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Shane Levesque
slevesqu@slu.edu

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PREEMPTION AND THE PUBLIC HEALTH: HOW WYETH v. LEVINE STANDS TO CHANGE THE WAYS IN WHICH WE IMPLEMENT HEALTH POLICY

SHANE LEVESQUE*

I. INTRODUCTION

On April 7, 2000, Diana Levine, a Vermont musician who operated a children’s record label, visited a local health center for the treatment of a migraine headache,¹ as she had many times before.² There, Levine was administered two doses of the drug Phenergan, an anti-nausea medication manufactured and distributed by Wyeth Pharmaceuticals.³ The first of these was performed by means of intramuscular injection.⁴ However, because the initial dose proved ineffective against her migraine-related nausea, Levine returned to the center, where she received a second, intravenous injection of the medication by means of the “IV-push” method whereby the drug was injected directly into a vein in her arm through the use of a syringe.⁵ During the second injection, Phenergan entered Levine’s artery, either because the syringe’s needle punctured an artery or because the Phenergan escaped the vein into which it was administered and penetrate surrounding tissues.⁶ As a result, Levine developed gangrene, which required doctors to amputate her entire right forearm, causing her to lose her career as a professional musician.⁷

At the time that Levine received this treatment, Wyeth had for years known that Phenergan, if allowed to come into contact with arterial blood,

* J.D., Saint Louis University School of Law, 2009. Doctoral student in Bioethics, Saint Louis University. This paper would not have been possible without the mentorship of Professor Frederic Bloom, the generous guidance of Elizabeth Pendo, and the excellent research assistance provided by Lynn Hartke.

³ Wyeth, 129 S. Ct. at 1191.
⁴ Id.
⁵ Id.
⁶ Wyeth, 129 S. Ct. at 1191.
⁷ Id.
would make the development of gangrene “likely.”

In fact, the drug’s label expressly warned of this risk, and stated that because of it, it was “usually preferable” to administer the drug by means of the “IV-drip” method, because it presented a reduced chance of introducing the drug to the arterial system.

However, Levine argued that the label did not contraindicate all methods of administration other than the IV-push method.

In 2004, after reaching a settlement with the health center and the physician who oversaw the administration of the drug, Levine brought an action for damages against Wyeth after discovering that the pharmaceuticals company knew the risk of using the IV-push method in conjunction with Phenergan, but nonetheless failed to amend its labeling to eliminate what was known to be a very risky method of administration.

Consequently, she argued, Wyeth should be held liable under common-law products liability theories for its failure to adequately warn of the risks associated with that injection method, which she argued was “not reasonably safe for intravenous administration because the foreseeable risks of gangrene and loss of limb are great in relation to the drug’s therapeutic benefits.”

In response, Wyeth argued that the Vermont court should dismiss the case, stating that Levine’s state products liability claims were preempted by Food and Drug Administration determinations that the drug’s labeling was adequate. Despite its assertion, a Vermont jury agreed with Levine, awarding her $7.4 million dollars, which the court reduced to $6.7 million.

Following an unsuccessful series of appeals in Vermont state courts, Wyeth appealed to the United States Supreme Court, again arguing that Levine’s state-law claims were preempted by the FDA’s determination that the drug’s labeling was adequate. If plaintiffs were allowed to pursue such claims against drug manufacturers, Wyeth argued, not only would it be impossible for companies to comply with both federal and state requirements for prescription pharmaceuticals labeling, it would also frustrate the FDA’s ability to fully execute its duty to successfully oversee the safety of those drugs that have been introduced to the marketplace.

This, it asserted, would be a necessary consequence if layperson juries were

8. Levine, 944 A.2d at 183 n.1.
9. Id.
10. Id. at 182.
13. Levine, 944 A.2d at 183-84.
14. Id. at 182-83.
15. Id.
16. Id.
17. Wyeth, 129 S. Ct. at 1193-94.
allowed to substitute their judgment regarding what labeling is adequate for the specialized knowledge of an expert agency.\textsuperscript{18} The Court, however, agreed with Levine, holding first that Wyeth’s impossibility argument was entirely without merit since federal law allowed the company to amend its labeling at any time so long as it notified the FDA of the changes.\textsuperscript{19} Second, the Court held not only that state-law tort claims did not pose an obstacle to the objectives of Congress, but also that any attempts by the FDA to interpret the Food, Drug, and Cosmetic Act (FDCA) as granting preemptive authority to the agency over such claims “relie[d] on an untenable interpretation of congressional intent and an overbroad view of an agency’s power to pre-empt state law.”\textsuperscript{20}

Although the parties in \textit{Wyeth} may be relatively new actors, the story they tell has been told with increasing frequency throughout the course of the last few decades, and has become all-too-familiar fare to followers of constitutional law and political theory. This tale, like the ones that come before it, pits state sovereignty against federal supremacy in an ever-increasing struggle between federalization and federalism. It describes the profound tension that exists between the ideals of Democratic rulemaking and public health protectionism. And, perhaps most importantly, it forces its observers to consider what role, if any, courts should play in setting into motion the agendas of public health advocates.

Part II of this Article begins with a discussion of how state tort claims have, from an historical perspective, been used to institute new public health policy by means of indirect regulation, paying specific attention to the ongoing debate regarding whether this use of the court system is an appropriate exercise of judicial power. Because of its sheer power, and its history of use as a means of precluding state-law tort suits, Part III follows with a description of the general themes embodied in federal preemption jurisprudence. Part IV addresses the often-tangled intersection between federal administrative agency action and preemption, and uses the several ways in which FDA has viewed its own preemptive authority as a means of demonstrating the vast confusion that results. Finally, Part V of this Article concludes that, because of \textit{Wyeth}’s implications for both federal preemption jurisprudence, its outcome has not only affirmed the ways in which the courts have been used a means of achieving indirect regulation of one of the nation’s leading industries, but also stands to change the ways in which public health policy in general is implemented within the United States.

\textsuperscript{18} \textit{Id.}
\textsuperscript{19} \textit{Id.} at 1199.
\textsuperscript{20} \textit{Id.}
II. THE USE OF STATE-LAW TORT CLAIMS AS A METHOD OF REGULATING FOR THE PUBLIC HEALTH

In incredibly general terms, a tort can be defined as a “civil, non-contractual wrong for which an injured person or group of persons seeks a remedy in the form of monetary damages.”\(^\text{21}\) These wrongs are litigated in private, as opposed to public, forums, and typically result in legal, rather than equitable, relief.\(^\text{22}\) Throughout the course of American history, tort law has, in addition to being used as a tool for compensating individuals for the legal wrongs committed against them by others, proved an effective means of regulating for the public health.\(^\text{23}\) Through the use of state-law tort claims, the nation’s courts have played a consistent and significant role in the formulation of public health policy, in large part because of the nature of the law of negligence and the inherent effect of negligence on the health of actors other than the negligent party.\(^\text{24}\) In addition to compensating innocent actors for the injuries sustained as a result of another’s negligent acts, state-law tort claims also serve an important deterrent function.\(^\text{25}\) In fact, the imposition of civil liability on individuals as a means of punishing and preventing the wrongful infliction of injury on another is known to have a direct effect on rates of injury within the public, causing one commentator to aptly state that, “when the first common law court determined that an individual was liable for an action endangering another, public health policy was made.”\(^\text{26}\)

To that end, although there is no universally accepted list of the tort system’s general goals, four have emerged in regard to the use of tort law as a means of indirect regulation for the public health. These include the “(1) assignment of responsibility to individuals or businesses that impose unreasonable risks causing injury or disease; (2) compensation of persons for loss caused by the conduct of individuals or businesses; (3) deterrence of unreasonably hazardous conduct; and (4) encouragement of innovation in product design, packaging, labeling, and advertising to reduce the risk of injury or disease.”\(^\text{27}\)

These articulated goals reflect the recognition that the tort system has proven to be an incredibly effective means of creating and implementing

\(22\) Id.
\(23\) See id. at 270 (“[T]ort law can be an extremely effective method of advancing the public’s health.”).
\(24\) See id. at 288-89.
\(25\) Id. at 288.
\(27\) Gostin, supra note 21, at 270.
wide-ranging public health policy. Decades in the recent past have given rise to new strategies for using state-law tort claims as a means of regulating for the public health that are both powerful and highly sophisticated. Not only did the last half of the Twentieth Century see the birth of the toxic tort, it also saw the rise of the mass tort—also known as the class action lawsuit. And while the primary objective of these legal innovations has, arguably, continued to focus on winning compensation for the unlawful injuries suffered by plaintiffs, the effects of their “secondary” purpose—that of indirect regulation of industries by means of the judicial system—have been nothing short of great.

