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

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Executive Summary

In recent years, the Bush administration has launched an unprecedented aggressive campaign to persuade the courts to preempt state tort actions. Under the Supremacy Clause of the Constitution, Congress may choose to preempt state law from operating, and where Congress's intent is not clear, it is up to the judiciary to determine if Congress intended preemption.

Widespread preemption of state tort law would significantly undermine, if not eliminate, the rights of individuals to seek redress for injuries caused by irresponsible and dangerous business practices and to hold manufacturers and others accountable for such socially unreasonable conduct.

At the same time, the administration has made a concerted effort to weaken federal health and safety standards, making state tort law protections all the more vital. Ironically, this apparent sweeping effort to nationalize standards is being made by an administration that professes deep attachment to notions of federalism.

The Supreme Court traditionally has declined to find preemption of state law in the absence of a clear indication of congressional intent to preempt. This presumption gives effect to the federalist structure of the Constitution and preserves states' traditional role in protecting public health and safety. Furthermore, the Court traditionally has tended to factor into its preemption analysis the important differences between state positive law, which is composed of legislative enactments and regulations, and tort law.

The Court has recognized that positive law establishes standards of conduct by prescribing or proscribing certain actions, while tort law provides compensation after people are injured or killed by socially unreasonable actions. Because of these fundamental differences, tort law generally does not conflict with federal positive law—even when state positive law might. In fact, tort law's protective effects by and large complement those of positive law.

In the early 1990s, the Supreme Court departed from its traditional approach to preemption by ignoring the differences between tort law and positive law in analyzing whether state tort law had been preempted. In more recent cases, the Court has vacillated between these approaches, although the Court appears to have returned to its traditional interpretation in its latest preemption case involving state tort law.

The Bush administration has sought to take advantage of the Court's vacillation by pushing the lower courts away from the traditional approach that properly preserved tort law's role in protecting public health and safety.

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The Food and Drug Administration (FDA) spearheaded the administration's preemption efforts. FDA has filed amicus briefs supporting industry-defendants' claims that federal drug-safety authority preempted state tort actions. More broadly, FDA inserted language in the preamble to a drug-labeling rule declaring that it preempts all state tort actions for inadequate warnings about the risks posed by a prescription drug. FDA's actions are a sharp departure from its long-standing position that tort actions complemented, rather than conflicted with, the agency's statutory mandate.

Similarly, the National Highway Traffic Safety Administration (NHTSA) and the Consumer Product Safety Commission (CPSC) have each made agency history by inserting tort-preemption language in recent rulemakings.

The administration's backing of industry tort-preemption claims—involving multiple agencies charged with implementing health and safety protections—substantially exceeds anything even suggested by prior administrations. Prior to the Bush administration, agencies by and large took one of two positions. They either opposed preemption of state tort remedies or stayed on the sidelines and did not take a position. In light of the novelty of the administration's support of industries' claims of tort preemption, it remains unclear how courts will respond.

The successful preemption of state tort law would deprive consumers and patients of their rights to recover damages if they are injured by a product or service and to hold those responsible accountable to their victims and society at large. Moreover, people will be at greater risk of being injured or killed because tort law currently complements and augments the protective function of federal safety regulation. For example, the tort system has provided crucial protections in areas of vehicle safety largely neglected by NHTSA, including the safety of volatile fuel-tank systems.

Tort cases also have the important effect of unearthing industry secrets that reveal health and safety shortcuts manufacturers take. Such information has in the past proved useful to regulators seeking to protect the public.

To protect tort law from unwarranted preemption, CPR recommends that each branch of the federal government take certain actions, including:

- *Congress*: Congress should restore its constitutional prerogative, which certain agencies it created are now attempting to usurp, by:
  - monitoring and investigating agencies' actions regarding preemption, and
  - making its intent regarding preemption of tort law clear.
- *The Supreme Court*: The Court should explicitly restore its traditional preemption analysis that does not equate the functions of positive law and tort law. Further, the Court should clarify that judges should not defer to agency pronouncements about preemption and require agencies to make specific factual findings in rulemakings to support preemption whenever an agency believes that state tort law conflicts with federal law.
- *Administrative Agencies*: Agencies should stop improperly urging courts to accept regulated industries' preemption claims and return to the agencies' pre-Bush-administration position of avoiding preemption of state tort law. Additionally, agencies should look for ways in which they can strengthen the role that state tort and damage law plays in reinforcing federal regulation. Finally, agencies should strive to avoid disproportionate business influence by encouraging and hearing a diversity of viewpoints.

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Preemption and Its Significance

The U.S. Constitution created a structure to ensure that the states would play an important and concurrent role in democratic governance.[1] As a result, the national and state governments generally work cooperatively to provide services and protect the public. In fact, until the federal government began taking a lead role in setting public health and safety standards in the late 1960s and early 1970s, health and safety protections were provided primarily by state and local governments. Even after Congress began legislating heavily in the area of health and safety, states have continued to play a significant—and often essential—role in public health and safety protection.

On occasion, there is federal-state disagreement on an important policy question or conflict over which approach to take. In such circumstances, under the Supremacy Clause of the Constitution, Congress may choose to "preempt" the states from implementing their preferred policy or approach. Although there are limited situations in which federal preemption of state law is necessary to implement national policy most effectively, there has always been a preference for respecting state sovereignty and permitting the states to develop their own policies and approaches. This preference is grounded in the country's constitutional structure and the recognition of the states' traditional role in providing public protections and services. Importantly, this preference has democracy-enhancing effects, as citizens often have greater opportunities to participate in government at the state and local levels. Consequently, Congress historically has considered preemption of state law a rather drastic action that should be taken only where clearly necessary for a federal statutory program to work. In all other situations, Congress expects the states to decide how to complement or augment federal law—and it often even depends on their doing so.

How Courts Determine Preemption

The Constitution's Supremacy Clause provides that laws duly enacted by Congress are "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[2] If, therefore, a federal law directly contradicts a state law by, for instance, imposing requirements that are flatly at odds with those imposed by federal law, the Supremacy Clause requires preemption of the state law. Furthermore, Congress, at times, passes legislation with "express-preemption" provisions that specifically allocate power between the federal government and state (or state and local) governments. Congress also sometimes enacts laws that are silent on preemption, but where one might reasonably infer that Congress intended federal law to, at least in part, displace state law. Because Congress is the body of the federal government with preemption authority, the question for courts in such "implied-preemption" cases is always what was the intent of Congress.

Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947), is the earliest Supreme Court case that continues to be frequently cited by courts and commentators for its framework for implied-preemption analysis. In *Rice,* the Court set out the two categories of implied preemption that have come to be known as "field" preemption and "obstacle" preemption. Field preemption occurs where the comprehensiveness and nature of the federal regulatory scheme or the dominance of the federal interest in the area justify the inference that Congress intended to displace state law. Obstacle preemption occurs where the state law stands as an obstacle to the accomplishment of the full purpose and objectives of Congress.

In *Rice*, the Court also emphasized two principles as fundamental to preemption analysis. First, a question of preemption is solely a question of congressional intent. Second, and to ensure that this first principle is given effect, courts presume state law is not preempted unless Congress clearly expresses its intent otherwise. These are important principles for two related reasons. First, they ensure that the responsibility for deciding to supersede state policy decisions or approaches remains with Congress, the body of government constitutionally empowered to make such decisions. Second, it deters unelected federal judges with lifetime appointments from injecting their own policy views into decisions whether state law should be preempted.

The risk of such judicial policymaking is particularly high in implied-preemption cases, in which it is often unclear whether state policies or approaches are actually in conflict with the implementation of federal law. As a result, implied-preemption cases present courts with significant room to incorporate their own policy preferences into their examination of analytically-

malleable factors such as the overall nature of the federal regulatory regime or the purpose of the federal statute. Thus, in these cases, strict adherence to the requirement of a clear expression of congressional intent is particularly crucial.

