

Preemption of State Common Law by Federal Agency Action: Striking the Appropriate Balance that Protects Public Safety*

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I. INTRODUCTION

Perhaps no area of the law has become so controversial in recent years as federal preemption of state tort law. The personal injury bar, joined by consumer groups, is waging an all-out battle in the courts, Congress, the Executive Branch, and even the American Bar Association to eliminate federal preemption of tort claims. They argue that tort liability complements federal regulation and provides an additional needed incentive for manufacturers to design safer products. Business groups decry the unfairness of complying with detailed federal regulations and having their products scrutinized and approved for safety and effectiveness by federal agencies, only to face unpredictable and potentially conflicting liability.

Both sides, to some extent, can be perceived as driven by self interest. What may be lost in the multifront battle over preemption is that public safety can suffer when products and services are regulated in an ad hoc fashion through individual lawsuits involving unique facts and often highly sympathetic plaintiffs. Thousands of individuals who may have benefited from a drug, medical device, or other product are not in court. Standards developed and product approvals reached by experts at agencies charged with the delicate risk-benefit and risk-risk

balancing are often critical to effectively regulating products. These decisions should be given due deference.

After a brief review of the basics of preemption, this Article considers the public policy underlying preemption of common law claims by federal agency regulations. Next, the Article examines the recent development of preemption law, following two major United States Supreme Court decisions on preemption and President Barack Obama's instructions on preemption to heads of federal regulatory agencies. Finally, the Article notes that when the tension between federal regulations and state tort claims does not rise to the level of preemption, state law provides courts with discretion to consider the manufacturer's compliance as satisfying the common law standard of reasonable care and establishing that the product is not defective. The Article concludes by expressing concern that the recent rage against preemption in favor of litigation may lead to less safe products and place the public at risk.

II. THE BASICS OF PREEMPTION

The Supremacy Clause of the United States Constitution gives Congress authority to preempt any state law that conflicts with the exercise of federal power.¹

Congress sometimes provides that a federal law preempts state statutes and common law within the text of a statute, a practice known as "express preemption."² Preemption can also be implied through the purpose or structure of the federal law. The Court has recognized that "[e]ven without an express provision for preemption, we have found that state law must yield to a congressional Act."³ This occurs in two situations: when Congress intends to occupy an entire regulatory field leaving no room for state lawmaking (field preemption) or when there

1. U.S. CONST. art. VI, cl. 2. The Supremacy Clause provides:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby; any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

2. Congress also uses "savings clauses" to express its intention not to preempt state law, including tort claims. For instance, savings clauses have conveyed Congress's intent to preserve the authority of state and local governments to enact parallel requirements that may have additional remedies (e.g., consumer protection laws), to adopt additional or more stringent regulations to fit local conditions (e.g., railroad regulation), or to regulate a specific matter upon the approval of a federal agency (e.g., workplace safety).

3. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000).

is a conflict between the state and the federal law (conflict preemption).⁴ Under conflict preemption principles, a state law is preempted if the regulated party cannot comply with both the state and federal regulation.⁵

Additionally, state statutes or common law claims are preempted where, under the circumstances of a particular case, state law conflicts with federal law or “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”⁶

The Court has “held repeatedly that state laws can be pre-empted by federal regulations as well as by federal statutes.”⁷ This is because federal regulations are legally binding and developed to fulfill the purposes of Congressional legislation. The Supremacy Clause makes no distinction between types of federal laws.

Federal agencies play an important role in interpreting the preemptive effect of their own regulations. Justice Breyer has recognized that “in the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect.”⁸ The Court has recognized that “because agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretative statements, and responses to comments, we can expect that they will make their intentions clear if they intend for their regulations to be exclusive.”⁹

Courts have also accorded substantial deference to an agency finding that a state law conflicts with a federal law it administers when such findings are expressed through other informal agency actions, such as a letter to a manufacturer, state government official, or citizen group.¹⁰ In fact, the Court has instructed federal agencies that, if they

4. *Id.*

5. See *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985).

6. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); see *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869-74 (2000); *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992).

7. *Hillsborough County*, 471 U.S. at 713 (citing cases); see also *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) (“Federal regulations have no less preemptive effect than federal statutes.”).

8. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 505 (1996) (Breyer, J., concurring).

9. *Hillsborough*, 471 U.S. at 718.

10. See, e.g., *California v. Tri-Union Seafoods, LLC*, No. CGC-01-402975, CGC-04-432394, 2006 WL 1544384, at *54-56 (Cal. Super. Ct. May 11, 2006) (according deference to FDA position expressed in an informal letter issued by the agency, in response to a request from the tuna industry, that a California law requiring cans of tuna to include a warning on

find that state law claims would conflict with the accomplishment and execution of the full purposes and objectives of Congress, they need to say so in an “authoritative” manner—otherwise courts will generally not find regulatory preemption.¹¹ Moreover, it is important to note that on some occasions, federal agencies arrive at the opinion that their actions do *not* preempt state law.¹² Agency interpretations of their own regulations—whether finding or disclaiming a preemptive effect on state law—should receive the same due deference in the courts.

III. THE PUBLIC POLICY UNDERLYING PREEMPTION OF TORT LAWSUITS BY FEDERAL SAFETY REGULATIONS

Federal agencies are charged with overseeing various aspects of public safety ranging from automobile and aircraft design, to the availability of prescription drugs and medical devices, to specific workplace equipment and safety practices.

A. *Federal Agencies Are Charged by Congress with Protecting the Public*

Congress has charged federal regulators with protecting the public interest by approving practices and setting standards in a variety of industries.

For example, the National Highway Traffic Safety Administration (NHTSA) has closely researched and developed Federal Motor Vehicle Safety Standards that require vehicles to meet crashworthiness

the potential harmful effects of mercury not required by the agency was preempted because it would conflict with agency decision making and frustrate the federal objective of promoting healthy eating of fish by overexposing consumers to warnings, creating a far greater public health problem), *aff'd*, 90 Cal. Rptr. 3d 644 (Cal. Ct. App. 2009); Dowhal v. SmithKline Beecham Consumer Healthcare, 88 P.3d 1, 5-6, 9-11 (Cal. 2004) (according deference to the FDA position expressed in letters responding to an inquiry from a manufacturer and to a citizen petition finding that California law was preempted to the extent it required warnings on nicotine replacement devices that conflicted with the FDA's determination that a manufacturer could include only approved warnings).

11. *Spietsma v. Mercury Marine*, 537 U.S. 51, 66-67 (2002); *see also* *Cal. Coastal Comm'n v. Granite Rock Co.*, 480 U.S. 572, 582-84 (1987) (finding that Forest Service regulations did not preempt state law where there was no expression of such an intent in the regulations).

12. *See, e.g., N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114, 130-31 (2d Cir. 2009) (adopting the FDA stance, in an amicus brief invited by the court, that a New York City regulation requiring caloric content on restaurant menu boards was not preempted by federal nutritional labeling laws); *Frank Bros. v. Wis. Dep't of Transp.*, 409 F.3d 880, 891 (7th Cir. 2005) (giving deference to the Federal Highway Administration's opinion that the federal Davis-Bacon Act and Federal-Aid Highway Act did not preempt application of the state's prevailing wage law to truck drivers).

standards. These regulations require seatbelts, airbags, windshields, headlights, signals, door beams, roofs, steering columns, tires, door locks, latches, and hinges to meet certain safety performance standards.¹³ The FDA review and approval processes for prescription drugs and medical devices can span thousands of hours over many years.¹⁴ The National Institute for Occupational Safety and Health (NIOSH) and Mine Safety and Health Administration (MSHA) jointly test and certify nearly every aspect of the respiratory protective devices that are mandated for use in certain workplaces by the Occupational Safety and Health Administration (OSHA).¹⁵

B. The Regulatory Process, Unlike Litigation, Comprehensively Considers the Risks and Benefits of Products

Federal standards and approvals should receive strong deference in tort litigation when courts consider institutional expertise and competence in making decisions about very complex issues. In developing product safety and consumer protection regulations, government agencies evaluate scientific literature, results of tests, and the state of technological development. Agencies and their experts consider public comment from stakeholders, including consumer groups, businesses, and the general public. They then adopt safety standards and approve products and services based on their evaluations of the universe of information available. Agencies make sensitive balancing decisions as to the appropriate level of safety and consumer protection requirements. Government regulations provide clear expectations to manufacturers and employers in the design and use of products, and to service providers in their practices.