The sizeable judgments that often result from successful litigation against large companies whose actions affect the public health have proven effective means of indirectly regulating industries because of the incredibly financial pressure they impose. Businesses, which have fiduciary duties to maximize profits for their shareholders, are more likely to steer clear of behaviors when there exist substantial risks of financial loss that outweigh any foreseen benefit. After all, “it matters to a business whether it must bear the cost of . . . personal injury.” The result is that adverse judgments in tort incentivize increased industry attention to product safety measures, or even the complete withdrawal from the market of those products that cannot be made safe for human use. In some cases, though, a company may elect to pass the costs of any litigation on to the consumer through pricing increases. This sort of activity may “powerfully affect consumer choice and action” to such a degree that consumers are increasingly deterred from consuming those products that the courts have deemed unsafe. The result

28. See id. (describing tort litigation as “an effective tool to reduce the burden of injury and disease”).
29. See Parmet, supra note 26, at 1666-67 (discussing “toxic tort,” automobile, and children toy litigation as forms of tort litigation that create public health policy).
30. See id. at 1666; Robert F. Blomquist, American Toxic Tort Law: An Historical Background, 1979-87, 10 PACE ENVTL. L. REV. 85, 85-86 (1992) (In re Agent Orange Products Liability Litigation, decided in 1979, was the first major toxic tort case.).
31. See generally Richard A. Nagareda, Turning from Tort to Administration, 94 MICH. L. REV. 899, 899 (1996) (offering a detailed explanation of the mass tort litigation system and its use as an indirect method of regulating industries).
32. See GOSTIN, supra note 21, at 270 (noting that “civil litigation [redresses] many different kinds of public health harms”).
33. Id. at 289.
34. Id. at 270, 304.
35. Id. at 288-89, 304.
36. Id. at 288.
is that consumption is driven down, which itself has a direct effect on the public health.\footnote{\textit{Gostin}, supra note 21, at 289 (noting that this was the case with youth’s cigarette use).}

Viewed in this way, it becomes increasingly clear that tort law can be one of the sharpest weapons in the arsenal for those who wish to bring into effect powerful, yet indirect, regulation of industry for the purpose of fulfilling public health objectives; however, despite its flexibility, tort law is no gentle giant. In addition to the great good it can bring about, it also has the potential to profoundly disrupt or otherwise harm the public health. First, as discussed, adverse tort verdicts against industries may have the effect of driving up production costs. Some of those industries affected by these judgments may choose to pass on the costs of litigation not to their customers, but to their own employees by eliminating positions, reducing pay, or through the withdrawal of health care benefits.\footnote{Id. at 304.} Because of the fact that socioeconomic status and health are so inextricably interwoven,\footnote{Robert A. Hahn et al., Poverty and Death in the United States—1973 and 1991, \textit{6 EPIDEMIOLOGY} 490, 490 (1995).} critics argue, it becomes increasingly important to consider the broader potential effects of indirect regulation through tort.\footnote{\textit{Gostin}, supra note 21, at 304.} Others argue that, when large judgments in tort are levied against industries, it has the effect of smothering the innovation and growth of those services and goods that are desirable and good for the American people.\footnote{Id.}

\textbf{A. Indirect Regulation Illustrated: The Tobacco Litigation and the Public Health}

There is, perhaps, no better example of how state tort claims have been used to set public health directives into motion than those presented by the series of lawsuits and settlements that have collectively come to be known as the “tobacco litigation.”\footnote{See Robert L. Rabin, \textit{A Sociolegal History of the Tobacco Tort Litigation}, \textit{44 STAN. L. REV.} 853, 854 (1992); Parmet, supra note 26, at 1672-78.} Separated by scholars into three waves,\footnote{Id. at 291.} the tobacco litigation began as an exercise in futility. The first two waves, which began in 1954 and ended in the early 1990s, were marked by the abject failure of plaintiffs to secure victories against the tobacco industry, despite the fact that the risks associated with the use of tobacco were becoming
increasingly well known. However, in 1994, confidential documents belonging to the Brown and Williamson Tobacco Company were leaked to the public. These documents, which came to be known as the “Tobacco Papers,” contained evidence that the tobacco industry was not only aware of the dangers associated with smoking and nicotine’s addictive properties, but also that it had every intention of keeping that information from the public. With this revelation, the “third wave” of tobacco litigation began in earnest.

What followed was a flurry of litigation. First, state attorneys general sued the tobacco industry for the reimbursement of state medical expenditures made in the care of individuals with tobacco-related diseases. The settlement agreements that resulted from that litigation included over $200 billion in compensation to states, instituted new standards for the advertising and promotion of tobacco products, precluded tobacco companies from sponsoring sporting events, disbanded the Council for Tobacco Research, and created a foundation dedicated to preventing adolescent smoking. Inspired by the staggering financial impact the state suits had on the tobacco industry, as well as the huge strides in regulating an industry that manufactured a product that was hazardous to human health, but that had ironically been subjected to little regulation by the federal government, other actors began to follow the example provided by the states. Before long, the tobacco industry was fielding lawsuits filed by

44. Parmet, supra note 26, at 1672-73 (explaining that, despite a Surgeon General’s report offering proof that cigarette smoking was hazardous to the public’s health, no plaintiff was successful in private litigation against a tobacco company).
46. Id. at 232.
48. The first of these claims was filed by the State of Mississippi in 1994, and was consequently joined by most other states. See Settlement Agreement and Release, In re Mike Moore, Attorney General, ex rel. State of Miss. Tobacco Litig., No 94-1429 (Ch. Ct. Jackson Co., Miss. Oct. 17, 1997).
49. GOSTIN, supra note 21, at 295-96.
50. Id. at 296.
51. Although it was at one time listed in the 1890 edition of the U.S. Pharmacopoeia, tobacco was deleted from the 1905 edition, and thus escaped regulation under the 1906 Food and Drug Act. For an historical account of tobacco’s regulation within the United States, see 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. 63, 66-67 (1997).
52. GOSTIN, supra note 21, at 296.
the federal government, individuals and their families, and even foreign governments.

Public health advocates consider the tobacco litigation an overwhelming success, and count among its primary achievements the driving up of cigarette prices, a correlating reduction in consumption, and a less visible presence in American culture. However, this litigation was not without its associated costs. Foremost among these, scholars argue, is the loss of inside information regarding tobacco use by the Council for Tobacco Research, which, despite being designed to serve the tobacco industry, provided the lion’s share of the damning information regarding tobacco that was used to secure judgments against manufacturers.

B. The Propriety of Indirect Regulation

While it may be true that the use of tort verdicts is a powerful tool for effecting broad public health policy, there remains the question of whether such a use is in fact an appropriate exercise of judicial power. Some may convincingly argue that verdicts affecting the legal behavior of individuals and entities in the absence of a legislative directive amounts to nothing


58. GOSTIN, supra note 21, at 297.

59. Id.
more than legislation from the bench by “philosopher king” judges, who use their positions of authority to substitute their personal normative determinations as to what ought to be the law, as opposed to what the law is.60

Critics may then attack as undemocratic the use of the nation’s courts—as opposed to the legislative process—as a means of putting into action public health agendas.61 This may be especially so when public health goals are realized as the result of an industry’s attempt to avoid civil liability, in which cases public health advocates may be criticized as having “evade[d] the legislative process” by “turning to the courts to establish policies when neither legislatures nor public health agencies have acted.”62

While these criticisms are valid, it must be noted that the realities of human nature and the American political mechanism make the purely democratic process “neither responsive nor representative when it comes to public health.”63 One of these is the problem of public apathy: because individuals tend to frame health agendas on a personal, rather than on a population, level, they are less inspired to take action unless that action is calculated to address a personal concern that touches their own lives.64 Another factor that limits the effectiveness of the legislative process in regard to public health is that, often, the industries that are subject to public health regulation wield immense political, financial, and social power, enabling them to engage in pushback against proposed legislation that is so strong that the ultimate effects of that legislation are fatally diminished.65 Taken together, these factors combine to create such an enormous obstacle for public health regulations that “it is not surprising that individuals concerned about public health threats have turned to the courts.”66

