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**BEFORE THE COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE**

HEARINGS ON

**REGULATORY PREEMPTION:
ARE FEDERAL AGENCIES USURPING CONGRESSIONAL
AND STATE AUTHORITY?**

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Mr. Chairman and Members of the Judiciary Committee, thank you for inviting me to be here today to share with you my views on whether federal regulatory agencies are usurping the authority of Congress and the States by asserting that federal regulatory action preempts state law. I am a Professor of Law at Georgetown University Law Center and also serve as Member Scholar with the Center for Progressive Reform. I have written extensively on regulatory preemption.¹ I commend the Committee for grappling with this important and timely issue, which raises fundamental questions about federalism, the allocation of power between Congress and the Executive Branch, and the importance of state law in disciplining the marketplace, providing consumers information about the risks of products they use, and assuring compensation to those injured through the fault of others.

In my view, recent assertions of preemption of state law by federal regulatory agencies are, in the main, nothing less than an effort by the Executive Branch to arrogate power that properly belongs to Congress. Displacing state law is no trivial matter. Our federalist system of government is based on the premise that federal and state law can generally comfortably coexist. And for most of our nation's history, state tort and damages law has served as a background to state and federal regulatory law. That makes sense. At its core, tort law serves a complementary purpose to direct government regulation. Regulation seeks to prevent injuries, weed out products

¹ Submitted along with this testimony are a White Paper I prepared jointly with other scholars with the Center for Progressive Reform entitled *The Truth About Torts: Using Agency Preemption to Undercut Consumer Health and Safety* (CPR White Paper # 704, July 2007) and a recent law review article I wrote that focuses on medical devices, David C. Vladeck, *Preemption and Regulatory Failure*, 33 *Pepperdine L. Rev.* 95 (2005). My recent writings on preemption also include a book chapter, *PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION* (William Buzbee, ed., Cambridge Univ. Press 2008) (forthcoming); and a law review article co-authored by former Food and Drug Administration Commissioner David A. Kessler, M.D., *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 *Geo. L.J.* ____ (2008) (forthcoming).

that are unsafe or ineffective, and reward innovation. Tort law serves related but different functions — it compensates those injured through the fault of others, alerts the public about unforeseen hazards, and deters excessive and unwarranted risk taking.

Consider the following example. When the *Titanic* set out on its maiden and final voyage on April 10, 1912, it was in full compliance with applicable regulations regarding the number of lifeboats it had to carry, which had been set in 1884 by the British Board of Trade when the largest vessel afloat was one-quarter the *Titanic*'s size. The *Titanic* carried sixteen lifeboats, with a maximum capacity of 980 people, although it had on board 2,227 passengers and crew. When the *Titanic* hit an iceberg and sank, over 1,500 people perished. The *Titanic* example demonstrates the perils of relying on regulatory standards alone to define the appropriate level of care. When functioning well, a regulatory system prevents injury and rewards innovation. But all too often there are gaps in our regulatory process that jeopardize the public's safety. That is certainly true today, where one only needs to read the day's headlines to see examples of regulatory failure and ossification.

To be sure, the Constitution's Supremacy Clause recognizes that, when federal and state law conflict, state law must give way, and there are instances when state law must yield in order to achieve federal objectives. The question before this Committee is which branch of government should decide when federal law should displace state law — Congress or the Executive Branch.

The Constitution supplies the answer to that question: Decisions on whether to displace state law to achieve federal objectives are quintessentially legislative judgments that Article I,

Section 1 of the Constitution entrusts to Congress.² Federal administrative agencies do not have the power to regulate with the force of law, absent a clear and express delegation of that authority from Congress. This directive takes on special force because Congress stands alone as the constitutional body structured to accommodate state interests. For these reasons, a regulatory agency may exercise preemptive authority if, but only if, the agency has been explicitly delegated that power by Congress, and does so in a way that is faithful to Congress’s mandate.³

In the past few years, however, regulatory agencies have routinely, and in my view, wrongly, claimed that federal regulatory action broadly preempts state law. I want to be clear at the outset about what I find objectionable about this practice. It is not the agency’s act of *declaring* its views on preemption. That is desirable and required. Executive Order 12,988 directs agencies, when issuing regulations, to “specif[y] in clear language the preemptive effect, if any, to be given to the law.”⁴ Executive Order 13,132 further instructs agencies to construe federal law to preempt State law “only where the statute contains an express preemption provision or there is some other clear evidence that Congress intended the preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.”⁵

The problem that I see is that agencies are going well beyond what is called for in these

² “All legislative Power herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.”

³ See *Gonzales v. Oregon*, 126 S. Ct. 904, 195-16 (2006).

⁴ 61 Fed. Reg. 4729, 4731 (Feb. 7, 1996).

⁵ 64 Fed. Reg. 43,255, 43,257 (Aug. 10, 1999).

Executive Orders — that is, to identify the preemptive effect of the governing statute or regulation promulgated pursuant to authority delegated by the governing statute. Agencies are also ignoring Executive Order 13,132’s mandate to avoid preemption when at all possible. Instead, agencies are attempting to stake out the scope of preemption with little or no guidance from Congress. In so doing, agencies have strayed from their proper function of *applying* the law as defined by Congress into the constitutionally impermissible role of *making* the law on their own — untethered by guidance from Congress, unconstrained by the political process, and using backdoor means that escape serious oversight — all in an effort to eliminate state law.⁶

There are three threads that tie the actions of these agencies together. First, as just noted, none of the statutes the agencies administer explicitly bars tort claims. Indeed, in one case, the governing statute has no preemption provision at all, and in two others, the agency’s governing statute contains a “savings clause” reflecting Congress’ determination to preserve state law. For this reason, the agencies are not making what lawyers call “express preemption” claims. Instead, the only preemption argument available to the agencies is that state law claims are *impliedly*