Courts and lay juries deciding individual state tort claims are not equipped to hold hearings and evaluate the wider impact of their

13. See generally 49 C.F.R. pt. 571 (2008).

14. See Henry I. Miller, *Failed FDA Reform*, REGULATION, Summer 1998, at 24 (attributing an increase in cost for new drug development and approval from \$359 million to \$500 million—in pretax 1990 dollars—between 1990 and 1993, and an increase in the time for approval from 8.1 years to 15.2 years since the 1960s to the “FDA’s regulatory zeal”); Riegel v. Medtronic, Inc., 552 U.S. 312, 318-19 (2008) (noting that the FDA spends an average of 1200 hours on each submission of a medical device application during the rigorous premarket approval process and approves a device only if it finds there is a “reasonable assurance” of the device’s “safety and effectiveness” after “weigh[ing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use” (internal quotations marks omitted)).

15. See Victor E. Schwartz, Cary Silverman & Christopher E. Appel, *Respirators to the Rescue: Why Tort Law Should Encourage, Not Deter, the Manufacture of Products that Make Us Safer*, 33 AM. J. OF TRIAL ADV. 13, 31-35 (2009).

decisions, such as the risk-benefit and risk-risk tradeoffs carefully evaluated by regulatory agencies. Rather, courts are generally confined to the issues and arguments raised by two lawyer advocates concerning a specific alleged defect in a product during a single case. The jury views only (and appropriately) the set of facts relevant to the case in controversy before the court. The tort system does not include the broad participation from which the regulatory process benefits, nor do judges and juries have the expertise or the staff of an administrative agency. Court decisions are imposed retroactively on a case-by-case basis, leaving the potential for conflicting rulings from different courts, and creating confusion and unpredictability for manufacturers, service providers, and employers.

Opponents of preemption often suggest that federal regulations merely provide “minimum standards” that can and should be supplemented by requirements imposed by state tort claims. What is a “higher” or “stricter” standard in the product liability context is often not black and white, but many shades of gray.

Nearly any product or service can be made “stronger” or “safer” in some respect. Often, measuring “safety” is a complex judgment. A product made safer for some situations, may become more dangerous in others.

A prime example of a tunnel vision view about safety occurred in the 1980s when personal injury lawyers backed by consumer groups filed claims against automobile manufacturers claiming that all cars should include passenger-side airbags. The NHTSA, however, disagreed. Studies had found that the airbag technology of the time posed an unacceptable risk of hurting or killing people, particularly “out-of-position” passengers, such as small women and young children.¹⁶ NHTSA also cautioned that mandating airbags just as

16. See, e.g., NAT’L HIGHWAY TRAFFIC ADMIN., U.S. DEP’T OF TRANSP., FOURTH REPORT TO CONGRESS, EFFECTIVENESS OF OCCUPANT PROTECTION SYSTEMS AND THEIR USE, at ii (1999), available at <http://www-nrd.nhtsa.dot.gov/Pubs/808-919.pdf> (“As of September 1, 1998, NHTSA has confirmed 90 crashes where the deployment of the passenger-side air bag resulted in 24 serious injuries, one fatal abdomen injury, and 65 fatal head or neck injuries to infants or children.”); NAT’L CTR. FOR STATISTICS & ANALYSIS SPECIAL CRASH INVESTIGATIONS, U.S. DEP’T OF TRANSP., COUNTS OF FRONTAL AIR BAG RELATED FATALITIES AND SERIOUSLY INJURED PERSONS, at ii (2001), available at <http://www-nrd.nhtsa.dot.gov/Pubs/AB0108.pdf> (finding 119 child fatalities related to airbag technology of the time); Occupant Crash Protection, 65 Fed. Reg. 30,680, 30,681 (May 12, 2000) (“While air bags are saving an increasing number of people in moderate and high speed crashes, they have occasionally caused fatalities, especially to unrestrained, out-of-position children, in relatively low speed crashes. As of April 1, 2000, NHTSA’s Special Crash Investigation (SCI) program had confirmed a total of 158 fatalities induced by the deployment of an air bag. Of that total, 92 were children, 60 were drivers, and 6 were adult

seatbelt usage was slowly gaining public acceptance could lead passengers to abandon seatbelts and rely solely on airbags, a far more dangerous alternative. The personal injury bar, ignoring NHTSA's judgment, filed lawsuits based on the theory that all cars should have airbags. Fortunately, the Court found that NHTSA regulations preempted such lawsuits.¹⁷ Not only did preemption likely save lives, especially of young children, but it likely averted a disaster that would have irreparably damaged public acceptance of airbags and possibly delayed for many years the implementation of safer designs. It was not until the 1990s that technological advances and public education about airbags had reduced the inherent risks of airbags to an acceptable level, and NHTSA required manufacturers to install them in all vehicles.

Such conflicts may also come into play in workplace safety regulations. For example, OSHA regulations require forklifts to include only an operator-controlled horn and provide that other devices to alert those who might be struck by the vehicle are to be installed only if the employer/customer finds a need dependent upon the intended area of use. This is because in some work environments, such devices may actually distract and endanger workers. Yet, after workplace accidents, lawyers have argued that forklift manufacturers should have installed additional audio or visual alarms. Courts have found such claims preempted, finding that they are in direct conflict with the purpose behind the OSHA regulations, that is, to protect employees by allowing end users of the product to determine which safety device would be the most effective in a particular situation.¹⁸

Also, requiring additional or "stronger" warnings on certain products may have the undesirable effect of distracting consumers, workers, or patients from warnings of more significant potential

passengers. An additional 38 fatalities were under investigation by SCI on that date, but they had not been confirmed as having been induced by air bags.").

17. See *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881 (2000). *Gade* presents another example of conflict preemption. In *Gade*, Illinois attempted to require licensing of hazardous equipment operators and laborers. The Court found that "Congress intended to subject employers and employees to only one set of regulations, be it federal or state, and that the only way a State may regulate an OSHA-regulated occupational safety and health issue is pursuant to an approved state plan that displaces the federal standards." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 99 (1992). The Court repeatedly emphasized the need for uniformity of occupational safety and health standards and avoidance of duplicity. Ultimately, the Court found that even if both the federal and state standards promote worker safety, the state standard is preempted if it interferes with the federal regulation. *Id.* at 102-03.

18. See, e.g., *Gonzalez v. Ideal Tile Imp. Co.*, 877 A.2d 1247, 1253 (N.J. 2005); *Arnoldy v. Forklift*, 927 A.2d 257, 266 (Pa. Super. Ct. 2007); *Kiak v. Crown Equip. Corp.*, No. 3340, 2008 WL 2090791 at *5 (Pa. Ct. Com. Pl. Phila. Feb. 29, 2008).

harms.¹⁹ Warnings that are not scientifically supported can deter use of beneficial products. For instance, requiring antidepressant drug packaging to warn of an increased risk of suicidality could discourage its use, and have precisely the opposite effect.²⁰

Even when incorporation of a safety device would increase a product's overall safety, in some cases, adding the extra device may not be financially practical or desirable for the consumer. For example, if the addition of a safety device would significantly increase the cost of the product, then consumers might either be unable to afford to purchase it or believe that the nominal reduction in the risk of injury does not warrant the higher price. These consumers might be drawn to purchase a less safe product of a competitor.

Government agencies are in the best position to engage in this type of balancing when they set regulatory safety standards. They take a holistic approach to product safety, which cannot be duplicated or replaced by litigation in individual cases.

IV. THE STATE OF PREEMPTION LAW

In the past several years, there has been significant debate over the scope of preemption in a variety of federally regulated areas, most notably, prescription drugs and medical devices granted approval by the FDA. Preemption has led to substantial litigation, presidential action, and legislation. In addition, an American Bar Association (ABA) task force is currently evaluating whether the organization that represents members of the legal profession should alter any of its previous positions or adopt new policies related to preemption. Overall, while the preemption landscape has changed significantly in recent years, the fundamental principles and policy underlying preemption have not.

