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The Truth About Torts: Rethinking Regulatory Preemption and Its Impact on Public Health

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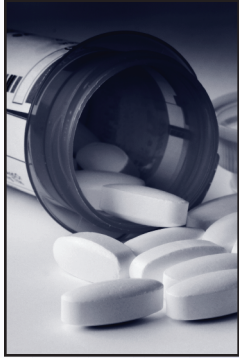
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The Truth about Torts:

Rethinking Regulatory Preemption and its Impact on Public Health

By William Buzbee, William Funk,
Thomas McGarity, Nina Mendelson,
Sidney Shapiro, David Vladeck, and Matthew Shutz

About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization comprising a network of scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation and improved public access to information. The Center for Progressive Reform is grateful to the Bauman Foundation, the Beldon Fund, and the Deer Creek Foundation for their generous support of its work in general.

This white paper is a collaborative effort of the following Member Scholars and staff of the Center for Progressive Reform: **William Buzbee** is a Professor of Law and Director of the Environmental and Natural Resources Law Program at Emory Law School and a Member Scholar of the Center for Progressive Reform. **William Funk** is a Professor of Law at Lewis & Clark Law School in Portland, Oregon and a Member Scholar of the Center for Progressive Reform. **Thomas McGarity** holds the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas in Austin, is a member of the board of directors of the Center for Progressive Reform, and the immediate past president of the organization. **Nina Mendelson** is a Professor of Law at the University of Michigan Law School and is a Member Scholar of the Center for Progressive Reform. **Sidney Shapiro** holds the University Distinguished Chair in Law at the Wake Forest University School of Law, is the Associate Dean for Research and Development, and a member of the board of directors of the Center for Progressive Reform. **David Vladeck** is a Professor of Law and Co-Director of the Institute for Public Representation at Georgetown University Law Center and a Member Scholar of the Center for Progressive Reform. **Matthew Shultz, J.D.**, is a Policy Analyst with the Center for Progressive Reform.

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The Truth about Torts

This White Paper is the sixth installment of the Center for Progressive Reform’s “Truth about Torts” series. CPR Member Scholars have conducted extensive research on the topic, and in a series of reports on various aspects of the subject, have debunked most of industry’s claims about the need for “tort reform.”

Previous Installments in the Series:

■ The Truth about Torts: Regulatory Preemption at NHTSA and the CPSC

by William Funk, Thomas McGarity, Nina Mendelson, Sidney Shapiro, David Vladeck, and Matthew Shutz

<<http://www.progressivereform.org/articles/NHTSA_Preemption_804.pdf>>

<< http://www.progressivereform.org/articles/Truth_About_Torts_CPSC_807.pdf>>

Taking a close look at the problems with federal regulatory preemption in the automobile safety and consumer product safety arenas, these White Papers describe the important role of state tort law as a complement to regulations promulgated by NHTSA and CPSC.

■ The Truth about Torts: Using Agency Preemption to Undercut Consumer Health and Safety

by William Funk, Sidney Shapiro, David Vladeck and Karen Sokol

<<http://www.progressivereform.org/articles/Truth_Torts_704.pdf>>

This White Paper provides a concise description of the constitutional law governing preemption and describes in general terms why preemption is dangerous for consumers of pharmaceuticals, medical devices, automobiles, and other consumer products.

■ The Truth about Torts: Lawyers, Guns, and Money

by Thomas O. McGarity, Douglas A. Kysar, and Karen Sokol

<<http://www.progressivereform.org/articles/Truth_About_Torts_Immunity.pdf>>

In this White Paper, we critique the argument that certain industries deserve blanket immunity from tort suits on the theory that tort liability amounts to “regulation by litigation.” The White Paper exposes the lack of content in the idea of “regulation by litigation” and highlights the dangers of granting immunity to the firearms and food industries.

■ The Truth about Torts: An Insurance Crisis, Not a Lawsuit Crisis

by Thomas O. McGarity, Douglas A. Kysar, and Karen Sokol

<<http://www.progressivereform.org/articles/Torts_509.pdf>>

In our first White Paper in the series, we tackled the complex issues of medical malpractice litigation, doctors’ malpractice insurance, and healthcare costs. The paper presents the empirical data that prove that litigation is not the driving force behind rising malpractice premiums and healthcare costs, but rather insurers’ poor business decisions and consequent need to recoup financial losses.

Executive Summary

As consumers, we assume that the automobiles, pharmaceuticals, medical devices, and other products we purchase are generally safe for their intended uses. We rely on manufacturers to design and produce safe products, and we assume that federal regulators are conscientious watchdogs of the marketplace. In most instances, our assumptions are valid and we safely go about our lives. But the regulatory system is now frayed to the point that dangerous products sometimes slip through the cracks. Vioxx, Firestone/ATX tires, and toxics-laden children's toys have endangered and harmed millions. In these cases, society depends on the state courts as a venue for injured people to seek justice.

Over the years, product manufacturers have worked hard to deny injured consumers' access to the courts – and during the Bush Administration, they had powerful allies in the White House and throughout the Executive Branch. Complaining of excessive damage awards and unpredictable legal terrain, manufacturers have adopted the argument that federal regulatory actions preempt injured consumers' lawsuits for things like negligence, defective design, or failure to warn. The preemption argument is based on the Constitution's Supremacy Clause, under which Congress has the power to invalidate, or "preempt," state law through enactment of appropriate legislation. The defense bar has misappropriated that limited legal doctrine. Protective regulatory action should not be used to shield manufacturers from having to prove that their products are safe. But that is precisely what the regulatory preemption doctrine does: it gives judges the ability to throw legitimate victims out of court before they have even had a chance to make their case that their injuries were caused by a dangerous product. Furthermore, the claim asserted by numerous federal agencies late in the Bush Administration that federal actions could and should preempt state common law constituted an unsound and unprecedented policy shift.

This white paper lays out a different perspective on regulatory preemption. Instead of looking at regulatory preemption as a tool for limiting corporate liability, this paper recognizes that preemption is a tool for structuring power between states and the federal government. Especially in the context of public health and safety, all levels of government have a legitimate interest in determining the ideal level of protective regulation. In addition, this paper treats the preemption debate as a question of the relative powers of Congress, the courts, and federal administrative agencies. The Supremacy Clause makes Congress the primary decisionmaker in setting federal preemption policy, though the courts and agencies have tried to usurp some of that authority in recent years.

The paper begins with four fundamental preemption principles. They are principles that must be embodied in any good policy on preemption. It is only a partial list, focused on four principles that have been most overlooked in recent years. They are:

1. State tort law is a necessary complement to federal regulation.
2. Courts should limit their deference to agencies' preemption claims.

Especially in the context of public health and safety, all levels of government have a legitimate interest in determining the ideal level of protective regulation.

- 3. Congress should expand its interaction with both agencies and the courts concerning preemption.
- 4. States should have a significant role in debates about preemption.

The second part of this white paper describes a number of legislative and regulatory solutions designed to reinvent federal preemption policy. Solutions aimed at Congress include:

- 1. Amendments to individual statutes, like the Medical Device Amendments Act; the Food, Drug, and Cosmetics Act; the National Traffic and Motor Vehicle Safety Act; and the Consumer Product Safety Act.
- 2. A new statutory definition of the word “requirements.”
- 3. New regulatory mechanisms to promote accountability, such as reporting and consultation requirements.