⁶ It should be noted that recent Supreme Court decisions have played a role in encouraging agencies to set forth their position on preemption as a way of influencing the outcome of private litigation. For instance, in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), the Court found preempted a claim by a woman injured when her car crashed into a tree. The car was outfitted with a shoulder belt, but no airbag, and Ms. Geier claimed that the omission of an airbag was a design defect. The Court rejected that argument on conflict preemption grounds, based on the government’s contention that the Department of Transportation had decided to phase-in airbags and a ruling in Ms. Geier’s favor would conflict with the agency’s decision. And in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court suggested that an agency’s views on preemption were entitled to consideration by the Court. But the Court has not resolved the question of what degree of deference, if any, should be accorded to an agency’s views. My colleague at the Center for Progressive Reform, Professor Nina Mendelson, has argued that agency views on preemption should get minimal deference. *Chevron and Preemption*, 102 Mich. L. Rev. 737 (2004).

preempted because they either actually *conflict* with federal law or erect an impermissible *obstacle* to the achievement of federal objectives.⁷ Conflict preemption claims are very difficult to sustain because the legal test is demanding. The agency must show an actual, irreconcilable conflict — not simply the burden of paying an adverse judgment.⁸ For a conflict preemption claim to succeed, the agency has to show that a regulated entity cannot comply with specific federal and state requirements at the same time.⁹ That is a very heavy burden that agencies cannot meet. For that reason, agencies do not make explicit claims of conflict preemption but instead place their emphasis on obstacle preemption.

But obstacle preemption requires a clear-eyed appraisal of whether state law in fact imposes a barrier to the attainment of federal objectives. And the agencies apply a myopic, one-sided test that focuses only on the theoretical problems that could arise (but have not arisen) with the concurrent application of federal and state law. Under governing law, that is plainly not enough. As the Supreme Court made clear in *Medtronic* and *Geier v. American Honda Motor Corp.*,¹⁰ for an agency to sustain an obstacle preemption claim, there must be a particularized showing that state law *in fact* impedes the attainment of federal objectives. Preemption determinations may not be based on abstract concerns and dire predictions. There must be *evidence* of interference. Yet in no case has an agency assertion of preemption been based on

⁷ See, e.g., *United States v. Locke*, 529 U.S. 89, 109 (2000); *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873-74 (2000).

⁸ *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 445 (2005).

⁹ *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

¹⁰ 529 U.S. 861 (2000).

evidence of actual interference.

Second, in arguing in favor of obstacle preemption, agencies ignore the benefits that flow from traditional tort litigation. If the question that an agency has to answer is how best to fulfill the goals set for it by Congress, then the agency must also consider whether state tort litigation *advances* those goals. No agency has done that, even though, long before there were agencies, we depended on tort law to safeguard us from dangerous products, to compensate those injured through the fault of others, and to provide an early warning system about newly emerging risks. Agencies also fail to come to grips with the effect of regulatory ossification. It now takes years, or at times, decades, for agencies to promulgate regulations, and often even longer to revisit older, out-of-date regulations. All too often, an agency's first regulation on a subject is its last. But outdated regulations enshrine obsolete requirements and stifle the development of newer and better protections. Tort law, by contrast, is dynamic and responsive to technological advances that can better protect consumers. The Supreme Court has often highlighted the beneficial interplay between tort litigation and regulation. "[T]ort suits can serve as a catalyst" to improve industry and federal regulatory practices by "aid[ing] in the exposure of new dangers" and addressing their consequences.¹¹

Third, agency decisions to extinguish common law remedies are not made in a transparent way. Agencies simply announce their conclusions in preambles. They do not go through notice

¹¹ *Bates*, 544 U.S. at 451 (quotation omitted). *Bates* is yet another example of the Administration's pro-preemption push. In that case, the government abandoned its no-preemption position asserted before the Court only five years earlier, to argue that the Federal Insecticide, Fungicide, and Rodenticide Act broadly preempted state law. The Court called "particularly dubious" the government's claim that the Act set forth a "nonambiguous command" to preempt. *Id.* at 449.

and comment rulemaking to formulate their positions, even though, in the past, agencies generally submitted regulatory proposals on preemption to the rulemaking process, thereby subjecting the agency's decision to public comment and ultimately to judicial review.¹² Nor do agencies even make a pretense of complying with Executive Order 13,132, which requires agencies to provide States and local governments with notice and an opportunity to participate in any proceeding that may affect State and local law. Indeed, the agencies' excuses for ignoring the notice and consultation requirements of the Executive Order range from the far-fetched to the disingenuous.¹³

It may be that, in some cases, there are sound arguments why federal law ought to displace state law. But let us have that debate in Congress, where all views can be aired, and those directly accountable to the American people can make decisions on the public record.

¹² Consider one example. Although the FDA now argues that all claims involving medical devices it has specifically approved are preempted, it has never rescinded its regulation governing preemption and medical devices, which limits preemption to positive state law. This regulation was developed through notice and comment rulemaking, thereby enabling affected members of the public and state and local governments to submit comments and otherwise engage the agency. 21 C.F.R. § 808.1(b); *see also* 42 Fed. Reg. 30383, 30385 (June 14, 1977); 43 Fed. Reg. 18,661, 18,663 (May 2, 1978).

¹³ The FDA could not comply with these requirements for its recent position on drug preemption because the preamble to its proposed labeling rule stated unequivocally that "this proposal does not contain policies that have federalism implications or that preempt State law." FDA, *Proposed Rule, Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products*, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000). The preamble to the final rule addresses preemption in detail and argues that FDA approval of drug labels broadly preempts state law. Nonetheless, the FDA claims that its pro-preemption conclusion in its final rule represents its "longstanding view" without even acknowledging that the proposal took the opposition position. The National Highway Traffic Safety Administration avoided complying with the Executive Order by asserting that its roof crush standard "would not have any substantial impact on the States" and therefore did "not have sufficient federal implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement." NHTSA, *Federal Motor Vehicle Safety Standards; Roof Crush Resistance, Notice of Proposed Rulemaking*, 70 Fed. Reg. 49,223, 49,245 (Aug. 23, 2005).

