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

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

SEPTEMBER 12, 2007

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

WEDNESDAY, SEPTEMBER 12, 2007

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The Committee met, Pursuant to notice, at 11:11 a.m., in room SD–226, Dirksen Senate Office Building, Hon. Patrick J. Leahy, Chairman of the Committee, presiding.

Present: Senators Leahy, Feingold, Whitehouse, and Specter.

OPENING STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM THE STATE OF VERMONT

Chairman LEAHY. Good morning. Unfortunately, with wrapping up one last bill on the floor and with the Appropriations Committee meeting one floor down on the defense appropriations bill, a number of us on this Committee are also on that Committee. Unlike members of the judiciary and other branches of Government, the Senators are not able to set their schedule with any kind of clarity in advance, and so we were delayed.

Today we will focus on a little-known abuse of Executive authority that threatens devastating consequences for American consumers. Diana Levine was a successful musician in Vermont. She and her husband performed and recorded children's music. A few years ago, when she sought medical treatment at a local clinic for nausea, she was injected with an antihistamine. A subsequent infection resulted in gangrene, and Diana, the musician, had to have her arm amputated.

She filed a common law negligence claim at her local courthouse against the drug's manufacturer. A jury awarded her $2.4 million in economic damages and $5 million in non-economic damages for her life-altering injuries—a figure that is certainly much, much lower than it might have been in some other States, but it seemed reasonable in our State. The drug company defendant appealed. The Vermont Supreme Court upheld the verdict and judgment upon review.

This tragic case demonstrates how our civil justice system can work. It also, though, reveals a practice by this administration to usurp laws through Federal regulations at the expense of consumers. In this case, the drug company has ignored the jury findings, ignored the Supreme Court finding. Instead, it is seeking review from the U.S. Supreme Court because it argues that Federal

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regulation—not Federal law but a Federal regulation—of the drug's label should prevent even the filing of the suit for these injuries, that somehow a bureaucratic regulation should close the courthouse doors to 300 million Americans.

In this case, the Vermont Supreme Court held that the FDA labeling rules create only minimum requirements, and that the rules are not intended to and do not immunize drug companies from liability. It would be one of the most amazing things in the world if it did. And I agree with the Vermont Supreme Court. But I fear that some on the U.S. Supreme Court will follow the lead of the Bush administration and try to throw Diana out of court—just as it did Lilly Ledbetter last year in a terribly cramped legal opinion written by Justice Alito that prevented redress for employment discrimination. It leads many to ask what kind of an insulated, cosseted life some judges lead, totally devoid from the realities of life of most Americans.

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

Today's hearing will examine the Bush administration's efforts to assist corporations in this effort and the Bush administration trying to override State laws that protect Americans. Just yesterday, a judge appointed by this President struck down a New York City law requiring fast food restaurants to include calorie counts on their menus because local law supposedly conflicted with Federal regulations. Ironically, of course, it is different when you are out campaigning and talking. President Bush once told a group of Governors whose political support he needed that the role of the Federal Government is "not to impose its will on States and local communities...it's to empower the States and people and local communities to be able to realize the vast potential of this country." Unfortunately, the reality catches up with the rhetoric, and the rhetoric rings hollow when the record shows clearly the administration's attempt to grant corporate defendants blanket civil immunity by aggressively preempting State law in the course of issuing administrative regulations.

Now, in addition to concerns about the administration's actions threatening the principles of federalism, Senator Specter and I joined to voice our concern about how the administration's efforts in this regard violate the powers assigned to Congress. On November 17, 2005, we wrote to the National Highway Transportation Safety Administration about a proposed agency rule on "roof crush standards" that sought to preempt numerous State laws and ultimately, of course, weaken consumer protections for Americans. Senator Specter and I pointed out in our letter that it appeared the Federal agency was plainly acting beyond the authority granted to it by Congress in the Transportation Equity Act. But, unfortunately, the Federal agency's response did nothing to address our questions about its claimed authority to override State laws that may compensate motorists critically injured in car accidents. Those roof crush regulations are just one example of at least a dozen issued by the Consumer Product Safety Commission, the Department of Homeland Security, the Federal Drug Administration, and

other Federal agencies that are being used not to protect consumers but to shield drug and other product manufacturers.

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

I have gone way over my time. I will put the rest of my statement in the record. But when this administration attempts to override the efforts of State authorities to provide meaningful health and safety and consumer protections, all Americans are more vulnerable.

[The prepared statement of Chairman Leahy appears as a submission for the record.]

Chairman LEAHY. Senator Specter?

STATEMENT OF HON. ARLEN SPECTER, A U.S. SENATOR FROM THE STATE OF PENNSYLVANIA

Senator SPECTER. Thank you, Mr. Chairman. This is an important hearing to focus on the congressional role in specifying whether there should or should not be preemption. We have a large body of State law, common law, opening remedies, and now we have the regulatory agencies coming in and on their own authority saying that their regulatory process preempts the State law. And it requires a very close look at precisely what is going on and whether we are looking at the rule of law or whether we are looking at the ideas of public policy which are expressed by a specific administration.

We have the case of the Consumer Product Safety Commission where the administration changes and there is a new Chairman and there is a totally different policy—picking up cases which had been decided, leading to very severe chastisement by the administrative law judge on the retreat from what is the rule of law. And we find that the Environmental Protection Agency comes out with regulations which modify the Clean Air Act on power plant emissions. You find the Children's Health Insurance Program is affected by what regulations are issued reflecting the policy position of the administration. And so often you have the judgments based upon so-called scientific evaluations which are highly suspect, whether the books are being cooked on these matters to provide a basis for a different regulatory process.

You have the global warming contest. Finally, there is an acknowledgment—or at least so it seems—that there is a problem on global warming. But a lot of tests were advanced of dubious scientific value, and now the President has said there is a problem on global warming.

You had the issue of the mercury pollution. You had the Surgeon General Richard Carmona testify about the White House directing him as to what to say about scientific findings. The Surgeon General is a scientist, not the Office of Management and Budget.

You have the Endangered Species Act. You have the Concerned Scientists, 60 leading scientists, including Nobel laureates, coming out with a very severe challenge to the findings of the National Ambient Air Quality Standards, the regulations on asbestos. And so it leads to the inference that there is politicization. If you take the public policy determination by one administration changing from another, that is what you call politicization. And we really are a Nation where the rule of law governs.

But you find the case involving 44,000 children riding in all-terrain vehicles who were injured, 150 of them fatally. And then you have groups like the National Association of Pediatricians, the emergency room doctors coming out wanting a change in the ATVs. And you have the agency with its general counsel, former counsel on the defense of ATVs.

So I think we really have traditionally and wisely looked to the courts to decide these matters as opposed to the regulatory process. But it is a very deep and involved subject, and if I had the time, I would read the very excellent statement prepared by my staff as my opening statement, which I will include in the record.

Chairman LEAHY. I will read it.

Senator SPECTER. I said to my superb lawyer—I have got a great law firm, by the way.

[Laughter.]

Senator SPECTER. And I said, after reading it, and taking some time to read it, I said, "What am I going to do with this?" I certainly cannot read it. And I am going to put it in the record with the hope that somebody will read it. And it is recommended reading—not for insomniacs. It will not put you to sleep. But we are dealing on some very, very complex issues, and I have tried to boil them down in the limited time allotted to a comparison of the rule of law versus public policy as one administration sees it. "Politicization" may be to harsh a word, or it may be too accurate a word.

I do want to say this, Mr. Chairman. The schedule is just extraordinary right now, as tough as I have seen it.

Senator Leahy and I were at the Appropriations Committee on the defense appropriation bill, and it is a bad meeting to miss. And I am sitting down with the military experts on the Webb amendment as to whether we have rotation of troops. So I am going to have to excuse myself early from the hearing, even though it is a very, very important one. But I will be following the transcript very closely.

Again, I thank you, Mr. Chairman, for your perspicacity in scheduling this important hearing.

[The prepared statement of Senator Specter appears as a submission for the record.]

Chairman LEAHY. I never even try to say that word because I get it all screwed up, but I thank you. And it is true, we do have excellent lawyers on both sides of the aisle here, another reason why some of us Senators consider ourselves constitutional impediments

to the staff running everything, and we might be a lot better off if they did.

Senator Feingold, did you wish to add anything to this?

STATEMENT OF HON. RUSSELL D. FEINGOLD, A U.S. SENATOR FROM THE STATE OF WISCONSIN

Senator FEINGOLD. I would like to make a brief statement, which my staff prepared for me.

[Laughter.]

Senator FEINGOLD. I want to thank you, Mr. Chairman, for holding this hearing. In recent years, this administration has quietly undermined the longstanding relationship between Federal public safety regulation and State common law. After decades of recognizing that State common law is an indispensable partner to Federal safety regulation, our Federal agencies are suddenly taking the position that State lawsuits and Federal regulation cannot coexist and that State lawsuits intended to compensate the victims of defective products must be preempted.

This is a 180-degree turnaround, and it is being implemented through a deliberate end-run around Congress. In at least one of these cases, Congress considered and rejected the idea of preempting State law. Likewise, agencies are ignoring their legal obligation under Executive order 13132 to avoid preemptive regulations where possible and to consult with States before they issue preemptive regulations.

This back-door dismantling of State tort law suggests that this administration's rhetoric about States rights is really just that—rhetoric. It also disserves the public. For all their good points, Federal agencies react slowly to industry developments and lack the power to subpoena product information from corporations. Cases brought by consumers in State courts can help ensure that safety standards keep up with the industry, and they can provide an invaluable source of information for regulators as well as for the public. They also provide a critical safeguard against so-called "agency capture," the all-too-common phenomenon of agencies falling under the influence of industries that they are supposed to regulate.

Even if Federal agencies worked perfectly, Federal safety standards are meant, in my view—and, I know, in the view of the people in my State—to be a floor, not a ceiling. When you prevent consumers from bringing cases in State courts, you remove a key incentive for manufacturers to provide safety features beyond the bare minimum. And make no mistake—people will continue to be injured by defective products. The only difference will be who pays the price. It will be the victim and the taxpayers instead of the corporation that caused the harm.

So I thank the witnesses for being here. And as Senator Specter indicated, it is a very busy morning, so I regret not being able to stay long, but I do feel strongly that this is an important matter requiring our close attention.

Thank you, Mr. Chairman.

Chairman LEAHY. Thank you.

Would the witnesses please stand and raise your right hand? Do you solemnly swear that the testimony you will give in this matter

will be the truth, the whole truth, and nothing but the truth, so help you God?

Ms. STONE. I do.

Mr. UNTEREINER. I do.

Ms. PEDDIE. I do.

Mr. DINH. I do.

Mr. VLADECK. I do.

Chairman LEAHY. Let the record show that all indicated yes. We will go in the order they are there. Donna Stone is a Republican member of the Delaware General Assembly and the President of the National Conference of State Legislatures.

Alan Untereiner is a partner in the Robbins, Russell law firm here in Washington, D.C., representing drug manufacturers in product liability suits.

Collyn Peddie is an attorney at Williams, Kherkher in Houston, Texas. She represents victims who have been injured by prescription drugs.

Viet Dinh is a professor of law at my alma mater, Georgetown University Law Center. He is a private consultant. He served from 2001 to 2003 as Assistant Attorney General for Legal Policy at the Justice Department and is no stranger to this room.

David Vladeck is a professor of law at Georgetown University Law Center—my alma mater, I add again, but that is not why they are here—where he teaches classes in Federal courts, civil procedure, and government processes.

Representative Stone, thank you very much for being here. Let's begin with you. Go ahead.

STATEMENT OF HON. DONNA STONE, STATE REPRESENATIVE, DELAWARE GENERAL ASSEMBLY, AND PRESIDENT, NATIONAL CONFERENCE OF STATE LEGISLATURES, DOVER, DELAWARE

Ms. STONE. Thank you. Good morning. I am State Representative Donna Stone, and the President of the National Conference of State Legislatures. I am very grateful to Chairman Leahy and Ranking Member Specter—I am so sorry. This is my first time—and the members of the Senate Judiciary Committee for inviting me to speak to you about the preemption crisis that is facing States today. I ask that my written testimony be incorporated into the record.

Chairman LEAHY. Without objection, so ordered.

Ms. STONE. Thank you, sir.

NCSL is troubled by the growing trend in Congress and the Federal agencies to pass legislation and promulgate rules that have a detrimental impact on States because of their intrusively preemptive nature. This trend is problematic. If not curbed, it will undermine the genius of our Federal system.

I am particularly alarmed by the emergence of agency regulatory actions that preempt without standing. Agency bureaucrats are unelected and have no real accountability to those impacted by an agency's preemptive regulations. This lack of accountability was the reason behind the 1999 revisions to Executive order 13132, better known as "the federalism Executive order." This order requires agencies to consult with State and local elected officials and their

national associations, like NCSL, whenever a proposed rule contains preemptive provisions. The goal of this consultation is for agencies to better understand the preemptive impact of the proposed rule and to minimize the preemption.

Unfortunately, the federalism Executive order does not have the force of statute and cannot be enforced. Agencies arbitrarily abuse and ignore it. Several recent rulemakings serve to illustrate this point, and they share these common elements:

One, enabling legislation contained no statutory authority granting the agency permission to preempt the established bodies of State law.

Two, there was no consultation conducted with State and local officials.

And, three, the agency acts sought to preempt significant areas of State law not within the purview of the Federal regulation.

The first agency to attempt this recently was the National Highway Traffic Safety Administration, or NHTSA. NHTSA tried to promulgated a roof crush rule it claimed had no State impact, warranting a consultation under the federalism Executive order, but then went on brazenly to state that, if finalized, the rule would preempt all conflicting State common law in this area, including tort law. The rule has not yet been finalized.

Shortly thereafter, the FDA finalized its 5-year-old Notice of Proposed Rulemaking on prescription drug labeling. Just prior to finalizing the rule, but long after the public comment period had closed, the FDA unilaterally decided to insert policy language expressly stating that the rule would preempt State product liability laws. Again, NCSL was not consulted, had no opportunity at that point to comment against the provision, and the FDA's enabling statute granted no authority to the FDA to preempt in this area.

The most recent agency action occurred earlier in 2007 when the IRS sought to issue a ruling that would have preempted State Constitutions and statutes defining what constitutes a legislative day. Once again, there was no consultation with NCSL and no statutory authority.

The problem of unwanted preemption is not solely limited to regulation, but is found also in recent acts of Congress. Examples include the REAL ID Act; the vaccine liability exemption, which prohibits any lawsuit under Federal law or any applicable State law from being filed for any claim arising from the use of the vaccine or the drug in question; and pending election reform legislation that would preempt State laws governing voting machine technology and election audit procedures.

NCSL believes that the federalism Executive order should be codified in statute to strengthen the intergovernmental relations and to enhance transparency in legislative actions undertaken by Congress. I have detailed a five-part legislative proposal in my written testimony that I think will ameliorate these preemption problems. The components of this solution include:

One, enhanced consultation—can I finish up?

Chairman LEAHY. Why don't you just name those parts? I have read that. They make a lot of sense. But go ahead and just name them.

Ms. STONE. Enhanced consultation with State and local government officials prior to the consideration of preemptive Federal legislation or regulation.

Two, a rule of construction that would pay due deference to State law when there is no express intent to preempt present law.

Three, an enforcement provision.

Four, legislative reporting of a bill's preemptive impact on States.

And, five, an agency impact statement to ensure that agencies engage in meaningful consultation with State and local elected officials or their national organizations.

I will stop there. Thank you very much.

Chairman LEAHY. Thank you very much, and your full statement is part of the record, Ms. Stone.

Ms. STONE. Thank you.

[The prepared statement of Ms. Stone appears as a submission for the record.]

Chairman LEAHY. Mr. Untereiner?

STATEMENT OF ALAN E. UNTEREINER, ATTORNEY, ROBBINS, RUSSELL, ENGLERT, ORSECK & UNTEREINER LLP, WASHINGTON, D.C.

Mr. UNTEREINER. Good morning Chairman Leahy, Ranking Member Specter, other distinguished members of the Committee. Thank you for the opportunity to testify today.

Chairman Leahy, you indicated that I was here today representing drug companies and have represented them and am currently representing them in litigation. That is not true. I am actually here on behalf of the U.S. Chamber of Commerce as well as the Chamber's Institute—

Chairman LEAHY. Is your microphone on, Mr. Untereiner? Is your microphone on?

Mr. UNTEREINER. It is on. I will try to speak up.

Chairman LEAHY. Thank you.

Mr. UNTEREINER. I am here on behalf of the U.S. Chamber and the Chamber's Institute for Legal Reform, and the views expressed today are my own, based on my experience in private practice and involvement in a wide range of preemption cases. I have submitted a written statement that discusses the doctrine of Federal preemption in detail and addresses a number of proposals that have been made for limiting that doctrine in its various forms, and I would like to ask that that written statement be made part of the record.

Chairman LEAHY. Without objection, it will be.

Mr. UNTEREINER. Thank you.

The doctrine of Federal preemption is critically important to the business community, to the creation of unified national markets, and to the health of our national economy. These benefits are often overlooked in the heated debates over whether a particular court decision that is controversial or a particular agency action that is controversial is correct.

We live in a sprawling and large country that is rich in many things, including Government. The multiplicity of Government actors below the Federal level ensures that businesses with national operations will be subject to complicated, overlapping, and sometimes even conflicting legal regimes.

These overlapping regulations have the potential to impose undue burdens on interstate commerce. When Congress exercises its unquestionable power to legislate preemptively, rather than merely concurrently with the States, by prescribing a set of uniform rules for the entire economy, it streamlines the legal system. It also reduces the regulatory burdens on business, lowers the barriers to new entry to small businesses, and helps to create a unified national marketplace for goods and services.

It is important to remember that many preemption schemes created by Congress also vest additional regulatory authority in an expert Federal agency. This ensures that preemption does not result in a regulatory vacuum. It also means that the legal rules governing complex areas of the economy or products are formulated by expert regulators with a broad national perspective and needed scientific or technical expertise rather than by decisionmakers—such as municipal officials, elected State judges, and lay juries—who have a far more parochial perspective and limited set of information.

Federal preemption of State law is an ordinary and ubiquitous feature of our scheme of Government. By virtue of the Supremacy Clause, each new State statute, each new Federal statute or regulation automatically preempts conflicting State and local law. Also, Congress has passed scores of statutes that contain express preemption clauses spanning a very wide array of areas, including the design and labeling of many types of specific products. These preemption schemes contain carefully crafted limitations and other provisions that accommodate the interests of State and local governments.

Reasonable people can and do disagree about such matters as the regulatory function of tort law and liability judgments, whether it makes sense to treat common law or tort law differently under a preemptive Federal regime, and whether preemption gives rise to serious federalism concerns or is instead fully consistent with the Constitution's structure.

Because reasonable people disagree, the courts in express preemption cases look to the actual language used by Congress to discern how Congress has resolved these issues in each particular case. There is no need to skew that inquiry with special new default rules pointing one way or another.

Criticisms of so-called obstacle preemption are unfounded. The Supreme Court has made clear that obstacle preemption flows directly from the Supremacy Clause. Like ordinary conflict preemption, obstacle preemption plays a vitally important role in ensuring the supremacy and the full effectiveness of all Federal laws against incursions by the States. Obstacle preemption does not vest too much discretion in judges or administrative agencies. True, it does require judges to identify the relevant congressional purpose or purposes and to decide whether those Federal purposes are being frustrated. But Congress often declares its purposes explicitly in a statute or in the accompanying legislative materials. In any event, the Framers intended that the Supremacy Clause would be enforced by the courts.

It makes little sense to disregard the views of an administrative agency concerning whether State or local law conflicts with or frus-

trates the purposes underlying a statute the agency is charged with administering. As Justice Stevens's opinion in *Medtronic* explained, an agency to which Congress has delegated authority to implement the statute is "uniquely qualified to determine whether a particular form of State law stands as an obstacle to the accomplishment and execution of the full purposes of Congress."

Finally, the Committee should keep in mind that the doctrine of Federal preemption applies to all Federal laws and the operation of all Federal agencies. Additional generalized limits on preemption would impair the ability of Congress and administrative agencies to bring about the many significant benefits that flow from preemptive statutes and regulations. Congress should not allow controversies over a limited subset of preemption cases or administrative decisions to drive far-reaching changes to this important area of law.

Thank you.

[The prepared statement of Mr. Untereiner appears as a submission for the record.]

Chairman LEAHY. Thank you. We will be getting back to that, but keep in mind we are not—I am not as concerned about cases where Congress very specifically preempts State law. It is something we should do rarely. But there are times when we do. I just do not agree when a Federal agency, not having been given the authority to preempt, directly or indirectly, suddenly does it on their own. At that point nobody is responsible. Ms. Stone, Senator Specter, Senator Whitehouse, and myself have to respond to our constituents, we have to respond to our States if we do something, if we vote for something. Somebody who has no responsibility to anybody other than the administration in power, it worries me if they are given too much authority. It is like these activist judges that we all worry about, and currently with the most activist Supreme Court I have seen in my lifetime.

Ms. Peddie?

STATEMENT OF COLLYN A. PEDDIE, ATTORNEY, WILLIAMS, KHERKHER, HART & BOUNDAS LLP, HOUSTON, TEXAS

Ms. PEDDIE. Thank you. Chairman Leahy, Ranking Member Specter, and members of the Committee, my name is Collyn Peddie, and I am lead counsel in three ongoing preemption battles in Texas and Pennsylvania involving thousands of Vioxx and vaccine claims. I am grateful to the Committee for allowing me this opportunity to give it a firsthand report from the front lines of those battles.

With alarming frequency, those injured by prescription drugs see their right to seek compensation and a day in court eliminated entirely by the preemption doctrine. For 90 years, the FDA maintained that its prescription drug regulations only provided minimum standards; therefore, it did not consider State actions which asserted higher duties to be in conflict with those regulations or preempted by them.

Beginning in 2002, however, the FDA aggressively asserted a new philosophy that FDA regulations provided both minimum and maximum standards for prescription drugs. State tort claims based on the failure to include in proposed warnings information that the FDA considered and rejected would, therefore, be impliedly pre-

empted. In 2006, the FDA formalized this policy in a preamble to its drug labeling regulations.

Although most courts have refused to defer to the FDA's pronouncement, a handful of courts have ignored Federal law and bedrock constitutional principles or relied upon the preamble to apply the implied preemption doctrine to preclude thousands of claims without trial or any consideration at all of their merits.

Ruby Ledbetter's case is a good example. As a result of taking Vioxx for a year and a half, this active, healthy grandmother suffered heart attack. She sued Merck for failure to warn her doctor of its potential cardiovascular effects. Although Texas law would have permitted Ruby to show that Merck had withheld from or misrepresented material information to the FDA during the Vioxx approval process and, therefore, that Merck was not entitled to assert FDA approval as a defense in her case, Judge Wilson found that her ability even to try to make that threshold showing was impliedly preempted and dismissed her claim. In the name of Congress, then, he immunized from suit in Texas even drug manufacturers who lie to the FDA to gain approval and potentially locked the courthouse door to thousands of pharmaceutical plaintiffs.

In Pennsylvania, Hannah Bruesewitz suffered a similar fate. While a normal toddler, Hannah received DPT vaccine. Within 2 hours, she was in convulsions and has suffered from seizures ever since. Ignoring language in the Vaccine Act that expressly preserves suits like Hannah's that involve vaccines for which there were safer alternatives, a Federal judge held that Congress intended to preempt all design defect claims and dismissed hers. Worse, a second Federal judge, relying in part on the FDA Preamble, would have dismissed as impliedly preempted Hannah's failure to warn claims too, even though Congress expressly preserved those claims as well.

Ruby's and Hannah's cases, therefore, reveal an emerging pattern of judicial and executive legislating, and nullification of laws permitting them to assert tort claims against drug companies. During the same period, however, the FDA has increasingly failed to enforce regulations designed to protect them. In one noteworthy instance, field inspectors revealed a corporate-wide problem involving the substitution of industrial nitrogen gas for medical oxygen. When nitrogen gas was pumped into an Ohio nursing home's oxygen delivery system, ten residents went into cardiac arrest and four died. Despite strong recommendations from field staff and the indictment of the company on negligent homicide charges, FDA officials ignored the matter for almost 2 years and took no enforcement action of any kind.

With FDA enforcement actions in free fall and private suits increasingly preempted, what must be done to protect the public?

First, Congress must make its intent clear. The FDA's pronouncements on preemption will be entitled to little or no deference in the face of clear expressions of congressional intent.

Second, Congress must increase its oversight of the FDA and other safety agencies. The U.S. Supreme Court in a Vermont case is poised to review cases addressing the question of whether to give agency assertions of preemption so-called Chevron or conclusive

deference. It is, therefore, critical that Congress police such statements now.

Third, Congress should consider limiting legislation for preemption. Congress should specifically define and restrict the circumstances under which it will permit preemption to be implied.

And, finally, Congress should consider passage of uniform statutory interpretation rules, including those addressing preemption. These laws are already in the common law. They should be codified. By providing more guidance to the court and agencies in interpreting Federal statutes, Congress can increase the likelihood that State and Federal courts will follow established principles and not legislate from the bench. New studies released just this week reveal that injuries for prescription drugs have increased dramatically in recent years. Unless Congress acts, and acts now, more citizens like Ruby and Hannah will be deprived of their day in court and any compensation at all for their injuries. Instead, these costs will be shifted entirely to the American taxpayer.

For these reasons, I urge Congress to adopt the recommendations outlined here, and I ask that my more extensive written testimony be included in the record.

Chairman LEAHY. Without objection, the testimony will be part of the record.

Ms. PEDDIE. Thank you.

[The prepared statement of Ms. Peddie appears as a submission for the record.]

Chairman LEAHY. Professor Dinh?

STATEMENT OF VIET D. DINH, PROFESSOR OF LAW, GEORGETOWN UNIVERSITY LAW CENTER, WASHINGTON, D.C.

Mr. DINH. Thank you very much, Mr. Chairman, members of the Committee. Mr. Chairman, thank you for having me here and thank you for being such a loyal alumnus of Georgetown University Law Center.

I must start with a note of full disclosure since we are in that spirit. My written statement, which is submitted for the record, is based upon and in some cases recycled from a series of articles I have written over the past decade on the question of preemption, and many of which I co-authored with Paul Clement, then my colleague on the Georgetown University Law faculty. And so, Chairman and members of the Committee and other witnesses, it is right to focus on this issue as one of longstanding concern and potential great constitutional and policy import in the past, present, and certainly in the future.

A number of considerations I want to use my limited time in order to highlight. That is, we all know Article VI of the U.S. Constitution declares the laws of the United States to be the supreme law of the land and that judges shall be bound thereby. And so when we are talking about preemption, especially when we talk about conflict preemption, what we are really talking about is supremacy—that is, Federal law is supreme to conflict State law. And so conflict preemption, true conflict preemption—that is, it is impossible to comply with both State and Federal law is simply a choice of law rule that is under operation by the text of Article VI of the United States Constitution.

The question of preemption, either express or implied, is, properly conceived, a method of regulation which Congress may employ pursuant to its power under Article I, Section 8, in order to regulate areas of Federal concern, most notably the regulation of interstate commerce. And so in that sense, when we are talking about preemption, one thing that we should note is that we start with a background, even though it was a very significant intrusion into State legislative prerogatives, as Ms. Stone has so cogently identified, but it works in the background of supremacy—that is, the Constitution set forth that Federal law shall be supreme. And as long as Congress acts within the scope of its power enumerated under Article I, Section 8, those laws would be supreme. I agree, however, that when Congress so acts, it should be very careful and only preempt when it deems necessary.

The next area of concern that the Chairman has raised is the difference between regulatory preemption versus statutory preemption. And here I think the unbroken line of Supreme Court precedent is clear and unchallenged and correct. That is, so long as Congress delegates the power to regulate generally to the agencies in their organic statute, then that implication of power, that grant of power also implies the methods with which to regulate, including to preempt where necessary by express provision within the regulation.

Of course, policies can change across agencies, across administrations, across administrators. When those policies change, they would be considered arbitrary and capricious unless accompanied by a well-reasoned explanation and, therefore, answering the Ranking Member's concern about the politicization or unwarranted reversals in courses of action.

To this extent, I do not think that Congress has much to worry about in terms of runaway agencies because Congress has ample authority to correct such runaway action or to correct the course on which the administrative train is headed. It can revise the organic statute to deny the power to preempt, if that is a specific area of concern. It can amend the underlying text of a statute to make clear that the preemption action is contrary to congressional intent. And, also, I would not object to and, indeed, I would support the codification of the federalism Executive order. As Paul Clement and I wrote in 1999, anything that forces—

Chairman LEAHY. Professor, it is easy to say we can always change the statute, but if they are following basically what is either spoken or unspoken administration policy of whatever administration, that means you have to get those changes past a Presidential veto, which means a two-thirds vote in both bodies. It is not quite as simple as—I agree with you on the basic theory. The reality is a lot more difficult than the theory.

Mr. DINH. Bicameralism and presentment do work a rather significant check on the legislative process, but I do think that it remains for Congress to have that tool. Anything that forces the Federal Government to stop, listen, and think about whether or not it is the proper forum to regulate and to displace State law I think is something to be advocated, which is why I support the codification of the federalism Executive order.

The only note with which I will end is that I think it is profound constitutional policy and interpretive mistake to adopt any type of clear statement rule that requires an express statement of preemption. Otherwise, there would not be a preemption of State law. As you have seen in the progression of Federal regulation in the last 50 years, this era of Federal regulation has brought a lot of great changes to our society and a lot of the changes that many people on the opposite of this argument would advocate. And I think that to throw the baby out with the bath water because of a temporal fear of abuse may be overreaching and an overreaction.

Thank you very much.

[The prepared statement of Mr. Dinh appears as a submission for the record.]

Chairman LEAHY. Professor Vladeck?

STATEMENT OF DAVID C. VLADECK, PROFESSOR OF LAW, GEORGETOWN UNIVERSITY LAW CENTER, WASHINGTON, D.C.

Mr. VLADECK. Good morning. Mr. Chairman, Senator Whitehouse, thank you very much for inviting me here to testify before you today.

I want to begin by commending the Committee for grappling with this important and timely question. The administration's campaign to use regulatory agencies to broadly preempt State law raises fundamental questions about federalism, the allocation of power between Congress and the executive branch, and the importance of State law in compensating people injured through no fault of their own, and spurring innovation.

Recent assertions of preemption by Federal agencies are, in the main, nothing less than an effort to arrogate to the executive branch power that properly belongs to Congress. Displacing State law is no trivial matter. Our federalist system is based on the premise that Federal and State law can comfortably co-exist, and for most of our Nation's history, State tort law has served as an important backstop to both Federal and State regulatory law.

At its core, tort law serves a complementary purpose to direct Government regulation. Regulation seeks to prevent injury and to weed out products that are unsafe. But there are very few Federal statutes that provide compensation for injured parties—very few—Price Anderson Act, the 9/11 Act. But typically, when Congress regulates, it leaves it to the States to compensate people injured through the fault of others. Tort law serves that function. It informs the public about unforeseen hazards, and it deters unwarranted risk taking.

Now, why should Congress care about this preemption campaign? First and foremost, the administration's policy is unsound. If you strip all the legalese that enshrouds the debate, what is going on here is that the administration is pushing silently and behind closed regulatory agency doors a public policy campaign that I do not think they could get through Congress.

Second, the Congress is being pushed as the party that is responsible for these wholesale displacements in State law. If you look at every agency pronouncement announcing broad preemption, they blame Congress. The argument is that "We are simply carrying out the will of Congress." So when the FDA preempts claims for drugs

or medical devices and says that people who are injured can no longer sue, Congress is the culprit. The executive branch is placing the responsibility squarely on your shoulders, where it ought not to be.

Third, in making these broad preemption claims, agencies are repudiating decades, at times, centuries worth of practice. These positions that are being set aside were set by their predecessors, Republicans and Democrats alike. The FDA's new position on failure-to-warn claims is contrary to the position taken by every administration since at least 1962 when this Congress passed the efficacy requirements of the Food, Drug, and Cosmetic Act.

Fourth, the Constitution makes it quite clear that the final say over when State law ought to be displaced is Congress's to make, not the executive branch. This is plainly an arrogation by the executive branch that Congress ought not to stand by and tolerate.

There have been many discussions about what can be done today. I do not share my colleague Professor Dinh's view that the process will sort itself out. For one thing, no agency has yet actually used the regulatory process as he describes to preempt State law. What has happened here is that although in the past agencies actually went through notice and comment rulemaking to develop regulations that set forth the borderline between State and Federal law, they are not doing that. They are simply announcing their conclusions in preambles to final rules. They are avoiding the notice and consultation requirements of the Executive order. This is the Clinton Executive order, but it is modeled on its predecessor Executive order that was issued by President Reagan.

Since President Reagan, agencies have faithfully consulted with States and local governments before preempting. This new campaign is happening, by and large, behind closed agency doors, without adequate consultation with the State and local leaders like we have here today, and without any opportunity for the public to participate in any meaningful sense.

I realize my time is up. Let me just say that I endorse many of the proposals here today. Part of what Congress has to do is wrest control of this question back to itself by being much more specific when it legislates, by contemplating omnibus legislation that will enshrine some of the substantive components of the Executive order, and by holding the executive branch feet to the fire. This problem has existed since 2002. As far as I know, this is the first time that Congress has tried to focus its attention on it.

[The prepared statement of Mr. Vladeck appears as a submission for the record.]

Chairman LEAHY. We have a new Congress.

[Laughter.]

Mr. DINH. We are painfully aware of that, Mr. Chairman.

Chairman LEAHY. People suddenly found out these things. We realize Congress has the ability for oversight. I rather like that, and we will do it.

As I listen to you, Professor Vladeck, I am struck by the parallels between this and the whole question of signing statements. Probably the most egregious was all this talk about we are going to have a law against torture and the United States will not be involved with torture. And I recall one Senator, now running for

President, who had great press conferences on it, and the President had great statements on it, and they signed the bill which had been passed virtually overwhelmingly by the Congress, and then very quietly on a Friday afternoon, put a signing statement saying we will not have torture—unless we decide to torture. That is basically what it said. And, you know, thus it goes.

There is a derogation on our part, on the Congress's part. I was not in the majority at that time, but what we should have done, of course, was immediately pass the law again making it very clear that there are no exceptions.

But you have written extensively about the issue of regulatory preemption. Your testimony, which is part of the record, has a whole litany of preemption language that has been put into Federal regulations.

It is interesting that a number of these agencies suddenly decided almost at the same time to do this. Do you think this is a coincidence, Professor?

Mr. VLADECK. No, it plainly is not. And we know this for two reasons. One is this campaign sprung forth at many agencies at exactly the same time, and that it came forward in regulatory proposals, all of which had to be reviewed extensively by the Office of Management and Budget. So the idea that the White House somehow doesn't have its fingerprints on this effort, writ large, is simply implausible.

Federal Register notices must be cleared by OIRA, the Office of Information and Regulatory Affairs at OMB, before they can be published. So this is not just a coincidence.

Chairman LEAHY. Well, also, the Consumer Product Safety Commission for the first time recently included language in its mattress flammability rules to state that the Flammable Fabrics Act necessitates the preemption of State law, including State tort law. Why would they make such a change? What would this do for product safety?

Mr. VLADECK. Well, as you know, Senator, there have been many, many lawsuits brought and successfully prosecuted under that statute. There have been many settlements of claims under mattress flammability. So the current law today is that if you or your children are injured in a fire with a mattress that caught on fire—and they are not supposed to—you would have a claim under State tort law and there would be no preemption. If the courts agree with the Consumer Product Safety Commission's interpretation, this would foreclose State claims across the country, and manufacturers of mattresses would be insulated from liability in the event that you or your loved ones or one of your constituents was injured in such a fire.

Chairman LEAHY. I am going to submit a question on the National Highway Transportation Safety Administration, the question that Senator Specter and I have raised. Representative Stone, you are here speaking for all legislatures. You are a Republican legislator. You have showed a lot of concern about this. The administration has given great speeches about States rights. But am I correct that this is preempting State laws, the laws that you and the other legislators pass, or the members of the Vermont General Assembly or Rhode Island's Legislature or anybody else?

Ms. STONE. That is absolutely what is happening, sir, and our biggest concern—and I mentioned this in my remarks, and several other of the panelists have pointed it out as well. The folks that write these regulations at the agencies are not elected officials. They do not answer to a constituency. You do, sir. I do. Senator Whitehouse does as well. I mean, it is—I believe that they are operating in a vacuum. I believe that oftentimes the draft rules are put out by staff. I am not sure actually that always the agency heads are aware of what is going out there. Or maybe they are very aware of it and it is going out with their blessing.

Chairman LEAHY. Either way it is bad.

Ms. STONE. Either way it is preempting our ability for oversight and for taking care of our constituents.

We are not anti-preemption. There are many instances where preemption has served all of our constituents well—the Civil Rights Act, women's rights, fair housing. But what we are, sir, is we are pro-process. We want to be included in the dialog. We want a seat at the table because we are part of the stakeholders.

Chairman LEAHY. When you are talking about something like the Civil Rights Act, we had years and years and years of debate. It became a national issue and then was voted on.

Ms. STONE. Exactly. Exactly.

Chairman LEAHY. Senator Whitehouse is with me, and I am going to turn the gavel over to him in just a moment. But to followup on what Senator Specter and I had raised about the National Highway Transportation Safety Administration, we had raised the question with them about their preemption language they put in regulations to set the standards for the integrity of car roofs, an obvious safety issue if cars overturn.

Now, they assert that their rules supplant all State laws, but is that consistent with the clear presumption against preemption that has been reiterated by even this activist Supreme Court?

Mr. VLADECK. Not at all, Senator Leahy, and it is even worse with respect to the Safety Act. The Safety Act contains a savings clause that expressly preserves common law. But the roof crush standard is an important for another reason, which is this standard, once it takes effect, will amend the standard that was adopted 37 years ago. And so if an agency revisits a regulation every 37 years, in the interim that regulation becomes out of date; it stultifies the development of stricter and better rules.

And one of the ironies, of course, is the new NHTSA standard will affect very few vehicles because tort litigation—and we have had lots of rollover problems, the Ford Explorer and so forth—has forced manufacturers over time to innovate and to develop stronger roofs. So the new NHTSA standard, which if the courts accept this view will preempt all State tort law involving roof crush, will affect very few new cars—very few new cars because most cars on the road today already meet this new standard. But it will freeze product liability law until NHTSA chooses to revisit the standard.

Chairman LEAHY. Thank you.

Senator WHITEHOUSE. [Presiding.] I would like to followup on some of Chairman Leahy's questions, because I thought he was right in the important area for discussion here.

Professor Vladeck, twice you have used the phrase "the administration's campaign" to accomplish this. You are a professor of law. You do not use terms unadvisedly. You said more or less directly to the Chairman that you believe that this is a deliberate political maneuver—that is my phrase, not yours—by the administration. My question to you is: Would you hazard an opinion as to why? What is the motivation for doing this, and particularly in the context of a party that has strongly, from the very tippy-top of the party, identified itself with States rights for a long period of time? How do you reconcile an affirmative campaign to do this by the Bush administration with the principle of States rights that the Republican Party has allied itself with for so many years?

Mr. VLADECK. That is a tough question. Let me answer it this way. If I can talk about the consequence rather than the motivation, I would prefer to do that. I do not know what is pushing the administration to do this. I know what the consequence is.

If you look up and down the products that every consumer uses—drugs, medical devices, vehicles, the mattresses on which they and their families sleep. We have not talked about railroad safety or consumer finance issue. On each of these issues, the administration has pushed and has pressed very broad preemption of State law remedies, particularly consumer remedies that go to compensation.

Now, one could argue that this is simply their view of how the justice system ought to work. One could argue that this is simply the administration showing that its allegiance really is to the business interests that benefit enormously from having State tort law withdrawn. But the loser, without any question at all, is the American consumer who has had his or her right to sue when a medical device fails, a right that pre-dated the Medical Device Amendments of 1976, a right that has existed indisputably until recently, taken away by the Federal Government. And if you look—

Senator WHITEHOUSE. Over and over again that is the common theme of which side—

Mr. VLADECK. Over and over again—

Senator WHITEHOUSE.—against the consumer and in favor of the manufacturer.

Mr. VLADECK. Right. And if you look at my testimony—I just collected a handful of cases. But if you do the math, those few cases involve over 100,000 American consumers who have defective heart valves, defibrillators, pacemakers, you know, implants, hip and other prostheses. These are serious, serious problems. And to tell a consumer who has got a defective heart valve they have to go through open heart surgery to get it replaced but, by the way, the manufacturer of that defective product bears no liability or responsibility for your injury, that is a blow to the American consumer.

Senator WHITEHOUSE. Professor Dinh, we talked a little bit about States rights already. Do you agree that this whole question of States rights has been an issue or a cause that has recently been strongly associated with the Republican Party?

Mr. DINH. Absolutely. The Executive order was first issued in 1982 by President Reagan. Preemption itself was the subject of a Judicial Conference pamphlet written by then-Judge Starr advocating the use of a presumption against preemption as a second-best alternative to reinvigorating enumerated powers.

I happen to take a different view from Judge Starr in the Judicial Conference report. I think that federalism is properly protected by returning to the system of enumerated powers. And where Congress acts, and acts properly, then there should be no presumption one way or the other for or against preemption, but let Congress's intent speak for itself; and the same goes for the regulators.

Senator WHITEHOUSE. But the very principle of federalism, first of all, certainly implies a significant policymaking role in our society at the State government level, does it not?