III. FEDERAL PREEMPTION OF STATE LAWS

While constitutional scholars may not see eye to eye on many points regarding the history and scope of federal preemption, most would agree

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61. See Parmet, supra note 26, at 1689.
62. Id. at 1690, 1691.
63. Id. at 1692.
65. See Kelder & Daynard, supra note 51, at 68-69 (describing how tobacco companies capitalized upon their relationships with political officials to minimize the impact of tobacco regulations).
66. Parmet, supra note 26, at 1694.
that our contemporary formulation of the doctrine is at the very least “muddled.”67 Some commentators have gone so far as to describe it as an “awful mess,”68 “chaos,”69 or even “profound[ly] confusing.”70 Even Supreme Court justices have found themselves frustrated by the jurisprudential tangle, one proclaiming it a “crazy quilt,”71 and another stating that it is “difficult to apply.”72 It is perhaps because of this confusion that other, more easily navigated areas of constitutional law have traditionally upstaged the discussion of federal preemption.73 Its lack of popularity in the legal literature is made more acute by the fact that the doctrine is one of the most-used defenses in cases that pose a constitutional question.74

Despite the fact that state-law tort claims serve as a powerful tool for effecting sweeping public health reform, federal preemption has proven to be an equally potent foil against those who wish to use the courts as a means of indirectly regulating industries. Consequently, it is instructive to review the ways in which federal preemption has stood as an obstacle to those wishing to change the market behaviors of industries regulated by the federal government. Although a complete reformulation of federal preemption jurisprudence is beyond the scope of this Article, the following Section endeavors to lay a foundation of bedrock principles upon which a basic understanding of the doctrine may be built. To do so, it begins by defining federal preemption, paying particular attention to the constitutional basis for the doctrine and to the ways in which it has been applied throughout the past one hundred years.

A. Preemption Defined

The United States Constitution envisions a national system in which federal and state governments remain independent sovereigns “within their respective spheres.”75 However, this paradigm of “dual sovereignty”76 lies

73. Gardbaum, supra note 70, at 768.
74. Id.
in tension with the doctrine of federal preemption, which holds that states are relieved of their sovereign authority when Congress validly exercises an enumerated power, and in doing so indicates its intent to have the exclusive say in respect to a particular area of regulation or law.\textsuperscript{77} The Court has recognized the Supremacy Clause as the primary constitutional basis for federal preemption doctrine,\textsuperscript{78} which declares that the “Constitution, and the Laws of the United States. . .shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby. . .”\textsuperscript{79} Consequently, “state law is naturally preempted to the extent of any conflict with a federal statute,”\textsuperscript{80} with the result that “any state law, however clearly within a State’s acknowledged power, which interferes with or is contrary to federal law, must yield.”\textsuperscript{81}

Preemption analysis, as with any consideration of the legality of a congressional act, begins with the threshold question of whether that act was done pursuant to a constitutional exercise of Congress’ enumerated powers.\textsuperscript{82} If not, the law is unconstitutional, with the result that the law is held to have no preemptive effect.\textsuperscript{83} If the federal law is constitutional, the analysis moves into its second phase, which turns largely on the question of whether Congress intended the federal law or scheme to preempt state authority.\textsuperscript{84}

The Court has stated that, when determining congressional intent to preempt state law within a realm that is traditionally regulated by the states, it “start[s] with the assumption that the historic police powers of the States were not intended to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”\textsuperscript{85} This requirement of a “clear

\textsuperscript{76} Printz v. United States, 521 U.S. 898, 919, 935 (1997).
\textsuperscript{77} Gardbaum, supra note 70, at 771.
\textsuperscript{79} U.S. CONST. art. VI, cl. 2.
\textsuperscript{83} See, e.g., United States v. Lopez, 514 U.S. 549, 566 (1995) (holding unconstitutional a statute on the ground that it was not within Congress’s enumerated power to regulate commerce among the several states).
\textsuperscript{85} Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) (citing Napier v. Atlantic Coast Line, 272 U.S. 605, 611 (1926)).
and manifest” purpose has over the years come to be known as the “presumption against preemption,” which “provides assurance that ‘the federal-state balance’ will not be disturbed unintentionally by Congress or unnecessarily by the courts.”

Although the Court’s adherence to the presumption appears to wax and wane, legal scholars have been largely uniform in their support. This is so in the face of increasing challenges to the presumption, both scholarly and judicial. Despite these attacks, though, the presumption has remained a “part of hornbook law,” and thus has not fallen entirely by the wayside. However, more troubling to public health advocates and proponents of


88. Eid, supra note 86, at 33.

89. Nelson, supra note 67, at 232. Professor Nelson argues that the Supremacy Clause is incompatible with the “artificial” presumption against preemption, because it establishes federal law as supreme: “any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” Id. (quoting U.S. CONST. art. VI, cl. 2.). He consequently argues that such a legal “presumption” must yield to the Supremacy Clause. Id.

90. See ALAN E. UNTEREINER, THE PREEMPTION DEFENSE IN TORT ACTIONS: LAW, STRATEGY AND PRACTICE 31-32 (2008). Untereiner posits that the Supreme Court has chosen to ignore the presumption against preemption on several occasions in recent years. Id. First, he points to Riegel, 128 S. Ct. at 1008, where the court relied on the plain meaning of an express preemption clause without ever addressing the presumption against preemption. Id. at 33. Second, he describes how the Court similarly ignored the presumption against preemption in its consideration of an express preemption clause, despite the fact that the case involved the ability of an individual plaintiff to bring a tort action against a defendant manufacturer for personal injury. Id. at 31-32 (citing Sprietsma v. Mercury Marine, 537 U.S. 51, 63-64 (2002)). Finally, he cites Locke, 529 U.S. at 108, in which the Court described the “artificial” the presumption against preemption, and consequently refused to apply it. Id. at 32.

91. Id. at 32.
States’ regulatory autonomy alike, who consider the presumption an important judicial check on the balance of federal and state power, is the way in which the Court ignored entirely its application in its holding in *Buckman*, where it declared its inapplicability without ever providing a satisfying explanation as to why it reached that conclusion. The result is that advocates of the presumption may, in recent years, have rightly felt as if its legitimacy has been on shaky ground. However, in *Wyeth*, the Court revived its support for the principle, stating that it “rel[ies] on the presumption because respect for the States as ‘independent sovereigns in our federal system’ leads [it] to assume that ‘Congress does not cavalierly pre-empt state-law causes of action.’”

B. The Faces of Federal Preemption

1. Express Preemption

Federal preemption falls into two primary categories based on Congress’ intent: express and implied. Express preemption occurs when Congress’ intent regarding the preemptive effect of legislation is apparent on the face of legislation, and includes explicit language “call[ing] for the displacement or nullification of state law in specified circumstances.” In these instances, Congress is thought to have “‘unmistakably [so] ordained’ that its enactments alone are to regulate” a sphere of activity, and that, consequently, “state laws regulating that aspect. . .must fall.” The Supreme Court has recognized as valid the express preemption of state authority, so long as it falls “within constitutional limits,” in that Congress’ exercise of preemptive authority was done pursuant to one of its enumerated powers. In 2007, approximately 350 federal statutes expressly preempted state law.

This form of “jurisdiction-stripping” occurs regardless of whether a state’s regulatory efforts conflict with the federal law at issue. Because of the fact that express preemption can apply even when there is no conflict

95. Untereiner, *supra* note 90, at 159.
99. Gardbaum, *supra* note 70, at 771 (arguing that “preemption resolves a ‘false conflict’ [because] there is only one valid law governing the issue, namely the federal”).
between a federal and state law, some scholars have argued for the recognition of a second constitutional basis for federal preemption within the Necessary and Proper Clause,\(^{100}\) which instructs Congress “[t]o make all laws which shall be necessary and proper for carrying into execution the foregoing power. . . .”\(^{101}\)

2. Implied Preemption

Congress’ intent to preempt state authority need not be expressly stated to be effective; instead, it can be implied from the character of the federal law or regulatory scheme. This “implied” preemption falls into two categories. The first, field preemption, arises when state action touches upon a field of law that Congress has intended (either expressly or impliedly) to exclude from state regulation.\(^{102}\) One factor indicating this intent is when the federal government’s interest in the class of regulation is “so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.”\(^{103}\) It may also be found where the “Act of Congress. . .touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject,” or the “object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose.”\(^{104}\)

The second category, conflict preemption, is itself divisible into two classes: “ordinary” or “obstacle” preemption and “impossibility” preemption.\(^{105}\) Ordinary conflict preemption arises when a state action, whether it is regulatory or judicial in nature, “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”\(^{106}\) The Court has applied the theory of ordinary conflict preemption as a means of stripping states of their rulemaking authority in a

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100. See id. at 782 (Gardbaum has famously argued that supremacy and preemption are entirely separate in nature, the first deriving from the Supremacy Clause, and the second deriving from the Necessary and Proper Clause.); Thomas W. Merrill, Preemption and Institutional Choice, 102 NW. U. L. REV. 727, 735-37 (2008) [hereinafter Merrill, Preemption] (discussing the Necessary and Proper Clause as possible authority for Congress to displace or preempt state law).
104. Id.
105. UNTEREIENER, supra note 90, at 266-67.
However, while the general rule regarding when ordinary conflict preemption applies seems basic enough, the determination of whether a conflict does in fact exist is not always quite as clear.