Preemption and State Tort Law

Before 1992, most of the Supreme Court's preemption cases involved state positive law, i.e., enacted laws, rules, and regulations. In the relatively few cases involving state tort law, the Court generally considered the distinctive nature of tort law in its preemption analysis, requiring a clear indication of congressional intent to preempt common-law liability. In 1992, however, the Court equated tort law with positive law in response to a novel preemption argument raised by the tobacco industry against tort claims in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). That case led to a surge in industry assertions of preemption defenses against state tort actions, and in these post-*Cipollone* cases the Supreme Court has vacillated between its historical approach that recognized the distinctive features of tort law and the approach used in *Cipollone* that ignored those distinctive features. In the Court's most recent case involving an industry's claim of tort preemption, however, it appears that the Court may have restored its historical, tort-specific approach.

The Supreme Court Recognizes Tort Law is Different

Prior to the early 1980s, there were relatively few preemption cases, and most of those that did arise involved federal laws and regulatory schemes relating to the national economy. When courts did find preemption during this period, it was mainly federal displacement of state and local positive law. Claims asserting preemption of state tort actions were rarely asserted. As a result, the preemption doctrine that the Supreme Court carved out in its foundational cases was largely conceived based on a "federal positive law versus state positive law" paradigm.

Until 1992, the Court generally analyzed the preemption question with the understanding that state tort law serves a different and complementary function to state and federal positive law.[3] Positive law operates *ex ante* by proscribing certain types of behavior to deter individuals and firms from injuring persons (or the environment) by such behavior. State tort and damage law, by comparison, operates *ex post* by providing compensation for injuries caused by tortious conduct. Moreover, while positive law specifically requires or prohibits certain types of conduct, tort law requires defendants only to pay compensation or in rare instances punitive damages. Tort law does have a deterrent function, but individuals and firms are not required to change their behavior, and they sometimes do not, choosing instead to pay damages if someone is harmed. In addition, while individuals or firms may change their behavior in response to losing a tort case or cases, tort law, unlike positive law, does not require any specific type of alternative behavior.

Because of these differences between tort law and positive law, the Court has historically been unwilling to preempt state tort law absent clear and manifest evidence that Congress intended to preempt *tort* law when it enacted a law creating a federal regulatory scheme. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), illustrates the Court's approach to preemption. In *Silkwood*, an Oklahoma jury awarded punitive damages in a tort suit brought by the father of a woman who had suffered from significant plutonium contamination while working as a laboratory analyst at a Kerr-McGee facility that manufactured plutonium fuel for nuclear power plants. The Court rejected Kerr-McGee's argument that Congress had preempted state tort law when it passed a federal regulatory regime for nuclear energy. The Court determined there was no indication that Congress intended to preempt the tort remedy of punitive damages in light of the differences between positive law and state tort law. In so doing, the Court distinguished a prior case in which it held that Congress intended to supplant state *positive* law regulating nuclear energy.

Cipollone *Ignores the Distinction*

In *Cipollone v. Liggett Group, Inc.*, the Supreme Court departed from the approach used in *Silkwood*. In *Cipollone*, the jury had found that the cigarette companies had failed to issue adequate warnings about the dangers of smoking. But the Supreme Court upheld the argument by the tobacco industry that the express-preemption provision of the Public Health Cigarette Smoking Act of 1969 preempted tort law, and therefore reversed the jury's verdict in favor of the son of Rose Cipollone, who died of lung cancer after smoking for forty years. The Act

contained a provision preempting any state "requirement or prohibition" concerning smoking.

In accepting the industry's argument that "requirement or prohibition" extended to tort actions as well as positive law, the Court dispensed with its prior understanding that, because of the distinction between the functions of positive law and tort law, the two forms of law must be treated differently for purposes of preemption analysis. Since positive law orders someone to undertake some action or refrain from some action, it is a "requirement or prohibition." By comparison, since tort law comes into play only *after* a person or company has caused an injury by some action or failure to act by compelling payment as a remedy for such injuries, tort law is not a "requirement or prohibition." Had the Court factored this difference into its analysis of the express-preemption provision in *Cipollone*, the Court would undoubtedly have determined that the words "requirement or prohibition" did not clearly indicate a congressional intent to preempt state tort law. Instead, a majority of the Court characterized both state tort law and federal positive law as serving prescriptive roles, thus leading to the erroneous conclusion that state tort law conflicted with federal statutory law.

The Court Vacillates

In preemption cases since *Cipollone*, the Court has vacillated between the approach to preemption it used in *Silkwood* and the approach used in *Cipollone*. That is, the Justices have recognized a distinction between positive law and tort law in some opinions and assumed tort law functions in the same way as positive law in others. For example, the Court recently has decided three important cases involving preemption defenses against state tort actions. One decision takes the *Cipollone*, positive-law approach[4] and the other two recognize the distinction between tort law and positive law.[5]

In the decision taking the *Cipollone* approach—*Geier v. Honda Motor Co.*, 529 U.S. 861 (2000), the Court held that a tort action was preempted by a federal regulation under implied-preemption principles, which, as noted above, were developed in preemption cases involving positive state enactments. Importantly, a five-justice majority reached this decision in *Geier* notwithstanding Congress's inclusion in the auto-safety statute at issue a "savings clause" providing that a manufacturer's compliance with federal auto-safety standards does not exempt the manufacturer from tort liability.

However, in *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002), and *Bates v. Dow Agrosciences*, 544 U.S. 431 (2005), the Court's most recent preemption decisions involving tort law, the Court found no preemption on the basis of the differences between tort law and positive law. In *Sprietsma*, the Court emphasized that it would have been "perfectly rational" for Congress to intend for the Federal Boat Safety Act to displace state positive law regarding boat safety but to work in tandem with tort law. "[U]nlike most administrative and legislative regulations," the Court pointed out, tort claims "perform an important remedial role in compensating accident victims."

Bates arose out of Dow's assertion that the express-preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) preempted state tort law. The company argued the Supreme Court should prevent West Texas farmers from suing Dow for serious damage to their peanut crops caused by Strongarm, a pesticide manufactured by Dow. According to the farmers, Dow knew or should have known that Strongarm would harm peanut plants growing in areas, such as West Texas, with alkaline soil, but nevertheless included a statement in Strongarm's label recommending that the pesticide be used in all regions where peanuts are grown and made similar claims to the farmers through its sales agents. The Court rejected Dow's claim of preemption and certainly limited any expansion of *Cipollone*.

The future of state tort law in the Supreme Court's preemption jurisprudence —and thus of tort law's role in providing public health and safety protections—remains in doubt because of the Court's vacillation. *Sprietsma* and *Bates* appear to reestablish the Court's traditional position that Congress must clearly indicate its intent to preempt state tort law and that express preemption of state "requirements" does not necessarily indicate such a congressional intent in light of the differences between the functions of tort law and positive law. This outcome, however, is by no means certain. One reason is that the Bush administration is making a determined effort to convince the Supreme Court to preempt state tort law. The next section discusses this unprecedented effort to influence the courts.

The Campaign to Preempt State Tort Law

The current administration, undoubtedly aware that the Supreme Court seems to be at a critical juncture in its preemption jurisprudence, has been increasingly aggressive in attempting to push courts back in the direction of broadly preempting state tort law. The courts may be receptive to this effort unless Congress acts to protect its decisionmaking authority in this area.

The Administration's Systematic Preemption Push

Although executive-branch support of industry's claims of preemption of tort actions is not unprecedented,[6] the systematic nature of this administration's backing of industry tort-preemption claims—involving multiple agencies charged with implementing health and safety protections—substantially exceeds anything done in prior administrations. Prior to the Bush administration, agencies by and large took one of two positions. They either opposed preemption of state tort remedies or stayed on the sidelines and did not take a position.