Mr. DINH. Yes, it does, and that is why we have provisions in the Constitution preserving to the States their autonomy, and more significantly, the Ninth and Tenth Amendments and the prohibition in Article—

Senator WHITEHOUSE. And establishing the Federal Government, indeed, as a Government of expressly limited powers.

Mr. DINH. Absolutely, sir.

Senator WHITEHOUSE. Entirely apart from the structural system which sets up policymaking and recognize policymaking at the State level.

Mr. DINH. Absolutely, with one significant—

Senator WHITEHOUSE. That is an important backdrop in this debate, isn't it?

Mr. DINH. Right. It is—

Senator WHITEHOUSE. It is not just the Supremacy Clause we are talking about. If you look at the Constitution in toto, you have to look also at the limited-government provisions and at the whole principle of federalism.

Mr. DINH. Absolutely. Two halves of the same coin. Specifically enumerated powers in Article I, Section 8, where it is properly exercised, those powers take supremacy over conflicting State laws. And you are absolutely right in order to point to both halves of our federalism, as the court has put it.

Senator WHITEHOUSE. I think back to Ronald Reagan and his run for the Presidency and the extent to which in that run he championed the idea that there was too much power in Washington, that States rights needed to be recognized, that Washington was out of touch, and that you needed to disaggregated the power away from bureaucrats in Washington. And now I see another Republican administration whose procedures in this respect run directly contrary to that.

Is there anything other than irony that would explain that contradiction?

Mr. DINH. Two observations, Mr. Chairman. The first is that there is a good reason why I strongly support the codification of the federalism Executive order. To the extent that it has been ignored and has not worked, I think we should amp it up in order to make it truly enforceable and work, because the process of consultation, assessment, and reflection on whether or not we intrude upon State legislative prerogatives is one that will simply result in better Federal policy.

My second observation is that there are—you know, I don't think we—none of us in this room or in the Republican Party or elsewhere is disagreeing with the system of our federalism. There may be different questions asked to what is the proper forum for a par-

ticular resolution of a public policy. Is it through the rulemaking process with expertise—

Senator WHITEHOUSE. But the forum is essential to federalism, isn't it?

Mr. DINH. It is, but not simply at the State versus Federal level but, rather, rulemaking versus—general rulemaking versus ad hoc jury decision, which is one example in relevance to—

Senator WHITEHOUSE. You have provoked me with that.

[Laughter.]

Mr. DINH. I didn't mean to.

Senator WHITEHOUSE. Well, to remember a phrase in the Washington Post article of yesterday on this subject, somebody whose name is Darren McKinney, who is apparently a spokesman for something called the American Tort Reform Association, which apparently has about 300 businesses and trade associations as its members, said this: "Regulatory experts are better arbiters of what is a potential threat to a consumer than a judge or jury in Michigan."

Now, I assume he means that across the board and he is not making a complaint about the way judges or juries behave just in Michigan. But as somebody who has been a lawyer most of his life—I was the Attorney General in Rhode Island. I was the U.S. Attorney. I have been in courtrooms pretty much my entire professional life. I have got an awful lot of confidence in the good common sense of judges and juries. In fact, the Constitution really sets out the jury as a very special device for making sure that people ultimately can be heard by knowledgeable common-sense neighbors rather than, as Mr. McKinney says, "regulatory experts."

So it is interesting to me that this individual would say that regulatory experts are better than judges and juries. I find that highly improbable. But setting aside on the merits whether it is true or not, how do you think Ronald Reagan would respond to the view that regulatory experts in Washington bureaucratic agencies are better arbiters of what is a potential threat to people in their homes and neighborhoods across this country than their local judges and juries?

Mr. DINH. I think President Reagan, as the recent publication of his speeches and handwritten radio addresses, had some fairly specific views about the litigation system and the civil justice system, and I will not try to characterize them here. But the fundamental question—and it is a very, very good question that you ask, Senator, as you know—is the following: Juries and judges in litigation must act also according to law. Agencies in exercising their powers delegated by you, by this Congress, must act according to the law set forth by this Congress. And so ultimately it is a system of how do we go about setting forth the best legal rules and are those rules going to be followed.

One of the key elements that, you know, is lurking in this room that nobody has put a face to it is this notion of regulatory compliance. You know, is it OK for businesses and individuals to rely upon the fact that if they comply with the regulations issues, they are no longer in jeopardy of suit, either criminal or civil? And I think that is a question that fundamentally goes to the nature of

regulation, be it by Congress or by agencies or by State legislatures.

Senator WHITEHOUSE. In the context of what you have been saying about the principle of States rights and federalism and the observation that Professor Vladeck drew that one side in the political struggle seems inevitably to be the winner in these determinations, as a general proposition wouldn't you agree that one of the things that defines a principle as a principle is that you are willing to stick by it even when your team loses?

Mr. DINH. Absolutely, and that is why I say that where Judge Starr and I differ on preemption is we see different paths to the mountaintop.

Senator WHITEHOUSE. Ms. Peddie, we have been talking about the role of judges and juries. You practice before judges and juries. I think you and I probably share a view as to the ability of judges and juries to get to the bottom of a matter, to hash through evidence and to make a fair decision. So I am not going to ask you about that because I suspect we agree.

Ms. PEDDIE. I think we would.

Senator WHITEHOUSE. Let me ask you about a different though related point, which is that it strikes me that our Constitution goes to considerable effort to preserve judges and juries from political interference or control. And entirely apart from whether they are better quality decisionmakers, they are protected as being independent decisionmakers. And, clearly, a bureaucrat in Washington making these decisions, being told what to do by the President or the White House counsel or the Office of Management and Budget or the Office of Information and Regulatory Affairs is in a very different position. Would you comment on that distinction between the independence of judges and juries versus the political control over bureaucracies and how that bears on the rights of Americans in these circumstances?

Ms. PEDDIE. Well, I think there is all the difference in the world. In the case of political appointees, which in many cases are the ones who are making these decisions, they change, and they change with administrations. And so you may have a very pro-preemption policy until 2008, and after 2008, you will have a very anti-preemption policy. And so what leaving it to political appointees does is to make things very unpredictable.

In the case of judges and juries, my experience, I think, has been yours, that they usually reach the right result. Now, a few judges in Texas and in Pennsylvania have missed that goal, but on the whole, I think they try to do as best they can.

Senator WHITEHOUSE. The ones that are willing to give you a clean shot usually—

Ms. PEDDIE. Absolutely. A level playing field and I am there. That is what we are looking for. But when they are hamstrung, as they are or will be in the case if something like the FDA Preamble is given conclusive deference, Chevron deference, they will not be able to exercise their independent judgment and do what they want to do.

I think one of the examples that I would use here is in the case of Vioxx. One of the purposes of FDA regulations that came in a few years back when Vioxx was withdrawn from the market and

much of the reaction that has taken place to that is, oh, we have got to get rid of all these claims because there are too many, and, oh, some of them have been lost—I think that is the best example of the value of jury systems. This is not a case—the Vioxx cases are not cases in which, you know, runaway juries have done, you know, horrible things. They have weighed the evidence; and in some cases they have found for the plaintiff, in some cases they have found for the defendant. It has been about an even split. And so I think what that illustrates is they are doing their job and there is nothing that needs to be fixed by an agency coming in and saying, I am sorry, you never even get to hear this.

Senator WHITEHOUSE. There is a phrase we hear in politics from time to time that politicians are obliged to "dance with the guy or girl that brung 'em." And when you have an executive branch that is making its own rules through the administrative process, is it not more likely that the principle that that political entity has to dance with the organizations that support it, that that will infiltrate and affect the decisionmaking process than it is among, say, a jury in Michigan?

Ms. PEDDIE. I think that is absolutely the case. For example, the best example I can give you is the architect of the preemption policy at the FDA was Daniel Troy, who was a lawyer for Pfizer before he ever went into the Administration. If the only voice that you hear is the voice of drug companies—and I have represented them. I have no problem with their exploiting the advantages given. I am here because I do not think they should be given those advantages. But when the only voice you hear is the voice of the drug companies, when they are writing the legislation, when their lawyers are in your agency, then, of course, you are going to get results that favor those drug companies.

The people that I represent have no advocate. I am here on their behalf, and there are a few organizations that try to advocate on behalf of consumers. But we do not get in the halls of power very often. And so there is a real disproportionate access and voice, particularly in the prescription drug area, that we think is very unfair and has resulted in a lot of people losing their claims improperly.

Senator WHITEHOUSE. Mr. Untereiner, there is a famous judge who once referred to the States as "laboratories of democracy." If you accept that principle that the States are laboratories of democracy and that we do not always get the answer right away and it is sometimes worth kind of working your way through a problem in the real world before you settle on the final solution, isn't that an argument in favor of Federal regulatory agencies standing back and letting the States work this out on their own rather than having there be central control out of a bureaucratic agency in Washington?

Mr. UNTEREINER. Sure, that is an argument in favor of that, and I think the States do have substantial control over tort law, and the common law develops in many different ways. Preemption of State common law or State tort law is, I would argue, rather limited if you look at Congress's handiwork. If you look at the express preemption provisions that you have passed, it is limited, sometimes only to labeling requirements, sometimes only to labeling requirements that differ from the Federal requirements so that an in-

jured plaintiff can still bring a tort suit under State tort law for violation of the Uniform Federal Standard.

There are all sorts of federalism safeguards built into many of Congress's preemption schemes. Those includes things like the ability of States to go to the agency and ask for an exemption from preemption. In some preemptive schemes—

Senator WHITEHOUSE. It is a different kettle of fish, you will agree, if Congress is going out and making a decision about what preempts than it is if an Assistant Secretary of something or other is doing that. Isn't it?

Mr. UNTEREINER. Yes, although these—

Senator WHITEHOUSE. Constitutionally different and practically different.

Mr. UNTEREINER. Yes, although these agencies are operating under grants of authority from Congress to regulate health and safety and to ensure that interstate commerce is not unduly burdened and to ensure that there is some level of uniformity. So imagine you are an agency regulator and you are asked by a company that has a label that you have approved and that the company is required to use going forward whether a new warning should be added, and the agency looks at that and decides that there is no scientific basis for that warning, that the risk does not exist, the warning should not be given, and if it is given, it is going to actually discourage people from using a valuable product, and, in fact, you know, it is going to be contrary to the public health.

I think a responsible regulator faced with that scenario might well conclude that it would be contrary to Congress's purposes and to a regulation requiring—or refusing to allow that warning, to allow State civil liability judgments to punish manufacturers to the tune of millions and millions—

Senator WHITEHOUSE. Why does that get to be his call, though? There are lots of things that, if you put the person in power and you could have all the power in the world, they would, in fact, make the right decision. But what characterizes American democracy is the way to which we have divided and subdivided power, both among the separated powers laterally and in terms of federalism vertically. And I think it is a very dangerous shortcut to say, well, because you can get to a good result by violating those provisions, we should violate them. I think they should and that the person who is in that position, it is their job to go to Congress and ask for the appropriate delegation, because that is the place where that authority should lie rather than with an executive branch official acting essentially unilaterally.

Mr. UNTEREINER. The background principle of law against which Congress has acted since the early 1960s is that when it gives regulatory authority to an agency, that includes the authority of the agency to regulate preemptively. That does not mean agencies should do it willy nilly. Obviously, agencies, like Congress, should pay attention to the prerogatives of State and local governments. Congress has, if you look at the handiwork, if you look at the range of statutes. And I think many of the examples that trouble the Committee involve rather narrow instances of preemption where there is, in fact, a conflict between a requirement imposed by State tort law and a requirement imposed by a Federal agency.

Senator WHITEHOUSE. Representative Stone, thank you so much for being here. I appreciate it.

Ms. STONE. It is my pleasure.

Senator WHITEHOUSE. I know that somebody with a position like yours, both in the Delaware Legislature and with the National Conference of State Legislatures, has a lot of demands on their time, and I am grateful that you have taken the trouble to be here.

I just would like to ask you to comment a little bit on the process. You used an important phrase earlier. You are pro-process.

Ms. STONE. Exactly.

Senator WHITEHOUSE. And I spent my life before coming here in State government, and, you know, I have seen how hard it is to get elected Governor. I have seen how hard it is to get elected Representative or Senator. I have seen how hard people, once they are elected to those positions, work to fight their way through issues. It is all done publicly. The galleries of the Rhode Island General Assembly are usually filled. There are press people scribbling away. There are microphones in the hallways. The Governor operates under a similar level of scrutiny and attention. Particularly where there is some conflict, it gets even greater attention. An enormous amount of the energy and the will of the people of my State and of the people of Delaware has gone into electing people to those positions, electing you to yours.

From a governmental point of view, isn't that entitled to a lot more credit than a decision that may well have been the result of a lobbyist's phone call to somebody in the White House who called somebody at OMB who called the Director who said this goes in and nobody ever saw any of that trail?

Ms. STONE. We are in agreement. I think that a lot of what is happening is you have special interest groups who are not able to push their agendas legislatively at the State level.

Senator WHITEHOUSE. Because they do not have public policy merit.

Ms. STONE. That is exactly right. And so they have found a way to circumvent that process. They now have the opportunity to do it through bureaucratic agencies, through regulations, and that is not what the process should be. These folks are not elected. They do not answer to a constituency like you do, like I do. They are bureaucrats. And I do not—

Senator WHITEHOUSE. They may answer to a constituency, but it is not like the one that you or I answer to. It is a narrower constituency.

Ms. STONE. A much narrower constituency. And as I said earlier, we want to be part of the process. You have been a legislator. I am still a legislator. When you are dealing with issues, the absolute best way to deal with them is to involve the stakeholders. And we in State government are every bit as much a stakeholder as anyone else in the issues that we have talked about here today.

We want a seat at the table. We want to be able to be part of the conversation. We are where the rubber meets the road, so to speak. And your constituents and my constituents are who we are answerable to, and that is what we want. We want the best for our constituents. That is who we swear an oath to protect and to work in the best capability that we can. And that is not what is hap-

pening. I mean, this is not the way I believe federalism was ever intended to work, and we want to get back to being included in the conversation and to be listened to, not to have an agency make a decision that, oh, by the way, the comment period is over and now we have decided that the rule that we have put forth actually does preempt State law.

That is outrageous. It is absolutely outrageous. And we would very much appreciate being partners with you. We believe that an open process benefits everyone. It allows a better way to share information. And I think ultimately it results in much better policymaking.

Senator WHITEHOUSE. Well, thank you, Representative Stone. And I want to as I conclude the hearing—we all have places we have to be, and I am late for the place I have next to be. But I do want to say that I have found this a very, very interesting hearing. All of the witnesses have been very knowledgeable. I appreciate that they have shared their time and their trouble with us. It is an important issue, I think, for us to address the campaign that Professor Vladeck has identified in this administration, to utilize this, what Representative Stone has identified as highly nondemocratic process, is one that I think merits our attention as a matter of genuine significance. And I want to commend Chairman Leahy and the Ranking Member of this Committee, Arlen Specter of Pennsylvania, for having had the wisdom to pull it together. And I thank all of you for your testimony.

The record will remain open for a week for any further comment or answers to questions that you wish, and with that, if there is nothing further, we are adjourned.

[Whereupon, at 12:35 p.m., the Committee was adjourned.]

[Questions and answers and submissions for the record follow.]

QUESTIONS AND ANSWERS

Senator Grassley's Questions for the Record for Senate Judiciary Committee Hearing of September 12, 2007 titled, "Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?"

Professor Viet D. Dinh

1. In your written statement, you say that "Federal agencies are uniquely positioned to promulgate rules with wide-sweeping national effects precisely because regulation in these areas on the state level may negatively impact that field. When a state regulates, it does so with its own citizens, circumstances, and particular needs in mind." Is it your position that injuries due to specific medical devices or adverse drug reactions are a universal concern, rather than one of any particular state or its particular citizens? In your opinion, are there any situations related to individuals being injured by medical devices or drugs where state laws and interests in citizens' safety and welfare would be appropriate? Are there any situations that would be uniquely tailored to any specific state? Are private tort claims warranted when drug companies or device manufacturers have been less than forthcoming about the risks of their products? Please explain your answer.

There is no doubt that injuries due to specific medical devices or adverse drug reactions are a concern for every state and its citizens. However, the issue of whether Congress or the FDA should preempt state action in these areas is one of policy, not constitutional or legal authority.

As a constitutional law professor, my testimony focuses on the role of preemption in our constitutional structure, an analysis of which leads to the inevitable conclusion that executive agencies have the power to preempt state law,[1] although the exercise of that power must comport with constitutional requirements and the agencies' statutory authority. The policy decisions that Congress faces in determining whether preemption is, or is not, warranted, however, are questions for the legislative branch. It is my contention that Congress should not establish a broad rule that would require all future legislative enactments to preempt explicitly or not at all. As I stated in my testimony, such legislation would upend constitutional supremacy and create a presumption in favor of overlapping regulations by multiple jurisdictions. It would favor regulation by a limitless number of governments at three or four different levels—a national Congress, state legislatures, numerous county boards, and countless city councils. This is not to say that Congress cannot decide, when passing a particular piece of legislation that it wishes to allow the states to craft their own remedies. But that decision should be made at the time of enactment or during the deliberations leading to enactment.

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[1] *Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714 (1985). Indeed, if the agency's choice to preempt "represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, the accommodation should not be disturbed unless it appears from the statute or its legislative history that the accommodation 'is not one that Congress would have sanctioned.'" *City of New York v. F.C.C.*, 486 U.S. 57, 70 (1988) (quoting *United States v. Shimer*, 367 U.S. 374, 383 (1961)); *see also* Robert N. Weiner, *Preemption and the FDA Preamble*, *in* PATENTS, COPYRIGHTS, TRADEMARKS, AND LITERARY PROPERTY COURSE HANDBOOK SERIES (Practicing Law Institute, PLI Order No. 9046 2006).

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2. You state in your written testimony that the Administrative Procedure Act requires that "before an agency issues a rule, the proposed rule be subject to 'notice and comment' procedures." However, when the FDA proposed its prescription drug labeling rule in December 2000, the agency explicitly stated that "this proposed rule does not preempt State law."[2] Further, the FDA stated, "FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law." Yet in the preamble to the final rule, the FDA states, "FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law." In your opinion, did the FDA act appropriately in this case? Please explain your answer. What deference should be given to an agency's policy statements on preemption in the preamble to a final rule when an agency states in the proposed rule that the rule has no federalism implications?

Whether as a policy matter the FDA's action reflects sound policy is something that must be left to those with expertise with the particular issues involved. However, as a general matter, the FDA does possess the power to preempt state law as long as its exercise of that power is consistent with the applicable statutory and constitutional constraints. Indeed, the Supreme Court has noted that "[b]ecause the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the [Food, Drug, and Cosmetic] Act, the agency is uniquely qualified to determine whether a particular form of state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, and, therefore, whether it should be pre-empted."[3]

3. You say that "Congress cannot possibly foresee all of the potential conflicts that may materialize when it first enacts a statute." Please describe any actual—as opposed to theoretical or potential—conflicts that have occurred that are undermining or have undermined the Food and Drug Administration's ability to carry out its mission?

It is a matter of fact that Congress cannot possibly foresee all the potential conflicts that may materialize when it first enacts a statute. Thus, to require Congress to expressly preempt state laws would require it to know of all statutes that could hypothetically touch on the subject matter reached by a Congressional proclamation. Moreover, a presumption against preemption is not supported by the Constitution's text, structure, or history.

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[2] Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels; Proposed Rule, 65 Fed. Reg. 81082, 81103 (proposed Dec. 22, 2000).

[3] *Medtronic v. Lohr*, 518 U.S. 470, 496 (1996) (citations omitted).

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MEMORANDUM

To: Jennifer Price

From: Collyn A. Peddie

Re: Written question from Sens. Feingold, Grassley and Leahy to supplement the record in Senate Judiciary Committee Hearing, "Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority," Sept. 12, 2007

Date: October 4, 2007

I very much appreciated the opportunity to testify before the Senate Judiciary Committee and am grateful for the chance to expand my remarks in response to written questions.

It is my understanding that Gerie Voss at AAJ has already sent you my response to Senator Leahy's Question No. 1. What follows are my responses to the remaining written questions Senator Leahy sent to me.

Should you have any further questions, please do not hesitate to contact me.

WRITTEN QUESTION FROM SENATOR LEAHY

2. ***Advocates of broad federal preemption powers generally claim that it is necessary because a range of state verdicts would require corporations to develop different products for sale in different states, leading to financial burdens for corporations and stifling efficiency. How would you respond to this argument? Does the argument for national standards affect a court's legal analysis of whether preemption should be allowed by executive agencies without an expression of intent to preempt by Congress?***

Reports that the sky is falling for drug companies and other product manufacturers have been greatly exaggerated.

These companies marketed products, including pharmaceuticals, across the nation and the world and were subject to varying regulations in each jurisdiction for decades. They sought approval for the same drug or product from scores of governments, most with different standards. Somehow, the companies who now complain most loudly managed to market their products and to make a profit in this environment. Even now, a few more visionary international automobile manufacturers make different products to respond to varying standards in different countries and made a tidy profit doing it. For these reasons, even if every state tort claim in the United States were preempted, corporations would still face wide variations in international standards governing their products.

Equally important, for almost 90 years in this environment, the FDA and most federal agencies

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rarely, if ever, asserted absolute and exclusive authority over enforcement of safety standards or preemption of private tort claims. Instead, they conceded that their regulation imposed only minimum standards and that state tort claims provided an important check on product safety. So the real concerns that undergird the "efficiency" argument you describe are not about the need for national standards. If not, then what has changed?

As I indicated in my written testimony, in the pharmaceutical area, because of budget cuts, the FDA has progressively moved from relying primarily on extensive pre-approval investigations, most of which are now out-sourced to state and foreign governments anyway, and trying to keep unsafe drugs off the market in the first place to emphasizing recalls after using the American public as so many guinea pigs in a massive, uncontrolled, and involuntary clinical trial. The FDA's enforcement actions are demonstrably in steep decline. Not surprisingly then, new studies reveal that more and more citizens are being injured by prescription drugs. And drugs companies have been called to account financially for those injuries. That is costing them money, sometimes a lot of money, and Wall Street does not like it. Preemption of state tort claims for such injuries, therefore, takes away that cost and financial accountability for the damage caused in one fell swoop without the need to sway legislators or voters, in short, without the need to deal with the messy byproducts of the democratic process. In short, preemption today, particularly in the pharmaceutical area, is about extinguishing liability, not about protecting the public.

The solution is not, therefore, to complete the race to the bottom by making what were always minimum standards maximum ones by allowing federal law to preempt state tort claims. Even if it were, that is for Congress to decide as part of its legislative and policy-making function. Preemption should not be done in the dark or behind closed doors. As the result, trial courts should not be swayed in any respect in their preemption analysis by such concerns. Such result orientation is antithetical to the courts' role as neutral arbiter. Instead, courts must analyze preemption statements by federal agencies under traditional analysis, employing a strong presumption against preemption, weighing whether such statements were made following proper procedures, such as notice and comment, and giving such statements the deference, if any, these often highly mutable policies deserve.

If the considerations you mention are taken into account at all, however, then they must be carefully balanced against the harms that will result if private tort claims are prohibited. First, preemption leaves the victims of dangerous products with no compensation. These costs do not disappear. Instead, they will be shifted from the wrongdoer to the taxpayer or the victims. Second, by freeing companies from the financial consequences of their actions or inactions, the incentive to improve product safety will be reduced dramatically. This is particularly true in the case of the FDA, where government regulators have neither the resources nor the political will to engage in the vigorous enforcement activities necessary to fill the void caused by the loss of state tort claims.

There are very real consequences to very real people when faceless bureaucrats begin to legislate private lawsuits out of existence. Congress should be vary wary in permitting them to do so.

3. The preamble to the Bush Administration's prescription drug labeling rule states that the

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courts have been upholding the FDA's preemption of state laws for years. Is the preamble's statement an accurate description? Please explain any recent changes in FDA approach to this issue and what you believe prompted these changes.

In this respect, the Preamble is a work of fiction unless the term "for years" means only since 2002. It is indisputable that in the vast majority of instances, the consistent position of the FDA for decades has been that its regulations do not preempt state tort claims.

Only when the current administration took office and Daniel Troy, who formerly represented Pfizer, came to the FDA did it began systematically injecting the FDA into private lawsuits and asserting broad preemption of private tort suits. This shift culminated in the 2006 Preamble which provides:

> "FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in [drug] labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated.

See Preamble, Requirements on Content and Format of Labeling for Humans Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006). As one court explained, "The position of the FDA as outlined in the Preamble is

> ***[o]pposite to the position of the FDA as stated in its December 2000 proposal of the same amendments*** . . . The 2000 Proposal explicitly stated that its regulations ***do not*** have preemptive effect. Rather, the preamble to the 2000 Proposal explained that the FDA did not want its regulations to preempt state tort law, stating that 'there should be little, if any, impact from this rule, if finalized, on the States' and that the 'FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.'

McNellis v. Pfizer, Inc., 2006 U.S. Dist. LEXIS 70844 *25 26 (D.N.J. 2006) (quoting See 65 Fed. Reg. 81082 (Dec. 22, 2000)). The Court continued: "The Court notes too that the position taken by the FDA in the 2000 Proposal ***was entirely consistent with the position the Agency took in 1998 in the Preamble to the new regulations regarding consumer medications' guides***." *Id.* at 26, n.6; see 63 Fed. Reg. 66378 (Dec. 1, 1998).

Even the FDA, however, has recently backed off the position it took in the Preamble. In one recent amicus brief, the FDA noted

> To the extent, therefore, that the defendants argue that federal preemption bars any failure to warn claims premised on a drug manufacturer's failure to provide a warning not contained in the drug's approved labeling, the defendant is incorrect. ***FDA has not attempted to 'occupy the field' of prescription drug labeling, and state tort liability for failure to warn does not necessarily prevent FDA from carrying out its regulatory goals.*** Federal regulations explicitly provide for labeling changes to be made to warn of new hazards or cautions relating to a drug without prior FDA approval. Under this regulatory scheme, ***preemptive conflict does not exist in every***

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> ***instance in which state tort law seeks to impose liability for the failure to provide a warning not affirmatively mandated by FDA.***

Amicus Curiae Brief of the United States in *Perry v. Novartis*, Civ. No. 05-5350, filed Sept. 21, 2006, at 11.

The FDA's attempt to rewrite the history of its position on preemption is likely grounded in an attempt to have the courts give the Preamble a higher level of deference that it deserves. In *Hillsborough County v. Automated Med.Labs., Inc.*, 471 U.S. 707, 714-15, 85 L. Ed. 2d 714, 105 S. Ct. 2371 (1985), the Court held that FDA's statement that particular regulations ***did not*** preempt state law was "dispositive on the question of implicit intent to pre-empt unless either the agency's position is inconsistent with clearly expressed congressional intent, or ***subsequent developments reveal a change in that position***"). Thus, where an agency's position on interpretation of a regulation has been mutable, it receives less deference.

For these reasons, even if Congress or the Courts decides that agency pronouncements on preemption are generally entitled to *Chevron* or the highest level deference, the FDA's pronouncement should not receive such deference because it has shifted so dramatically in the last 5 years.

WRITTEN QUESTIONS FROM SENATOR GRASSLEY

1. In Levine v. Wyeth, the Vermont Supreme Court rejected Wyeth's preemption defense against a failure to warn claim regarding its anti-nausea drug, Phenergan. Wyeth petitioned for certiorari, and, in May, the United States Supreme Court asked the Solicitor General to file a brief expressing the views of the United States. What, in your opinion, is the impact of this case?

In *Levine*, the Court would be faced squarely with the question of whether the FDA Preamble and its pronouncement on conflict preemption of state failure to warn claims is entitled to so-called *Chevron* or conclusive deference.

The Vermont Supreme Court rejected the notion that the FDA Preamble should be given any deference. In doing so, the Court was on very solid ground. It stated:

> Congress has expressed its purposes clearly, not only in the general sense that the statute was intended to "protect the public " but also more specifically, with respect to the FDCA's preemptive effect. In the ***1962 amendments to the FDCA***, Congress included a clause expressly limiting the preemptive effect of the statute: "Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962 (Harris Kefauver Act), Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962).
>
> ***This amendment essentially removes from our consideration the question of***

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> ***whether common-law tort claims present an obstacle to the purposes and objectives of Congress. Congress intended that the FDCA would leave state law in place except where it created a "direct and positive conflict" between state and federal law.***
>
> Instead, we are interpreting an unambiguous express preemption clause that specifically preserves the type of state law at issue. Under these circumstances, ordinary preemption principles must give way to Congress's intent to preserve state laws that do not create a "direct and positive conflict" with federal law. Drug Amendments § 202. There is no such conflict here. ***Accordingly, the FDA's statement is neither an authoritative interpretation of an ambiguous statutory provision entitled to deference,*** *Chevron*, 467 U.S. at 842-43, ***nor a persuasive policy statement entitled to respect.*** *Mead*, 533 U.S. at 235. Plaintiff's claim does not impose conflicting obligations on defendant or present an obstacle to the objectives of Congress. ***We therefore agree with the trial court that the claim is not preempted by federal law.***

_____ (emphasis supplied). Even if the Supreme Court takes this case, depending on how its opinion is written, it will ***not*** solve all of the problems in this area. Even if the Court addresses and resolves fully the question of 1) nature of "direct and positive" conflict and 2) the deference, if any, to be given FDA Preamble and its pronouncements, the Court is likely to leave open questions concerning the general deference to which other pronouncements on preemption by other agencies are entitled. Moreover, such a holding will not revive claims dismissed or appeals exhausted on this ground. So the question of compensating these injured victims remains.

This case may also have a significant impact on the appeal in *Warner-Lambert v. Kent*, a case on which the Court granted certiorari last week and which reassesses the preemption analysis in *Buckman* v. *Plaintiff's Legal Committee.* It will be very difficult for the Court to expand broadly the so-called *Buckman* doctrine concerning the preemption of claims of fraud on the FDA in light of the FDA's pronouncements on conflict preemption in its Preamble and subsequent amicus briefs. If the Court holds that the Preamble and its statements on strict conflict preemption are to given *Chevron* deference, how can it then find the complete preemption of state failure to warn claims ***without*** the need to show an actual conflict the Appellants have sought in *Kent*? In other words, if the FDA' s pronouncement on preemption ties the Court's hands on that issue, how can the Court then find broader preemption than even the FDA has claimed for itself?

2. ***When the FDA proposed its prescription drug labeling rule in December 2000, the agency explicitly stated that "this proposed rule does not preempt State law." Further, the FDA stated, "FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law." Yet in the preamble to the final rule, the FDA states, "FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law." What do you think Congress should be doing in response to agency efforts to preempt by preamble? What deference should be given to agency policy statements on preemption in amicus briefs and preambles to final rules?***

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Agency preambles are essentially agency "signing" statements to federal regulations. Rather than give these statements any deference at all, they should be treated as the gratuitous pronouncements of a hegemonic executive they are. This is particularly true where such pronouncements have been made completely outside the democratic process, without benefit of notice and comment, or, in the case of the FDA Preamble, where notice and comment have been avoided by an affirmative misrepresentation as to what the final pronouncement would be.

The best way for Congress to insulate itself and the citizens it represents from such naked power grab would be for Congress to make its intent to preempt or not to preempt express. Agency pronouncements are only entitled to deference in the absence of Congressional statements of intent. Congress can do so both by making express statements about its intent to preempt, in omnibus legislation or with regard to particular areas such as prescription drugs, or pass legislation limiting the circumstances in which an agency can assert preemptive power or under which preemption may be implied, in other words by limiting Congress' grant to agencies of the power to preempt. For example, Congress could say that the power to preempt does not include the power to preempt by rule or regulation where that rule, regulation or Preamble has not been the subject of notice and comment. In addition, Congress can circumscribe the courts' power to give high deference to such pronouncements by enacting a federal code construction act. Finally, Congress must increase its oversight of the FDA and other safety agencies. It should hold hearings on why, for example, for the first time in 90 years, the FDA suddenly finds the need to preempt state failure to warn claims and whether such preemption is needed to preserve the FDA's own authority or is simply an accommodation to drug companies.

3. ***What is your response to the argument that private claims may lead drug companies to over-warn and patients not to take needed drugs?***

I think it starkly illustrates the fact that the drug companies would like to have it both ways and belies a fundamental misunderstanding of the way prescription drugs get to consumers.

Most states employ what is called the "learned intermediary" doctrine, that is, that a drug warning is directed to the doctor, and not the patient, who acts as a "learned intermediary" by making informed decisions to provide medication to his or her patients. Under that doctrine, if ***the doctor*** receives an adequate warning about an adverse drug reaction, a drug manufacturer is not liable if the patient experiences the reaction. State courts in virtually all 50 states have adopted some variation of this doctrine based upon the notion that the person most knowledgeable about both the drug and the patient should be the one who decides if the side effects are worth the benefit to the patient.

By contrast, drug companies have successfully fought efforts to hold them liable for statements made in the explosion of direct-to-consumer advertising facing consumers today. So there are no private claims based on direct-to-consumer warning in most states. And consumers are not being protected by the FDA from such false claims. In November 2002, for example, House oversight efforts revealed that FDA enforcement actions against false and misleading drug ads declined precipitously, falling by ***more than 70 percent*** compared with the period from 1999 to 2000. This decline could not be explained by a change in the number of drug ads reviewed by the FDA (which increased) or a drop in complaints about ad content (which remained constant).

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What is at work then in the argument you describe is an effort by drug manufacturers both to preserve the protections of the learned intermediary doctrine while aggressively and sometime inappropriately courting consumers directly in a deluge of advertising. Only since the advent of such blanket consumer advertising has the new-found concern for over-warning emerged.

In every study of which I am aware, the doctors who actually are the real targets of the warnings for prescription drugs want more information about the drugs they prescribe, not less. And, as educated "consumers" of such information, there is little danger that doctors will be overwhelmed by it. So the danger, if any, that a doctor will not prescribe a drug because of over-warning is quite small. I would ask that Congress contrast this unfounded concern with the demonstrated dangers of failing to warn learned intermediaries about the dangers of Vioxx and other prescription drugs. We know that "under-warning" hurts and kills people. By contrast, over-warning has never been demonstrated to be a real danger to anyone.

There was, however, a recent, well-publicized effort to promote a "study," whose primary author was an expert witness for Wyeth in drug litigation, that allegedly showed that the "black-box" warning on SSRI anti-depressants had somehow led to an increase in the teen suicide rate, based upon a study of drug sales. The study, however, is a perfect example of the kind of junk science tort reformers have been claiming for years needed to be kept out of our courts.

The study, for example, assumed that the drop in sales was due to the increased warning and that patients, therefore, went untreated if they did not take SSRI's. In making these assumptions, however, it ignored the impact of other medications and more important factors, such as the fact that

- Paxil, one of the SSRI's analyzed, went generic on 9/11/2003 after temporary withdrawal leading to an expected drop in its sales.

- There was a massive off-label switch to the use of anti-psychotic drugs like Zyprexa, and, in particular, a 6-20 fold increase in their ***pediatric*** use. Between 2001-2005, the period studied, prescriptions for teens for such drugs increased by 80%. Ironically, there have been fights between consumers, drug companies, and the FDA over including a suicide warning for these drugs as well. If anything then, the study illustrates that Zyprexa and similar drugs ***increase*** the suicide rate.

    - Between 2001 and 2005, there was also a 110% increase in use of atypical antipsychotic drugs in girls under 20, who sadly account almost entirely for the increase in suicides during the period..

- Sadly, these girls switched suicide methods during the period and became more successful at killing themselves. During the period, there was a 119% increased in the number of girls who hanged or suffocated themselves.

Until there is valid proof that over-warning physicians is even possible and that it hurts anyone, Congress should take no action to prevent drug companies from providing physicians with as much relevant and material information about the drugs they prescribe as possible.

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WRITTEN QUESTIONS FROM SENATOR FEINGOLD

1. ***You have pointed out that, during the same time period FDA has been claiming that state lawsuits would frustrate FDA's enforcement scheme, there has been a dramatic decline in the agency's own enforcement efforts. What might explain that decline?***

The best explanation is money and politics. FDA budgets for enforcement and inspections have been slashed over the course of the last 7 years. The Bush Administration's fiscal year 2006 budget, for example, cut nearly all of the FDA's funds for food and drug inspections. With fewer dollars spent for enforcement, the FDA simply lacks the resources to protect the public.

Second, more of the money for enforcement is coming from user fees under PDUFA. As a larger the portion of the enforcement budget comes from industry, FDA has less incentive to be as aggressive about enforcement.

Third, political appointees have instituted a "delay game" strategy at the FDA. Before the arrived at the FDA, Daniel Troy, named Chief Counsel of FDA in 2001, had been a lawyer for the tobacco and pharmaceutical industries, aggressively fighting FDA regulation. According to House oversight reports, upon his arrival, Mr. Troy implemented a new policy that all warning letters and notices of violations issued by the FDA had to go through his office, resulting in serious delays and a dramatic decline in enforcement. According to the GAO's reports, the Bush Administration's new policy drastically increased the time it takes to issue warning letters from 2 weeks, prior to the new policy, to 4 months, after implementation of the new policy.

That assumes, however, that the Office decides to issue any letter or institute any enforcement action at all. Congressman Waxman's reports on FDA oversight reveal an alarming tendency for the Office of Chief Counsel to ignore recommendations of field staff. I outlined one example in my prepared testimony in which nursing home residents were given industrial nitrogen gas instead of medical oxygen yet the FDA took no enforcement action at all. FDA field inspectors also found significant violations at the Chiron vaccine production plant in Liverpool, England, in June 2003 and recommended the initiation of enforcement action. Their recommendation was rejected. Instead, ***British*** regulators closed the facility after discovering sterility problems in some batches of FluVirin vaccine. The result was a dangerous shortage of flu vaccine in the U.S. the next year.

The FDA is not alone. The Bush Administration's 2006 budget for the Environmental Protection Agency not only cut overall budgetary spending by 5.6 percent but specifically targeted

money that passes through EPA to the states. The EPA delegates 75 percent of its work to the states, and the states are responsible for 90 percent of enforcement efforts.

2. ***From your perspective as an experienced litigator, what are some of the advantages that private lawsuits have over agency action when it comes to enforcing safety standards and protecting public safety.***

While private lawsuits, particularly in the pharmaceutical area, do not result in direct enforcement of safety standards, they do perform critical and recognized functions in insuring that

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the public is safe. First and foremost, they insure accountability. When a wrongdoer is responsible for compensating his victim, there is an incentive to avoid inflicting such injuries. Where the victim is left uncompensated or the cost of his or her medical care shifted to the taxpayer, there is little incentive to make safer products or drugs.

Second, lawsuits put the power to seek accountability from wrongdoers in the individual's hands and insulate it from political forces there. That is particularly important in the case of agencies, like the FDA today, who lack the resources or political will to hold companies who make defective or unsafe products responsible for the injuries they inflict.

Third, lawsuits allow the victim of a defective or unsafe product to be compensated. One of the important concerns that has been lost in the discussion of preemption of drug claims is compensation for the victims. Apparently, concerns of economic efficiency have eclipsed concerns for making sure a child injured by a vaccine like Hannah Bruesewitz or a heart attack victim like Ruby Ledbetter get the medical care they need. That should not be the case.

Finally, lawsuits perform an important public information function. As in the case of Vioxx, often lawsuits and the discovery they generate illuminate issues that would never have been brought to light otherwise. They lead to later enforcement actions. Lawsuits and public outcry in large part led the FDA to place a suicide warning on SSRI's that might not otherwise have been there.

These important functions would be lost if private claims are preempted.

CAP

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Question: In his written testimony, Mr. Utereiner noted that Congress sometimes includes in a preemption scheme an exception for state or local requirements that are needed to address special or unique local conditions as in the Federal Rail Safety Act (FRSA). He cited this as an example to illustrate that nothing needs to be done about this preemption problem. But, how can that be true when courts were so misconstruing the FRSA's preemption language after the devastating Minot train derailment in 2002 that Congress needed to enact legislation in July that would clarify that Congress never intended to preempt state law claims?

Response: Mr. Utereiner's statement is not correct. While the FRSA does carve out exceptions, that was not enough to adequately address Congress' intent to not preempt state tort law claims. For example, after the tragic train derailment in Minot, North Dakota, several plaintiffs filed claims against the railroad who had admitted its negligence. However, in *Mehl v. Canadian Pacific Railway*, 417 F. Supp. 2d 1104 (D.N.D. 2006), the Federal District Court in North Dakota reluctantly dismissed all claims against Canadian Pacific on the basis of federal preemption. Judge Hovland, obviously distressed by what he believed to be the current state of the law at that time, stated:

> "While the Federal Railroad Safety Act does provide for civil penalties to be imposed on non-compliant railroads, the legislation fails to provide any method to make injured parties whole and, in fact, closes every available door and remedy for injured parties. As a result, the judicial system is left with a law that is inherently unfair to innocent bystanders and property owners who may be injured by the negligent actions of railroad companies."

Mehl, 417 F. Supp. 2d at 1120.

This distorted reading of the FRSA preemption clause was not limited to the Minot derailment cases. In *Kalan Enterprises LLC v BNSF Ry*, 415 F. Supp. 2d 977 (D. Minn. 2006), the federal district court dismissed all causes of action against the BNSF railroad arising out of a derailment in Perham, Minnesota, on the basis FRSA preemption. As in the Minot cases, the court expressly rejected the idea that a railroad has to comply with federal regulations promulgated pursuant to the FRSA in order to be entitled to preemption. The mere reference to a federal regulation and allegation that the regulation had been violated was enough to deprive the injured party of any cause of action.