The paper also explores the idea of revising or replacing Executive Order 13132, the Federalism Executive Order, which lays out rulemaking requirements for federal agency actions that might affect the balance of power between state and federal government institutions. Amending the Order would give President Obama the opportunity to redefine the Executive Branch’s philosophy on preemption and establish procedures for ensuring government-wide compliance with that philosophy.

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Introduction

Over the last six years, federal regulatory agencies have undertaken an unprecedented effort to preempt state common law through regulation. Their efforts rely on the constitutional doctrine of preemption, which is derived from the Supremacy Clause and empowers Congress to invalidate certain state laws through enactment of proper legislation.¹ In the most basic case, Congress passes a law with an “express preemption clause” that says, in essence, “this law preempts state law.” But the more common case involves the doctrine of “implied preemption,” where Congress has not expressly determined the preemptive effect of the statute. When Congress’s intent is unclear, the courts must determine whether particular state laws are preempted. And when these cases involve complex regulatory matters, like consumer protection or drug safety laws, administrative agencies also become embroiled in the debate over the scope of Congress’s preemptive intent.

The Food and Drug Administration (FDA), National Highway Traffic Safety Administration (NHTSA), and the Consumer Product Safety Commission (CPSC) have gone to great lengths in recent years to support industry’s attempts to shield itself from litigation through the doctrine of regulatory preemption. In most instances, these agency positions deviate from previous agency views. The agencies have asserted preemption in the preambles to regulations, created new preemptive regulations, and filed *amicus* briefs in support of defendants’ preemption claims. And when California Attorney General Bill Lockyer sued Tri-Union Seafoods for failing to warn consumers about mercury in its canned tuna, FDA went so far as to send a letter to Lockyer parroting weak arguments devised by industry lawyers to claim that the suit should be preempted by federal law.²

This trend poses significant threats to public health and safety. First, regulatory preemption eliminates the incentives that state tort law gives manufacturers to keep up with advancements in safety technology. Second, regulatory preemption eliminates Americans’ fundamental right to go to court to seek redress when harmed by the negligence of others. Third, the preemption trend concentrates power in the hands of the executive branch of the federal government alone, ignoring the positive contributions that common law can provide in the field of public health and safety.

This paper proposes changes to legislation and regulatory policy that will counteract recent attempts to expand regulatory preemption. It is organized in two parts. It begins with a section describing four “fundamental preemption principles” that inform the “concrete solutions” presented in the second section.

Fundamental Preemption Principles

Principle 1: State common law is a necessary complement to federal regulation.

Federal regulatory programs in the public health arena are generally incomplete. They are designed to prevent injury, but almost never include a mechanism to provide compensation to those who are injured when the preventative standards fail. The “corrective justice function” of tort law fills this gap, and has done so since the advent of English common law. The concept of corrective justice embodies the fundamental principle that individuals should be able to rely on the legal system to provide them with compensation when they are injured through the fault of others. When people are injured despite a manufacturer’s compliance with existing federal safety standards, the corrective justice function of state tort law recognizes that manufacturers should still be liable for those injuries if they have not acted reasonably in light of existing information or available technologies not yet reflected in federal safety standards. It ensures that those injured are properly compensated in light of the evolving state of technology and new information available to the manufacturer. Companies should compensate those who are injured as a result of their failure to act responsibly, even if they are not subject to fines or other sanctions for violating any particular regulatory requirements. This presumption in favor of compensation is also supported by basic economic principles: an entity causing harms should be forced by the legal system to internalize those costs imposed on others. In this way, goods and activities will be priced accurately and markets will function better.

The regulatory system’s lack of a compensation mechanism and reliance on state common law to provide corrective justice is no oversight; it is a matter of design. The same cannot be said for a number of other gaps in the regulatory framework intended to protect Americans from health and safety hazards. But the opportunity to recover damages under common law provides a backstop for the other gaps, as well.

One such gap is created by the very significant problem of insufficient resources. When agencies lack money and staff, or when those resources are shifted to non-regulatory programs, the development of well-designed safety standards languishes, which can leave in place inadequate, older regulatory standards. And with inadequate resources, regulatory oversight and enforcement can languish. If weak federal standards preempt state tort law, manufacturers operate without sufficient incentive to update their products in ways that reduce risks to consumers. Unfortunately, the health and safety agencies leading the effort to increase regulatory preemption have some of the most striking resource problems.

The National Highway Traffic Safety Administration (NHTSA) has claimed in several recent rulemakings that new (but weak) safety standards preempt state common law. NHTSA suffered a 50-percent cut in its budget during the Reagan years and has only slowly climbed back upward. In terms of the agency’s ability to develop or revise safety standards, budget shortfalls have led to a rulemaking staff that has shrunk from 103 employees to 62 between 1981 and 2007.³ NHTSA’s entire staff, including those responsible for vehicle safety research, consists of a mere

635 full-time employees.⁴ Meanwhile, 50 million more vehicles are on U.S. roads today than were in 1981,⁵ and NHTSA's regulatory responsibilities have become increasingly complex. To make matters worse, citizen group challenges to and judicial review of NHTSA's rulemakings, which can act as oversight of the adequacy of standards, have been stymied by new standing requirements invented by the D.C. Circuit.⁶

Agency capture is a second problem. "Agency capture" describes the many ways that powerful interest groups can wield undue influence over decisionmakers who should be setting safety standards according to statutory mandates and a professional duty to protect consumers, rather than ideological preferences. But especially under the Bush Administration, high-level agency decisionmakers were often former (and future) business lobbyists, industry lawyers, and employees of trade associations.⁷

The rulemaking process also generally favors regulated industry. Product manufacturers have better access to information about safety data and design and engineering capabilities than do consumer advocates or regulatory officials. Such information is the fundamental basis for regulatory standards, and its concentration in the hands of those who would be regulated creates an unequal balance of power in the formal and informal negotiations that inform the rulemaking process. The tort system, on the other hand, is built on procedures that are designed to put all parties on equal footing, with equal access to relevant safety information. Moreover, the tort system involves harmed individuals and lawyers who can dig deeply into facts about a risk. Indeed, they often elicit information never known to regulatory officials.

The regulatory system's inability to access all relevant information during the standard-development process underscores the importance of complementary state tort law. The informational interactions of tort law and agency decisionmaking can be conceptualized as "feedback loops ... in which each institution draws on information, experience and different incentives of the other."⁸ Litigants employ expert witnesses who provide technical data, analyses of the state of the science from the relevant literature, and other information that can inform subsequent regulatory decisions. The Firestone/ATX tire recall, for example, directly followed a series of tort actions in which expert witnesses exposed the tires' faulty design. Meanwhile, courts can look to the agencies for analysis of the risks and benefits of regulated products, as well as regulatory standards that can factor into decisions about whether regulated parties have met their duty of care. Feedback loops "have unquestionably improved the quality of decisionmaking in both institutions."⁹ Preemption of state common law through regulation destroys the feedback loop, unwisely limiting the useful information that federal agencies can get from the tort system.