The Bush administration's support for preemption of state tort law has appeared in two forms. One form has been to intervene on the side of industry in tort litigation by the filing of amicus briefs arguing that the plaintiff's claims against the corporate defendant are preempted by the agency's regulations or its general authority over the health or safety matters at issue. For example, the Environmental Protection Agency (EPA) filed a brief in support of Dow's assertion of preemption in *Bates*, reversing the position that the agency had taken a mere five years earlier in an amicus brief filed with the California Supreme Court. The other form of administration support for preemption began not long after the Court handed down its decision in *Bates* rejecting Dow's and the administration's preemption arguments. After *Bates*, the administration began taking the more aggressive approach of declaring in rulemaking preambles that state tort law is preempted by the regulation that the agency is issuing or proposing.

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Advocating preemption in amicus briefs

The Food and Drug Administration (FDA) has led the administration's efforts to convince courts in amicus briefs that state tort law is preempted.[7] According to Professor James O'Reilly, author of a widely used multi-volume book on FDA law, this intervention is "a dramatic change [from] what FDA has done in the past."[8] FDA changed its position regarding preemption even though there has been no intervening change in the law of preemption that would justify such actions by the agency. The Supreme Court has not reversed its reading of preemption provisions in the Food, Drug, and Cosmetic Act (FDCA) or its mandates on the presumptions that inform any preemption decision (express or implied). Nor has Congress passed any legislation amending the FDCA concerning preemption.

FDA's backing of the drug industry's preemption claims appears to be making an impact. In one recent case in which FDA supported the defendant drug manufacturer's preemption claim, the district court sought out FDA's position on preemption largely because of the agency's voluntary intervention on the side of the same drug-company defendant in a previous tort action.[9] In another case, the district court concluded that it was obligated to defer to FDA's position, articulated in its amicus brief and in the agency's drug-labeling rule's preamble (discussed below), that the plaintiff's failure-to-warn claim was impliedly preempted by the FDCA.[10]

As noted above, under the Bush administration, EPA also reversed its position on preemption of state tort law in its amicus brief supporting Dow's preemption defense against the peanut farmers' tort claims in *Bates*. Significantly, in its brief, EPA did not add any insights to the preemption issue in its capacity as an agency with experience administering FIFRA. Rather, the Court's opinion makes clear that EPA's arguments by and large simply echoed those of Dow.

Declaring preemption in rule preambles

Besides amicus briefs, the administration has been active in declaring in the preambles to final or proposed rules that state tort law is preempted. These actions are unprecedented at each of the agencies involved in this effort.

National Highway Traffic Safety Administration

In the summer of 2005, the National Highway Traffic Safety Administration (NHTSA) announced the preemption of state tort law in proposed rulemaking preambles addressing the placement of seatbelts[11] and roof-crush resistance.[12] NHTSA has acknowledged that the express-preemption provision in the agency's statute (the National Traffic and Motor Vehicle Safety Act) preempts only state positive law. Nevertheless, the agency asserts that both proposed rules would impliedly preempt state common-law claims. Bill Walsh, a senior official at NHTSA who worked on the roof-crush rule before retiring from the agency in 2004, told the *L.A. Times* that such preemption of tort law was "different from how we normally operated . . . in issuing regulations."[13] The preemption language in the roof-crush rule's preamble, he stated, "was dropped in from out of the blue."

Senators Arlen Specter and Patrick Leahy, the then Republican chairman and ranking Democrat of the Senate Judiciary Committee, respectively, also expressed dismay in reaction to NHTSA's asserted preemption of tort law in the proposed roof-crush rule, indicating in a letter to the agency that it lacked congressional authority to make such a preemption determination.[14]

In September of 2005, NHTSA asserted preemption of common-law liability in yet another notice of proposed rulemaking. In this rulemaking—one that would require large trucks to be equipped with rear-object detection systems—the agency provides merely a perfunctory statement that, under the National Traffic and Motor Vehicle Safety Act's express-preemption provision, the proposed rule would preempt not only differing state statutes and regulations, but also "common law requirements."[15]

In the preambles, NHTSA neither tied its determinations to congressional intent in any meaningful way nor provided any justification for preemption of tort law based on its experience as the agency charged with implementing the National Traffic and Motor Vehicle Safety Act. Consequently, NHTSA ignored Executive Order 13132, which specifies agencies' obligations when taking action that preempts state law. The order was promulgated by President Clinton and retained by President Bush. According to the order, where the relevant statute does not expressly preempt state tort law, as in the case of the NHTSA rules, an agency should not support preemption in the absence of a direct conflict between the exercise of federal authority and that of state authority or of "clear evidence" of congressional intent to preempt.[16] NHTSA failed to establish either basis for its authority to preempt in the recent rulemaking preambles.

As Senators Specter and Leahy pointed out in their letter to NHTSA, "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."[17] "We are interested to learn how NHTSA," the senators further queried, "concluded that preemption of State law was the intent of Congress when it passed the Transportation Equity Act."

NHTSA's disregard of Executive Order 13132's requirements, which serve to enforce agency adherence to the Constitution's federalist structure, renders the agency's preemption assertion suspect—particularly given that the agency's effort to preempt state tort law in these 2005 rulemaking proposals is a first in the agency's 35-year history.[18] In fact, in a 1995 rule, NHTSA explicitly rejected an auto-industry trade association's contention that the agency should include language in the rule preempting tort liability. Because constitutional law dictates the circumstances in which a tort action would be preempted by the regulation, the agency stated, "it is not necessary to put a specific provision to that effect in the regulation."[19]

Food and Drug Administration

FDA also recently declared preemption of tort liability in a rulemaking preamble concerning the content and form of drug labeling.[20] Unlike NHTSA, however, the agency did not give the public any opportunity to comment on its preemption decision. FDA included its

preemption language *only* in the preamble of the final version of its drug-labeling rule, which was issued five years after publication of the proposed version. Furthermore, FDA explicitly took the opposite position in the proposed rule, stating that "this proposed rule does not preempt State law."[21] Consequently, FDA deprived most of the public—including state officials, Congress members, and interested individuals and citizen groups—of any chance to weigh in on the matter before the rule was finalized. The National Conference of State Legislatures wrote FDA that "[i]t is unacceptable that FDA would not permit the states to be heard on language that has a direct impact on state civil justice systems nationwide."[22]

In a letter to FDA protesting the agency's failure to consult state and local governments about the preemption issue, Representative Lee Terry (R-NE) pointed out that, because the "preemption language did not appear in any earlier versions of the proposed rule[,] FDA's response that no state or local government responded is disingenuous."[23]

In two separate letters to FDA, two senators and three representatives similarly criticized the agency's failure to give state and local governments the opportunity to comment on the preemption issue, particularly given that the preemption assertion rested, at best, on extremely shaky legal grounds.[24] In their letter, Senators Edward Kennedy and Christopher Dodd, the senior Democrats on the Senate's Health, Education, Labor, and Pensions Committee, which oversees FDA, further noted that the agency's assertion of preemption represented "a drastic reversal of policy with . . . far-reaching implications."[25]

FDA's pro-preemption amicus briefs and its rulemaking preamble are significant departures from the agency's long-standing views on preemption. As then-FDA Chief Counsel Margaret Jane Porter stated in 1996, the agency maintained a "long-standing presumption against preemption" of state tort law, even in its implementation of a section of the FDCA concerning medical devices that contains an express-preemption provision. Referring to medical devices, Porter explained that "FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."[26]

Since the drug-labeling rule, FDA has issued four rules and one proposed rule with language asserting preemption of tort actions in the preambles of the rules. In these five subsequent rulemakings, which impose marketing requirements on food as well as drugs, FDA provides a much more cursory justification than in the drug-labeling rule. Like NHTSA's September 2005 proposed rule, FDA states merely that the relevant express-preemption provision of the FDCA (i.e., addressing the regulation of food or drugs) "displaces both State legislative requirements and State common law duties."[27]

Indeed, it appears that FDA may have adopted boiler-plate tort-preemption language to be inserted in rulemakings on a regular basis. Moreover, like NHTSA, FDA failed to comply with Executive Order 13132 because the agency established neither the existence of a direct conflict between the exercise of federal authority and that of state authority nor "clear evidence" of congressional intent to preempt.