As a result of courts misconstruing Congressional intent, Congress exercised its power with the passage of the "Implementing Recommendations of the 9/11 Commission Act of 2007" (the 9/11 Act). Congress added a new subsection (b) to 49 U.S.C. § 20106 titled "Clarification Regarding State Law Causes of Action" which specifically states that the law should not "be construed to preempt an action under State law seeking damages for personal injury, death, or property damage."

Therefore, Mr. Utereiner is incorrect. The FRSA is a poor example to support his argument that nothing needs to be done to solve this preemption problem. It is clear that some action needs to be taken to clarify congressional intent as to unauthorized preemption, as Congress did with the FRSA.

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NATIONAL CONFERENCE *of* STATE LEGISLATURES

The Forum for America's Ideas

Donna D. Stone
State Representative
Delaware
President, NCSL

Sharon A. Crouch Steidel
Director, Information Systems
Virginia House of Delegates
Staff Chair, NCSL

William T. Pound
Executive Director

The Honorable Patrick Leahy
Chair, Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

February 11, 2008

Dear Chairman Leahy:

I am writing to you in response to questions I received regarding my testimony on behalf of the National Conference of State Legislatures (NCSL) presented to the Committee last fall. I apologize for the delay in getting my responses to you. My answers are as follows:

Questions Submitted by U.S. Senator Russell D. Feingold

1. In his written testimony, Professor Dihn stated that the notice and comment procedures for federal regulations provide "an excellent opportunity for interested parties to object to the opposed rule's preemption of state law … If sufficient opposition is voiced, the rule will not be issued." How does this claim square with your experience in representing the concerns of state legislatures to federal agencies.?

Answer: In theory where state and local governments are alerted to a proposed rule's potential impact on them, Professor Dihn is correct. However, NCSL's experience has been that certain federal agencies have made calculated decisions to ignore the Executive Order on Federalism (E.O. 13132) and promulgate preemptive regulatory provisions despite their duty under that Executive Order to notify and consult with state and local government representatives. For example, as I stated in my testimony, FDA initially put forth a proposed rule on prescription drug labeling that did not have a preemptive impact on state laws; therefore there was no need for NCSL to comment. Five years later, FDA decided to insert preemptive language and declined to re-open the comment period. The result was that NCSL was effectively denied the right to comment on language that became part of a final rule that had a very deleterious impact

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on state law. To add insult to injury, FDA re-opened the record to permit certain large pharmaceutical companies to submit comments at various points after the official comment period had closed. NCSL finds this practice both disturbing and disingenuous.

2. Corporations that operate on a national scale claim that differing state standards make it overly difficult and expensive for them to do business. In your view, is this claim valid? If so, as an alternative to federal regulatory preemption with its deleterious effects on public safety, are there any steps that states can or do take, either on their own or working together, to mitigate the burden on companies that do business in multiple states?

Answer: It may be that the cost of doing business in multiple states can be expensive. It really depends on what different state laws require with respect to standards, forms, filings, etc... with technology being what it is today, software exists that can lessen costs for businesses in certain areas. Even if that were the case, it is NCSL's belief, as elected state officials, that the health and the welfare of our citizens come first – at **any** cost. States do work together to mitigate the fiscal burden on companies doing business in multiple states. An example of this is the states streamlined sales tax initiative which was spearheaded by NCSL.

A recent national study commissioned by a partnership of business and government organizations, showed that businesses cost of compliance burden to collect state and local sales taxes averaged more than three percent of the sales tax collected, **a $ 6.8 Billion annual cost to retailers at 2003 sales tax levels**. The Streamlined Sales and Use Tax Agreement, formulated by state policymakers and businesses, substantially simplifies state and local sales tax systems, removes the burdens, costs and complexities to retailers in interstate commerce, and protects state sovereignty. As of January 1, 2008, 22 states have enacted changes to their states and use tax statutes that allow them to comply to the Streamlined Sales and Use Tax Agreement. It is expected that implementation of the Streamlined Sales and Use Tax Agreement will reduce and overtime eliminate all cost of compliance burden on sellers to collect state and local sales taxes.

Question Submitted by U.S. Senator Charles Grassley

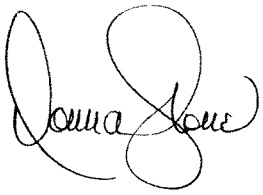
1. You mentioned in your written statement that the National Highway Traffic Safety Administration (NHTSA) Roof Crush Resistance preemption will cost State governments between $49 and $71 million per year, primarily as a result of increased state-paid medical and disability costs. Are you aware of, or do you have, any estimates of what the Food and Drug Administration's attempted preemption of state product liability laws with respect to medical devices and /or drugs would cost states?

Answer: NCSL does not have an estimate of what the state cost of this preemptive rule would be. However, it is important to look at the record of this rule's enactment. In its first iteration, the FDA NPRM on Prescription Drug Labeling did not contain any preemption language, and actually made the affirmative statement that the rule would not preempt state law. As a result, NCSL had no reason to prepare any type of cost estimate. Two weeks before the rule became final, FDA inserted its preemption language. The timing of this insertion occurred after the

official comment period had closed, was so close to the final issue date of the rule that not even the Congressional Budget Office had time to prepare an estimate and NCSL had no time to mobilize either. The Agency never offered up any cost estimates either, which it is actually required to do under EO 13132.

Thank you again for the opportunity to testify and put forward NCSL's concerns on this troubling trend of preemption. I look forward to working with you to craft appropriate legislation to remedy the problems outlined in my testimony. If you have any further questions or concerns, please don't hesitate to contact NCSL staff Susan Parnas Frederick at (202)624-3566 or susan.frederick@ncsl.org.

Sincerely,



Donna D. Stone

State Representative, Delaware
President, NCSL

RESPONSE TO WRITTEN QUESTIONS

BY

ALAN E. UNTEREINER
ROBBINS, RUSSELL, ENGLERT, ORSECK,
UNTEREINER & SAUBER LLP
WASHINGTON, D.C.

ON BEHALF OF

THE U.S. CHAMBER OF COMMERCE AND
THE U.S. CHAMBER INSTITUTE FOR LEGAL REFORM

WITH RESPECT TO THE HEARING HELD

BEFORE

THE SENATE JUDICIARY COMMITTEE
UNITED STATES CONGRESS

ON SEPTEMBER 12, 2007

SUBMITTED: OCTOBER 5, 2007

Question 1:

It took nearly 2 years after the manufacturer and the Food and Drug Administration first became aware of a cardiovascular risk for a change to be made in the drug labeling for Vioxx. In your opinion, are there any situations related to individuals being injured by medical devices or drugs where state laws and interests in citizens' safety and welfare would be appropriate? Are private tort claims warranted when drug companies or device manufacturers have been less than forthcoming about the risks of their products? Please explain your answer.

Answer:

These questions can be answered only against the backdrop of a proper understanding of the respective roles of state and federal law in the regulation of the labeling of prescription drugs and medical devices. Ordinarily, States have the power to pass statutes, develop their common law, and issue regulations aimed at regulating the safety of all products sold within their borders. This residual authority, however, is subject to two important limitations. First, Congress may elect to displace the States' authority in this area through the passage of preemptive legislation – and it clearly has done so, for example, albeit in a limited way, with respect to medical devices by passing the Medical Device Amendments of 1976, 21 U.S.C. § 360k(a). See *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). Second, by virtue of the Supremacy Clause, state and local governments are precluded from passing laws or ordinances, issuing regulations, and taking other steps that conflict with, or frustrate the purposes of, federal law. This protective principle applies to federal law in all of its forms – the Constitution, federal statutes, regulations, or treaties. There is no "tort exception" or "common-law exception" in the Supremacy Clause (and indeed it would be odd to accord more deference to the decision of a lay jury than to the official act of a State's legislature).

Subject to these limitations (and any other limitations imposed by the federal Constitution), the States remain free to determine the substantive rules of tort law as well as the procedural rules governing tort lawsuits in state court. Ideally, those ground rules should be informed not only by the need to ensure compensation to persons injured by the negligence or wrongful conduct of others but also by an awareness of the burdens that meritless claims and abusive litigation can impose on manufacturers and on the economy as a whole. The law of torts has evolved over time to meet new challenges and societal problems, while at the same time retaining certain traditional limitations (such as the requirement of proof of causation). The law of negligence is well-settled and uncontroversial. Strict products liability is also well established in this country. With respect to individuals who are injured by medical devices or drugs specifically, the States retain very substantial authority under current law to regulate those products and to protect their respective citizens' safety and welfare through various means. Because of the special nature of these complex products, state tort law has developed certain specialized rules governing them (such as the learned intermediary doctrine).

At the same time, Congress has created an expert federal agency, the FDA, and armed it with very broad regulatory powers aimed at ensuring both the safety and efficacy of drugs as well as medical devices. Under current law, the FDA serves as a gatekeeper relating to the introduction of new medical products and imposes detailed reporting requirements on manufacturers with

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respect to adverse affects that occur in connection with the use of medical devices and drugs. Moreover, the FDA retains very substantial control over the format and content of the labeling of both medical devices and prescription drugs. The FDA is properly concerned about the impact of such labeling on the public health, and regards the product labeling as a critically important means of assuring that physicians (and therefore patients) are adequately informed of the true risks and benefits associated with drugs and medical devices. See *Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products*, Final Rule, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("The centerpiece of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively.").

For this reason, drug and device manufacturers have only limited authority to make changes to labeling without obtaining FDA approval. See *ibid.* (discussing changes to prescription drug labeling permitted under 21 C.F.R. § 314.70); Brief for the United States As Amicus Curiae, *Riegel* v. *Medtronic*, No. 06-179 (U.S. pending) (filed May 23, 2007) ("U.S. *Riegel* Br."), at 3 & n.2 (discussing changes to labeling of premarket-approved medical devices under 21 C.F.R. §§ 314.39 and 314.80). Conversely, except in the limited circumstances where changes are permitted by FDA's regulations without *prior* FDA approval, manufacturers of prescription drugs and premarket-approved medical devices are *required* to continue to use the FDA-approved labeling – and failure to do so will render the product misbranded in violation of federal law. In cases where new warnings may be added to product labeling immediately without prior FDA approval (on a "Changes Being Effected" basis), the manufacturer must first notify the FDA by filing an application to change the labeling and the FDA "retains the authority to reject the application and to require the manufacturer to stop distributing the product with the change." U.S. *Riegel* Br. 3 n.2. In light of FDA's extensive control over product labeling, it should come as no surprise that, "in practice, manufacturers typically consult with FDA prior to adding risk information to labeling." 71 Fed. Reg. at 3934; see also Richard Cooper, *Drug Labeling & Products Liability: The Role of the Food & Drug Administration*, 41 FOOD DRUG COSM. L.J. 233, 236 (1986) (same).

In recent years, FDA has expressed increasing concern about the potential for state-law tort litigation, in certain circumstances, to undermine the public health by causing overwarning and by undermining the FDA's considered judgments about the scientific basis (or lack thereof) for proposed product warnings. For example, the FDA has become aware of instances where plaintiffs have sued under state tort law for the manufacturer's failure to give a warning that the FDA considered and rejected as lacking any scientific basis. In that circumstance, the maintenance of the state tort action directly conflicts with the FDA's expert judgment and decision. Moreover, the FDA's rejection of the proposed warning means that, under federal law, the manufacturer is barred from providing it. Yet in this scenario state tort law requires the manufacturer – on pain of multimillion dollar liability – to do exactly what federal law prohibits. A more direct collision between state and federal law is difficult to imagine. Under current law, such tort claims should be found to be barred under the doctrine of implied conflict preemption.

With the exception of state tort requirements that conflict with, or frustrate the purposes of, federal law, the States remain free to regulate prescription drug labeling through their tort law.

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According to the FDA's preamble, this includes certain situations where the FDA "has made a finding that the [manufacturer] withheld material information" about the risks of its products. 71 Fed. Reg. at 3935-36 (identifying several such circumstances where implied conflict preemption would not operate). Of course, a pure "fraud-on-the-FDA" claim would be impliedly preempted for all the reasons set forth in the Supreme Court's unanimous decision in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

In the area of medical devices, the law is somewhat different because as noted above Congress has enacted an express preemption clause, 21 U.S.C. § 360k(a). That provision has been interpreted narrowly by the FDA as being limited to requirements that are "specific," which means that the FDA's approval of so-called "510k" devices does not trigger express preemption and neither does the agency's generalized regulations governing good manufacturing practices and device labeling. See *Medtronic* v. *Lohr*, *supra*. On the other hand, most courts have concluded that the FDA's approval of a premarket-approved device *does* give rise to preemptive federal requirements with respect to the design, manufacturing, and labeling of such devices. Most courts have also concluded that those preemptive federal requirements nullify state requirements that are not substantially equivalent to the federal requirements. (These issues are currently before the Supreme Court in the *Riegel* case, however.) In addition, the preemption provision applicable to medical devices authorizes States to seek exemptions from express preemption under certain circumstances. See 21 U.S.C. § 360k(b). Except for areas in which this express preemption provision operates, the States remain free to regulate medical devices through tort law.

Question 2:

When the Food and Drug Administration proposed its prescription drug labeling rule in December 2000, the agency explicitly stated that "this proposed rule does not preempt State law." [fn omitted] Further, the FDA stated, "FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law." Yet in the preamble to the final rule, the FDA states, "FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law." In your opinion, did the FDA act appropriately in this case? Please explain your answer.

Answer:

Yes, it appears the agency acted appropriately.

As noted above and explained in greater detail in my written testimony, the Supremacy Clause of the Constitution is the source of the doctrine of implied conflict preemption. Under that doctrine, state and local law that conflicts with, or frustrates the purposes of, federal law is preempted by direct operation of the Supremacy Clause. It is well settled that the Supremacy Clause covers federal regulations. Thus, state or local law that conflicts with or is contrary to a federal regulation is preempted by the Supremacy Clause.

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The FDA's statement in its preamble appears to be nothing more than a recognition and restatement of these long-settled principles of *implied* preemption. As such, it is difficult to see why the FDA's statement would be controversial.

The principles of implied conflict preemption operate *whether or not* Congress (or an administrative agency delegated the authority to regulate) makes an explicit statement that it intends to regulate preemptively. This is settled law. See *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 884 (2000) ("[C]onflict pre-emption . . . turns on the identification of an actual conflict, and not on an express statement of pre-emptive intent.") (internal quotation marks omitted). And it makes perfect sense. Suppose, for example, that Congress passes a law saying that all school buses in the United States must be canary yellow. If Alaska or Florida decided to pass a law requiring all school buses to be blue and imposing fines or even criminal penalties on those who own or operate any bus painted canary yellow, the Alaska or Florida laws would be directly contrary to Congress's mandate and would be preempted by the Supremacy Clause. That would be true whether or not Congress expressed an intent that contrary or conflicting state law be preempted. Indeed, whenever Congress legislates it does so against the backdrop of these settled principles of implied preemption law.

The same is true of a federal regulation. An agency that enacts a regulation requiring all school buses to be canary yellow is not required to say expressly in the regulation (or elsewhere) that contrary or conflicting state law is preempted in order for the Supremacy Clause to have its ordinary effect. In the case of the FDA's proposed rule published in 2000, the agency's statement that "this proposed rule does not preempt State law" (*Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologicals; Requirements for Prescription Drug Product Labels*, Proposed Rule, 65 Fed. Reg. 81082, 81103 (Dec. 22, 2000)) cannot reasonably be interpreted as suggesting that the regulation should be exempt from the Supremacy Clause or ordinary principles of implied conflict preemption. Under that reading, the agency would be perfectly content, for example, if a state imposed fines or criminal penalties on pharmaceutical companies for complying with the new labeling format mandated by the FDA's proposed regulation. Equally unobjectionable to the FDA, under this implausible reading, would be a state's decision to compel a manufacturer to use labeling that the FDA has forbidden. It is difficult to believe that any administrative agency would welcome such direct affronts to its authority and such undermining of its regulatory programs and requirements. See *Geier*, 529 U.S. at 885 ("[O]ne can assume that Congress or an agency ordinarily would not intend to permit a significant conflict.").

Instead of suggesting that implied conflict preemption should not be applied to its proposed rule, the FDA appears to have been saying merely that it had no intention of *going beyond* the background principles of implied conflict preemption law by preempting state law that does *not* conflict with the FDA's regulation. Alternatively, the agency may have wanted to make clear that it had no intention of occupying the entire field of prescription-drug labeling.

This reading is fully consistent with the FDA's later statement that, under the new *as well as the old* labeling regulations, FDA's approval of labeling "preempts conflicting or contrary State law" under "existing preemption principles." See *Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products*, Final Rule, 71 Fed. Reg.

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3922, 3933-34 (Jan. 24, 2006) (emphasis added). Since the proposed regulation did not alter the scope of preemption, the FDA evidently took the view that it did not contain "policies that have federalism implications" within the meaning of Executive Order 13,132. See 65 Fed. Reg. at 81103. If anything, the "federalism" implications flow from the Supremacy Clause, not the proposed regulation. See generally Christine Kim, *The Case for Preemption of Prescription Drug Failure-To-Warn Claims*, 62 FOOD & DRUG L.J. 399, 414-16 (2007) (explaining why FDA's actions did not violate the notice-and-comment requirements of Executive Order 13,132 and the Administrative Procedure Act); 71 Fed. Reg. at 3969 (explaining FDA's compliance with Executive Order 13,132).

All that said, it is certainly true that in the preamble to the Final Rule, the FDA, in response to comments submitted about the product liability implications of the agency's labeling rules, did offer additional comments on its understanding of how the principles of implied conflict preemption should be applied to its labeling regulations and to agency decisions either approving or disapproving specific warnings in prescription-drug labeling. 71 Fed. Reg. at 3933-3936. The FDA also described in detail the positions the agency had taken over the previous six years in *amicus* briefs filed in a line of implied preemption cases. *Id.* at 3935. But for at least three reasons, it is difficult to fault the agency for offering this additional guidance in the preamble.

First, the FDA's statements were made in response to comments submitted to it. Ordinarily, we applaud it when agencies give consideration and respond to comments submitted by the public in a formal rulemaking proceeding. Indeed, the Administrative Procedure Act requires agencies to give consideration to public comments. See 5 U.S.C. § 553(c); see also Christine Kim, *supra*, 62 FOOD & DRUG L.J. at 414-15 (arguing that because the preamble itself was not a regulation, it "did not require any notice or comments"); 5 U.S.C. § 553(b)(3)(A). Second, to a large extent the FDA's comments merely summarize positions the agency had taken in *amicus* briefs since 2000. And third, the preamble to the Final Rule suggests that the FDA's comments are to some extent a response to new developments occurring since 2000. Specifically, the agency explained, "[s]ince the proposed rule was published, FDA has learned of several instances in which product liability lawsuits have directly threatened the agency's ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the [Food, Drug & Cosmetic] [A]ct." 71 Fed. Reg. at 3934. Such "[s]tate-law attempts to impose additional warnings," the agency explained, "can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products and encouraging inappropriate use and undermining the objectives of the act." *Id.* at 3935. Moreover, the FDA observed, "[i]n recent years, there has been an increase in the length, detail, and complexity of prescription drug labeling, making it harder for health care practitioners to find specific information and to discern the most critical information." *Id.* at 3922. This in turn has exacerbated the problems that flow from overwarning, a phenomenon that in the FDA's judgment can "have a negative effect on patient safety and public health." *Id.* at 3935.

As for the suggestion by some critics that the FDA did not consult with state and local officials before it issued the preamble in 2006, the Final Rule states: "Officials at FDA consulted with a number of organizations representing the interests of state and local governments and officials about the interaction between FDA regulation of prescription drug labeling (including this rule) and state law." 71 Fed. Reg. at 3969.

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As the Committee is well aware, courts around the country are actively considering how much weight to give to the FDA's views on implied conflict preemption as expressed in the 2006 preamble. In my view, that issue is ultimately one for the courts to decide, since they are the ultimate arbiters of the Supremacy Clause's meaning and the doctrine of implied conflict preemption. As explained in my written testimony, however, there are good reasons – not to mention Supreme Court precedent – to accord the agency's views on this subject at least "substantial weight." *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 495-96 (1996); see also *Auer* v. *Robbins*, 519 U.S. 452, 461 (1996) (agency's interpretation of its own regulations is "controlling unless plainly erroneous or inconsistent with the regulation") (internal quotation marks omitted).

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GEORGETOWN UNIVERSITY LAW CENTER

David C. Vladeck
Professor of Law

October 4, 2007

Honorable Patrick Leahy
Chairman, Committee on the Judiciary
United States Senate
224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Leahy:

I testified before the Committee on the Judiciary on September 12, 2007 at the Committee's hearing on "Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?" By letter dated September 20, 2007, several members of the Committee posed additional questions and asked that I reply in writing. My responses follow. Please let me know if I can be of any further assistance to the Committee.

Respectfully,

David C. Vladeck

Attachments

cc: Jennifer Price, Hearing Clerk

600 New Jersey Avenue NW Suite 312 Washington DC 20001-2075
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Responses of David C. Vladeck, Professor of Law,
Georgetown University Law Center
to Questions Posed by Members of the Senate Judiciary Committee

Questions By Chairman Leahy:

Question 1: In November of 2005, Senator Specter and I wrote to the National Highway Traffic Safety Administration (NHTSA) expressing concerns that NHTSA's proposed rule concerning automobile roof strength contained unwarranted preemption language. We were particularly concerned with language in the proposed rule that claimed to "preempt all conflicting State common law requirements, including rules of tort law." In response, NHTSA stated that it "wanted to raise the possibility of preemption during the rulemaking process . . . rather than after the fact during possible litigation."

In your view is NHTSA's stated reason for the inclusion of preemption language a valid basis for the sweeping preemption language it included in its proposed rule? Do you agree that by inserting this preemption language NHTSA was merely "rais[ing] the possibility of preemption"?

Answer: In my view, the agency's response to the questions posed by you and Senator Specter was not a candid one. NHTSA has no interest in simply "rais[ing] the *possibility* of preemption." Had that narrow mission been the agency's goal, a far more balanced and nuanced discussion of the preemption question would have sufficed. But that was not the agency's purpose. The statement was included in the proposed rulemaking for one reason and one reason alone: To *foreclose* litigation involving claims by individuals injured or killed in rollover crashes involving automobiles that are manufactured in compliance with NHSTA's new roof strength standards. NHTSA's statement leaves no doubt that that is the agency's view.

What is remarkable about this is not simply the agency's lack of candor in response to you and Senator Specter. What is also remarkable is that the agency makes this claim even though, as I pointed out in my written testimony, 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.[1] 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. This point takes on special force here, since NHTSA acknowledges that its new standard, when adopted, will have only minimal impact on driving the death and injury rate down because the wide majority of

[1] 49 U.S.C. §§ 30103(b)(1) & (e).

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vehicles manufactured today meet or *exceed* its proposed new standard. If NHTSA gets its way, its rulemaking will stifle innovation and product development in the future.

NHTSA's statement in the preamble to the roof strength standard cannot be reconciled with *Congress's* judgment that NHTSA standards not preempt common law tort claims. Perhaps that is why the agency chose evasion rather than answer directly the question posed by you and Senator Specter.

Question 2: In its response, NHTSA also points to Section 4a of Executive Order 13,312, which states that "Agencies shall construe, in regulations and otherwise, a Federal statute to preempt State law . . . where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."

In light of the other portions of Executive Order 13,132, which circumscribe the process by which executive agencies preempt State law, is NHTSA's citation to this portion of the Executive Order a sufficient basis on which to include the preemption language it did? Did the NHTSA faithfully follow the guidance in Executive Order 13,132?

Answer: NHTSA's pro-preemption statement in the roof standard violates both the substantive and procedural requirements of Executive Order 13,132, and this is troubling for many reasons. As to substance, the Executive Order instructs executive agencies to preempt if, but only if, circumstances leave the agency with no choice. That is the clear message of Sections 2, 3, and 4 of the Executive Order. Rather than a license to preempt, as NHTSA appears to understand it, the Executive Order is actually a charter against preemption. It limits strictly the ability of executive agencies to preempt.

To be sure, Section 4(a) of the Executive Order does empower agencies to preempt where the "exercise of State authority conflicts with the exercise of Federal authority under the Federal statute," but it forbids an agency from doing so unless (a) the "statute contains an express preemption provision," or (b) "there is some other clear evidence that Congress intended the preemption of State law." The problem, which NHTSA simply ignores, is that the Safety Act not only does not contain an express preemption clause, it contains a *savings* clause that provides "clear evidence that Congress" did *not* intent the preemption of State law. Only by disregarding the first half of Section 4(a) can NHTSA claim that the section supports its position. Thus, there is no way to square NHTSA's preemption statement with the substantive dictates of Section 4(a), or indeed the Executive Order taken as a whole.

Nor did NHTSA comply with the Executive Order's procedural requirements. Sections 3, 4 and 6 of the Order sets forth detailed consultation requirements that obligated NHTSA to, among other things, consult with "state and local officials early in the process of developing the proposed regulation." NHTSA did not bother to do that, much to the dismay of State officials who have made significant efforts to engage the agency on this issue.

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What is especially troubling about NHTSA's wholesale disregard of the Executive Order is that the White House plainly endorsed, or indeed even encouraged, NHTSA to take this position. Executive Order 13,132 gives the Director of the Office of Management and Budget (OMB) a central role in supervising the relationship between executive agencies and the States. For instance, Sections 6(a), 6(b)(2)(B) & (C) and Section 6(c)(2) and (3), make the Director of OMB responsible for supervising an agency's compliance with the consultation provisions of the Order. It is therefore fair to conclude that OMB was aware of, and condoned, NHTSA's failure to follow those procedures. And it is fair to conclude that the White House has played a central role in orchestrating this seismic shift in the agencies' positions on preemption.

Question 3: In the article you wrote with Dr. Kessler, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, you discuss the "complementary discipline" that state tort claims can add to the marketplace and the government's efforts to make prescription drugs safe for consumers. You argue that failure-to-warn claims can play an important new role in discovering new information about drug safety, providing that information to the public, and prompting changes where changes need to be made.

Please describe for the Committee a few relevant examples of how State failure-to-warn claims have increased public awareness of dangers or led to beneficial product changes. Do efforts at other regulatory agencies to preempt state laws, such as the NHTSA, pose similar risks in removing an important external force on the relationship between the regulatory agency and the industry?

Answer: In response to the Committee's request for relevant examples, it is probably most efficient to refer the Committee to pages 39-48 of the article I co-authored with Dr. David A. Kessler, former Commissioner of the Food and Drug Administration. The article is available here: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1014094. In addition to the examples set forth in the article, it also bears emphasis that problems with long term use of pharmaceuticals such as Vioxx, Betra, Celebrex, Avandia, Rezulin, and Baycol, to name just a few, were first identified by failure-to-warn cases, and that action taken by the FDA to remove the drugs from the market, or to strengthen the warnings on the drugs, came *after* the first wave of failure-to-warn cases.[2]

As to the broader question of whether litigation has been an important external force that prompts better and safer products, NHTSA could well serve as the poster-child agency for this phenomenon. Take the safety of fuel systems in our nation's cars. NHTSA's *current* regulation

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[2] *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) (citing examples); Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks,* 287 J. Am. Med. Ass'n 308, 310 (2007) (citing examples).

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is at least 35 years out of date.[3] It is the same standard that governed General Services Administration automobile purchases in 1967. That standard requires that a car be able to sustain certain impacts from the rear, the front and the side without rupturing the fuel tank. NHTSA adopted the standard shortly after the agency was created in 1966. Although NHTSA has modified the testing used in the standard, it has not overhauled the standard itself since then, notwithstanding enormous strides in fuel system safety. In 1991, NHTSA conducted a study of the safety of fuel systems and found that cars on the road then were every bit as likely to sustain a fuel tank ruptures as they were in 1967.[4] Indeed, during the 1980s and early 1990s, GM sold tens of thousands of C/K pickup trucks that had their fuel tanks *outside* of the vehicles' protective frame-rail, making them especially prone to fuel-fed fires.[5]

So imagine this: Suppose that the NHTSA fuel safety standard adopted in 1967 preempted State law claims? For one thing, automobile manufacturers would have little incentive to improve the safety of their fuel systems, thereby stifling the development of safety products and better technologies. And for another thing, the people injured in poorly designed cars would have no recourse and, for the most part, be dependent on public programs to pay for their health care and rehabilitation services.

Now suppose that the NHTSA roof standard cuts off tort claims by people killed and injured in rollover crashes — 10,000 killed and another 25,000 seriously injured *each year*. NHTSA acknowledges that its new standard will barely make a dent in this death and injury toll. All the standard will accomplish, for the vast majority of cars already on the road, is cut off the right of injured people to sue. Until NHTSA gets around to revising the rule — and remember, the last time it addressed roof strength was over 35 years ago — little if anything will change in terms of safety improvements. This flies in the face of Congress's judgment that the Safety Act's standards are to set a floor, not a ceiling.

Question 4: Mr. Alan Untereiner stated in his written testimony that an "agency is no more obligated to avoid preemption than is Congress when determining whether federal regulation should be exclusive." Is this proposition consistent with Executive Order 13,132, which requires agencies to minimize as much as possible the preemptive effect of their regulations?

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[3] See 49 C.F.R. § 571.301.

[4] *See generally* Barry Meier, *Officials Did Little, Despite Report Saying U.S. Rules Wasn't Cutting Fatal Fires*, N.Y. Times, Nov. 21, 1992, at A7.

[5] *See In re GMC Pick-Up Truck Fuel Tank Prods. Liab. Litig.*, 55 F.3d 768 (3d Cir. 1995); *GM's Fuel-Tank Problems May Lead to Rule Changes*, Orlando Sentinel Trib., Dec. 3, 1992, at G4 (reporting that because of controversy surrounding fuel fed fires on GM vehicles, "the agency may have to beef-up safety rules").

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Answer: No. Mr. Untereiner's statement is directly at odds with the clear instructions of the Executive Order and with black letter constitutional law. As to the Executive Order, multiple provisions in Sections 2, 3, 4 and 6 drive home a single point: executive agencies may not preempt unless there is a clear evidence that *Congress* intended the agency to preempt or federal and state law actually conflict. The clearest expression of this command comes in Section 4, which addresses "Special Requirements for Preemption." Section 4(a) then emphasizes that preemption is acceptable only where the underlying statute contains an express preemption provision, where "there is some other clear evidence that Congress intended the preemption of State law," or where there is an actual conflict between federal and state law.

Congress, of course, is not constrained in its power to preempt. Congress can, if it so chooses, decide to "occupy a field," and thus displace state law across the board, as it has done with employee benefit plans. Or Congress can decide to displace law, even in the absence of a conflict between state and federal law, to advance goals such as national uniformity. Agencies do not have this authority unless they have clearly been given it by Congress.

Worse still, Mr. Untereiner's statement is wrong even on its own terms. The Constitution entrusts Congress, not agencies, with the responsibility for enacting the law. Agencies may exercise the power given to the them by Congress, and nothing more. For that reason, agency power to preempt is far more limited than that of Congress. Congress has plenary authority to preempt; agencies have the power to preempt only to the extent that Congress has clearly delegated preemptive power to them. To claim, as does Mr. Untereiner, that agencies have as much right as does Congress to define the boundaries between federal and State law, is to misstate the limited role of executive agencies in our system of constitutional government.

Questions Posed by Senator Feingold:

Question 1: Supporters of regulatory preemption have argued that subjecting corporations to liability when they have met all applicable federal standards is unfair. What is your response to that argument?

Answer: My response is that compliance with applicable federal standards has never been thought to be a defense to tort claims, for good reason. We have almost two centuries of experience with tort law — and nearly a century of tort law with the added layer of extensive state and federal regulation. Yet, until recently, the idea that compliance with regulatory standards should provide an immunity from tort litigation has been a non-starter.

There is good reason for this historical rejection of this argument. Except in the rarest circumstances, federal standards define *minimum* standards of care at the time the standard was adopted. Compliance with these standards is an affirmative defense in tort litigation, and juries almost invariably consider whether the defendant company did, in fact, comply with these minimal standards. When the federal standard is thought to be sufficiently stringent and up-to-date, then juries will often find for the defendant on that basis. Remember, defendants *win* a high

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percentage of tort claims against them, and the defense of compliance with regulatory standards remains an important weapon in the defendant's arsenal.

Moreover, minimum standards should not be transformed into ceilings. If companies may not depart from federal standards, they have no incentive to work to improve safety or to adopt newer, more effective technologies. Fixed, prescriptive standards stifle development, not encourage it.

There are several additional reasons for not giving minimal federal standards preemptive effect, each of which is important. One problem is that agencies are often "captured" by the businesses they regulate. It is easy to see how this happens. Agency officials work closely with their counterparts in industry. They are all members of a small and discrete group of experts on a subject, so there is a natural interaction among them. Industry representatives also rotate in and out of the government through a "revolving door" that leads directly to the boardrooms and law offices of regulated industry. Over time, close relationships emerge and the agency begins to see itself as much as an industry helpmate as a cop on the beat.[6] This problem is especially acute in those agencies that regulate a single industry, like the National Highway Traffic Safety Administration (NHTSA), which regulates the automobile industry, or the Federal Railroad Administration (FRA), which regulates railroads. These agencies tend to form "partnerships" with the industries they regulate, which translates into decreased enforcement efforts and lenient regulation, often at the expense of public safety.[7]

A second recurring problem is that agencies, unlike plaintiffs in litigation, are forced to depend on the industries they regulate for the information they need to regulate.[8] The asymmetry in information-gathering resources gives regulated industry an ability to manipulate the outcome of agency proceedings by withholding information, by cherry-picking the information they provide to the agency, or by manufacturing uncertainty by giving the agency incomplete, outdated, or inaccurate information. Generally, agencies have little ability to validate the information provided to them. Most agencies have limited information-gathering authority, most lack basic subpoena authority, and federal law circumscribes even the agencies' ability to secure information by surveying the industries they regulate.[9] There is little risk to companies that

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[6] *See, e.g.*, Stigler, *The Theory of Economic Regulation*, 2 Bell J. of Econ. and Management Sci. 3, 11-13 (1981); *see generally Symposium on the Theory of Public Choice*, 74 Vand. L. Rev. 167 (1988).

[7] *See, e.g.*, Perry Quirk, INDUSTRY INFLUENCE IN FEDERAL REGULATORY AGENCIES (Princeton Univ. Press 1981).

[8] See Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 Geo. L.J. 693 (2007).

[9] See Paperwork Reduction Act, 44 U.S.C. §§ 3501-3520.

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engage in game-playing with agencies; indeed, sanctions are rarely if ever meted out to companies that fail to provide the agencies with complete and accurate information. But information drives the regulatory process, and in this respect, it is industry, not the agency, that has the upper hand. Litigation is different. Court rules empower plaintiffs to engage in far-reaching discovery, permitting them to gain access to virtually any information that might be relevant to the plaintiff's claim. As a result, plaintiffs in litigation generally unearth information that was unavailable to the regulatory agency.[10]

The third and most pressing weakness of the regulatory process is chronic resource limitations. Agencies can only go as far as their resources will take them, but over the past decade or so, our regulatory agencies have suffered severe reductions in funding and in personnel while their regulatory responsibilities have increased.[11] NHTSA has fewer than 700 employees, yet it is responsible for regulating the automobile industry. The Occupational Safety and Health Administration is responsible for safeguarding our nation's workplaces, yet it has fewer than 3,000 employees nationwide. And the Consumer Product Safety Commission, responsible for regulating a vast array of consumer products, has fewer than 500 employees — half the staff it had when it was first founded.

These limitations have real world consequences. With meager staffs, agency enforcement efforts are by necessity limited. And without adequate staffing, agencies cannot hope to promulgate needed regulations in a timely way, let alone keep regulations up-to-date. Many of the regulations on the books today are twenty or thirty years out-of-date, even though new technologies and other advances enable far more protective regulation. NHTSA's roof strength standard, for instance, is over 35 years old. And agencies often take years, or even decades, to put new standards in place. NHTSA, for example, has been promising to issue a rollover standard for a decade, but has still not come forward with a proposal, let alone a final rule. Regulatory delay, or what experts call "ossification," led to the shortage of lifeboats on the *Titanic*, as I explained in my written testimony. That problem remains a serious one today.

Question 2: If corporations are required to pay out tort claims in state lawsuits, won't they simply pass this cost on to consumers through higher product prices?

Answer: They may, but not for long. Companies compete on many bases — but safety is plainly a critical issue that consumers care about. Unsafe products hurt companies' bottom line in two ways. First, safety problems with a company's products reduce consumer demand; conversely, consumers gravitate to safer products. Volvo, for instance, has carved out a niche

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[10] David C. Vladeck, *Defending Courts: A Brief Rejoinder to Professors Fried and Rosenberg*, 31 Seton Hall L. Rev. 631 (2001).

[11] *See generally* Jerry Mashaw, *Reinventing Government and Regulatory Reform: Studies in the Neglect and Abuse of Administrative Law*, 57 Univ.of Pitts. L. Rev. 405 (1996).

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market in the United States by touting the safety advantages its cars have over other brands. Consumers take safety into account in making purchasing decisions, and a company plagued with safety problems will take a hit in the market. Second, losing tort claims adds considerable red ink to a company's bottom line. If a company responds by increasing prices, it will be disadvantaged significantly in the marketplace by companies whose products have a better safety record. That is the way the tort system forces company to keep apace with emerging safety technologies.

Finally, it bears noting that the full cost of liability judgments can never be passed on to consumers unless the demand for the product is completely inelastic. Even if the company is a monopolist, it could not pass on the entire cost of liability unless demand for the product was completely unresponsive to price, and it is hard to imagine a real-world situation in which that would be the case.

Question 3: In your written testimony, you stated: "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." Could you provide examples?

Answer: This question calls for the same information requested by Chairman Leahy, in his third question to me. The simple answer is that the statement quoted in your question comes in part from an article that I have recently co-authored with Dr. David A. Kessler, former Commissioner of the Food and Drug Administration, entitled *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*. The article is available here: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1014094. I would also point out that problems with long term use of pharmaceuticals such as Vioxx, Betra, Celebrex, Rezulin, and Avandia, among others, were first identified by failure-to-warn cases, and that action taken by the FDA to remove the drugs from the market or to strengthen the warnings on the drugs, came *after* the first wave of failure-to-warn cases. The literature also reflects many other illustrations of the same point.[12]

Question 4: How do you respond to corporations which claim that having to comply with differing and often conflicting state standards is overly burdensome and will render American businesses less competitive?

Answer: With all respect, I disagree with the premises of this claim. Corporations make this argument in order to raise the specter of corporations being tied in knot by a bewildering welter of conflicting rules. But this contention rests on two assumptions that are either highly contestable or just wrong. The first assumption is that state tort litigation imposes "standards."

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[12] *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) (citing examples); Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 287 J. Am. Med. Ass'n 308, 310 (2007) (citing examples).

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That just is not so. A company can lose a state tort case, or even many tort cases, and not change its product at all. As the Supreme Court recently explained, "A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement" forcing the defendant company to do anything but pay a judgment.[13] Of course, the company might decide to take measures to avoid future adverse rulings, including making product modifications. But a company could also rationally decide to do nothing, reasoning that the prospect of a recurrence is too remote to justify a change, or that the cost of defending cases and paying judgments is less than the profits that would be lost as result of making such a change. For instance, it has been reported that Ford made no change to the Pinto, even after it began losing tort cases based on the car's vulnerability to fuel-fed fires. And it appears that Ford did not strengthen the roof of the Ford Explorer, even after the vehicle experienced a raft of rollover crashes. The cars was profitable, despite their design flaws.

On the other hand, tort litigation often does force manufacturers to make important safety improvements to their products — and that is part of the complementary discipline tort law serves. Take the Guidant Prizm 2 heart defibrillator, which was ultimately recalled by Guidant because the product had a design defect causing it to short-circuit. That device was modified by Guidant, not as a result of pressure from the FDA, but because of product liability concerns. In this case — and many of the medical device cases described in my testimony — tort law prescribed the *only* standard of care and prompted important safety improvements in otherwise dangerous devices.[14]

Second, the notion that businesses have to endure "conflicting" state and federal standards is simply mythology, not fact. There are many legal protections that guarantee that a business will not be put to the Hobson's choice of obeying one set of laws and thereby violating another. For one thing, it is longstanding and settled doctrine, under the Constitution's Supremacy Clause, that state law that conflicts with federal law is preempted and may not be enforced.[15] And there are due process guarantees, in both the Fifth and Fourteenth Amendment, which shield a business from sanction for disobeying one set of laws in order to abide by another. So the bleak picture painted by corporations who make this claim are simply inaccurate.

Just as fundamentally, however, our system of concurrent state and federal regulation is deeply embedded in our Constitution and has been our guiding force since the founding of the Republic. If Congress wants to wide away state law in the name of reducing "burden" on U.S. corporations, that is in Congress's power. But most of us believe deeply that our federalist

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[13] *Bates v. Dow Agrosciences LLC*, 544 U.S.431, 445 (2005).

[14] *See* David C. Vladeck, *Preemption and Regulatory Failure*, 33 Pepp. L. Rev. 95 (2006).

[15] *See, e.g., United States v. Locke*, 529 U.S. 89, 102 (2000); *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873-74 (2000).

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system of government is its greatest strength, since it permits states to serve as the laboratories of innovation.[16] Divesting states of their power to define the standards of care owed to their citizens threatens to disrupt, if not destroy, the federalism that is part of the fabric of our Constitution.

Question 5: You and other critics of regulatory preemption have counseled Congress to pass legislation to address the problem. Why is it not sufficient for Congress to express its disapproval of preemptive regulation through the mechanism provided by the Congressional Review Act?

