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Deconstructing *Wyeth v. Levine*: The New Limits on Implied Conflict Preemption

David C. Vladeck

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DECONSTRUCTING **Wyeth v. Levine**: THE NEW LIMITS ON IMPLIED CONFLICT PREEMPTION

*David C. Vladeck*

This Symposium was convened to explore the state of the civil justice system in the United States. At the time, *Wyeth v. Levine* was pending before the United States Supreme Court, and a decision was not anticipated until the end of the Term. My project was to comment on the state of the Court’s jurisprudence in regulatory implied conflict preemption cases. These are cases in which federal regulatory action is said to pre-empt state tort or products liability law because the application of state law is alleged to obstruct the fulfillment of federal regulatory objectives. The issue is important, not just because the disposition of *Wyeth* would decide whether failure-to-warn cases against drug companies are preempted, but also because *Wyeth* was seen as a test case for President George W. Bush’s campaign to use regulatory implied conflict preemption to provide businesses insulation from state tort and products liability cases. From 2002 through 2008, each of the nation’s key federal health and safety regulatory agencies—including the Food and Drug Administration (FDA), the National Highway Traffic Safety Administration (NHTSA), the Consumer Product Safety Commission (CPSC), and the Federal Railroad Administration (FRA)—took the position that virtually any regulatory action taken by the agency, including statements in regulatory preambles and obscure references on agency

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1 Director, Federal Trade Commission Bureau of Consumer Protection; Professor of Law and Director, Institute for Public Representation, Georgetown University Law Center. Prior to joining Georgetown’s faculty, Professor Vladeck was an attorney with Public Citizen Litigation Group, where, among other things, he handled cases for public health organizations against federal agencies, including those agencies discussed in this Essay, as well as cases involving preemption questions, arguing in favor of preserving state law. The author is grateful for the comments of Catherine M. Sharkey, Roderick M. Hills, Linda S. Mullenix, other symposium participants, members of the Case Western Reserve Law School Law Review, and my Georgetown colleague Kathryn A. Sabbeth.

1 129 S. Ct. 1187 (2009).
web-sites, had the effect of wiping away state law. If that position were upheld by the courts, Americans injured through no fault of their own by everyday consumer products might find themselves without any remedy at all.

As discussed below, the Court’s recent ruling in *Wyeth* emphatically rejects the FDA’s argument that its approval of a drug’s label preempts state failure-to-warn claims. The decision also clarifies and, in my view, narrows considerably the doctrine of regulatory implied conflict preemption, and does so in a way that likely consigns the Bush Administration’s pro-preemption efforts to repudiation by the courts.

Before turning to *Wyeth*, it is useful to explore the critique of the Court’s regulatory implied preemption jurisprudence before *Wyeth*, which helps explain why the Bush Administration thought it could reshape tort law through implied regulatory preemption and why many commentators predicted a big win for *Wyeth*. The Essay then turns to discuss the background for the *Wyeth* litigation and the possibly far-reaching implications of the Court’s decision.

I. THE PRE- *WYETH* CRITIQUE

The analysis courts apply in preemption cases is, at least as a matter of structure, well settled. Courts are instructed first to examine whether Congress has included in the relevant statute an express preemption provision that specifically forecloses the state law, regulation, requirement, or other state-mandate under attack.\(^2\) Difficult interpretative questions often arise about the reach of express preemption provisions.\(^3\) But in express preemption cases, the Court’s first focus is on the meaning of the preemption provision Congress drafted, an inquiry guided by well-settled tools of statutory construction.\(^4\)


\(^3\) Compare, e.g., Riegel, 128 S. Ct. 999 (interpreting the preemption provision in the Medical Device Act to preempt state product liability cases regarding medical devices specifically approved by the FDA), with Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) (interpreting the preemption provision in the Medical Device Act not to preempt cases regarding medical devices permitted on the market because they are substantially equivalent to devices on the market at the time the Act was passed or substantially equivalent to devices specifically approved by the FDA).

\(^4\) In these cases, the statutory canon the Court employs most frequently is the federalism canon that presumes “that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (citing *Napier v. Atlantic Coast Line R.R. Co.*, 272 U.S. 605, 611 (1926)). This presumption “applies with particular force when Congress has
More complicated analytical questions arise if there is no express preemption provision that forecloses the state action. Courts then must undertake field, conflict, and implied conflict preemption analysis. The inquiry is to determine whether, although Congress did not say so explicitly, circumstances compel the conclusion that Congress intended to displace state law, because Congress wanted a federal regulatory regime to occupy the field or because state law either actually conflicts with federal dictates or would frustrate the attainment of federal objectives. As the Court has repeatedly driven home, """"[t]he purpose of Congress is the ultimate touchstone"""" in every pre-emption case.7

As I have written elsewhere, this analytical structure has led courts to hold far more state law—especially state tort and damages law—preempted than Congress intended or is necessary to the achievement of federal goals.8 Adding to the confusion is that the justifications legislated in a field traditionally occupied by the States.9 Altria Group, 129 S. Ct. at 543 (citing Lohr, 518 U.S. at 485); see also Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005). The Court most recently emphasized the vitality of this canon in Altria Group, 129 S. Ct. at 543, although the Court left the canon unmentioned in Riegel, 128 S. Ct. 999. There is, of course, a long-simmering debate over the utility of substantive canons, but this Essay leaves that debate to others. Compare, e.g., ANTONIN SCALIA, A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW 28–29 (1997) (denigrating substantive canons generally), with William N. Eskridge, Jr., Public Values in Statutory Interpretation, 137 U. PA. L. REV. 1007 (1989) (defending substantive canons).

5 See, e.g., English v. General Elec. Co., 496 U.S. 72, 79 (1990) (describing field preemption); Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963) (describing conflict preemption); Rice, 331 U.S. at 230 (describing field preemption); Hines v. Davidowitz, 312 U.S. 52, 67 (1941) (describing obstacle preemption). It bears noting that, even where Congress has included an express preemption provision, questions of field, conflict, and implied preemption questions may arise. Altria Group, 129 S. Ct. 538, is an example of such a case. Having rejected the tobacco company’s claim that the Federal Cigarette Labeling and Advertising Act expressly preempted state fraud cases against the company, the Court then turned to the company’s fall back argument that such claims were impliedly preempted because they conflicted with the Federal Trade Commission’s policies on tobacco regulation. Id. at 546, 549. Although the Court rejected both arguments, it nonetheless recognized the possibility that implied preemption principles could apply even where there was an express preemption case. Id. at 549; see also Sprietsma v. Mercury Marine, 537 U.S. 51, 65 (2002) (stating that the “inclusion of an express pre-emption clause ‘does not bar the ordinary working of conflict [or implied] pre-emption principles’” (quoting Geier v. Am. Honda Motor Co., 529 U.S. 861, 869 (2000))); Geier, 529 U.S. at 873–74 (applying implied preemption principles to find product liability claim preempted even though the claim was not covered by the statute’s express preemption provision).


7 Altria Group, 129 S. Ct. at 543 (quoting Lohr, 518 U.S. at 485 (quoting Retail Clerks v. Schermerhorn, 375 U.S. 96, 103 (1963))).

courts invoke for non-express preemption—field, conflict, and implied conflict preemption—are imprecise, overlapping, and inconsistently applied, which leads to uncertainty about when state law will be set aside. This lack of analytic clarity is a problem not simply for regulated entities, those injured by products made by regulated entities, and the courts, but it is also a serious problem for Congress and state legislatures trying to reach sensible accommodations about the allocation of regulatory power.