Maintaining feedback loops between common law and the regulatory system is important because even an initially sound regulatory choice can become ineffective or outdated over time. One reason that dated regulatory choices lay dormant is that political rewards tend to be much greater for exploring new regulatory ground than for revisiting and improving past regulatory choices. This is especially so if regulatory changes would require agencies to admit that past actions were inadequate or in error. But to avoid obsolescence, regulatory policy needs to be

Tort law is important because even an initially sound regulatory choice can become ineffective or outdated over time.



revised continually, to reflect evolving knowledge about the magnitude and sources of risk and the technologies that can safeguard us against that risk.

The tort system is far more likely to reveal such regulatory inadequacies than are agencies themselves, especially when one takes into account industry's investments in light of past regulatory actions. After all, even if industry would prefer no regulation, once regulation is imposed, industry will invest in meeting those requirements. Hence, any change by an agency to correct error or address an unforeseen risk will not only potentially embarrass agency officials, but it could also require yet more industry investments to meet new regulatory requirements. Absent some clear benefit to them, neither agencies nor industry will be eager for changed regulation, especially more stringent regulation.

Regulatory failures such as insufficient information, agency capture, and limited resources necessitate reliance on the tort system to identify and resolve situations where basic standards of reasonable behavior require manufacturers to do more to protect consumers than simply comply with federal regulations. Federal policies on regulatory preemption must recognize the complementary roles of the tort and regulatory systems.

The three remaining fundamental preemption principles focus on how the courts, Congress, and administrative agencies can internalize the idea that state common law is a necessary complement to federal regulatory requirements.

Principle 2: Courts should limit their deference to agencies' preemption decisions.

When arguing that federal regulatory action preempts a common law claim against them, defendants often support their arguments by referring the court to statements made by the relevant agency. Agency statements that a regulatory action preempts state tort law have been found in regulatory preambles, *amicus* briefs, and even letters from agency officials, especially in recent years. When considering these records, an important question that the courts have yet to answer uniformly is: Should agency claims of preemption be accorded any deference by a reviewing court, and if so, what degree of deference is appropriate?

As a preliminary matter, the degree of deference depends on whether the agency published the statement pursuant to some statutory authority. Absent a clear and contrary indication from Congress, courts should presume that a statute has not authorized an agency to define the scope of regulatory preemption. Using this "presumption against agency preemption" to resolve preemption arguments is an approach that builds on the Supreme Court's recent decision in *Gonzales v. Oregon*.¹⁰ In that case, the Court declined to defer to an agency's interpretation of its regulations that would have displaced a state's different policy choices because the interpretation was not made under clear statutory authority. In the preemption context, Congress has only rarely given an agency the express authority to determine the preemptive scope of its

regulations.¹¹ In cases where Congress has not specifically delegated to an agency the power to define the scope of regulatory preemption, courts should be critical of agency interpretations that state common law is preempted.

The presumption against agency preemption is justified because federal agencies generally do not possess the institutional competence to appropriately determine the usefulness of state common law or the appropriateness of state regulation.¹² Agencies can suffer from a narrow institutional focus that leads them to overlook the importance of complementary state common law or regulation. Moreover, their technical regulatory expertise far exceeds their capacity to account properly for federalism concerns. In contrast, courts are more likely to make preemption decisions without prejudice to state autonomy.

Since preemption questions raise concerns about the complementary roles of state common law and federal regulation, agency preemption analyses often delve into factual arguments about whether state common law will stand as an obstacle to the execution and accomplishment of the agency’s statutory mandates. In other words, the issue of preemption is more than a question of statutory interpretation – it also requires some factual analysis. Courts traditionally subject these questions of law and fact to a form of “hard look” review to assure that the agency has “examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including ‘a rational connection between the facts found and the choice made.’”¹³

Subjecting agencies’ primarily factual preemption determinations to this kind of review will ensure that agencies do more than just make conclusory statements. For example, NHTSA, in its new rule on “designated seating positions,” alleges that state tort judgments would create an obstacle to achievement of the agency’s statutory goals and are therefore impliedly preempted.¹⁴ NHTSA claims that tort judgments premised on a different number of seating positions than what NHTSA would allow might cause manufacturers to install “an excessive number” of seatbelts in a vehicle, thus making it inconvenient or uncomfortable for passengers to wear them, ultimately reducing seatbelt use. NHTSA provides no evidence to support this claim. Courts reviewing this and other implied preemption claims based on “impossibility” or “obstacle” preemption theories should take a hard look to ensure that agencies have evidentiary support for their claims.

In practice, the presumption against agency preemption means that courts should subject agencies’ preemption decisions to so-called *Skidmore* deference. (Unless, of course, there is a clear statutory indication that Congress intended for courts to give some special deference to the agency’s preemption decisions.) Under *Skidmore v. Swift*, a particular preemption finding should get the deference that the reviewing court finds appropriate after examining the “thoroughness evident in [the finding’s] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”¹⁵ *Skidmore* deference thus gives agencies incentives to allow deliberation over the preemption question and gives courts greater leeway in reviewing agency findings than they would have under the more familiar *Chevron* standard of deference.

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Principle 3: Congress should expand its interaction with both agencies and the courts.

Empirical evidence shows that Congress rarely responds to Supreme Court preemption decisions with corrective legislation.¹⁶ Of the 127 Supreme Court decisions that addressed preemption (either of positive or common law) from the 1983 Term through the 2003 Term, Congress responded to only eight cases with legislation. Only two pieces of legislation were responses to the cases that addressed preemption of state common law. These data reflect the difficulty of moving legislation through Congress. And as a practical matter, the data suggest that, if the courts find that a regulatory action preempts state law, it might be the final word on regulatory preemption in the relevant field.

Congress has a responsibility to ensure that the courts do not have the last word. That is, legislators have a responsibility to maintain active inter-branch consultation regarding regulatory preemption. Congress's failure to draft statutes that clearly define the relationship between federal regulation and state tort law is a root cause of much of the litigation that ends up in the courts.

New legislation addressing federal courts' preemption decisions is one way for Congress to take back its primary role in defining the scope of preemption, but there are other methods that might demand less "political capital" and encourage better outcomes. For example, the Senate Commerce Committee's Subcommittee on Consumer Affairs, Insurance, and Automotive Safety held a hearing on June 4, 2008 to question NHTSA and several interest group representatives about the agency's proposed roof crush regulations. Members of both political parties present at the hearing sought to persuade NHTSA to remove a provision of the proposed rule that indicated the agency believed the rule would preempt state tort law. Following the hearing, NHTSA shelved the roof crush proposal, delaying the rulemaking process until the Obama Administration took office.

It is important that Congress use all available tools, including committee hearings, reports, and other oversight activities, to ensure that agencies do not impose their preferences about regulatory preemption absent clear guidance from Congress. But Congress must also be mindful that anything less than enacted legislation will likely be discounted by judges who follow strict textualist approaches to interpreting the preemptive power of existing statutes. Additionally, the defense bar will not refrain from making preemption arguments in product liability cases simply because Congress pressured an agency to curtail its efforts to engage in regulatory preemption. So new legislation designed to clarify congressional intent with respect to preemption will be necessary.