The Supreme Court has traditionally used a two-step process for determining whether a conflict exists between federal and state law. First, the reviewing court must “ascert[ain] the construction” of the statutes to determine the law’s primary purpose. When a state court has construed a statute, the reviewing court’s work is made significantly easier, because it will defer to the state court construction as authoritative. However, after the law’s purpose is determined, the court’s work becomes increasingly difficult. The reviewing court will then address the “constitutional question” of whether the state’s action conflicts with the federal statute. Because conflict is a matter of degree, this question turns on “the extent of the inconsistency between state and federal law and whether that amount is sufficient, under the Supremacy Clause, to warrant preemption.”

The second form in which conflict preemption appears is “impossibility preemption.” This occurs in those instances where it is “impossible for a. . .party to comply with both state and federal law.” In these instances, the reviewing court’s work is arguably easiest, because “[a] holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design.”


109. See id. (discussing an example of the U.S. Supreme Court deferring to the authoritative construction of an Arizona statute after the Arizona Supreme Court consistently adhered to that construction of its legislation).

110. Id. at 649.

111. UNTEREINER, supra note 90, at 269.

112. Id.


114. Florida Avocado Growers, 373 U.S. at 142.

115. See, e.g., Southland Corp. v. Keating, 465 U.S. 1, 16 (1984) (holding a state law attempting to undercut a rule created by Congress violated the Supremacy Clause); Bibb v. Navajo Freight Lines, 359 U.S. 520, 521-22 (1959) (discussing whether a state statute requiring the use of a specific type of rear fender mudguard on trucks and trailers conflicts
IV. ADMINISTRATIVE AGENCIES AND FEDERAL PREEMPTION

Although federal administrative agencies have been a part of our scheme of national government since George Washington’s administration, the birth of the modern administrative era is commonly thought to have begun with the creation of the Interstate Commerce Commission (ICC) in 1887.116 The ICC’s success in regulating the railroad industry was “crucial to the nation’s development,” and inspired Congress to further capitalize on the administrative agency model.117 Throughout the course of the twentieth century, Congress delegated an increasing share of its lawmaking power to federal administrative agencies, granting to them regulatory authority over a wide array of industries and activities, including food and drugs, methods of competition, freight and shipping, radio, securities, labor relations, airlines, the environment, social insurance programs, and consumer fraud, to name but a few.118 Today, as testament to our nation’s “enchantment”119 with the administrative agency model, our nation has in place hundreds of federal agencies charged with administering countless federal statutes.120 The vastness of the responsibility entrusted to these agencies is made apparent by the fact that in 2001, federal agencies issued 4,132 final rules—handily eclipsing the 108 bills passed by Congress and signed into law that same year.121 Further, the cost of running these agencies is staggering, amounting to over $850 billion that same year, which amounts to 8.4% of 2001’s U.S. gross domestic product.122
The Court has in several respects played an important role in this redistribution of power.123 First, it set a standard of review that prohibits the imposition by the courts of rulemaking procedures exceeding those outlined by Congress in the Administrative Procedure Act.124 Second, it granted administrative agencies discretion in deciding which procedures to use when engaging in rulemaking.125 Finally, it introduced the Chevron doctrine, an often-cited policy granting judicial deference to agency interpretations of ambiguous statutory language.126

The rise of the modern administrative state has provided Congress with yet another means of exercising its authority to enact laws that displace or prevent entirely their state-law analogues. As a consequence of the Court’s holding that “[f]ederal regulations have no less pre-emptive effect than federal statutes,”127 these lawmakers have been empowered with putting into play expansive regulations that are capable of interrupting the achievement of state public health objectives.

The redistribution of rulemaking authority from a Congress made up of elected officials, to anonymous bureaucracies with little to no public accountability, gives rise to “unique concerns” when agencies assert the power to preempt state law in the absence of an explicit congressional grant, especially when it is coupled with the deferential posture adopted by the Court toward agency decision-making.128 These concerns, in turn, lead to “critical questions” regarding whether administrative agencies have the expertise necessary to justify supplanting a body of state law, and whether federal regulatory bodies or the states are better positioned to respond to the particular needs of their citizens within the twin realms of health and safety.129 A reexamination of the constitutional basis for the preemptive authority of administrative agencies, as well as the Court’s review of that authority, is therefore warranted.

A. The Delegation of Preemptive Authority to Administrative Agencies

It is generally accepted that the Necessary and Proper Clause grants Congress the authority, within constitutional limits, to delegate its legislative

124. Id. at 618 n.2 (citing Vt. Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 548 (1978)).
126. Id. at 619 n.3 (citing Chevron U.S.A. v. Natural Res. Def. Council, 467 U.S. 837, 844-45 (1984)).
128. Helvin, supra note 123, at 619.
129. Id.
power to administrative agencies. The Court has consistently held that Congress’ power to issue laws with preemptive effect may attach to this delegation. And while the permissible boundaries of that delegation are unclear, commentators argue that, at the minimum, those regulations issued by federal administrative agencies that conflict with state law must “have the force and effect of federal law,” and “must have been adopted ‘in Pursuance’ of the Constitution” to have preemptive effect. And while some argue that administrative agencies are unable to issue “Laws” as understood in a constitutional sense and that they are therefore unable to tap the Supremacy Clause’s guarantee of preemptive authority, the

130. Thomas W. Merrill, Rethinking Article I, Section I: From Nondelegation to Exclusive Delegation, 104 COLUM. L. REV. 2097, 2129-31 (2004) (citing U.S. CONST. art. I, §8, cl. 18, which states, in relevant part, “[Congress shall have the power to] make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof.”).


132. Merrill, Preemption, supra note 100, at 762.

133. See id. at 761. Thomas Merrill explains that “[o]ne can question as an original matter whether [it] is correct” to assume that Congress may delegate its authority to issue laws with preemptive effect, since the Supremacy Clause grants the power of preemption to only “[t]his Constitution,” “the Laws of the United States,” and “Treaties.” Id. Some argue that since regulations do not maintain the level of “concurrence by representative institutions” inherent to federal treaties, statutes and the Constitution, the actions of administrative agencies cannot satisfy the criteria for triggering preemptive effect. Id. (citing Bradford R. Clark, Separation of Powers as a Safeguard of Federalism, 79 TEX. L. REV. 1321, 1355-67(2001)). However, Merrill points out that the Court effectively nixed this argument when it held that the term “Laws” includes “both federal statutes themselves and federal regulations that are properly
character and sheer number of the Court’s decisions affirming that ability give rise to the conclusion that there is a solid argument “in support of the idea that agency action can qualify as ‘Laws of the United States’ for Supremacy Clause purposes.”

When administrative agencies issue regulations that propose to have preemptive effect even in the absence of a conflict between state and federal law, it may be even less difficult to rationalize their compliance with the constitutional requirements for validity. As discussed previously, while the Supremacy Clause is most often cited as the source of Congress’ preemptive authority, some scholars conclude that the Necessary and Proper Clause provides another source for the power to preemt. As Thomas Merrill explains, through the application of a basic syllogism: “If Congress can expressly preemt, and if it also has the power under the Necessary and Proper Clause to delegate legislative authority to agencies, then it would follow that Congress can delegate legislative authority to agencies to preemt.” This leads to the conclusion that, when an administrative agency’s preemptive power does not stem from the Supremacy Clause, but instead from another constitutional source, that agency’s actions are not required to comply with the clause’s strictures in order to maintain their preemptive effect.