But the point of this brief Essay is not to launch a broad-sided attack on conventional preemption analysis. There has already been a tank car’s worth of ink spilled doing just that. Rather, this Essay focuses solely on the Court’s regulatory implied conflict preemption analysis—that is, the analytical path the Court follows where a party (generally backed by a federal regulatory agency) claims that application of state law will frustrate the attainment of federal goals, even where it is possible to comply simultaneously with both federal and state dictates. The Court has ruled that state law may be ousted in such circumstances, notwithstanding the fact that there is (a) no express preemption provision, (b) no direct conflict between federal and state law, and (c) no indication that Congress wanted to foreclose all state regulation in a given field. Some Justices have expressed discomfit with the very idea that courts can displace state law in these

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10 Consider the uncertainty engendered by the Court’s ruling in Geier, 529 U.S. 861, where the Court found the plaintiff’s product liability action preempted, even though the relevant statute, the Motor Vehicle Safety Act, has a savings provision directly addressed to common law actions that states “[c]ompliance with a motor vehicle safety standard prescribed under this chapter does not exempt a person from liability at common law.” 49 U.S.C. § 30103(e) (2000). See generally Sandi Zellner, When Congress Goes Unheard: Savings Clauses’ Rocky Judicial Reception, in PREEMPTION CHOICE, supra note 9, at 144, 164–65 (arguing that “giving savings clauses appropriate weight would honor congressional choices, avoid regulatory gaps, and enhance institutional competency by empowering governments at all levels to protect the public”).


12 See, e.g., Geier, 529 U.S. 861.
circumstances. But because the implied preemption doctrine is by now embedded deeply in the Court's preemption jurisprudence, this Essay does not call for its reevaluation.

Prior to the Court's ruling in Wyeth v. Levine, my claim would have been that the Court's approach in implied preemption cases—exemplified in the Court's 5–4 ruling in Geier v. American Honda Motor Co.—pushed courts to find preemption in cases in which the displacement of state law actually subverts the attainment of goals articulated in the federal statutes. The theory of preemption, of course, is that the Supremacy Clause of the Constitution requires state law to yield when it interferes with the attainment of goals Congress set in the legitimate exercise of its powers, generally under the Commerce Clause.

Before Wyeth, the failure of courts to consider whether federal regulatory efforts, on their own, are adequate to fulfill Congress's objectives threatened to stand the purpose of implied preemption analysis on its head. Where a finding of preemption removes a market discipline imposed by state law, and that market discipline in fact serves to advance Congress' goals (even indirectly), then a finding of implied preemption may undermine rather than advance federal objectives. There are two reasons often related for why federal regulatory efforts may not satisfactorily advance federal goals; first, the agency may lack the competence to do its job effectively, generally because it lacks needed resources or statutory authority; or, second, the agency may be "captured" or unduly influenced by the industry it is charged with regulating. In either case, a ruling that federal action—no matter how ineffectual—preempts state law may result in thwarting federal objectives.

As noted, Geier was, prior to Wyeth, the Court's main pronouncement on regulatory implied preemption. Geier involved a claim by Alexis Geier, a young woman who was seriously injured

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13 For instance, in Bates v. Dow Agrosciences LLC, Justice Thomas, joined by Justice Scalia, wrote approvingly of the "Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption." 544 U.S. 431, 459 (2005) (Thomas, J., concurring in the judgment in part and dissenting in part). In Geier, Justice Stevens' dissent, in which Justice Thomas joined, emphasized the importance of "preven[ing] federal judges from running amok with [the] potentially boundless (and perhaps inadequately considered) doctrine of implied conflict pre-emption based on frustration of purposes." 529 U.S. at 907 (Stevens, J., dissenting). And in Gade v. National Solid Waste Management Ass'n, Justice Kennedy voiced concern that "[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is Congress rather than the courts that pre-empts state law." 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part, concurring in judgment).
15 It goes without saying that displacement of state law subverts the state's goals.
16 See, e.g., Schroeder, supra note 9.
when her 1987 Honda, equipped with just a shoulder harness and a lap belt, crashed into a tree. She sued, claiming that cars lacking air bags were defectively designed. But the Court held, 5-4, that her claim was preempted because a standard promulgated by NHTSA gave manufacturers a choice of installing air bags or non-detachable belts.

Congress established NHTSA in 1966 to set safety standards that are “practicable” and that “meet the need for motor vehicle safety.” When Congress wrote the Motor Vehicle Safety Act (“Safety Act”)—the legislation creating NHTSA—it included an express preemption provision that said no state may “prescribe or continue in effect a standard applicable to the same aspect of performance” that is not “identical” to the federal standard. But Congress went on to add a “savings clause” that provides that “[c]ompliance with” a NHTSA standard “does not exempt a person from liability at common law.”

Geier called on the Court to decide whether NHTSA’s “occupant protection” (passive restraint) standard preempted state tort law. The standard, first adopted in 1967, initially required manufacturers to install lap and shoulder belts, but NHTSA soon found that many occupants did not bother fastening their belts. Consumer groups urged NHTSA to require a new technology—air bags—that operated automatically. NHTSA revised the standard in 1971 to require either air bags or automatic seatbelts for front seat occupants by 1975.

But the auto industry objected. Henry Ford and Ford President Lee Iacocca met secretly with President Nixon to urge that the standard be scrapped. After the meeting, Nixon called Secretary of Transportation John Volpe and told him to rescind the rule, which he did. NHTSA then adopted the industry’s proposal to mandate the use of “ignition interlock” devices that prevented the car from starting until front-seat occupants had buckled up. The public hated the

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18 Id. § 30103(b)(1).
19 Id. § 30103(e).
21 Geier, 529 U.S. at 875.
22 Id. at 875–76.
23 Id.
25 Id.
26 Geier, 529 U.S. at 876.
hard-to-use interlock devices, and Congress soon amended the Safety Act to forbid their use.\textsuperscript{27}

It was not until the Carter Administration that NHTSA revived the passive-restraint standard. In 1977 the agency gave the industry until model year 1982 to install air bags or automatic belts, but the Reagan Administration rescinded the standard in 1981.\textsuperscript{28} Insurance companies and consumer groups sued NHTSA, challenging the validity of the rescission. In \textit{Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.},\textsuperscript{29} the Supreme Court agreed, finding that NHTSA had arbitrarily bowed to industry pressure in withdrawing the standard. Responding to this defeat, and having no choice, NHTSA finally issued a new standard that required manufacturers, over a lengthy phase-in period, to install either air bags or non-detachable belts with shoulder harnesses, although the standard reflected a slight preference for air bags.\textsuperscript{30}

NHTSA’s new standard was criticized for further delaying the widespread introduction of air bags.\textsuperscript{31} By this point, the evidence demonstrated that air bags were easy to install, affordable, and far more protective than automatic belts.\textsuperscript{32} As a result of NHTSA’s gradual phase-in, however, many new cars were not equipped with air bags, leading to needless injuries and deaths.\textsuperscript{33} One such case involved Alexis Geier, who sued Honda, claiming that cars lacking air bags were defectively designed.