Principle 4: States should have a significant role in deliberations about preemption.

In testimony before the Senate Judiciary Committee in September 2007, Delaware Rep. Donna Stone, then the President of the National Conference of State Legislatures (NCSL), decried federal agencies' repeated failure to consult with representatives of state interests when working on new regulations that would potentially preempt state law.¹⁷ She gave numerous examples of agencies' attempts to preempt state law through regulation without abiding by the basic consultation requirements of Executive Order 13132, which were first imposed by President Ronald Reagan. That Executive Order instructs agencies to "provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings" any time "an agency proposes to act through adjudication or rulemaking to preempt State law."¹⁸ And when agencies undertake to formulate or implement policies that have "federalism implications," the Executive Order requires agencies to "consult with appropriate State and local officials as to the need for national standards and any alternatives that would limit the scope of national standards or otherwise preserve State prerogatives and authority."¹⁹

These consultation requirements embody the principled notion that each branch and level of government has a responsibility to engage the others in meaningful discussions when taking actions that affect constitutional balances of power. Not only is consultation a simple matter of institutional respect, it might well produce policy-relevant information that the federal agency would not have developed on its own. Consider, for instance, a NCSL-sponsored study of the financial impact on states of NHTSA's roof crush proposal. The study found that the rule would likely result in extra costs to the states totaling between \$49 and \$71 million per year. NHTSA had failed to account for these costs when it analyzed the federalism impacts of the proposed rule.

Congress, too, could benefit from increased consultation with representatives of state interests. When Congress considers statutes that will adjust the balance of power between federal regulation and state tort law, there are some structural features that ensure that state interests are part of the debate. But their impact is limited. Individual legislators are chosen through local elections and are generally receptive to local lobbying groups that support states' rights; thus, they might be assumed to hold strong federalist opinions. However, that assumption is countered by the fact that the legislators have other concerns that inform their voting decisions and prevent consistent anti-preemption voting. And while the "Big Seven" state interest groups (e.g., National Governors' Association, National Association of Attorneys General, NCSL, and others) testify regularly about federal preemption, there is no procedural safeguard that ensures they will always be afforded the opportunity to provide their unique insight.

Congress, of course, must carefully weigh the input from state and local policymakers against the national interest in preventing a "race to the bottom" in areas such as public health, safety, and civil rights.

Solutions

President Obama and the 111th Congress have significant opportunities to reconsider the roles of state common law and federal regulation in protecting public health. As they move forward with their agendas, Congress and the new administration should re-affirm the four fundamental principles outlined above. The remainder of this paper suggests legal and regulatory reforms that would accomplish that goal.

Legislative Solutions

Congress has the primary authority to define the scope of the administrative agencies' power to preempt state law. The agencies themselves only have the power granted to them by statute, and the judiciary's role is limited to resolving uncertainties in statutory effect, decisions that are subject to correction by Congress. Thus, this paper begins with proposals aimed at Congress.

Substantively, these proposals are a way for Congress to ensure that common law courts are available to people who are injured when protective regulations fail. The "protector agencies" that regulate consumer products, pharmaceuticals, and automobiles were designed against a backdrop of a vibrant state tort system. They were granted regulatory powers aimed at preventing future harm, but lack the authority to compensate people when the preventive measures fail. Over time, agencies' responsibilities grew with the expanding population and consumer marketplace, but staff and budget levels have failed to keep pace. As a result, overworked agencies are unable to promulgate state-of-the-art safety standards. For example, CPSC's clothing flammability standard is so weak that newsprint often passes the test. And NHTSA's roof crush standard has not been revised in nearly forty years, despite all of the advancements in materials science and engineering that could be harnessed to create lighter weight but stronger roof frames.

The proposals that follow give Congress the opportunity to reassert its primacy in setting federal preemption policy. The federal courts' decisions that have validated agencies' claims of regulatory preemption are rooted in a steadily expanding doctrine of implied preemption. The Supreme Court set the stage for this trend in *Geier v. American Honda*,²⁰ holding that the doctrine of implied-obstacle preemption applied despite the Vehicle Safety Act's clearly drafted savings clause, which expresses a congressional intent not to preempt state common law. This decision, and others that invoke the doctrine of implied-obstacle preemption, give administrative agencies great power to define broadly their regulatory goals, making it more likely a lawsuit could somehow stand as an obstacle to the achievement of those goals. In fact, courts' decisions about the preemptive effect of a regulatory program under the rubric of implied-obstacle preemption almost always coincide with agency opinions. Congress can attempt to recapture its role as the primary authority on matters of regulatory preemption through careful legislative drafting.

Amendments to Individual Statutes

Following the Eighth Circuit's decision in *Lundeen v. Canadian Pac. Rwy. Co.*,²¹ in which the court held the Railroad Safety Act preempted state tort law, Congress amended the statute to make clear that it did not preempt state tort law.²² Following *Riegel v. Medtronic*,²³ Rep. Frank Pallone, along with 71 co-sponsors, introduced the Medical Device Safety Act of 2008, which was designed to clarify that courts should not construe anything in the Medical Device Amendments of 1976 to limit individuals' right to sue device manufacturers in state courts. Sen. Kennedy introduced a companion bill, with 14 cosponsors. With these examples in mind, Congress should consider preparing anti-preemption legislation for other regulatory statutes.

Court decisions and agency actions over the last decade provide a clear picture of the statutes most in need of congressional attention.

The Medical Device Amendments to the Food, Drug, and Cosmetics Act (MDA): Mirroring arguments made by FDA, the Supreme Court in February 2008 held that FDA approval of a medical device preempts state common law causes of action. The statute has an express preemption clause that prohibits states from establishing "requirements" that are different from or in addition to requirements established by FDA. The Court held that common law can be the source of state "requirements." That decision, in *Riegel v. Medtronic*,²⁴ set a precedent that Congress should reject swiftly. A new version of the Medical Device Safety Act of 2008 for the 111th Congress would be a good solution.

The Food, Drug, and Cosmetics Act (FDCA): Although the FDCA does not include an express preemption clause like the MDA, an upcoming Supreme Court decision could prove even more detrimental to public health law if the Supreme Court rules in favor of the defendant drug manufacturer. *Wyeth v. Levine* pits a guitarist who lost her arm due to an adverse drug reaction against the manufacturer of that drug, who argues that FDA approval of the drug's warning labels preempts Levine's state common law claims. Congress should prepare legislation that amends the FDCA to clarify that injured patients have the right to sue pharmaceutical manufacturers, even when manufacturers have complied with FDA approvals.

The National Traffic and Motor Vehicle Safety Act: Even though the Motor Vehicle Safety Act includes a savings clause that plainly states "compliance with a motor vehicle safety standard ... does not exempt a person from liability at common law," the Supreme Court has held that the implied preemption doctrine can justify preemption of state common law in certain circumstances. NHTSA has latched onto this holding and devised some creative explanations for why new regulations preempt state tort law. For example, recent changes to the definition of "designated seating position" allegedly preempt state tort law because tort judgments premised on a different definition might prompt manufacturers to install "an excessive number" of seatbelts on bench seats and NHTSA fears that passengers might refrain from using their belts because of the inconvenience or discomfort caused by sitting too close to other passengers or the sides

Court decisions and agency actions over the last decade provide a clear picture of the statutes most in need of congressional attention.



of the vehicle.²⁵ Congress should consider amending the statute's savings clause so that it states clearly that it saves damages claims in the face of express, field, and obstacle preemption arguments.