But it is exactly this type of activity—the independent pronouncement by federal administrative agencies that their regulations displace or supplant state law—that so often gives pause to observers of our regulatory state. This may be especially so because, throughout the past decade, administrative agencies have made these pronouncements with increasing frequency, causing some to comment that agencies are “flexing their preemptive muscles.” In 2003, for example, the Office of the Comptroller of the Currency published a “Preemption Determination and Order” in the Federal Register expressly declaring that Georgia’s consumer protections laws that conflicted with federal regulations governing mortgage adopted in accordance with statutory authorization.”

134. Id. at 761-62.
135. Specifically, scholars posit that the Necessary and Proper Clause is the source of Congress’ ability to expressly preemt state law in the absence of any conflict. See, e.g., id. at 766-67; Gardbaum, supra note 70, at 782.
136. Merrill, Preemption, supra note 100, at 766.
138. See id. at 696-97, 699 (providing several examples detailing the ways in which agencies have declared the preemptive effect of their regulations).
lenders owned by national banking firms.\textsuperscript{140} Similarly, in 2006, the
Department of Homeland Security, to which Congress had granted the
authority to oversee domestic high-risk chemical manufacturing facilities,
proposed a rule that it said would preempt state law.\textsuperscript{141}

Although in both of these instances the preemptive effect of the agency’s
regulations was settled in favor of the states, more recent activity within the
Court has signaled a trend toward deferring to an agency’s interpretation of
the preemptive effect of its issued regulations.\textsuperscript{142} In the realm of state
products liability law, for example, every decision issued by the Supreme
Court between 1992 and 2008, save one, has come out in favor of
agencies that make unilateral determinations that a regulation or set of
regulations preempted state law.\textsuperscript{143} Because of this trend, and the unique
questions about federalism, sovereignty and institutional choice it inspires, it
is helpful to review how deference is afforded to administrative agencies
generally, and how that deference has factored into decisions regarding the
preemptive authority of these bodies.

\textbf{B. Judicial Deference to Administrative Agency Action}

One of the reasons that the administrative agency model of government
has been so successful may be the broad judicial deference afforded by the
courts to agency action. Federal agencies are charged with administering
federal statutes so as to bring into effect Congress’ intent. The problem, of
course, is that Congress is not always forthcoming about what end it
intends. To bridge this frequent gap, federal courts defer to an
administrative agency’s interpretation of ambiguous statutory language so
long as that interpretation is “permissible.”\textsuperscript{144} However, a finding of
permissibility alone does not end the inquiry.

The amount of deference afforded to an agency’s interpretation of
ambiguous statutory language depends largely on the form in which that
interpretation appears. When the interpretation is announced in a
regulation that enjoys the force of law, heightened deference is warranted;
however, where the interpretation in question did not result from a formal
adjudication or rulemaking, it is not entitled to deference.\textsuperscript{145} Instead, these

\begin{footnotesize}
\begin{enumerate}
\item[140.] Mendelson, supra note 137, at 695 (citing Preemption Determination and Order, 68
\item[141.] Id. (citing Chemical Facility Anti-Terrorism Standards, 71 Fed. Reg. 78,276, 78,293
(Dec. 28, 2006)).
\item[142.] See Catherine M. Sharkey, Products Liability Preemption: An Institutional Approach,
\item[143.] Id.
\item[145.] See Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944). The Supreme Court, in
deciding a Labor Standards Act case, determined that some weight—but not absolute
\end{enumerate}
\end{footnotesize}
interpretations are merely “entitled to respect” . . . but only to the extent that those interpretations have the “power to persuade.”

It is helpful to keep in mind these levels of judicial deference when considering the ways in which administrative agencies have asserted their own power to preempt state law, as well as the Court’s response to these averments. Traditionally, the declarations of administrative agencies that their regulations have preemptive effects on state law have been analyzed in much the same way as interpretations of ambiguous statutory language. However, while the Court has, as discussed supra, overwhelmingly deferred to agency decisions regarding preemption, it has failed to articulate a specific standard for considering the effect of agency preemption decisions. What has resulted is a mishmash approach to the preemption question as it applies to federal agencies, with standards of deference ranging from extremely to tacitly deferential.

1. Arguments in Support of Agency Deference

Navigating the way to an operative test for divining the length and breadth of judicial deference to agency preemption determinations does nothing to address the normative question of whether courts ought to do so in the first place. Those who favor a deferential stance in relation to agency
defence—could be given to an Administrator’s opinion regarding what constitutes on-call time. Although the Administrator did not arrive at his conclusions by “trial in adversary form,” his opinions and interpretations were still “properly resort[ed] [to] for guidance. In short, there may be circumstances where such an opinion might provide some persuasive value, but there will never be circumstances in which it will have the “power to control.” Id. at 140.

147. UTERER, supra note 90, at 34.
148. Helvin, supra note 123, at 627. In her discussion of the treatment of agency preemption decisions by the Supreme Court, Helvin explains that, prior to Chevron, the Court “applied an extremely deferential standard of review to agency determinations” that either the enabling statute or its regulations preempted state law. Id. at 626. Consequently, she notes, “[i]t might have seemed inevitable that, following . . . Chevron . . . the Court would formalize its deferential standard by explicitly extending Chevron deference to agency preemption decisions.” Id. at 626-27. However, in City of New York v. FCC, decided four years after Chevron, the Court did not accord the FCC Chevron deference, although it did ultimately defer to its decision. City of New York v. FCC, 486 U.S. 57, 63 (1988); Helvin, supra note 123, at 627.
149. Fed. Sav. & Loan Ass’n v. de la Cuesta, 458 U.S. 141, 154 (1982) (explaining that the operative inquiry in determining whether an agency’s regulation had preemptive effect was whether it intended its rule to preempt state law, and whether it had the delegated authority to do so).
150. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 496-97 (1996) (indicating first that agencies should be granted substantial deference in their interpretations that state law is preempted by regulation, but then engaging in a full statutory construction analysis).
interpretations of preemptive effect commonly cite the institutional expertise of these agencies and their administrators in support of their position.151 Not only have these agencies developed institutional competence within their area of concentration, they argue, this competence has made them better suited than courts to recognize the potential for, and the consequences of, conflict between their regulatory schemes and state law.152 Furthermore, the argument goes, it is not as if federal agencies are completely unburdened by the yoke of accountability.153 Quite to the contrary, although Congress could, “[w]ith the stroke of a pen. . .definitively answer the question of state common-law preemption,”154 both it and the President enjoy additional, less strenuous means of influencing agency decision-making, such as the withdrawal of agency funding,155 or the use of executive order.156

2. Arguments Against Agency Deference

Those who oppose a highly deferential standard for reviewing pro-preemption agency interpretations argue that, all too often, agencies promote preemption as a means of increasing their institutional power, and seldom consider the effects on the federal-state balance.157 Thus, many of these attempts to preempt state law may “reflect a self-aggrandizing power grab more than reasoned policymaking.”158 The result, they say, is that “courts should actively police against self-interested administrative interpretations of ambiguous preemption provisions” lest they “permit

151. Helvin, supra note 123, at 631.
152. See id.; Catherine M. Sharkey, Preemption by Preamble: Federal Agencies and the Federalization of Tort Law, 56 DePaul L. Rev. 227, 252 (2007) (stating that “[g]iven their unique understanding of the ways in which state law interacts with a federal regulatory scheme, federal agencies may have a critical role to play in preemption determinations, either directly or in forcing Congress to confront the vexing issue of the displacement of state common law”).
154. Sharkey, supra note 152, at 251.
156. For example, in 1999, President Bill Clinton issued an executive order that expressly instructed agencies to interpret federal statutes as preempting state law only in those circumstances where Congress included an express preemption provision, where there existed “some other clear evidence” that Congress intended it to preempt, or where there was actual conflict between federal and state law. Exec. Order No. 13,132, 3 C.F.R. 208 (2000) reprinted in 5 U.S.C. § 601 app. at 750-51 (2006).
agencies to expand their jurisdictional and preemptive capabilities at the expense of the states.”

Critics further argue that, while it may be true that administrative agencies develop significant technical expertise within their particular regulatory demesnes, it does not necessarily follow that this knowledge brings with it an equally nuanced understanding of the federal-state balance.