Justice Breyer’s majority opinion in \textit{Geier} first rejected Honda’s argument that the Safety Act expressly preempted Geier’s claim because the Act’s savings clause explicitly preserved it.\textsuperscript{34} Nonetheless, the Court turned to Honda’s implied preemption arguments under “the ordinary working of conflict pre-emption principles.”\textsuperscript{35} The Court recognized that Congress intended the savings clause to “preserve[] those actions that seek to establish greater safety protection than the minimum safety achieved by a federal regulation intended to provide a floor,” but concluded that

\textsuperscript{27} \textit{Id.}
\textsuperscript{28} \textit{Id.} at 876–77; \textit{see also} \textit{McGarity}, \textit{supra} note 20, at 63.
\textsuperscript{29} 463 U.S. 29 (1983).
\textsuperscript{32} Keebler \& Pinto, \textit{supra} note 31.
\textsuperscript{33} \textit{McGarity}, \textit{supra} note 20, at 65.
\textsuperscript{34} \textit{Geier} v. \textit{Am. Honda Motor Co.}, 529 U.S. 861, 868 (2000).
\textsuperscript{35} \textit{Id.} at 869.
the savings provision did not necessarily "save" all state-law tort actions, regardless of their potential threat to the objectives of federal safety standards." The express preemption provision did suggest a congressional interest in avoiding "conflict, uncertainty, cost, and occasional risk to safety itself that too many different safety[standard[s] . . . might otherwise create"—policy considerations the Court saw as favoring implied preemption of state common law. Relying heavily on NHTSA's preamble to the final standard, the Court concluded that permitting Geier's tort claim to go forward would conflict with NHTSA's decision to provide for a "gradual phase-in" of air-bags to "lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance."

Writing for the dissenters, Justice Stevens argued that federal regulatory objectives "would not be frustrated one whit by allowing state courts to determine whether in 1987 the lifesaving advantages of air bags had become sufficiently obvious that their omission might constitute a design defect in some new cars." Indeed, as the dissent explained,

The phase-in program . . . thus set minimum percentage requirements for the installation of passive restraints . . . . Those requirements were not ceilings, and it is obvious that the Secretary favored a more rapid increase. The possibility that exposure to potential tort liability might accelerate the rate of increase would actually further the only goal explicitly mentioned in the standard itself: reducing the number of deaths and severity of injuries of vehicle occupants.

The dissenters' point was borne out by NHTSA's later estimation that as many as sixty-three thousand more lives could have been saved had all manufacturers installed air bags at the outset.

Geier has been subject to three lines of criticism. The first is that the Court approached NHTSA's effort with an unrealistic view of the ability of federal agencies to achieve regulatory goals on their own, without the backstop of state tort and products liability law. In some cases, including Geier, that assumption might have been unwarranted.

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36 Id. at 870.
37 Id. at 871.
38 Id. at 875, 879.
39 Id. at 888 (Stevens, J., dissenting).
40 Id. at 903–04.
41 See Keebler & Pinto, supra note 31. See generally McGarity, supra note 20, at 61–64 (discussing preemption in the context of transportation regulation of automobiles).
That assumption is based on an idealized view of the state of our federal regulatory agencies that may have little grounding in reality. It assumes that agencies have the resources they need to do their jobs; that agencies have the budget, equipment and personnel to accomplish their mission; that agencies have the ability to obtain all of the information they need swiftly and with no questions about the information’s accuracy or completeness; that agencies are able to quickly and decisively respond to emerging hazards; and that agencies can operate free of untoward political influence and can take action based on the merits and only on the merits. Each of these assumptions may be unjustified. And each is a potential danger signal that the agency lacks the resources to do its job effectively. In those instances, a pro-preemption determination rests on nothing more than the fiction that an under-funded, under-staffed, information-deprived, politically-constrained agency can, on its own, fulfill the function that Congress assigned to it.\footnote{There certainly were danger signals that NHTSA fit that description. NHTSA faces a formidable challenge in trying to regulate the automobile industry, which includes not only all of the car makers (domestic and foreign), but also the manufacturers of trucks, school buses, and the component parts used in motor vehicles. NHTSA has a skeletal staff, numbering well below 1,000 employees. It has a tiny research budget. It is one “David” facing many Goliaths. \textit{See McGarity, supra note 20, at 60–111} (discussing the preemption war in the courts); David C. Vladeck, \textit{Defending Courts: A Brief Rejoinder to Professors Fried and Rosenberg}, 31 \textit{SETA\textsc{n} HALL L. REV.} 631, 639–41 (2001) (discussing the shortcomings of the NHTSA and the effect on its regulatory abilities); U.S. DEP’T OF TRANSP., FISCAL YEAR 2008 BUDGET IN BRIEF 70, http://www.dot.gov/bib2008/pdf/bib2008.pdf (identifying NHTSA staffing authorization at 635 full time employees).}

The second critique of \textit{Geier} is that it failed to address the possibility that state law, including state liability law, helps further federal health and safety objectives by deterring excessive risk-taking, providing information that might otherwise not come to light, and serving a compensatory function generally unaddressed but complementary to federal goals.\footnote{See, e.g., Kessler & Vladeck, \textit{A Critical Examination, supra note 8, at 491–95} (citing numerous authorities and arguing that failure-to-warn litigation helps further the FDA’s efforts to ensure the safety of drugs); \textit{see also McGarity, supra note 20, at 60–111} (discussing the preemption war in the courts); Aaron S. Kesselheim & Jerry Avorn, \textit{The Role of Litigation in Defining Drug Risks}, 297 JAMA 308, 310 (2007) (citing examples of the impact that litigation has on regulatory behavior).} As the dissenter pointed out, accelerating the introduction of airbags would have furthered, not frustrated, the Safety Act’s goals, which are fundamentally to protect motor vehicle occupants from injury.

Third is the agency-capture critique, which the Court also side-stepped in \textit{Geier}. Courts must be alert for danger signals of agency capture that suggest an agency’s plea for preemption may not be consistent with Congress’ goal or otherwise serve the public...
interest. What is surprising about the *Geier* majority opinion is that it accepted uncritically the Department's assertion that it made a considered judgment that a gradual phase-in of air bags was important to develop public acceptance of air bags and a better understanding of how to make better and safer air bags, and that its phase-in plan best served the Safety Act's purpose. Although the Court cited *State Farm* as part of its discussion of the history of the regulation of air bags, it said nothing about the ruling in *State Farm*—namely, that the Department of Transportation (DOT), succumbing to intense pressure from the automobile industry, had arbitrarily and capriciously determined to delay the phase-in of air bags. Indeed, the *State Farm* Court famously observed that “[n]early a decade, the automobile industry waged the regulatory equivalent of war against the airbag,” and the Court faulted DOT for capitulating to the industry rather than serving the public interest.44 *State Farm* is the paradigmatic agency capture case.

In my view, the signal defect of *Geier* is that it is completely ahistoric. The Court’s opinion in *State Farm* shows that it had every reason to be skeptical that the phase-in of air bags was designed to fulfill the Safety Act and to question whether the phase-in was implemented in part to appease a disgruntled and powerful industry still waging the regulatory equivalent of war against the mandatory introduction of airbags. The lesson of *Geier* is that where there is evidence of an agency giving ground to placate a powerful industry, courts should independently examine whether the agency’s assertion of fidelity to statutory goals is sound, rather than simply accepting the agency’s assertion at face value.