Answer: Congressional Review Act (CRA) supervision provides a partial, but far from complete, answer to the problem of regulatory preemption. The CRA sets up an elaborate procedure to compel agencies to submit regulations to Congress for its review, to ensure that regulations do not take effect until Congress has an opportunity to review them, and to permit Congress, if it so chooses, to disapprove of the regulations.[17] However, as far as I know, the procedure has been used only once to disapprove a regulation — the ergonomics standard promulgated by the Occupational Safety and Health Administration.

As the question suggests, this process *could* be used by Congress to overturn regulations that have a preemptive effect. But there are a number of problems with this approach. For one thing, the Act gives Congress only sixty days to act — often an inadequate period of time for Congress to respond. For another, agencies are not making regulatory preemption decisions by promulgating regulations that define the boundaries of federal and state law; they are simply announcing their pro-preemption conclusion in a range of documents, including regulatory preambles. I am far from certain that the CRA process extends to comments in preambles to final regulations.

More fundamentally, agencies have been announcing their new pro-preemption positions in a variety of ways — most of which would evade review under the CRA. For instance, the FDA first announced its new position, that its decisions regarding drug labeling preempt state failure-to-warn litigation, in friend-of-the-court briefs and in meetings between the agency's chief counsel and lawyers for the pharmaceutical industry. And the FDA changed its position regarding preemption on medical device claims only by filing amici briefs supporting industry. The CRA would not give Congress notice or the opportunity to address these agency efforts to preempt state law.

For these reasons, I and others urge that Congress consider more sweeping measures to restore to Congress the power to decide when federal law ought to displace state law.

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[16] *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1868) (Brandeis, J., dissenting).

[17] See 5 U.S.C. §§ 801-808.

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Questions Posed by Senator Grassley:

Question 1: In your written statement, you say that the FDA "claims the 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 . . .." You also state that "Congress should not countenance this usurpation of its authority." What specific actions do you think Congress should be taking? What do you think that Congress should be doing in response to agency efforts to preempt by preamble?

Answer: As I explained in an answer to a question posed by Senator Feingold, review of agency decisions under the Congressional Review Act is one way for Congress to keep apace of agency preemption activity. But there are other measures that should be taken as well. First, there must be more searching and effective oversight of agency conduct. As far as I know, this Committee's hearing was the first to address this issue at all, let alone probe how agencies like the Food and Drug Administration or the National Highway Traffic Safety Administration determined to jettison decades of bi-partisan decisions that its regulatory action did not preempt state law and adopt diametrically opposed positions. Second, Congress should consider enacting a statute, modeled in Executive Order 13,132 that formalizes the general rule that agencies should preempt state law only when they have no other option, and that, prior to reaching a preemption decision, agencies must consult with their state and local counterparts. Finally, Congress should revisit immediately some of the most dire agency preemption determinations that threaten to destabilize long-standing law. The FDA's new position on drug and medical device preemption, for example, raises sweeping questions about the regulation of products Americans depend on for their health and well-being. These decisions should be made by Congress, not by the FDA.

Question 2: In Levine v. Wyeth, the Vermont Supreme Court rejected Wyeth's preemption defense against a failure to warn claim regarding its anti-nausea drug, Phenergan. Wyeth petitioned for certiorari, and in May, the United States Supreme Court asked the Solicitor General to file a brief expressing the views of the United States. What, in your opinion, is the impact of this case?

Answer: The *Levine* decision by the Vermont Supreme Court is in keeping with the vast majority of rulings holding that FDA labeling decisions do not preempt state law failure-to-warn claims. In *Levine*, of course, although Wyeth was well aware that the "push IV" method of injecting Phenergan carried a high risk of serious adverse effects, Wyeth had never warned patients of the risk, let alone sought permission from the FDA to include such a warning on its label. So, in my view, *Levine* is a clear case where preemption would disserve the public interest in alerting physicians and patients to serious risks attending the use of drugs and it would deny Ms. Levine the compensation that she will need to get on with her life.

Of course, should the Supreme Court grant review the case will assume even greater importance. It would, in my view, be preferable for Congress rather than the Court to decide

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when, if ever, FDA labeling decisions preempt state law. But here, I think it is likely that the Court will side with Ms. Levine, even though the FDA is now taking a contrary view.

Question 3: In your written statement, you say that FDA's pro-preemption arguments "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." The United States Senate and House of Representatives are in the process of working out differences between S. 1082, the Food and Drug Administration Revitalization Act, and H.R. 29000, the Food and Drug Administration Amendments Act of 2007. In their current form, both bills would give the FDA the authority to require labeling changes, among other things. What impact, if any, do you think that this new authority will have on the FDA's ability to protect the public's health?

Answer: First of all, I'd like to commend Senator Grassley and others in the Senate and House who worked for the passage of this legislation on a job well done. If ever an agency needed a boost in terms of its statutory authority and resources, the FDA did and the new legislation is an important step forward.

Once the new legislation is implemented by the FDA, the new legislation should prevent the recurrence of the sorry spectacle of the FDA negotiating with a drug company over modest changes in labeling — moving mention of a heart attack risk from the precaution section of the label to the warning section — for over a year, while literally millions of patients were exposed to a risk that threatened their well being and indeed their lives. That is what happened with Vioxx. And it should not happen again. Not only does the new legislation strengthen the FDA's power to compel needed labeling changes, but it also reaffirms the agency's longstanding position that drug manufacturers have an independent duty to update labels to provide different and additional warnings, contraindications, and other instructions for use when there is an association between a drug and a particular risk. Moreover, stepping up the FDA's resources for post-approval monitoring of drug safety ought to reduce dramatically the number of injuries and death caused by newly emerging risks because we will have better information, and we will get that information far more quickly than in the past.

But make no mistake, the new legislation is no panacea. Drug companies will still have access to information unavailable to the FDA, will still better appreciate the risks posed by their drugs than the FDA, and will still have incentives to keep even risky drugs on the market while they reap big profits. I would hope that the new legislation reduces sharply the number of drug-related injuries and deaths, but we will still see some instances of drugs entering the market despite risks, drugs that are allowed to remain on the market despite their risks, and drugs that failed to provide doctors and patients adequate warnings of risk. In those kinds of cases, a robust tort system is still the consumers best and last line of defense against unsafe products.

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SUBMISSIONS FOR THE RECORD

CONFERENCE OF CHIEF JUSTICES

Resolution 1

In Support of the Efforts by the U.S. Congress to Promote Respect for Principles of Federalism and Separation of Powers

WHEREAS, the Conference of Chief Justices, in fulfilling its leadership role for state judicial systems, has traditionally taken positions to defend against proposed policies that threaten principles of federalism or that seek to preempt proper state court authority; and

WHEREAS, recent actions by federal agencies have led to a growing concern by the Conference of Chief Justices about federal regulatory agency efforts to preempt federal and state statutes and common law through the promulgation of proposed rules; and

WHEREAS, Executive Order 13,132 (August 10, 1999) confirms fundamental federalism principles and instructs federal 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"; and

WHEREAS, Executive Order 13,132 (August 10, 1999) requires in Section 6 that each agency shall have an accountable process to ensure meaningful and timely input by State and local governments in the development of regulatory policies that have federalism implications; and

WHEREAS, Executive Order 13,132 (August 10, 1999) is not binding or enforceable absent codification by Congress; and

WHEREAS, on September 12, 2007, the Judiciary Committee of the United States Senate held a public hearing on "Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?" disclosing a pattern of conduct by federal agencies to use preamble statements in proposed rulemaking to circumvent or nullify established state public policy and common law; and

WHEREAS, the concern regarding regulatory preemption of state law is shared by the legislative as well as the judicial branches of state government as demonstrated by the President of the National Conference of State Legislatures (NCSL) who testified at the September 12, 2007 hearing on behalf of the entire NCSL concerning the growing lack of federal/state consultations in federal rulemaking; and

WHEREAS, federal agencies continue to assert the authority to preempt state law, as exemplified by the proposed rule published by the U.S. Department of Health and Human Services in January 2008 regarding the labeling of FDA-approved drugs, biologics, and medical devices;

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NOW, THEREFORE, BE IT RESOLVED that the Conference of Chief Justices urges Congress to enact: (1) the federalism protections contained in Executive Order 13,132; (2) a requirement that a federalism assessment of proposed legislation having federalism implications be included in every Congressional committee and conference report; and (3) a rule of statutory construction to resolve any ambiguities in favor of state law in order to improve and encourage respect by the executive branch of the federal government for the principles of federalism and separation of powers.

Adopted as proposed by the CCJ/COSCA Government Affairs Committee at the 31st Midyear Meeting on January 30, 2008

PREPARED STATEMENT OF

PROF. VIET D. DINH

GEORGETOWN UNIVERSITY LAW CENTER
AND BANCROFT ASSOCIATES, PLLC

Before the

COMMITTEE ON THE JUDICIARY

of the

United States Senate

On

Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?

September 12, 2007

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Mr. Chairman and Members of the Committee,

Thank you for the invitation to appear before you today on the issue of regulatory preemption. The question of preemption in our constitutional structure is an important but often misunderstood concept with significant consequences to ordinary Americans. Given the growth of federal legislation and regulation into virtually all aspects of human endeavor beginning in the second half of the last century, it is understandable that some policymakers, scholars, and judges would look to curb the effect of such federal activity by revamping preemption doctrine to circumscribe the preemptive effect of federal law and regulations. I think this effort, although very well-intended, is a mistake.

The Supremacy Clause, Article VI, cl. 2, of the Constitution provides that "the Laws of the United States * * * shall be the supreme Law of the Land." The practical effect of this declaration is that federal law displaces conflicting state laws or local ordinances. Although this clause makes clear that federal enactments trump (or "preempt") conflicting state law, the Supremacy Clause itself does not authorize Congress, or federal agencies through regulations, to preempt state statutes. Instead, the Supremacy Clause simply provides a choice-of-law rule that favors federal law over state law in the event of a conflict.

Thus, to the extent that there are constitutional policy questions raised by federal preemption of state law, the Framers have answered them in favor of the federal government through inclusion of the Supremacy Clause. Solicitude for the regulatory province and sovereign prerogatives of the states–a sentiment that I share—must find constitutional expression elsewhere, apart from a disdain for or presumption against preemption.

The inquiry into the circumstances under which federal law will displace state law is no more and no less than an exploration into the division of state and federal legislative authority. The constitutional structure in this regard is straightforward: Article I, section 8 enumerates the powers of Congress; Article I, section 9 limits the powers of Congress; Article I, section 10 limits the powers of the states; and the Tenth Amendment reserves to the states the legislative powers not delegated to Congress or prohibited to the states. Importantly, clause 2 of Article VI provides that congressional enactments consistent with the Constitution "shall be the supreme Law of the Land." Although the Supremacy Clause makes clear that congressional enactments have an extraordinary displacing effect on state law, the clause itself does not authorize Congress to preempt state laws. If the clause were an affirmative grant of authority, it would likely reside in the metropolis of congressional power, Article I, section 8, rather than in the suburbs of Article VI.

The history of the Constitutional Convention supports this reading. The Virginia Plan included among its proposed congressional powers the broad authority "to negative all laws passed by the several States, contravening in the opinion of the National Legislature the articles of the Union."[1] The alternative New Jersey (or Small State) Plan,

[1] 1 The Records of the Federal Convention of 1787, at 21 (M Farrand ed., rev. ed. 1937) [hereinafter "Farrand"]

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on the other hand, did not include such authority among the powers of Congress, but rather separately proposed language similar to the current Supremacy Clause. When the competing proposals were debated by the Convention, James Madison, as he had done throughout the debates, warned against the "propensity of the States to pursue their particular interests in opposition to the general interest" and advocated "the negative on the laws of the States as essential to the efficacy & security of the Genl. Govt."[2] Governor Robert Morris of Pennsylvania opposed the congressional power to negative state laws with the telling explanation that "[a] law that ought to be negatived will be set aside in the Judiciary department and if that security should fail; may be repealed by a National Law."[3] The Virginia Plan's proposal for a legislative power to negative state laws was defeated by a vote of 3 to 7. The Convention then adopted a revised version of the New Jersey proposal which was almost identical to the current Supremacy Clause.[4] Consistent with the New Jersey Plan's structure and Morris' explanation, the adopted text does not mention any affirmative authority of Congress, but simply sets forth the hierarchy between federal and state laws.

The power to preempt state law, therefore, must be found elsewhere in the Constitution, most logically in the affirmative grants of power to Congress under Article I, section 8. For example, should Congress legislate pursuant to its powers under the Commerce Clause and wish to include a provision expressly preempting certain state laws, the authority for the preemption provision must come from the Commerce Clause alone or perhaps from the Commerce Clause with some help from the Necessary and Proper Clause. The Supremacy Clause then makes clear that the preemption provision trumps state laws that conflict with it.

Accordingly, to the extent that there are questions of constitutional policy in preemption — "the Danger . . . that the national, would swallow up the State Legislatures,"[5] and the like — the framers answered them with the specific enumerations and limitations of federal legislative power in Article I and inclusion of the Supremacy Clause in Article VI. To find in this structure some additional substantive reason to disfavor federal preemption of state law, it seems to me, risks rewriting the balance envisioned by the Framers — a balance that, it bears reminding, James Madison and others thought should have been weighted even more in favor of Congress.

In sum, the Constitution's text, structure, and history provide no support for a presumption against preemption. Indeed, the constitutional provision most frequently invoked in preemption analysis, the Supremacy Clause, evinces, if anything, a presumption favoring preemption. Finding a presumption against preemption in the Supremacy Clause is rather like locating in the Eleventh Amendment a presumption favoring federal jurisdiction over suits against States.

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[2] 2 The Records of the Federal Convention of 1787, at 27 (M. Farrand ed., rev ed 1966) [hereinafter "Farrand 2"].

[3] 2 Farrand at 28.

[4] 2 Farrand at 28-29

[5] 1 Farrand at 160 (Statement of George Mason, June 7, 1787)

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The lack of support for a presumption against preemption is equally apparent in the context of regulatory preemption. It is of no moment that the federal enactment displacing state law is one promulgated by a federal agency through regulations rather than a statutory provision enacted by Congress. Consistent with traditional administrative law principles, validly promulgated regulations authorized by the agency's organic statute have the force of law and thus also trump state law by operation of the Supremacy Clause, because "[t]he phrase 'Laws of the United States' encompasses both federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization."[6] Indeed, federal agencies are given a great degree of latitude to pre-empt state laws to the extent it is believed that such action is necessary to achieve its purposes, even absent express authorization from Congress: "A pre-emptive regulation's force does not depend on express congressional authorization to displace state law . . . ."[7]

The absence of any firm constitutional basis for the presumption against preemption deprives any attempts to limit regulatory preemption of any claim of superior fealty to the Framers. Congress, nonetheless, could prefer as a policy matter to preserve state law. The simplest way for Congress to do so is to recognize the limits on its enumerated powers and decline to legislate. When Congress does legislate, it can preserve state law by including an express savings provision. Finally, Congress can enact background rules to govern how it will preempt state law in the future. This third category would require future Congresses to preempt explicitly or not at all.

Although Congress has the power to enact such legislation, I question the wisdom of such a background rule based on its effects on the concurrent operation of state and federal regulatory authority. I do not address here the possible challenges to such legislation based on intrusion into the judicial function in interpreting statutes or on infringement of the prerogative of future Congresses. I have no quarrel with an enactment aimed at forcing the Executive Branch to consider the implications of displacing state law—anything that forces the federal government to stop and think whether it is the proper forum to address a problem ultimately should produce better policy. However, it bears noting that regulatory agencies have been required to do so since 1987, when President Reagan issued an executive order entitled "Federalism," and thereafter by an Executive Order issued by President Clinton in 1999.

Any Congressional action that would limit preemption to only those cases where Congress explicitly states that preemption is intended or where there is a direct conflict between state and federal law would work a sweeping legislative repeal of the doctrine of implied preemption. It would compel Congress to preempt in express terms not only state laws, but also local ordinances. One will search the Constitution in vain for any solicitude for the legislative province of a city council.

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[6] *City of New York et al., v. Federal Communications Commission et al.*, 486 U.S. 57, 63 (1988). *See also Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

[7] *De la Cuesta*, 458 U.S. at 154.

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Such legislation would upend constitutional supremacy and create a presumption in favor of overlapping regulation by multiple jurisdictions. It would favor regulation by a limitless number of governments at three or four different levels — one Congress, 50 state legislatures, numerous county boards, and countless city councils. Nothing in our constitutional structure provides any support for such a presumption. Indeed, many of the enumerated powers expressly granted to Congress — from the power "to borrow money on the credit of the United States," to the power "to establish an uniform rule of naturalization, and uniform laws on the subject of bankruptcies throughout the United States," to the power "to declare war" — were meant to be exclusive. The Framers identified the areas in which overlapping state regulations created problems or potential for havoc. They then gave Congress limited, enumerated powers to legislate in those areas and avoided the problem of conflicting regulation by thirteen separate sovereigns. From this perspective, it is actually more difficult to justify non-preemptive federal legislation than federal legislation that occupies the regulatory field. If there is no need to provide a uniform federal rule, it should be harder — not easier — to justify the need for any federal rule at all.

The requirement that Congress must preempt explicitly or not at all creates an additional practical problem: Congress cannot possibly foresee all of the potential conflicts that may materialize when it first enacts a statute.[8] In *Cipollone v. Liggett Group, Inc.*, 505 US. 504 (1992), the Court concluded that Congress' explicit preemption of certain laws evidenced an intent not to preempt other laws, a holding much less dramatic than the Act's requirement that Congress always be explicit about preemption. Nonetheless, it was too much for Justice Scalia, who predicted that such a rule of construction would work havoc: "The statute that says anything about pre-emption must say everything; and it must do so with great exactitude, as any ambiguity concerning its scope will be read in favor of preserving state power. If this is to be the law, surely only the most sporting of Congresses will dare say anything about preemption." *Cipollone*, 505 US. at 548 (Scalia, J., concurring in part, dissenting in part).

To establish a presumption against preemption in the regulatory field would be to remove from Congress the option of not saying anything about the topic. It forces every Congress to be sporting, to anticipate and address with clarity every potential conflict that could arise. That task will prove impossible.[9] Even if Congress could somehow divine

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[8] *See* Daniel E Troy, *The Case for FDA Preemption in* FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 81, 83 (Epstein & Greve ed., 2007)(hereinafter "Troy, *The Case for FDA Preemption*") ("It would be impossible to implement a drug approval process that sought to prevent all adverse reactions and costly beyond measure to do so ").

[9] *See* Thomas W Hazlett, *Federal Preemption in Cellular Phone Regulation in* FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 113 (Epstein & Greve ed., 2007)(hereinafter "Hazlett, *Federal Preemption in Cellular Phone Regulation*") (The Omnibus Budget Reconciliation Act of 1993 establishes that "'no State or local government shall have an authority to regulate the entry of or the rates charged by any commercial mobile service or any private mobile service' . [and] states were left with jurisdiction over 'other terms and conditions of commercial mobile services.' How much regulatory authority this provision cedes to the states is legally uncertain . . . The Telecommunications Act of 1996 instituted further preemption . . which inhibited the siting of towers for wireless networks. Again, the extent to which state and local authorities are prohibited from regulating is under debate.")

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the myriad ways that extant state and local regulations may frustrate a federal regulatory regime, it simply cannot predict developments in state common law or anticipate the future legislative agendas of States and localities. Whether Congress would react by preempting more or less than necessary is anyone's guess. However, I rather doubt that such an enactment will lead to more intelligent legislation or better consideration of the proper balance between state sovereignty and federal interests.

Federal agencies exist to coordinate areas of national public concern. To allow state law to preempt or even coexist with certain areas of federal regulation undermines the very existence of these agencies and Congress's objectives in delegating specific authority to the agencies.[10] These agencies have expertise in regulatory areas and are attune to the national problems in those areas, allowing them to balance national needs and public concerns with the need for innovation and public protection in a realistic manner.[11]

Courts and juries applying state law in *ex post* situations are not in a vantage point to adequately take into account the nation's needs or the far-reaching effects of their decisions. When lawsuits under state law are brought — indeed, encouraged by other such successful lawsuits — in an area of regulation that has previously been regulated by an executive agency, the implication is that the plaintiff is in a better position to assess the safety determinations made by experts in federal agencies.[12] Few would argue that this is the case.

Federal agencies are uniquely positioned to promulgate rules with wide-sweeping national effects precisely because regulation in these areas on the state level may negatively impact that field. When a state regulates, it does so with its own citizens, circumstances, and particular needs in mind. Although Madisonian republicanism aims to utilize states as "experimental laboratories," in some areas of governmental concern — namely, those areas in which federal agencies exist — regulation at the state level will be

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[10] *See* Troy, *The Case for FDA Preemption, supra* note 8, at 90 ("The liability system interferes with the basic objective underlying Congress's delegation to the FDA of the power to regulate prescription drug labeling—providing physicians with the information necessary to make rational prescribing decisions. . . . A tort suit alleging failure to warn is an explicit allegation that a manufacturer had a duty to supply a warning beyond that which the FDA found appropriate ")

[11] *See id* at 97 (noting that the FDA's expertise allows it to balance national needs and concerns in order to promulgate national rules on medical prescriptions because "excessive warnings about suicide-related risks may have the paradoxical effect of increasing suicides by preventing appropriate prescription of antidepressants"); *id* at 102 ("FDA decisions intrinsically, and by statutory mandate, constitute an effort to establish a sensible trade-off among competing considerations, rather than a mere 'floor.'").

[12] Robert R. Gasaway & Ashley C. Parrish, *The Problem of Federal Preemption Toward a Formal Solution in* FEDERAL PREEMPTION· STATES' POWERS, NATIONAL INTERESTS 236 (Epstein & Greve ed., 2007) ("A state tort suit questioning the safety or efficacy of a federally registered pesticide must, by definition, rest on the improbable proposition that Congress intended for state tort plaintiffs to have greater authority to look behind safety and efficacy determinations made in the EPA registration process than federal enforcement officials In order to find implied conflict preemption, all a court need do is to reject this improbable proposition.").

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done without adequate information and feedback on the overall efficacy and effects of a governmental program.[13]

Such state regulation in these spheres may be inefficient in other ways. States may expend time and money formulating and enforcing rules and regulations which are duplicative. Those who are regulated will also feel the effects of duplicative, confusing or conflicting state regulations. For example, regulation at the state level for national (or international) companies will result in a single company being subject to many different or even conflicting laws.[14] As a result, a company will expend time and money researching and ensuring compliance with the laws of various jurisdictions—time and money that could be spent on research and development.[15] Inevitably, the added costs of compliance will be passed down to the consumer — the American public. Concerns about liability and confusion over jurisdictional differences may deter companies from engaging in the development of new innovations.[16] This confusion will also result merely from allowing state regulations to coexist alongside federal regulations.[17]

Regulation at the federal level also helps prevent nationwide market failures. For example, the federal government is in a better position to constrain monopoly pricing and to remedy "externality problems"[18] that result when costs do not fall on those making decisions. States will be placed in a position where they may be able to "free ride" off the investments of other states.[19] Because costs will spill over to other jurisdictions, the actual effects of local regulations will not fully be accounted for when decisions are made.[20] The same is true at the international level. Regulations created in the United

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[13] *See* Hazlett, *Federal Preemption in Cellular Phone Regulation*, *supra* note 9, at 116

[14] *See* Hal S Scott, *Federalism and Financial Regulation in* FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 139, 156 (Epstein & Greve ed., 2007)(hereinafter "Scott, *Federalism and Financial Regulation*") ("Within the United States, most large financial firms operate in several states; several operate in most Left to their own devices, states may impose conflicting or unnecessarily duplicative regulation on these multistate financial institutions.")

[15] *See* Troy, *The Case for FDA Preemption*, *supra* note 8, at 89 ("The current liability environment makes available drugs cost more than they otherwise would.")

[16] *See id.* at 88 ("'[A]pphrehensions (about tort liability) act as a deterrent to vaccine production and thereby threaten the public's health' . . . . Concerns about liability have slowed the progress of particular identifiable vaccines, including an AIDS vaccine ") (quoting INSTITUTE OF MEDICINE, VACCINE SUPPLY AND INNOVATION 2 (1985)), *id.* at 92-93 ("[In *Feldman v. Lederle Labs*, 125 N J 117, 128 (1991),] Lederle followed the FDA labeling requirements—and was held liable for violating conflicting state requirements ")

[17] *See id.* (noting that despite the FDA's approval of the marketing of the drug Bendectin, 1,700 lawsuits under state law were brought against the manufacturer due to assertions that Bendectin could produce birth defects)

[18] Hazlett, *Federal Preemption in Cellular Phone Regulation*, *supra* note 9, at 115

[19] *See id.* at 117 (discussing the free rider problem associated with state regulation and using national defense as an example)

[20] *See id* at 117-118 ("Given that costs and/or benefits spill over to other jurisdictions, effects of local regulatory decisions will likely escape the attention of policymakers. Analogous to a 'race to the bottom,' state regulators search for rules that will bestow benefits locally while shifting costs to network investments that enable local benefits to be subsidized by users elsewhere . . [S]tate regulators have no reason to take into account what ripples across state borders.").

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States — particularly in areas such as U.S. capital markets — affect both the national and international growth of the country, and thus its position in the global arena.[21] The national government, the repository of diplomatic and foreign affairs powers, is better situated to deal with such considerations.

Independent federal agencies in particular are able to capably perform their jobs better than state regulators because they are also more insulated: agencies such as the SEC and Federal Reserve are subject to terms of office that do not fully correspond to presidential elections and are able to issue rules without review by the White House.[22] Furthermore, all federal agencies promulgate rules according to the Administrative Procedure Act. This requires that, before an agency issues a rule, the proposed rule be subject to "notice and comment" procedures. This is an excellent opportunity for interested parties to object to the proposed rule's preemption of state law on the issue. If sufficient opposition is voiced, the rule will not be issued. This is a significant check on the power of the federal government to preempt state law.

Executive Order 13132,[23] which revoked previous Executive Order 12612,[24] also provides a valuable check on federal regulatory action. The Order ensures that executive departments taking federal action that would limit the policymaking discretion of the states only act when it is necessary.[25] Such action also may occur only when constitutional authority for the action is clear and certain, and the national activity is necessitated by the presence of a problem of national scope.[26] This Executive Order guarantees that federal agencies will only take action when the aforementioned advantages afforded by federal regulation outweigh the problems presented by state regulation. Further, it provides that federal agencies cannot submit proposals for legislation that would preempt state law or directly regulate the states in ways that interfere with traditional state functions, except where there is a "clearly legitimate national purpose."[27] Because there are certain areas in which federal government action is more desirable than decentralized state regulation, one might be concerned about federal government inaction. However, notice and comment periods (as well as direct petitioning of Congress) can be used by states to voice concerns regarding lack of effective federal enforcement.[28]

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[21] *See* Scott, *Federalism and Financial Regulation*, *supra* note 17, at 155 ("[T]he rules governing U.S. capital markets have a profound effect on national and international economic growth through their impact on the cost of capital. U.S. rules do not exist in an international vacuum.").

[22] *See id.* at 156.

[23] Executive Order 13132, 64 Fed. Reg. 43255 (Aug. 4, 1999).

[24] Executive Order 12612, 52 Fed. Reg. 41685 (Oct. 26, 1987).

[25] *Id.* § 3.

[26] *Id.* §§ 3, 4.

[27] *Id.* § 5.

[28] *Cf.* Scott, *Federalism and Financial Regulation*, *supra* note 17, at 159 ("States should be given access to information about all forms of federal enforcement so they can reach informed judgments as to the degree of and effectiveness of federal enforcement. If state officials perceive a lack of enforcement, they should bring the matter to the attention of Congress, which has the power to do something about inadequate federal enforcement.").

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I respect the principles that preserve and protect the delicate structure of "Our Federalism" against the aggrandizing propensities of the national government. Well-meaning scholars and legislators have lamented the fact that expansive congressional power under Article I, section 8 coupled with the displacing effect of preemption means that the Framers' fear that the Federal Government would swallow up the State Legislatures has been realized in the modem regulatory state. The solution, it is advocated, comes in the form of a judicial presumption against preemption or a pre-imposed requirement by Congress of a clear statement of preemption in order to counterbalance the awesome effect of the Supremacy Clause. It seems to me that these proposed solutions are supported by neither constitutional theory nor sound legislative policy.

Redefining the proper balance of state and federal legislative powers is better accomplished directly, through an insistence on the limits of Congress' enumerated powers under Article I, rather than circuitously and ineffectually through tinkering with the Supremacy Clause. When Congress refrains from exercising its power under, say, the Commerce Clause and its attendant authority to preempt state law, it properly recognizes the competency, legitimacy, and authority of states to regulate matters within their legislative jurisdiction. At the same time, the federal government remains free to regulate, and displace state law if necessary, in order to protect national interests in areas within its legislative responsibility, as enumerated in the Constitution.

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Kessler & Vladeck, 96 Geo. L.J. ___ (2008) (forthcoming)

A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims

David A. Kessler and David C. Vladeck[1]

I. *Introduction*

For most of its seventy-seven year history, the Food and Drug Administration (FDA) has regulated the drugs sold in the United States without any significant interaction with the world of state-law damages litigation.[2] Nothing in the statutes the FDA administers suggests that they eliminate state damages actions for pharmaceutical products. No appellate court, before or after the advent of the FDA, has held that a state-law failure-to-warn claim for a prescription drug is

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[2] The agency's modern history dates back to the enactment of the Food, Drug, and Cosmetic Act in 1938. John P. Swann, *History of the FDA*, http://www.fda.gov/oc/history/historyoffda. But the federal government's systematic regulation of pharmaceuticals began with the Federal Food and Drugs Act of 1906, when agency was known as the Bureau of Chemistry. The agency's name was changed to the Food, Drug, and Insecticide Administration in July 1927, and was shortened to its present form in July 1930. *Id.*

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preempted by federal law.[3] And Congress has not acted to preempt or limit state damage actions, even though it has long been aware of tort litigation over drug products.[4]

To be sure, there has been a steady stream of failure-to-warn cases brought against pharmaceutical manufacturers by consumers injured by FDA-regulated drugs. But historically the FDA has stayed on the sidelines in that litigation. Courts adjudicated those cases under the ordinary rules that govern state damages actions, and the question of preemption rarely, if ever, arose.[5] The FDA made no effort to intercede in those cases. Indeed, the agency generally

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[3] This article focuses on the FDA's effort to persuade courts to find state-law failure-to-warn claims preempted. It does not address the broader question of whether federal law preempts other state-law claims that are advanced against drug companies, such as strict liability, design defect, negligent manufacture, and breach of warranty. As explained in more detail below, because the Federal Food, Drug, and Cosmetic Act does not contain an express preemption provision for drugs, drug companies have generally not asserted preemption defenses, and it is only recently, spurred on in part by the FDA, that companies have argued that state-law failure-to-warn claims are impliedly preempted by virtue of the FDA's approval of drug labeling.

[4] *See Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 167 (1989) (ascribing significance to Congress' failure to provide for preemption); *see also* Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok,* 59 Mo. L. Rev. 895, 924 (1994) (pointing out that Congress rejected a proposal to include a right of action for damages in the 1938 Food, Drug and Cosmetic Act because "a common law right of action (already) exists.").

[5] Compliance with regulatory standards is the common defense raised in pharmaceutical product liability litigation. *See generally* Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 Geo. L.J. 2049 (2000); *cf.* Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 Geo L.J. 2119, 2122-23 (2000). Drug companies did not begin to raise preemption as a routine defense until after the Supreme Court's ruling in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). There, the Court held that certain state damage claims for injuries alleged to have been caused by cigarette smoking were preempted by the Federal Cigarette Labeling and Advertising Act because common law duties could impose "requirements" akin to state positive law. *Id.* at 521. *Cipollone* also marked the first time that the Court invoked preemption to nullify a state damage action where the effect of doing so was to

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resisted efforts by parties to force it to take sides in private litigation.[6]

The agency's practice of non-participation in litigation was in keeping with the FDA's view that its regulatory efforts could coexist with state-law damages claims by consumers injured by drugs. As the agency saw it, state-law failure-to-warn litigation did not interfere with the agency's regulatory efforts. The agency is not the only institution that plays a role in monitoring the emergence of unforeseen adverse events. State damages litigation helps uncover and assess risks that are not apparent to the agency during a drug's approval process. Until recently, in the FDA's view, this "feedback loop" enabled the agency to better do its job. The agency also wanted to avoid the "harsh implications" of eliminating judicial recourse for consumers injured by dangerous drugs.[7]

The past few years have witnessed a seismic shift in FDA policy. The agency now maintains that state-law failure-to-warn cases threaten its ability to protect the public health. According to the agency, a determination in civil litigation that an FDA-approved label fails

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leave injured parties without a remedy. *See generally* David C. Vladeck, *Preemption and Regulatory Failure*, 33 Pepp. L. Rev. 95, 105-06,112 (2006).

[6] *See* 21 C.F.R. § 20.1; *cf. In re: David A. Kessler*, 100 F.3d 1015 (D.C. Cir. 1996).

[7] *See* Margaret Jane Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 Food & Drug L.J. 7, 9 (1997); *see also* FDA, Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998) (codified at 21 C.F.R. pts. 201, 208, 314, 601, 610) (requiring Medication Guides for products that are deemed to pose significant public health concern) ("FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's regulations."); FDA, Final Rule, Labeling and Prescription Drug Advertising; Content and Format for Labeling of Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,437 (Jun. 26, 1979) (codified at 21 C.F.R. pts. 201 & 202) ("It is not the intent of the FDA to influence the civil tort liability of the manufacturer...").

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adequately to warn of risks may force manufacturers to add warnings that are not approved by the FDA, thus rendering the product "misbranded." Even worse, the FDA says, adverse rulings could force manufacturers to add warnings that the FDA considered and rejected — thus placing manufacturers in the untenable position of having to violate federal law to avoid state damages judgments. For these reasons, the FDA now argues that the federal Food, Drug and Cosmetic Act (FDCA) impliedly preempts many failure-to-warn claims based on product labeling approved by the FDA. The FDA first announced this position in 2002, by filing amici briefs asking courts to dismiss failure-to-warn cases. More recently, the agency formalized this position in the preamble to a 2006 rule that revises requirements for drug labeling.[8]

This essay does not seek to review comprehensively the history of the FDA's regulation of drug labeling, its new position favoring preemption of failure-to-warn claims for drugs, or the arguments that have been advanced in support of or in opposition to the FDA's new policy.[9]

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[8] FDA, Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601).

[9] We address the FDA's main argument supporting preemption below. *See infra* at __-__. But we do not canvass many of the arguments that have been raised against the FDA's position. Among them are (1) the contention that the FDA's position new position is not entitled to deference (a) because Congress has not delegated to the FDA the authority to determine the preemptive effect of labeling decisions on state law, *see Gonzales v. Oregon*, 126 S. Ct. 904, 915 (2006), (b) because the FDA did not develop its new position through notice and comment rulemaking or other formal means, *see United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001), and (c) because the agency's new position on preemption conflicts with its longstanding contrary position, *see Mead*, 533 U.S. at 228; (2) the claim that the FDA's new preemption position can be applied, if at all, only prospectively, *see Bowen v. Georgetown University Hospital*, 488 U.S. 204-208-09 (1988); and (3) the more general claim that the agency's position cannot be squared with basic principles of compensatory justice. *See generally* Thomas O. McGarity, THE PREEMPTION WAR (Yale Univ. Press) (forthcoming).

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Others have plowed that field, and have done it well.[10]

Rather, this essay highlights what we believe are two of the most problematic aspects of the FDA's pro-preemption position — one legal, the other practical — that do not stand out in more comprehensive treatments of the issue. The first point we make is that the FDA's pro-preemption arguments are based on a reading of the FDCA that, in our view, 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.

Our second concern is that the FDA's pro-preemption arguments are based on what we see as an unrealistic assessment of the agency's practical ability, once it has approved the

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[10] *See generally* Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. VOL. 1 (2005), http://bepress.com/jtl/vol1/iss1/art4; Allison M. Zieve & Brian Wolfman, *The FDA's Argument for Eradicating State Tort Law: Why Its Wrong and Warrants no Deference*, 21 TOXICS L. REP. 516 (2006); Mary J. Davis, *The Final Battle for Preemption: The FDA and* Prescription *Drug Labeling Product Liability Actions* (Berkeley Elec. Press, Working Paper No. 1591, 2006) http://www.bepress.comexpresso/eps/1591; Thomas O. McGarity, THE PREEMPTION WAR (Yale Univ. Press) (forthcoming); *but see* Richard Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda,* 1 J. TORT L. VOL. 2 (2006) (making normative argument for a broad liability shield for drug companies). This essay leaves to one side the somewhat more complicated question of preemption of claims relating to medical devices — more complicated only because the 1976 Medical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act contain a preemption provision. *See* David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95 (2005) (arguing that the MDA preemption provision is addressed only to conflicting state positive law, not state tort or damages claims).

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marketing of a drug, to detect unforeseen adverse effects of the drug and to take prompt and effective remedial action. After all, there are 11,000 FDA-regulated drugs on the market (including both prescription and over-the-counter drugs), with nearly one hundred more approved each year.[11] The reality is that the FDA does not have the resources to perform the Herculean task of monitoring comprehensively the performance of every drug on the market. Recent regulatory failures have demonstrated the FDA's shortcomings in this regard. Given the FDA's inability to police drug safety effectively on its own, we question the wisdom of the FDA's efforts to restrict or eliminate the complementary discipline placed on the market by failure-to-warn litigation.

Our differences with the FDA's current policy can be traced to a difference in perspective about the relevant agency decision that would be subject to review in a state-law failure-to-warn case. The FDA focuses on the approval process, suggesting that the FDA's approval of a drug's labeling reflects the agency's definitive judgment regarding risks that must be shielded from the possible second-guessing that might take place in a failure-to-warn case. Otherwise, the FDA claims, court rulings adverse to drug companies might force companies to add warnings not approved, or even rejected by, the FDA, thereby upsetting the balance of risks and benefits set by

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[11] *See* Davis *supra* n._, at n.76 and accompanying text; Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA CONSUMER (Jan./Feb. 2006), http://www.fda.gov/fdac/features/2006/106_cder.html; CENTER FOR DRUG EVALUATION AND RESEARCH, REPORT TO THE NATION 2005: IMPROVING PUBLIC HEALTH THROUGH HUMAN DRUGS 12 (Food and Drug Administration, 2005), *available at* http://www.fda.gov/cder/reports/rtn/2005/rtn2005.pdf (stating that the FDA approved 78 new drugs and two new biologic products in 2005). Many of the new approvals are for new indications of drugs that have already been approved by the agency; only a handful of new drugs are approved each year that are new molecular entities.

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the FDA when it approves a drug label. Of course, the moment the FDA approves a new drug is the one moment the agency is in the best position to be the exclusive arbiter of a drug's safety and effectiveness. On that day, the FDA has had access to and has devoted considerable resources to reviewing carefully all of the extant health and safety data relating to the drug.[12] On that day, and that day only, we agree that the FDA's determinations about labeling ought not be subject to re-examination by courts or juries in failure-to-warn cases.

But in our view the FDA is wrong to focus on the moment of approval as determinative of the preemption question. The relevant time-frame is *post*-approval, and the question, in our view, is what the drug company knew about a drug's risks at the time the patient/plaintiff sustained injury and what the company told the FDA. After all, the FDA's knowledge-base of the risks posed by a new drug is far from static. At the time of approval, the FDA's knowledge-base may be close to perfect, but it is also highly limited because, at that point, the drug has been tested on relatively small populations of patients.[13] Once the drug enters the marketplace, risks that are relatively rare, that manifest themselves only after an extended period of time, or that

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[12] This assumes, of course, that the drug's sponsor has complied with the requirements governing new drug applications. That is not always the case. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

[13] *See* INST. OF MED., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 36 (Alina Baciu, Kathleen Stratton & Shelia P. Burke, eds., The National Academies Press 2006) *available at* http://www.iom.edu/CMS/3793/26341/37329.aspx (hereinafter IOM REPORT) (estimating that drugs are generally tested on between 600 and 3,000 patients).

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affect vulnerable subpopulations, begin to emerge.[14] These are often not risks foreseen by the drug's manufacturer or the FDA and, for that reason, are not addressed on the label. After a drug is approved, the FDA cannot unilaterally compel labeling changes, but must instead negotiate changes with the drug's sponsor.[15] The FDA's statutory and regulatory tools for gathering post-approval information are relatively crude and often ineffective, especially when contrasted with its tools for information gathering prior to approval. For that reason, the tort system has historically provided important information about these newly-emerging risks to physicians, patients and the FDA.[16]

The FDA's shift of position also comes at a particularly inopportune time for the agency. Although the FDA now argues for broad preemption of failure-to-warn claims, the agency's

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[14] *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).

[15] See IOM Report *supra* n. __, at 157; GOVERNMENT ACCOUNTABILITY OFFICE, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 10 (GAO-06-402) (March 2006), *available at* www.gao.gov/cgi-bin/getrpt?GAO-06-402 (hereinafter GAO DRUG SAFETY).

[16] *See* Nagareda *supra* n. __, at 5-6 & n.16 (referring to this as "a process of 'information updating' over time"); Wendy Wagner, *When All Else Fails: Regulating Risky Products through Tort Litigation*, 95 Geo. L. J. 693, 711 (2007); Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2068-71 (2000) (ascribing to tort litigation an "educational role"); Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 Yale J. Health Pol'y L. & Ethics 587, 612 (2005) ("The tort system should remain free to redetermine product safety in the light of information developed during litigation, because the FDA may not always uncover relevant safety information and may not act quickly enough upon the information that it does receive"). There are feedback loops other than damages litigation, such as those governing adverse reporting, but, as discussed later on, they have not proved adequate. *See infra* at__.