A. *Regulatory Preemption in the Courts*

The Supreme Court recently decided two key cases on preemption—one finding preemption and the other finding no preemption of state tort claims. The cases are *Riegel v. Medtronic* and *Wyeth v. Levine*. What do these decisions mean for the future development of preemption law?

19. Victor E. Schwartz & Russell W. Driver, *Warnings in the Workplace: The Need for a Synthesis of Law and Communication Theory*, 52 U. CIN. L. REV. 38 (1983).

20. See *infra* note 41 and accompanying text.

1. *Riegel v. Medtronic*: The Sound Public Policy Behind Preemption

In 2008, the Supreme Court issued an eight-to-one ruling in *Riegel*, which addressed whether the Medical Device Amendments Act of 1976 (MDA) preempted state products liability lawsuits claiming that the design of a medical device is defective, even when approved by the FDA.²¹ The Court principally decided the case through its interpretation of an express preemption provision in the MDA that instructs that states may not maintain device requirements “different from, or in addition to” the FDA’s requirements.²²

The broader significance of *Riegel*, which extends beyond the context of medical devices, is the Court’s recognition of the sound public policy supporting preemption of tort claims. Specifically, the Court expressed the value of a definitive, uniform approval process unencumbered by the potentially varying and inconsistent interpretations of juries across fifty states.²³ The Court appreciated that a jury evaluating a product such as a medical device “sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.”²⁴ The majority also recognized the careful cost-benefit analysis undertaken by government regulators and the delicacy of their decision making, asking rhetorically, “How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm?”²⁵

Such public policy considerations helped the Court conclude that the federal government’s approval and certification process for medical devices preempts state common law claims. As the Court explained, allowing a state tort action here would “disrupt[] the federal scheme no less than state regulatory law to the same effect.”²⁶

2. *Wyeth v. Levine*: Federal Law Does Not Broadly Preempt All Lawsuits Challenging the Labeling of Prescription Drugs

Within a year of finding that federal law expressly preempted tort claims challenging FDA-approved medical devices, the Court

21. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

22. *Id.* at 321 (quoting the Medical Devices Amendments Act of 1976, 21 U.S.C. § 360(K)(a)(1) (1976)).

23. *See id.* at 326.

24. *Id.* at 325.

25. *Id.*

26. *Id.*

considered the scope of preemption in claims involving FDA-approved prescription drugs. *Levine* considered whether the labeling of the antinausea drug Phenergan adequately warned of the risk of gangrene when injected directly into the patient's vein rather than through a safer IV-drip method.²⁷ Wyeth and the FDA had corresponded repeatedly over decades regarding the drug's label and, even though Wyeth had submitted labeling regarding the risk at issue, the FDA eventually instructed Wyeth to retain the current label. The labeling noted that the drip method was "preferable," but it did not include a specific warning on the risks of direct injection. The plaintiff, who suffered from severe migraines, received a direct injection of Phenergan to provide immediate relief for the nausea that accompanied the Demerol she received for her headache. It was her second visit to the clinic in a single day. The Phenergan was improperly injected into an artery, contrary to specific warnings. This act, which appeared to be medical malpractice, led to gangrene and ultimately the loss of her arm.²⁸ Ms. Levine was a professional musician, so this was a particularly devastating injury.

A majority of the Court did not focus on the act of malpractice in the specific case but instead focused on whether the FDA's approval of the labeling of the drug preempted the plaintiff's common law claim. In so doing, the Court considered and rejected the position of the FDA, expressed in the preamble to a final rule providing new requirements for the content and format of labeling for prescription drugs, that FDA approval preempted certain common law claims.²⁹ That rule requires new and recently approved prescription drugs to include "highlights" of the prescribing information, a table of contents for the full prescribing information, and other changes with the purpose of making it easier for health care professionals to access, read, and use prescribing information.

During the comment period, manufacturers expressed concern that the FDA's requirement that they provide brief highlights of the full labeling insert could lead to litigation that the label insufficiently warned consumers of the risks involved because certain warnings were

27. *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

28. *Id.* at 1191. There was evidence that the plaintiff's injury occurred as a result of the physician assistant's negligence in administering the drug, including ignoring other aspects of its labeling and injecting the drug into an especially risky area, which the jury did not find to be an intervening cause. *Id.* at 1193, 1226-27.

29. Requirements on Content and Format of Labelling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3921, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

not included in the highlights or were simplified so as not to provide a full understanding of the risk.³⁰ Manufacturers also raised the possibility of the potential for claims that the new labeling format demonstrated recognition by the FDA that the “old format” of the label provided an insufficient warning to consumers.³¹ Thus, prescription drugs already on the market with the “old format” label could be subjected to failure-to-warn lawsuits. The FDA’s statement on preemption was, in part, a response to those comments.³² In the preamble to the rule, the FDA specifically identified six types of tort law claims that directly conflicted with FDA decision making and could compromise patient care.³³

A 6-3 majority of the Court found that Congress, in passing the Food Drug & Cosmetic Act (FDCA), did not intend to broadly preempt all state tort law claims.³⁴ Rather, the Court concluded that “Congress took care to preserve state law” in the FDCA, which, unlike the MDA, did not expressly preempt state law.³⁵

30. *Id.* at 3933.

31. *Id.* at 3933-34.

32. These points were not raised in oral argument before the Court. *See generally Levine*, 129 S. Ct. 1187.

33. The preamble identified the following types of tort claims as preempted:

(1) Claims that a [manufacturer] breached an obligation to warn by failing to put in Highlights [required by the new rule] or otherwise emphasize any information the substance of which appears anywhere in the labeling; (2) claims that a [manufacturer] breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling, in those cases where a drug’s sponsor has used Highlights consistently with FDA draft guidance regarding the “brief summary” in direct-to-consumer advertising; (3) claims that a [manufacturer] breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the [FDA regulatory standards, i.e. over-warning]; (4) claims that a [manufacturer] breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling . . . if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had the obligation to warn); (5) claims that a [manufacturer] breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising; and (6) claims that a drug’s sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug’s label (unless FDA has made a finding that the sponsor withheld material information relating to the statement).

Requirements on Content and Format of Labelling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3935-36 (internal citations omitted).

34. *Levine*, 129 S. Ct. at 1200.

35. *Id.* at 1196.

Some commentators, perhaps hastily, questioned the continued viability of conflict and obstacle preemption following the *Levine* case. Those who suggest that the case represents the death knell for implied or agency preemption exaggerate its scope. Rather, the Court found no preemption for reasons particular to the case before it. *Levine* stands for several principles of importance to the continuing dialogue on preemption.

First, implied preemption is a fact-specific inquiry. After examining the legislative history of the FDCA, the Court found that “Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.”³⁶ In essence, the Court found that the scope of preemption asserted by the FDA went too far. Post-*Levine*, courts may continue to adopt more targeted assertions of preemption by federal agencies, particularly when the agency shows that tort claims would interfere in a specific decision made after careful balancing of risks, benefits, and public policy.

Second, courts may reduce the level of deference that they accord an agency’s interpretation of the preemptive effect of its regulations where there are procedural irregularities or the opinion represents a reversal of the agency’s prior position. In *Levine*, the Court did not provide deference to the FDA’s view on preemption expressed in a preamble to a final rule on drug labeling because it found that (1) the proposed rule explicitly stated that the rule would not have preemptive effect, but a “sweeping position” was included in the preamble of the final regulation;³⁷ and (2) the position finding preemption in the preamble was a “dramatic change” from the FDA’s previous, longstanding position. For these reasons, the Supreme Court found the FDA’s opinion was “inherently suspect.”³⁸ These procedural irregularities, not a reversal of decades of case law giving deference to agency opinions on preemption expressed through informal means, motivated the Court’s hostility toward the FDA preamble. Post-*Levine*, courts are likely to continue to accord due deference to agency positions on preemption, whether expressed through opinion letters, amicus briefs, policy statements, or regulatory preambles.

Third, conflict preemption continues to apply both within and outside the prescription drug context. In *Levine*, the Court looked to whether an impossible situation was created in which the manufacturer was not legally permitted to alter the federally approved label to

36. *Id.* at 1200.

37. *See id.* at 1201.