The relevant passage of the Court’s opinion in *State Farm* is worth quoting in its entirety:

The automobile industry has opted for the passive belt over the airbag, but surely it is not enough that the regulated industry has eschewed a given safety device. For nearly a decade, the automobile industry waged the regulatory equivalent of war against the airbag and lost—the inflatable restraint was proved sufficiently effective. Now the automobile industry has decided to employ a seatbelt system which will not meet the safety objectives of Standard 208. This hardly constitutes cause to revoke the Standard itself. Indeed, the Act was necessary because the industry was not sufficiently responsive to safety concerns. The Act intended that safety standards not depend on current technology and could be ‘technology-forcing’ in the sense of inducing the development of superior safety design. If, under the statute, the agency should not defer to the industry’s failure to develop safer cars, which it surely should not do, *a fortiori* it may not revoke a safety standard which can be satisfied by current technology simply because the industry has opted for an ineffective seatbelt design.

*Id.* (footnote omitted) (citation omitted).
II. THE BUSH ADMINISTRATION'S PRO-PREEMPTION PUSH

In the wake of Geier, the Bush Administration decided to try to accomplish "tort reform" by directing health and safety agencies to seek to preempt state tort and products liability law by declaring that agency regulatory action had the effect of wiping away state law.\(^45\) After all, the Court in Geier signaled that, in assessing implied regulatory preemption claims, the courts should take their cues from the federal agency's assertion that state law was an obstacle to the fulfillment of federal goals.

The FDA started and perhaps was the incubator of this campaign. For most of its long history, the FDA had consistently taken the position that its regulatory efforts could comfortably coexist with state failure-to-warn litigation brought by consumers injured by FDA-regulated drugs.\(^46\) But the agency did an about-face in 2002, claiming, first in amicus briefs and then in a 2006 Federal Register notice accompanying a new rule on labeling, that failure-to-warn litigation threatens the agency's ability to protect the public health.\(^47\) According to the agency, warnings that overstate or exaggerate risks are no more helpful to physicians and patients than warnings that inappropriately downplay those risks. Striking the right balance is uniquely the FDA's province. A judicial determination that an FDA-approved warning label fails adequately to warn may force manufacturers to add warnings the FDA did not approve, or even warnings that the FDA considered and rejected.\(^48\) To prevent this conflict between FDA-mandated warnings and state court judgments, the FDA asserted


\(^{46}\) See Kessler & Vladeck, A Critical Examination, supra note 8, at 463; Margaret Jane Porter, The Loehr Decision: FDA Perspective and Position, 52 Food & Drug L.J. 7, 9 (1997).


\(^{48}\) See Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products, 71 Fed. Reg. at 3935.
that its approval of labeling preempts most failure-to-warn litigation.\textsuperscript{49}

Other agencies soon joined in, with the CPSC and NHTSA asserting that their standards preempt state law.\textsuperscript{50} And similar pronouncements from other agencies, including the Federal Railroad Administration and the Department of Homeland Security, followed. In just a few years, literally dozens of agency Federal Notices took the position that some agency action short of a regulation preempted state tort law.\textsuperscript{51} And some agencies, like the FDA, claim that even notices on agency web-sites preempt state tort law.\textsuperscript{52}

\textsuperscript{49} See id. ("[A]dditional requirements for the disclosure of risk information . . . can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.").


\textsuperscript{51} Final agency rules which assert in the preamble to the final rule that the rule will preempt tort law include:

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National Highway Traffic Safety Administration

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<td>Federal Motor Vehicle Safety Standards; Occupant Protection in Interior Impact; Side Impact Protection; Fuel System Integrity; Electric-Powered Vehicles; Electrolyte Spillage and Electrical Shock Protection; Side Impact Phase-I Reporting Requirements, 72 Fed. Reg. 51,908, 51,953 (Sept. 11, 2007).</td>
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### Proposed rules containing preamble language claiming preemption:

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<td>OTC drugs in trial size packages</td>
<td>Over-the-Counter Human Drugs; Labeling Requirements, 71 Fed. Reg. 74,474, 74,480–81 (proposed Dec. 12, 2006).</td>
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<td>Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Required Warnings and Other Labeling, 71 Fed. Reg. 77,314, 77,345 (proposed Dec. 26, 2006).</td>
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### Fatty acids

### Pregnancy and lactation labeling

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### National Highway Traffic Safety Administration

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**Federal Railroad Administration**

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<td>Incident reporting requirements</td>
<td>Miscellaneous Amendments to the Federal Railroad Administration’s Accident Incident Reporting Requirements, 73 Fed. Reg. 52,496, 52,519 (proposed Sept. 9, 2008).</td>
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<td>Continuous welded rail (inspections)</td>
<td>Track Safety Standards; Continuous Welded Rail, 73 Fed. Reg. 73,078, 73,089–90 (proposed Dec. 1, 2008).</td>
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One reason why a campaign of this magnitude received only modest attention from the press and the academic community is that the agencies, for the most part, have simply announced their views on preemption in a preamble to a regulation that does not itself address preemption or in some other informal agency statement. Professor Catherine Sharkey has aptly dubbed this approach “preemption by preamble.” There are consequences to this informality. There is no record against which to evaluate the agency’s action, and the agency is under no obligation to back up with evidence its argument that implementation of state requirements is interfering with, or will impair, the agency’s ability to achieve federal objectives. To be sure, the informality of the agency pronouncement deprives it of the strong deference more formal agency action receives from reviewing courts. But many courts have found that agency statements on preemption are entitled to some deference.

III. WYETH v. LEVINE—BACKGROUND

The Achilles’ heel in the Bush Administration’s preemption campaign is that agency pronouncements of preemption are not self-executing. They are not set forth in a binding regulation or any other

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These tables were compiled in part with help from justice.org.


The FDA’s position on preemption generated substantial litigation, with courts dividing on whether to give the FDA’s position deference and, if so, how much. Although the majority of lower courts had rejected the FDA-backed implied preemption argument, some courts accepted the argument and dismissed cases on that ground.57

The signature case, however, is Wyeth v. Levine, which the Court decided on March 4, 2009. These are the facts. On April 7, 2000, Diana Levine went to a clinic for treatment of a migraine headache.58 She received an injection of Demerol for her headache and a dose of Wyeth’s drug Phenergan for nausea caused by her migraine headache and a common side effect of Demerol.59 Ms. Levine’s headache returned and she went back to the clinic, where she received a second dose of the Demerol-Phenergan combination. This time the Phenergan was administered through an intravenous (or IV) push injection into Ms. Levine’s right arm.60 Phenergan’s label permits this method of administration, but warns that it carries a serious risk if the drug inadvertently comes into contact with the patient’s artery. Tragically, the Phenergan penetrated one of Ms. Levine’s arteries, causing the surrounding tissue to die and become gangrenous.61 In the following weeks, doctors had to amputate her hand and, ultimately, the remainder of her arm below the elbow. Ms. Levine had been a professional musician. She now struggles to perform daily tasks and

56 Indeed, given the absence of any delegation of preemption authority to the FDA by Congress, it is doubtful that the FDA could have issued a binding regulation that would have foreclosed state failure-to-warn litigation. See generally Gonzales v. Oregon, 546 U.S. 243, 255–256 (2006) (holding that because the FDA chose to articulate its new position in an informal way, it is not entitled to Chevron deference); United States v. Mead Corp., 533 U.S. 218, 226–28 (2001) (rejecting the argument that the substantial deference described in Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984), applies to informal agency action).