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assertion that it is able single-handedly to ensure drug safety has been undermined by a number of highly-publicized regulatory failures. Two recent independent studies of the FDA's oversight of drug safety — one by the Government Accountability Office and the other by the National Academy of Sciences' Institute of Medicine — have been critical of the agency's ability to keep unsafe drugs off the market and to respond effectively to unforeseen hazards with newly-approved drugs.[17] Even the FDA has acknowledged its own limitations. In the aftermath of the agency's ineffective response to the reports of increased cardiac adverse events among Vioxx users, the FDA in 2005 established the Drug Safety Oversight Board (DSOB) to better monitor drugs on the market.[18] But, by all accounts, the DSOB is too poorly funded and staffed to do its job effectively.[19] In our view, these regulatory gaps in the FDA's system undermine the agency's case for preemption of state-law failure-to-warn claims.

II. *Background*

Since the passage of the landmark 1938 Federal Food, Drug, and Cosmetic Act, all drugs must be evaluated and approved by the FDA before they may be marketed in the United States.

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[17] *See* GAO DRUG SAFETY *supra* n.__, at 18; IOM REPORT, *supra* n. __, at 153-54.

[18] *See FDA's Drug Approval Process: Up to the Challenge? Hearings Before the S. Comm. on Health, Education, Labor and Pensions*, 109th Cong., 10 (March 1, 2005) [hereinafter *Hearings: Up to the Challenge?*] (joint statement of Sandra L. Kweder, M.D., Deputy Director, Office of New Drugs, FDA and Janet Woodcock, M.D., Acting Deputy Commissioner for Operations, FDA); *see also* Davis, *supra* n.__, at n.78 and accompanying text; FDA Improvements in Drug Safety Monitoring, FDA Fact Sheet, http://www.fda.gov/oc/factsheets/drugsafety.html (Feb. 15, 2005) (describing the creation of the DSOB).

[19] See GAO DRUG SAFETY *supra* n. __, at 1, 6.

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Prior to 1962, the FDA's review focused on the drug's safety. Since then, the drug's sponsor must demonstrate that the drug is "safe and effective" for its approved uses and that its labeling is not "false or misleading."[20]

To obtain the FDA's approval, a drug manufacturer must submit a "new drug application" (NDA) for the agency's review. An NDA must include all information bearing on a drug's safety and effectiveness, including the results of animal testing, pharmacological studies, and full reports of all of the clinical trials performed on human subjects.[21] Drug companies are responsible for supervising and controlling these studies.[22] Premarket human trials generally involve only a few thousand subjects and study design necessitates a careful control of the conditions of the study.[23] These conditions are a far cry from those that face a drug once it is approved and widely prescribed by thousands of doctors.[24] New drugs designed to "address unmet medical needs" for "serious or life-threatening conditions" may receive accelerated or

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[20] In 1962, Congress passed the Kefauver-Harris amendments to the FDCA, Pub. L. No. 87-781, 76 Stat. 788-89 (1962) (codified at 21 U.S.C. §§ 321(p)(1)-(2) & 355(b)-(d) (2000)) (sponsor of the drug has to provide substantial evidence of effectiveness for the product's intended use as precondition to approval.)

[21] 21 U.S.C. § 355(a)-(b) (2006); *see* Davis, *supra* n. __, at n.77 and accompanying text; *see also* http://www.fda.gov/cder/cderorg/ond_reorg.htm (describing the Office of New Drugs); http://www.fda.gov/cder/regulatory/applications/default.htm (describing the drug approval process).

[22] *See* McGarity *supra* n. __, at 279; IOM REPORT, *supra* n. __, at 34.

[23] Charles Steenburg, *The Food and Drug Administration's Use of Postmarketing (Phase IV) Study Requirements: Exception to the Rule?*, 61 Food & Drug L.J. 295, 297 (2006).

[24] *Id.*

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"fast track" consideration by the FDA. These drugs are subject to shorter review periods and may be approved based on less safety and effectiveness information than other drugs.[25]

Because drug labeling provides doctors and other health care professionals information needed to make informed prescribing decisions, the FDA's NDA review includes a detailed examination of the manufacturer's proposal for the drug's labeling. The labeling must accurately and fairly describe the drug's intended uses. Because all drugs have adverse side effects, the labeling must also address the drug's potential risks, contraindications, warnings, precautions and adverse reactions.[26] The manufacturer and the FDA ordinarily discuss the content of these warnings in some detail during the approval process.[27] When the FDA approves a drug, it also approves the precise final version of the drug's label.[28]

When the application is complete, the FDA then determines whether it meets a number of requirements set forth in the Act, including (1) whether the drug is "safe for use under the conditions prescribed, recommended or suggested in the proposed labeling," (2) whether there is

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[25] 21 U.S.C. § 356(a)(1) (2006); *see* McGarity, *supra* note 8, at 279-80; GAO DRUG SAFETY, *supra* n. __, at 11; Struve, *supra* n. __, at 595. *See also* 21 C.F.R. § 314.500-.520.

[26] 21 U.S.C. § 355(d) (2006). The FDA labeling regulations are extensive and include specific requirements on the format and content of drug labels. *See* 21 C.F.R. §§ 201.56, 201.57, 201.80. The FDA revised these regulations in 2006. *See* FDA, Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3922 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601).

[27] McGarity *supra* n. __, at 281; *see Hearings: Up to the Challenge?, supra* n. __, at 79 (response to questions by Sen. Hatch by Sandra L. Kweder, M.D., Deputy Director, Office of New Drugs, FDA).

[28] 21 C.F.R. § 201.57(c)(6)(i).

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"substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use" reflected on the proposed labeling, and (3) whether, "based on a fair evaluation of all material facts, such labeling is false or misleading in any particular."[29] If the statutory conditions are met, the FDA must approve the NDA.

The FDA's approval of a drug does not spell the end of the agency's oversight of the drug or its labeling. Prior to FDA approval, drugs are tested on relatively small populations of patients, for durations rarely exceeding a year or two. Thus, pre-approval testing generally is incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect subpopulations not included or adequately represented in the studies (*e.g.*, the elderly, ethnic minorities and pregnant women).[30] As one expert put it, most clinical studies "can detect drug-related injuries that occur at a rate of between one in 500 and one in 1,000. Yet, if the drug is used by 200,000 people . . . a serious adverse event appearing in as few as one in 10,000 people is very significant, since it would occur 20 times. These rare reactions can be identified only

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[29] *See generally* 21 U.S.C. § 355(d) (2006). The "substantial evidence" of safety and effectiveness required by the Act is "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved." *Id.*

[30] *See* IOM REPORT *supra* n. __, at 38; *see also* Louis Lasagna, *Discovering Adverse Drug Reactions*, 249 J. Am. Med. Ass'n 2224, 2225 (1983) (pointing out that a study would have to have more than 600,000 subjects in order to have a ninety-five percent chance of detecting side effects that might injure 1 or 2 subjects out of 1,000 tested); Bruce M. Psaty & Curt D. Furberg, *COX-2 Inhibitors - Lessons in Drug Safety*, 352 New Eng. J. Med. 1133, 1134 (2005) ("In the initial evaluation of the COX-2 inhibitors [the class of drugs that includes Vioxx], the use of small, short-term trials, the exclusion of high-risk patients, and the methodologic inattention to cardiovascular events all minimized the possibility of uncovering evidence of cardiovascular harm.").

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after a drug has been widely used."[31] For these reasons, the FDA's approval of a drug is not a warrant that the drug will not cause serious adverse effects even if properly used for its approved purposes.[32] The FDA does have a program in place for post-market surveillance of approved drugs, but that program has been chronically under-funded by Congress and, according to recent studies by the Institute of Medicine and the Government Accountability Office, has not performed well.[33] And although the FDA strengthened its system for the collection of adverse reaction data in the early 1990s to solicit reports from health care providers and consumers, only a small fraction of adverse reactions are reported to the FDA.[34]

Because unanticipated adverse effects often emerge with approved drugs, there are

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[31] William B. Schultz, *How to Improve Drug Safety*, Washington Post (Dec. 2, 2004), A35 (Mr. Schultz served as the FDA's Deputy Commissioner for Policy from 1994 to 1998). Many drugs are used by far more patients. Vioxx, for example, was used by an estimated 20 million patients. *See In re Vioxx Prods. Liab. Litig.*, 2007 U.S. Dist. LEXIS 43867 (E.D. La. July 3, 2007).

[32] The FDA does not warrant the safety of the drugs it approves, and recognizes that even the most up-to-date and informative labels cannot avert adverse reactions. But the incidence of adverse reactions is cause for concern. Adverse drug reactions are believed to be a leading cause of death in the United States. *See* Joshua Lazarou, *et al.*, *Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies*, 279 J. Am. Med. Ass'n 1200-1205 (1998) (estimating that adverse drug reactions are the fourth to sixth leading cause of death in the United States, with an estimated 106,000 deaths from adverse drug reactions in 1994).

[33] *See* GAO DRUG SAFETY, *supra* n. __, at 18, 28; IOM REPORT, *supra* n.__, at 51.

[34] *Reauthorization of the Prescription Drug User Fee Act: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 107th Cong. 49 (2002) (statement of Rep. Henry A. Waxman); *see also* IOM REPORT, *supra* n. __, at 53 (reporting that although the FDA receives more than 400,000 reports each year, this is only a "small fraction of all adverse effects of drugs.").

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detailed procedures that regulate modifications to drug labeling. Generally labeling changes proposed by the manufacturers require prior FDA approval.[35] There are exceptions, however, and these exceptions are especially relevant to the preemption debate. Most importantly, "labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitively established."[36] Statements that may be added without prior FDA approval are those (1) to "add or strengthen a contraindication, warning, precaution, or adverse reaction," (2) to "add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage," (3) to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the product," or (4) to "delete false, misleading, or unsupported indications for use or claims of effectiveness."[37] To be sure, the manufacturer must promptly inform the FDA of the change and submit a Supplemental New Drug Application that the FDA then reviews after-the-fact.[38] But this "safety valve" option gives manufacturers the ability to provide physicians, health care professionals, and patients with up-to-date information on an ongoing basis so long as a drug remains on the market, without the need to secure the

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[35] 21 C.F.R. § 314.70(b) (2006) (FDA must approve any "major" labeling change in advance); *see also id.* (defining what changes are deemed "major").

[36] 21 C.F.R. §§ 201.57(c)(6)(i); 201.80(e).

[37] 21 C.F.R. § 314.70(c)(6)(iii)(A)-(C) (2006).

[38] 21 C.F.R. § 314.70(c)(6)(iii) (2006).

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FDA's advance approval.[39] And the FDA has long made it clear that its labeling rules are no obstacle to manufacturers providing warnings to doctors and patients through labeling, advertising, or "Dear Doctor" letters as soon as the manufacturer discovers risks that are not clearly stated on the label.[40]

In 2006, the FDA issued revised labeling regulations to streamline labeling and make it easier for health care providers to access key information. The new rules add a number of features, including a "Highlights" section of the label that sets forth the major warnings that are described in more detail elsewhere on the label, a new format for labeling, and new requirements to make hazard and adverse reaction information generally more accessible.[41] Consolidating important risk information on labeling will better ensure that physicians and patients are alerted to the drug's most serious potential side effects. But nothing in the new regulations alters the agency's longstanding requirements that manufacturers revise their labels to protect public health and may do so without first obtaining the agency's approval.

Nonetheless, the FDA contends in the preamble to the new regulations that state failure-to-warn actions have "directly threatened the agency's ability to regulate manufacturer

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[39] *See generally* 21 C.F.R. §§ 201.57(c)(6), 201.80(e) (2006).

[40] Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,447 (Jun. 26, 1979) (codified at 21 C.F.R. pts. 201, 202).

[41] 21 C.F.R. § 201.57(a); FDA, Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601).

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dissemination of risk information for prescription drugs" and are therefore preempted.[42] In the past, when the FDA has claimed that its regulatory action has the effect of preempting state law, it has said so explicitly in regulations adopted through notice and comment proceedings that have the force of law.[43] But the FDA did not adopt a regulation that spells out the boundaries between federal and state law, as it has done for medical devices.[44]

Rather, it is the preamble alone that addresses preemption, and there the FDA sketches out its case for preemption. Among other things, the agency asserts that its pro-preemption position reflects the agency's "longstanding view," even though the available evidence suggests otherwise.[45] The agency also reviews the pro-preemption position it has recently taken in a

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[42] FDA, Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601).

[43] *E.g.*, 21 C.F.R. § 808.1 (defining the scope of the preemption provision in the Medical Device Amendments of 1976, 21 U.S.C. § 360k).

[44] The FDA's failure to address preemption directly in a regulation may be traced to the fact that, while there is an express preemption provision in the Medical Device Amendments of 1976, which specifically forbids states from imposing "requirements" in addition to or that are different from those imposed by the FDA, 21 U.S.C. § 360k(a), there is no counterpart provision in the FDCA for drugs.

[45] *See In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, 2006 WL 2374742 at *8 (N.D. Cal. 2006) (observing that "the FDA's current view of the preemptive effect of its labeling regulations is a 180-degree reversal of its prior position"); Davis, *supra* n.__, at n.140 and accompanying text; Brief for Public Citizen as Amicus Curiae Supporting Cross-Appellee Motus, Motus v. Pfizer, Inc., 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372, 02-55498), 2003 WL 22716063, at *12. Additionally, the proposal for the rule change stated that the new rules would not have a preemptive effect. *See* FDA, Proposed Rule, Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998) ("the written patient medication information provided does not alter the duty, or set the standard of care for manufacturers....FDA does not believe that the evolution of

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number of state failure-to-warn cases. And the agency argues that its labeling requirements are not minimum standards, as some courts had observed, but instead establish both a floor and a ceiling. Additional requirements imposed by state failure-to-warn rulings risk "erod[ing] and disrupt[ing] the careful and truthful representations of the benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug."[46] As the FDA sees it, many failure-to-warn claims are impliedly preempted, including those based on choices manufacturers make about what to put in the "Highlights" portion of labels, and labeling claims that were proposed to the FDA but not required by the agency at the time the claim arose.[47] The FDA does concede, however, that failure-to-warn claims based on state-law duties that parallel federal ones, or seek to enforce federal duties, are not preempted.[48]

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state tort law will cause the development of standards that would be at odds with the agency's regulations."). The FDA itself has acknowledged in amicus briefs that this pro-preemption stance is a change from past views held by the agency. *See* Brief for the United States as Amicus Curiae Supporting Appellee, Horn v. Thoratec, 376 F.3d 163 (3d Cir. 2004), 2004 WL 1143720 at *2 ("We acknowledge that...this [preemption] position represents a change for the United States.").

[46] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935.

[47] *Id.*

[48] *Id.* at 3936. This concession appears to be dictated by the Supreme Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996), which held that, a tort claim premised on state-law duties "equal to, or substantially identical to," duties imposed by federal law are not preempted. *See also id.* at 513 (O'Connor, J., concurring in part, dissenting in part). The FDA has amplified its position on the scope of preemption in a September 21, 2006, amicus submission in *Perry v. Novartis Pharmaceuticals, Inc.*, Civ. No. 05-5350 (E.D. Pa.), although the agency is still less than clear about what claims might be permitted to proceed under its theory.

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III. *FDA Labeling Determinations Are Subject To Constant Reevaluation and Revision and Failure-to-Warn Litigation Does Not Threaten to Displace the FDA's Role as Final Decision-Maker Regarding a Drug's Label.*

As noted above, one cornerstone of the FDA's preemption argument is its claim that agency decisions regarding a drug's labeling, made at the time of approval, are essentially set in stone and should therefore not be reviewed, in any way, by a court in a failure-to-warn case. The FDA also cites its expertise in balancing the benefits and risks of pharmaceuticals. According to the FDA, labeling decisions are often difficult and require the agency to engage in a complex balancing of interests. Warnings that overstate or exaggerate risks are no more help to physicians and patients than warnings that downplay risks or side effects. Striking the right balance takes expertise and judgment. For these reasons, the FDA claims, the final say over drug labeling must be left to the manufacturer and the FDA, and should not be subject to second-guessing by courts.

We agree that labeling decisions are often fraught with complexity and that the FDA should have the final word on drug labeling. We do not doubt that if a state enacted a drug labeling law that purported to compel drug manufacturers to add warnings unapproved by the

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In *Perry*, the FDA acknowledged that the defendant's argument "that federal preemption bars *any* failure-to-warn claim premised on a drug manufacturer's failure to provide a warning not contained in the drug's approved labeling" is "incorrect." *Id.* at 11. The FDA further noted that it "has not attempted to 'occupy the field' of prescription drug labeling, and state tort liability for failure to warn does not necessarily prevent FDA from carrying out its regulatory goals. Federal regulations explicitly provide for labeling changes to be made to warn of new hazards or cautions relating to a drug without prior FDA approval. Under this regulatory scheme, preemptive conflict does not exist in every instance in which state tort law seeks to impose liability for the failure to provide a warning not affirmatively mandated by the FDA." *Id.* Under this approach, it appears that the FDA would not necessarily object to claims that a manufacturer has failed to provide a warning about a newly-discovered risk that the FDA has not considered, so long as the warning would not render the drug misbranded.

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FDA, such an effort would properly be struck down on conflict preemption grounds.[49]

Our claim does not challenge the FDA's supremacy over labeling. But we do not agree with the FDA's conclusion about preemption of failure-to-warn claims. In our view, the factors the FDA cites to support its position do not justify insulating labeling decisions from state failure-to-warn litigation, for two related reasons. First, failure-to-warn litigation does not challenge the FDA's decision to approve a label for a new drug; instead, it challenges the *company*'s failure to revise its labeling to warn about risks that were unknown at the time the drug was approved, or risks that turn out to be more grave than the company and the FDA thought at the time of approval. Second, failure-to-warn litigation does not seek to force labeling changes or to substitute a jury or court's judgment for the FDA's; failure-to-warn litigation seeks compensation for injured patients.

A. Failure-to-Warn Claims Seek Compensation, Not Injunctions to Force Labeling Changes, and Preemption of Failure-to-Warn Claims Would Remove Incentives for Drug Manufacturers to Update Labels.

The first and most serious flaw in the FDA's interference argument is the assumption that failure-to-warn litigation seeks to supplant the FDA as final decision-maker as to the content and format of drug labeling. That is not the case. The FDCA gives that authority to the FDA and no one else. Failure-to-warn litigation does not undercut that authority. Failure-to-warn litigation challenges the *company*'s failure to warn doctors and patients about a risk and seeks money damages for injuries caused by the lack of an adequate warning. Plaintiffs do not seek

[49] In fact, in just such a case, the California Supreme Court rejected, on conflict preemption grounds, the argument that California's Proposition 65 could require additional warning labels on certain drug products. *Dowhal v. SmithKine Beecham,* 88 P.3d 1 (Cal. 2004).

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injunctions or other court decrees forcing a labeling change; they seek compensation for their injuries.

In the typical failure-to-warn case, the plaintiff alleges that the drug's label failed adequately to warn of risks that were unknown, or poorly understood, at the time the drug was approved but were evident at the time the plaintiff was injured. In that kind of case, a judgment in favor of the plaintiff — or even serial plaintiffs' judgments — may cause one or both of two things to happen, neither of which impairs the FDA's decisional authority. First, the company might agree that the risk is worthy of a warning label and either ask the FDA to approve a labeling change or decide to add the warning and then seek the FDA's approval. Or second, as a result of the information that comes to light during the litigation, the FDA might recognize the risk as one requiring a warning and initiate discussions with the company to bring about such a change. Either way, the overriding public health interest is served, and the FDA exercises control over the labeling.

Even if the warning at issue was one considered and rejected by the FDA at the time of approval, that does not mean that a failure-to-warn case seeks to force the substitution of a court-required label for the label approved by the FDA. As noted above, because pre-approval testing is subject to serious limitations, post-approval use in large numbers of patients brings about a deeper understanding of the nature and magnitude of the risks posed by the drug. In a failure-to-warn case involving such a risk, a plaintiff's verdict might well prompt the company and the FDA to reconsider the appropriateness of a warning, even though they rejected it earlier on the

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basis of less complete data.[50] As the Supreme Court has frequently observed, tort law often informs regulatory decisions,[51] and the FDA has often acted in response to information that has come to light in state damages litigation.[52]

But preemption would not be justified even if, in the midst of failure-to-warn litigation, the FDA reviews all of the new safety information and determines that a labeling change is not warranted. Of course, should such a case arise, the drug company would have a powerful defense. It would be able to argue to the jury that it complied with applicable FDA requirements and that the plaintiff is complaining about the absence of a warning the FDA had *rejected*. Moreover, as the FDA acknowledges, the FDCA does not *expressly* preempt state-law damages claims, or even occupy the field of drug regulation.[53] Accordingly, the only preemption argument available to the company and the FDA is that such claims are *impliedly* preempted because they either actually conflict with federal law or erect an impermissible obstacle to the achievement of

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[50] The Supreme Court has noted that state damages actions "may aid the exposure of new dangers associated" with the product and prompt the agency to "decide that revised labels are required in light of new information that has been brought to its attention." *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 451 (2005) (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541-42 (D.C. Cir. 1984)).

[51] *See, e.g., id.*

[52] *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).

[53] 71 Fed. Reg. 3922, 3935 n.8; *see also* n.__, *supra*.

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federal objectives.[54]

Permitting failure-to-warn litigation to proceed does not pose a conflict with federal law or threaten the fulfillment of federal objectives. To begin with, there is no reason why a drug manufacturer cannot comply with both FDA-required labeling and pay a state damage judgment based on a determination that the labeling failed to adequately warn of a discrete risk.[55] The legal test is actual, irreconcilable conflict — not simply the burden of incurring the expense of an adverse judgment. As the Supreme Court recently explained in *Bates v. Dow Agrosciences LLC*, "a requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision [whether to add a new warning to a drug label] is not a requirement" triggering preemption.[56] An adverse ruling in a failure-to-warn case would not *require* the manufacturer to do anything other than pay money damages. Of course, a

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[54] *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).

[55] Conflict preemption requires something more coercive than paying a judgment. As an example of conflict preemption, Justice Breyer's concurrence in *Lohr* said "[i]magine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the '2-inch' MDA regulation, pre-empts the state '1-inch' agency regulation, why would it not similarly pre-empt a state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire." 518 U.S. at 504 (Breyer, J., concurring). Similarly, in *Geier v. American Honda Co.*, the Court found that a claim that a passenger vehicle that was not equipped with airbags was defectively designed preempted because permitting it go forward would conflict with NHTSA's decision to provide for a gradual phase-in of air-bags. 529 U.S. 861, 867-71 & 875 (2000).

[56] 544 U.S. 431, 445 (2005); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988); Vladeck *supra* n. __, at 115-16.

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manufacturer might decide to take measures to avoid future adverse rulings, including adding a warning to the drug's labeling. But a manufacturer could also rationally decide to do nothing, reasoning that the prospect of a recurrence is too remote to justify a labeling change, or that the cost of defending cases and paying judgments is less than the sales that would be lost as a result of making a labeling change.[57]

Nor would an adverse ruling in a state failure-to-warn case stand as an obstacle to federal objectives. As articulated by the FDA, its overarching objective is to safeguard the public's health by ensuring that drug labeling is uniform, accurate, and fairly addresses the possible risks of a drug without overstating those risks.[58] But an adverse ruling in a state failure-to-warn case, even where the FDA has had access to all of the information before the court and believes that the plaintiff's claim is unsubstantiated, does not jeopardize that interest. If the FDA has considered the labeling change addressed in the litigation and found that it is unwarranted, the

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[57] Consider one example. As explained in detail below, *see infra* n. __, manufacturers of a certain class of widely-prescribed antidepressants, known as "selective serotonin reuptake inhibitors," or "SSRIs," were the target of failure-to-warn cases brought by families whose children committed suicide while taking the drug. The plaintiffs claimed, and some courts and juries agreed, that the drugs should have warned of the association between use of the drug and an increased risk of suicidal thoughts, ideations and acts. Despite having to pay judgments to prevailing plaintiffs, the companies resisted calls to change their warnings, and did so only after being directed to do so by the FDA.

[58] *Cf.* Brief for the United States as Amicus Curiae Supporting Appellee, Horn v. Thoratec, 376 F.3d 163 (3d Cir. 2004), 2004 WL 1143720 at *2-3 (in a case involving a medical device, the FDA stated that "the United States has a substantial stake in ensuring that state common law tort judgements do not interfere with implementation of this important federal scheme [of regulating safety and effectiveness]....A contrary rule would undermine overall public health protection."); *see also* FDA, Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3928 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601).

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court cannot compel a labeling change. The company may be forced to pay a price for the FDA's decision, but the court's ruling will not displace the FDA's authority over the label.[59]

This result may appear harsh, but in reality there are few instances in which the company (which is trying to sell its drug) wants a *stronger* label than the FDA and the FDA (which is trying to safeguard public health) *resists* the change.[60] The FDA does not identify such a case. And if such a case arose, the company would have an out: the FDCA gives it the authority to change its label unilaterally to add the warning addressed in the litigation, so long as the amended label is not false and misleading, and then file a Supplemental New Drug Application seeking the FDA's after-the-fact approval. In such an instance, it is likely that the FDA and the company would strive to avoid an impasse over the labeling. To be sure, the FDA would have the authority to reject such a labeling change, but we are not aware of cases in which the FDA has refused any change to a label when pressed for a *stronger* warning by a manufacturer.[61] And,

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[59] Strict liability theory acknowledges that dangerous products will cause harm on occasion, but on balance, the product's benefits to society outweigh its risks. The product remains on the market, its manufacturer is responsible for warning users of the product's risks, but the manufacturer also compensates people injured using the product. *See generally* DAVID G. OWEN, JOHN E. MONTGOMERY & MARY J. DAVIS, PRODUCTS LIABILITY AND SAFETY: CASES AND MATERIALS 474 (Foundation Press 2007).

[60] *See* Kesselheim & Avorn, *supra* n.__, at 310 (reporting that discovery in civil litigation demonstrated the *manufacturer*'s resistance to the FDA's effort to persuade the manufacturer to place a strong warning on the drug dexfenfluramine). Of course, if the "harshness" of the result factors into the preemption analysis, it bears mention that the abolition of a failure-to-warn remedy — as the FDA advocates — would be especially harsh to individual patients who are injured by drugs that do not carry adequate warnings of risk but would then be deprived of compensation for their injuries.

[61] *See Feldman v. Lederle Laboratories*, 592 A.2d 1176, 1193 (N.J. 1991) ("for the FDA to have prevented a drug manufacturer from warning the public of a newly-discovered danger

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as best as we can tell, the FDA has never brought a misbranding claim against a company in those circumstances.[62] Ironically, if it did, the agency would be back to where it started, because the ultimate decision-maker in a misbranding action would be the jury and not the FDA.[63]

More serious is the problem the FDA barely mentions. Manufacturers often *resist* labeling changes the FDA believes are needed due to emerging safety concerns. For instance, the FDA acknowledges that it took over a year to persuade Merck, the manufacturer of Vioxx, to add a warning of the risks of heart attack and stroke to Vioxx's label.[64] During the lengthy

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pending development of unequivocal factual evidence of adverse reaction in man 'would seem anomalous'").

[62] This is not necessarily surprising. Bringing a misbranding action would consume substantial agency resources, the agency would bear the burden of proving that the drug was misbranded, and because the manufacturer has superior information about a drug's performance after the drug's approval, the agency might be at an informational disadvantage. The agency has brought successful misbranding actions for both injunctions and restitution against companies selling unapproved drugs or approved drugs for unapproved uses. *See, e.g.*, *United States v. Lane Labs-USA, Inc.*, 427 F.3d 219 (3d Cir. 2005) (upholding restitution and injunction order against company selling shark cartilage as cancer treatment); FDA Consumer, *Drug Maker to Pay $430 Million in Fines, Civil Damages* (July/Aug. 2004) (reporting that Warner-Lambert had agreed to plead guilty and to pay $430 million to resolve criminal and civil charges stemming from its promotion of unapproved uses of Neurotin) available at http://www.fda.gov/fdac/features/2004/404_wl.html. But as best as we can tell, the FDA has rarely if ever brought a misbranding action against the manufacturer of an approved drug being promoted only for approved uses.

[63] 21 U.S.C. § 332(b) (providing jury trial right in injunction actions brought by FDA); *see also* 21 U.S.C. §§ 333, 334(b).

[64] The FDA's inability to force a labeling change to Vioxx is only the most recent, and perhaps most widely publicized, example of this problem. Dr. Sandra Kweder, Deputy Director of the FDA's Office of New Drugs, said in testimony in a Senate Hearing that safety concerns over Vioxx prompted the FDA to convene an advisory committee meeting in 2001 to examine whether the drug raised the risk of heart attacks and strokes. But despite the panel's recommendation that Vioxx's label be changed to reflect this risk, it took more than a year of negotiations between the FDA and Merck before the company changed Vioxx's label. "They

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negotiations, no change was made to Vioxx's label, and in the end, the FDA settled for a weaker warning than it had proposed. As noted, the FDA does not have statutory authority to compel manufacturers to make labeling changes, but must instead rely on its power of persuasion, backed up by the FDA's authority to seek withdrawal of the drug's NDA or to file a misbranding action. The FDA generally gets its way, but the negotiations with manufacturers are often quite lengthy and frequently result in compromise decisions, as was the case with Vioxx.[65] Removing the possibility of failure-to-warn litigation, as the FDA seeks to do, would further weaken the incentives a drug company has to comply with an FDA-requested labeling change.[66]

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rejected many of our proposals," Dr. Kweder told the Senate. "We don't have the authority to tell a company, 'This is how your label has to look.'" Instead, she said, "[w]e have to negotiate with the company the specific language of how things should be worded, the placement, those kinds of things, after talking to them." *Hearings: Up to the Challenge?*, *supra* n __, at 23. And the Vioxx negotiations show that the FDA does not always get its way. The FDA had pushed Merck for a strong warning on Vioxx, but settled for a much weaker warning that simply said that patients with a history of heart disease should use Vioxx with caution. *See* Gardiner Harris, *FDA Official Admits "Lapses" on Vioxx*, N.Y. Times, A15 (March 2, 2005); Jim Drinkard, *Label Quibble Helped Cause Vioxx Lapse*, USA Today, (March 1, 2005). This problem is not a new one. *See, e.g., Salmon v. Parke-Davis & Co.*, 520 F.2d 1359, 1362-63 (4th Cir. 1975) ("the F.D.A. suggested, and Parke, Davis opposed, language that would tell physicians that they 'must' take certain precautions and 'must not' incur needless risks.").

[65] *See id. See also* IOM REPORT, *supra* n.__, at 157; *see also* Gardiner Harris, *F.D.A. Issues Strict Warnings on Diabetes Drugs*, N.Y. TIMES, Jun. 7, 2007, at A1 (announcing that prominent warnings about the risks of heart attacks would be placed on two diabetes drugs and reporting that the new warnings came several years after risks were known).

[66] As the Vioxx example shows, when confronted with an emerging threat from an approved drug, a company has to make a difficult economic choice — add a warning to the drug's label, almost certainly at the cost of lower sales, or resist a labeling change, recognizing that the company may be subject to future failure-to-warn litigation. It is hard to imagine that Merck did not make that calculus as evidence of Vioxx's heart attack and stroke risk mounted. If the threat of litigation is taken off the table, companies will have even less incentive to make needed labeling changes.

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B. The FDA's Justifications for Preemption are Legally Flawed.

In defending its preemption position, the FDA cites a handful of examples in the Federal Register preamble to support its claim that recent lawsuits have "threatened the agency's ability to regulate ... risk information for prescription drugs."[67] But these examples do not support the agency's interference claim. The chief case the FDA relies on, *Dowhal v. SmithKline Beecham*,[68] was *not* a product liability case. Instead, it was an action for injunctive relief brought to compel a drug company to comply with labeling requirements imposed under California's Proposition 65. Relying on conflict preemption principles, the California Supreme Court held that state-required warnings presented an actual conflict with FDA-imposed labeling requirements, and thus state law had to yield. Two other cases the FDA cites also involved state law actions to compel changes to drug labeling; neither succeeded.[69] Only a few of the FDA's illustrative cases are failure-to-warn actions, and the FDA offers no explanation of how these cases threatened the FDA's authority to control the content of drug labeling.[70] None sought to compel a labeling

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[67] FDA, Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601)

[68] 88 P. 3d 1 (Cal. 2004) cited in *id.*

[69] *In re Paxil Litigation*, 2002 WL 1940708 (C.D. Cal. 2002), was a class action brought against GlaxoSmithKline by users of Paxil who sought to enjoin the company from advertising that "Paxil is not habit forming." Although the court initially agreed to enter injunctive relief, it reversed that ruling two months later. 2002 WL 31375497 (C.D. Cal. 2002). *Bernhardt v. Pfizer, Inc.*, 2000 U.S. Dist. LEXIS 16963 (S.D.N.Y. 2000), was an action seeking an order requiring that a "Dear Doctor" letter to be sent to physicians. The court found that the plaintiffs lacked standing and that the injunctive relief sought was preempted by the FDCA.

[70] The brevity of the FDA's description is not altogether surprising because even the FDA's "best cases" do not provide unalloyed support for its position. The case that apparently

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change; no case resulted in a labeling change; and the only relief sought by the plaintiffs in these cases was money damages for injuries caused by the drugs.

Nor does the FDA address how its pro-preemption argument can be reconciled with the fact that the FDCA and the agency's own regulations give manufacturers significant leeway to revise labeling to reflect up-to-date risk information about a "clinically significant hazard"

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disturbed the FDA the most — *Motus v. Pfizer* — could well be the bellwether case for those arguing against preemption. *Motus* was a damage action brought by the widow of a man who committed suicide after taking the anti-depressant Zoloft. Although there were a number of reports linking anti-depressants in Zoloft's class of drugs ("selective serotonin reuptake inhibitors," or "SSRIs") with suicide, the FDA rejected efforts by consumer and patient groups to add a warning for this class of drugs reflecting that possibility. 127 F. Supp. 2d 1085,1089-91 (C.D. Cal. 2000). Although the district court initially rejected Pfizer's preemption defense, *id.*, it later granted Pfizer summary judgment based on the plaintiff's inability to prove causation, 196 F. Supp. 2d 984 (C.D. Cal. 2001). The Ninth Circuit affirmed. 2004 U.S. App. LEXIS 1944 (9th Cir. Cal., Feb. 9, 2004). There were many failure-to-warn cases against the drug companies that sold SSRIs. A few district courts agreed with the FDA's pro-preemption argument. *See, e.g., Dusek v. Pfizer, Inc.*, 2004 WL 2191804 (S.D. Tex. 2004), *Needleman v. Pfizer, Inc.*, 2004 WL 1773697 (N.D. Tex. 2004). Many did not. *See, e.g., Zikis v. Pfizer, Inc.*, 2005 WL 3019409 (N.D. Ill. 2005); *NcNellis v. Pfizer, Inc.*, 2005 WL 3752269 (D. N.J. 2005); *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726 (D. Minn. 2005); *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876 (E.D. Tex. 2005). What is important about *Motus* and similar cases is that, although Pfizer lost on preemption, the FDA did *not* change the labeling for SSRIs directly as a response to the litigation, and no one could plausibly argue that it had an obligation to do so. On the other hand, cases like *Motus* provided the FDA with substantial information about the correlation between SSRIs and suicidal behavior. Ultimately, after reexamining its position, the FDA ordered that labels of SSRIs include prominent warnings about the risk of suicide. *See* Food and Drug Administration, FDA Public Health Advisory: Suicidality in Children and Adolescents Being Treated with Antidepressant Medications (Oct. 15, 2004); Food and Drug Administration, FDA Public Health Advisory: Suicidality in Adults Being Treated with Antidepressant Medications (June 30, 2005). The FDA recently proposed to add warnings for young adult patients. Food and Drug Administration, FDA News: FDA Proposes New Warnings about Suicidal Thinking, Behavior in Young Adults Who Take Antidepressant Medication (May 2, 2007) http://www.fda.gov/bbs/topics/NEWS/2007/NEW01624.html.

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without first obtaining the FDA's permission.[71] To be sure, the FDA's approval must be sought after-the-fact. But the FDA's pro-preemption argument rests on the proposition that it, and it alone, determines drug labeling. That just is not so. The process is a dynamic one in which the manufacturer also plays a critical role. The ability of manufacturers to make labeling changes first and then seek the FDA's approval undercuts the FDA's claim.

That the FDA had to struggle to find a handful of isolated (and ambiguous) cases to make out its interference claim also raises a red flag. There is a seventy-seven year history of federal regulation of drug safety, and yet all the evidence the FDA can muster in support is, at most, a few cases that it claims raise a specter of interference, even though there are hundreds of failure-to-warn cases brought each year. The FDA does not cite jury verdicts that actually disrupted the agency's functioning, let alone explain how the agency has been able to carry out its responsibilities in the face of this steady procession of failure-to-warn cases.[72]

Nor does the FDA's account come to grips with the other side of the ledger, that is, the benefits that flow to the FDA from failure-to-warn cases. Failure-to-warn litigation has often preceded and clearly influenced FDA decisions to modify labeling, and, at times, to withdraw drugs from the market. Preemption of failure-to-warn cases would thus come at a high price — information provided by this litigation would be lost to the FDA. That is a serious trade-off

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[71] *See supra* at ___.

[72] *See* Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 87, 107-08 (1973) (arguing that consumers should not bear the risk of unsafe medications, that some form of no-fault system should be developed to compensate injured consumers, and never suggesting that companies might have a preemption defense based on FDA-approved labels or that such a liability regime would impair the FDA's ability to protect the public).

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which at least merits the FDA's consideration.[73] The FDA has benefitted considerably from the interplay between state damages litigation and federal regulatory efforts. We see no reason to disturb this system.[74]

IV. *The FDA's Post-Approval Monitoring System Cannot, By Itself, Assure Drug Safety and Failure-to-Warn Litigation Provides an Important Backstop.*

In addition to our concerns about the FDA's legal position, we also have reservations about the FDA's preemption position because it depends on the proposition that the FDA is capable of policing the marketplace effectively on its own. Again, the FDA views the preemption question through the prism of the initial approval process, and spends little time addressing its ability to monitor drug safety *post*-approval. In its public statements, the FDA paints a confident self-portrait, describing itself as capable of single-handedly monitoring drug safety, of reacting swiftly and effectively to warning signs that a drug may pose unanticipated risk, and possessing the personnel, resources and statutory authority it needs to safeguard the public health.[75]

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[73] It is a trade-off that other commentators argue would short-change the FDA. *See generally* Nagardea, *supra* n._, at 6 (expressing concern that preemption may do "too little in return" to benefit the FDA); *cf.* Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 96 Geo. L. J. 693, 711-13 (2007) (explaining the informational advantages of litigation).

[74] *See, e.g.*, Karen Lasser, *et al.*, *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 J. Am. Med. Ass'n 2215, 2218 (2002); Kesselheim & Avorn *supra* n.__ , at 310 (citing examples).

[75] *See Ensuring Drug Safety: Where Do We Go From Here? Hearings before the S. Comm. on Health, Education, Labor and Pensions,* 109th Cong., 4-6 (March 3, 2005) (testimony of Janet Woodcock, M.D., Acting Deputy Commissioner for Operations, FDA); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed.

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We question whether the FDA's resources and performance match its rhetoric. The case for preemption must be examined in light of a clear-eyed appraisal of the FDA's ability to assure the safety of the drugs being marketed in the United States. As we see it, the reality departs from the one described by the FDA. In our view, the FDA is hamstrung by resource limitations and gaps in the agency's statutory authority. The FDA benefits from failure-to-warn litigation that forces the disclosure of information that otherwise would be unavailable to the agency.

A. *The FDA Faces Resource Limitations.*

An agency can go only so as far its resources can take it, and the FDA, like other federal regulatory agencies, faces serious resource constraints. The FDA now regulates products that amount to one-quarter of consumer spending in the United States.[76] But it has only 9,000 employees nationwide.[77] Not surprisingly, there are resource limitations that impair the agency's ability to detect adverse reactions and to take prompt and effective measures once previously unidentified risks surface. The Institute of Medicine reported in 2006 that the FDA "lacks the

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Reg. 3922, 3934 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601); Brief for the United States as Amicus Curiae Supporting Appellee, *Horn v. Thoratec*, 376 F.3d 163 (3d Cir. 2004), 2004 WL 1143720 at *1-2.

[76] 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.

[77] 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 veterinary medicines and cosmetics. *Id.*

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resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future."[78] FDA doctors and scientists share this view; 70 percent believe that the FDA lacks sufficient resources to protect the public health, and two-thirds worry that the FDA is not adequately monitoring the safety of drugs once they are on the market.[79] Even the pharmaceutical industry has urged Congress to increase FDA appropriations to shore up its flagging drug safety resources.[80]

Resource constraints are especially acute with the agency's post-marketing surveillance efforts. According to the most recent statistics available, the FDA's Office of New Drugs (OND), which reviews NDAs, employs over 1,000 physicians and scientists to review the approximately 100 new NDAs 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) the agency has approved over the

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[78] IOM REPORT, *supra* n. __, at 193.

[79] U NION OF CONCERNED SCIENTISTS, VOICES OF SCIENTISTS AT FDA: PROTECTING PUBLIC HEALTH DEPENDS ON INDEPENDENT SCIENCE 2 (Union of Concerned Scientists, 2006); *see also* DEP'T OF HEALTH & HUMAN SERVS. OFFICE OF THE INSPECTOR GENERAL, FDA'S REVIEW PROCESS FOR NEW DRUG APPLICATIONS, 12, 19 (March 2003) *available at* http://oig.hhs.gov/oei/reports/oei-01-01-00590.pdf (finding that significant numbers of FDA's own physicians and scientists reported pressure to recommend that drugs be approved even when they had reservations about safety or efficacy, and that two-thirds of the agency's drug reviewers lacked confidence that the agency "adequately monitors the safety of prescription drugs once they are on the market.").