These decisions are simply too important to entrust to unelected and largely unaccountable senior political appointees, many of whom will simply return via the revolving door to the industry that they have overseen during their brief tenure in government.¹⁴

Unfortunately, there are many examples of agencies claiming for themselves the power to define the boundaries between federal and state law. Let us start with the Food and Drug Administration (FDA):

FDA and Drug Safety

Reversing a position held by the agency since its founding, the FDA has recently announced that its approval of a drug's label immunizes the manufacturer from failure-to-warn claims. The FDA now maintains that state failure-to-warn litigation threatens its ability to protect the public health. A determination in civil litigation that an FDA-approved warning fails adequately to warn of risks may force manufacturers to add warnings not approved by the FDA, or even warnings that the FDA considered and rejected.¹⁵ For that reason, the FDA asserts that most

¹⁴ This is far from an idle concern. The concept of agency capture is not new to Washington, D.C. For example, the architect of the Food and Drug Administration's new preemption position is a partner at a major law firm where he specializes in representing companies regulated by the FDA — the very companies that benefit from the agency's new preemption position. Prior to joining the FDA, he worked at a different law firm representing pharmaceutical industry clients. See, e.g., Anne C. Mulkern, *Watchdogs or Lapdogs? When Advocates Become Regulators*, The Denver Post, May 23, 2004. At NHTSA, career employees have suggested that the preemption language was inserted by political employees with ties to the auto industry. Myron Levin & Alan Miller, *Industries Get Quiet Protection from Lawsuits*, L.A. Times, Feb. 19, 2006. And career employees at the Consumer Product Safety Commission complain that the agency's leadership has been drawn from industry lawyers and others hostile to the agency's consumer-protection mission. See Eric Lipton, *Safety Agency Faces Scrutiny Amid Changes*, N.Y. Times, Sept. 2, 2007, A1.

¹⁵ FDA, *Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products*, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).

failure-to-warn litigation is preempted.

The FDA makes this claim even though Congress has declined to enact a preemption provision shielding drug manufacturers from failure-to-warn litigation, even though there has been a steady procession of failure-to-warn litigation both before and after the advent of the FDA with no evidence that any case has, in fact, interfered with the FDA's control of drug labels, and even though the federal Food, Drug and Cosmetic Act (FDCA) and FDA implementing regulations obligate manufacturers to modify drug labels to reflect newly-discovered risk information unilaterally, or with the FDA's permission.¹⁶

In an article that will soon be published in the *Georgetown Law Journal*, former FDA Commissioner David A. Kessler and I argue that the factors the FDA cites to support its new preemption position do not justify insulating labeling decisions from state failure-to-warn litigation. We make three overarching points:

First, the FDA's pro-preemption arguments are based on a reading of the FDCA that, in our view, is not only unsupported by the Act (which has no preemption provision), but also, if adopted, would undermine the incentives drug manufacturers have to change labeling unilaterally to respond to newly-discovered risks, or to seek labeling changes from the FDA. In fact, drug manufacturers have significant authority — and indeed a responsibility — to modify labeling when hazards emerge and may do so without securing the FDA's prior approval. The background possibility of failure-to-warn litigation provides important incentives for drug companies to ensure that drug labels reflect accurate and up-to-date safety information.

Second, the FDA does not have the resources to perform the Herculean task of monitoring

¹⁶ 21 C.F.R. § 201.80(e).

the performance of every drug on the market. The Institute of Medicine reported in 2006 that the FDA “lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future.”¹⁷ The FDA regulates products that amount to one-quarter of consumer spending in the United States,¹⁸ but it has only 9,000 employees nationwide.¹⁹ According to the most recent statistics, the FDA’s Office of New Drugs, which reviews new drug applications, employs over 1,000 physicians and scientists to review the approximately 100 new drug applications each year and to supervise post-marketing studies. In contrast, FDA’s Office of Drug Safety, the unit charged with monitoring adverse events associated with the 3,000 prescription drugs (and 11,000 drugs altogether) on the market, has about 100 professional employees.²⁰

¹⁷ INST. OF MED., *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC* 193 (National Academies Press 2006) *available at* <http://www.iom.edu/CMS/3793/26341/37329.aspx>.

¹⁸ FDA News, *The Food and Drug Administration Celebrates 100 Years of Service to the Nation* (Jan. 4, 2006) *available at*: <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01292.html>.

¹⁹ Food and Drug Administration, *An Overview of the FDA* (*available at* www.fda.gov/oc/opacom/fda101/sld015.html (last visited July 11, 2007)). In addition to drug safety, these employees also review applications to market new medical devices, monitor the safety of the medical devices on the market, inspect drug and device manufacturing facilities, inspect virtually all of the non-meat food products sold in this country (including a rising flood of imported foods), inspect food processing and storage facilities, regulate dietary supplements, oversee the safety of the blood supply and tissues for transplantation, regulate radiologic and biologic products, and regulate veterinary medicines and cosmetics. *Id.*

²⁰ *FDA’s Approval Process: Up to the Challenge?*, Hearings before the S. Comm. on Health, Education, Labor and Pensions, 109th Cong., 10 (Joint Statement of Sandra L. Kweder, M.D., Deputy Director, Office of New Drugs, and Janet Woodcock, M.D., Acting Deputy Commissioner for Operations, Food and Drug Administration, to the Committee on Health, Education, Labor and Pensions, U.S. Senate) (March 1 & 3, 2005) (reporting that for fiscal year 2005 the Office of Drug Safety had about 90 full time employees, but projecting for fiscal year 2006 an increase to about 110 full time employees) *available at*:

Third, state damages litigation helps uncover and assess risks that are not apparent to the agency during a drug's approval process, and this "feedback loop" enables the agency to better do its job. FDA approval of drugs is based on clinical trials that involve, at most, a few thousand patients and last a year or so. These trials cannot detect risks that are relatively rare, affect vulnerable sub-populations, or have long latency periods. For this reason, most serious adverse effects do not become evident until a drug is used in larger population groups for periods in excess of one year.²¹ Time and again, failure-to-warn litigation has brought to light information that would not otherwise be available to the FDA, to doctors, to other health care providers, and to consumers. And failure-to-warn litigation has often preceded and clearly influenced FDA decisions to modify labeling, and, at times, to withdraw drugs from the market.²²

Congress is, of course, acutely aware of the shortcomings in the FDA's ability to police the marketplace on drug safety, which have been driven home by the recent public health failures involving widely-prescribed drugs like Vioxx and Bextra. The FDA's current claim that it, and it alone, can single-handedly discipline this market is a difficult claim to accept. For the Committee's purposes, however, the key point here is that the agency's claim that it is authorized to direct the preemption of state law is not based on any mandate from Congress. Congress has

<http://www.fda.gov/ola/2005/drugsafety0301.html> (table).

²¹ See, e.g., *Hearings on Risk and Responsibility: The Roles of the FDA and Pharmaceutical Companies in Ensuring Safety of Approved Drugs, Like Vioxx*, Before the H. Comm. on Government Reform, 109th Cong., 23, 55 (2005) (testimony of Steven Galston, Acting Director, Center for Drug Evaluation and Research, FDA).

²² See, e.g., Lasser, *et al.*, *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 J. Am. Med. Ass'n 2215, 2218 (2002); Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 287 J. Am. Med. Ass'n 308, 310 (2007) (citing examples).

not delegated to the FDA the authority to define the borderline between federal regulation and state tort law. Nonetheless, the agency claims authority to cut off state law *now* because, at some point in the future, a state court *might* issue a ruling that undercuts the agency's regulatory authority. With all respect, that is a decision for Congress, not agency officials, and Congress should not countenance this usurpation of its authority.

FDA and Medical Devices

The FDA has also recently reversed field and now contends that approval of specific medical devices triggers the preemption provisions of the 1976 Medical Device Amendments (MDA) to the FDCA. The shift in positions here is as dramatic as it is for drug preemption. For more than twenty-five years after the MDA's enactment, the government formally opposed preemption for medical devices, including devices specifically approved by the FDA through the premarket approval process (so-called PMA devices).²³

As I explained in my article *Preemption and Regulatory Failure*, the case for preemption of medical device claims is especially weak. The Medical Device Amendments were enacted in the wake of the Dalkon Shield debacle to strengthen, not weaken, consumer remedies. At no point during Congress's extensive deliberations on the Amendments did anyone suggest that Congress should strip people injured by defective medical devices of their only recourse. Indeed, Congress was well aware of the massive litigation over the Dalkon Shield and cited it favorably in its deliberations.²⁴ Nor is the FDA's argument consistent with the narrow preemption provision in

²³ See generally Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 Food & Drug L.J. 7 (1997); U.S. Amicus Brief, *Smith Indus. Med. Sys., Inc. v. Kernats*, No. 96-1405, *cert. denied*, 522 U.S. 1044 (1998).

²⁴ See S. Rep. No. 94-33, at 1 (1975); H.R. Rep. No. 94-853, at 3-8 (1976)

the Act, which is aimed at displacing state laws and regulations that are out of step with the FDA's.²⁵ And the Supreme Court's decision in *Medtronic* strongly suggests that it will reject a preemption claim for medical devices, since the Court was, above all else, concerned with actual inconsistencies between federal and state mandates, not with an abstract potential for tension.²⁶ Given the long history of litigation over medical devices, both before and after the MDA, a showing of actual tension or conflict is, in my view, highly unlikely.

The FDA has also had to strain to suggest that its approval of a device is a warrant for its safety. In fact, premarket approval is a one-time licensing decision that is based on whether the device's sponsor has shown a "reasonable assurance" of safety. There is no provision in the MDA for devices to be periodically re-certified by the FDA. Unlike drugs, which are extensively tested, medical devices are often approved on the basis of a single clinical trial. Once on the market, the FDA engages in only limited surveillance and defective devices typically remain on the market until the manufacturer commences a voluntary recall.

The FDA's track record demonstrates the agency's inability to single-handedly protect the

²⁵ The preemption provision in the MDA has two parts: the first part, 21 U.S.C. § 360k(a), preempts state requirements that are "different from, or in addition to," those imposed by the FDA. The second part, 21 U.S.C. § 360k(b), sets up a procedure to permit states to get waivers from the first part to enable the state to impose stricter standards than the FDA. For that reason, the argument that the word "requirements" subsumes state tort law seems especially strained since there is no way for the waiver provision in subsection (b) to apply to rulings in tort litigation.

²⁶ 518 U.S. at 500-503. The Court in *Medtronic* rejected the company's argument that the preemption provision in the Medical Device Amendments to the Food, Drug and Cosmetic Act preempted state tort claims for medical devices approved by the FDA because they were substantially equivalent to devices on the market at the time the Amendments were enacted, or devices specifically approved by the FDA. Unlike with drug products, the Amendments do contain a preemption provision, although, in my view, it is limited to positive state law and not tort claims.