Consumer Product Safety Commission

The Consumer Product Safety Commission (CPSC) has also joined the administrative drive for tort preemption. The agency recently declared preemption of tort liability in the preamble to its long-awaited mattress-flammability rule.[28] Like NHTSA and FDA, CPSC failed to cite any instances from its 33-year history in which tort liability interfered with the implementation of its statutory mandate, and this rule's preamble is the first time the agency has declared preemption of tort law in the rulemaking process.[29]

CPSC, like FDA, did not assert its intent to preempt tort law at the proposal and public comment stage of the rulemaking process.[30] Thomas H. Moore, a CPSC Commissioner who dissented from the assertion of preemption of tort law in the preamble, questioned why the agency denied the public a meaningful opportunity to respond to the agency's preemption assertion.[31] He objected to the "twelfth hour" release of the preemption language, which was "buried in the tabs of the briefing package on our web site, [and] did not give it the public exposure it deserved."

Federal Railroad Administration

The Federal Railroad Administration (FRA) also appears to have adopted the tactic of pushing for greater

preemption in two recent railroad-safety rulemaking preambles—one a proposed rule and the other a final rule.[32] In the preambles of both rules and in the text of one of the rules, FRA cites language from the express-preemption provision of the Federal Railroad Safety Act, which provides that FRA regulations and orders preempt state "laws, regulations, and orders" that cover the "same subject matter" as the federal rule.[33] In contrast to FRA rules issued in previous administrations, however, FRA includes in the preambles what appears to be a broad interpretation of the reach of this preemption provision. According to FRA, the rules preempt all "state requirements covering the same subject matter," which, the agency further specifies, include common law.

The issue of preemption under the Federal Railroad Safety Act is still developing and some lower court opinions finding preemption contain questionable logic. Nevertheless, there is a general drift towards greater preemption in response to the vigorous assertion of preemption by railroad companies in tort cases against them, and FRA's inclusion of an apparently sweeping interpretation of the statute's express-preemption provision in rulemaking preambles could hasten this trend.

The Clinton administration attempted to convince the Supreme Court to adopt a narrow interpretation of preemption concerning one key preemption issue, but the Court did not go along.[34] By contrast, the current administration has not only made no similar efforts to promote and defend legal interpretations that would create more room for tort law to operate, but also appears to be advocating for broad preemption of tort law in rulemaking preambles.

Courts May Accept the Administration's Preemption Push

At least three factors may make federal court judges susceptible to the administration's calls for preemption of state tort actions. First, lower-court judges depend on guidance from the Supreme Court, which, as discussed above, has failed to develop a coherent approach to tort-preemption analysis. The unfortunate result is complex statute-by-statute litigation.

The Supreme Court could end this debate simply by conditioning a finding of preemption of state tort law on a clear statement by Congress of its intent to preempt *tort* law (i.e., in addition to any such a statement regarding state positive law). The Court has established such "clear-statement" rules in its Spending Clause jurisprudence and other areas in which federal law can displace state law.[35]

Second, the courts usually defer to agency statutory interpretations in cases where the authorizing statute is ambiguous as required by *Chevron v. Natural Resources Council*, 467 U.S. 837 (1984). The propriety of such deference is based on the assumption that when Congress leaves a gap to be filled in an administrative scheme, Congress intends to delegate to the agency the authority to fill in the gaps. Whether this *Chevron* doctrine should apply to agency claims of preemption raises a number of questions. One is the extent to which statements in preambles should ever receive *Chevron* deference. Another is whether it should be presumed that Congress would not delegate preemption determinations to an agency.[36] In the absence of clear Supreme Court direction, some lower courts have deferred to agency interpretations claiming preemption,[37] while others have not.[38] The state of the case law at the present time does not provide confidence that lower courts will be asking these relatively sophisticated questions regarding deference, much less answering them in a correct fashion.

Finally, because of the Supreme Court's ambiguity, judges have more room to act on their policy preferences against state tort actions. It is therefore likely that some judges will adopt the administration's preemption arguments.[39]

With its vacillation, the Supreme Court has opened the door a crack to widespread preemption of state tort law in the absence of a clear expression of congressional intent, and even in spite of clear congressional statements of its intent not to preempt. With its amicus briefs and increasingly with its rulemaking preambles, the Bush administration is at this tort-preemption door, pushing hard to open it wider. There is a real risk that the administration could succeed in this effort, particularly given the potential for judicial proclivity to accept the administration's preemption assertions.

Preemption Will Harm Consumers and Patients

As the areas preempting state tort law expand, consumers and patients injured by a product or service will increasingly be deprived of their rights to recover damages and to hold those responsible accountable.

Moreover, people will be at greater risk of being injured or killed because tort law currently complements and augments the protective function of federal safety regulation.

Tort Law Compensates Victims for Their Injuries

Since federal health and safety laws are primarily prescriptive, they generally do not provide compensation for those injured by regulated entities. Preemption therefore deprives injured consumers and patients of their right to recover for harms wrongfully perpetrated against them. Moreover, taxpayers will end up picking up medical and other expenses of increasing numbers of injured persons because they will be unable to obtain tort compensation and will not be able to pay for the resulting medical expenses out of their pockets.

Compensation Is Basic Justice

One of the key distinctive aspects of tort law is that it has historically served to provide compensation for those injured by socially unreasonable behavior. The expectation of the common law has long been that a person (or firm) who commits a tort is responsible for paying compensation to the injured party as a matter of basic justice.

Congress understands the importance of the compensatory mechanism provided by tort law. It has never expressly preempted state tort law without providing for an alternative compensation mechanism. Moreover, when Congress does explicitly preempt state law, it usually enacts provisions preempting "requirements" or "prohibitions," which are most naturally read as being limited to state positive law. Additionally, Congress also sometimes includes a savings provision that specifies that the legislation does not preempt common-law liability.

Congressional intent to preserve state tort law makes sense. In the 1960s and 70s, when Congress passed the health and safety statutes, Congress was seeking to expand the public's protection against irresponsible manufacturers. In this context, it is simply implausible that Congress intended to cut off long-standing protections provided by tort law. As the Supreme Court stated in *Sprietsma*, it would have been "perfectly rational" for Congress to preempt state positive law with federal positive law, but to leave state tort law undisturbed. Nevertheless, now industry and the current administration are attempting to reinterpret health and safety laws as a shield against tort liability.

Preemption Shifts Compensation to the Public

Preemption of tort actions also shifts the burden of redressing injuries from the responsible party to the victims, to taxpayers, and to society as a whole. For example, consider a report issued by the National Conference of State Legislatures on NHTSA's proposed roof-crush rule.[40] The report estimated that the agency's asserted preemption of tort suits would cost the states $60.2 million a year because some persons who would become disabled as a result of rollover accidents would be forced to resort to Medicaid (partially funded by states) because of the lack of tort compensation.

Moreover, it is important to bear in mind that the damages involved in most viable tort suits are for deaths or extremely severe injuries, and federal law does not guarantee health or accident insurance. In this political reality, tort preemption is not replacement of state protection with federal protection; it is simply withdrawal of state protection.

Tort Law Reinforces and Enhances Safety Laws

In addition to compensating injured persons, tort law reinforces and works in tandem with regulatory law. Because of the differences between tort law and positive law, the two are rarely at cross purposes and are, in fact, by and large complementary in their protective effects.

Tort law often responds more quickly

The tort system has often been able to respond more quickly than regulators to hold companies accountable for dangerous products or services. For example, medical devices implanted in the human body—such as pacemakers and mechanical heart valves—were practically unregulated until 1976, when Congress passed the Medical Device Amendments (MDA) to the FDCA. Before the MDA, the civil justice system was essentially the only governmental authority policing the medical-device industry, and thousands of people looked to tort law for redress from injuries caused by dangerously

defective medical devices. It was the dangers brought to light by this medical-device tort litigation, particularly litigation over the intrauterine device known as the Dalkon Shield, that led Congress to recognize the need for greater regulation and to pass the MDA.

