



## Overview of Corporate Immunity from Lawsuits

All three branches of government are facing critical issues that – depending on how it is resolved – could provide negligent corporations complete immunity from lawsuits. It's called federal preemption and it refers to situations in which federal regulation trumps state law. And, perhaps most surprising, Americans and many policymakers have never heard of it. When viewed through the context of unsafe products, preemption of state law means complete immunity from lawsuits for corporations and a full escape from accountability when they have knowingly injured and endangered Americans. Under this doctrine, the federal regulatory scheme provides the only remedies to injured Americans, which means that these individuals cannot be compensated for their injuries. The injured person's own personal insurers, such as a health insurance provider, because the cost of the injuries instead of the wrongdoers. Therefore, protecting consumer safety requires both government regulation and civil justice remedies. Regulations alone are not perfect and cannot anticipate every safety problem, which is why unsafe product lawsuits remain an important safeguard.

Complete immunity preemption is truly a stealth issue. It began quietly and without much fanfare only after President Bush was inaugurated in 2005 for a second term. Federal agencies – without any authority from Congress – started putting language in the preamble of regulations. Previously the preamble was used as the agency's interpretation of the regulation. Suddenly, the agencies shifted to use the preambles to change to law.

**The Bush Administration included complete immunity preemption language in more than sixty federal regulations.** To date, seven federal agencies – many times without any opportunity for public comment which is required by law (the Administrative Procedure Act) – have issued more than 60 rules with preemption language in the preamble to the rule.<sup>1</sup> The Constitution of the United States holds that the decision to preempt state law rests entirely with the United States Congress. Yet, some agencies have adopted these regulatory preambles in the absence of strong federal regulation or even in direct contradiction to Congress' direction. In addition, these new rules have not been voted on by any member of Congress, and in some cases not even revealed during the public comment period.

**The Bush Administration's preemption policy was a 180 degree reversal from prior history.** Over the past several years, the Food and Drug Administration (FDA), in many cases by way of the Department of Justice, has filed amicus briefs in at least five cases, as well as several statements of interest in pharmaceutical and medical device cases arguing that agency regulation trumps state law when their interests come into conflict. This is contrary to the position the FDA took following the 1996 U.S. Supreme Court case *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), whose outcome set the FDA's long-standing presumption against preemption. A year after *Medtronic*, then FDA Chief Counsel Margaret Porter wrote that, "FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection." Margaret J. Porter, *The Lohr Decision: FDA Preemption and Position*, Food and Drug Law Journal 52(1), 1997, 11.

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<sup>1</sup> The attached chart provides the status of each rule and the measures that need to be taken to ensure that the rules do not preempt state tort law claims.



The FDA's turnaround on preemption was led by FDA Chief Counsel Daniel Troy, who was the most senior FDA executive from 2001 to 2004. Troy had previously received hundreds of thousands of dollars in compensation from tobacco and pharmaceutical companies whom he had represented, often against the FDA. Jessica R. Dart, *Preemption Issues and Prescription Drug Litigation*, Mealey's Litigation Report, 1(8) (March 2005). Troy announced his resignation from the FDA in November 2004. In January 2005, Sidley Austin Brown & Wood LLP hired Troy to represent drug companies, including Pfizer. Most recently, Troy became the General Counsel for GlaxoSmithKline, a company that will continue to use Troy's preemption strategy.

**Scholars and lawmakers have criticized complete immunity preemption.** The move to curtail the authority of the states prompted criticism from commentators and insiders alike. Professor James T. O'Reilly of the University of Cincinnati College of Law, author of a widely cited treatise on food and drug law said, "The capture of the FDA by forces favoring judicial preemption is a travesty." Gary Young, *FDA strategy would pre-empt tort suits*, National Law Journal (March 1, 2004). Professor David Vladeck of Georgetown University Law School, who has practiced for more than 25 years in one of the nation's preeminent public interest law firms, explained that: "[i]f this trend continues, the public will soon have the worst of both worlds--agencies that don't protect them and judges who deny them access to the tort system when they are injured." David C. Vladeck, *Safety Last*, The Nation (Oct. 16, 2008).