American people against defective and dangerous medical devices. Just in the past few years, we have seen massive recalls of defibrillators,²⁷ pacemakers,²⁸ heart valves,²⁹ hip and knee prostheses,³⁰ and heart pumps³¹ — all of which have exacted a terrible toll on the patients who

²⁷ Consider the case of the Guidant defibrillators, discussed in my Pepperdine article. Even after Guidant learned of serious defects in its defibrillators, and even after Guidant had developed a newer, safer model, it kept selling the defective defibrillators until forced by adverse publicity (generated by the death of a 21-year-old college student and tort litigation) to recall the devices. By that time, more than 24,000 of the defective devices had been implanted in patients, who then faced the daunting decision of whether to have replacement surgery. *See generally In Re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, 2007 WL 1725289 (D. Minn. June 12, 2007); Barry Meier, *FDA Expanding Inquiry into Heart-Device Company*, N.Y. Times, Aug. 25, 2005, at C3.

²⁸ Although Medtronic's 4004M pacemaker was approved by the FDA, it was later determined to be defectively designed. Some patients died when the pacemaker's defective lead failed; many patients were forced to undergo open-heart surgery to replace the defective lead. The courts have split on whether the plaintiffs' claims were preempted. *Compare Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005) (finding claims preempted) *with Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (finding no preemption).

²⁹ The St. Jude Silzone heart valve is another instructive case. This valve was approved on the basis of only scanty testing involving 20 human subjects. After St. Jude starting selling the valve, testing revealed that its silver coating not only did not protect against infection, but it also caused the valves to leak. Litigation publicized the risk and forced St. Jude to recall the problem valves, but not until they had been implanted in over 36,000 patients. *See generally In re St. Jude, Inc. Silzone Heart Valves Prod. Liab. Litig.*, 2004 WL 45503 (D. Minn. Jan. 5, 2004); *see also Bowling v. Pfizer*, 143 F.R.D. 141 (S.D. Ohio 1992) (class action involving 55,000 patient implanted with defective heart valve).

³⁰ The Sulzer hip and knee implant litigation underscores the need for tort law to compensate patients whose lives are disrupted and health jeopardized by defective devices. The FDA granted approval to these implants, but it soon turned out that a manufacturing defect kept the implants from bonding properly with the patients' bones. *In re Sulzer Hip Prothesis & Knee Prothesis Liab. Litig.*, 455 F. Supp. 2d 709, 712 (N.D. Ohio 2006). Testimony in litigation exposed the fact that the leakage was caused by unsanitary conditions at the manufacturing facility. *See J. Scott Orr & Robert Cohen, Messy Plant Made Faulty Hip Joints*, Times-Picayune, Aug. 13, 2002, at 1. Finally, in December 2000 Sulzer notified the FDA that it recalled about 40,000 defective hip implants, 26,000 of which had been implanted in patients. *In re Sulzer Hip Prothesis & Knee Prothesis Liab. Litig.*, 268 F. Supp. 2d 907, 911 (N.D. Ohio 2003). Even after the recall, Sulzer reprocessed 6,000 of the implants and sold them to patients;

have had them implanted in their bodies, and who often face the daunting prospect of explantation and replacement surgery. If the FDA gets its way, all of these people would be left without any remedy at all.³² Premarket approval is an important process intended to put an end to the marketing of devices without meaningful testing and with no assurance of safety. But while the PMA process provides minimum safeguards, it cannot replace the continuous and comprehensive safety incentives, information disclosure, and victim compensation that tort law has traditionally provided.³³

many of these devices failed as well. Many of the victims needed to undergo multiple additional surgeries to explant the faulty devices and replace them with more effective ones. Ultimately, due to a settlement, patients received some compensation for their pain and suffering, as well as compensation for each additional surgery that was needed to replace a defective implant. *See Orr & Cohen*. Again, under the FDA's approach, the agency's approval of the Sulzer device might well have absolved the company of liability.

³¹ *See Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (finding claim against manufacturer of device heart pump preempted; even though evidence showed that it was defectively designed and that the pump had been redesigned to correct design defect).

³² I do not mean to suggest that the FDA's pro-preemption campaign has been limited to drugs and medical devices, although they constitute the bulk of specific product regulation in which the agency engages. The FDA has gone so far to claim that its proposed regulation of sunscreen products, once finalized, will preempt not only conflicting state positive law (statutes and regulations), but also state common law claims. *See FDA, Sunscreen Drug Products for Over-the-Counter Human Use, Proposed Amendment of Final Monograph; Proposed Rule*, 72 Fed. Reg.49070, 47109-10 (Aug. 27, 2007). Perhaps the most egregious misuse of regulatory preemption is the FDA's claim that a consumer advisory posted on the agency's website, but not generally distributed, has a preemptive effect. The agency contends that a consumer warning it posted on its website alerting pregnant women of the risks of methyl mercury in tuna fish preempts a private action brought by a women who contracted severe mercury poisoning after making tuna fish a significant component of her diet. The district court accepted the company's argument that the FDA's consumer advisory cut off state law, and the case is now pending before the United States Court of Appeals for the Third Circuit. *Fellner v. Tri-Union Seafoods LLC*, 2007 WL 87633 (D.N.J. 2007), *appeal filed*, No. 07-1238 (3d Cir.).

³³ The Supreme Court has granted review in a case presenting the question whether the MDA preempts tort claims involving PMA devices. *Reigel v. Medtronic, Inc.*, No. 06-179.

NHTSA and Roof Strength

The campaign to engage in what one scholar has dubbed “preemption by preamble”³⁴ is not limited to the FDA. The National Highway Traffic Safety Administration now routinely claims that its regulatory actions preempt state law — both state statutory and regulatory law *and* state damages actions. NHTSA makes these claims even though its governing statute, the federal Motor Vehicle Safety Act (Safety Act), contains a “savings clause” that says that “compliance with” a NHTSA standard does “not exempt a person from liability at common law.” The Act also makes clear that NHTSA standards are *minimum* standards that manufacturers may exceed.³⁵ If that were not so, then all cars would have identical safety equipment, and the Volvo, which markets its cars on the basis of safety, would in all likelihood have gone the way of the Edsel.