38. *See id.*

“strengthen” a warning. A majority of the Court found that the manufacturer was not barred from changing its label on its own, and, therefore, the manufacturer should be subject to state tort lawsuits. In cases involving injuries allegedly related to other prescription drugs, or involving other types of products, there may well be instances in which it is impossible to comply with the federal law and the alleged deficiency stated in the tort claim or where the tort claim would serve as an obstacle to accomplishment of the agency’s regulatory objectives.

3. Circumstances in Which a Preemption Defense Is Particularly Strong

Agency preemption of state law remains particularly strong in three circumstances: impossibility of compliance, irreconcilable policy conflicts, and areas of longstanding federal regulation.

a. Where It Is Impossible To Comply with Both Tort Theory and Federal Regulation

Following *Levine*, manufacturers continue to have, in appropriate situations, the ability to assert strong claims that federal regulations preempt state tort law when it is impossible to cure the deficiency alleged by the lawsuit without running afoul of the requirements of a federal agency. For example, just prior to *Levine*, the United States Court of Appeals for the Third Circuit found that the FDA’s mandating particular warnings with respect to antidepressant drugs precluded a lawsuit claiming that the manufacturer should have warned of increased adult suicidality.³⁹ In that instance, the FDA had considered and rejected several citizen petitions to include such a warning due to the lack of scientific evidence supporting such a link, expressed its opinion on preemption in an amicus brief, repeatedly approved of the drug’s labeling, and decided to include a warning for pediatric users, but not for adults.⁴⁰ A “stronger” warning may have discouraged beneficial use of the drug.⁴¹ While the Supreme Court vacated and

39. *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009); *see also Dobbs v. Wyeth Pharmas.*, 530 F. Supp. 2d 1275 (W.D. Okla. 2008) (same).

40. *See Colacicco*, 521 F.3d at 269-70.

41. For example, after the FDA required pharmaceutical companies to include a prominent “black box” warning indicating an increased risk of suicidality in children taking such drugs, prescriptions declined and child suicide rates spiked, reversing a decade of progress. *See, e.g.*, Laurence Y. Katz et al., *Effect of Regulatory Warnings on Antidepressant Prescription Rates, Use of Health Services and Outcomes Among Children, Adolescents and Young Adults*, 178 CAN. MED. ASSOC. J. 1005 (2008); Robert D. Gibbons et al., *Early Evidence on the Effects of Regulators’ Suicidality Warnings on SSRI Prescriptions and*

remanded the 2008 decision for further consideration in light of *Levine*, there is a significant possibility that the Third Circuit will reaffirm its earlier conclusion.⁴²

b. Where There Is an Irreconcilable Policy Conflict

In some cases, the action sought by tort lawsuits would interfere in a federal agency's ability to achieve a public policy goal. As in the earlier case involving airbag requirements, automobile design regulations also provide a source of a more recent example of such a policy conflict.

At the time of manufacture, a specific Federal Motor Vehicle Safety Standard (FMVSS) required manufacturers to install either a lap-only seat belt or a lap/shoulder belt in the rear center position where the decedent was seated. Nevertheless, a manufacturer faced a lawsuit by survivors of a passenger killed in a collision while wearing a lap-only seat belt. The plaintiffs claimed that the vehicle's passive restraint system was defectively designed and that the manufacturer failed to warn of the danger. The United States Court of Appeals for the Fifth Circuit affirmed a district court decision dismissing tort claims against an automobile manufacturer based on the preemptive effect of compliance with the FMVSS.⁴³ The court found that that history of the FMVSS indicated that the agency's decision to provide manufacturers with options was "deliberate and for specific policy reasons."⁴⁴

More recently, post-*Levine*, the D.C. Court of Appeals applied conflict preemption to preclude tort claims against cell phone manufacturers alleging that radiation from cell phones that met the Federal Communications Commission's (FCC) Radio Frequency radiation standard injured consumers.⁴⁵ The court noted that, during

Suicide in Children and Adolescents, 164 AM. J. PSYCHIATRY 1356 (2007); Jeffrey A. Bridge et al., *Suicide Trends Among Youths Aged 10 to 19 Years in the United States, 1996-2005*, 300 JAMA 1025 (2008); K.M. Lubell et al., *Suicide Trends Among Youths and Young Adults Aged 10-24 Years—United States, 1990-2004*, 56 MORBIDITY & MORTALITY WKLY. REP. 905 (2007); M.E. Schneider, *Sustained Rise in Youth Suicide Sparks Call for Data*, CLINICAL PSYCHIATRY NEWS 4 (Oct. 2008).

42. *But cf.* *Mason v. Smithkline Beecham Corp.*, No. 08-2265, 2010 WL 605922 (7th Cir. Feb. 23, 2010) (declining to find that that FDA would have rejected a label change warning of increased risk of suicide by young adults at the time of the plaintiff's suicide because facts did not reach the level of "clear evidence" required for preemption by *Levine*).

43. *Carden v. Gen. Motors Corp.*, 509 F.3d 227 (5th Cir. 2007), *cert. denied*, 128 S. Ct. 2911 (2008).

44. *Id.* at 232.

45. *See Murray v. Motorola, Inc.*, 982 A.2d 764 (D.C. 2009).

the rulemaking process, the FCC carefully considered over 150 sets of comments, extensively consulted with all of the relevant health and safety agencies, and found no reliable scientific evidence of health risks from cellular phone radiation.⁴⁶ The court gave deference to the agency view, expressed in an *amicus* brief, that verdicts holding manufacturers liable for approved levels of radiation emanating from FCC-certified cell phones “would necessarily upset the balance the agency struck and contravene the policy judgments of the FCC regarding how safely and efficiently to promote wireless communication.”⁴⁷ In such circumstances, effectively lowering the FCC’s standard through litigation would stand as an obstacle to the federal goal of meeting consumer demand for wireless telecommunications services with lower costs and a greater range of options.⁴⁸

c. In Areas of Longstanding Federal Regulation

The Court has found a “presumption against . . . pre-emption” that is particularly applicable where Congress has legislated “in a field which the States have traditionally occupied” and areas involving the “historic police powers of the States.”⁴⁹ On the other hand, there are several areas that federal law has closely regulated for decades. These diverse areas range from railroads to financial services. In these instances, the presumption against preemption fades away. When state law creates tension with traditional federal regulations, courts are more prone to find preemption in these areas.

For example, the United States Court of Appeals for the Sixth Circuit has found that the National Bank Act and regulations promulgated by the Office of the Controller of the Currency preempt conflicting state banking laws concerning operating subsidiaries of nationally chartered banks.⁵⁰ In so doing, the Sixth Circuit recognized that the presumption against preemption in areas typically left to the

46. *Id.* at 775.

47. *Id.* at 777 (internal quotation marks and alterations omitted).

48. *Id.* at 776.

49. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (citations omitted). A substantial minority of the Court has also found that the presumption against preemption “dissolves” where Congress has expressly provided for preemption in legislation because there is conclusive evidence of intent to preempt in the express words of the statute itself. *See Altria Group v. Good*, 129 S. Ct. 538, 555-58 (2008) (Thomas, J., dissenting) (citing cases in which the court has not raised a presumption against preemption).

50. *Wachovia Bank, N.A. v. Watters*, 431 F.3d 556 (6th Cir. 2005), *aff’d*, 550 U.S. 1 (2007).

states “disappears . . . in fields of regulation that have been substantially occupied by federal authority for an extended period of time,” and it provided significant deference to the Commissioner’s opinion on preemption expressed in a regulation.⁵¹ This ruling was affirmed in 2007 by the Supreme Court, suggesting preemption may be important in this area, especially as Congress takes an increasing role in regulating the financial services industry.