The Consumer Product Safety Act (CPSA) and CPSC's "transferred acts:" Congress recently passed the Consumer Product Safety Improvements Act, which included a section instructing CPSC to refrain from construing any of the statutes it administers "as preempting any cause of action under State or local common law or State statutory law regarding damage claims." But CPSC is only part of the problem – courts may still construe those statutes as preempting state tort law. Congress could best address the problem through wholesale changes to the preemption clauses in the CPSA, Federal Hazardous Substances Act, Flammable Fabrics Act, and Poison Prevention Packaging Act. Congress should also consider adding clear savings clauses to the FHSA, FFA, and PPPA. As with the Motor Vehicle Safety Act, Congress might amend the CPSA and transferred acts to clarify that the courts should not entertain express, field, or obstacle preemption arguments.

Congress should be prepared to amend other statutes as well. For instance, federal preemption of state tort law in the railroad grade crossing arena may deserve congressional attention.

An Amendment Applicable to Multiple Statutes

Some consumer protection laws, covering products as diverse as cigarettes, medical devices, hazardous consumer products, and pesticides, expressly preempt "requirements" created or enforced under state law if those "requirements" differ from the federal regulatory standards. But in none of those statutes does Congress explain what the term "requirements" means. In 1992, the Supreme Court made that decision for Congress. In *Cipollone v. Liggett Group, Inc.*,²⁶ the high court held that "requirements" can be interpreted broadly to encompass both positive law (i.e., statutes or regulations) and common law. The rationale behind the holding posits that a defendant held liable at common law might alter its practices in a manner similar to how it would act in the face of new regulatory requirements, thus a statute preempting state "requirements" could be read to preempt state common law. More recently in *Riegel v. Medtronic*,²⁷ this judicially derived definition wiped out many consumers' right to seek corrective justice when injured by dangerous medical devices.

The statutes at issue in *Cipollone* and *Riegel*, along with others that preempt state law "requirements," were drafted before the Supreme Court held that "requirements" include common law. That holding has potentially redefined the preemptive scope of numerous regulatory regimes designed to protect consumers, without express approval by the legislature. Moreover, the Court's decisions are not entirely consistent. Its conclusions in *Riegel* sowed confusion due to an almost exactly contrary conclusion in *Bates v. Dow Agrosciences LLC*,²⁸ where the Court held that the term "requirements" in federal pesticide law did not encompass or preempt state common law claims.

Congress should consider drafting an across-the-board definition for the term “requirements” to clarify that the term only includes state common law where that interpretation is manifest in the text of a particular statute. This proposal could be accomplished through an amendment to Title 1 of the U.S. Code, placing the new interpretive rule alongside other basic rules of construction like “man also means woman.” The new definition would limit the extent to which courts can grant defendants immunity from liability under even more public health laws.

Procedural Amendments

Cross-cutting legislative solutions could also take the form of procedural requirements. New procedural rules could be designed to ensure that agencies’ preemption decisions are finalized only after meaningful consultation with relevant stakeholders.

Congress, given its constitutional role as the primary decision maker in setting preemption policy, is the first stakeholder with which agencies should consult. There are many examples of complex regulatory legislation, politically sensitive legislation, and other statutes of particular concern to the enacting Congress that include mandates on administrative agencies to report back to the legislature on their implementation of the statutes. The reporting requirements serve as a mechanism for Congress to retain systematic oversight after delegating regulatory power to the executive branch, reinforcing the checks and balances inherent in the Constitution.

In the preemption context, creating a reporting requirement would be a way for Congress to systematize agency deference to the legislature on matters of regulatory preemption. The reporting scheme could be used to ensure that relevant congressional committees are kept abreast of agencies’ interpretation of their preemptive power. For example, Congress could enact a statute that requires agencies, any time they take a position in favor of preempting state law, to submit notice of that position to relevant committees as soon as the position is adopted, but no less than 90 days before its effective date.

Alternatively, Congress could use the oversight tools available through amendments to the Congressional Review Act. Under the CRA, a rule classified as a “major rule” generally cannot become effective until 60 days after the responsible agency notifies Congress that the rule is in final form.²⁹ Congress could amend the definition of “major rule” under the CRA to include rules that preempt state law, thereby delaying their effective date to permit Congress to review and reject them by legislation if it were so inclined. Such legislation might help Congress to identify at an early stage instances where agencies are acting beyond the authority granted to them by statute, thereby creating an opportunity for the legislature to push back before an agency’s attempt to preempt has serious public health consequences.

There are other stakeholders with whom Congress could require agencies to consult. State-level elected officials should have an opportunity to weigh in when an agency is proposing to preempt state law. However, there are a huge number of elected state and local officials, and they all operate under time and resource constraints that limit their ability to voice their opinion on

federal agencies' preemption claims. If Congress were to mandate stakeholder consultation specifically about preemption, the requirements should include the organizations that elected officials have formed to represent their interests in DC – groups like the National Governors' Association, National Conference of State Legislatures, National Association of Attorneys General, and the rest of the so-called “Big Seven.”

Solutions for the Executive Branch

Unlike Congress, which must overcome significant institutional inertia to amend any laws that would change federal preemption policy, the President is able to make almost immediate changes to administrative agencies' practices. To do so in a responsible manner, though, the President should first develop and then publicize an overarching philosophy on preemption. Procedural safeguards could then be established to ensure that agencies do not act contrary to that policy.

A Review of the Bush Record

Before a new set of procedural safeguards is established, the Obama Administration should undertake the task of reviewing the myriad administrative actions in which the Bush Administration argued for regulatory preemption. Some stakeholders have suggested that Congress could use the Congressional Review Act (CRA) to do this “look back” at the Bush record. While the CRA can be an effective tool to overturn regulations adopted by an outgoing administration, it requires a significant commitment of congressional time and resources, and there are a number of late-term Bush regulations vying for consideration for repeal. Accordingly, the CRA is not a “silver bullet” for dealing with Bush-era preemption decisions.

A supplementary approach would call on individual agencies to reevaluate specific, problematic rules and actions. President Obama could direct each agency to publish a notice in the *Federal Register* that lists all of the rules or other actions in which agencies have argued that their actions preempt state law. The notice would state that the agency is reconsidering its original analysis and will take comments on the issue of preemption for 30 days. Following the comment period and a reanalysis of the law and policy that went into the preemption decision, the agency should publish another *Federal Register* announcement describing changes to the rule or revisions to the preamble. In any instance where an agency had previously assumed a power to preempt state law without express statutory authority or without sufficient evidence of a direct conflict between state law and federal regulation, the agency should rescind the preemptive decision.