Despite these clear signals from Congress, NHTSA now claims that its new standards preempt state law. Take one illustration of the problems with NHTSA’s new pro-preemption position.³⁶ More than 10,000 people die and another 24,000 are seriously injured each year in rollover crashes. After considerable prodding from Congress, NHTSA is finally on the brink of issuing a new standard on roof strength. Regrettably, NHTSA’s proposed standard would save fewer than 60 lives a year, mainly because most vehicles manufactured today meet or exceed

³⁴ Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DePaul L. Rev. 227 (2007).

³⁵ 49 U.S.C. §§ 30103(b)(1) & (e).

³⁶ NHTSA has also claimed that its new standard governing door locks preempts state common law, *see* NHTSA, *Federal Motor Vehicle Safety Standards; Door Locks and Door Retention Components, Final Rule*, 72 Fed. Reg. 5385 (Feb. 6, 2007); and NHTSA has argued that its proposed standard on designated seating positions and seat belt assembly anchorages will preempt state common law. 70 Fed. Reg. 36094 (June 22, 2005).

NHTSA's proposal. Nonetheless, NHTSA contends that its new standard will preempt all state law claims for roof crush, thereby cutting off the only redress injured consumers have and stifling innovation.³⁷ Nowhere has NHTSA satisfactorily explained how its position can be reconciled with Congress' clear instruction in the Safety Act to preserve common law remedies.³⁸

There are other reasons for concern over NHTSA's new preemption theory. To begin with, there are questions about NHTSA's capacity to regulate the massive automobile industry without the backstop of state damages law. NHTSA faces formidable challenges in doing battle with the industry because it is so profoundly outmatched. NHTSA is a tiny agency, with only a skeletal staff (625 employees), with limited information-gathering authority, and no demonstrated

³⁷ Survivors of rollover crashes often face serious brain and spinal cord injuries. Consider the example of Major Barry Muth, who was serving in the Army in Saudi Arabia when a rollover crash changed his life forever. He and a colleague were driving in a Ford Crown Victoria near Riyadh when the colleague, who was driving, lost control of the vehicle and ran it into a barrier. Apparently the left front wheel climbed the side of the barrier, causing the vehicle to flip. Both men were wearing seat belts. The driver sustained only minor injuries. But on Major Muth's side of the vehicle, the roof crush was so severe that he sustained serious spinal damage, leaving him a quadriplegic. Muth and his family sued Ford, alleging that the Crown Victoria provided inadequate protection in a rollover crash. Muth's expert testified that the roof had collapsed twelve to fifteen inches on the passenger side, and that a slight increase in the thickness of the steel in the roof structure would have reduced roof collapse to only one or two inches. Ford did not dispute this, but argued instead that the cause of injuries in rollover accidents is the fact that even a belted passenger in a rollover will drop five inches — more than the normal three-to-four inches of headroom in most cars. The jury sided with Major Muth, concluding that if the roof had buckled only a few inches rather than a foot or more, Muth would not likely have been seriously injured. Ford appealed, but the court of appeals rejected Ford's argument. *Muth v. Ford Motor Co.*, 461 F.3d 557 (5th Cir. 2006). Of course, if NHTSA gets its way, cases like Major Muth's will be preempted, and the families of the 10,000 people killed each year in rollover crashes, and the 24,000 more who are seriously injured, will have no recourse.

³⁸ NHTSA, *Federal Motor Vehicle Safety Standards; Roof Crush Resistance, Notice of Proposed Rulemaking*, 70 Fed. Reg. 49,223, 49,225-27, 49,245-56 (Aug. 23, 2005).

ability to act quickly in the face of emerging safety hazards.³⁹ It took the Ford Explorer/Firestone Tire debacle, and considerable prodding from Congress, to prompt NHTSA to revise its roof strength standard. Congress had to step in to require NHTSA to force manufacturers to install tire pressure warning gauges.⁴⁰ And NHTSA's fuel safety standard is at least thirty-five years out of date, even though fuel-fed fires are a leading cause of fatalities in vehicle crashes.⁴¹

NHTSA also has a track record of giving ground to placate the powerful automobile industry. Consider airbags. The majority in *Geier v. American Honda Motor Corp.*, discussed earlier, accepted at face value the agency's assertion that a gradual phase-in of airbags was important to develop "widespread public acceptance" of the device, and cited the Supreme Court's earlier ruling in *Motor Vehicle Manufacturers Association v. State Farm Insurance Co.*,⁴² to set out the history of airbag regulation. But the *Geier* majority says nothing about the Court's ruling in *State Farm* --- namely, that NHTSA had improperly succumbed to industry pressure to delay the introduction of airbags. Indeed, the *State Farm* Court famously observed that "[f]or nearly a decade, the automobile industry has waged the regulatory equivalent of war against the

³⁹ See David C. Vladeck, *Defending Courts: A Brief Rejoinder to Professors Fried and Rosenberg*, 31 Seton Hall L. Rev. 631, 638-39 (2001); see also Dept. of Transp. Fiscal Year 2008 Budget Request, at 70, available at: <http://www.dot.gov/bib2008/pdf/bib2008.pdf> (NHTSA staffing authorization).

⁴⁰ See *Public Citizen v. Mineta*, 340 F.3d 39 (2d Cir. 2003) (noting that Congress mandated tire pressure warning gauges be installed in passenger vehicles and overturning NHTSA rule because it wrongly adopted the approach preferred by industry).

⁴¹ See Vladeck, *Defending Courts*, *supra*, 31 Seton Hall L. Rev. at 638-40; Barry Meier, *Officials Did Little, Despite Report Saying U.S. Wasn't Cutting Fatal Car Fires*, N.Y. Times, Nov. 21, 1992, at A7.