This reasoning not only applies to state statutes and regulations but also to common law claims. For instance, the United States Court of Appeals for the Ninth Circuit found that federal law preempted a class action lawsuit alleging E*Trade’s policy not to refund lock-in fees after mortgage applicants cancelled the transaction within the three-day window prescribed by the Truth in Lending Act constituted false advertising under California law.⁵² The court recognized that “[b]ecause there has been a history of significant federal presence in national banking, the presumption against preemption of state law is inapplicable.”⁵³ Thus, the court found that a federal Office of Thrift Supervision regulation governing federal savings associations promulgated under the Home Owners’ Loan Act (HOLA) preempted the entire field of lending regulation.⁵⁴

B. Regulatory Preemption in the Executive Branch

While preemption issues have advanced in the courts, the issue also drew the attention of the executive branch. In May 2009, the Obama Administration issued a memorandum to the heads of all Executive departments and agencies providing guiding principles on preemption.⁵⁵ The memorandum, which is not law, but rather a statement of Administration policy, directs federal officials to assert preemption under their own regulations only after “full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption.”⁵⁶ The memorandum appears to be a direct response to a substantial lobbying effort by the plaintiffs’ bar and its

51. *Id.* at 560 n.3 (quoting *Flagg v. Yonkers Sav. & Loan Ass’n*, 396 F.3d 178, 183 (2d Cir. 2005)).

52. *Silvas v. E*Trade Mortgage Corp.*, 514 F.3d 1001, 1004 (9th Cir. 2008).

53. *Id.* at 1005 (quoting *Bank of Am. v. City & County of S.F.*, 309 F.3d 551, 559 (9th Cir. 2002)).

54. *Id.* at 1008.

55. See Memorandum from President Obama and The White House Office of the Press Secretary to the Heads of Executive Departments and Agencies (May 20, 2009), http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/.

56. *Id.*

allies that began even before the new President took office.⁵⁷ The plaintiffs' lawyers' efforts were in response to the perceived "excesses" of the prior administration in the area of preemption.

Specifically, the memorandum instructs department and agency heads to not use regulatory preambles to state the department or agency's intention to preempt state law except where the preemption provision is included in the codified regulation. To many knowledgeable observers, this statement is a response to the view that some federal agencies have used regulatory preambles to reverse longstanding positions without appropriate opportunity for notice and comment of all interested and affected parties.

In addition, the memorandum instructs departments and agencies to refrain from including preemption provisions in codified regulations, except where justified under traditional preemption principles and an Executive Order issued by President Bill Clinton respecting federalism.⁵⁸ Again, this policy is meant to temper agencies from inappropriately applying preemption where it is not legally supported or from unnecessarily intruding into areas traditionally regulated by state law.

Finally, the memorandum directs federal departments and agencies to review regulations issued within the past ten years that contain statements of preemption to ensure that such statements are justified under traditional legal principles.⁵⁹

The Obama Administration's approach does not go as far as that sought by the Center for Progressive Reform. The Center for

57. See Letter from Nan Aron, President, Alliance for Justice, to Peter Orszag & Cass Sunstein, Executive Office of the President-Elect (Jan. 13, 2009), http://www.citizen.org/documents/Preemption_letter_to_orszag_sunstein_20090114.pdf (signed by fifteen groups including the American Association for Justice and providing as an attachment a draft Executive Order amending Executive Order 13132 on Federalism); AM. ASS'N FOR JUST., TRANSITION NOTEBOOK—EXECUTIVE SUMMARY, available at http://change.gov/page/-/open%20government/yourseatatthetable/20081211_TransitionMemo.pdf (last visited Mar. 26, 2010) (submitted to Obama-Biden Transition Project and focusing entirely on preemption issues, including a recommended executive order, and attaching Center for Progressive Reform report among supporting materials); see also WILLIAM FUNK ET AL., CTR. FOR PROGRESSIVE REFORM, LIMITING FEDERAL AGENCY PREEMPTION: RECOMMENDATIONS FOR A NEW FEDERALISM EXECUTIVE ORDER (2008), available at http://www.progressivereform.org/articles/ExecOrder_Preemption_809.pdf; REBECCA M. BRATSPIES ET AL., CTR. FOR PROGRESSIVE REFORM, PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT BY THE STROKE OF A PRESIDENTIAL PEN: SEVEN EXECUTIVE ORDERS FOR THE PRESIDENT'S FIRST 100 DAYS (2008), available at http://www.progressivereform.org/CPR_ExecOrders_Stroke_of_a_Pen.pdf.

58. Memorandum, *supra* note 55; see Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999).

59. See Memorandum, *supra* note 55.

Progressive Reform's recommendations were endorsed by the American Association for Justice (AAJ), formerly the American Trial Lawyers Association (ATLA), which is the lobbying arm of the plaintiffs' bar.⁶⁰ The memorandum does not fundamentally alter preemption principles or the analysis undertaken. Rather, it instructs agencies to perform a thorough review when deciding whether their regulations should preempt state law.

Whether relying on the Executive Memorandum or prior motions for reconsideration, NHTSA has already abruptly changed course in two rulemakings in which it had found preemption necessary to protect public safety. In the first, NHTSA reversed its finding that its strengthened roof crush resistance standards preempted state law. In 2005, NHTSA carefully explained why it believed that tort claims "requiring a more stringent level of roof crush resistance for all vehicles could increase rollover propensity of many vehicles and thereby create offsetting adverse safety consequences."⁶¹ Four years later, and four months into the new Administration, NHTSA did a one hundred-eighty degree turn. In reversing its position, the agency offered a two-sentence explanation: "We have reconsidered the tentative position presented in the [Notice of Proposed Rulemaking]. We do not foresee any potential State tort requirements that might conflict with today's final rule."⁶²

More recently, NHTSA took the same approach with respect to a 2008 regulation mandating a certain number of seat belts in vehicles based on a calculation of the space available. Earlier, NHTSA cautioned that requiring more seat belts than mandated by its calculation would reduce safety because cramped seating discourages

60. CPR had urged the Administration to amend Executive Order 13132 to instruct agencies not to define the scope of implied preemption, adopt a presumption against "ceiling preemption," instruct agencies to differentiate between preemption of "positive law" (state statutes and regulations) and tort law, add a statement supporting a "vibrant tort system," require agencies to publish a written justification when deciding to preempt state law, require agencies to publish any decision to deny a state request to impose stronger regulations than required by federal law, and charge the Office of Management and Budget or another agency with responsibility to police each agency rule for compliance with the Executive Order's provisions on preemption. *See Funk, supra* note 57. The Obama Memorandum is more closely modeled on the January 13, 2009, letter, *supra* note 57, except that it was issued as a memorandum to agency heads rather than an Executive Order that would continue into future administrations unless revoked.

61. Roof Crush Resistance, 70 Fed. Reg. 49,223, 49,245-46 (proposed Aug. 23, 2005).

62. Roof Crush Resistance; Phase-In Reporting Requirements, 74 Fed. Reg. 22,348, 22,349 (May 12, 2009) (to be codified at 49 C.F.R. pts. 571, 585).

the use of seatbelts by everyone.⁶³ Nevertheless, future tort claims could assert that particular cars are defective because they should have included more seatbelts than mandated by NHTSA. For that reason, NHTSA found such claims should be preempted. In response to a petition filed by AAJ,⁶⁴ just thirteen months later, NHTSA reversed its position.⁶⁵ The agency's explanation for this turn was only that it later found such conflicts "unlikely," speculating that manufacturers would reduce seat width or install an impediment or void in vehicles rather than undertake the additional expenses of providing an additional seat belt.⁶⁶

While the petitions leading to the NHTSA reversals preceded the President's Memorandum, other agencies have done an about face based on the review the Memorandum requires.⁶⁷

Regardless of the merits of whether preemption should or should not apply in such instances, it is disconcerting that agencies have reversed positions related to public health and safety so quickly, casually, and with little explanation. Even while antipreemption advocates urge agencies to carefully develop their positions on preemption to ensure adequate notice and comment, and sufficient legal authority, agencies have summarily reversed well-developed positions. As this Article explains, tort lawsuits, with random and varied results, do not always increase public safety. They can create confusion in regulatory obligations, trade one risk for a greater risk, or lead consumers to ignore important warnings that are buried in fine print. When considering whether a regulation preempts state tort law, agencies should consider these aspects and not overly defer to the positions of those whose interests are in increased litigation.

63. See Designated Seating Positions and Seat Belt Assembly Anchorages, 73 Fed. Reg. 58,887 (Oct. 8, 2008).

64. Letter from Les Weisbrod, President, Am. Ass'n for Justice et al., to David Kelly, Acting Adm'r, Nat'l Highway Traffic Safety Admin. (Nov. 24, 2008), *available at* http://www.aplanet.org/resources/NHTSA_dsp_petition.pdf (regarding petition to reconsider final rule and requesting that NHTSA remove language supporting preemption from the preamble and rule text).