A New (or Revised) Federalism Executive Order

Executive Orders provide the President a powerful tool for announcing substantive policy and setting Executive Branch-wide procedural requirements. Executive Order 13132, or the “Federalism Executive Order,” describes a philosophy on federalism (including policies on preemption and cooperative federalism) and sets out certain policymaking criteria and rulemaking requirements for administrative actions that implicate the President’s philosophy.

The explosion of regulatory preemption claims by federal agencies in recent years underscores the necessity of revising the Federalism Executive Order. The Order was designed to ensure that the Executive Branch does not prevent states from acting as “laboratories of democracy.” It was meant to encourage consultation with state and local officials when agencies consider the need for nationally uniform standards. And it seems to indicate that agencies should avoid claims of regulatory preemption except in limited circumstances. Yet under the Bush Administration, FDA, NHTSA, CPSC, and other agencies repeatedly attempted to expand the doctrine of regulatory preemption. Rarely during that period did the agencies engage state and local officials in the decisionmaking process.

A revised Federalism Executive Order could reestablish a principled Executive Branch philosophy on preemption and set up mechanisms to ensure that all agencies adhere to that philosophy.

Amend the Fundamental Principles of Federalism

One of the strengths of the current Executive Order is that it clearly defines many crucial federalism principles. But the principles enunciated in the Order are incomplete. Many facets of a complete philosophy on federalism go beyond the scope of this paper, but there are five points – one general, and four specific to the issue of preemption – that relate to the issues discussed in this paper and should be part of a new Federalism Executive Order.

As a general matter, the Order should begin with the idea that all types of government can play a positive role in our lives. The first two paragraphs of the “Fundamental Federalism Principles” section of the current Order emphasize the Constitution’s limits on federal power and the belief that issues lacking national scope should be “addressed by the level of government closest to the people.” This traditional concept of federalism as a description of limits on government power is rooted in a fundamentally negative view of government – the idea that government is bad and should be limited. A new Executive Order should instead begin by explaining that federal and state governments play a cooperative role in setting public policy and that each branch or level of government has strengths and weaknesses that complement the others. Federalism should be viewed as a framework for ordering the interaction of the various government institutions in a way that accounts for each institution’s strengths and weaknesses, and in a way that will encourage coordinated decisionmaking.

The Federalism Executive Order should begin with the idea that all types of government can play a positive role in our lives.

In addition to this general principle, there are four principles specific to the issue of preemption that should be included in a new Federalism Executive Order.

Agencies should limit their attempts to preempt state law under theories of implied preemption.

During the Bush Administration's era of expanding regulatory preemption, agencies overlooked an important issue: What statutory authority can they claim as the basis for their assumed power to define the scope of regulatory preemption? Only in limited circumstances has Congress expressly granted an agency the authority to define the scope of its preemptive power. Agencies' authority to make those determinations is less apparent when they use theories of implied preemption to justify their efforts to preempt state law. The Executive Order's "Principles" section should emphasize the idea that statutes that might impliedly preempt state law do not grant agencies the power to define the scope of that preemptive power. Even if a statute does expressly authorize an agency to preempt state laws, the fact that the agency has been granted that authority does not suggest that it should be utilized unless absolutely necessary.

Agencies should adopt a presumption against "ceiling preemption." The term "ceiling preemption" refers to any instance where federal law invalidates states' attempts to create or enforce more stringent or more protective regulation. In some limited circumstances, Congress has created a statutory scheme that relies on ceiling preemption. Absent such explicit directions from Congress, however, agencies should adopt and follow a strong presumption against ceiling preemption.

The Executive Order should mandate that agencies adopt this theory of preemption because it ensures that all levels of government have a role in important public policy debates. Unless Congress has unequivocally decided to displace certain government institutions, the President should encourage broad inter-governmental interaction through the enforcement of a presumption against ceiling preemption. That presumption should be strong in cases in which the federal government seeks to preempt state law that regulates activities traditionally addressed under the states' police powers (e.g., public health and safety or land use). The presumption against federal preemption of state tort law should be especially strong when the federal statute does not provide its own vehicle for compensating injured individuals, as is the case with most of the existing environmental, health, and public safety statutes.

Different concerns arise when considering preemption of state positive law versus state common law.

The current Executive Order fails to differentiate between state common law and state positive law. State positive law, such as statutes and regulations, is developed and enforced in ways that parallel federal statutes and regulation. State common law, on the other hand, relies on institutional structures and decisionmakers that are entirely different from those found in the federal regulatory system. State legislatures, regulatory agencies, and common law courts have different institutional strengths and weaknesses that could – depending on the situation – either complement or complicate federal agencies' work. The Executive Order should force agencies to acknowledge these differences in their preemption analyses.

Agencies should respect and support the principles embodied in the idea of corrective justice, and the right of states to define those principles as they see fit. The current Executive Order emphasizes the freedom of “[t]he people of the States” to “define the moral, political, and legal character of their lives.” The Obama Administration should build on this language by adding a statement supporting a vibrant state common law system. That statement should highlight the common law’s capacity to provide corrective justice, as well as its embodiment of the principle of state sovereignty.

Create new Procedures to Safeguard the Fundamental Principles of Federalism

The remainder of the Executive Order, which outlines procedural safeguards for ensuring executive branch compliance with those principles, also needs significant improvement. In its current form, it suffers from the lack of a strong accountability mechanism. The White House’s Office of Management and Budget (OMB) is responsible for reviewing certain agency actions for compliance with the Federalism Executive Order, but its responsibility is limited. In conjunction with the requirements of Executive Order 12866 (“Regulatory Planning and Review”), OMB simply ensures that each draft final regulation with federalism implications includes a certification from the agency stating that the requirements of the order “have been met in a meaningful and timely manner.” OMB has published a guidance memorandum on Executive Order 13132, but the guidance does little more than reiterate the minimal requirements found in the order itself.³⁰

More robust procedures would have two important advantages over the current system. First, well-crafted guidelines could ensure better transparency in agencies’ decision-making processes. Second, improvements in transparency will produce the possibility of better accountability.

The new Executive Order should establish a regulatory process that discourages agency preemption and provides rigorous procedures to protect fundamental federalism principles in the rare cases where an agency wishes to make a case for preemption. The procedures that an agency must follow if it wants to make a case for preemption should have three general “performance requirements.” They should: (1) enforce the presumption against agency preemption; (2) protect state authority to regulate; and, (3) ensure that state and local officials (and their affiliates) have input into any federal decision that limits the effectiveness of state law.

To enforce the presumption against agency preemption, the new Executive Order should require agencies to publicly announce and allow advance comment any time an agency considers declaring that its action has a preemptive impact. In addition, the Order should require agencies to publish a written justification if they believe they need to preempt state law. The justification should include at least two elements. First, it should include an analysis of the legal authority the agency has to preempt state law. That analysis must demonstrate that Congress intended to grant

The new Executive Order should require agencies to publish a written justification for any denial of a state request to regulate in a manner more protective of public health than the coordinate federal standards.

the agency the power to determine the preemptive effect of its regulation. Second, any agency written justification should include robust factual evidence and policy rationale that supports the agency's decision that it is necessary to preempt state or local law. The written justification must also respond to comments on the preemption proposal.

