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Hearing: Federal Regulatory Jurisdiction

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U.S. Senate Committee on the Judiciary

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. 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 Brand 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 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, "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."

Section 1 of the Constitution entrusts to Congress. 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.

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." 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."

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

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 preempted because they either actually conflict with federal law or erect an impermissible obstacle to the achievement of federal objectives. 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. 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. 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, onesided 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., 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 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.

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 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. 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.

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.

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.

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. For that reason, the FDA asserts that most 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.

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 pro-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 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." The FDA regulates products that amount to one-quarter of consumer spending in the United States, but it has only 9,000 employees nationwide. 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.

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. 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.

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 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).

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. Nor is the FDA's argument consistent with the narrow preemption provision in the Act, which is aimed at displacing state laws and regulations that are out of step with the FDA's. 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. 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 American people against defective and dangerous medical devices. Just in the past few years, we have seen massive recalls of defibrillators, pacemakers, heart valves, hip and knee prostheses, and heart pumps -- all of which have exacted a terrible toll on the patients who 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. 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.

NHTSA and Roof Strength

The campaign to engage in what one scholar has dubbed "preemption by preamble" 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. 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. 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 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. Nowhere has NHTSA satisfactorily explained how its position can be reconciled with Congress' clear instruction in the Safety Act to preserve common law remedies.

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 ability to act quickly in the face of emerging safety hazards. 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. 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.

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

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. 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.

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
The CSPC 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."

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. 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." 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 Act. This passage of a House Report suggests that CPSC standards preempt state standards, not state tort law. 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. 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."

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."

FRA and Railroad Safety

The Federal Railroad Administration (FRA) has also pushed regulatory preemption. 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) has failed to comply with a State law, regulation or order that is not incompatible" with the preemption provision.

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. 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.

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 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." 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. 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 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.