60 Levine, 944 A.2d at 182.

61 Id.
household chores, has lost her livelihood, and has incurred hundreds of thousands of dollars in medical bills.\(^2\)

Ms. Levine sued her health care provider and Wyeth, Phenergan's manufacturer, in Vermont state court.\(^3\) The health care provider settled, leaving Wyeth as the only defendant.\(^4\) Because of the acute risk of arterial exposure when Phenergan is administered through an IV-push, Ms. Levine argued that Wyeth failed to provide sufficient warnings about the foreseeable risks from the IV-push.\(^5\) Experts testified that the benefits of IV-push administration, as compared to IV-drip (where the drug is slowly introduced through a drip bag), are marginal, and that the use of IV-drip effectively precludes inadvertent arterial contact.\(^6\) Ms. Levine claimed, therefore, that the drug's label should have contained an explicit warning directing physicians not to use IV-push.

Wyeth's main defense was that the FDA approved Phenergan's labeling and a Vermont jury was not free to second-guess the FDA's determination.\(^7\) Wyeth argued the principles of conflict preemption precluded Ms. Levine's claim because a jury ruling for Ms. Levine might force Wyeth to add warnings the FDA had not approved and, therefore, potentially subject the company to FDA sanctions. But the jury found for Ms. Levine, awarding her damages amounting to $7,400,000, which the court reduced to account for Ms. Levine's earlier settlement with her health care providers.\(^8\)

The Vermont Supreme Court affirmed.\(^9\) The court held that Wyeth had showed neither an actual conflict between FDA mandates and Vermont state law nor frustration of federal objectives.\(^10\) Indeed, the court found state and federal requirements compatible because each requires drug manufacturers to add and strengthen warnings that might be insufficient to protect patients.\(^11\) The court found no evidence the FDA had ever considered and approved the IV-push method of administration or intended to prohibit Wyeth from strengthening its label to warn physicians against using IV-push.\(^12\)

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\(^3\) Levine, 944 A.2d at 182.
\(^4\) Id. at 183.
\(^5\) Brief for Respondent, supra note 59, at 15.
\(^6\) See Levine, 944 A.2d at 182.
\(^7\) See id. at 183.
\(^9\) Levine, 944 A.2d at 197.
\(^10\) Id. at 189, 194.
\(^11\) See id. at 188–89.
\(^12\) Id.
The Vermont Supreme Court's affirmance set the stage for the United States Supreme Court to consider the issue.

The importance of the case is at least in part a consequence of the breadth of the arguments made by the parties and their supporters. The United States broadly argued that all state failure-to-warn claims are preempted because state courts might "strike a different balance" regarding the drug risks and benefits than the FDA. And "the fact that juries instead of an expert agency would second-guess FDA's judgments in individual cases only exacerbates the conflict." The United States also argued Wyeth could not change its labeling without prior FDA approval unless it could point to "new" safety information warranting an immediate change, which was not the case. For this reason, the United States contended an adverse ruling against Wyeth would effectively require Wyeth to rewrite Phenergan's labeling and undermine the FDA's control of drug labeling.

Wyeth took a slightly different position. Wyeth argued that principles of conflict and implied conflict preemption required reversal because changing the drug's label without FDA approval would render the drug "misbranded" and thus violate federal law. Wyeth acknowledged that FDA regulations establish "a limited safe harbor from enforcement for manufacturers that implement labeling changes prior to FDA approval when the change reflects newly-acquired information about a drug's risks." In this case, Wyeth argued, the FDA approved the Phenergan labeling "with full information about the risks and benefits of the drug, and it instructed Wyeth to use labeling that FDA had concluded best accommodated those risks and benefits." Wyeth also argued that FDA labeling decisions set a floor and a ceiling, and it was not free to depart from FDA-prescribed labeling under these circumstances. Accordingly, Wyeth also argued for outright reversal.

Predictably, Ms. Levine and her supporters argued that, beyond the ordinary presumption against preemption, the case for preemption was especially weak because Congress never expressed any intent to preempt state-law actions for prescription drugs, although there are express preemption provisions in the Food, Drug, and Cosmetic Act.

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74 Id. at 9.
75 See id. at 10.
76 Brief for Petitioner, supra note 59, at 30–39.
77 Id. at 27.
78 Id.
79 Id. at 55.
Moreover, since the FDCA’s passage, courts had continued to adjudicate state-law failure-to-warn claims, and Congress had not given drug companies the immunity from liability they covet, even though it had repeatedly fine-tuned the FDCA. Ms. Levine also argued that state tort law is no obstacle to the fulfillment of federal objectives. Ms. Levine pointed out that the FDA has long encouraged drug manufacturers to strengthen the warnings on drug labels to address safety concerns. FDA regulations give companies an unqualified right to change a drug’s labeling when necessary to protect patients, provided the companies seek FDA approval after making the change. Although Wyeth and the United States claimed companies must base such changes on newly discovered risk information, Ms. Levine argued that the regulation contains no such limitation, and such a rule would impair public health by precluding labeling changes based on a reexamination of existing evidence. Indeed, in that key respect, Ms. Levine contended, federal and state requirements are parallel—they both place a duty on drug manufacturers promptly to warn doctors and patients about risks not adequately addressed on the drug’s label.

Finally, Ms. Levine contended that, “as the Vermont courts found, the record contain[ed] no evidence that FDA ever weighed the risks and benefits of IV-push administration of Phenergan or made a judgment that some benefit of IV-push injection in treating nausea justified its increased risks of gangrene requiring amputation.” There was no preemption, Ms. Levine claimed, because there was no basis to conclude the FDA had engaged in a specific balancing of the benefits and risks of the IV-push method of administration.

IV. WYETH v. LEVINE—THE COURT’S OPINION

The Court’s opinion in Wyeth deserves close attention. After reviewing the facts of the case, the Court declares that its analysis “must be guided by two cornerstones of our pre-emption jurisprudence.” The Court first repeats its familiar refrain that “the purpose of Congress is the ultimate touchstone in every pre-emption

80 See Brief for Respondent, supra note 59, at 21.
81 Id. at 27–28.
82 Id. at 32–44.
83 Id.
84 Id. at 23, 48–55.
85 Id. at 24.
86 Id.
Second, and more controversially, the Court extends its "clear statement" federalism rule to "all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied." In these cases, courts should "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Applying the presumption against preemption to Wyeth’s claim of a direct conflict preemption claim, argues the dissent, constitutes an unwarranted extension of existing law.

The Court then briefly reviews the evolution of federal regulation of drugs and drug labeling in an effort to identify the "purpose of Congress." In the course of tracing this more than century long history, the Court notes that as Congress "enlarged the FDA’s powers," it "took care to preserve state law." The Court points out that with the FDCA’s 1962 amendments—requiring drug manufacturers to show that drugs are not just safe but also effective for their intended use—Congress added a savings clause providing that "state law would only be invalidated upon a ‘direct and positive conflict’ with the FDCA," and thereafter "common-law suits ‘continued unabated despite . . . FDA regulation.’" When Congress revisited the FDCA in 1976 to add an express preemption provision for medical devices, it again "declined to enact such a provision for prescription drugs." And after Ms. Levine’s lawsuit was filed, the Court notes Congress again amended the FDCA in 2007 to, for the first time, give the FDA authority to direct drug manufacturers to change drug labeling on the basis of information that emerges after the drug’s initial approval, rejecting a Senate bill “that would have required the FDA to preapprove all changes to drug labels” and instead “adopt[ing] a rule of construction to make it clear that manufacturers remain responsible for updating their labels.”