To protect state authority to regulate, the new Executive Order should require agencies to publish a written justification for any denial of a state request to regulate in a manner more protective of public health than the coordinate federal standards. A number of statutes that give federal agencies the power to write uniform federal regulations also give them the power to grant waivers to individual states that want to create their own, more stringent regulations. The existing Executive Order instructs agencies to review state waiver applications "with a general view toward increasing opportunities for utilizing flexible policy approaches at that State or local level." The new Executive Order should further that objective by requiring a written justification similar to the one required when a federal agency wants to preempt state law without explicit congressional authority. The written justification, again, should have sound legal, policy, and factual evidence to support the agency's decision.

Finally, to ensure proper consultation with state and local officials, the new Executive Order should require agencies to improve their outreach efforts. When an agency plans to preempt state law, it should provide state and local officials adequate opportunity to review the proposal at an early stage in the rulemaking process, as well as a chance to meet with agency staff and management. The agency should also be required to publish a detailed account of the consultation that took place, with a summary of the state and local officials' concerns and the agency's detailed responses to those concerns. The consultation process should also engage nonprofit advocacy groups that represent state and local officials. Among the groups that should be included: the National Association of Attorneys General, National Governors Association, National Conference of State Legislatures, Council of State Governments, National League of Cities, U.S. Conference of Mayors, National Association of Counties, and the International City/County Management Association. In recent years, some regulatory agencies have complained that their notices to state and local officials about new preemptive regulatory actions did not produce a response. Actively engaging the nonprofit advocacy organizations might be more fruitful.

The three "performance requirements" listed above must be enforced through some sort of regulatory mechanism. The Executive Order provides the President with flexibility in establishing the framework for that mechanism, but there are a number of factors that should be considered in making a final choice.

Individual agency decisions should be made consistently. One way to ensure consistency is by using the Executive Order to establish an analytical framework for agencies to follow when making federalism choices. Following the issuance of Executive Order 13132, OMB drafted a memorandum to the heads of all Executive Branch departments describing the procedures they should follow to ensure compliance with the Order. The purpose of that memorandum was to

promote some level of consistency across the government. And the Order itself instructed agencies to develop standardized procedures “to ensure meaningful and timely input by State and local officials in the development of policies that have federalism implications” – an effort to promote intra-agency consistency.

A new Federalism Executive Order might utilize a more formalized regulatory mechanism. Government-wide guidance or regulations with step-by-step instructions are two options. Alternatively, the Order could instruct each agency to develop its own guidance or regulations. President Obama should consider the following issues when choosing a mechanism for promoting consistency in agency decisionmaking:

- Is there an office with the resources and expertise to develop government-wide guidance or regulations?
- Is there a need to ensure government-wide consistency through uniform guidance/regulations, or is it sufficient to simply instruct agencies to develop procedural safeguards on their own (based on requirements outlined in the Executive Order)?
- Guidance documents are generally thought to be more flexible. Regulations might provide the potential for enforcement through judicial proceedings. Do these or other factors weigh in favor of one type of regulatory mechanism over the other?

All decisions should be made transparently. The Executive Order itself could include recordkeeping and disclosure requirements that would promote transparency. If the Order mandates the creation of guidance or regulations, they should reinforce the transparency requirements. It is especially important that agency consultation with outside parties – including all stakeholders and any state or local officials – be memorialized in publicly accessible documentation.

Centralized oversight might provide a useful mechanism for promoting accountability. Under the Federalism Executive Order’s current formulation, agencies include in the preamble to any new rule a statement about the rule’s federalism implications. This analysis, and a form certifying compliance with Executive Order 13132, are submitted to OMB for review under Executive Order 12866. Executive Order 12866 tasks the Office of Information and Regulatory Affairs (OIRA) with reviewing agency rules, and it gives OIRA the power to request changes to those rules through “return letters.”

The combined effect of Executive Orders 13132 and 12866 create significant opportunity for White House oversight of agencies’ federalism analyses. White House review triggered by agency statements in support of preemption raises some difficult questions.

- Is centralized review of all agency rulemaking a good idea, or does it represent an unwarranted intrusion on the discretion delegated to specific agency officials?
- Does OMB have the expertise to analyze the legal and policy questions bound up in agencies’ federalism determinations?

- Is there any other agency or office that has the expertise, infrastructure, and resources to engage in this sort of review? If so, is there a justification for taking centralized review out of the White House?

Resource demands on the agency might be the best way to differentiate among the various policy choices. The content of any government-wide or agency-specific guidance will be the determinative factor since those requirements will dictate the procedural hurdles that must be overcome for each new rule. But the degree of centralized review is also important. The more substantive review power that is given to some authority, the more complicated the rulemaking process will be. For instance, if OMB were to review agencies' substantive decisions and have the power to request changes using return letters, it is more likely that rules will be delayed than if agencies were simply required to certify to the White House that they have followed a pre-approved federalism review process.

Of course, the resource demands from both litigation and centralized review should not be counted simply as detriments to the rulemaking process. They create important avenues for public and political accountability. And they create incentives for agencies to carefully consider their preemption decisions, since wrong decisions will require the expenditure of even more resources on remand.

In considering all of these factors, we have developed a list of potential regulatory mechanisms that might be established through a new Federalism Executive Order. Those ideas are outlined in the appendix to this white paper.

Conclusion

Adequate protection of public health depends on the continued existence of state common law as a complement to federal regulation. Common law has a unique ability to provide corrective justice and is a useful way to fill regulatory gaps caused by outdated or imperfect regulation. States have traditionally enjoyed primary authority to protect the health, safety, and welfare of their citizens. This fundamental principle of American government should not be abandoned in a simplistic effort to relieve corporate defendants of liability for producing dangerous products.

Appendix: Four possible regulatory mechanisms

The white paper outlines performance requirements and other considerations that President Obama should take into account when crafting revisions to Executive Order 13132. This appendix provides four options for translating those concepts into practical regulatory solutions. Each depends on some centralized authority to act in a coordinating role. For convenience, these descriptions use OMB as the central authority; however, OMB is used here mainly as a placeholder. President Obama should consider using another office or even creating a new office to address the difficult law and policy questions implicated by the analyses required under the new Federalism Executive Order.