65. Designated Seating Positions, 74 Fed. Reg. 68,185 (Dec. 23, 2009).

66. *Id.* at 68,188.

67. See, e.g., Refuge Alternatives for Underground Coal Mines, 74 Fed. Reg. 61,531 (Nov. 25, 2009) (rescinding a portion of the agency's intent stated in the preamble to the rule issued in 2008 concerning preemption of tort claims with respect to the agency's approval of specifications for a refuge alternative that requires that coal mine operators provide an environment that can sustain miners unable to escape during an underground emergency for as long as 96 hours, as "at best, interpretive guidance").

C. Consideration of Preemption by Congress

Efforts to eliminate preemption have also reached the U.S. Congress. In the Consumer Product Safety Improvement Act of 2008 (CPSIA), Congress took the unprecedented step of effectively placing a gag order on the Consumer Product Safety Commission (CPSC).⁶⁸ The CPSIA, which reauthorized and strengthened the CPSC, prohibits the CPSC from asserting preemption or expressing an interpretation of the preemptive effect of its rules or regulations, particularly with respect to common law or statutory law providing for damages.⁶⁹ Such language, which may be incorporated into legislation affecting additional agencies, will deprive courts of guidance that they come to expect from the entity in the best position to understand whether federal health and safety objectives would be impeded by application of inconsistent state tort claims.

Currently, legislation pending before the Congress would overturn the Court's well-reasoned decision in *Riegel*. The Medical Device Safety Act would strike the express preemption clause of the Medical Device Amendments of 1976, and instead have state courts throughout the nation make decisions on the safety of medical devices in an ad hoc manner in individual cases.⁷⁰ In effect, a lay jury in a single case with a bad outcome would have the ability to overturn 1200 hours of review by experts at the FDA. Such a lawsuit could jeopardize the availability of needed treatments for those whom it could benefit and discourage innovation of future potentially life-saving devices. The plaintiffs' bar allocated a significant portion of its \$4.6 million annual lobbying budget and staff toward advancing this bill in 2009 and can be expected to continue to do so this year.⁷¹

D. American Bar Association Policy on Preemption

The American Bar Association (ABA) has also been drawn into the current preemption debate. Historically, the ABA has taken a measured approach to preemption. In the early 1980s, the ABA opposed legislation that would have broadly preempted the product

68. See Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, § 231(a), 122 Stat. 3016, 3070 (codified at 15 U.S.C. § 2051 note).

69. See *id.*

70. H.R. 1346, 111th Cong. (2009); S. 540, 111th Cong. (2009).

71. See Lobbying Spending Database—American Ass'n for Justice, 2009, http://www.opensecrets.org/lobby/client_reports.php?lname=American+Assn+for+Justice&year=2009 (last visited Mar. 5, 2010).

liability laws of the fifty states.⁷² The ABA has supported federal asbestos litigation reform that would preempt common law claims,⁷³ while expressing concern for principles of federalism in opposing federal legislation that would abolish strict seller liability.⁷⁴ By and large, the ABA has followed the reasonable policy embodied in a 1988 resolution, which focuses on the need for Congress and federal agencies to clearly communicate their intention to preempt state law through their statutes or regulations to affected states and to the courts.⁷⁵ The report accompanying the 1988 resolution expressed the sound principle that the ABA will “not address substantive questions concerning the desirability of Federal preemption in general or in particular regulatory contexts.”⁷⁶

In 2006, the ABA considered and opted not to reverse this longstanding policy on preemption when a recommendation of the Tort Trial and Insurance Practice Section (TIPS) failed to move forward in the House of Delegates.⁷⁷ That resolution would have categorically opposed preemption of state or consumer protection laws by federal agencies.⁷⁸

72. B.C. HART, SECTION OF TORT & INS. PRACTICE, A.B.A. REPORT TO THE HOUSE OF DELEGATES (1981) (opposing “enactment of legislation . . . which would impose a Model Products Liability proposal as federal law”); JOHN E. CAVANAGH & WILLIAM F. KENNEDY, SPECIAL COMM. TO STUDY PROD. LIAB., A.B.A. REPORT TO THE HOUSE OF DELEGATES (1983) (opposing “enactment of broad federal legislation that would codify the tort laws of the 50 states as they relate to product liability”).

73. CAVANAGH & KENNEDY, *supra* note 72 (supporting “federal legislation which addresses the issues of liability and damages with respect to claims for damages against manufacturers by those who contract an occupational disease” with long latency periods due to the threat of insolvency to manufacturers and excessive burden on the judicial system).

74. DAVID C. WEINER, A.B.A. RECOMMENDATION (1995) (supporting “the continued right of the states and territories to regulate product liability law” and opposing “federal legislation [abolishing] strict seller liability”).

75. ARTHUR E. BONFIELD, SECTION ADMIN. LAW, A.B.A. REPORT TO THE HOUSE OF DELEGATES (1988).

76. A.B.A., RECOMMENDATION NO. 3 OF THE SECTION OF ADMIN. LAW (Aug. 1988). The report also observed, “Federal agencies have significant institutional advantages over federal courts in determining initially whether a state action can and should be preempted by federal regulation.” *Id.* at 297. In addition, the report found that “agencies are more appropriate institutions than courts to resolve the policy questions that frequently are embedded in federalism/regulation controversies,” given their political accountability, statutory authority, and congressional and executive oversight. *Id.* Finally, the report recognized that judicial review provides a check on federal agency preemption to ensure its action has appropriate legal authority. *Id.* at 297-98.

77. SANDRA R. McCANDLESS, TORT TRIAL & INS. PRACTICE SECTION, A.B.A., REPORT TO THE HOUSE OF DELEGATES (2006) (Resolution No. 103).

78. *Id.* (“RESOLVED, That, absent Congressional authorization, the American Bar Association opposes the promulgation by federal agencies of rules or regulations that pre-

In December 2008, then-ABA President H. Thomas Wells, Jr. interpreted these ABA policies as providing him with sufficient authority to urge Congress to reintroduce legislation that would overturn the Court's preemption decision in *Riegel*.⁷⁹ Although his letter purported to speak on behalf of 400,000 members of the ABA, no ABA committee or subcommittee considered such a position, nor did the ABA's House of Delegates vote upon the issue at its 2008 annual meeting,⁸⁰ which occurred several months after the Court's decision.⁸¹

The resulting controversy regarding whether President Wells had appropriately interpreted existing ABA policy led to creation of an ABA task force on federal agency preemption in early 2009.⁸² This

empt state tort and consumer protection laws in instances where the state laws hold parties to a higher or stricter standard than that being promulgated by a federal agency.”).

79. Letter from H. Thomas Wells, Jr., President, A.B.A., to Rep. Frank Pallone, Jr., Chairman, Subcomm. on Health, Comm. on Energy & Commerce, U.S. House of Representatives (Dec. 29, 2008), *available at* http://www.abanet.org/poladv/letters/tortlaw/2008dec29_medicaldeviceh_1.pdf; Letter from H. Thomas Wells, Jr., President, A.B.A., to Sen. Edward M. Kennedy, Chairman, Comm. on Health, Educ., Labor, and Pensions, U.S. Senate (Dec. 29, 2008), *available at* http://www.abanet.org/poladv/letters/tortlaw/2008dec29_medicaldevices_1.pdf.

80. The House of Delegates considered and adopted several recommendations to Congress on issues related to access to courts and medical liability during the annual meeting, but not the Medical Device Safety Act. *See, e.g.*, PAULETTE CHAPMAN, A.B.A., RECOMMENDATION 10B (2008) (urging “Congress to examine the ‘incident to service’ exception to the Federal Tort Claims Act . . . created by the Supreme Court” and urging certain amendments); JOSEPH D. O’CONNOR, A.B.A., RECOMMENDATION 103 (2008) (urging Congress to establish and support decision-making protocols to ensure that the wishes, including those expressed in any prior advance directive, of those who have “advanced chronic progressive illnesses are appropriately translated into visible and portable medical orders”); JANICE MULLIGAN, A.B.A., RECOMMENDATION 115 (2008) (urging Congress to adopt legislation establishing “pilot programs that enable and encourage medical personnel to report hospital events which, if repeated, could threaten patient safety”); ROBYN SHAPIRO, A.B.A., RECOMMENDATION 117A (2008) (urging “Congress to support quality and accessible justice by ensuring adequate, stable, long-term funding for tribal justice systems”).