The Court then addresses, and quickly dismisses, Wyeth’s direct conflict preemption argument. Wyeth argued it would be “impossible” to comply with its federal labeling duties and those

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88 Id. (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).
89 Id. (quoting Lohr, 518 U.S. at 485 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947))) (ellipsis in original).
90 Id. at 1194–95 (quoting Lohr, 518 U.S. at 485 (quoting Rice, 331 U.S. at 230)).
91 Compare id. at 1195 n.3, with id. at 1228 (Alito, J., dissenting) (criticizing the majority for extending the presumption against preemption to cases involving direct conflict claims).
92 Id. at 1195–96 (majority opinion).
93 Id. at 1196 (citations omitted) (ellipsis in original).
94 Id.
95 Id.
imposed under state law because, "if it had unilaterally added" a warning, "it would have violated federal law governing unauthorized distribution and misbranding" of drugs. But the Court rejects Wyeth's reading of the FDCA, noting the "FDCA does not provide that a drug is misbranded simply because the manufacturer has altered an FDA-approved label." More broadly, the Court rejects what it calls "Wyeth's cramped reading" of FDA regulations permitting drug companies to make labeling changes without FDA's prior approval for safety reasons. The Court also criticizes Wyeth's suggestion "that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling." As the Court puts it, "through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times."

Because Wyeth retained authority to change the drug's label, the Court frames the dispositive question as whether Wyeth presented "clear evidence that the FDA would not have approved a change to [the drug's] label" to warn more forcefully against the IV-push method of administration. Wyeth "offered no such evidence," and thus "Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements." It bears noting that, in so ruling, the Court erects a high barrier to future preemption claims based on conflict preemption principles. Not only does the Court place squarely on the manufacturer the burden of

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96 Id. at 1197.
97 Id.
98 Id. Here the Court side-steps a road-block the FDA added to the litigation once the Court granted review. In 2008, the agency promulgated a rule modifying its "changes being effected," or CBE, rules governing when drug manufacturers may change labels without first securing the FDA's approval. Id. at 1196. The 2008 rule, Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,609 (Aug. 22, 2008) (to be codified at 21 C.F.R pts. 314, 601, and 814), provides that manufacturers may make unilateral changes to a drug's label only "to reflect newly acquired information." Wyeth, 129 S. Ct. at 1196 (quoting 73 Fed. Reg. at 49,609). Although the rule was not in effect at the time of Ms. Levine's injury, Wyeth and the Government argued that it reflected the FDA's historic understanding, even though, as the Court pointed out, the FDA's drug labeling regulations make clear that drug manufacturers may make labeling changes without the FDA's prior approval to address safety concerns. The Court pointed out that, even under the FDA's 2008 CBE rules, Wyeth would have been free to make the labeling changes Ms. Levine sought because, in light of the twenty or so amputations caused by Phenergan, Wyeth would have been able to do a new analysis of the drug's risks and make a labeling change based on that analysis. Id. at 1197.
99 Id.
100 Id. at 1197-98.
101 Id. at 1198.
102 Id. at 1198, 1199.
producing "clear evidence" that the FDA would not have permitted a stronger warning, but the Court also adds that "[i]mpossibility pre-emption is a demanding defense." It remains to be seen whether the Court's conflict preemption discussion leaves open any door for drug companies to successfully assert conflict preemption.

The Court concentrates most of its attention on Wyeth's implied preemption claim, supported by the United States, that "requiring it to comply with a state-law duty to provide a stronger warning about IV-push administration would obstruct the purposes and objectives of federal drug labeling regulation." The Court emphatically rejects this argument: "We find no merit in this argument, which relies on an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." The Court is equally dismissive of Wyeth's argument on congressional intent. "Wyeth contends that the FDCA establishes both a floor and a ceiling for drug regulation." But "[t]he most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary." After all, if "Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history." Congress's "silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."

Having established that "Congress did not regard state tort litigation as an obstacle to achieving its purposes," the Court next examines Wyeth's claim that the FDA's 2006 preamble statement rightly determined that "the FDCA establishes both a floor and a ceiling, so that FDA approval of drug labeling . . . preempts conflicting or contrary State law." Citing Geier, the Court notes that "an agency regulation with the force of law can pre-empt

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103 Id. at 1199.
104 One indication may come with the Third Circuit's reconsideration of Colacicco v. Apotex Inc., 521 F.3d 253 (3d Cir. 2008), which found drug claims preempted on conflict preemption grounds. After the Court's ruling in Wyeth, the Court granted the pending petition for certiorari in Colacicco, vacated the Third Circuit's prior ruling, and remanded the case for further consideration in light of Wyeth. See Colacicco v. Apotex, Inc., 129 S. Ct. 1578 (2009).
105 Wyeth, 129 S. Ct. at 1199.
106 Id.
107 Id.
108 Id.
109 Id. at 1200.
110 Id.
111 Id. (internal quotation marks omitted) (ellipses in original).
conflicting state requirements,” but there is “no such regulation in this case.” The Court recognizes that in prior cases, including Geier, it has given some weight to an agency’s view on preemption, but that the weight to be accorded an agency’s position “depends on its thoroughness, consistency, and persuasiveness.” Once again, the FDA was in for rough sledding: “Under this standard, the FDA’s 2006 preamble does not merit deference.”

The Court rejects the FDA position on both procedural and substantive grounds. The Court first criticizes the FDA for what it sees as bait-and-switch Federal Register notices. The Court notes that the labeling rule’s notice of proposed rule-making explained the rule would not preempt state law, while the preamble to the final rule “articulated a sweeping position on the FDCA’s preemptive effect,” “without offering States or other interested parties notice or opportunity for comment.” These procedural failures led the Court to conclude that the “agency’s views on state law are inherently suspect.”

The Court is just as critical of the FDA’s substantive arguments, addressing and rejecting, often in quite dismissive language, each of the agency’s pro-preemption arguments. To start, the Court finds the preamble statement “is at odds with what evidence we have of Congress’ purposes.” This discrepancy, says the Court, is especially troubling because the agency’s 2006 statement “reverses 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.” Indeed, “[n]ot once prior to Levine’s injury did the FDA suggest that state tort law stood as an obstacle to its statutory mission.” To the contrary, the agency “cast federal labeling standards as a floor upon which States could build and repeatedly disclaimed any attempt to pre-empt failure-to-warn claims.”

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\( \text{id. at 1201.} \)

\( \text{id.} \)

\( \text{id.} \)

\( \text{id.} \)

\( \text{id.} \)

\( \text{id.} \)

\( \text{id.} \)

\( \text{id.} \)

\( \text{id. at 1201-02.} \)

\( \text{id. at 1202.} \)
This abrupt about-face on preemption, the Court observes, also weakens the FDA’s ability to safeguard the public. “[T]he FDA traditionally regarded state law as a complementary form of drug regulation,” because the agency has “limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge.” The Court also finds considerable fault in the FDA’s failure to look at the consequences of its pro-preemption position, namely the removal of the market disciplines provided by state-law tort suits that both “uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly” and “serve a distinct compensatory function that may motivate injured persons to come forward with information.”