- 1. Rule-by-rule review:** If the new administration decides to continue the existing system of OMB review of agency regulations under Executive Order 12866, that system could be used to review individual agency proposals to preempt state law. In contrast to the existing Order's requirements, OMB would not simply rely on agencies' attestations that they have abided by the Order's principles. Instead, agencies would be asked to articulate clearly their findings with respect to the Executive Order's Fundamental Federalism Principles, and OMB would carefully review those findings.
- 2. A DQA-style approach:** Under the Data Quality Act, OMB published detailed guidance that instructed agencies how to implement the law. Subsequently, agencies were required to develop their own internal policies and seek approval of those policies from OMB. A revised Federalism Executive Order might follow that model, requiring OMB to develop minimum procedural requirements that will ensure agencies adhere to the Order's fundamental principles. As is the case under the DQA, each federal agency would be required to develop agency-specific guidelines that comport with the OMB guidance, and OMB would have to certify that the agency's guidelines are adequate. For each rule completed after OMB has approved the agency's guidelines, the agency would simply have to certify in writing that it has followed the approved guidelines in developing the rule. This approach is very similar to the requirements of Executive Order 13132 in its current form, but it would require more detailed guidance from OMB at the outset.
- 3. A hybrid system:** A third option would be to combine the DQA-style approach with the rule-by-rule review process. In this scheme, OMB would first develop a government-wide guidance document that outlines some basic procedures agencies should adopt and questions they should answer in reviewing the federalism implications of their actions. Then, agencies would be required to develop their own guidelines that match the OMB guidance, have them approved by OMB, and compile a document describing their compliance with the procedures and answers to the questions for each action reviewed by OMB. OMB would be responsible for both ensuring that agencies have complied with their guidance for each reviewable rule and reviewing the substance of the decisions. Again, OMB is not necessarily the best institution to have centralized review power under this option.
- 4. Regulations, not guidelines:** The last scheme the new President might adopt is one in which the revised Executive Order prompts agency adoption of regulations that dictate procedures for assessing the federalism impacts of agency actions. This scheme might be modeled on the National Environmental Policy Act (NEPA), under which the White House's Council on Environmental Quality crafted government-wide regulations for implementing NEPA and each agency has come up with its own, more detailed version of the regulations.

End Notes

- ¹ For an overview of law on preemption, see Funk, Shapiro, Vladeck, and Sokol, *The Truth About Torts: Using Agency Preemption to Undercut Consumer Health and Safety* (Sept. 2007), available at http://www.progressiveregulation.org/articles/Truth_Torts_704.pdf (accessed Feb. 16, 2009).
- ² See *People v. Tri-Union Seafoods, LLC*, 2006 WL 1544384, *58 (Cal. Super. Ct. May 11, 2006); see also, *Fellner v. Tri-Union Seafood*, 539 F.3d 237 (3d Cir. 2008) (rejecting the argument that a product liability suit is preempted by FDA regulatory actions concerning mercury in fish). Tri-Union Seafoods cited a letter from the FDA Commissioner to Lockyer in support of its argument that Fellner's suit is preempted by FDA regulatory action. In declining to give anything more than "a particularly low level of deference" to the letter, the Third Circuit noted that it "follows, and bears a striking resemblance to, a letter and memorandum that counsel at a private law firm – counsel who, according to his public law firm biography, represents the canned tuna industry in the California litigation – sent to the agency's chief counsel urging the FDA to 'issue[] an appropriately worded letter' asserting preemption over the litigation in California and offering suggestions for the content of such a letter." *Id.* at p.25 (note 8).
- ³ Roy Ulrich, *Where have you gone, Otis Chandler?*, L.A. Times, Apr. 24, 2007.
- ⁴ U.S. Dept. of Trans., National Highway Traffic Safety Administration, *Budget Estimates: Fiscal Year 2009*, 19, available at <http://www.dot.gov/bib2009/budgetestimates/nhtsa.pdf> (accessed Feb. 16, 2009).
- ⁵ Jeff Plungis, *Money, dont key to fixing NHTSA*, Det. News, Mar. 6, 2002.
- ⁶ See *Public Citizen, Inc. v. NHTSA*, 513 F.3d 234 (D.C. Cir. 2008). Note that the additional standing requirements imposed by the D.C. Circuit apply asymmetrically – consumers face substantial hurdles to suing NHTSA for implementing weak safety standards, while manufacturers can always challenge NHTSA over standards they think are too stringent.
- ⁷ CPR has published several papers highlighting these links. See Funk et al., *The Truth about Torts: Using Agency Preemption to Undercut Consumer Health and Safety* (2007), available at http://www.progressivereform.org/articles/Truth_Torts_704.pdf (accessed Feb. 16, 2009); Funk et al., *The Truth about Torts: Regulatory Preemption at the National Highway Traffic Safety Administration* (2008), available at http://www.progressivereform.org/articles/NHTSA_Preemption_804.pdf (accessed Feb. 16, 2009); Funk et al., *The Truth about Torts: Regulatory Preemption at the Consumer Product Safety Commission*, available at http://www.progressivereform.org/articles/Truth_About_Torts_CPSC_807.pdf (accessed Feb. 16, 2009). See also, Stigler, "The Theory of Economic Regulation," 2 *Bell Journal of Economics and Management Science*, 3, 11-13 (1981); see generally "Symposium on the Theory of Public Choice," *Vanderbilt Law Review* 74 (1988) 167.
- ⁸ Thomas O. McGarity, "The Regulation-Common Law Feedback Loop in Non-Preemptive Regimes," in *Preemption Choice: The Theory, Law, and Reality of Federalism's Core Question* ch.11 (William W. Buzbee ed., 2009).
- ⁹ *Id.*
- ¹⁰ 546 U.S. 243 (2006).
- ¹¹ One example is the Secretary of Transportation's express authority to determine whether federal regulations preempt state standards related to hazardous materials transportation. See 49 U.S.C. § 5125(d).
- ¹² See Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 *Northwestern U. L. Rev.* 695 (2008).
- ¹³ *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).
- ¹⁴ NHTSA, *Designated Seating Positions and Seat Belt Assembly Anchorages*, 73 Fed. Reg. 58887, 58894-95 (Oct. 8, 2008).
- ¹⁵ *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).
- ¹⁶ Note, *New Evidence on the Presumption Against Preemption: An Empirical Study of Congressional Responses to Supreme Court Preemption Decisions*, 120 *Harv. L. Rev.* 1604 (2007).
- ¹⁷ The Honorable Donna D. Stone, State Representative, Delaware; President, National Conference of State Legislatures, *Testimony before the Committee on the Judiciary, United States Senate*, (Sept. 12, 2007).
- ¹⁸ Executive Order 13132, *Federalism*, § 4(c), 64 Fed. Reg. 43255, 43257 (Aug. 10, 1999).
- ¹⁹ *Id.* at § 3(d)(3).
- ²⁰ 529 U.S. 861 (2000).
- ²¹ 447 F.3d 606 (8th Cir. 2006).
- ²² See *Lundeen v. Canadian Pacific Ry. Co.*, 532 F.3d 682 (8th Cir. 2008) (reversing and remanding its earlier decision finding preemption).
- ²³ 552 U.S. ___, 128 S.Ct. 999 (2008).
- ²⁴ *Id.*
- ²⁵ NHTSA, *Designated Seating Positions and Seat Belt Assembly Anchorages*, 73 Fed. Reg. 58887, 58895 (Oct. 8, 2008).
- ²⁶ 505 U.S. 504 (1992).
- ²⁷ 552 U.S. ___, 128 S.Ct. 999 (2008).
- ²⁸ 544 U.S. 431 (2005).
- ²⁹ See 5 U.S.C. § 801 (a)(3).
- ³⁰ See Memorandum for Heads of Executive Branch Departments and Agencies, and Independent Regulatory Agencies, from Jacob J. Lew, Director, OMB (Memorandum M-00-02) (Oct. 28, 1999), available at <http://www.whitehouse.gov/omb/memoranda/m00-02.pdf> (accessed Feb. 16, 2009).

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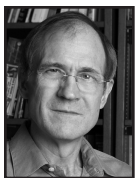
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