⁴² 463 U.S. 29 (1983).

airbag,” and the Court faulted NHSTA for capitulating to industry rather than fighting to serve the public interest.⁴³

NHTSA may have bowed to industry pressure on preemption as well. Career NHSTA employees claim that the preemption language inserted into the roof strength standard was written by political employees at the behest of the auto industry.⁴⁴ Given how little the standard will accomplish in terms of reducing deaths and injuries from rollover crashes, some auto safety groups claim that the new standard’s main purpose is to provide a liability shield to industry, not enhanced protection to consumers.⁴⁵

Indeed, there is a powerful argument that the most effective discipline on the automobile industry has not been NHTSA, but has been state damage actions, which have forced the industry to develop roofs far stronger, and fuel systems far safer, than NHTSA’s outdated standards. This concern is reflected in the Safety Act itself. The “savings clause” stands as a clear signal that Congress intended to preserve the corrective justice function of state damage claims, and the minimum standards provision reflects Congress’s determination that manufacturers should compete on the basis of enhanced safety. None of those concerns is effectively addressed by NHTSA.

⁴³ 463 U.S. at 49.

⁴⁴ Myron Levin & Alan Miller, *Industries Get Quiet Protection from Lawsuits*, LA Times, Feb. 19, 2006.

⁴⁵ 35 BNA Product Safety Liability Reporter, *Roof Crush: Safety Advocates Discuss Adequacy of Roof Strength Standard, Seek Upgrade*, 695 (July 30, 2007).

The CPSC and Mattress Flammability

The Consumer Product Safety Commission (CPSC) has also joined the Administration’s drive for preemption of state law remedies for injured consumers. Like the FDA and NHTSA, it too has seen a substantial reduction in its personnel and resources over the years. At present, it has only 400 full-time staff and an annual budget of about \$63 million — less than half of its size when it was created. According to its former Chair and Executive Director, “the agency oversees about 15,000 types of products that are associated with about 27,000 deaths and 33 million injuries each year, costing the nation more than \$700 million annually.”⁴⁶

In the preamble to the agency’s long-awaited mattress flammability rule, the agency contends that, once in effect, the rule will displace state common law remedies.⁴⁷ As with the FDA and NHTSA, nowhere does the CPSC explain why it has reversed field and, for the first time in the agency’s history, taken the position that its regulatory action extinguishes tort law remedies. This claim is especially troubling because the preemption provision of the Flammable Fabrics Act is expressly limited to positive state law; it says that “no State or political subdivision of a State may establish or continue in effect” a flammability standard unless it “is identical to the Federal standard.”⁴⁸ But the CPSC was not deterred by the plain language of the law. Instead, the agency contends that the statute preempts all state “requirements” — even tort litigation — because that word appears not in the statute, but in one passage of the legislative history of the

⁴⁶ Ann Brown & Pamela Gilbert, *Reviving a Consumer Watchdog*, Wash. Post, Aug. 26, 2007, B7.

⁴⁷ CPSC, *Final Rule, Flammability (Open Flame) of Mattress Sets*, 71 Fed. Reg. 13,472 (March 15, 2006).

⁴⁸ 15 U.S.C. § 1203(a).

Act. This passage of a House Report suggests that CPSC *standards* preempt state *standards*, not state tort law.⁴⁹ This is the sum total of the legal analysis offered by the agency, which of course says nothing about *Congress's* intent to displace state tort law. Nor does the agency cite, let alone address, the many court rulings holding that the Act does *not* preempt state tort law.⁵⁰

The Commission's action was so out of line that Commissioner Thomas H. Moore filed a statement expressing his strong disagreement with the Commission's position on preemption. Commissioner Moore noted that "States are often pioneers in consumer protection, providing the impetus for new or improved federal regulation and California is usually on the forefront on consumer issues." Commissioner Moore was especially troubled because, although he saw the standard as a step forward, he did not believe in the CPSC's ability to set standards that would stand the test of time: "If we have gotten this standard right, then [lawsuits] against manufacturers should be a rarity and prevailing ones even less common. But if we have gotten it wrong, the fastest way we will find out is through people bringing lawsuits that challenge our conclusion."⁵¹

⁴⁹ See CPSC, *Final Rule, Flammability (Open Flame) of Mattress Sets*, 71 Fed. Reg. 13,472, 13,496 (March 15, 2006) citing H. R. Rep. No. 1022, 94th Cong. 29 (1976). The Supreme Court has repeatedly cautioned against using the language of legislative reports to deviate from the text of statutes. See, e.g., *Arlington Central School Dist. Bd. of Educ. v. Murphy*, 126 S. Ct. 2455 (2006).

⁵⁰ See, e.g., *Topliff v. Wal-Mart Stores East LP*, 2007 U.S. Dist. LEXIS 20533 (N.D.N.Y. 2007); *Davis v. N.Y. City Housing Auth.*, 246 A.2d 575 (N.Y. 1998); *Feiner v. Calvin Klein, Ltd.*, 157 A.D.2d 501, 502 (N.Y. 1990); see also *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025 (1st Cir. 1973) (addressing predecessor statute). The agency also overlooks the fact that manufacturers routinely settled these cases, which strongly suggests that they do not believe that they have a viable preemption defense. See, e.g., Marsha K. Seff, *Fanning the Fire for Safer Bedding*, San Diego Union-Trib., Feb. 1, 2000, at H1; Caroline E. Mayer, *Rules Would Limit Lawsuits*, Wash. Post, Feb. 16, 2006, D1.