Finally, the Court addresses Geier and explains why Wyeth, the FDA, and the dissent are wrong to suggest it is controlling. To the Court the most salient difference between the cases is that the Geier Court itself conducted an independent preemption analysis, and did so on the basis of a complete record made by NHTSA during the course of a full-scale notice and comment rulemaking. Only “[a]fter conducting [its] own pre-emption analysis” did the Geier Court consider “the agency’s explanation of how state law interfered with its regulation.” The Court regarded the agency’s statement “as further support for [its] independent conclusion that the plaintiff’s tort claim obstructed the federal regime.” Not only did the Court find no “specific agency regulation bearing the force of law” here, but also noted that the agency’s 2006 preamble statement “does not merit deference for the reasons [the Court has] explained.” And the Court also notes that in Geier the “‘complex and extensive’ regulatory history and background relevant” to the case was consistent with the agency’s position, while in this case the relevant history and background “reveal the longstanding coexistence of state and federal law and the FDA’s traditional recognition of state-law remedies.”

The Court ends its opinion with a parting shot to the FDA: “Congress

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122 Id. (footnote omitted).
123 Id.
124 Id. at 1203.
125 Id.
126 Id.
127 Id. The Court goes on to also say that “[t]he United States’ amicus brief is similarly undeserving of deference.” Id. at 1203 n.13. In contrast to the Government’s brief in Geier, “which explained the effects of state law on the DOT’s regulation in a manner consistent with the agency’s prior accounts,” the Court said that here “the Government’s explanation of federal drug regulation departs markedly from the FDA’s understanding at all times relevant to this case.” Id.
128 Id. at 1203 (quoting Geier v. Am. Honda Motor Co., 529 U.S. 861, 883 (2000)).
has repeatedly declined to pre-empt state law, and the FDA’s recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight.”

Five Justices joined Justice Stevens’s majority opinion: Justices Kennedy, Souter, Ginsburg, and Breyer. Justice Breyer wrote a brief separate concurrence leaving open the possibility that a specific agency regulation bearing the force of law might serve as a ceiling as well as a floor, but recognizing that no such regulation was before the Court. Justice Thomas concurred only in the judgment and wrote a separate opinion criticizing the Court’s implied preemption jurisprudence. Indeed, he explains that he writes separately “because I cannot join the majority’s implicit endorsement of far-reaching implied pre-emption doctrines.” Justice Thomas’ criticisms of implied preemption doctrines echo his prior writings. Justice Alito authored the dissent, joined by Chief Justice Roberts and Justice Scalia, arguing that principles of both conflict and implied conflict preemption dictate a ruling in Wyeth’s favor.

V. IMPLICATIONS OF THE COURT’S RULING IN WYETH

As I made clear at the outset, Wyeth’s significance extends well beyond the confines of this case, and indeed well beyond the confines of informing our understanding of the Court’s implied conflict preemption jurisprudence. Wyeth is important because (a) it reshapes and significantly limits the reach of the implied conflict preemption doctrine, and in so doing, restrains the impact of Geier; (b) it likely consigns the Bush Administration’s effort to cut back on tort law by regulatory fiat to judicial repudiation; and (c) it reinvigorates the role of tort law in deterring excessive risk-taking, in serving as a sentinel in detecting risk information that is not available to regulators, and in compensating those injured through no fault of their own.

A. Wyeth and Regulatory Implied Conflict Preemption

From a doctrinal standpoint, Wyeth’s most important contribution is to change dramatically the framework for evaluating claims of regulatory implied conflict preemption. As noted at the outset, Geier suggests that agency pronouncement should play an important, and
often decisive role in judicial determinations of preemption.\textsuperscript{134} And as I have argued above, one problem with \textit{Geier} is that it took the agency’s claims of interference at face value.

\textit{Wyeth} takes the opposite tack, undoubtedly, in part, because the many danger signals that factors other than a genuine concern about state law standing as an obstacle to federal goals spurred the FDA’s about-face on preemption were not seen by the Court as false alarms. Indeed, it is hard to read the majority opinion in \textit{Wyeth} as anything but an outright repudiation of the FDA’s pro-preemption position. The Court’s language—calling the FDA’s position “without merit” and assailing the FDA’s assertions as “not merit[ing] deference,\textsuperscript{135} “inherently suspect,”\textsuperscript{136} “at odds with what evidence we have,”\textsuperscript{137} having “no merit” and “entitled to no weight”\textsuperscript{138}—is the language of condemnation, not the more measured language the Court generally uses in critiquing the views of a coordinate branch of government.

Perhaps more importantly, under \textit{Wyeth} courts are to look beyond an agency’s statements about the nature and degree of state law interference with federal objectives and to instead make an independent determination that the agency is able to accomplish federal goals and that state law actually stands as an obstacle to the agency’s mission.\textsuperscript{139} To be sure, the agency’s pro-preemption statement might inform the court’s decision, depending on “its thoroughness, consistency, and persuasiveness.”\textsuperscript{140} But it is up to the court to determine the preemption question based on an inquiry that takes into account three factors: (a) is the federal agency able to achieve its statutory goals single-handedly; (b) are the agency’s claims of preemption based on hard evidence or are there danger signals that the claims are the product of agency capture; and (c) the extent to which the informational and compensatory functions of state tort law help fulfill federal objectives.\textsuperscript{141}

\textit{Wyeth} makes clear that considerations of agency competence are now part of the mix in regulatory implied preemption cases. The Court takes a hard look at the FDA’s assertion that it can single-handedly guarantee the safety of each of the 11,000 drugs on the market and that state failure-to-warn cases undermine the FDA’s ability to do its job. But the Court finds no evidence to support the

\textsuperscript{135} \textit{Wyeth}, 129 S. Ct. at 1203.
\textsuperscript{136} \textit{id.} at 1201.
\textsuperscript{137} \textit{id.}
\textsuperscript{138} \textit{id.} at 1204.
\textsuperscript{139} \textit{id.} at 1203–04.
\textsuperscript{140} \textit{id.} at 1201.
\textsuperscript{141} See \textit{id.} at 1200, 1202–1203, 1202 n.11.
agency's claim and substantial evidence that undermines it. The Court observes that, "[i]n keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state [tort] law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market . . . ." And then, in a lengthy footnote, the Court cites four studies of the FDA's performance in monitoring the safety of drugs—one dating back to 1955, the others recent reports from the Institute of Medicine of the National Academies of Sciences, the Government Accountability Office, and the FDA's own Science Advisory Board—that are each highly critical of the agency's ability to successfully engage in post-marketing surveillance of drugs because of chronic resource limitations and serious gaps in the agency's statutory authority. In the face of this evidence, the Court seems unwilling to accept the FDA's "mere assertion" that it alone, without the backstop of state tort law, can effectively discipline the marketplace.