[80] *See, e.g.*, Diedtra Henderson, *Drug Makers Lobby U.S. to Hike FDA Funds*, BOSTON GLOBE, July 13, 2006, at E1.

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years, has around 100 professional employees.[81] Part of the disparity is historic, but part of it stems from the fact that when Congress initially authorized "user fees" — fees companies pay for NDA reviews — it directed the FDA to use the fees to support the review of new drug applications, and nothing else.[82] When Congress reauthorized the user fee statute in 2002, it eased the restrictions on the FDA's use of the funds, but the resource disparity remains.[83]

B. *Statutory Gaps Hamper FDA's Post-Approval Data Gathering.*

But it is not just resource limitations that impair the agency's ability to engage effectively in post-approval surveillance. The agency is also hamstrung by statutory gaps that limit the data demands it may make on drug companies after a new drug is approved. As noted above, pre-approval clinical testing cannot identify all of the possible adverse effects associated with new

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[81] *Hearings: Up to the Challenge?, supra* n. __, at __ (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: http://www.fda.gov/ola/2005/drugsafety0301.html (table).

[82] As originally enacted, the user fee legislation restricted the use of fees to the costs of "the process for the review of new drug applications." 21 U.S.C. § 379h(g)(1)-(2) (2000). More recent user fee legislation has relaxed that requirement somewhat. 21 U.S.C. § 379g(6)(F) (Supp. 2004) (providing for the use of PDUFA funds "In the case of drugs approved after October 1, 2002, under human drug applications or supplements: collecting, developing, and reviewing safety information on the drugs including adverse event reports, during a period of time after approval of such applications or supplements, not to exceed three years.") One result of user-fee funding is that the new drug approval process has remained fully funded. On the other hand, funding for other FDA programs has not kept pace. *See generally* Prescription Drug User Fee Act (PDUFA); Public Meeting, 65 Fed. Reg. 47,993, 47,994 (Aug. 4, 2000).

[83] *See* n.__, *supra*.

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drugs.[84] Professor Richard Merrill once quipped that "[a]ll consumers of prescription drugs serve as guinea pigs for the pharmaceutical industry."[85] So the question that the FDA has long faced is how to acquire information about risks systematically once a drug has been approved. Until recently, for most new drugs the FDA "could count on cautious practicing physicians to assure a gradual, measured roll-out" that would permit the agency time to assess actual marketing experience.[86]

But those days are gone, mainly for two reasons. First, as a result of the 1992 user fee legislation, the FDA devotes enormous resources to expediting the new drug review process. With the infusion of $400 million or more annually in user-fees, the FDA is now generally the first regulatory agency in the world to approve new drugs, and thus the agency cannot look to experiences elsewhere in evaluating an NDA.[87]

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[84] Congress has understood these limitations for decades. Shortly after the 1962 Kefauver-Harris Amendments went into effect, then FDA Commissioner George P. Larrick explained to a House panel that "even the most extensive" clinical trials will reveal only a fraction of the information that emerges once the drug is generally marketed. *See Drug Safety (Part One) Hearings before a Subcomm. of the H. Comm. On Gov't Operations*, 88th Cong., 152 (1964). This history is discussed in Steenburg, *supra* n. __, at 297.

[85] Merrill, *supra* n. __, at 20; *see generally* Steenburg, *supra* n.__, 298 & nn.23-24.

[86] Steenburg, *supra* n.__, at 299.

[87] *See* Steenberg, *supra* n. __, at 324 ("In 1988, FDA was the first agency in the world to approve a given drug only four percent of the time. That figure rose to sixty-six percent in 1998."). Faster drug reviews, however, may spawn safety problems as well. In 2002, the General Accounting Office, now the Government Accountability Office, (GAO) found that "a higher percentage of drugs has been withdrawn from the market for safety reasons since [user fee legislation] was enacted." GENERAL ACCOUNTING OFFICE, FOOD AND DRUG ADMINISTRATION: EFFECT OF USER FEES ON DRUG APPROVAL TIMES, WITHDRAWALS, AND OTHER AGENCY ACTIVITIES 4 (GAO-02-958) (Sept. 2002) *available at* http://www.gao.gov/new.items/d02958.pdf. *See also Hearings: Where Do We Go?, supra* n. __.

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Second, and perhaps more daunting, drug companies often launch mass marketing campaigns for their drugs directed at consumers, not just doctors, as soon as they obtain FDA approval.[88] Drug companies spend over $27 billion annually to promote their products, including $11.4 billion on advertising. Nearly forty percent of the advertising expenditures — over $4.2 billion annually — pay for direct-to-consumer (DTC) ads that are designed to encourage patients to ask their doctors to prescribe the advertised drug.[89] DTC advertising has proven to be highly successful in stimulating demand for drugs.[90] As a result of these developments, for many drugs

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at 45 (statement of Bruce Psaty) (stating that "drug recalls following approval increased from 1.56 percent in 1993-1996 up to 5.35 percent for 1997-2001.")

[88] Merck, for example, trumpeted the FDA's approval of Vioxx with what it proclaimed to be its "biggest, fastest, and best launch ever." *See, e.g.,* Robert Langreth, *FDA Approval of Vioxx Allows Merck to Compete with New Arthritis Drugs*, Wall S. J., May 24, 1999, at B3.

[89] A 2005 study found that $4.2 billion was spent on DTC advertising annually, or 37% of total pharmaceutical advertising. Kaiser Family Foundation, *Prescription Drug Trends*, May 2007, http://www.kff.org/rxdrugs/upload/3057_06.pdf. To put these expenditures in context, the pharmaceutical industry spends as much money on advertising as the tobacco industry spends on all of its product promotion (including price reductions and samples). *Compare id., with* FEDERAL TRADE COMMISSION CIGARETTE REPORT FOR 2003, at 2 (2005), *available at* http://www.ftc.gov/reports/cigarette05/050809cigrpt.pdf (reporting that the tobacco industry spent a total of $15.15 billion in 2003 to promote its products). To give one example, in 2000, Vioxx was the number one DTC-advertised drug – at $160 million, larger than the campaigns that year for Pepsi and Budweiser – and retail sales of Vioxx quadrupled. NATIONAL INSTITUTE FOR HEALTH CARE MANAGEMENT, PRESCRIPTION DRUGS AND MASS MEDIA ADVERTISING, 2000, at 5 (2001) *available at* http://www.nihcm.org/DTCbrief2001.pdf.

[90] Several studies have shown that DTC advertising does have an impact on patients and doctors. An assessment by the National Institute for Health Care Management found that between 1999 and 2000 the number of prescriptions written for the 50 most advertised drugs rose 24.6%, as compared to a 4.3% increase in prescriptions for all other drugs, although this study did not take into account the fact that these drugs are also heavily promoted to doctors. *See* n.__, *supra*; *see also* GAO Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising has Limitations 16 (GAO-03-177) (Oct. 2002) ("surveys...consistently show that DTC advertisements have an impact on whether consumers request and receive a specific brand-name

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there is no longer a transitional period between pre- and post-approval. Drugs that have been tested in controlled clinical trials involving at most a few thousand patients are, within a few weeks after approval, being prescribed by thousands of doctors to perhaps hundreds of thousands of patients.[91]

Despite these new pressures on the agency, its ability to systematically gather and evaluate post-marketing information has not kept pace and is far from optimal. According to the IOM, "[t]he existing regulatory framework is structured around the premarketing testing process; few tools are available for addressing postmarketing safety issues, short of the blunt instruments available to respond to clear-cut adulteration and misbranding."[92]

The "blunt instruments" available to the FDA are two far-from-perfect tools. First, the FDA often requires companies to perform post-marketing studies (so-called Phase IV studies) to see how the drug performs when given to large numbers of patients over a period of a year or

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prescription"). The FDA also has problems regulating the content of these ads, some of which the FDA has found misleading. *See id.* at 22-23 ("reviews of draft regulatory letters from FDA have taken so long that misleading advertisements may have completed their broadcast life cycle before FDA issued the letters."); *see also* Barry Meier, *et al.*, *Medicine Fueled by Marking Intensified Trouble for Pain Pills*, N.Y. TIMES, Dec. 19, 2004, at 1 (finding that COX-2 drugs are "perhaps the clearest instance yet of how the confluence of medicine and marketing can turn hope into hype" and stating that Vioxx and Celebrex are examples of "how difficult it is for the Food and Drug Administration to monitor the safety of drugs after they have been approved for the market.").

[91] More than 19 million prescriptions for Celebrex were written its first year on the market, largely due to a massive DTC ad campaign. *See* Diedtra Henderson, *How Safe Is Celebrex?*, Boston Globe, D1 (Feb. 25, 2007). During the five years Vioxx was on the market, over 100 million prescriptions were written for drug for an estimated 20 million patients. *See In re Vioxx Prods. Liab. Litig.*, 2007 U.S. Dist. LEXIS 48367 (E.D. La. July 3, 2007).

[92] IOM REPORT, *supra* n. __, at 153.

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more.[93] Indeed, recent studies show that the FDA requires Phase IV testing in nearly three-quarters of all new drug approvals.[94] But the FDA has been lax in its oversight of Phase IV studies. Fewer than one-quarter of the Phase IV studies required by the FDA have ever been completed and many have never been started.[95]

In addition to requiring Phase IV studies, the FDA monitors post-approval performance by gathering reports of adverse reactions through its Adverse Event Reporting System (AERS)

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[93] The FDA's authority to mandate Phase IV studies is clearly set forth in statute only where the drug received accelerated approval (typically drugs for life-threatening diseases), where preapproval human subject studies of drugs for protection against chemical, radiological or nuclear materials are barred by ethical issues, or where the use of an approved drug for children requires study. 21 U.S.C. § 356(b)(2) (2000) (for "fast-track" drugs); 21 U.S.C. § 355c (Supp. 2004) (for pediatric studies); 21 C.F.R. §§ 314.610(b)(1), 601.91(b)(1) (for drugs that protect against chemical, radiological and nuclear materials); *see generally* Steenburg, *supra* n. __, at 343-44. In those cases in which the FDA wants a company to engage in a Phase IV study of a drug that does not fall into one of these categories, the agency generally imposes the Phase IV study as a condition of approval. The FDA claims that FDCA § 505(k), 21 U.S.C. § 355(k) (2000), which requires drug companies to "establish and maintain" records of "data relating to clinical experience and other data," and to report this information to the agency, empowers the agency to require Phase IV studies whenever it sees fit. That interpretation of section 505(k) has been questioned by drug company lawyers. *See* Steenburg, *supra* n.__, at 343.

[94] Tufts Center for the Study of Drug Development, *FDA Requested Postmarketing Studies in 73% of Recent New Drug Approvals*, IMPACT REPORT, July/August 2004, at 2, *available at* http://csdd.tufts.edu/InfoServices/ImpactReportPDFs/SampleIssue2005.pdf.

[95] GAO REPORT, *supra* n. __, at 28 (citing *id.*). At least in some cases, there may be sound reasons for the FDA's failure to demand that companies initiate and complete Phase IV studies. For one thing, the FDA may be uncertain of its legal authority under section 505(k), and thus may be reluctant to force the issue. *See supra* note 80. For another, once a drug is approved and is accepted by physicians, it becomes more difficult for a manufacturer to find participants meeting necessary criteria who are willing to enroll in the study (thereby risking getting a placebo) and more difficult to secure institutional review board approval for a double-blind study with a placebo group. *See* Steenburg, *supra* n.__, at 372-73. Drug companies may also be reluctant to conduct comparative efficacy studies for fear that their products will not measure up to other drugs on the market. IOM REPORT, *supra* n. __115-16.

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and its "MedWatch" program. Under the AERS, companies have a duty to report adverse reactions to the FDA, and to report serious or life-threatening adverse reactions quickly.[96] MedWatch extends the reporting program, on a voluntary basis, to health professionals and consumers.[97] Even with these programs in place, most adverse reactions go unreported to the FDA.[98] As a result, many serious adverse reactions escape the FDA's attention.[99] Moreover, adverse reactions reports are of limited utility from an epidemiological standpoint because the FDA does not know how many people are using the drug or have information about their conditions and therefore may have difficulty determining the incidence of an adverse reaction.[100]

Finally, even when the FDA identifies an unanticipated risk, the agency's statutory authority gives it only limited options to remedy or ameliorate the problem. As noted above, the

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[96] 21 C.F.R. § 310.305 (2006).

[97] The MedWatch program was inaugurated by the FDA in 1993 to enable the FDA to obtain adverse reaction reports directly from physicians and other health care providers, thereby skipping the intermediate step of having such reports go first to the drug companies. *See* David A. Kessler, *Introducing MedWatch: A New Approach to Reporting Medication and Device Adverse Effects and Product Problems*, 269 J. Am. Med. Ass'n 2765 (1993). The MedWatch program is described in depth on the FDA's website. Food and Drug Administration MedWatch, http://www.fda.gov/medwatch/index.html (last visited June 15, 2007).

[98] *Reauthorization of the Prescription Drug User Fee Act: Hearing Before the Sucomm. on Health of the H. Comm. on Energy and Commerce*, 107th Cong. 49 (2002) (statement of Rep. Henry A. Waxman).

[99] *See* Steenburg, *supra* n. __, at 298. Steenburg also points out that such systems require reporting but do not require manufacturers to "develop their own data-gathering efforts or otherwise track clinical experiences in an organized manner." *Id.*

[100] This is the so-called "denominator" problem, which is addressed in FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: GOOD PHARMACOVIGILANCE PRACTICES AND PHARMACOEPIDEMIOLOGIC ASSESSMENT 11 (2005). *See also* GAO DRUG SAFETY, *supra* n. __, at 24; IOM REPORT, *supra* n. __, at 53-54.

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agency has no statutory right to direct a company to add warnings to the label of an approved drug. The statutory options available to the FDA — initiate a proceeding to withdraw the drug's NDA or file a misbranding action against the drug company[101] — are so Draconian that they are rarely employed by the FDA.[102] The FDA's threat to take action does give the agency bargaining leverage to persuade companies to add warnings the companies would otherwise omit or would not voluntarily place in a prominent, "black box" warning.[103] But, as both the Institute of Medicine and the Government Accountability Office point out, because the agency cannot simply require labeling changes, negotiations between the FDA and drug companies over labeling issues are often drawn out, often result in compromises, and, as a result, often have adverse effects on safety.[104]

C. *Litigation Uncovers Information Within the Control of Drug Companies That Is Otherwise Unavailable to the FDA.*

Failure-to-warn litigation exposes the shortcomings in the FDA's statutory authority to

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[101] 21 U.S.C. §§ 331(a), 355(e). A drug is "misbranded" if its labeling is false or misleading, does not provide adequate directions for use, or warnings against any use dangerous to health. *Id.* at §§ 331(a), (b) & (k); and id. at §§ 352(a), (f), and (g).

[102] Indeed, all of the ten drugs withdrawn from the market between 2000 and 2006 were withdrawn voluntarily by the drug's sponsor. GAO DRUG SAFETY, *supra* n. __, at 10.

[103] "Black box" warnings signal a high degree of risk and are taken seriously by physicians and patients. 21 C.F.R. § 201.57(e); *see generally* Judith E. Beach, *et al., Black Box Warnings in Prescription Drug Labeling: Results of a Survey of 206 Drugs*, 53 Food & Drug L.J. 403 (1998). As discussed above, Merck and the FDA did battle for more than a year over whether the heart attacks and stroke risks warranted a black box warning for Vioxx. The FDA finally relented, and agreed to a warning that simply said that patients with a history of heart disease should use Vioxx with caution. *See* Gardiner Harris, *FDA Official Admits "Lapses" on Vioxx*, N.Y. Times, A1 (Mar. 2, 2005).

[104] *See id.* at 10; IOM REPORT, *supra* n. __, at 157.

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gather information.[105] Prior to a drug's approval, drug companies are required under the new drug application provisions of the FDCA to provide the FDA with all data — positive and negative — relating to the drug's safety and effectiveness, chemical formulation, proposed manufacturing, and patent protection.[106] But companies are not under an obligation to provide the agency with records of internal discussions or evaluations by company physicians and scientists. Post-approval, the FDA's information-gathering power is more limited. Companies have an ongoing obligation to provide to the FDA records "relating to clinical experience"[107] and adverse reactions,[108] and have a duty to permit the FDA to review business records during the course of a factory inspection.[109] But companies have no obligation to provide the FDA with the company's evaluations of the drug's performance in the market, let alone the company's assessment (memos, E-mails, and so forth) of the drug's safety profile. So while the FDA has substantial information-gathering power, its authority is by no means comprehensive.

The information-gathering tools lawyers have in litigation are, by any measure, more extensive than the FDA's. Indeed, the FDCA does not give the FDA the most important tool

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[105] *See generally* Kesselheim & Avorn *supra* n. __ , and authorities cited therein.

[106] Section 505(b)(1)(A)-(F) of the Act, 21 U.S.C. § 355(b)(1)(A)-(F). An NDA must contain, among other things, "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use."

[107] *See* FDCA § 505(k), 21 U.S.C. § 355(k).

[108] *See supra* at ___.

[109] *See* FDCA § 704, 21 U.S.C. § 374.

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trial lawyers have — the right to subpoena relevant information from any source.[110] A few examples drawn from the litigation over Vioxx and Celebrex make this point. For instance, litigation uncovered the fact that Pfizer, the maker of Celebrex, conducted an unpublished clinical study in 1999 to see if Celebrex could be used to treat Alzheimer's disease. That study showed a statistically significant increase in heart attacks. But Pfizer waited to submit the study to the FDA until 2001 — *after* the FDA convened an advisory committee meeting to consider whether drugs of Celebrex's class should carry warnings for heart attack and stroke. The advisory committee recommended a warning be added to the labeling for Vioxx, Celebrex's main competitor. But without the Pfizer study linking Celebrex to increased heart attacks and strokes, the committee did not make a similar recommendation for Celebrex.[111]

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[110] *Compare* Fed. R. Civ. P. 26-27, 45, *with* 21 U.S.C. §§ 355(k), 374. Under the Federal Rules, any party to civil litigation in federal court may compel any person to provide testimony under oath or furnish records relevant, or reasonably calculated to lead to the discovery of any information relevant, to any issue. State discovery rules are generally equally permissive. As noted above, the FDA's information-gathering power is much more limited. The FDA's authority does not reach evaluations and other analyses performed by companies about the performance of their drugs, let alone to company E-mails and internal deliberations over possible safety hazards. It is an odd system that gives plaintiff's lawyers far more leeway to probe company records than the FDA, but that is the system that exists today. See David C. Vladeck, *Defending Courts: A Brief Rejoinder to Professors Fried and Rosenberg*, 31 Seton Hall L. Rev. 631 (2001) (explaining comparative advantage plaintiff's lawyers engaged in civil litigation have in information-gathering over agency officials). We do not suggest that the FDA, as a matter of routine, should be provided internal company documents. We do suggest that the agency ought to have the authority, when necessary, to examine any company record relating to scientific information that may be relevant to the FDA's regulatory responsibilities, even where that information does not appear in reports required to be filed with the agency.

[111] *See* Alex Berenson & Gardiner Harris, *Pfizer Says 1999 Trials Revealed Risks With Celebrex*, N.Y. TIMES, Feb. 1, 2005, at C1. An equally telling example is reported regarding the antipsychotic medication olanzapine. Lawsuits filed after the drug's approval alleged that the

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Kessler & Vladeck, 96 Geo. L.J. ___ (2008) (forthcoming)

Litigation also brought to light the fact that Merck was acutely concerned about the heart attack risk associated with Vioxx before the FDA understood the risk, and before Merck alerted the FDA to the risk. During the Vioxx cases, the plaintiffs' lawyers uncovered internal company memos and E-mails that were not provided to the FDA. One memo warned that a study of Vioxx, conducted to show that it decreased the risk of gastrointestinal bleeding, should be limited to patients also taking aspirin; otherwise there would be a "substantial chance that significantly higher rates" of cardiovascular disease would show up in the Vioxx group. An internal E-mail similarly warned that if Vioxx patients did not receive aspirin, "you will get more thrombotic events and kill [the] drug." In response, a senior company doctor agreed that "the possibility of increased CV [cardiovascular] events is of great concern," and she recommended that potential subjects with high risk of cardiovascular problems be kept out of the study so cardiovascular problems "would not be evident."[112] Evidence uncovered in litigation also revealed the fact that Merck scientists in 2000 were considering combining Vioxx with other

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manufacturer, Eli Lilly, recognized that the drug was linked to weight gain and diabetes, but did not warn patients about the risks. In September 2003, after the litigation was filed, the FDA required Lilly to change the drug's label to warn about the diabetes-related adverse effects. During litigation, documents were uncovered that Lilly had long downplayed the research showing the links to weight gain and high blood sugar, informing sales-staff "Don't introduce the issue!!!" *See* Kesselheim & Avorn *supra* n. __, at 309. For a detailed treatment of the Celebrex incident, *see* McGarity, *supra* n. __, at 13.

[112] Anna W. Mathews & Barbara Martinez, *Warning Signs: E-Mails Suggest Merck Knew Vioxx's Dangers at Early Stage*, WALL ST. J., Nov. 1, 2004, at A1; *see also* McGarity, *supra*, n. __, at 17.

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agents to reduce the risk of heart attacks and strokes.[113]

These recent examples echo prior FDA experience. Litigation brought to light the risks associated with the sleeping medication Halcion, the arthritis medication Zomax, ultra-absorbent tampons, and the weight loss pill ephedra, leading the FDA to take Halcion, Zomax, and ephedra off the market, and to more rigorously regulate tampons.[114] Litigation also revealed evidence that manufacturers of a certain class of anti-depression medication — selective serotonin reuptake inhibitors (SSRIs) — withheld adverse event data regarding children. The issue was pushed into the spotlight in June 2004 when New York State Attorney General Eliot Spitzer brought a civil action against GlaxoSmithKline, alleging that the company had fraudulently withheld clinical studies showing that its SSRI drug, Paxil, increased the risk of suicide in children and young adults but did not effectively treat their depression. The complaint further alleged that the company's internal memos urged company officials to "manage the dissemination of data in order to minimize any potential negative commercial impact" while, at the same time, the company told its sales representatives to tell doctors that "Paxil demonstrates remarkable efficacy and safety in the treatment of adolescent depression."[115] Three months later, GlaxoSmithKline

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[113] *File Shows Merck Sought to Change Vioxx*, L.A. Times, June 23, 2005, at C3. *See also* Heather Won Tesoriero, *Attorneys Question Disclosure by Merck of Vioxx-Study Deaths*, Wall St. J., Sept. 28, 2005, at D4 (reporting that litigation uncovered Merck-sponsored studies finding a high death rate among Alzheimer's patients taking Vioxx as compared to placebo group).

[114] Wagner, *supra* n. __, at 707 n.73, and 711 & nn.79-82 (and authorities cited therein).

[115] *See, e.g.*, Gardiner Harris, *Spitzer Sues a Drug Maker, Saying It Hid Negative Data*, N.Y. Times (June 3, 2004), A1; *see also* Press Release, Office of the New York State Attorney General, *Settlement Sets New Standard for Release of Drug Information* (Aug. 26, 2004)

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settled the case by, among other things, agreeing to make its data public. Shortly thereafter, the FDA required warnings on SSRIs to highlight the association between use of SSRIs and an increased suicide risk in children and adolescents.[116]

Litigation helped force silicone gel breast implant makers to conduct long-overdue safety studies of their products. In 1976, Congress enacted the Medical Device Amendments to the FDCA.[117] Part of that law required manufacturers of medical devices on the market in 1976 to submit health and safety data to the FDA showing that the device was safe for its intended use.[118] In May 1990, the FDA called for the makers of silicone gel breast implants to provide safety information for their products. It was not produced. After giving the implant manufacturers several extensions, the FDA ultimately withdrew the implants from the market. The agency took this drastic step, not because there was evidence proving the implants to be unsafe (although there was evidence raising safety concerns),[119] but because the industry failed to submit evidence

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available at http://www.oag.state.ny.us/press/2004/aug/aug26a_04.html (last visited July 13, 2007).

[116] *See supra* n.__. *See also* Shankar Vedantam, *Depression Drugs to Carry A Warning; FDA Orders Notice of Risks to Youths*, Wash. Post, Oct. 16, 2004, at A1.

[117] 21 U.S.C. §§ 351-360m.

[118] 21 U.S.C. § 301.

[119] By the early 1990s, there had already been a number of lawsuits against silicone gel breast implant manufacturers, some of which ended in sealed settlements, but some of which ended in judgments against the manufacturers. *See* Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 Tex. L. Rev. 1, 19-21 (1995). Some scientists reported that silicone breast implants could cause a serious autoimmune disorder. *See, e.g., Researcher Says Breast Implants May Be Linked To Autoimmune Disease*, Cancer Weekly, Dec. 21, 1992, at 16. Others reported a high incidence of rupture, running as high as thirty percent at five years, fifty percent at ten years, and seventy percent at seventeen years. J.S. Marotta et al., *Silicone Gel*

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showing that the implants did not pose an unreasonable risk when used as intended.[120] Whatever one might think about the breast implant product liability litigation,[121] there is no doubt that the litigation "was uniquely successful in divulging important, asymmetric information about the risks of implants held by implant manufacturers," including information that one major implant manufacturer not only knew that its implants were leaking, but suppressed internal research on the few animal studies that had been conducted to assess the risks associated with the leakage.[122]

We could go on. But we do not believe that there is any serious dispute on this point. Statutory gaps in the FDA's authority to gather information, especially post-approval, hamstring its ability to ensure the safety of the drugs on the market. Failure-to-warn litigation brings to light information that would not otherwise be available to the FDA, to doctors, to other health care providers, and to consumers. At some point, Congress may close the gaps in the FDCA and give the agency comprehensive authority to obtain whatever records it deems necessary to do its

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Breast Implant Failure and Frequency of Additional Surgeries: Analysis of 33 Studies Reporting Examination of More Than 8,000 Explants, J. Biomed. Materials Res. 48(3):354-64 (1999). In 1999, a study by the Institute of Medicine did not find a greater risk of chronic illness in women with silicone implants. IOM, *Safety of Silicone Breast Implants* (1999) available at: http://www.nap.edu/books/0309065321/html.

[120] David A. Kessler, *The Basis of the FDA's Decision on Breast Implants*, 326 New Eng. J. Med. 1713, 1715 (1992). Even Marcia Angell, a critic of the breast implant litigation, acknowledges that these legal interventions led to long delayed scientific research on implants. Marcia Angell, *Shattuck Lecture — Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion*, 334 New Eng. J. Med. 1513, 1515 (1996).

[121] See, e.g., Rochelle Cooper Dreyfuss, *Galileo's Tribute: Using Medical Evidence in Court*, 95 Mich. L. Rev. 2055, 2070 (1997) (discussing competing views); Feldman, *supra* n. __, at 19-21.

[122] Wagner, *supra* n. __, at 715 & nn.95-97 (and authorities cited therein).

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work. But that day has not come. And closing that gap would not guarantee that emerging safety information is made available to physicians and patients, who need it just as much as the FDA.[123]

V. *Conclusion*

The point of this essay is not to denigrate the job the FDA does in protecting consumers. The talented and dedicated men and women who work at the FDA do an admirable job with the tools they have been given. But those tools are imperfect, and the FDA cannot, at least at this point, effectively safeguard our nation's drug supply on its own. In an ideal world, the FDA would have immediate access to data enabling it to pinpoint problems as they emerge, the personnel and other resources needed to deal effectively and swiftly with emerging hazards, and the insulation from political and other forces that often seek to apply pressure to influence agency decision-making. In the meantime, however, we believe it would be a mistake to broadly preempt state-law failure-to-warn cases, which impose a complementary discipline on the marketplace, prompt disclosure of safety information that is not otherwise available to the FDA and the public, and provide redress for consumers injured through no fault of their own.

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[123] As of this writing, Congress is considering drug safety legislation that would strengthen the FDA's ability to force drug companies to accept labeling changes the FDA deems necessary, increase the agency's information-gathering authority, and clarify the obligation of drug companies to report data to the FDA. *See Food and Drug Administration Revitalization Act*, S.1082, 110th Cong. (2007) (as passed by the Senate on May 9, 2007); *Enhancing Drug Safety and Innovation Act of 2007*, H.R. 2900, 110th Cong. (2007); *see also* Congressional Research Service Report for Congress, *FDA Legislation in the 110th Congress: A Guide to S. 1082 and H.R. 2900* (July 18, 2007).. These are important measures, but our views about preemption would not change even if they are adopted. Enhancing the FDA's statutory authority does not solve the agency's resource problems. Nor would it ensure that physicians and patients have timely access to up-to-date safety information for approved drugs. And this essay has steered clear of the corrective justice rationale underlying state-law damage claims — a rationale we believe independently justifies the preservation of state-law claims by injured consumers, but has been addressed in-depth by other commentators. *See* n.__ *supra*.

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Statement of Senator Patrick Leahy
Chairman, Senate Judiciary Committee
Hearing on "Regulatory Preemption:
Are Federal Agencies Usurping Congressional and State Authority"
September 12, 2007

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

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

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

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

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

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

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civil immunity by aggressively preempting State law in the course of issuing administrative regulations.

In addition to concerns about the Administration's actions threatening principles of federalism, Senator Specter and I joined to voice our concern about how the Administration's efforts in this regard violate powers assigned to Congress. On November 17, 2005, we wrote to the National Highway Transportation Safety Administration about a proposed agency rule on "roof crush standards" that sought to preempt numerous State laws, and ultimately weaken consumer protections for Americans. Senator Specter and I pointed out in our letter that it appeared the federal agency was plainly acting beyond the authority granted to it by Congress in the Transportation Equity Act. Unfortunately, the federal agency's response did nothing to address our questions about its authority to override State laws that may compensate motorists critically injured in car accidents. Those roof crush regulations are just one example of at least a dozen issued by the Consumer Product Safety Commission, the Department of Homeland Security, the Federal Drug Administration and other federal agencies that are being used to shield drug and other product manufacturers from liability without congressional action.

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

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

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

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Written Statement of the
North American Securities Administrators Association, Inc.

U.S. Senate Committee on the Judiciary

"Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?"

September 12, 2007

The North American Securities Administrators Association, Inc. ("NASAA"), is the nonprofit association of state, provincial, and territorial securities regulators in the United States, Canada, and Mexico. The members of NASAA include the state agencies that are responsible for regulating securities transactions under state law. Their fundamental mission is protecting consumers who purchase securities or investment advice, and their jurisdiction extends to a wide variety of issuers and intermediaries—many of them securities affiliates of banks—who offer and sell securities to the public.

NASAA believes that the trend toward preemption of state regulatory authority over the past fifteen years has exposed the public to a heightened risk of abuse at the hands of unscrupulous bankers, brokers, advisers, and insurance agents. Today's hearing is focusing on *regulatory* preemption and two recent regulatory actions are of particular concern to NASAA: Rule 7.4006 promulgated by the Office of the Comptroller (OCC), 12 C.F.R. § 7.4006, and the opinion letter issued by the Office of Thrift Supervision (OTS) on October 25, 2004.

Office of Comptroller of the Currency

In rule 7.4006, the OCC rule substantially amended the National Bank Act and insulated hundreds of state-chartered operating subsidiaries of national banks across the country from regulation under state banking laws. A single federal agency in Washington, acting without a Congressional mandate, has thus determined that state banking laws enacted to protect consumers do not apply to national bank subsidiaries.

Congress did not intend such a result. Although the National Bank Act restricts the power of states to regulate national banks, it imposes no restraints on the states' authority over *operating subsidiaries* of national banks. Congress has never expressly forbidden states from regulating bank operating subsidiaries, nor has it occupied the field of banking regulation to the exclusion of all state authority. Moreover, the application of state consumer protection laws to national bank operating subsidiaries does not significantly interfere with the operation of national banks or their affiliates and thus does not conflict with federal law.

Regrettably, the federal courts have repeatedly upheld the validity of rule 7.4006—a trend that bodes ill for consumers. *See, e.g., Watters v. Wachovia Bank, N.A.,* 127 S. Ct. 1559 (2007). The most immediate harm flowing from rule 7.4006 is that it shields

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operating subsidiaries of national banks from the application of state banking laws that provide consumers with significant protections against abusive lending practices, particularly in the area of mortgage loans. NASAA harbors an additional concern: As the worlds of banking, insurance, and securities increasingly intersect, NASAA and its members fear that the OCC may seek to encroach further upon state regulatory jurisdiction, not only in banking, but potentially in the areas of insurance and securities as well. National banks have already invoked the OCC's visitorial powers rule to impede investigations by state securities regulators relating to the securities activities of banks and their subsidiaries, even though such investigations are unquestionably permitted under the Gramm-Leach-Bliley Act (GLBA).

In short, OCC Rule 7.4006 constitutes an impermissible attempt by a regulatory agency to expand the preemptive scope of a federal statute in derogation of Congressional intent. The result is less consumer protection. Consumers are best served when regulators at the federal and state level work together to ensure not only the safety and soundness of the banking system, but also the fair and equitable treatment of banking customers.

Office of Thrift Supervision

In an opinion letter issued on October 25, 2004, the OTS concluded that state licensing and registration requirements do not apply to independent contractor agents who market deposit and loan products on behalf of State Farm Bank, a federal savings association (State Farm). The letter claims that these agents are exempt not only from state banking laws but also from state securities laws requiring the licensure of those who sell securities. This interpretation applies to agents selling all types of certificates of deposits (CDs) on behalf of State Farm, regardless of whether or not those products are fully insured by the FDIC and regardless of how complex or risky they may be. The OTS opinion letter is particularly troubling since it preempted an important body of state law without first being subject to the public comment and hearing process.

Once again, a federal banking agency exceeded Congressional authority. The Home Owner's Loan Act, under which the OTC operates, nowhere expressly or impliedly preempts the application of state law to State Farm's agents marketing CDs. Furthermore, although federal case law holds that conventional CD products do not constitute securities, the issue is far from settled with respect to unconventional CDs that pose heightened risks because of their inherent features or the way in which they are marketed.

Early indications are that the federal judiciary will side with the OTC. *See State Farm Bank, F.S.B. v. Burke,* 445 F. Supp. 2d 207 (D. Conn. 2006). Thus, as in the case of OCC rule 7.4006, it appears the only way to ensure that American investors and consumers are adequately protected from abusive practices in the financial services arena is for Congress to reign in these banking agencies and clearly delineate the appropriate role for state regulation.

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Because of the potential risk to investors, states securities regulators should retain the right to require independent sales agents acting on behalf of State Farm or similar banking associations to become licensed with their state securities regulator in order to sell CD's. State licensing requirements add a significant layer of protection by screening out agents who are unfit by reason of training, education, or disciplinary history to market securities.

Conclusion

Where Congress has left room for the application of state law to financial institutions, federal regulatory agencies should not be permitted to "preempt" Congress's judgment. The public needs the protections that state law offers. From NASAA's standpoint, this approach is especially important in the area of securities regulation. In keeping with the modern regulatory approach known as functional regulation, state securities regulators assert their jurisdiction based principally upon the nature of the financial activity involved, not the nature of the entity engaged in that activity. Accordingly, with certain exceptions, bank entities offering securities to the public are subject to state securities regulation, along with more traditional broker-dealers and their registered representatives. Congress intended states to exercise this regulatory authority for the benefit of our nation's investors and consumers.

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TESTIMONY

OF

COLLYN A. PEDDIE

WILLIAMS KHERKHER HART BOUNDAS, L.L.P.

HOUSTON, TEXAS

BEFORE THE

SENATE JUDICIARY COMMITTEE

SEPTEMBER 12, 2007

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My name is Collyn Ann Peddie and I am a foot-soldier in the on-going battle over the federal preemption of state pharmaceutical claims. I want to thank Chairman Leahy, Ranking Member Specter and the members of the Committee for the opportunity to speak on this matter.

For most of my career, I have represented corporate defendants, including many Fortune 500 companies and large pharmaceutical companies. In recent years, I have tried a number of lawsuits for pharmaceutical companies and have personally advised senior executives at Pfizer concerning federal preemption issues and strategy involving the diabetes drug Rezulin.

For the last two years, I have practiced trial and appellate law with the firm of Williams Kherkher Hart Boundas, L.L.P. in Houston, Texas, where I currently take the leading role in several key appeals in Texas and Pennsylvania state and federal courts involving federal preemption of prescription drug or vaccine claims. For some time, I have regularly consulted with other counsels around the nation on preemption issues.

In short, I have been on the front lines virtually every day for the last 5 years dealing first-hand with federal preemption of state pharmaceutical claims and the impact of these decisions on the lives of injured Americans.

THE PROBLEM

Increasingly, those injured by prescription drugs are seeing their right to seek compensation in court eliminated entirely by the preemption doctrine. Derived from the Supremacy Clause of the U.S. Constitution, the doctrine means that federal law – even a regulation of a federal agency – may trump a conflicting or parallel state law. Preemption can be express or implied, either because federal law so occupies the field that there is no room left for state regulation, because state law directly conflicts with federal law, or because enforcement of the state law might frustrate federal purposes. Congress has never expressly preempted prescription drug claims and neither Congress nor the FDA has ever asserted that federal law occupies that field.[1] Thus, the current dispute over preemption has involved conflict preemption principles and whether permitting state tort claims somehow frustrates federal purposes.

Breaking sharply with express Congressional dictates[2] and a century-long policy of claiming no preemption of state-law failure to warn claims,[3] the FDA has, in the last few years,

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[1] Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S.Ct. 2240, 2250, 135 L.Ed.2d 700 (1996), the Supreme Court found no "indication that either Congress or the FDA intended the relevant FDA regulations to occupy any relevant field." *Id.* at 2261.

[2] The FDCA provides that "[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 21 U.S.C. § 379(e). The Senate Committee Report for the bill enacting that provision similarly noted that "the legislation explicitly provides that it shall not be construed to modify or otherwise affect the traditional product liability law of any State. Tort liability rules and requirements would remain unchanged and unaffected." S. Rep. No. 105-43, at 66 (1997).

[3] Hillsborough County v. Automated Med.Labs., Inc., 471 U.S. 707, 714-15, 85 L. Ed. 2d 714, 105 S. Ct. 2371 (1985) (FDA's statement that particular regulations did not preempt state law was "dispositive on the question of implicit intent to

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aggressively asserted the doctrine of implied preemption of state pharmaceutical claims in a series of amicus briefs filed in private lawsuits. This power grab culminated in the FDA including a Preamble to its 2006 drug labeling regulations, in which it announced its position that state failure to warn claims - based upon the failure to include in proposed warnings information that the FDA considered and rejected - are preempted.[4] In 2007, in another amicus brief, the FDA retreated somewhat from the position it took in its Preamble and it now asserts a very strict form of direct conflict preemption.[5]

Since 2006, a few courts have ignored express Congressional directives and federal law, some relying on the FDA amicus briefs and the Preamble to the 2006 drug labeling regulation instead, to expand the application of the preemption doctrine. Thus, in Colacicco v. Apotex, et al., 432 F. Supp. 2d 514 (E.D. Pa. 2006), Judge Michael Baylson solicited an FDA amicus brief himself, held that it and the FDA's prior amicus briefs' and Preamble's statements on preemption were entitled to Chevron[6] or conclusive deference, that the federal courts were

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pre-empt unless either the agency's position is inconsistent with clearly expressed congressional intent, or subsequent developments reveal a change in that position") (emphasis supplied). The position of the FDA as outlined in the Preamble is

> [o]pposite to the position of the FDA as stated in its December 2000 proposal of the same amendments . . . The 2000 Proposal explicitly stated that its regulations do not have preemptive effect. Rather, the preamble to the 2000 Proposal explained that the FDA did not want its regulations to preempt state tort law, stating that "there should be little, if any, impact from this rule, if finalized, on the States" and that the 'FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.'

McNellis v. Pfizer, Inc., 2006 U.S. Dist. LEXIS 70844 *25-26 (D.N.J. 2006) (quoting *See* 65 Fed. Reg. 81082 (Dec. 22, 2000)). "The Court notes too that the position taken by the FDA in the 2000 Proposal was entirely consistent with the position the Agency took in 1998 in the Preamble to the new regulations regarding consumer medications' guides." *Id.* at 26, n.6; *see* 63 Fed. Reg. 66378 (Dec. 1, 1998).

[4] "FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in [drug] labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated." *See* Preamble, Requirements on Content and Format of Labeling for Humans Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006).

[5] *See, e.g.*, Amicus Curiae Brief of the United States in Perry v. Novartis, Civ. No. 05-5350, filed Sept. 21, 2006, at 11. In it, the FDA states:

> To the extent, therefore, that the defendants argue that federal preemption bars any failure to warn claims premised on a drug manufacturer's failure to provide a warning not contained in the drug's approved labeling, the defendant is incorrect. FDA has not attempted to 'occupy the field' of prescription drug labeling, and state tort liability for failure to warn does not necessarily prevent FDA from carrying out its regulatory goals. Federal regulations explicitly provide for labeling changes to be made to warn of new hazards or cautions relating to a drug without prior FDA approval. Under this regulatory scheme, preemptive conflict does not exist in every instance in which state tort law seeks to impose liability for the failure to provide a warning not affirmatively mandated by FDA.

(Emphasis supplied)

[6] The Supreme Court's decision in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), set forth the standard for review of federal agency decisions and stated that if Congressional intent is clear, the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.