After all, the policy of judicial deference to agency interpretations was built upon the premise that, at least in regard to some questions, administrative agencies are better suited to answer than are the courts. However, it is difficult to imagine a situation in which a federal agency is by any means a greater expert on the execution of a particular state law than the state in which it originates. Similarly, it is unlikely that federal agencies, as opposed to the courts, better understand the expansive yet delicate interplay of issues that make up the Federalism debate, considering that courts are staffed by “generalist judges, who are,” out of necessity, “well-suited to balancing” the varying interests of federal and state government.

It is, perhaps, because of these reasons that critics emphasize the importance of keeping in play the presumption against preemption when courts consider this class of agency action. If the courts uniformly enforced the presumption, federal agencies would be required to show that Congress’ intention to preempt state law is “clear and manifest.” This requirement would result in the conveyance to the states of additional protections to assure that “regulatory autonomy” is not cavalierly displaced by “incidental” agency action.

Others posit that the best way to protect the presumption in light of the Court’s increasing deference to agency preemption determinations is through the application of the further requirement that Congress make a “clear statement” of its intent to preempt state law through the agency’s administration of a statute. The benefit of such a requirement, they say, is

159. Helvin, supra note 123, at 633.
160. Mendelson, supra note 137, at 710-11.
161. Frankel, supra note 158, at 32.
162. Id.
163. Id. at 32, 34.
164. Helvin, supra note 123, at 635 (stating that the application of the presumption is “frequently touted as [a] solution”)
166. Mendelson, supra note 137, at 710.
167. See Helvin, supra note 123, at 635-36. See also David S. Bogen, The Market Participant Doctrine and the Clear Statement Rule, 29 SEATTLE U. L. REV. 543, 569-70 (2006) (expressing approval of the Supreme Court’s refusal to apply general federal provisions to the states absent a clear statement); Thomas W. Merrill, Rescuing Federalism After Raich: The
that agencies would be capable of exercising preemptive authority only in those instances where political figures with true public accountability have acted. The political pressure resulting from such a procedural requirement would contribute to a more deliberate weighing of federal and state interests, and allow states targeted for preemption a better opportunity to prepare for and prevent the passage of preemptive statutes. Further, it does so without destroying the government’s discretion in determining institutional roles.

Yet, regardless of what deference the courts should afford agencies in their preemption determinations, the fact remains that, with escalating regularity, they do defer. The potential effects of this policy have come into increasingly stark relief in recent years, due to the work of scholars who point out a new trend in the pronouncement by agencies of these preemption determinations. That trend features the delivery of agency interpretations favoring the displacement of state law not by way of the publication of a rule that has received notice and comment, but instead by means of a rule’s preamble. While there is no consensus regarding whether preambles are entitled to judicial deference, the trend has been identified as a potential strategy for effecting stealth tort reform by means of this “backdoor federalization.”


168. Helvin, supra note 123, at 636.

169. Id. (quoting Merrill, Rescuing Federalism, supra note 167, at 833).

170. See Merrill, Preemption, supra note 100, at 767 (noting that “courts are as a rule better institutions to resolve preemption questions than agencies. If we allow agencies to preempt based on a general grant of rulemaking authority, or an ambiguous grant of rulemaking authority, then the institutional choice question would in effect be decided by agencies and courts in collaboration. . . . [G]iven that there are general reasons to prefer courts to agencies in determining whether to preempt, it is better to leave the decision to substitute agencies for courts squarely with Congress. Requiring a super-strong clear statement from Congress secures this result.”).


173. See generally Samuel Issacharoff & Catherine M. Sharkey, Backdoor Federalization, 53 UCLA L. REV. 1353, 1358 (2006) (identifying a national trend toward increased federalization of statutory and regulatory schemes inspired by market protectionism, and discussing the evidence of collaboration between the branches of government to effect that outcome).
C. The Debate Illustrated: FDA, Pharmaceuticals, and Agency Preemption

Even before the FDA’s birth in 1927, some of the nation’s first modern preemption cases to reach the Supreme Court addressed whether statutes governing food and drugs preempted state efforts at concurrent regulation. However, throughout most of the Twentieth Century, the preemption defense was employed sparingly within the Supreme Court. When it was, industry defendants were the ones who raised it. It wasn’t until the last part of the century that preemption would emerge as a major defense strategy, and the FDA would become a champion for the displacement of state law in regard to pharmaceuticals litigation. In Wyeth, though, the Court held for several reasons that the FDA’s pharmaceuticals labeling determinations did not preempt state-law tort claims. First, the Court held that Congress did not make an express statement in the FDCA that indicated its intent that the FDA enjoy such sweeping authority. Secondly, the Court found that the regulatory preamble in which the FDA announced its preemptive authority dramatically shifted the agency’s course and failed to openly allow notice and comment on its interpretation. Third, it noted the important remedial function served by state-law tort claims. Finally, it noted the agency’s likely inability to sufficiently monitor the safety of consumers.

174. Initially, the administration of the Pure Foods and Drugs Act of 1906 was entrusted to the USDA Bureau of Chemistry. U.S. Food & Drug Admin., FDA History—Part I: The 1906 Food and Drugs Act and Its Enforcement, http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm (last visited Apr. 25, 2010). However, in 1927, the Bureau was reorganized into the Food, Drug, and Insecticide Administration, which was charged with regulating food and drugs, and a Bureau of Chemistry and Soils, which was charged with conducting research. See U.S. Food & Drug Admin., About FDA: Significant Dates in U.S. Food and Drug Law History, http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm (last visited Apr. 26, 2010). In 1930, the FDA’s official name was shortened to the Food and Drug Administration. Id.

175. See generally McDermott v. Wisconsin, 228 U.S. 115 (1913) (holding that a Wisconsin law requiring highly detailed labeling of glucose products was invalid because it came into conflict with federal labeling requirements and had the effect of infringing upon rights granted by the federal regulation); Savage v. Jones, 225 U.S. 501 (1912) (holding that an Indiana statute mandating the disclosure of ingredients of foods offered for sale in Indiana in interstate commerce was valid because there was no conflict between the statute and federal regulations; the statute merely expanded on the federal regulations).

177. Id. at 1201-02.
178. Id. at 1202.
179. Id.
1. FDA’s Changing Positions on Preemption

Congress has not granted the FDA express authority to preempt state law relating to prescription pharmaceuticals. Congress has, however, granted express preemptive effect to FDA’s labeling requirements for nonprescription drugs. It is no surprise then that, before 2000, the FDA maintained that its regulations did not preempt state law tort claims, but instead set “minimum standards” for enforcement. The agency’s interpretation regarding the preemptive effect of its prescription pharmaceutical labeling requirements were made evident in a 1998 comment to regulations setting requirements for medication guides, in which the FDA stated that the agency’s regulations “were not intended to preclude the states from imposing additional labeling requirements,” but were merely a regulatory floor. The agency echoed its position two years later when it issued for comment a proposed rule outlining revised labeling requirements. There, the FDA again expressed its opinion that its proposed rule did not preempt state law, and that its adoption would result in “little, if any, impact” on “the distribution of power and responsibilities among the various levels of Government.”

The FDA abruptly changed course in 2006, resulting in “a seismic shift in FDA policy.” Throughout the notice and comment period for the proposed rule, the FDA was urged to interpret its labeling requirements as preempting state law. Further, the Bush Administration encouraged agencies to explore new ways of using the preemption defense as a means

181. Rodríguez, supra note 172, at 169 (explaining that prior to 2000 the FDA issued several statements indicating that its labeling requirements did not preempt state-law failure-to-warn claims, but set a floor for standards). See also Mary J. Davis, The Battle over Implied Preemption: Products Liability and the FDA, 48 B.C. L. REV. 1089, 1117-18 (2007) (discussing the FDA’s position against the preemption of state law in regard to its blood collection regulations). Cf. Howard L. Dorfman, Vivian M. Quinn & Elizabeth A. Brophy, Presumption of Innocence: FDA’s Authority to Regulate the Specifics of Prescription Drug Labeling and the Preemption Debate, 61 Food & Drug L.J. 585, 590 (2006) (“Since at least 1991, [the] FDA has expressed that its prescription drug labeling determinations are both a floor and a ceiling regarding the sufficiency of safety-related information.”).
184. Id. at 81,103.
185. Id.
187. Rodríguez, supra note 172, at 170.
of curbing industry tort liability.\textsuperscript{188} It is perhaps because of these external pressures that, when the FDA published its final rule in 2006, it for the first time included language stating that the FDCA\textsuperscript{189} preempted “conflicting or contrary State law.”\textsuperscript{190} In doing so, it announced that it now interpreted its labeling requirements as “establish[ing] both a ‘floor’ and a ‘ceiling,’” citing as its primary justification the potential for harm that can result from “defensive labeling.”\textsuperscript{191} However, the agency further opined that state claims based on a drug manufacturer’s failure to comply with the FDA’s requirements were not preempted.\textsuperscript{192}

The 2006 preamble was attacked as the epitome of the “backdoor federalization” decried by critics.\textsuperscript{193} Though some suggest that the preamble should have been granted broad deference by the courts,\textsuperscript{194} others argued that the deference afforded it should have been minimal,\textsuperscript{195} or that deference was completely unwarranted.\textsuperscript{196} And while some critics cited in support of their arguments against deference objections to stealth tort reform,\textsuperscript{197} most instead chose to focus on what they saw as the inevitable outcome of the acceptance of the FDA’s position: that individuals would be left without legal recourse for injuries sustained as the result of negligence, and thus severely impaired in their ability to vindicate their rights within the courts. And it was that argument in particular that may have

\textsuperscript{188} See generally James T. O’Reilly, Losing Deference in the FDA’s Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise, 93 CORNELL L. REV. 939 (2008) (arguing that the politicization of FDA during George W. Bush’s administration resulted in a shift away from judicial deference to the agency).