Before the tort suits over the Dalkon Shield forced the manufacturer to withdraw the product from the market, the device killed many otherwise healthy women and seriously injured thousands.[41] The manufacturer had introduced and extensively marketed the Dalkon Shield without prior FDA approval, which was not required with respect to medical devices until Congress passed the MDA. Although the MDA thus plugged a gaping regulatory hole exposed by the tort system, the availability of tort remedies remains a vital complement to FDA protections in the area of medical devices as well as drugs.

As made clear by the recent revelations about the dangers presented by FDA-approved drugs and medical devices, such as Guidant defibrillators, Medtronic and Baxter infusion pumps, Johnson & Johnson and Boston Scientific heart stents, Merck's Vioxx, and Pfizer's Bextra and Zoloft, FDA's approval process does not offer sufficient protection to the public. Rather, the federal regulatory system permits drug and medical-device manufacturers to evade safety requirements and maintain strict control of information on the health risks presented by their products. Senators Kennedy and Dodd highlighted this deficiency in federal protection in their letter to FDA protesting the preemption language in the drug-labeling rule's preamble. The senators noted that "the label is owned by the manufacturer," and FDA is severely limited in its ability to require manufacturers to make changes in their labels. Consequently, "manufacturers can delay for months before adding important new risk information to a drug's label, and can water down the language requested by FDA." Thus, as three representatives stated in a similar letter denouncing FDA's preemption declaration, "[t]his is not the time to prevent States from filling in the gaps in the federal safety net."[42] Tort law is necessary both to highlight dangers that FDA misses or fails to address and to provide compensation to the victims of unreasonably dangerous healthcare products.

In addition to compensating injured persons, tort law reinforces and works in tandem with regulatory law. Because of the differences between tort law and positive law, the two are rarely at cross purposes and are, in fact, by and large complementary in their protective effects.

The tort system has also provided crucial protections in an area of public safety largely neglected by NHTSA; namely, the safety of vehicle fuel-tank systems. In 1999, a jury found General Motors liable for severe burn injuries suffered by six people (including four children) as a result of an explosion of the fuel tank in the company's Chevrolet Malibu.[43] The jury issued a large punitive damages award based on evidence showing that GM knew the fuel-tank design was unsafe, yet decided not to equip its vehicles with a safer design because the company determined that doing so would cost more than paying compensation for injuries caused by fuel-tank fires.

Similar lawsuits involving deaths and severe injuries caused by fuel-tank fires in the Malibu and other GM models brought attention to the dangers of the design and provided victims with the ability to seek compensation and to hold GM accountable for irresponsible practices unchecked by NHTSA.[44] GM's fuel-tank system complied with the applicable NHTSA safety standard, which, having been in place for over three decades, lags far behind current knowledge and technology. NHTSA has long been aware of the need to upgrade the standard; the agency made efforts to do so in the 1970s and again in the 1990s. But pressure from auto manufacturers, including GM, played a significant role in thwarting the agency in these efforts toward strengthening the standard.[45]

Moreover, agencies can and do act on the basis of information revealed in tort litigation. According to Joan Claybrook, current president of Public Citizen and former head of NHTSA, tort litigation made the agency aware of the dangers presented by the Ford Pinto's gas tank.[46] After a significant jury award in 1977, Claybrook launched a federal investigation of the problem. Similarly, based primarily on documents uncovered as a result of civil actions brought against the tobacco industry by various states, the U.S. Department of Justice (DOJ) brought suit against the tobacco industry.[47] DOJ alleged, *inter alia*, that the tobacco companies were unjustly

enriched as a result of their decades-long conspiracy to defraud and deceive the public, in violation of the Racketeer Influenced and Corrupt Organizations Act.

Tort law finds hidden information

The tort system has proven to be more adept than agencies at obtaining and making public information about dangerous products or services that firms attempt to keep secret. The civil discovery system is well-suited to permit plaintiffs to compel corporations to produce important public health and safety information previously kept hidden from agencies and the public. And the adversarial nature of the civil justice system provides litigants with strong incentives to uncover information and to examine closely the information provided by the opposing side.

In contrast, agencies are in many ways ill-equipped to gather information that firms do not want known. The primary problem is that safety agencies lack subpoena power.[48] One particularly revealing example is the tobacco industry documents made public as a result of litigation against the industry. A continuing stream of cases brought by state attorneys general and private plaintiffs eventually produced the release of troves of previously secret industry documents. Through these documents, a picture began to emerge of an industry whose top officials not only knew of the deadly, addictive nature of tobacco products, but also deliberately manipulated the design and nicotine content of cigarettes in order to enhance the products' addictiveness, and intentionally targeted children in advertising campaigns in order to continually "recruit" new smokers into the market.[49] FDA, which lacks subpoena authority and consequently must rely on companies to cooperate in providing complete information, had failed to obtain this sort of information even though it spent three years investigating the industry.[50]

Another, more recent example illustrating the tort system's superior information-gathering ability is the litigation brought by municipalities and individuals against the petroleum and chemical industries for contamination of groundwater by MTBE, a widely-used gasoline additive.[51] The documents produced in the litigation showed that, to prevent Congress and EPA from regulating MTBE, the industries made a concerted effort to suppress, prevent the generation of, and repackage information on the health impacts of the chemical (a suspected carcinogen) and on the great risk of widespread groundwater contamination by it. The industry succeeded in this information-skewing effort with respect to the agency, but not to the tort system.

Tort Law Offsets Weak Regulation

The tort system has another important advantage for consumers and patients. It is less susceptible to disproportionate influence by large companies and trade associations than the federal regulatory system. When agencies respond to such influence by failing to regulate, or by adopting inappropriately weak regulations, the tort system becomes the primary legal vehicle for consumers to obtain protection from dangerous products and services.

Disproportionate business influence

Political scientists use the term "capture" to refer to the ability of economically and politically powerful business interests to gain disproportionate influence at regulatory agencies. Capture occurs because of two features of the regulatory system. First, agencies are more likely to hear from lawyers and lobbyists representing regulated entities than from consumers or others who support stronger regulatory protections. Second, it is common for presidents to pay back groups that gave or organized significant campaign contributions by appointing administrators likely to be favorable to their policy preferences. Regulated entities are generally in a better position to make such donations than consumers or patients.

Superior Resources

The ability of regulated entities to capture the agencies charged with regulating them results primarily from the entities' concentrated, long-term incentives to resist regulation and the significant resources that the entities can marshal in pursuit of this goal. In contrast, consumers are largely unorganized and cannot match industry's financial resources. Consequently, regulated entities are often able to inundate agencies with arguments and data reflecting industry's concerns, drowning out any attempts by the few consumers' groups in existence to advocate for the general public's safety interests.

Friendly Administrators

The appointment of business-friendly administrators to head up regulatory agencies further enhances the influence of business interests over regulatory policy. Typically the persons appointed have worked for or represented the entities that they will now regulate, and many times they return to working for or representing the same entities after they leave government.

For example, Jacqueline Glassman, the acting head of NHTSA when the agency asserted preemption of tort liability in the two proposed rules discussed above, was one of DaimlerChrysler's senior attorneys before becoming NHTSA's chief counsel in 2002.[52] And, before becoming general counsel at the Department of Transportation in 2003, Jeffrey Rosen was a senior partner at a large corporate law firm that represented General Motors in several product-liability cases and that counts the Alliance of Automobile Manufacturers among its clients.[53]

Some key FDA and CPSC officials also have had close ties to the industries their agencies are charged with regulating. Before becoming FDA's general counsel and leading the agency's effort to back the preemption claims of drug and medical-device manufacturers in tort cases, Daniel Troy sued FDA on behalf of the Washington Legal Foundation and represented Pfizer as an attorney at the law firm of Wiley, Rein, & Fielding.[54] Having resigned from the agency at the end of 2004,[55] he is currently representing the pharmaceutical and medical-device industry as a partner at the law firm of Sidley Austin.[56]

Tort law resists business influence

In contrast to agencies, the tort system is more resistant to business influence. This allows the tort system to protect consumers when agencies fail to regulate or adopt weak regulations in response to business influence. Because tort decisions are made by juries, and because plaintiffs' lawyers have the necessary skill and incentives to seek appropriate levels of protection for consumers and patients, the civil justice system puts individual consumers on the same footing as large corporations.

