approved through fraud? Toxic toys? Tainted foods?

Preemption eliminates accountability for corporate negligence of dangerous products.

Preemption eliminates accountability through the civil justice system while also removing incentives for manufacturers to make their products safer.

- In late February 2007, the U.S. Supreme Court ruled in *Riegel v. Medtronic, Inc.* to limit patients’ rights against negligent medical device manufacturers. In this case, Charles Riegel received a balloon catheter made by Medtronic which subsequently ruptured due to overinflation.

- This ruling seriously misconstrues Congressional intent and prohibits people from holding a negligent device manufacturer accountable if the product receives initial FDA approval, despite what the manufacturer may learn during the post-approval process.
- If a manufacturer of an FDA-approved device learns of a problem without notifying health officials and consumers, they will be immune from liability. More warnings are likely to cause fewer people to use the product; therefore, manufacturers rarely disclose new hazards unless compelled to do so. And, without tort suits triggering disclosure of hazard information, potential patients will be less likely to obtain crucial information before it is too late.

***Philadelphia Inquirer*, ,
2/26/08, "Medical Device
Immunity. FDA to the
Rescue?"**

"As a result, injured patients who want to sue for damages in state court are basically out of luck. The impact from the high court's decision was immediate. Hours after the ruling, a state court judge in Florida asked attorneys with cases involving Johnson & Johnson's drug-coated Cypher heart stent whether the lawsuits should continue. This is part of a pattern by the pro-business Roberts court that is undermining individuals' rights to seek justice through the courts."

The Institute of Medicine, the Government Accountability Office, and the FDA's own science board have all issued reports stating the FDA is incapable of protecting the country against unsafe drugs, medical devices, and food. Yet the U.S. Supreme Court's ruling in *Riegel v. Medtronic, Inc.* indicates that the FDA's regulations would trump state laws for certain medical devices.

Then, on February 25, the Supreme Court heard another case involving a challenge to a Michigan law which said that, while preemption may govern in most FDA cases, if a drug manufacturer engaged in fraud to obtain regulatory approval, the state case may continue. Pfizer argued that, even in a case of fraud, federal law trumps state law and civil justice. On March 4, in a 4-to-4 vote, the Supreme Court was unable to decide the case, leaving the Circuit Court opinion in place and allowing the lawsuit involving Rezulin to proceed. Chief Justice Roberts recused himself because he owns stock in the drug's manufacturer, Warner-Lambert Co.

State remedies are designed to complement, not conflict with, federal health and safety regulations. Congress should take the lead in ensuring federal regulatory agencies are following Congressional intent and not preempting state law and tort remedies.

CASE EXAMPLES – THE AGENCIES

Food & Drug Administration (FDA)

A 2006 FDA rule on drug labeling declared state tort law was preempted despite the fact that the agency had long held the opposite view.¹ In fact, when the rule had been proposed five years earlier, it had specifically stated “this proposed rule does not preempt state law.”² In a letter to the FDA, Senators Edward Kennedy and Chris Dodd, senior Democrats on the committee that oversees the FDA, criticized the agency for adding the language without allowing comments, and described the assertion of preemption as “a drastic reversal of policy with ... far-reaching implications.”³

The FDA’s drug labeling rule did not include the preemption provision in draft form. Only after the comment period had ended and the final version of the rule was issued was the preemption language publicly seen. There was an immediate outcry from Congress and states’ groups. In a letter to the FDA, Representative Lee Terry (R-NE) stated that because the “preemption language did not appear in any earlier versions of the proposed rule FDA’s response that no state or local government responded is disingenuous.”⁴ The National Conference of State Legislatures (NCSL) complained that “[i]t is unacceptable that FDA would not permit the states to be heard on language that has a direct impact on state civil justice systems nationwide.”⁵

The FDA’s turnaround on preemption was led by FDA Chief Counsel Daniel Troy, who was the most senior FDA executive from 2000 to 2002.⁶ Troy had previously received hundreds of thousands of dollars in compensation from tobacco and pharmaceutical companies whom he had represented, often against the FDA.⁷ In Troy’s three years at the FDA he held 129 meetings with representatives of industries with interests in the regulatory processes of the FDA.⁸ At an industry conference in 2003, Troy stated that he was the initiator of the amicus briefs filed on behalf of manufacturers, which had been the agency’s first vehicle for advocating preemption.⁹

New York Times, 2/21/08, “Justices Add Legal Complications to Debate on F.D.A.’s Competence”: “The politics of these cases are bewildering, said Susan P. Frederick, federal affairs counsel for the National Conference of State Legislatures. Republican administrations generally advocate limited regulation and deference to state oversight, Ms. Frederick said. But in what she said was its push to reduce court damage awards, the administration has written a blizzard of rules that do just the opposite.”

National Highway Traffic Safety Administration (NHTSA)

In 2005, NHTSA declared preemption of state law in preambles to proposed rules on seatbelts, roof-crush resistance, and rear-object detection systems.¹⁰ This marked the first time NHTSA had advocated preemption of state law, a concept it had specifically rejected previously.¹¹ Senators Arlen Specter and Patrick Leahy wrote to NHTSA criticizing the agency for claiming grounds for preemption without any congressional authority.¹² The letter pointed out, “In the section of the Transportation Equity Act directing NHTSA to initiate

rulemaking proceedings on roof resistance, we have been unable to find references to State tort law or language similar to that included in your agency’s proposed rule.” The letter went on, “We are interested to learn how NHTSA concluded that preemption of State law was the intent of Congress when it passed the Transportation Equity Act.”