Federal lawmakers also have criticized the Bush Administration's preemption strategy. The House Government Reform Committee held a hearing entitled: "Should FDA Drug and Medical Device Regulation Bar State Liability Claims?" and the Senate explored how medical device preemption is allowing manufacturers to obtain complete immunity from claims brought by injured consumers, no matter how serious the injuries. In addition, at a Senate Commerce Committee (Subcommittee on Consumer Affairs, Insurance and Automotive Safety) oversight hearing on the National Highway Traffic Safety Administration's roof crush rule, both Republican and Democratic Senators voiced their disapproval of the agency's attempts to preempt state common law rights and afford complete immunity to manufacturers.

**The Supreme Court will continue to weigh in on preemption policy.** In 2009, the United States Supreme Court will rule on the issue of preemption as it relates to prescription drug labeling in *Wyeth v. Levine*. The Supreme Court already issued its decision in *Riegel v. Medtronic, Inc.*, which held that state law claims regarding medical devices are preempted under the Medical Device Amendments (MDA) where the device manufacturer complied with federal requirements.

Eight years ago, Diana Levine was wheeled into a Vermont health clinic with a severe migraine headache and nausea. She ended up having her hand and half her forearm amputated because of the failure of Wyeth Pharmaceuticals to change its label so that only the safe ways of administering Wyeth's anti-nausea drug Phenergan were provided to the medical caregivers – even though Wyeth knew this method increased risk of contact with arteries and serious injuries. In its appeal, Wyeth argued that since the FDA had approved the drug's labeling instructions, victims such as Levine are barred—"preempted"—from being able to hold them accountable regardless of the fact that the company knew its warnings were not adequate.



## Summary of Bush Administration Regulations That Preempt State Law (as of November 17, 2008)

This chart lists the federal agencies that attempted to unlawfully preempt state tort law actions, the current status of each proceeding, and the measures needed to address these rules. These rules will need to be addressed by a combination of three actions: (1) January 20, 2009 memo to federal agency heads to stay pending or recently completed rules; (2) revised Executive Order 13132;<sup>1</sup> and (3) re-issuance of a notice of proposed rulemaking.

**(1) Rules requiring Jan. 20, 2009 memo – This will stay all non-final rules and allow the Obama Administration to issue a final rule that repudiates preemption of state tort law.**

### *Food and Drug Administration*

<u>Subject Matter</u>	<u>Citation</u>
Skin bleaching products	71 Fed. Reg. 51146 (2006).
OTC drugs in trial size packages	71 Fed. Reg. 74474 (2006).
OTC analgesics	71 Fed. Reg. 77314 (2006).
Sunscreen products	72 Fed. Reg. 49070 (2007).
Fatty acids	72 Fed. Reg. 66103 (2007).
Pregnancy and lactation labeling	73 Fed. Reg. 30831 (2008).

### *National Highway Traffic Safety Administration*

<u>Subject Matter</u>	<u>Citation</u>
Roof crush resistance <sup>2</sup>	70 Fed. Reg. 49223 (2005); 73 Fed. Reg. 5484 (2008).
Rearview mirrors	70 Fed. Reg. 53753 (2005).
Occupant protection	72 Fed. Reg. 54402 (2007).
Electric-powered vehicles	72 Fed. Reg. 57260 (2007).
Brake hoses	72 Fed. Reg. 57459 (2007).
School bus passenger seating	72 Fed. Reg. 65509 (2007).
Platform lifts	72 Fed. Reg. 72326 (2007).
Child restraint systems	73 Fed. Reg. 3901 (2008).
Windshield zone intrusion	73 Fed. Reg. 38372 (2008).
Occupant crash (remove sunset provision)	73 Fed. Reg. 52939 (2008).
Motorcycle brake systems	73 Fed. Reg. 54020 (2008).
Motorcycle helmets	73 Fed. Reg. 57297 (2008).

### *Federal Railroad Administration*

<u>Subject Matter</u>	<u>Citation</u>
Passenger safety equipment standards	72 Fed. Reg. 42016 (2007).
Incident reporting requirements	73 Fed. Reg. 52496 (2008).

<sup>1</sup> However, it is unclear whether courts will rely on a revised Executive Order to undo preemptive regulations.

<sup>2</sup> This rule also may require re-issuance of notice of proposed rulemaking.

*Pipeline Hazardous Materials Safety Administration*

<u>Subject Matter</u>	<u>Citation</u>
Crashworthiness protection of rail cars (joint rule with FRA)	73 Fed. Reg. 17818 (2008).
Enhancing rail transportation security (joint rule with FRA)	73 Fed. Reg. 20752 (2008).