81. The December 29, 2008, letters state that federal legislation to overturn *Riegel* is “consistent with ABA policy supporting the continued right of the states and territories to regulate product liability law with discrete exceptions.” Letter from H. Thomas Wells to Sen. Kennedy, *supra* note 79. There is a fundamental difference, on the one hand, between the ABA’s opposition in 1983 to “enactment of broad federal legislation that would codify the tort laws of the 50 states as they relate to product liability,” and narrow opposition to product-seller liability reform, and, on the other hand, support for overturning a Court decision that ruled on the application in the specific context of FDA-approved medical devices. CAVANAUGH & KENNEDY, *supra* note 72.

82. *See* Letter from Mark E. Williams, President, Def. Research Inst., to H. Thomas Wells, President, A.B.A. (Mar. 17, 2009), *available at* <http://dri.org/dri/webdocs/DRI%20letter%203-17-09.pdf> (requesting withdrawal of the letter on behalf of DRI’s 23,000 members, many of whom are also members of the ABA); Quin Hillyer, Editorial, *ABA Policy Could Be Horrible Medicine*, WASH. EXAMINER, Feb. 10, 2009, *available at* <http://www>.

task force was initially composed of twelve members and later expanded to include an additional three members by ABA President Carolyn Lamm. Its purpose is to review existing ABA policy regarding federal preemption of state tort laws and recommend an update or amendment to ABA policy, if necessary.

As the task force completes its report and recommendation, it has wisely taken an approach that, consistent with the 1988 ABA policy, emphasizes procedural aspects of preemption by federal agencies (as well as by Congress). To its credit, thus far, the task force has not suggested that the House of Delegates adopt a policy that weighs in for or against preemption in general or in any particular area of the law.⁸³ Rather than taking a substantive position on which its members, who encompass both plaintiffs' and defense lawyers, are divided, the task force seems to be focused on process. It will likely recommend adoption of a resolution at a meeting of the House of Delegates later this year.

V. PREEMPTION IS NOT THE END OF THE INQUIRY

Preemption is often expressed as an issue of federalism. There may be understandable backlash from state courts who might feel that decisions made by federal agencies should not tie their hands to decide common law claims. What should not be overlooked is that regardless of preemption, state court judges (and legislators) have the ability to consider a manufacturer or other party's compliance with government regulations as fulfilling the standard of care, or supporting a presumption that a product is not defective.

For instance, a court may find in a specific case that the level of tension between a federal regulation or objective and a state tort claim does not rise to the level that requires preemption. Such a finding, however, is not the end of the inquiry as to whether a manufacturer or other defendant that met federal safety standards, or whose product was specifically approved or certified by a federal agency, should be subject to tort liability. State common law, statutes, and public policy considerations then come into play.

washingtonexaminer.com/opinion/columns/QuinHillyer/ABA-policy-could-be-horrible-medicine-39358237.html.

83. The task force's draft resolution and report neither endorses nor repudiates former President Wells' letter in support of the Medical Device Safety Act.

A. Regulatory Compliance May Fulfill the Common Law Standard of Care

When federal preemption does not apply, product liability claims are subject to state law and state standards of care. Most courts consider compliance with government standards as a factor for the jury in determining whether or not a product is unreasonably dangerous.⁸⁴ Some of these courts reason that government regulations provide only “minimum standards” and, therefore, are not dispositive.⁸⁵ On the other hand, most jurisdictions consider violation of a safety regulation as evidence that a product is defective as a matter of law, but the same jurisdictions do not accord evidence of compliance with government regulations similarly deferential treatment.⁸⁶

In other cases, courts have accorded weight to government safety standards and approvals, even if they find compliance is not conclusive of whether liability should be imposed.⁸⁷ Courts occasionally find that meeting a safety standard set by government regulations precludes tort liability.⁸⁸ For example, Maryland’s highest court has recognized that “where no special circumstances require extra caution, a court may find that conformity to the statutory standard amounts to due care as a matter of law.”⁸⁹ Courts frequently cite compliance with safety regulations as a factor used to justify a directed verdict for a defendant.⁹⁰

84. See RESTatement (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. d (1998); see also Richard C. Ausness, *The Case for a “Strong” Regulatory Compliance Defense*, 55 MD. L. REV. 1210, 1241 (1996) (“[M]ost courts agree that federal safety regulations are relevant evidence in products liability cases.”).

85. See Ausness, *supra* note 84, at 1241-47 (providing examples of cases in which courts gave little weight to federal safety regulations spanning a variety of areas, such as flammability standards for clothing, pesticide warnings, automobile design, prescription drug warnings, aircraft design, and workplace safety standards).

86. See *id.*

87. See, e.g., Sims v. Washex Mach. Corp., 932 S.W.2d 559, 565 (Tex. App. 1995) (“Compliance with government regulations is strong evidence, although not conclusive, that a machine was not defectively designed.”).

88. See, e.g., Lorenz v. Celotex Corp., 896 F.2d 148, 150-51 (5th Cir. 1990) (finding that compliance with safety regulation is strong and substantial evidence of lack of defect); Ramirez v. Plough, Inc., 863 P.2d 167, 176 (Cal. 1993) (“[T]he prudent course is to adopt for tort purposes the existing legislative and administrative standard of care . . .”); Dentson v. Eddins & Lee Bus Sales, Inc., 491 So. 2d 942, 944 (Ala. 1986) (ruling that when the legislature has not required seatbelts, a school bus that is not equipped with seatbelts is not defective).

89. Beatty v. Trailmaster Prods., Inc., 625 A.2d 1005, 1014 (Md. 1993).

90. See RESTatement (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. e (1998) (citing Hawkins v. Evans Cooperage Co., 766 F.2d 904, 909 (5th Cir. 1985)).

In 1991, the American Law Institute (ALI), a well-respected organization composed of judges, lawyers, and law professors, published a Reporter's Study recommending that compliance with regulatory requirements imposed by a government agency precludes tort liability in certain situations. Under the Reporter's Study recommendation, tort liability would be precluded when (1) a legislature has placed the risk at issue under the authority of a specialized administrative agency, (2) that agency has established and periodically revises regulatory safety controls, (3) the manufacturer or other entity complied with the relevant regulatory standards, and (4) the manufacturer or other entity disclosed to the agency any material information in its possession or of which it has reason to be aware concerning the products' risks and means of controlling them.⁹¹

Ultimately, the ALI officially incorporated a similar approach into the Restatement Third, Products Liability. The Restatement Third, Products Liability says that a product should not be considered defective as a matter of law

- when the safety statute or regulation was promulgated recently, thus supplying currency to the standard therein established;
- when the specific standard addresses the very issue of product design or warning presented in the case before the court; and
- when the court is confident that the deliberative process by which the safety standard was established was full, fair, and thorough and reflected substantial expertise.⁹²

Conversely, the Restatement Third, Products Liability acknowledges that this liability protection would not apply "when the deliberative process that led to the safety standard . . . was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that promulgated the standard or certified or approved the product."⁹³

91. See 2 A.L.I., REPORTER'S STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 95-97 (1991); see also Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167, 2168-70 (2000).

92. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. e; see also James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure To Warn*, 65 N.Y.U. L. REV. 265, 321 (1990) ("Courts recognizing the limits of their institutional capabilities should refuse to second-guess the judgments of agencies who possess not only expertise but also a capacity for knowledge and memory which the courts cannot match."); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 335 (1985) ("Once that determination has been made by an expert licensing agency, the courts should respect it.").

93. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. e.

Cases in which the design of a product, as well as its packaging, labeling and instructions, are scrutinized and approved by a government agency, or those in which the product or service is in compliance with detailed, comprehensive standards, are particularly strong candidates for application of these established principles of state common law.