\textsuperscript{190} Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products and Draft Guidances and Two Guidances for Industry on the Content and Format of Labeling for Human Prescription Drug and Biological Products; Final Rule and Notices, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).

\textsuperscript{191} Id. at 3935.

\textsuperscript{192} Id. at 3936.

\textsuperscript{193} Issacharoff & Sharkey, supra note 173, at 1358; Rodriguez, supra note 172, at 161; Sharkey, supra note 153, at 228.

\textsuperscript{194} See generally Christine H. Kim, The Case for Preemption of Prescription Drug Failure-to-Warn Claims, 62 FOOD & DRUG L.J. 399, 399-401 (2007) (arguing that the Court should defer to the preemption determination found in the 2006 preamble not only because the evidence shows that FDA was moving in the direction of such a position, but also because state law tort claims are disruptive to the federal regulatory scheme).

\textsuperscript{195} See id. at 414, 416.

\textsuperscript{196} O’Reilly, supra note 98, at 145.

\textsuperscript{197} See Margaret H. Clune, Stealth Tort Reform: How the Bush Administration’s Aggressive Use of Preemption Doctrine Hurts Consumers, in CTR. FOR PROGRESSIVE REGULATION WHITE PAPER, at 1, 10 (Ctr. for Progressive Regulation, CPR White Paper No. 403, 2004), http://www.progressivereform.org/articles/preemption.pdf (suggesting that “consumers should be outraged at [FDA’s] clandestine attempts to erode their legal protections”).
carried the day in Wyeth for those who opposed the view that the FDA’s labeling requirements had preemptive effect on state law tort claims.

In Wyeth, Justice Stevens noted that when the preamble was disseminated in 2006, it was done so “without offering States or other interested parties notice or opportunity for comment,” stating that “[t]he agency’s views on state law are inherently suspect in light of this procedural failure.” Justice Stevens also pointed out the irony of the FDA’s sudden shift in policy, which “reverse[d] the FDA’s own longstanding position without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA’s regulation of drug labeling during decades of coexistence.”

2. The Importance of an Available Remedy

When considering preemption cases, the Court has often applied greater scrutiny in those instances where the preemption of state law would result in the complete denial of judicial recourse to injured plaintiffs. In Silkwood, for example, the Court considered whether plaintiffs may bring negligence claims against operators of nuclear power plants, despite the fact that the Atomic Energy Act preempts the ability of states to regulate the safety aspects of nuclear energy, and that the defendant complied with federal safety requirements. There, after reviewing the Atomic Energy Act, Justice White, writing for the majority, found that:

[T]here is no indication that Congress even seriously considered precluding the use of [state law] remedies either when it enacted the Atomic Energy Act in 1954 or when it amended it in 1959. This silence takes on added significance in light of Congress’ failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.

Because of these reasons, the Court held that the Atomic Energy Act did not preclude the plaintiff’s claim for punitive damages.

Similarly, in Bates v. Dow Agrosciences, the Court considered whether the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) preempted state-law claims against manufacturers of products that had been approved by the Environmental Protection Agency (EPA), which had been charged by Congress with the task of administering the act. Citing its earlier decision

199. Id.
201. Id. at 251.
202. Id. at 258.
in *Silkwood*, the Court stated that “[t]he long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.”204

The Court’s tendency to consider the availability of relief for those plaintiffs for whom compensation would be precluded entirely by preemption may therefore weigh against the FDA’s assertion that its labeling requirements preempt state law failure-to-warn claims. After all, the FDCA does not include a federal remedy for those who are injured because of a drug manufacturer’s negligence.205 Neither does the Court look favorably on the efforts of administrative agencies to “read in” federal remedial schemes in the absence of compelling evidence that Congress intended for a statute to provide one.206 Therefore, even if the FDA were to announce that there did exist a federal private right of action for those injured as the result of negligent labeling practices, it is unlikely that the remedy would be recognized by the courts.207

Further, the 2006 preamble outlined six broad classes of state law claims that it considered preempted by its labeling requirements.208 The list

204. *Id.* at 449.
205. See *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 788 (E.D. La. 2007) (“Because there are no federal remedies for individuals harmed by prescription drugs, a finding of implied preemption in these cases would abolish state-law remedies and would, in effect, render legally impotent those who sustain injuries from defective prescription drugs.”); *Wack v. Lederle Labs.*, 666 F. Supp. 123, 128 (N.D. Ohio 1987) (“Congress has not provided any federal remedies for collecting damages for inadequate labeling [sic] and design defects in [] products liability cases.”).
206. *Sharkey*, supra note 153, at 228-29 (“[A]gencies’ hands are tied by judicial tether.”).
207. *Id.* at 242.

FDA believes that at least the following claims would be preempted by its regulation of prescription drug labeling: (1) Claims that a drug sponsor breached an obligation to warn by failing to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling; (2) claims that a drug sponsor 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 sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule . . . ; (4) claims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been
is so expansive that it is hard to imagine an instance in which any negligence claim that even indirectly challenged the sufficiency of an FDA-approved prescription drug label could proceed. The result was then that if the FDA’s drug labeling requirements were found to have preemptive effect on state law tort claims, individuals who were injured because of the inadequacy of labeling would have been left without any judicial recourse.

The Court’s explanation for its sensitivity to the availability of remedies for injured plaintiffs in *Silkwood* and *Bates* easily translates into the realm of pharmaceuticals labeling. First, there is no evidence that Congress ever intended for the FDCA to strip individuals of legal compensation for injuries sustained as the result of a drug manufacturer’s negligent labeling practices. To the contrary, in the 1997 amendments to the FDCA, Congress seemed to indicate its intent that the FDA and the States collaborate on the regulation of drugs when it included a provision that required the manufacturers of drugs already approved by the FDA to obtain state licensing to distribute their products. Second, the FDA never indicated in the 2006 preamble that Congress intended labeling regulations to preempt state law, thus buttressing the argument against deferring to the FDA’s unilateral declaration of the preemptive effect of its labeling requirements.

Although Justice Stevens mentioned only briefly the importance of an available remedy in his opinion in *Wyeth*, he notes the importance of the “distinct compensatory function” served by state law tort claims that “may motivate injured persons to come forward with information.” This, he states, in combination with the deterrent effects that adverse judgments have on the behaviors of those companies that market and distribute dangerous

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Id.

209. Rodríguez, supra note 172, at 182.
211. Rodríguez, supra note 172, at 182.
212. See id.
products, shows that “FDA traditionally regarded state law as a complementary form of drug regulation.”