The Public Decides

Unlike the regulatory system, the civil justice system makes it possible for members of the general public to be directly involved in governing. As plaintiffs and members of civil juries, citizens supplement and back up the legislative and executive branches as society's "quality-control guardian[s] of products and services."[57] This is a crucial distinction since individuals normally lack the same incentives as politically appointed government officials to resolve regulatory problems in favor of regulated entities.

Similarly, although corporate interests expend significant resources in an attempt to populate the judiciary with industry-friendly judges in states where judges are elected, there is simply no way to "capture" all the judges throughout the country's numerous state and federal, trial and appellate courts. Moreover, even where judges are elected, citizens serving on juries are responsible for making decisions about liability. Influence is much more readily exerted upon a handful of federal safety agencies.

Plaintiffs' Attorneys

Plaintiffs' attorneys, the other key element in the civil justice system, are in a position to use the civil justice system to secure redress for victims of industry misconduct left unchecked by the political branches, to deter such misconduct in the future, and to highlight agency failures to protect the public from the sort of dangers encountered by their clients. Moreover, it is often much easier for plaintiffs' attorneys to accomplish these ends than for thousands of consumers to organize a collective effort to convince an agency to regulate more strictly.

The Tort System Rarely Undermines Federal Policies

The weaknesses in the administrative system—i.e., agencies' frequent inability to respond quickly to threats to public health and safety, their compromised information-gathering capacity, and their susceptibility to capture—often result in insufficiently protective or non-existent regulations. When the tort system is in place, it can provide the public with back-up protection, give victims and society at large the opportunity to assert their safety interests, and spur Congress and agencies to act to protect these interests by enhancing federal protections.

By comparison, preemption can leave the public stuck with weak or non-existent federal protections and no remedies when things inevitably go wrong. As Sen.

Daniel K. Inouye, co-chairman of the Senate Commerce, Science and Transportation Committee, explained in a letter protesting CPSC's assertion of preemption of tort law in its recent mattress-flammability rule: "(Federal) [s]afety standards are baseline starting points" and "should not be ceilings."[58]

Nevertheless, those advocating preemption of tort law frequently argue that tort suits can undermine federal policies. These claims, however, are generally based on misperceptions about how the tort system actually operates.

The Tort System Does Not Require Different Products

Product manufacturers have a significant financial interest in producing uniform products that can be sold in every state. This goal is also important for the country because it maximizes economic efficiency. The tort system, however, does not require manufacturers to produce different products for different states. It is true that a principal purpose of the tort system (in addition to providing compensation) is to have the regulatory-like effect of pushing manufacturers to make safer products. But that does not mean that tort law is equivalent to positive law, which, in fact, regulates behavior much more directly. In *Bates*, the Supreme Court highlighted the relatively weak regulatory effect of tort law in interpreting the word "requirement" in the express-preemption provision at issue: "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."

Agencies can exercise direct authority over the marketing practices of manufacturers in various ways, including by seizing products off the market, denying regulatory approval, restricting advertising, and imposing specific safety standards. In contrast, a tort verdict is not prescriptive—i.e., defendants are not required to change a product or label in response to a verdict in any particular way or at all. Moreover, if and when a seller decides to change a product or label, it will adopt a uniform new design or label unless it is less expensive not to do so. As a practical matter, industry actors react slowly or not at all to tort-liability pressures. Even when manufacturers do make changes after repeated suits, settlements, and findings of liability, there is often not a clear direct causal relationship between liability pressures and the change.

The Tort System Does Not Undermine Federal Regulation

Agencies that have sought to preempt state tort law in their rulemaking preambles have claimed that tort law conflicts with the administration of federal safety regulation. In the rulemaking preambles discussed previously, however, none of the agencies cites any instance in its entire history in which tort liability interfered with the implementation of its statutory mandates. Rather than providing evidence of conflicts between regulation and tort law, the agencies conclusorily assert in the preambles that tort actions would upset the balancing of factors the agency engaged in when it decided what type of regulation was appropriate. Furthermore, this claim is unprecedented. Prior to the Bush administration, none of the agencies currently involved in preemption efforts took the position that preemption was necessary in order to carry out its statutory mandates.

FDA's effort to justify preemption in its drug-labeling rule illustrates the utter absence of credible evidence that tort law conflicts with federal safety regulations. According to FDA's preamble, its authority over drug labeling must be exclusive to ensure that warnings of risks are adequate yet not unnecessary.

A recent article in the *New England Journal of Medicine*, however, disputes this conclusory claim.[59] The physician authors argue that the rule makes only modest improvements in FDA drug labeling, and that FDA's efforts to preempt state tort law will leave drug patients without adequate protection. The article supports FDA's efforts to make drug labels clearer, but points out that this effort is not likely to have much effect on either "medication use" or "patient safety." The problem for drug patients is that the information about risks to patients in FDA-approved drug labels "often lag behind the available evidence by as much as several years."

Consequently, they conclude, the agency's assertion of preemption—a rather "low-profile aspect of the new rules"—"could have an effect on the health care system

that is much more profound than the small-scale improvements of the new labeling rules themselves"; namely, "severely limit[ing] the accountability of companies that fail to adequately evaluate or report the risks associated with their products."

The Tort System Does Not Mishandle Scientific Evidence

Preemption proponents also suggest that decisions about the safety of products should be exclusively in the hands of federal administrative agencies because these decisions often rest on the interpretation of complex scientific evidence. They perceive that federal agencies are in a better position to interpret such evidence than jury members because agencies have scientists on their staffs or they can solicit scientific advice from independent scientists. Agencies clearly have more scientific expertise and experience than civil juries, but the expertise advantage of agencies relative to juries is less overwhelming than an abstract comparison of the nature of the two institutions might suggest. Highly qualified experts usually play a significant role in the process of information evaluation that takes place in a civil trial, and the civil justice system has mechanisms in place for preventing the misuse of scientific evidence.

Studies indicate that civil trials provide juries with the information and the tools necessary to make judgments well-grounded in facts and reason, even where complex scientific and technical issues are involved.[60] Moreover, as mentioned above, juries often have more complete information available to them because civil discovery rules require companies to produce documents that they are not required to submit to agencies.

Furthermore, agencies are limited in the extent to which they can use their scientific expertise—although it may be considerable—because they are largely dependent on regulated entities for information, and because the combination of the capture phenomenon and the inherent uncertainty of scientific inquiry and judgment often results in politicization of scientific information.

For example, in a survey recently conducted by the Union of Concerned Scientists and Public Employees for Environmental Responsibility, 60 percent of the almost 1,000 FDA scientists who responded stated that they were aware of cases "where commercial interests have inappropriately induced or attempted to induce the reversal, withdrawal or modification of FDA determinations or actions."[61] Eighteen percent of the agency scientists reported that they had "been asked, for non-scientific reasons, to inappropriately exclude or alter technical information or [their] conclusions in an FDA scientific document."

How to Preserve Tort's Health and Safety Role

Congress

Congress should act to restore its constitutional prerogative as the body in the federal government that decides preemption issues. Elected members of Congress alone possess preemption authority and are more accountable to the public than agency officials and the courts. Congress has decided over the years to maintain state and federal tort law, and recently, the administration and the courts have been ignoring that preference. If the federal regulation-as-baseline principle recently asserted by Senator Inouye is to be abandoned in the area of public health and safety, that radical change should be—and must be under the Supreme Court's interpretation of the Supremacy Clause—accomplished by Congress and not by relatively politically unaccountable agencies and courts.

- *More Monitoring* – Congress should therefore monitor what agencies are doing regarding preemption and rein them in when they overstep the bounds of their authority by pushing for preemption in the absence of a clear expression of congressional intent.
- *Clearer Legislation* – Congress should also state explicitly when it intends to preempt state *tort* law, and, before doing so, give serious consideration to the impact of depriving parties injured through the fault of others of their rights to redress and of depriving the public of the health and safety protections tort law has traditionally provided. Where Congress does not intend to preempt state tort law (which should be in most cases), it should routinely include in legislation explicit language of its intent.