*Department of Homeland Security*

<u>Subject Matter</u>	<u>Citation</u>
Chemical facility anti-terrorism	71 Fed. Reg. 78276 (2006); 72 Fed. Reg. 17688 (2007).

*Transportation Security Agency*

<u>Subject Matter</u>	<u>Citation</u>
Rail transportation security	71 Fed. Reg. 76852 (2006).

**(2) Rules requiring revised Executive Order 13132 – As explained in Section C of this Notebook, a revised Executive Order on federalism is needed to instruct agencies and courts regarding the Obama Administration’s preemption policies and to set policy where the Bush Administration has promulgated new rules that are now final and that include preemption language in the preamble of the rule. This Executive Order would help to nullify the preemption provisions included in regulatory preambles.**

*Food and Drug Administration*

<u>Subject Matter</u>	<u>Citation</u>
Physician labeling rule	71 Fed. Reg. 3922 (2006).
Noncariogenic sweeteners	71 Fed. Reg. 15559 (2006).
Raw fruits, vegetables, fish	71 Fed. Reg. 42031 (2006).
OTC nasal medication	71 Fed. Reg. 43358 (2006).
Calcium	72 Fed. Reg. 497 (2007); 73 Fed. Reg. 56477 (2008).
Nutrient content claims	72 Fed. Reg. 1455 (2007).
OTC dandruff products	72 Fed. Reg. 9849 (2007).
OTC laxatives	72 Fed. Reg. 14669 (2007).
Dietary sweeteners	72 Fed. Reg. 52783 (2007).
OTC contraceptives	72 Fed. Reg. 71769 (2007).
Skin protectant drug products	73 Fed. Reg. 6014 (2008).
Soluble fiber (coronary heart disease)	73 Fed. Reg. 9938; 73 Fed. Reg. 23947 (2008).
Toll-free number for reporting adverse events on labeling for human drug products	73 Fed. Reg. 63886 (2008).

*National Highway Traffic Safety Administration*

<u>Subject Matter</u>	<u>Citation</u>
Door locks and door retention components	72 Fed. Reg. 5385 (2007).
Electronic stability control	72 Fed. Reg. 17236 (2007); 73 Fed. Reg. 54526 (2008).



Head restraints	72 Fed. Reg. 25483 (2007).
Tire pressure monitoring	72 Fed. Reg. 38017 (2007).
Occupant crash protection	72 Fed. Reg. 40252 (2007).
Side impact protection	72 Fed. Reg. 50900 (2007).
Side impact (electric cars)	72 Fed. Reg. 51908 (2007).
Power-operated windows	73 Fed. Reg. 38338 (2008).
Lamps and reflective devices	72 Fed. Reg. 68234 (2007); 73 Fed. Reg. 50730 (2008).
Occupant crash protection (update to Appendix A)	73 Fed. Reg. 66786 (2008).

*Federal Railroad Administration*

<u>Subject Matter</u>	<u>Citation</u>
Railroad operating standards	71 Fed. Reg. 60372 (2006); 73 Fed. Reg. 8441 (2008).
Continuous welded rail	71 Fed. Reg. 59677 (2006).
Electronically controlled pneumatic brakes	72 Fed. Reg. 50820 (2007); 73 Fed. Reg. 61512 (2008).

*Consumer Product Safety Commission*

<u>Subject Matter</u>	<u>Citation</u>
Mattress flammability	70 Fed. Reg. 2470 (2005); 71 Fed. Reg. 13472 (2006).

**(3) Re-issuance of notice of proposed rulemaking – Where the agency’s preemption policy is included in the text of the rule, the agency should withdraw the current rule and re-open the proceeding by issuing a new notice of proposed rulemaking without the preemption language.**

*Food and Drug Administration*

<u>Subject Matter</u>	<u>Citation</u>
Supplemental application labeling rule	73 Fed. Reg. 2848; 73 Fed. Reg. 49603 (2008).

*National Highway Traffic Safety Administration*

<u>Subject Matter</u>	<u>Citation</u>
Designated seating positions	70 Fed. Reg. 36094 (2005); 73 Fed. Reg. 58887 (2008). In the event that the Obama Administration considers this a non-final rule given the pending Petitions for Reconsideration, the Administration can address this rule under Item #1 above.