3. The Relevance of an Agency’s Inability to Prevent Harm

Both recent litigation215 and independent studies216 have indicated that the FDA is plagued by institutional shortcomings that seriously compromise its ability to prevent the very harms that preemption would leave uncompensated. These indications give rise to fundamental questions about whether the FDA is at all capable of sole regulation of the drug marketplace, and if not, whether the agency’s recent assertion of its authority to do so should be granted deference.217

Both the Institute of Medicine and the FDA’s own employees agree that the agency lacks the resources it needs to adequately monitor the safety of drugs once they pass through the approval process.218 Considering that the FDA’s rigorous pre-approval process “cannot, and is not designed to, uncover risks that are relatively rare or have long latency periods,”219 that most post-release adverse events go unreported,220 and that most drug-related injuries occur during the post-release period,221 the potential for these injuries appears to be significant. Manufacturers exacerbate the risks of post-release adverse drug events by the direct-to-consumer marketing of prescription pharmaceuticals.222 The result of this practice is that, within

214. Id.
215. See, e.g., In re Vioxx Prods. Liab. Litig., 501 F. Supp. 2d 776, 788 (E.D. La. 2007) (“To abolish [state-law remedies available to those harmed by prescription drugs] based solely on a preamble inserted at the eleventh hour and drafted by an agency without the express or implied authority to abolish such remedies is Draconian and unacceptable.”).
216. INST. OF MED., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 17 (Alina Baciu, Kathleen Stratton & Sheila P. Burke eds., 2007) (“FDA does not have adequate resources or procedures for translating preapproval safety signals into effective postmarketing studies, for monitoring and ascertaining the safety of new marketed drugs, for responding promptly to the safety problems that are discovered after marketing approval, and for quickly and effectively communicating appropriate risk information to the public.”); U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-06-402, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA’S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 5 (2006), available at http://www.gao.gov/new.items/d06402.pdf (“FDA lacks a clear and effective process for making decisions about, and providing management oversight of, postmarket drug safety issues.”).
218. Id. at 484-85.
219. Id. at 483.
221. Kessler & Vladeck, supra note 186, at 471, 483.
222. See id. at 487.
weeks of release, a drug is “prescribed by thousands of doctors to perhaps hundreds of thousands of patients.” These illustrations of agency failure militate against the preemption of state tort claims, which remain, in the absence of a federal remedy, the only source of compensation to those injured as a result of the FDA’s recognized failure to identify drug risks.

The Wyeth Court pointed to these perceived shortcomings when it discussed the important role that state-law tort suits play in the regulation of prescription drugs, stating that the “FDA has limited resources to monitor the 11,000 drugs on the market,” and noting specifically that when Phenergan was approved in 1955, an advisory committee report declared “conclusively that the...budget and staff of the Food and Drug Administration are inadequate to permit the discharge of its existing responsibilities for the protection of the American public.” “State tort suits,” the Court said, “uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly.” These claims—especially when they are combined into mass tort suits—may in many ways “mirror[] the development of public administrative agencies” in that they “wield significant power over human lives and resources.”

V. THE POTENTIAL EFFECTS OF WYETH V. LEVINE ON PUBLIC HEALTH POLICY

Wyeth v. Levine is the newest chapter in a story that has been told since our nation’s earliest days. That story pits federal supremacy against state sovereignty in a tug-of-war battle over the right to determine when safety is safe enough. However, in Wyeth, its players brought with them new strategies for gaining ground. Foremost among these was the FDA’s attempt to declare its preemptive authority by means of regulatory preamble, the newest trend in “the increasing federalization of law governing products regulated in the national market.” The use of these preambles as attempts by administrative agencies to assert their preemptive intent breathed new life into strategies to relieve commercial companies from the strain brought about by adverse court settlements for state law tort claims. In addition, Wyeth revived debates that, in recent years, had been

223. Id. at 487-88.
225. Id. at 1202 n.11. (quoting Citizens Advisory Committee on the FDA, Report to the Secretary of Health, Education, and Welfare, H.R. Doc. No. 227, 84th Cong., 1st Sess., 53 (1955)).
226. Id. at 1202.
228. Sharkey, supra note 153, at 258. See also id. at 230-37 (describing how the Consumer Product Safety Commission and the National Highway Traffic Safety Commission have each issued preemption provisions in regulatory preambles).
thought to be somewhat settled, such as those questions that address what deference is due to federal agency action.

The stakes, however, were far greater in *Wyeth*. Had the FDA gained the upper hand in that contest, the agency’s determinations as to whether prescription drug labeling was sufficient would have precluded entirely any attempts by injured parties to win legal compensation for their injuries. The result would have been that drug manufacturers would have been able to escape entirely all accountability in the nation’s courts for their negligent labeling practices, and answered only to a solitary federal agency whose ability to ensure the safety of the American people may be seriously limited, so long as the FDA had approved the drugs, and their labels, as safe.

Aside from the federalism concerns that would have been raised if Wyeth had succeeded in its appeal, public health advocates would almost certainly have found one of their most effective tools for effecting sweeping public health objectives dulled. As discussed in Part II, and in the Court’s majority opinion in *Wyeth*, state law tort claims have, since our country’s earliest days, played a significant role in the development and implementation of public health policy. First, tort litigation creates a powerful financial incentive for industries to investigate more rigorously the risks and benefits of their products before releasing them to the public. Second, at least in regard to pharmaceuticals, tort claims can bring to light important safety information that has been previously unreleased by manufacturers, and which may therefore be unavailable to the FDA. Finally, and perhaps most importantly, it may serve to fill the regulatory gap that critics argue exists in the FDA’s oversight of drug safety, thus adding an additional layer of security to consumers who are privy to only the information available to them via drug company disclosures and doctor’s orders.

The importance of *Wyeth* is underscored by the fact that, regardless of how the Court decided the case, it was poised to change the face of public health policy in the United States. As discussed, if the Court had found in favor of Wyeth, holding that the FDA’s labeling requirements preempted state law tort suits, there would have been virtually no recourse for those individuals who were injured as the result of the negligent labeling practices of manufacturers. What’s more, if the Court had gone much further, and held that the FDA’s attempt to unilaterally declare its preemptive authority by
means of regulatory preamble was effective, it could have resulted in the
sharp curtailing of state law tort litigation involving any number of industries
regulated by the federal government. As noted, several federal
administrative agencies have attempted to use regulatory preambles as a
means of asserting the preemptive authority of their promulgated rules.232

If this strategy had been affirmed in Wyeth, it is likely that corporations
and industries, in an effort to avoid legal liability for their negligent acts,
would bring to bear against administrative agencies significant pressure to
use regulatory preambles as a means of asserting preemptive authority.
This, in turn, could have had the effect of chilling the use of state law tort
claims for public health purposes, forcing advocates to resort entirely to a
legislative process that is criticized as an inefficient means of guarding
human health and safety. That is, by setting a standard of deference that
validates agency interpretations that occur outside of formal rulemaking,
and in the absence of a congressional signal indicating the intent to
preempt state law, it may be that other regulated industries would have
eventually found themselves free from the burden of having to account
within the nation’s courts for their negligent actions.

However, this was not the case in Wyeth. Instead, the Court held that
the FDA’s labeling determinations are not conclusive on the issue of whether
pharmaceuticals companies failed to provide consumers with adequate
warnings regarding their products.233 This appears to have resolved what
was emerging as a nationwide split regarding the preemptive effect of the
FDA’s labeling requirements.234 Because the possibility of unfavorable
determinations can dissuade prospective plaintiffs from bringing claims, it is
possible that the resolution of this point in favor of consumers could have
the effect of encouraging injured parties to pursue compensation from
negligent pharmaceuticals companies for injuries sustained as the result of
inadequate warning labels on drugs. By affirming the use of state law tort
claims as a legitimate method of attaining relief for negligent labeling
practices, individuals will be allowed to continue influencing industry
behaviors that affect the public health. This could have huge implications

234. Prior to Wyeth, there was a split of authority regarding whether the FDA’s 2006
labeling requirements preempted state-law tort claims. See Sharkey, supra note 153, at 246
n.97 (citing two cases where courts have failed to find that the labeling requirements
preempted state law tort claims: Levine v. Wyeth, 944 A.2d 179, 192 (Vt. 2006) and Jackson
v. Pfizer, Inc., 432 F. Supp. 2d 964, 966 (D. Neb. 2006)). In contrast, Sharkey cites several
cases in which courts found that FDA labeling requirements did preempt state law, including
Colacicco v. Apotex, Inc., 521 F.3d 253, 276 (3d Cir. 2008) and In re Bextra & Celebrex
for the ways in which public health advocates use the nation’s courts to put
into motion their agendas. Where advocates may have once found their
efforts to indirectly regulate the pharmaceuticals industry frustrated by a lack
of legal clarity regarding the preemptive effect of the FDA’s labeling
determinations, the Court’s affirmation of both the legitimacy of these
claims, and the established practice of using state-law suits to affect public
health outcomes, may help to usher in new attempts to change the
behaviors of companies whose products and actions so directly influence the
wellbeing of individuals.