The Supreme Court

The Supreme Court should explicitly restore its historical preemption analysis which does not equate the functions of positive law and tort law. This approach is necessary to give effect to the presumption against preemption of state law in cases involving issues of preemption of state tort law.

- *Respect Savings Clauses* – The Court should clarify that, absent extraordinary circumstances, when Congress includes an express savings clause for state tort law, whether in combination with an express preemption provision or not, the savings clause should be read to protect state tort law from both express and implied preemption.
- *Clarify Deference* – The Court should also clarify that agency statements in preambles to regulation and amicus briefs should not receive deference according to the *Chevron* case. Moreover, in order to respect the presumption against preemption of state tort law, the courts should not presume that an agency has the legal authority to make a preemption determination in a regulation absent express legislative authority to make such determinations.[62] Finally, when Congress has expressly authorized an agency to make preemption decisions, courts should assess such determinations on the basis of the record in the proceeding and should reject determinations that do not have factual support in the record.

Administrative Agencies

Until the Bush administration, public-safety agencies apparently understood the importance of the tort system to maintaining the federal-law-as-baseline principle. Agencies should give appropriate consideration to Executive Order 13132 and return to their pre-Bush-administration position of avoiding preemption of state tort and damage law. Additionally, agencies should look

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for ways in which they can strengthen the role that state tort law plays in reinforcing federal regulation. Finally, agencies should strive to avoid disproportionate business influence by encouraging and hearing a diversity of viewpoints.

Notes

[1] *See* U.S. Const. amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."); U.S. Const. art. IV, § 4 ("The United States shall guarantee to every State in this Union a Republican Form of Government . . . .").

[2] U.S. Const. art. I, § 2.

[3] *See* United Construction Workers v. Laburnum Construction Corp., 347 U.S. 656 (1954); Int'l Union v. Russell, 356 U.S. 634 (1958); Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984); English v. General Electric Co., 496 U.S. 72 (1990). *But see* San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236 (1959).

[4] Geier v. Honda Motor Co., 529 U.S. 861 (2000).

[5] Sprietsma v. Mercury Marine, 537 U.S. 51 (2002); Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005).

[6] During the administration of the first President Bush, the Department of Transportation submitted an amicus brief to the Supreme Court in support of a railroad company's preemption defense against a tort claim based on the duty to operate trains at safe speeds. *See* Brief for the United States as Amicus Curiae at 27-30, CSX Transp., Inc. v. Easterwood, 507 U.S. 658 (1993) (Nos. 91-790 & 91-1206).

[7] A previous CPR report explains in detail the nature of FDA's efforts. *See* Margaret H. Clune, Ctr. for Progressive Reform, *Stealth Tort Reform: How the Bush Administration's Aggressive Use of the Preemption Doctrine Hurts Consumers* (Oct. 2004), *available at* http://www.progressiveregulation.org/articles/preemption.pdf. FDA, however, appears to have backed off from its efforts to expand preemption in two of its recent amicus briefs. *See* Perry v. Novartis, No. 05-5350, Brief of the United States as Amicus Curiae at 10-11 (E.D. Pa. filed Sept. 22, 2006) (taking the position that a state failure to warn claim would only be preempted where the agency "would have" found the proposed warning to be unsubstantiated or otherwise false or misleading); Colaccio v. Apotex, Inc., No. 06-3107, Brief of the United States as Amicus Curiae, at 22 & n. 10 (3rd Cir. filed Dec. 4, 2006) (taking the position that the test for preemption is whether the agency had considered and rejected the proposed warning at the relevant time).

[8] Anne C. Mulkern, *Watchdogs or Lap Dogs? When Advocates Become Regulators*, Denver Post, May 23, 2004, at A1.

[9] Amicus Brief for the United States at 1-2, Kallas v. Pfizer, Inc., No. 2:04CV0998-PGC (D. Utah 2005).

[10] *See* Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 524, 529 (E.D. Pa. 2006).

[11] Designated Seating Positions and Seat Belt Assembly Anchorages, 70 Fed. Reg. 36094 (proposed June 22, 2005) (to be codified at 49 C.F.R. pt. 571).

[12] Roof Crush Resistance, 70 Fed. Reg. 49223 (proposed Aug. 23, 2005) (to be codified at 49 C.F.R. pt. 571).

[13] Myron Levin & Alan C. Miller, *Industries Get Quiet Protection from Lawsuits*, L.A. Times, Feb. 19, 2006.

[14] *See* Letter from Sen. Arlen Specter & Sen. Patrick Leahy to Jacqueline Glassman, Acting Director, NHTSA (Nov. 17, 2005), *available at* http://dmses.dot.gov/docimages/pdf94/377136_web.pdf [hereinafter Specter/Leahy Letter to NHTSA].

[15] Federal Motor Vehicle Safety Standards; Rearview Mirrors, 70 Fed. Reg. 53753, 53768 (proposed Sept. 12, 2005).

[16] Exec. Order No. 13,132, 64 Fed. Reg. 43255, §§ 4(a), (b) (1999).

[17] Specter/Leahy Letter to NHTSA, *supra* note 14.

[18] *See* Levin & Miller, *supra* note 13.

[19] Motor Vehicle Content Labeling, 60 Fed. Reg. 47878, 47890 (Sept. 15, 1995) (codified at 49 C.F.R. pt. 583).

[20] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006).

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

[22] Letter from Sen. Steven J. Rauschenberger, President, Nat'l Conference of State Legislatures, to Mike Leavitt, Secretary of Health and Hum. Servs. (Jan. 13, 2006), *available at* http://www.ncsl.org/programs/press/2006/060113Leavitt.htm (emphasis omitted).

[23] Letter from Rep. Lee Terry to Andrew C. Von Eschenbach, Acting Commissioner, FDA (Mar. 31, 2006).

[24] *See* Letter from Sen. Edward M. Kennedy & Sen. Christopher J. Dodd to Michael O. Leavitt, Secretary, Health & Hum. Servs. (Feb. 23, 2006); Letter from Rep. Henry A. Waxman, Rep. John D. Dingell, & Rep. Sherrod Brown to Michael O. Leavitt, Secretary, Health & Hum. Servs. (Feb. 23, 2006) [hereinafter Waxman Letter]. Representative Waxman was the then ranking member of the House Committee on Government Reform, Representative Dingell the then ranking member of the House Committee on Energy and Commerce, and Representative Brown the then ranking member of the Subcommittee on Health (of the Committee on Energy and Commerce).

[25] Letter from Sen. Edward M. Kennedy & Sen. Christopher J. Dodd to Michael O. Leavitt, Secretary, Health & Hum. Servs. (Feb. 23, 2006).

[26] Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 7, 11 (1997).

[27] Skin Bleaching Drug Products for Over-the-Counter Human Use, 71 Fed. Reg. 51146, 51153 (Aug. 29, 2006) (to be codified at 21 C.F.R. pt. 310); Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use, 71 Fed. Reg. 43358, 43361-62 (proposed Aug. 1, 2006); Food Labeling; Guidelines for Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish , 71 Fed. Reg. 42031, 42043 (July 25, 2006) (to be codified at 21 C.R.R. pt. 101); Food Labeling: Health Claims; Soluble Dietary Fiber from Certain Foods and Coronary Heart Disease, 71 Fed. Reg. 29248, 29250 (May 22, 2006) (to be codified at 21 C.F.R. pt. 101); Food Labeling: Health Claims; Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries, 71 Fed. Reg. 15559, 15563 (Mar. 29, 2006) (to be codified at 21 C.F.R. pt. 101). Before the drug-labeling rule but still under the Bush administration, FDA issued three rules with the same language. *See* Food Labeling: Ingredient Labeling of Dietary Supplements that Contain Botanicals, 68 Fed. Reg. 51693, 51703 (Aug. 28, 2003) (codified at 21 C.F.R. pt. 101); Food Labeling: Health Claims; Soluble Dietary Fiber from Certain Foods and Coronary Heart Disease, 68 Fed. Reg. 44207, 44208 (July 28, 2003) (codified at 21 C.F.R. pt. 101); Food Labeling: Health Claims; D-tagatose and Dental Caries, 68 Fed. Reg. 39831, 39832 (July 3, 2003) (codified at 21 C.F.R. pt. 101).