⁵¹ U.S. Consumer Product Safety Comm'n, *Statement of the Honorable Thomas H. Moore on the Final Rule and Preamble for the Flammability (Open-Flame) of Mattress Sets* (Feb. 16,

Senator Daniel Inouye has made the same point about the ossification of safety standards: “I would hazard to guess that after this rule is finalized, the issue of home fire safety may not be addressed for several more decades, while science and the ability to make mattresses even safer will continue to evolve. Removing a significant incentive for industries to improve outside of meeting the federal standard may have a chilling effect on industries integrating new safety technology into their products.”⁵²

FRA and Railroad Safety

The Federal Railroad Administration (FRA) has also pushed regulatory preemption.⁵³ The FRA cites the express preemption of the Federal Railroad Safety Act (FRSA) as support for its broad preemption theory. But that statute preempts only a state “law, regulation or order” that covers the “same subject matter” as the federal rule. The reference to “law, regulation or order” is plainly a reference to positive state law — statutes, regulations and orders issued by regulatory bodies — not judicial rulings. This point is driven home by a separate savings provision in the Act, which says that “[n]othing in this section shall be construed to preempt an action under State law seeking damages for personal injury, death, or property damages alleging that a party . . . (C)

2006) <http://www.cpsc.gov/cspcpub/prerel/prhtml06/06091.html>.

⁵² Senator Inouye’s letter is quoted in Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DePaul L. Rev. 227, 233 (2007).

⁵³ The agency’s recent rulemakings claim that, once in effect, the rule will preempt common law remedies. See, e.g., FRA, *Passenger Equipment Safety Standards; Front-End Strength of Cab Cars and Multiple-Unit Locomotives*, 72 Fed. Reg. 42,016 (Aug. 1, 2007); FRA, *Railroad Operating Rules: Program of Operational Tests and Inspections; Railroad Operating Practices, Switches and Derails*, 71 Fed. Reg. 60,372 (Oct. 12, 2006); FRA, *Reflectorization of Rail Freight Rolling Stock*, 70 Fed. Reg. 144 (Jan. 5, 2005).

has failed to comply with a State law, regulation or order that is not incompatible” with the preemption provision.⁵⁴

Lest there be any doubt about *Congress’s* intention to limit preemption to cases in which there is an actual conflict between federal dictates and state common law, Congress recently enacted a provision in the Implementing Recommendations of the 9/11 Commission Act of 2007 (the 9/11 Act) which was intended as a “clarification” of the FRSA’s preemption provision. The 9/11 Act makes explicit that actions “under State law seeking damages for personal injury, death, or property damage” are preserved, and are preempted when, but only when, they are “incompatible with” federal mandates.⁵⁵ Notwithstanding this clear preservation of state damages law, the FRA now claims, in every rule that it is developing, that the rule, once finalized, will preempt any common law theory of liability.⁵⁶

Consider one particularly egregious case of overreaching by the FRA. Only three days after Congress passed the 9/11 Implementation bill, the FRA included significant preemption language in its notice of proposed rulemaking regarding passenger equipment safety standards. In the preamble the FRA claims that the rule preempts “any State law, regulation, or order, *including State common law*, concerning the operation of a cab car or [multiple-unit] MU locomotive as the leading unit of a passenger train” emphasizing that the “operation of cab cars and MU locomotives is a matter regulated by FRA, an not one which FRA has left subject to State

⁵⁴ See 49 U.S.C. §§ 20106(a)(2) and (b).

⁵⁵ See Implementing Recommendations of the 9/11 Commission Act of 2007, Pub. L. No. 110-53, § 1528 (entitled “railroad preemption clarification”), 121 Stat. 453, amending 49 U.S.C. § 20106.

⁵⁶ See n.51, *supra*.

statutory, regulatory, or common law standards on this matter.” The FRA claims to base this expansion of its preemption authority on Congress’ intent to “promote national uniformity and security standards.”⁵⁷ If the FRA issues a final rule, as currently drafted, and the courts defer to the FRA’s opinion in the rule’s preamble, victims of passenger train derailments, like the victims of the 2005 Metrolink commuter train accident in California, will be denied the ability to seek fair compensation.

On January 26, 2005, shortly after 6:00 am, a Metrolink train was traveling from Simi Valley, California, to downtown Los Angeles. The Metrolink train was in “push mode,” which means the locomotive was at the *rear* end of the train pushing three passenger cars ahead of it. The Metrolink train collided with another Metrolink train traveling in the opposite direction, causing both trains to derail.⁵⁸ This double train derailment resulted in eleven deaths and injuries, many quite serious, to approximately 150 passengers. Injured passengers and the families of those killed in the crash are currently suing Metrolink for compensation for their injuries or for the deaths of their loved-ones. There is no question that their claim is cognizable under California law. However, if the court defers to the FRA’s preamble claim of broad preemption, California law, and the law of every other state that requires railroads to exercise due care for the safety of passengers, will be swept aside. Passengers injured in similar crashes will also be left without a

⁵⁷ See, e.g., FRA, *Passenger Equipment Safety Standards; Front-End Strength of Cab Cars and Multiple-Unit Locomotives*, 72 Fed. Reg. 42016, 42,036 (Aug. 1, 2007)

⁵⁸ The details of this tragic crash are set forth in Ralph Vatabedian, *Crash Blamed on Confluence of Highly Improbable Factors*, L.A. Times, March 22, 2005.

remedy. This result cannot be squared with the FRSA or Congress's more recent *rejection* of a broad theory of preemption in the 9/11 Act.

* * *

I could go on. But as this list makes clear, this Administration has seized on regulatory preemption as a way to cut back dramatically on State law remedies for those injured by products and services Americans depend on every day for their health and well-being — medicines, medical devices, motor vehicles, the mattress on which we and our children sleep, and the commuter trains millions of us take to work every day. If the Executive Branch believes that these decisions represent sound policy, then let it come to Congress and have that debate in an open and democratic way. Let the Administration explain to the American public why people injured through the fault of others should have their right to compensation taken away by the federal government. But above all else, Congress should not let the Executive Branch arrogate these decisions to itself and then tell the American people that it is *Congress* that has determined to take away these rights.

I would be glad to take questions.⁵⁹

⁵⁹ I would like to acknowledge the assistance of Jennifer Dillard and Deanna Durrett, third year law students at Georgetown University Law Center, in the preparation of this testimony.