The sudden adoption of preemption by NHTSA followed a similar pattern. The language was added at the last minute, to the chagrin of the agency’s own career staffers. A senior NHTSA official involved in the roof-crush rule later told the L.A. Times that the preemption issue had been handled in a way, “different from how we normally operated... [The rule] was dropped in from out of the blue.”¹³

Consumer Product Safety Commission (CPSC)

The CPSC also broke with its own 33-year history by declaring in the preamble to a long-awaited rule on mattress flammability that state law would be preempted.¹⁴ The CPSC mattress-flammability rule also did not mention preemption of state tort law in either the proposal or comment stage. One of CPSC’s own commissioners, Thomas H. Moore, publicly questioned the decision to slip the provision in at the “twelfth hour” and complained that the language was “buried in the tabs of the briefing package on our web site, [and] did not give it the public exposure it deserved.”¹⁵

Department of Homeland Security (DHS)

DHS claimed preemption of state laws in a 2006 rule regarding chemical facility safety. The rule left state and local communities with the responsibility for any necessary clean-up and emergency response, but no sway in preventing either from being necessary in the first place. The rule was proposed despite the fact that the Senate Homeland Security and Governmental Affairs Committee expressly rejected such an approach just a year earlier.¹⁶ Three Senators who were actively involved in the Congressional debate (Senate Homeland Security and Governmental Affairs Committee Chairman Joseph Lieberman, I-Conn; ranking Republican Susan Collins of Maine; and Sen. Frank Lautenberg, D-NJ, member of the Senate Homeland Security Appropriations Committee) expressed objections to the preemption language as violating Congressional intent.¹⁷ Senator Lieberman wrote to DHS Secretary Michael Chertoff to admonish him for the failure to recognize, or even discuss, the fact that Congress never intended state laws to be preempted. “State and local protections are critical companions to our effort at the Federal level and should not be displaced,” wrote the Senator. DHS, he said, “should remain silent on preemption, as Congress did and as it intended the Department to do.”¹⁸

DHS claimed that Congress’ decision to remain silent on the preemption issue granted the agency regulatory authority to decide whether to preempt.¹⁹ In doing so, DHS relied upon a statement from then-Chairman Barton who stated that the parties “consciously decided ... to not include a provision” regarding federal preemption.²⁰ However, DHS conspicuously

omitted Cong. Barton's further statement that the *courts* should decide preemption questions, not DHS: "We are fully confident that courts of law, if ever faced with such a question, will examine the State or local provision and decide for themselves whether it conflicts with or frustrates the purpose of Federal law."²¹

In her comments in response to the proposed rules, Republican Senator Collins reiterated Congress' position on preemption stating:

Congress chose not to address pre-emption in the bill we passed, reflecting a careful compromise on a difficult issue ... The proposed regulation on pre-emption grants to the department a responsibility Congress never authorized, on an issue more properly presented to the courts – the difficult task of resolving complex preemption questions.²²

In the end the proposed rule, rather than helping to protect citizens from terrorist attacks on chemical facilities, left the situation more vulnerable than before because the provisions allowed the delayed implementation of important state protections. The states have a compelling interest in protecting their citizens and several already have enacted chemical safety regulations, some of which are stricter than the rules proposed by the federal government. New Jersey, Maryland and New York, for example, had already taken steps to protect citizens from the dangers instead of waiting for the federal government to act.²³ These states took the steps necessary to protect citizens from potentially hazardous materials and should be permitted to continue to enforce those laws.

FEDERAL RAILROAD ADMINISTRATION (FRA)

In 2006, the FRA proposed a rule on railroad operation.²⁴ The FRA referred to provisions of the Federal Railroad Safety Act (FRSA), which preempt state laws. However, in the preamble to the rule the FRA went significantly further by offering its own interpretation that state common law was also preempted. In doing so the FRA went against court interpretations of the FRSA. The U.S. Supreme Court has stated that "the States' historic power to regulate train safety must not be 'superceded... unless that [is] the clear and manifest purpose of Congress."²⁵ In 2006 the Supreme Court reaffirmed this presumption when it stated that the Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of action."²⁶

Nothing in the preamble or the FRSA offered any alternative remedy for those who might be injured, leaving the costs to the public through tax-payer funded programs such as Medicaid and Social Security. Furthermore, with railroads able to avoid accountability for their negligence, the provisions stripped the incentive to maintain and repair tracks to prevent future accidents involving the transport of hazardous material.

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ENDNOTES

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³ Letter from Sen. Edward M. Kennedy & Sen. Christopher J. Dodd to Michael O. Leavitt, Secretary, Health & Human Services, February 23, 2006.

⁴ Letter from Rep. Lee Terry to Andrew C. Von Eschenbach, Acting Commissioner, FDA, March 31, 2006.

⁵ Letter from Sen. Steven J. Rauschenberger, President, National Conference of State Legislatures (NCSL) to Michael O. Leavitt, Secretary, Health & Human Services, January 13, 2006, available at:

<http://www.ncsl.org/programs/press/2006/060113Leavitt.htm>.

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