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powerless to reject them, and, on that basis, dismissed the plaintiffs' failure to warn claims. The number of these cases are approaching a critical mass, and soon it will be difficult, if not impossible, to undo the damage done without significant Congressional intervention.

Ruby Ledbetter's[7] case is a good example. At the time she began taking Vioxx, Ruby was a 62-year old Texas grandmother who actively gardened, rode horses, cleaned their stalls as well as her own house, and walked up to a mile three times a week. As the result of taking Vioxx for a year and a half, however, she suffered a severe heart attack that has left her unable to live her previously-active life. She sued Merck, Vioxx's manufacturer, for failure to warn her of its potential cardiovascular effects.

A few months before her scheduled trial date, a Texas trial judge dismissed her failure to warn claim as impliedly preempted. Under a recent Texas law, there is a statutory presumption of no liability for a drug manufacturer if its drug was FDA-approved. There is, however, a statutory exception to that law that would have permitted Ruby to show that Merck had withheld or misrepresented to the FDA material information during the Vioxx approval process. Under those circumstances, Texas law would not have permitted Merck to avail itself of the statutory presumption based upon FDA approval as a defense in her case.

In holding her failure to warn claim impliedly preempted, Judge Wilson conceded that Ms. Ledbetter had made the requisite statutory showing that Merck withheld important information from the FDA. Nevertheless, he dismissed her failure to warn claim because he found that her ability even to make that threshold evidentiary showing was impliedly preempted by the Food Drug and Cosmetic Act under the Supreme Court's decision in Buckman because such a showing was somehow analogous to a preempted affirmative claim of fraud on the FDA and attempt to enforce privately violations of FDA regulations.[8] He refused, however, to declare the whole statute, including its rebuttable presumption in favor of drug manufacturers, preempted and return it to the Texas Legislature for reconsideration and amendment, but instead claimed that the exception was not wholly preempted. He opined that the statutory exception could be satisfied by proof that FDA itself had found, under the provisions of the Texas Act, that it had been defrauded during the approval process. This is the same conclusion reached by a Sixth Circuit Court of Appeals panel in interpreting a somewhat similar Michigan statute to find its exception preempted.

When, in a motion for new trial, Judge Wilson was informed that there were no possible

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[7] The Plaintiff, Ruby Ledbetter, in this case should not be confused with Lilly Ledbetter, the Plaintiff in the recent Supreme Court employment discrimination case, *Ledbetter v. Goodyear Tire & Rubber*, 127 S.Ct. 2162 (May 29, 2007).

[8] Even the drug industry lawyers in Buckman admitted that the claims Ms. Ledbetter asserts survive preemption analysis. In fact, during the *Buckman* oral argument, when asked about what remedies an injured plaintiff would have under his theory of the case, the industry attorney responded: "The fraud [on-the-agency] claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available . . ." *Id.* (quoting Oral Argument Transcript, Buckman, 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2000) (emphasis supplied).

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circumstances under which the FDA would ever make the requisite findings and, therefore, that no Texas plaintiff would ever be able to file a failure to warn claim under the exception expressly created by the Texas Legislature, he admitted that he would have to declare the entire statute preempted and return it to the Texas Legislature and that, under his interpretation, he was immunizing corporations who lied to the FDA to gain drug approval. Nevertheless, he failed to rule on that motion and let stand his original decision rather than take down the whole statute. As part of multi-district proceedings, his decision potentially affects thousands of Texas Vioxx and pharmaceutical plaintiffs and would bar their claims outright.

Under the guise of furthering perceived Congressional intent then, a Texas judge has immunized from suit in Texas even drug manufacturers who lied to the FDA to gain drug approval and expanded the implied preemption doctrine far beyond even what the FDA claims for itself. In the process, he has potentially locked the courthouse door to thousands of plaintiffs injured by prescription drugs. Is that really what Congress intended?

In Pennsylvania, Hannah Bruesewitz suffered a similar fate. Her personal injury claims have now been dismissed as preempted under the Vaccine Act. While a normal toddler, Hannah Bruesewitz was injected with DPT vaccine. Within 2 hours, she was in convulsions. She is 15 today and has suffered from seizures ever since. Even though she has a normal life expectancy, Hannah's life will never be normal. She will require hundreds of thousands of dollars in medical care for the rest of her life. Before she ever received the vaccine, the VAERS reporting system, created by Congress, had uncovered 2 child deaths and 66 serious injuries associated with the same vaccine lot administered to Hannah; however, no one told Hannah's parents or her doctor about these serious problems with the vaccine.

As required by federal statute, Hannah's parents filed claims seeking compensation for her injuries in the National Vaccine Injury Compensation Program. Because of budget cuts reclassifying her injury, she received no compensation at all through that program. As the result, her parents availed themselves of their express right under the Vaccine Act to sue in state court for her injuries.

Ignoring express Congressional language in the Vaccine Act which preserved suits based on drug side effects that are "avoidable," Judge Baylson, the judge in Colacicco, held that Congress intended to preempt all design defect claims, even those, like Hannah's, that involve vaccines for which there were suitable alternatives, including potentially substituting another lot of the same vaccine. Worse, a second Pennsylvania federal judge, relying in part on the FDA Preamble, would have impliedly preempted Hannah's failure to warn claims too, despite Congress' express reservation of such claims and express preemption of any state law that would stand in their way. In fact, when Judge Baylson specifically solicited an FDA amicus brief to give the FDA an opportunity to state its position on preemption in cases filed after participation in the National Vaccine Program, the FDA stated that it essentially had no dog in the fight at that point.

In short, even though Congress specifically preserved an injured but dissatisfied

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plaintiff's right to bring state tort claims after exhausting his or her administrative remedies under the Vaccine Act and expressly preempted state laws that would infringe upon that right, two federal court judges have decided that what Congress really meant to do was to limit such plaintiff's remedies, if any, to those afforded under the National Vaccine Program.

These examples reveal an emerging pattern of judicial and executive legislating, and nullification of federal and state laws permitting tort claims against pharmaceutical companies. The FDA and some activist courts are increasingly ignoring Congressional intent and casting aside bedrock legal and constitutional principles that once lent predictability and stability to the law in this area. In Texas and Pennsylvania, this has meant that, while courts have retained the statutory benefits for drug companies, they have removed important checks on those benefits, leaving many injured citizens with no remedy.

The absence of state tort claims also places enormous burdens on the FDA to ensure drug safety, burdens it is increasingly ill-equipped or unwilling to bear. Where private claims are preempted, the FDA becomes the only game in town. According to a recent report to the House Committee on Government Reform,[9] however, FDA enforcement actions have declined dramatically in the last 7 years, coincidentally, the period during which the FDA has most vigorously asserted the preemption doctrine. The number of warning letters issued by the FDA for violations of federal requirements, the true measure of enforcement activity, has fallen by over 50%, from 1,154 in 2000 to 535 in 2005, a 15-year low. Id. Internal FDA documents also show at least 138 cases in which FDA field inspectors found violations of FDA safety requirements but the FDA failed to take any enforcement action against the pharmaceutical manufacturer. Id.

In addition, longer term studies indicate that the FDA's response to continual budget cuts and increasing burdens has been to shift from monitoring and pre-approval investigation, actions which are resource-intensive, to product recalls, which are less expensive and time-consuming but make the public unwitting participants in a massive, uncontrolled clinical trial.[10] This means that more people will be hurt by prescription drugs in the future. Unfortunately, there is no federal scheme for compensating victims of most prescription drugs.[11] Thus, continued preemption holdings by the courts will mean that many victims will simply go uncompensated or the costs of their care will be shifted to American taxpayers through Medicaid or Medicare.

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[9] "Prescription for Harm - The Decline of FDA Enforcement Activity," U.S. House Comm. on Government Reform, Minority Staff, Special Investigations Division (June 2006).

[10] Mary Olson, "Substitution in Regulatory Agencies: FDA Enforcement Alternatives," JOURNAL OF LAW, ECONOMICS, & ORGANIZATION, Vol. 12, No. 2 (Oct., 1996) at 376-407.

[11] "The bar to finding preemption is raised even higher because the FDCA provides no remedy for an injured consumer. Thus a finding of preemption here will foreclose a remedy that was traditionally available and for which federal law provides no substitute. Courts have been particularly reluctant to find preemption in such a case without an unambiguous signal of Congressional intent." Perry v. Novartis, 456 F. Supp.2d 678, 684 (E.D. Pa. 2006) (emphasis supplied).

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Congress and the courts have traditionally recognized that private tort claims play an important role in ensuring that drugs are safe and that drug companies continue to improve their products. As one federal judge explained: "Rather than working at odds with each other, federal regulations and state common law acting in concert can improve vaccine safety of existing vaccines and spur the development of better safer products."[12] The critical role private lawsuits play will be lost if such claims continue to be held preempted.

RECOMMENDED SOLUTIONS

1. Make Congressional intent clear: include in each bill addressing the FDA and other critical safety agencies, language indicating that it is not intended to preempt state law and include such language in its legislative history. When Congress leaves a vacuum, the courts or executive agencies are only too happy to fill it. The Supreme Court held in its decision in Hillsborough County v. Automated Medical Laboratories Inc.,[13] that, in the absence of clearly expressed congressional intent or subsequent developments that reveal a change in that position, the FDA's position on the preemptive scope of its regulatory authority "is dispositive." To avoid usurpation of its powers by the FDA, Congress must speak clearly on the issue of preemption of pharmaceutical claims.

The recent Prescription Drug User Fee Act [PDUFA] is a good example of how Congress can begin to make its intent clear. The House version of the bill includes language seeking to ensure that the Act does not attempt to "occupy the field of drug labeling," thereby giving pharmaceutical companies additional means to argue preemption of state claims. In addition, during debate on the Senate bill, Senator Kennedy, a chief sponsor and floor manager, stated:

> We do not intend to alter existing State law duties imposed on the holder of an approved drug application to obtain and disclose information regarding drug safety hazards either before or after the drug receives FDA approval or labeling. Nor are we expressing a belief that the regulatory scheme embodied in the bill is comprehensive enough to preempt the field or every aspect of State law. FDA's approved label has always been understood to be the minimum requirement necessary for approval. In providing the FDA with new tools and enhanced authority to determine drug safety, we do not intend to convert this minimum requirement into a maximum. . . Nor are the bill's requirements that holders disclose certain safety information to the Government intended to substitute for the disclosure requirements that may be required under State law.

153 CONG. REC. S5759 (daily ed., May 9, 2007) (statement of Sen. Kennedy). The language in the House bill enhances the ability of practitioners to fight improper assertions of preemption

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[12] Mazur v. Merck & Co., 742 F. Supp. 239, 248 (E.D. Pa 1990); MacGillivray v. Lederle Labs Div., 667 F.Supp 743, 745 (D.N.M. 1987) (emphasis supplied).

[13] 471 U.S. at 714-15.

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and arms them with the tools they need to succeed in reversing such holdings.

2. Increase Congressional oversight of the FDA and other safety agencies, in particular, in their assertion of the preemption doctrine and enforcement activities. The United States Supreme Court may soon review cases addressing the question of whether to give agency assertions of preemption so-called Chevron or conclusive deference. This could mean that the FDA Preamble, which was issued in violation of applicable notice and comments requirements and in contravention of the FDA's own statement that its proposed rules involved no substantive changes,[14] could be considered dispositive of the preemption question. It is, therefore, incumbent upon Congress, in its oversight capacity, to police such statements and assertions that state law is preempted.

3. Consider legislation limiting preemption. Congress should consider limiting the ability of the state and federal courts to find implied preemption or the executive agencies to assert it by defining and restricting the circumstances under which Congress will permit preemption to be implied.

4. Consider passage of uniform statutory interpretation rules, including those addressing preemption. By providing more guidance to the Courts and agencies in interpreting federal statutes, particularly with regard to preemption, Congress can increase the likelihood that state and federal courts will follow established principles in interpreting federal law. Texas has a code construction act as do many states. While it is obviously not always followed, it does direct the state courts in interpreting state law. Even if it is ignored as it was in Ruby Ledbetter's case, however, it provides practitioners with a basis on which to challenge a trial court's idiosyncratic and improper interpretation of a statute and acts as an important check on judges who legislate from the bench.

CONCLUSION

Unless Congress acts by expressly limiting the application of the preemption doctrine, more citizens injured by prescription drugs, like Ruby Ledbetter and Hannah Bruesewitz, will be deprived of any day in court and any remedy for their injuries. Instead, these costs will be shifted to the American taxpayer. In addition, some trial courts and bureaucrats will continue to amend federal and state law at will in a frontal assault on Congressional authority and private rights. For these reasons and because the wide and improper use of federal preemption to supplant state-law claims is fundamentally incompatible with any notion of a limited government, reduced bureaucracy, and states' rights, I urge Congress to adopt the recommendations outlined here.

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[14] *See* 65 Fed. Reg. 81082, 81103 (2000).

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Opening Statement of Ranking Member Specter
Senate Judiciary Committee
"Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?"
September 12, 2007

The Constitution's Supremacy Clause provides that federal law shall be the "supreme law of the land" and the "judges in every state shall be bound thereby." While it is clear that Congress may pre-empt state law, in recent years, several federal agencies have asserted that their regulations preempt conflicting state laws, even where Congress has not expressly legislated. On this basis, some manufacturers have asserted in court that if their products meet standards set forth in federal regulations, then personal injury or other claims under state tort law are preempted and must be dismissed. Today we will be considering whether such preemption of state law exists in circumstances where Congress has not expressly preempted state authority and whether Congress may even delegate its preemption authority to regulatory agencies. Some say that these federal agencies are improperly infringing on state government authority. Others say that the federal agencies are properly enforcing uniform regulation and that the presence or scope of preemption when Congress has not explicitly addressed preemption is properly determined by the judiciary.

These are issues Senator Leahy and I have previously addressed. In 2005, the National Highway Transportation Safety Administration (NHTSA) contended that its regulations regarding car roof crush

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resistance would preempt state tort actions against car manufacturers. Senator Leahy and I wrote a letter to the NHTSA in November 2005, asking the Acting Director to clarify the basis of the agency's assertion of preemption. The response was less than satisfying.

Today, we are confronted with a similar issue arising from the Food and Drug Administration. In the preamble to its January 2006 prescription drug labeling rule, the FDA asserted that its "approval of labeling under the act…preempts conflicting or contrary State law." In addition, the most recent ruling handed down by the Consumer Product Safety Commission on mattress flammability includes a statement in the preamble that the new federal standard preempts "inconsistent state standards and requirements, whether in the form of positive enactment or court created requirements."

Whether Congress has, or even can delegate this preemption authority to federal agencies is of considerable interest. I note that the Supreme Court may soon address these issues. On June 25, 2007, the Court granted certiorari in Reigel v. Medtronic, a case in which the Court of Appeals for the Second Circuit affirmed the dismissal of certain claims filed by a patient who sued the manufacturer of a balloon catheter used in angioplasty. The patient asserted state law claims for strict liability, breach of warranty and negligent design, testing, inspection, distribution, labeling, marketing, sale and manufacture. The trial court ruled that all claims other than breach of express warranty and negligent manufacture were preempted by the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA).

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The Supreme Court is also considering a certiorari petition in Levine v. Wyeth, which presents the question of whether state law failure-to-warn liability conflicts with the FDA's goals of preventing patchwork regulation and of striking the right balance in providing sufficient information and warnings. In this case, the jury awarded damages to a patient who asserted negligence and failure-to-warn claims after she lost her hand and forearm as a result of the accidental injection of a drug into an artery instead of muscle.

When Congress enacts a statute, the Supremacy Clause makes it clear that the federal law displaces, or preempts, all conflicting state laws. In addition, when Congress expressly preempts state laws, the federal law displaces all state statutes and common law falling within the scope of the preemption provision. But what about situations or cases in which there is not a clear conflict between state and federal statutes, and where Congress has not expressly or stated its intent regarding preemption of state regulation? And should there be a different standard for preemption when the state law is a state statute or regulation—"positive law"—as opposed to a state common law prescription? Some suggest there should be differing standards because state tort law does not regulate conduct, but instead complements federal regulation because it compensates those who are injured as a result of unreasonable conduct.

This issue of preemption is important. If state law is preempted and lawsuits or claims are dismissed, public safety and health may be

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affected. In the past, some tort cases have unearthed industry secrets and safety shortcuts that manufacturers have taken. Information obtained in tort suits has turned out to be very useful to regulators seeking to protect the public. In addition, the unearthing of this information has caused manufacturers to improve the safety of their products, or make other changes that protect the public.

On the other hand, there is benefit to having uniform national safety standards. It may be unreasonable to expect manufacturers supplying a national market to comply with overlapping regulations from various states and the federal government. If, for example, the FDA has required certain labeling and warnings on pharmaceuticals, should the states be able to impose different rules—whether it is in a state statute or in a tort suit? Are federal agencies that employ or consult with independent scientists and experts in a better position than juries to interpret complex scientific evidence? Further, with respect to express preemption, is it reasonable to expect that Congress will always be able to predict all of the ways in which current or future state statutes or common law developments might frustrate the purpose of a federal regulatory regime or federal statute?

Another factor to consider is whether federal agencies are doing a good job of enforcing their regulations, and are issuing strong federal health and safety standards. What if those federal agencies are underfunded or are subject to what is called "regulatory capture"--an overly friendly relationship with the businesses they regulate?

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A September 2, 2007 NY Times article describes how, in March 2005, the Consumer Produce Safety Commission called together the nations' top safety experts to address this statistic: 44,000 children were injured while riding all terrain vehicles (ATVs) in 2004— this included nearly 150 deaths. Pediatricians, consumer advocates, and ER doctors urged the commission to ban sales of adult size ATVs for use by children, but the agency's director of compliance, a former lawyer for the ATV industry, opined that the current system of warning labels and other voluntary safety standards was working. Congress intended the CPSC to protect the public—yet this is an example that calls into question whether the agency is doing that. The CPSC has also drawn attention recently because of headlines about recalls of Chinese made toys containing lead, and dangerous propane grills, high chairs, computer batteries. I question whether federal health and safety standards have been weakened in certain areas, which makes state tort law all the more vital in protecting the public from dangerous products.

There may be wisdom to preserving FDA primacy in reviewing and approving labeling for products over which it has regulatory authority. I question how far that primacy should extend, however, and also whether other agencies should enjoy the same deference to their expertise. I expect our witnesses to comment on these very important issues today and look forward to their testimony and answers to our questions.

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United States Senate

COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

November 17, 2005

Ms. Jacqueline Glassman
Acting Director
National Highway Traffic Safety Administration
400 Seventh Street, S.W.
Washington, D.C. 20590

Dear Ms. Glassman:

We are writing to you concerning the Notice of Proposed Rulemaking recently published by the National Highway Traffic Safety Administration (NHTSA) regarding the roof crush resistance for motor vehicles.

Specifically, we are concerned about NHTSA's proposal to "preempt all conflicting State common law requirements, including rules of tort law." In the section of the Transportation Equity Act (P.L. 109-59) directing NHTSA to initiate rulemaking proceedings on roof resistance, we have been unable to find references to State tort law or language similar to that included in your agency's proposed Rule. We note that in other contexts, Congress has intended that State law be preempted and has expressed that intention in its legislation. For example, a Title X provision in the Transportation Equity Act regarding rented or leased vehicles expressly provides that owners of such vehicles "shall not be liable under the law of any state." However, it has not done so in the roof resistance context.

It may also be relevant to look to Executive Order 13132, which states: "Agencies shall construe, in regulations and otherwise, a Federal statute to preempt State law *only where the statute contains an express preemption provision or there is some clear evidence that the Congress intended preemption of State law.*" We are interested to learn how NHTSA concluded that preemption of State law was the intent of Congress when it passed the Transportation Equity Act.

In the Transportation Equity Act, Congress mandated that NHTSA establish standards to "reduce vehicle rollover crashes and mitigate deaths and injuries associated with such crashes." It seems to us that this end will not be served by the new proposed Rule. If you contend otherwise, we would appreciate you explaining why that is so.

We appreciate your time and attention to this matter. We look forward to your responses to the questions raised in this letter.

Sincerely,

Arlen Specter

Patrick Leahy

U.S. Department
of Transportation
National Highway
Traffic Safety
Administration

400 Seventh St., S.W.
Washington, D.C. 20590

January 12, 2006

The Honorable Patrick Leahy
Ranking Member, Committee on Judiciary
United States Senate
Washington, DC 20510

Dear Senator Leahy:

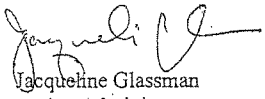
Thank you for your letter of November 17, 2005, cosigned by Senator Arlen Specter, concerning the preemption of State law as addressed in the notice of proposed rulemaking (NPRM) to improve roof crush resistance published by the National Highway Traffic Safety Administration (NHTSA) on August 23, 2005. In the NPRM, NHTSA discussed the possibility that an improved Federal roof crush resistance standard would impliedly preempt certain State tort law actions that would create inconsistent State and Federal obligations and undermine the purpose of a uniform national standard.

The issue of the relationship of Federal and State law is an important one. In addition to the partial text noted in your letter, Section 4a of Executive Order 13132, issued in 1993, says that "Agencies shall construe, in regulations and otherwise, a Federal statute to preempt State law ...where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." We wanted to raise the possibility of preemption during the rulemaking process, when there is a chance to obtain and consider public comments, rather than after the fact during possible litigation. We will fully consider your comments. For this purpose, NHTSA will place a copy of your letter in the docket for this rulemaking, along with this response.

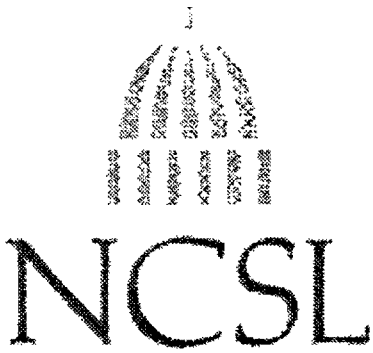
We are in the process of considering the comments that have been submitted to the docket on all aspects of the rulemaking involving roof crush resistance. We expect to complete the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users mandate and issue a final rule in a timely manner.

I hope this information is helpful. An identical letter has been sent to Senator Specter. If you have any questions, please have your staff contact me or Mr. Stephen P. Wood, Acting Chief Counsel, at (202) 366-2992.

Sincerely yours,



Jacqueline Glassman
Acting Administrator



The Honorable Donna D. Stone
State Representative, Delaware

President,
National Conference of State Legislatures

Testimony
Before the Committee on the Judiciary
United States Senate

September 12, 2007

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Good morning. I would like to thank Chairman Leahy, Ranking Member Specter and the members of the Senate Judiciary Committee for inviting me here this morning to speak to you about the preemption crisis facing states today. My name is Donna Stone and I am a state representative from the state of Delaware and the current President of the National Conference of State Legislatures. NCSL is a bipartisan organization representing the legislatures from the 50 states and the U.S. Territories. I ask that my written testimony be accepted and incorporated into the record.

NCSL is troubled by the growing trend in both Congress and federal agencies to pass or promulgate legislation and rules that have a substantial detrimental impact on states because of their intrusively preemptive nature. NCSL has tracked these preemptions in our Preemption Monitor, a publication that we initiated to alert state legislators nationwide to the alarming number of federal legislative and regulatory preemptions. As a result of federal preemption, a large part of the policy jurisdiction of state legislatures and of city and county officials has been lost. States and localities cannot legislate in response to their citizens' needs when the federal government has preempted the policy field. What is lost is the capacity for regional and local self-government.

The cornerstone policy of NCSL is our Federalism policy. Set forth in this policy resolution are the building blocks for a sound and robust state-federal partnership. The NCSL Federalism policy makes several important observations about the role of the states and federal government in our federal system of which we should all take note. Specifically, our policy recognizes that individual liberties can be protected by dividing

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power between levels of government; in other words, division of power between federal and state governments also serves as a check on the power of each. As the Supreme Court properly stated in *New York v. United States* (1992): "When one level of government becomes deficient or engages in excesses, the other level of government serves as a channel for renewed expressions of self-government."

Our Federalism policy also recognizes the importance of state innovation and creativity. As Justice Brandeis wrote in his dissenting opinion in the case of *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932)(Brandeis, J., dissenting):
"It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." NCSL believes that states are often in the best position to act quickly on a given issue and, in so acting, be more sensitive to the needs of the American people. NCSL believes that federalism allows for greater responsiveness and innovation though local self-government. State and local legislatures are accessible to every citizen. They work quickly to address problems identified by constituents.

Finally, NCSL is committed to the goal of restoring balance to our dual system of government by inviting Congress to reexamine some of its own recent preemptive actions, as well as to scrutinize some of the more recent federal agency actions that have frustrated this policy goal. We at NCSL hope that this hearing will serve as an important first step toward repairing the damage that has been done to states through ill-considered preemptive actions. However, before I address the solutions to this problem, I wish to highlight some of the lowlights of the last several years.

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Agency Preemptions

In recent years federal agencies have developed a troubling trend – preemption of established bodies of state law in the absence of underlying statutory authority through the rulemaking process. Several recent agency actions serve to illustrate this disturbing development.

In August, 2005, the National Highway Traffic Safety Administration (NHTSA) published a Notice of Proposed Rulemaking (NPRM) in the Federal Register on Roof Crush Resistance. The NPRM contained a federalism assessment required by Executive Order 13132 which stated that the agency had reviewed and analyzed the proposed rule against the criteria contained in the Executive Order and had determined that the NPRM did not have "sufficient federal implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement." See Federal Register, Vol. 70, No. 162 at 49245 (Tuesday, August 23, 2005). The NPRM further stated that "the proposal would not have any substantial impact on the States, or on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various officials." Id. The NPRM then went on to state that "if the proposal were adopted as a final rule, it would preempt all conflicting State common law requirements, including rules of tort law." Id. at 49246. Whether NHTSA recognized that a preemption of this nature would obviously impact states significantly, or whether NHTSA was being disingenuous is unknown. What is known is that there was no consultation conducted with NCSL, state attorneys general or any other state or local government entity, and the NPRM was allowed to pass through the Office of Management and Budget and be published in the Federal Register.

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The fact that NHTSA did not consult with NCSL prior to this NPRM's publication in the Federal Register is the critical one. Had this language become part of a final rule, NTSHA, a federal agency comprised of unelected civil servants, would have succeeded in establishing state tort law and liability standards. The parameters of state tort law, and more specifically whether to allow lawsuits on certain types of claims, are clearly policy decisions most appropriately crafted by elected state legislators and judges, not by federal agencies. This NPRM most definitely had significant impact on the federal-state relationship and had very substantial impact on every state in the country that allows wrongful death lawsuits in the event of a vehicle rollover.

Spurred by concern about this proposed rule, NCSL went one step further. We contracted with the Pacific Institute for Research and Analysis to conduct an analysis of how much a federal preemption of this nature would cost states. The ensuing report found that the financial burden placed on State governments as a result of the preemption provision contained in the NHTSA rule would be between $49 and $71 million per year, primarily as a result of increased state-paid medical and disability costs. Had NHTSA been required to consult with states by something more binding than an Executive Order, this impact would have been known in advance of the NPRM's publication, and efforts to minimize the preemption could have been undertaken.

Another important facet of this particular rulemaking that I alluded to earlier is that there was absolutely no statutory authority for the NHTSA preemption contained in the NPRM's underlying statute, which was Section 7251 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act of 2005. Instead, NHTSA placed its authority to act in the holding of a 2000 Supreme Court case called Geier v. Honda, Inc.,

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529 U.S. 861 (2000), which actually upheld the rights of citizens to file common law tort cases in vehicle airbag cases. Conversely, the NHTSA language in the NPRM expressly stated that common law tort lawsuits would be prohibited. I want to thank Senators Leahy and Specter for sending their letter of concern to NHTSA, which echoed the concerns of NCSL on this NPRM.

Close on the heels of the NHTSA NPRM came another, even more disturbing proposed rule, this time by the Food and Drug Administration. In December, 2005, the FDA determined that it was time to finalize a rule on prescription drug labeling which had lain dormant for five years. NCSL was aware of this rule, but did not submit comments because the original language of this NPRM expressly stated that there would be no federalism implications because the proposed rule would not preempt state law. See, Federal Register, Vol. 65, No. 247, p. 81103, December 22, 2000. Because of the express statement of non-preemption, the consultation requirements of Executive Order 13132 were not triggered.

On December 30, 2006, NCSL learned that the FDA planned to finalize its rule and include a policy statement that the provisions of the prescription drug labeling rule would preempt state product liability laws. NCSL approached FDA officials and asked for three things: a consultation meeting pursuant to the Federalism Executive Order, a copy of the proposed language, and that the FDA re-open the comment period to allow NCSL to file formal comments on this very significant and preemptive change. The FDA ignored the first request. The second and third requests were denied. However, it is interesting to note that during this rule's 5-year dormancy period, the FDA had allowed certain large pharmaceutical companies to submit comments pertaining to preemption

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after the expiration of the comment period. States, however, were not given the same deference, and the FDA finalized this rule in mid-January, 2006. Once again, unelected federal bureaucrats had succeeded in forming state tort law policy over the objections of the states.

Most recently, in early 2007, the IRS issued a revenue ruling concerning Section 162(h) of the Tax Code. Section 162(h) provides for the per diem deduction to any day that the legislature is in session. This section specifies that a legislative day, " shall be any day during such year on which – (A) the legislature was in session (including any day in which the legislature was not in session for a period of 4 consecutive days or less)". Section 162(h)(2)(A). Congress provided no more specificity or limitations in the definition of legislative session.

Pursuant to this revenue ruling, the IRS told state legislators that they could not take per diem deductions for days that the legislature was in session, but during which no substantial business was conducted. This interpretation was not based on any statute or existing rule of law, yet it sought to essentially define what would constitute a "legislative day." The unelected IRS officials unilaterally, and without any consultation with states as to the state impact, decided to craft state policy in a manner that preempted many state statutes or constitutions, or both, which specifically define what constitutes a "legislative day."

All of these circumstances surrounding the regulatory actions of the NHTSA, the FDA, and the IRS made it abundantly clear to NCSL that something more than an Executive Order on Federalism would be needed to keep agency action in check. We think we know how to bring our federal-state system back into balance.

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Additionally, the following examples illustrate what happens when there is a lack of agency/state consultations.. In the FY 2008 budget, the Administration proposed to make a number of "administrative" changes that would fundamentally alter and substantially reduce federal support for the Medicaid program. Many of these proposals were at one time submitted as legislative proposals and rejected by Congress. In some cases Congress has enacted moratoria on the proposed regulatory actions. In 2007, Center for Medicare and Medicaid Services (CMS) has promulgated the following rules that would significantly amend the Medicaid statute without guidance or consideration by Congress and without meaningful consultation with state and local governments or their national associations:

- January 18, 2007 –NPRM– Cost Limit for Providers Operated by Units of Local Government and Provisions to Ensure the Integrity of the Federal-State Financial Partnership. This NPRM proposed to alter the definition of "unit of local government" in the Medicaid statute for purposes of limiting local governments in the amount they can assist states in providing the "state share" of Medicaid funding. A Final Rule was published May 29, 2007 in the *Federal Register.* Congress imposed a one-year moratorium on the Final Rule in P.L. 110-28.
- March 23, 2007 – Notice of Proposed Rulemaking (NPRM) - Health Care-Related Taxes. In addition to establishing guidelines regarding the provision in the Tax Relief and Health Care Act of 2006, this NPRM reduces the allowable amount that can be collected by a state from a health care-related tax from 6

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percent to 5.5 percent of net patient revenues and substantially changes the hold harmless test which was not addressed in the Act.

- May 23, 2007 – Notice of Proposed Rulemaking (NPRM) – Graduate Medical Education. Proposed to change current law to no longer permit costs and payments associated with Graduate Medical Education (GME) to be reimbursed under Medicaid. Congress imposed a one-year moratorium on the NPRM in P.L. 110-28.
- August 13, 2007 – Notice of Proposed Rulemaking (NPRM) – Coverage for Rehabilitative Services. Amends the definition of rehabilitative services in the Medicaid statute. These changes are not required by any federal law or other Act of Congress.
- August 17, 2007 – Dear State Health Official Letter – Changes the income eligibility requirements in the State Children's Health Insurance Program (SCHIP). These changes became effective immediately, despite that Congress is in the midst of reauthorizing this critically important health care program for children.
- September 7, 2007 – Notice of Proposed Rulemaking (NPRM) – Elimination of Reimbursement Under Medicaid for School Administration Expenditures and Costs Related to Transportation of School-Age Children Between Home and School. This NPRM proposes to change Medicaid reimbursement policy related to school-based health care services. These changes are not required by any federal law or other act of Congress.

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NCSL believes the key to the successful implementation of Medicaid and SCHIP is stability in funding and rules of engagement. If the Department of Health and Human Services was required by law to consult with state and local government officials or their national associations, the adverse impact of these agency actions could have been minimized and perhaps avoided.

Legislative Preemptions

Over the last two and one-half years, NCSL has tracked over one hundred and fifty proposed legislative preemptions of state law. The legislation has spanned the range of issue areas from homeland security, to health, to election reform, and are all reported in NCSL's Preemption Monitor which can be found on our website at www.ncsl.org. I will highlight a few of the more notorious preemptions today.

Real ID ACT of 2005

The Real ID Act of 2005 requires states to adopt new federal standards for the issuance of driver licenses (DL) and identification cards (ID) by May 11, 2008 or their DL/ID cards will not be recognized for federal purposes, for example, boarding federally regulated commercial aircraft, accessing federal facilities, entering nuclear power plants, and any other purposes that the secretary determines.

The process whereby the Real ID Act was enacted, as well as the proposed DL/ID standards themselves, ignores the basic principles of federalism that respect diversity without causing division and that foster unity without enshrining uniformity. The Real ID Act of 2005 was added to a must-pass supplemental spending bill for the war on terrorism and tsunami relief. With its enactment, the Real ID Act repealed an existing negotiated rulemaking process for establishing DL/ID standards, in which NCSL

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participated, and instead put into statute prescriptive mandates. The negotiated rulemaking process would have made the development of standards a partnership instead of a preemption of existing state practices. The process ignored the fact that DL/ID cards have been issued by states for over 90 years under the constitutional authority of the 10th Amendment, and failed to provide state legislators with any notice of congressional intent or opportunity for formal or informal comment prior to the law's enactment.

Mr. Chairman and committee members, creative solutions to public problems can be achieved more readily when states are accorded due respect. Uniformity for uniformity's sake does not justify preemption. As you know, at least six states—Maine, Montana, New Hampshire, Oklahoma, South Carolina and Washington—have enacted legislation stating their refusal to comply with the provisions with the Real ID Act.

Vaccine liability exemption – H.R. 2863, defense appropriations rider

This provision was added as a rider to the Conference Committee report of H.R. 2863, the FY2006 Defense Appropriations bill. It prohibits *any* lawsuit, under federal law or any applicable state law, from being filed against a vaccine manufacturer, distributor or administrator for any claim arising or resulting from the use of the vaccine or drug in question. Any petitioner making a claim of willful misconduct by a drug manufacturer may only file a complaint with the Secretary of Health and Human Services, thus being further barred from the state and/or federal court system. Courts are restricted to the review of the Secretary's action, and may not ever consider the nature of the willful misconduct complaint. The bill was signed by President Bush on December 30, 2005, and became Public Law 109-148.

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S. 1082, The Prescription Drug User Free Act of 2007 (PDUFA) as part of The Food and Drug Administration Revitalization Act.

Language was stripped from all 10 House drafts of the PDUFA legislation which, if included, would have provided a safeguard against FDA preemption of state laws and would have undone the FDA Prescription Drug Labeling Rule preamble preemption which I discussed above.

Election Reform – H.R. 811

H.R. 811 is poised for House floor action any day. If passed, H.R. 811 will require states to have voting systems that provide a paper receipt or "trail" of a voter's ballot choices. While most states agree with the concept of H.R. 811-- that there ought to be some sort of paper trail, concurrence with the requirements of H.R. 811 ends there. Direct recording-electronic voting machines, or "DREs", which are the only voting machines in existence that permit the disabled voter to cast a secret ballot, are not considered to be compliant with the provisions of H.R. 811. These machines will need to be either scrapped or retrofitted with a paper printer. Both options are expensive. In the most recent iteration of the bill, it appears that AutoMark machines are not compliant either. Even more troubling is the requirement for a one-size-fits-all audit scheme that is not based on any state's current practices and would, therefore, preempt laws in all 50 states. The audit process contemplated by H.R. 811 would also be very expensive. Several states recently rejected audit provisions similar to those in H.R. 811 because they were cost prohibitive; Indiana and Virginia are two such states. Regrettably, state and local policy and elections officials were not given a seat at the table when this bill was

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drafted and, thus, the full scope of the preemptive impact and the resultant cost implications for states were never discussed.

If members of Congress are better informed about the preemptive impact of legislative proposals, then we believe, based on our experience with the Unfunded Mandates Reform Act, that fewer provisions preempting state law will be proposed. Even when Congress decides that preemption is necessary, we believe that preemptive language will be more carefully targeted and more narrowly crafted. We think that greater clarity in bill drafting will allow states, courts and the general public to know more precisely when Congress intends to preempt and where the limits are on the scope of the preemption.

Proposed Solutions to Excessive Preemptions

In 1999, NCSL and other state and local government national associations worked closely with the Clinton Administration to revise and refine the Federalism Executive Order, Executive Order 13132. Although the Federalism Executive Order is a noble first step in increasing agency awareness and accountability for preemptive regulations, as my testimony has shown, it does not go far enough for one main reason: an executive order is a guidance document that does not carry the weight of statute and, therefore, cannot be enforced. There are no consequences for its violation. There is no incentive for agencies to adhere to the Federalism Executive Order's requirements in any meaningful way. NCSL has found that in the years following the effective date of the Federalism Executive Order, overall agency adherence to its provisions has been spotty at best. As I have illustrated, agencies like the FDA and NHTSA have, at times, chosen to ignore its requirements altogether. Other agencies, like the Department of Homeland Security,

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choose to circumvent it by issuing interim rules so that the Federalism Executive Order cannot be applied; and a handful of agencies, like the Consumer Product Safety Commission, are expressly exempted from its requirements.

NCSL believes that the Federalism Executive Order should be codified into statute to protect elected state policymakers from the uninformed actions of unelected federal agency bureaucrats. Additionally, we believe that the provisions of this new law should be extended to legislative actions undertaken by Congress. Specifically, NCSL would like to see a new piece of congressional legislation that contains the following principles:

1. **Partnership and enhanced consultation**. NCSL would support provisions to provide for consultation with state and local elected officials or their representative national associations prior to the consideration of any legislation or federal regulations that would interfere with or intrude upon historic and traditional state and local rights and responsibilities.
2. **Rule of Construction.** NCSL would support provisions to ensure that, absent any explicit statement of intent to preempt or absent any irreconcilable conflicts with state law, any ambiguities would be construed in favor of state law.
3. **Enforcement**. NCSL supports provisions to ensure congressional and agency accountability and enforcement. The point of order in the Unfunded Mandates Reform Act (UMRA) has made members of Congress increasingly aware of potential impacts of federal laws and

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regulations on state and local taxpayers. We believe that a mechanism to ensure this recognition regarding preemption in both the legislative and the regulatory arenas is critical.

4. **Legislative Report.** NCSL supports efforts to include a federalism assessment in every committee and conference report. This will help members appreciate the potential impact on our levels of government, our taxpayers, and our programs.

5. **Agency Impact Statement.** Early in the rulemaking process, it is essential to codify the provisions of the Federalism Executive Order to ensure that every federal agency engages in a meaningful consultation process with elected state and local officials or their national associations, as well as with other impacted stakeholders. This will help to determine the potential impact of final administrative rules on our partnership.

NCSL believes that these recommendations, taken in the cumulative, will benefit everyone -- state and local governments, the federal government and the general public -- because they foster greater transparency, greater cooperation between governmental units and more information sharing all around. NCSL is prepared to work with you, Chairman Leahy, Ranking Member Specter and members of the Senate Judiciary Committee, to make these policy considerations a legislative reality. I believe that this type of legislation will serve to strengthen and fortify the intergovernmental partnership. My hope is that with your leadership, legislation to address the states' concerns on preemption will be introduced soon so that it can successfully make its way through the legislative process during this session. Thank you for your time today.

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TESTIMONY BY

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"Preserving The Vital Role Of Preemption In Our Constitutional Scheme And National Economy"

ON BEHALF

OF

THE U.S. CHAMBER OF COMMERCE AND
THE U.S. CHAMBER INSTITUTE FOR LEGAL REFORM

BEFORE

THE SENATE JUDICIARY COMMITTEE
UNITED STATES CONGRESS

ON

SEPTEMBER 12, 2007

Preserving The Vital Role Of Preemption In Our Constitutional Scheme And National Economy

Good morning Chairman Leahy, Ranking Member Specter, and other distinguished members of the Committee. I would like to thank you for the opportunity to testify today about a subject that is of substantial professional interest to me. I am testifying today on behalf of the United States Chamber of Commerce as well as the Chamber's Institute for Legal Reform. The views stated today are my own, based on my experience over the past 19 years of private practice during which I have represented business defendants, trade associations, and other clients in a wide variety of preemption cases.

The preemption doctrine is critically important to the business community and to the health of our national economy. In my experience, the positive impact of federal preemption very often gets lost in the sometimes heated debates over whether a particular court decision or agency action was correct. In recent years, these controversies have been particularly acute in the area of preemption of state requirements that are imposed by tort law or in product liability litigation. Although I will address those disputes later in my testimony, I think it is critically important for this Committee to keep in mind that the preemption doctrine has a far broader reach than this relatively narrow category of disputes – and that changes made to the preemption doctrine generally could have a far-reaching effect on the operations of the federal government.