[28] *See* Standard for the Flammability (Open Flame) of Mattress Sets, 71 Fed. Reg. 13472, 13496-97 (Mar. 15, 2006) (to be codified at 16 C.F.R. pt. 1633); Caroline E. Mayer, *Rules Would Limit Lawsuits*, WASH. POST, Feb. 16, 2006, at D1 (noting that CPSC's new mattress-flammability rule "update[s] a 30-year-old standard").

[29] *See* Stephen Labaton, *'Silent Tort Reform' Is Overriding States' Powers*, N.Y. TIMES, Mar. 10, 2006.

[30] *See* Standard for the Flammability (Open Flame) of Mattresses and Mattress/Foundation Sets, 70 Fed. Reg. 2470, 2492-93 (proposed Jan. 13, 2005).

[31] Press Release, Consumer Prod. Safety Comm'n, CPSC Approves New Flammability Standard for Mattresses: Statement of the Honorable Thomas H. Moore on the Final Rule and Preamble for the Flammability (Open-Flame) of Mattress Sets (Feb. 16, 2006), *at* http://www.cpsc.gov/cpscpub/prerel/prhtml06/06091.html.

[32] *See* Railroad Operating Rules: Program of Operational Tests and Inspections: Railroad Operating Practices: Handling Equipment, Switches, and Derails, 71 Fed. Reg. 60372, 60382, 60386, 60404 (proposed Oct. 12, 2006); Track Safety Standards; Inspections of Joints in Continuous Welded Rail (CWR), 71 Fed. Reg. 59677, 59690 (Oct. 11, 2006) (to be codified at 49 C.F.R. pt. 213).

[33] 49 U.S.C. § 20106.

[34] *See* Northern Southern Ry. Co. v. Shanklin, 529 U.S. 344, 355 (2000) (describing the argument of the government in an amicus brief seeking to limit the preemptive effect of the statute).

[35] *See, e.g.*, Pennhurst State Sch. & Hosp. v. Halderman, 451 U.S. 1, 15-18 (1981).

[36] *See, e.g.,* Gonzalez v. Oregon, 126 S. Ct. 904 (2006); FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

[37] *See, e.g.,* Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D. Pa. 2006).

[38] *See, e.g.,* Desiano v. Warner-Lambert & Co. 467 F.3d 85 (2d Cir. 2006); Perry v. Novartis Pharmaceutical Corp., 2006 WL 2979388 (E.D. Pa. 2006).

[39] *See, e.g., Colacicco*, 432 F. Supp. 2d at 526-28.

[40] *See* Ted R. Miller & Eduard Zaloshnja, Nat'l Conference of State Legislatures, Roof-Crush Standards: Costs to States of NHTSA Proposed Rule 2, 6 (Mar. 2006), *available at* http://www.ncsl.org/print/press/060406RoofCrush.pdf.

[41] The most common injury caused by the Dalkon Shield was pelvic inflammatory disease, which killed 18 women in the United States and prevented others from being able to have children. Russell Mokhiber, *The Dalkon Shield: A Deadly Product from A.H. Robins*, Multinat'l Monitor, Apr. 1987. 66,000 of the estimated 110,000 women who became pregnant while the Shield was implanted (the device was not nearly as effective as the company claimed) miscarried, mostly from spontaneous abortions, including septic spontaneous abortions (i.e., the result of infections). *Id.* Other women had stillborn children or children with birth defects. In addition to infections, women also suffered from pain and bleeding and perforation of the uterus. *Id.*

[42] Waxman Letter, *supra* note 24.

[43] Andrew Pollack, *$4.9 Billion Jury Verdict in G.M. Fuel Tank Case*, N.Y. Times, July 10, 1999.

[44] *See id.*; *see also* David C. Vladeck, *Defending Courts: A Brief Rejoinder to Professors Fried and Rosenberg*, 31 Seton Hall L. Rev., 631, 638 (2001).

[45] *See* Vladeck, *supra* note 43; Pollack, *supra* note 42.

[46] Pollack, *supra* note 42.

[47] C. Stephen Redhead, Cong. Research Serv., *Tobacco Master Settlement Agreement (1998): Overview, Implementation by States, and Congressional Issues* 10, (updated Nov. 5, 1999, code RL30058), *available at* http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL30058.pdf.

[48] Vladeck, *supra* note 43, at 633.

[49] *See* William Haltom & Michael McCann, Distorting the Law: Politics, Media, and the Litigation Crisis 237-39 (2004); Graham E. Kelder, Jr. & Richard A. Daynard, *The Role of Litigation in the Effective Control of the Sale and Use of Tobacco*, 8 Stan. L. & Pol'y Rev. 76-80 (1997).

[50] *See generally* David Kessler, A Question of Intent: A Great Battle with A Deadly Industry (2001).

[51] *See* Thomas O. McGarity, Ctr. for Progressive Reform, *MTBE and the Need for Effective Tort Law* (March 2005) *available at* http://www.progressivereform.org/articles/MTBE_506.pdf.

[52] Levin & Miller, *supra* note 13.

[53] *Id.*

[54] Mulkern, *supra* note 8.

[55] *See* Press Release, FDA, Statement of Dr. Lester M. Crawford, Acting Commissioner of Food and Drugs on the Resignation of Daniel E. Troy, http://www.fda.gov/bbs/topics/news/2004/NEW01135.html (Nov. 16, 2004).

[56] *See* Website of Sidley Austin, L.L.P., *Our Professionals: Daniel E. Troy: Partner*, *at* http://www.sidley.com/lawyers/bio.asp?ID=T314447880 (last visited Nov. 22, 2006).

[57] Dan Zegart, *The Right Wing's Drive for 'Tort Reform'*, The Nation, Oct. 25, 2004, at 15.

[58] Mayer, *supra*, note 28.

[59] Jerry Avorn & William Shrank, *Highlights and a Hidden Hazard—The FDA's New Labeling Regulations*, 354 New Eng. J. Med. 2409 (June 8, 2006).

[60] *See* Frank Sloan et al., Suing for Medical Malpractice 17-30 (1993) (study of Florida malpractice cases involving serious injuries found that jury negligence determinations tended to be the same as that of the independent physician experts whom the insurers consulted for purposes of honestly evaluating their chances of prevailing at trial); Henry Farber & Michelle White, *A Comparison of Formal and Informal Dispute Resolution in Medical Malpractice*, 23 J. Legal Stud. 777, 802 (1994) (study of cases against a self-insured hospital in Florida found that jury negligence determinations tended to be the same as that of the

independent physician experts retained by the insurer); Mark Taragin et al., *The Influence of Standard of Care and Severity of Injury on the Resolution of Medical Malpractice Claims*, 117 Ann. Internal Med. 780 (1992) (study of liability insurers' litigation files for medical-practice actions in New Jersey found that jury findings of whether a healthcare provider was negligent by and large tracked the determinations of the independent physician experts retained by the insurer).

[61] Union of Concerned Scientists, Voices of Scientists at the FDA: Protecting Public Health Depends on Independent Science (2006), *available at* http://www.ucsusa.org/scientific_integrity/interference/fda-scientists-survey-summary.html.

[62] As Judge Calabresi has recognized, "an agency cannot supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against preemption. *Cf. Alexander v. Sandoval*, 532 U.S. 275, 291, 121 S.Ct. 1511, 149 L.Ed.2d 517 (2001) ("Agencies may play the sorcerer's apprentice but not the sorcerer himself.")." Desiano v. Warner-Lambert & Co. 467 F.3d 85, 97 n.9 (2d Cir. 2006).

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