B. States Have Adopted Statutes According Manufacturers Who Comply with Regulatory Standards a Presumption Against Liability

In addition to recognition of regulatory compliance as a gauge of liability under common law, state legislatures have addressed this public policy issue by adopting statutes that respect the decision making of federal and state regulatory agencies charged with protecting public safety in tort lawsuits.

Seven states provide that compliance with federal or state government safety regulations or standards creates a rebuttable presumption that a product is not defective.⁹⁴ Courts have considered these statutes in cases involving a wide range of products, such as ladders,⁹⁵ nail guns,⁹⁶ cleaning products,⁹⁷ clothing,⁹⁸ airplanes,⁹⁹ and

94. COLO. REV. STAT. § 13-21-403(1) (2009); KAN. STAT. ANN. § 60-3304(a) (2009); KY. REV. STAT. ANN. § 411.310(2) (West 2009); MICH. COMP. LAWS ANN. § 600.2946(4) (West 2010); TENN. CODE ANN. § 29-28-104 (West 2010); TEX. CIV. PRAC. & REM. CODE ANN. § 82.008 (Vernon 2009); UTAH CODE ANN. § 78B-6-703(2) (2008). At least two additional states, Arkansas and Washington, specifically provide by statute that parties may introduce evidence of regulatory compliance to show that a product is not defective or that its warnings are not inadequate, but do not assign any particular evidentiary weight to compliance with safety standards. See ARK. CODE ANN. § 16-116-105(a) (West 2009); WASH. REV. CODE ANN. § 7.72.050(1) (West 2010).

95. *See* States v. R.D. Werner Co., 799 P.2d 427, 430-31 (Colo. App. 1990) (ruling that the trial court did not err by admitting expert testimony on a ladder's compliance with federal regulations).

96. *See* Slisze v. Stanley-Bostitch, 979 P.2d 317, 321 (Utah 1999) (ruling that federal OSHA standards regulating the design of a pneumatic nailer were admissible as government standards and established a rebuttable presumption of nondefectiveness as they provided "a legitimate source for determining the standard of reasonable care").

97. *See* Uptain v. Huntington Lab, Inc., 685 P.2d 218, 222 (Colo. App. 1984) (finding that manufacturer of a cleaning compound was entitled to presumption of nondefectiveness where an expert testified that the product label's warnings complied with federal and local laws and was approved by the Environmental Protection Agency).

98. *See* Alvarado v. J.C. Penney Co., 735 F. Supp. 371 (D. Kan. 1990) (ruling in a case involving a nightgown and robe that were ignited by a open flame gas heater that the regulatory compliance provision of the Kansas Products Liability Act did not create a conclusive presumption and thus a constitutional challenge by plaintiffs was moot).

99. *See* Champlain Enters., Inc. v. United States, 957 F. Supp. 26, 28 (N.D.N.Y. 1997) (ruling that regulatory compliance provision of the Kansas Products Liability Act would

automobiles.¹⁰⁰ The court instructs the jurors of this presumption when they consider the case.¹⁰¹

In addition, states have enacted statutes that reduce the threat of punitive damages in claims involving FDA-approved products.¹⁰² Typically, this protection does not apply if the manufacturer withheld or misrepresented material information during the approval process relevant to the claimant's injury.¹⁰³

Approximately two-thirds of state consumer protection statutes also provide a regulatory compliance defense, exempting conduct that is authorized or permitted by a state or federal government agency.¹⁰⁴

These types of laws help assure that courts allow juries to hear and appropriately consider a product's compliance with government regulations or standards when they consider whether the product is defective. They also give the jury a broader understanding of whether the manufacturer's conduct reaches a level justifying punishment. Those that provide for a rebuttable presumption assure that the jury will receive a specific instruction emphasizing the importance of considering the manufacturer's compliance with government safety standards in determining whether a product was unreasonably dangerous.

provide airplane manufacturer with a defense against liability if it established that the aircraft complied with government safety standards unless the plaintiff showed that "a reasonable prudent product seller could and would have taken additional precautions").

100. See *Brand v. Mazda Motor Corp.*, 978 F. Supp. 1382, 1393 (D. Kan. 1997) (ruling that automobile manufacturer's compliance with federal regulatory standards was not dispositive of liability or punitive damages absent clear and convincing evidence that the manufacturer acted with reckless indifference to consumer safety) (citations omitted).

101. See, e.g., COLO. REV. STAT. § 13-21-403(4) (2009). Kansas law provides that a claimant may overcome the presumption by showing that "a reasonably prudent product seller could and would have taken additional precautions." KAN. STAT. ANN. § 60-3304(a) (2009). In Texas, a claimant can overcome the standard by establishing that the safety standard or regulation was inadequate to protect the public or the manufacturer withheld or misrepresented information to the agency when it was formulating the applicable standard. TEX. CIV. PRAC. & REM. CODE ANN. § 82.008(b) (Vernon 2009).

102. See ARIZ. REV. STAT. ANN. § 12-701(A) (2009) (drugs); N.J. STAT. ANN. § 2A:58C-5(c) (West 2009) (drugs, devices, food, and food additives); OHIO REV. CODE ANN. § 2307.80(C)-(D) (West 2010) (drug, device, or other product); OR. REV. STAT. § 30.927 (2009) (drug); UTAH CODE ANN. § 78B-8-203 (2008) (drug). In Michigan, a state that does not recognize punitive damages, state law provides a rebuttable presumption that limits a drug manufacturer's liability for compensatory damages in product liability actions involving FDA-approved drugs. See MICH. COMP. LAWS ANN. § 600.2946(5) (West 2010).

103. See, e.g., OR. REV. STAT. § 30.927(2).

104. See Victor E. Schwartz, Cary Silverman & Christopher E. Appel, "*That's Unfair!?" Says Who—The Government or the Litigant?: Consumer Protection Claims Involving Regulated Conduct*, 47 WASHBURN L.J. 93, 104-05 (2007).

There are significant differences between preemption and state regulatory compliance defenses, whether provided by statute or common law. Federal preemption, originating from the Supremacy Clause of the United States Constitution, is a federal mandate. When Congress speaks (or an agency acts within its sphere of authority), federal law prevails, and state law or tort suits on the issue are void. State regulatory compliance defenses are state-based public policy choices. State courts and legislatures exercise their own judgment and authority to use a federal law or regulation as the standard of care for measuring tort liability. This way, liability rules distinguish the situation where a company has fully met government safety standards from when it failed to do so. In addition, some state regulatory compliance statutes go farther than preemption in the sense that they may be premised on compliance with *state* or federal regulations, rather than solely federal law.

Regulatory compliance defenses do not provide manufacturers with “immunity” or a free pass from liability. Rather, such laws presume that a manufacturer is acting properly when it meets existing government standards and regulations. If the regulatory decision-making process was compromised by misconduct of the defendant, such as through a material misrepresentation or omission of required information, then claimants may overcome the reasonable safeguards provided by the statute and pursue their claims. Wrongdoing has always been the essential lynchpin for tort liability.

Companies, just like all people, are supposed to know when they engage in conduct that could give rise to liability. Regulatory compliance statutes and common law presumptions refocus liability on those who do not follow the law. Thus, they provide a powerful incentive for companies to adhere to government safety standards, as well as for properly rewarding behavior that is in the public interest.

VI. CONCLUSION

As the courts, government agencies, Congress, and the ABA critically examine under what circumstances health and safety standards developed by federal agencies should preempt common law claims, they should not lose sight of the forest for the trees. Preemption of a common law claim may be perceived as unfair when applied to an individual plaintiff who seeks compensation for an injury, but those who benefit from a particular product are not before the court. The regulations at issue may be a result of careful risk-benefit and low risk-high risk balancing by experts for which the

outcome is an overall safer product for most consumers. Tort claims, in some instances, can disturb this equilibrium. When product safety is governed by individual lawsuits, the end result can be a product that is rendered safer in one unlikely situation, but made more dangerous in many others. It can also result in the most significant product warnings or instructions getting buried in fine print, leading consumers to miss important information or not accord it the weight it deserves. The recent rage against preemption, led by the plaintiffs' bar and its allies, needs to settle before irreversible damage is done. Litigation is not synonymous with public safety. Sometimes, reasoned decisions reached by government agencies after long study represent the best approaches for the overwhelming majority of the American public.