I would like to begin today by reviewing the significant benefits that can occur when Congress – or an administrative agency acting pursuant to delegated authority – elects to regulate preemptively rather than merely concurrently with state and local governments.

The Benefits Of Preemption: Regulatory Uniformity, Unified National Markets, Efficiency, And Regulatory Expertise

We live in a large and sprawling country that is rich in many things – including government. In addition to the 50 state governments, each with its own legislature, executive branch and administrative agencies, and courts, by last count there were more than 87,500 local governmental units in the United States, including more than 3,000 counties, more than 19,000 municipalities, and more than 16,000 towns or townships. See U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES 262 (2004). This multiplicity of government actors below the federal level ensures that businesses with national operations will be subject to complicated, overlapping, and sometimes even conflicting legal regimes.

These overlapping regulations have the potential to impose undue burdens on interstate commerce. That is why, as the Supreme Court has explained, it is "[a] fundamental principle of the Constitution . . . that Congress has the power to preempt state law." *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 372 (2000). When Congress elects to legislate preemptively by prescribing a single set of uniform rules for the entire country, it streamlines the legal system, reduces the regulatory burdens on business, and helps to create a unified national marketplace for goods and services. It also reduces the barriers to new entry by small businesses

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and lowers the cost of doing business (which in turn can result in reduced costs of goods and services to consumers). In many cases, Congress's adoption of a preemptive scheme also ensures that the legal rules governing complex areas of the economy or products are formulated by expert regulators with a broad national perspective and needed scientific or technical expertise rather than by decision makers – such as municipal officials, elected state judges, and lay juries – who have a far more parochial perspective and limited set of information. For businesses, having a single, uniform federal rule is usually far preferable to dealing with a welter of federal, state, and local requirements.

In light of these obvious benefits, it is not surprising that Congress has elected to pass scores of statutes that contain preemption clauses. According to one survey, between 1789 and 1992 Congress enacted "approximately 439 significant preemption statutes" – "more than 53 percent" of which were enacted between 1969 and 1992. U.S. ADVISORY COMM'N ON INTERGOVERNMENTAL RELATIONS, FEDERAL STATUTORY PREEMPTION OF STATE AND LOCAL AUTHORITY: HISTORY, INVENTORY, ISSUES, at iii (1992).[1] Federal preemption is common in the areas of copyright, telecommunications, banking, and labor law. Not surprisingly given Congress's responsibility for regulating interstate commerce, a large number of these express preemption provisions are aimed at freeing up nationally distributed products of one kind or another – including mobile products such as automobiles that regularly cross jurisdictional borders – from the burdens imposed by different or additional state regulations concerning product labeling or design. Separate federal statutes accomplish this for recreational boats, automobiles, pesticides, cigarettes, medical devices, flammable fabrics, hazardous substances, and many other consumer products. These uses of the preemption doctrine reduce the burdens on interstate commerce and help to create unified national markets – and thus serve a central purpose underlying the Commerce Clause.

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[1] Examples include the Federal Election Campaign Act, 2 U.S.C. § 453; the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136v; the Packers and Stockyard Act, *id.* § 228c; the Agricultural Marketing Act, *id.* § 1626h; the Plant Protection Act, *id.* § 7756; the National Bank Act, 12 U.S.C. § 484(a); the Flammable Fabrics Act, 15 U.S.C. § 1203(a); the Federal Hazardous Substances Act, *id.* § 1261 note; the Child Safety Protection Act, *id.* § 1278 note; the Federal Cigarette Labeling and Advertising Act, *id.* § 1334; the Fair Packaging and Labeling Act, *id.* § 1461; the Poison Prevention Packaging Act, *id.* § 1476(a); the Consumer Product Safety Act, *id.* § 2075(a); the Magnuson-Moss Warranty Act, *id.* § 2311(c); the Terrorism Risk Insurance Act of 2002, *id.* § 6701 note; the Nutritional Education and Labeling Act, 21 U.S.C. § 343-1; the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a); the Poultry Products Inspection Act, *id.* § 467e; the Federal Meat Inspection Act, *id.* § 678; the Egg Products Inspection Act, *id.* § 1052; the Occupational Safety and Health Act, 29 U.S.C. § 667; the Employee Retirement Income Security Act ("ERISA"), *id.* § 1144(a); the Price-Anderson Act, 42 U.S.C. §§ 2210(n)(2), 2014(hh); the Clean Air Act, 42 U.S.C. §§ 7543(a), 7573; the Volunteer Protection Act of 1997, *id.* § 14502; the Boat Safety Act, 46 U.S.C. § 4306; the Hazardous Materials Transportation Uniform Safety Act, 49 U.S.C. § 5125; the Federal Aviation Administration Authorization Act, *id.* § 14501(c); the Safety Appliance Acts, *id.* §§ 20301-20306; the National Traffic and Motor Vehicle Safety Act, *id.* § 30103(b)(1); the Surface Transportation Assistance Act, *id.* § 31114(a); the General Aviation Revitalization Act, *id.* § 40101; and the Airline Deregulation Act, *id.* § 41713(b).

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The Supremacy Clause And The Doctrine Of Implied Preemption

So far I have been talking mostly about what is usually called "express preemption" – the choice expressly made by Congress (or by an administrative agency delegated authority by Congress) to regulate preemptively instead of merely concurrently. But the preemption doctrine has another, vitally important function: it protects the authority of the federal government – and the full efficacy of federal law in all its various forms – against incursions and interference by state and local governments. The Framers of our Constitution understood the vital importance of ensuring the supremacy of federal law in the face of conflicting or contrary mandates imposed by state governments. That is why they included the Supremacy Clause, which provides that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

The Supremacy Clause is the fountainhead of the doctrine of implied preemption. The Supreme Court has identified several types of implied preemption. Implied *field* preemption occurs where federal regulation is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Implied *conflict* preemption involves conflicts between state and federal law and takes a number of forms. Conflict preemption occurs where "compliance with both federal and state regulations is a physical impossibility," *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132, 142-43 (1963), or state and federal law otherwise conflict, or state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941). The first of these three variants of conflict preemption is sometimes referred to as "impossibility" preemption; the last, "obstacle" preemption.

Thus, under the Supremacy Clause as interpreted by the Supreme Court, any state or municipal law that conflicts with – or frustrates the purposes of – federal law is automatically nullified. And the Court has made clear that "[t]he phrase 'Laws of the United States'" in the Supremacy Clause "encompasses both federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization." *City of New York* v. *FCC*, 486 U.S. 57 (1988). Thus, with every new statute passed by Congress, with every new regulation issued by a federal administrative agency, state and local governments are precluded, "by direct operation of the Supremacy Clause" (*Brown* v. *Hotel and Restaurant Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491, 501 (1984)), from taking legislative, judicial or executive action that conflicts with, or frustrates the purpose of, the federal enactment.

In the last century (and particularly since the New Deal), there has been a vast expansion of federal law in all forms – especially statutes and regulations. By virtue of the Supremacy Clause, the inevitable consequence of that expansion is to restrict the residual authority and police power of state and local governments to take actions that conflict with federal law. See *New York* v. *United States*, 505 U.S. 144, 159 (1992) ("As the Federal Government's willingness to exercise power within the confines of the Constitution has grown, the authority of the States has correspondingly diminished to the extent that federal and state policies have conflicted."). This dynamic helps to explain why preemption is so common today and why preemption cases

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are a staple of the Supreme Court's docket. It also shows why critics of the preemption doctrine are wrong in suggesting that preemption is extraordinary, unusual, suspect, or contrary to principles of federalism embodied in the Constitution. To the contrary, preemption is an ordinary, ubiquitous and highly beneficial feature of our scheme of government. And it is not only consistent with but compelled by the Supremacy Clause.

The Preemption Doctrine Should Not Be Weakened By Congress

Let me turn now to some of the criticisms of the preemption doctrine and proposals for weakening it that have been made by critics. I plan to first discuss express preemption, then implied preemption, then finally preemption by administrative agencies. Most of the proposals for change would apply only prospectively, *i.e.*, to statutes enacted and regulations promulgated in the future. Accordingly, I will generally leave to one side the set of problems that would arise if new limits on the preemption doctrine were applied retroactively to statutes enacted or regulations promulgated under entirely different ground rules.

I. Express Preemption

As previously explained, Congress has enacted a wide array of statutes that include provisions expressly stating that some defined area of state and local law is preempted. In such instances of "express preemption," the critical question is always what Congress intended – and courts deciding issues of express preemption apply all the usual tools of statutory construction by examining the text, structure, and legislative history of Congress's enactments.

Rules Of Construction Relating To Express Preemption Clauses

Although in the 1920s the Supreme Court briefly applied a presumption *in favor of* preemption to congressional statutes, see Stephen Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 801-08 (1994), it soon thereafter shifted gears and made clear that at least where Congress has "legislated . . . in [a] field which the States have traditionally occupied," courts must "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). In *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), the Supreme Court made clear that this "assumption" (which in other cases has been called the "presumption against preemption") did not merely disappear once Congress made its preemptive intent unmistakably clear by including an express preemption provision in a statute. Rather, it continued as a rule of construction requiring courts to interpret express preemption clauses narrowly in seeking to ascertain Congress's intent. Two Justices dissented from this conclusion. See 505 U.S. at 544 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part) ("Under the Supremacy Clause, . . . our job is to interpret Congress's decrees of pre-emption neither narrowly nor broadly, but in accordance with their apparent meaning.").

The presumption against preemption has been criticized by several prominent scholars, including Professor Viet Dinh, on the ground that it is inconsistent with the text of the

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Supremacy Clause. It has also been criticized by Justices Scalia and Thomas on the ground that it artificially skews the inquiry into Congress's intent. Although these criticisms are valid, the Supreme Court has shown no inclination to abandon the presumption, and indeed has reaffirmed it, even though in a number of recent cases business groups – including the U.S. Chamber of Commerce – have asked it do so. Thus, the presumption against preemption remains a part of preemption law.

Nevertheless, some have proposed that Congress codify the presumption against preemption by including it in a federal statute. In the view of these critics, Congress would do well to tie its own hands prospectively by mandating that no future federal statute will be understood to expressly preempt state or local law unless the statute states explicitly that such preemption is intended. It has also been proposed that Congress codify the rule of narrow construction of express preemption provisions set forth in *Cipollone* by stating that "[a]ny ambiguity" in any express preemption clause must be resolved against preemption. As an initial matter, it is difficult to see why Congress would want to codify such strictures on its own authority to exercise its legislative powers. If Congress's intent is the touchstone of preemption analysis, then why would Congress wish to put a distorting thumb on the scale of the inquiry into that intent? On the other hand, to the extent that these provisions merely restate the "presumption against preemption" that is already an accepted part of preemption law, they seem unnecessary. Finally, the proposal should be rejected because the criticisms leveled against the "presumption against preemption" by scholars and by Justice Scalia are valid.

Beyond these shortcomings, the proposal appears to rest on the assumption that Congress (or the courts) is insufficiently sensitive to federalism concerns when Congress expressly deploys its well-established power to regulate preemptively (or courts resolve disputes about the meaning of express preemption clauses included in federal statutes). As I will next explain, this assumption is mistaken.

Congress's Sensitivity To Federalism Concerns Is Already Reflected In The Express Preemption Schemes Congress Has Created

Congress often includes in preemptive federal statutes special safeguards – both substantive and procedural – that protect and preserve the authority of state and local governments to regulate and to meet their own operational needs. The existence of these provisions – which are so often overlooked by critics of preemption – confirms that the political safeguards of federalism are in very good working order and there is no need to codify the presumption against preemption.

Six examples of Congress's accommodation of state and local governments' interests in other preemption settings are illustrative. *First*, Congress often elects *only* to preempt state and local laws that relate to a particular, limited subject matter. For example, the preemption provision in the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v, is limited to state and local "requirements for labeling or packaging." 7 U.S.C. § 136v(b). State requirements unrelated to "labeling or packaging" are left intact by Congress's careful limitation on FIFRA's preemption clause.

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Second, Congress often elects only to preempt state and local laws that *are different from* federal law, thus leaving intact state and local laws that are identical or substantially similar to federal mandates. See, *e.g.*, Consumer Product Safety Act, 15 U.S.C. § 2075(a) (preempting state safety standards "unless such requirements are identical to the requirements of the Federal standard"); Medical Device Amendments, 21 U.S.C. § 360k(a). Under these schemes, state and local governments retain the authority to enforce requirements that parallel those imposed by the federal government.

Third, Congress frequently places an exclusion within express preemption clauses for goods or products purchased by states or local governments *for their own use*. Examples include the preemption provisions of the Flammable Fabrics Act, 15 U.S.C. § 1203(b), the Federal Hazardous Substances Act, 15 U.S.C. § 1261 note, and the Poison Prevention Packaging Act, 15 U.S.C. § 1476(b). These exclusions preserve the authority and autonomy of state and local governments to make procurement and spending decisions.

Fourth, Congress sometimes includes in a preemption scheme an exception for state or local requirements that are *needed to address special or unique local conditions*. The Federal Railroad Safety Act, for example, excludes certain "additional or more stringent" measures taken by a state "related to railroad safety or security" where the state's regulation, among other things, "is necessary to eliminate or reduce an essentially local safety or security hazard." 49 U.S.C. § 20106. See also 46 U.S.C. § 4306 (Boat Safety Act) (excluding certain state or local regulations concerning "uniquely hazardous conditions or circumstances within the State").

Fifth, Congress often *authorizes the granting of exemptions* to state and local governments under an express preemption scheme. Although these provisions vary somewhat in form, they typically allow the administrative agency to grant exemptions if a state or local standard: (1) provides a higher degree of protection than applicable federal standards; (2) does not unduly burden interstate commerce; and (3) does not cause the product to be in violation of any federal requirements. See, *e.g.*, Toxic Substances Control Act, 15 U.S.C. § 2617(b); Federal Hazardous Substances Act, 15 U.S.C. § 1261 note.

Sixth, Congress has sometimes specifically created a role for the states *in setting the preemptive federal standards*. The Federal Boat Safety Act, for example, provides for state input into the Coast Guard's process of formulating uniform federal design standards for recreational boats. The Coast Guard is required to "consult with" the National Boating Safety Advisory Council ("NBSAC"), 46 U.S.C. § 4302(c)(4), a group of experts and other persons interested in boat safety. One-third of the 21 members of the NBSAC must be state officials responsible for state boat safety programs. See *id.* § 13110(b)(1).

As these examples show, Congress is hardly inattentive to federalism issues in crafting preemptive legislation. The availability of these and other measures to accommodate the interests of state and local governments further demonstrates that the additional, across-the-board measures being proposed by some critics of preemption law are unwarranted.

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There Is No Need To Further Restrict The Ability Of Courts To Find Express Preemption

Equally unfounded is the suggestion of some critics that more stringent rules are needed to restrict the ability of *courts* to conclude, in express preemption cases, that Congress intended to preempt state or local laws. The state courts and lower federal courts are already bound, under the Supreme Court's cases, to apply a "presumption against preemption" in preemption cases involving areas of traditional state authority or the construction of express preemption clauses. The Supreme Court itself is also bound to follow that precedent.

Most of the criticism of the doctrine of express preemption is traceable to disagreements about the outcomes in a line of decisions of the U.S. Supreme Court in cases involving the preemption of state tort requirements. Those decisions include not only *Cipollone*, which involved the Cigarette Labeling Act, but also *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), which involved the Medical Device Amendments, and more recent cases such as *Sprietsma* v. *Mercury Marine*, 537 U.S. 51 (2002), and *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005), involving other statutes containing express preemption provisions.

The point I would make about those decisions is that they turn on very specific differences in the wording of the preemption clauses at issue, the structure of the preemption schemes (including the presence of savings and other provisions that shed light on the meaning of the preemption clause), and the relevant legislative history. It is true that some of these decisions are complex and confusing. But that is largely a function of the complexity of the underlying statutes and the Supreme Court's statute-by-statute approach to these issues, which is entirely appropriate for an exercise in determining Congress's preemptive intent underlying a particular statute.

Moreover, these decisions hardly show that the Supreme Court is too quick to find express preemption. In *Cipollone*, there were actually two preemption provisions at issue – one contained in the 1965 Act and another in the 1969 Act. Notably, the Court rejected the express preemption argument with respect to the 1965 Act. It accepted the preemption defense concerning the 1969 Act for certain claims, but rejected it for others. Beyond that, as explained above, *Cipollone* announced a new rule of narrow construction for express preemption clauses. Similarly, the Court in *Medtronic* held that all of the tort claims at issue in that case were *not* expressly preempted by Medical Device Act. And in *Sprietsma*, the Court also rejected the manufacturer's arguments for express preemption.

Why then are these cases so controversial? The only reason, I would suggest, is because they recognized that Congress's specification that state-law "requirements" in an express preemption clause can include requirements imposed under state tort law. Thus, Justice Stevens' plurality opinion in *Cipollone* stated that a preemption clause nullifying certain "requirement[s] or prohibition[s] . . . imposed under State law" "sweeps broadly and suggests no distinction between positive enactments and common law" and indeed "*easily* encompass obligations that take the form of common-law rules." 505 U.S. at 521 (plurality) (emphasis added). Justices Scalia and Thomas agreed with that conclusion. *Id.* at 548-49. In *Medtronic*, a majority of the

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Court endorsed Justice O'Connor's conclusion that the "ordinary meaning" of a provision preempting state "requirements" "*clearly* pre-empts any state common-law action." 518 U.S. at 511. In agreeing with that conclusion, Justice Breyer pointed out the "anomalous consequences" of "grant[ing] greater power . . . to a single state jury than to state officials acting through state administrative and legislative lawmaking." *Id.* at 504 (Breyer, J., concurring). Justice Breyer also gave as an example of a claim that would be preempted "a state law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire," where "a federal . . . regulation requires a 2-inch wire." *Ibid.* The Court has reached the same conclusion in cases involving other preemption provisions. See *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005) ("the term 'requirements' in [7 U.S.C.] § 136v(b) reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties"); *CSX Transp.* v. *Easterwood*, 507 U.S. 658, 664 (1993).

Contrary to the suggestion of some critics, this aspect of the Court's decisions in *Cipollone*, *Medtronic*, and other cases is not entirely new but rather builds on older decisions that recognize the same principle or acknowledge the clear regulatory effect of common-law judgments. In *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236 (1959), the Court observed that "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Id.* at 247. Similarly, in *Norfolk & Western R. Co.* v. *Train Dispatchers*, 499 U.S. 117 (1991), the Court held that the phrase "all other law, including State and municipal law" simply "does not admit of [a] distinction . . . between positive enactments and common-law rules of liability." *Id.* at 128. Indeed, "[a]t least since *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), [the Court] ha[s] recognized the phrase 'state law' to include common law as well as statutes and regulations." *Cipollone*, 505 U.S. at 522.

It is worth pointing out, however, that in other cases involving differently worded preemption clauses the Supreme Court has reached the opposite conclusion: that Congress intended to exclude requirements imposed under state tort or common law. One example is *Geier* v. *American Honda Co.*, 529 U.S. 861 (2000), which held that the preemption clause of the National Traffic and Motor Vehicle Safety Act, which refers to state "safety standards," does not encompass standards imposed under the common law. *Id.* at 867-68. Another is *Sprietsma*, which held that the Boat Safety Act's preemption clause does not cover common-law claims. See 537 U.S. 51, 63-64 (2002). Cf. also *Bates*. 544 U.S. at 445 ("A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common-law duty at issue . . . "). The differences in outcomes in these cases turn on subtle differences in language used by Congress in the specific statutes at issue.

Underlying these disputes about Congress's meaning in specific cases are vigorous disagreements about the regulatory effect of tort law and large-scale products liability litigation today and whether tort law's compensatory function makes it qualitatively different from all other types of legal obligations imposed by states. Business defendants in these cases tend to argue that it is illogical to draw a distinction between the requirements imposed under the

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common law of torts and requirements imposed by statute because many states have codified their tort law. They also argue that it simply ignores practical realities to suggest that massive common-law liability, for example, for a design defect does not "require" any future action by a product manufacturer. A manufacturer that ignored a multimillion-dollar verdict in a design defect case would risk not only similar verdicts but also *punitive* damages in the future. In arguing that modern tort litigation has a clear regulatory effect, business defendants also often point to the rise of mass tort litigation and large punitive damages awards. See Hensler, *The New Social Policy Torts: Litigation As A Legislative Strategy, Some Preliminary Thoughts On A New Research Project*, 51 DEPAUL L. REV. 493, 498 (2001) ("What seems to most distinguish the new tort actions from conventional damage class actions is that, in addition to seeking damages and enforcement of current regulations, the plaintiffs seek to change the rules that govern industry-wide business practices.").

On the other side of the debate, plaintiffs' lawyers argue that tort requirements are qualitatively different – or not "requirements" at all. They point out that the necessary effect of upholding preemption of a state tort requirement is to deprive injured persons of a right to recover damages – at least on the preempted theory.

Reasonable minds can also differ on the federalism implications of preempting state tort law. Some view any federal limitation on tort law as a serious interference with a core area of the states' police powers. But others may view modern-day products liability litigation as imposing exactly the kind of burdens on interstate commerce that the Framers had in mind in conferring on Congress the power to regulate interstate commerce.[2] And still others may agree with Justice Breyer's suggestion that the federalism implications of nullifying the action of a single state-court jury would appear to be far less serious than nullifying an Act of a state legislature. See *Medtronic*, 518 U.S. at 504 (Breyer, J., concurring) (pointing out the "anomalous consequences" of "grant[ing] greater power . . . to a single state jury than to state officials acting through state administrative and legislative lawmaking"). As explained above, Congress has passed many preemptive statutes that, albeit in measured and limited ways, indisputably preempt state statutes or ordinances that relate to product labeling and/or design.

The only point I would like to make today about these recurring debates is that I suspect they would not be resolved the same way by every Member of Congress. Reasonable people can and do disagree over these issues. And that is why courts look to the actual language used by

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[2] See Michael McConnell, *Federalism: Evaluating the Founders' Design*, 54 U. CHI. L. REV. 1484, 1499 (1987) ("S]tate-by-state determination of the law of products liability seems to have created a liability monster. This is because each state can benefit in-state plaintiffs by more generous liability rules, the costs being exported to largely out-of-state defendants; while no state can do much to protect its in-state manufacturers from suits by plaintiffs in other states."); Michael McConnell, *A Choice-of-Law Approach to Products-Liability Reform*, in NEW DIRECTIONS IN LIABILITY LAW 90, 92 (Walter Olson ed., 1988) (discussing the reasons why "the cost of a given state's liability laws, as they apply to mass-marketed products, is borne by consumers nationwide"); Robert Gasaway, *The Problem of Tort Reform: Federalism and The Regulation of Lawyers*, 25 HARV. J. LAW & PUB. POLICY 953, 958 (2002) ("[T]he stringent regulation of a truly national activity by a single State can have the effect of taking the power to regulate interstate commerce away from the national government.").

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Congress in preemptive statutes to discern how Congress has resolved the issue in each particular case.

II. Implied Preemption

Let me turn next to the doctrine of implied preemption. Some have suggested that implied "conflict" preemption should be eliminated by statute except for situations where there is a "direct" conflict between federal and state law that is incapable of being resolved. Presumably, this would do away with "obstacle" preemption and leave in place only "impossibility" preemption and some subset of ordinary conflict preemption (where the conflict is "direct," whatever that means).

Congress's Authority To Restrict Implied Conflict Preemption

As an initial matter, there is a serious question, in my view, whether Congress has the power to limit implied preemption in this fashion. As previously explained, the implied preemption doctrine flows directly from, and is based upon the Supreme Court's interpretation of, the Supremacy Clause. The classic formulation of obstacle preemption is often traced back to *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941) (assessing whether state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"). In *Perez* v. *Campbell*, 402 U.S. 637 (1971), the Supreme Court observed that "[s]ince *Hines* the Court has frequently adhered to this articulation *of the meaning of the Supremacy Clause*." *Id.* at 649-50 (emphasis added; citing multiple cases); accord *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 873-74 (2000). In *Perez*, the Court further noted that obstacle preemption has roots extending back to *Gibbons* v. *Ogden*, where the Court noted that state laws that "'interfere with, or are contrary to the laws of Congress, made in pursuance of the Constitution,' are invalid under the Supremacy Clause." 402 U.S. at 649 (quoting 22 U.S. (9 Wheat.) at 211); see also *Savage* v. *Jones*, 225 U.S. 501, 533 (1912) ("[W]hen the question is whether a Federal act overrides a state law, the entire scheme of the statute must, of course, be considered, and that which needs must be implied is of no less force than that which is expressed. If the *purpose* of the act cannot otherwise be accomplished – if its operation within its chosen field must be *frustrated* and its provisions refused their natural effect – the state law must yield . . . .") (emphasis added). Plainly, Congress lacks the authority to rewrite the Supremacy Clause.

Obstacle Preemption Protects The Efficacy Of Federal Law In All Of Its Forms

Putting the issue of authority to one side, I think it would be profoundly unwise to eliminate "obstacle preemption." Why would Congress want to permit state and local governments to subvert Congress's objectives? Beyond that, it is well settled that obstacle preemption can occur not only where the goals of state and federal law are incompatible, but also where state law "interferes with the *methods* by which the federal statute was designed to reach [its] goal." *International Paper Co.* v. *Ouellette*, 479 U.S. 481, 494 (1987) (emphasis added). Why would Congress want to permit state and local governments to interfere with or subvert the methods Congress has chosen to carry out its objectives? In *Geier* v. *American Honda Co.*, 529

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U.S. 861 (2000), the Supreme Court recently refused to impose on a party claiming obstacle preemption a "special burden" when the relevant federal statute includes a "savings" provision. The Court explained: "We see no grounds . . . for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case." *Id.* at 873-74.

Obstacle preemption plays a vitally important role in ensuring the supremacy – and full effectiveness – of federal law against incursions by the states. Those who advocate eliminating obstacle preemption, moreover, should bear in mind that the doctrine serves to protect the supremacy of *all* federal laws against encroachments by the states. For example, in *Felder* v. *Casey*, 487 U.S. 131 (1988), the Court ruled that 42 U.S.C. § 1983 preempted a Wisconsin notice-of-claim statute that required a civil rights plaintiff to provide written notice (of at least 120 days before filing suit) to putative government defendants of the circumstances giving rise to her constitutional claims, the amount of the claim, and her intent to bring suit. In the absence of such notice, the Wisconsin law required the state courts to dismiss the plaintiff's Section 1983 lawsuit. Writing for the Court, Justice Brennan explained that the Wisconsin statute was barred under the doctrine of obstacle preemption because, among other things, it "burdens the exercise of the federal right by forcing civil rights victims who seek redress in state courts to comply with a requirement that is entirely absent from civil rights litigation in the federal courts." *Id.* at 141; see also *id.* at 138, 144-56. That conclusion necessarily depended on a robust doctrine of obstacle preemption, because it plainly was not impossible to comply with both the Wisconsin statute and the requirements of Section 1983, and there was no direct conflict between the federal and state laws. Thus, the doctrine of obstacle preemption serves to protect *all* federal laws – those one likes as well as those one dislikes – against unwarranted subversion by the states. Before taking steps to weaken or eliminate obstacle preemption, Congress should get a very clear picture of all the varied contexts in which it has operated.

The Issue Of Judicial Discretion In Obstacle Preemption Cases

Why has obstacle preemption come under attack by some commentators and judges? The dissenting Justices in *Geier* v. *American Honda Co.*, 529 U.S. 861 (2000), expressed concern about the prospect of "federal judges . . . *running amok* with our potentially boundless . . . doctrine of implied conflict pre-emption based on frustration of purposes" and stated that "the Supremacy Clause does not give unelected federal judges *carte blanche* to use federal law as a means of imposing their own ideas of tort reform on the States." *Id.* at 894, 907 (dissenting opinion of Stevens, J.) (emphasis added). Thus, the central concern appears to be that the doctrine of obstacle preemption accords judges too much leeway or discretion in determining whether state law frustrates the purposes of federal law in a given case.

These concerns are overstated. To be sure, obstacle preemption does require federal and state judges to make subtle judgments in identifying the relevant congressional "purpose" or "purposes" and in deciding when the federal purposes are being frustrated by state law. See *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 373 (2000) ("What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects[.]"). But Congress often declares its purposes

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explicitly in the statute (or in the accompanying legislative materials). More importantly, such judgment calls are no different from a wide array of decisions made by federal and state courts every day. The law is filled with broad concepts – reasonableness, probable cause, excusable neglect, good cause, ordinary care – that call for the exercise of discretion by judges. Beyond that, issues relating to obstacle preemption also require judges, as a threshold matter, to construe the state and federal laws that are claimed to be in tension. That type of statutory construction, however, is the bread and butter of what judges do and hardly a basis for concern over unbridled judicial discretion.

Nor is there anything unusual or suspect about federal or state judges interpreting and applying the Supremacy Clause (as they do in all cases involving implied conflict preemption). The notion that federal judges lack institutional competency to engage in such tasks – or that their decisions should be systematically skewed in one direction because the federal Judiciary is unelected – is incorrect. Finally, the concerns about judicial competence voiced by the critics of obstacle preemption overlook that the Supremacy Clause is a provision that was intended by the Framers to be *enforced by the courts*. Federal courts are the institutions entrusted by the Constitution with the authority to police incursions by the states on the supremacy of federal laws.

III. Administrative Agencies And Preemption

There are at least three separate issues raised by the preemption doctrine as applied to administrative agencies. The first is the threshold question of an agency's authority to regulate preemptively. The second is the amount of deference that should be accorded by courts to an agency's interpretation of an *express* preemption clause. And the third is the amount of deference that should be given, in an *implied* preemption case, to the agency's judgment concerning the extent to which state law conflicts with or frustrates the purposes of either a federal law the agency administers or the agency's own regulations. I will discuss these in turn below.

Agency Power To Regulate Preemptively

The first question has a settled answer. In a line of cases, the Supreme Court has made clear that an administrative agency's authority to regulate preemptively is not dependent on an express grant by Congress of the power to preempt state law. Thus, in *Fidelity Federal Savings & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141 (1982), the Court explained:

> Where Congress has directed an administrator to exercise his discretion, his judgments are subject to judicial review only to determine whether he has exceeded his statutory authority or acted arbitrarily. When the administrator promulgates regulations intended to pre-empt state law, the court's inquiry is similarly limited: "If [h]is choice represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have

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> sanctioned." A pre-emptive regulation's force does not depend on express congressional authorization to displace state law . . . .

de la Cuesta, 458 U.S. at 153-54 (emphasis added) (quoting *United States* v. *Shimer*, 367 U.S. 374, 383 (1961)); accord *City of New York* v. *FCC*, 486 U.S. 57, 63-69 (1988); *Hillsborough County, Fla.* v. *Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714-15, 721 (1985); *Capital Cities Cable, Inc.* v. *Crisp*, 467 U.S. 691, 699-705, 708-09 (1984).

Recently, in *New York* v. *FERC*, 535 U.S. 1 (2002), the Supreme Court reaffirmed its traditional approach, squarely rejecting the argument that the "presumption against preemption" should be applied in deciding whether an agency has the authority to take regulatory action that preempts state law. The "presumption against preemption," the Court explained, has no bearing on issues relating to "the proper scope of . . . federal power" (including an agency's power to preempt state law). *Id.* at 18. The only question is "whether Congress has given [the agency] the power to act as it has," and that question is resolved "without any presumption one way or the other." *Ibid.*

This approach is sensible. Once Congress has delegated rulemaking power to an agency, the agency steps into Congress's shoes as the decision maker – its job becomes implementing the statute in whatever way best accomplishes the statutory aims. See, *e.g.*, *Smiley* v. *Citibank (South Dakota), N.A.*, 517 U.S. 735, 740-41 (1996) ("We accord deference to agencies under *Chevron* . . . because of a presumption that Congress, when it left ambiguity in a statute meant for implementation by an agency, understood that the ambiguity would be resolved, first and foremost, by the agency, and desired the agency (rather than the courts) to possess whatever degree of discretion the ambiguity allows."). Because an agency is left to make policy choices, it need not shy away from preemption; it need adhere only to the presumption that Congress wanted the statute administered effectively. The agency is no more obligated to avoid preemption than is *Congress* when determining whether federal regulation should be exclusive.

Once a court determines that the agency has the power to administer the statute, the focus shifts to whether *the agency* (not Congress) intended its regulations to preempt state law. For example, in *Hillsborough County*, the Food and Drug Administration (FDA) issued a statement at the time its regulations were promulgated *disclaiming* an intent to preempt state law. The Court found this disclaimer "*dispositive* on the question of implicit intent to pre-empt"; so long as the agency acted within the scope of its statutory authority, *it* (not Congress) had the discretion to decide whether to preempt state law. 471 U.S. at 714-15 (citing *Chevron*, 467 U.S. at 842-45) (emphasis added). Moreover, this Court observed that "the FDA possesses the authority to promulgate regulations pre-empting local legislation that imperils the supply of plasma *and can do so with relative ease*." *Id.* at 721 (emphasis added).

Despite the settled nature of these principles, some critics of preemption have suggested that the basic ground rules should be fundamentally altered so that administrative agencies would be *powerless* to issue preemptive regulations unless and until specifically authorized by Congress to do so. This would obviously result in a sea-change in the rules governing regulatory preemption. As explained above, the preemption doctrine has numerous benefits for the national

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economy. It can result in the reduction or elimination of regulatory burdens on business and on interstate commerce, help to create unified national markets for goods and services, and lower the costs of production and prices. In my view, it would be unwise to deprive agencies of *all* authority to bring about these benefits for the American public unless and until Congress has specifically authorized preemptive regulation.

Finally, the proposed new approach would create an anomaly because, under settled principles of *implied* preemption, *every* agency regulation automatically has preemptive effect under the Supremacy Clause with respect to state and local laws that *conflict with* the terms of the federal regulation. Yet under the change proposed by some, the same agency whose regulations have automatic preemptive effect under the Supremacy Clause would be powerless to expressly preempt non-conflicting state and local law by design through its own regulation. That is anomalous, to say the least.

The Deference Owed To Agency Interpretations Of Express Preemption Clauses

The important thing to remember about agency interpretations of express preemption clauses is that they can go in either direction, either upholding or defeating the preemptive effect of a statute. In *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), the Supreme Court gave "substantial weight" to the FDA's narrowing interpretation of the preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a). Although the statute, among other things, broadly preempts "any requirement" under state law that "relates to the safety or effectiveness" of a medical device and is not identical to the applicable federal requirements, the FDA had issued a regulation (21 C.F.R. § 808.1) interpreting Section 360k(a)'s references to "any requirement" as being limited to requirements that were "specific" in nature (or not of "general applicability"). See 518 U.S. at 498-500.

In previous cases, the Supreme Court had rejected the invitations of litigants to read similar limitations into the broad language of other express preemption provisions. In *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992), for example, the Court interpreted a provision of the Airline Deregulation Act of 1978 ("ADA") that "pre-empts the States from 'enact[ing] or enforc[ing] any law, rule, regulation, standard or other provision . . . relating to rates, routes, or services of any air carrier.'" *Id.* at 383 (quoting 49 U.S.C. App. § 1305(a)(1)). The Court categorically rejected the argument that "only state laws *specifically addressed* to the airline industry are preempted, whereas the ADA imposes no constraints on laws of general applicability." *Id.* at 386 (emphasis added). Such an interpretation, the Supreme Court explained, would create "an *utterly irrational loophole*." *Ibid.* (emphasis added); accord *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 47-48 (1987) (ERISA preemption is not limited to state measures targeting ERISA plans but also includes more general common-law tort and contract causes of action); *San Diego Building Trades Council* v. *Garmon*, 359 U.S. 236, 244 & n.3 (1959) ("Nor has it mattered [in cases involving NLRA preemption] whether the States have acted through laws of broad general application rather than laws specifically directed towards the governance of industrial relations.").

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Nevertheless, writing for the Court in *Medtronic*, Justice Stevens explained that "our interpretation of the pre-emption statute is *substantially informed* by" the FDA's regulation and there is a "sound basis" for giving "*substantial weight* to the agency's view of the statute." *Id.* at 495-96 (emphasis added). The Court explained that, as the agency to which Congress "has delegated its authority to implement the provisions of the Act," the FDA was "uniquely qualified to determine whether a particular form of state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress . . . and, therefore, whether it should be pre-empted." *Id.* at 496. In a concurring opinion, Justice Breyer also placed substantial weight on the FDA's interpretation of the express preemption provision. See *id.* at 505-06 (Breyer, J.) (it "makes sense" to infer that FDA "possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect"). Justice Stevens' and Justice Breyer's opinions both cite *Chevron*, but neither explicitly says that full-blown *Chevron* deference is owed to the FDA's interpretation.

This holding was not free of controversy. In dissent, Justice O'Connor pointed out that the majority did "not admit to deferring to these regulations" under *Chevron*. 518 U.S. at 512 (O'Connor, J., joined by Rehnquist, C.J., and by Scalia and Thomas, JJ., concurring in part and dissenting in part). Justice O'Connor's opinion also noted that "[i]t is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference." *Ibid.* (emphasis added).

As the division in the Court in *Medtronic* suggests, this is not an easy issue. On the one hand, it is certainly possible to conclude that express preemption provisions are, by their very nature, intended to be judicially enforced and interpreted in lawsuits between private parties rather than interpreted by administrative agencies. See *Adams Fruit Co.* v. *Barrett*, 494 U.S. 638, 649-50 (1990) (*Chevron* deference is not owed to an agency interpretation of provisions that were meant to be interpreted by the judiciary rather than the Executive Branch; "[a] precondition to deference under *Chevron* is *a congressional delegation of administrative authority*") (emphasis added); *Crandon* v. *United States*, 494 U.S. 152, 177 (1990) (Scalia, J., joined by O'Connor & Kennedy, JJ., concurring in the judgment) (*Chevron* deference is not owed to agency interpretations of provisions that are "not administered by any agency but by the courts"). Moreover, it is certainly possible that an administrative agency might seek to *reduce* the scope of a preemption provision enacted by Congress in a way that is contrary to Congress's intent.

Whatever the correct answer to this question should be, the Supreme Court's decision in *Medtronic* has provided a substantial answer. Agency interpretations of express preemption clauses are entitled to "substantial weight." There is no reason why an agency's expansive interpretation of an express preemption clause should be treated differently from a narrowing interpretation.

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The Deference Owed To An Agency's Views Concerning Whether State Law Conflicts With Or Frustrates The Purpose Of Federal Law

Finally, let me turn to the question of how much weight should be given to an administrative agency's determination that state law either conflicts with federal law or stands as an obstacle to the full accomplishment and execution of Congress's purposes. Here again, the Supreme Court's decisions point to the answer. In *Medtronic*, the Court stated that a federal agency may be "uniquely qualified to determine whether a particular form of state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." 518 U.S. at 496 (internal quotations omitted). Similarly, in *Geier* v. *American Honda Co.*, 529 U.S. 861 (2000), the Court "place[d] some weight" on the agency's interpretation of the objectives underlying its own regulation and the extent to which a tort suit would stand as an obstacle to those objectives. *Id.* at 883. The Court explained:

> Congress has delegated to [the Department of Transportation] authority to implement the statute; the subject matter is technical; and the relevant history and background are complex and extensive. The agency is likely to have a thorough understanding of its own regulation and its objectives and is "uniquely qualified" to comprehend the likely impact of state requirements. *Medtronic*, 518 U.S. at 496 . . . . And DOT has explained [the regulation's] objectives, and the interference that "no-airbag" suits pose thereto, consistently over time. In these circumstances, the agency's own views should make a difference.

529 U.S. at 883 (citations omitted).

This approach makes sense and should not be altered by legislation. An agency's assessment of whether state law poses an obstacle to Congress's purposes requires an understanding not only of how a complex regulatory scheme works and affects the real-world conduct of regulated parties but also of how the imposition of diverse state and local requirements affects that scheme and those regulated parties. It may also involve an identification of Congress's various purposes (which may be in tension with each other) and an assessment of the likely impact of state and local regulations on those purposes. Although (as explained above) the doctrine of implied conflict preemption is rooted in the Supremacy Clause, an agency's interpretations in these settings are little different from other interpretations that draw on the agency's expertise and specialized knowledge and to which *Chevron* deference is accorded.

Conclusion

Contrary to the suggestion of some, the law of federal preemption as it stands today is not in need of radical revision – and, indeed, it would be unwise to place additional limitations on the preemption doctrine, as some have proposed. Such additional limits would impair the ability of Congress and administrative agencies to bring about the many significant benefits that flow from preemptive statutes and regulations. By the same token, Congress should not allow controversies

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over a limited subset of preemption cases involving state tort requirements to drive far-reaching changes to the basic ground rules of preemption – changes that no doubt would have unintended effects across a wide range of federal law and federal programs.

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TESTIMONY OF DAVID C. VLADECK

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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?

September 12, 2007

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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 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

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[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).

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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,

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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

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[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).

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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*

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[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).

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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 objections. 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

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[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).

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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

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[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.

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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.

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[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).

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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

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[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 pro-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).

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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 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

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[16] 21 C.F.R. § 201.80(e).

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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]

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[17] I NST. 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:

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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

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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).

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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

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[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)

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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

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[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.

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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 pumps[31] — all of which have exacted a terrible toll on the patients who

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[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;

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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]

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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 sun-screen 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.

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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

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[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).

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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

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[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 NHSTA 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).

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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

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[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).

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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.

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[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).

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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."[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

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[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).

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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]

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[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,

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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).

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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

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[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*.

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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

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[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.

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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.

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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]

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[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.

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