Equally important, the Court was alert to suggestions of agency capture. Although set forth in a footnote, the Court cites with approval a Report of the Majority Staff of the House Committee on Oversight and Government Reform titled "FDA Career Staff Objected to Agency Preemption Policies." This report issued on October 29, 2008—after briefing had been completed and less than a week before the Wyeth case was argued before the Supreme Court—evaluates the key assertions underlying the FDA's new preemption position and concludes, as the Court notes, that "[t]he Office of Chief

142 Id. at 1202.
143 Id. at 1202 n.11.
144 Id. at 1201.
145 There had already been considerable discussion in the press and in the academic literature about what appeared to be evidence of agency capture at the FDA. This evidence is discussed in detail in 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). This is not the only FDA decision that has been criticized on agency capture grounds. Recently, in Tummino v. Torti, No. 05-CV-366, 2009 WL 750004 (E.D.N.Y. Mar. 23, 2009), the United States District Court for the Eastern District of New York set aside the Bush Administration's denial of a citizen petition to make available the post-coital contraceptive "Plan B" more accessible to woman seventeen years and older. The Court found that the FDA's decision was made "at the behest of political actors" and was subject to "political considerations, delays, and implausible justifications" that "evidence . . . a lack of good faith and reasoned agency decision-making." Id. at *2.
146 Wyeth, 129 S. Ct. at 1202 n.11. The Report suggests that the timing of the Report's release was a result of the delay by the FDA in providing its records and the unwillingness of the Department of Health and Human Services to provide relevant records to the Committee reflecting its role and the role of the White House. See HOUSE COMM. ON OVERSIGHT AND GOVERNMENT REFORM, MAJORITY STAFF REPORT, FDA CAREER STAFF OBJECTED TO AGENCY PREEMPTION POLICIES 14-15 (2008), available at http://oversight.house.gov/story.asp?id=2266 [hereinafter HOUSE STAFF REPORT].
Counsel ignored the warnings from FDA scientists and career officials that the preemption language [of the 2006 preamble] was based on erroneous assertions about the ability of the drug approval process to ensure accurate and up-to-date drug labels.\(^\text{147}\)

The House Staff Report points out that the preemption language in the 2006 preamble was proposed by the Office of Chief Counsel, not the agency’s career staff, and rested mainly on three factual claims: (1) the FDA, and not drug manufacturers, exercises principal responsibility over drug labels; (2) permitting drug companies to make changes to drug labels for safety reasons without the FDA’s prior approval is likely to result in “over-warning,” which may impair safety; and (3) the FDA’s longstanding view was that manufacturers may change labels to address safety concerns if, but only if, there is “new” information that justifies the change. The Staff’s investigation sought to determine whether the agency had supporting evidence for these assertions. The evidence the investigators uncovered showed that, in each case, the agency’s career scientific staff disagreed with the agency’s lawyers.

First, as to the Chief Counsel’s claim that the FDA exercises “virtually plenary authority over drug labeling,” Dr. John Jenkins, Director of the Office of New Drugs in the Center for Drug Evaluation and Research and the FDA’s most senior official in the new drug review process, explained to the Chief Counsel’s office that the assertion is “based on a false assumption that the FDA approved labeling is fully accurate and up-to-date in a real time basis. We know that such an assumption is false.”\(^\text{148}\) Indeed, Dr. Jenkins continued, the claim is “a major overstatement of the facts and actual situation” because “we know that many current approved drug labels are out of date and in many cases contain incorrect information”—at times the agency had “a backlog of over 1000 labeling supplements.”\(^\text{149}\) Dr. Jane Axelrad, Associate Director for Policy in the Center for Drug Evaluation and Research, similarly objected to the Chief Counsel’s claim that the “FDA is constantly monitoring the literature and that we force sponsors to add new risk information whenever we see a

\(^{147}\) Wyeth, 129 S. Ct. at 1202 n.11 (brackets in original) (quoting HOUSE STAFF REPORT, supra note 146, at 4).

\(^{148}\) HOUSE STAFF REPORT, supra note 146, at 6, i.

\(^{149}\) Id. at 6 (quoting E-mail from Dr. John Jenkins, Director, Office of New Drugs, Center for Drug Evaluation and Research (CDER), to Jane Axelrad, CDER Associate Director for Policy and Director, CDER’s Office of Regulatory Policy, Dr. Robert Temple, Director, CDER’s Office of Medical Policy, and Dr. Rachel Behrman, Deputy Director, CDER’s Office of Medical Policy (Aug. 6, 2003)).
study that suggests that one drug may be better than another. Nothing could be further from the truth."

Second, as to the Chief Counsel’s claim that permitting drug companies to strengthen warnings without advance FDA approval would lead to over-warning, Dr. Axelrad wrote the Chief Counsel that "'[w]e rarely find ourselves in situations where sponsors want to disclose more risk information than we think is necessary. To the contrary, we usually find ourselves dealing with situations where sponsors want to minimize risk information.'" Dr. Jenkins was even more critical:

"The entire argument put forward that sponsors are insisting on exaggerated statements of risk information is naïve to what actually occurs in practice. While I do not believe that most sponsors deliberately attempt to obscure risk information . . . in the product labeling, I also believe that it is true that sponsors attempt to present the information in a way that does not put their product at a competitive disadvantage to other products. . . ."

Third, as to the Chief Counsel’s argument that the FDA historically did not permit drug companies to strengthen labels without the agency’s prior approval, Dr. Axelrad said:

"'[T]he statement that 'FDA believes manufacturers should add risk information only after consulting with the agency' . . . is not true and is not consistent with our CBE [changes being effected] regulations. Granted we review CBE supplements, but we do not discourage sponsors from adding new information via this route. In fact, the regs encourage use of this route as it allows the label to be updated in the most timely manner.'"
Dr. Jenkins also disagreed with the Chief Counsel, noting that he objected to the Chief Counsel’s claim that “‘[m]anufacturers generally consult FDA before adding risk information to labeling,’” noting that “‘I don’t know what this statement is based on and it is not in agreement with the large number of CBE labeling supplements to add risk information that we receive each year.’”\textsuperscript{154}

Notwithstanding the uniform objections of the FDA’s senior scientific career staff, the 2006 preamble asserts that permitting state failure-to-warn cases could encourage “‘defensive labeling,’” could interfere with the FDA’s ability to “‘control[] the content of labeling,’” could impair the agency’s ability to continuously monitor “‘the latest available scientific information’ to ‘incorporate [that] information into [a] product’s label[,]’” and that “‘manufacturers typically consult with FDA’” before strengthening labels.\textsuperscript{155} These assertions, of course, were repeated in the brief of the Solicitor General defending the FDA’s position.\textsuperscript{156}

The fact that Justice Stevens not only cites the House Staff Report, but quotes its ultimate conclusion about the struggle within the FDA on preemption, is powerful evidence that agency capture concerns may have influenced the Court’s decision. The Report makes clear that, to the extent there was concern in the agency over the possibility that state failure-to-warn cases might obstruct the agency’s ability to do its job, that concern was localized within the Chief Counsel’s office and was not shared by the agency’s career experts. Thus, the Report may have reassured the Court that a ruling in Ms. Levine’s favor would not imperil the FDA’s ability to pursue its objectives.

To be sure, Wyeth may be the rare case where concerns about the agency’s competence and independence come to the fore. But post-Wyeth courts will likely be more sensitive to these concerns, which will be a step forward from Geier where the Court did not even acknowledge its own warning about the automobile industry’s inappropriate influence over NHTSA.\textsuperscript{157} Indeed, it is worth asking

\textsuperscript{154} \textit{Id.} at 6 (quoting E-mail from Dr. John Jenkins to Jane Axelrad, Dr. Robert Temple, and Dr. Rachel Behrman (Aug. 6, 2003)).

\textsuperscript{155} \textit{Id.} at 7–8 (quoting Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935, 3934 (Jan. 24, 2006)).

\textsuperscript{156} See Brief for the United States as Amicus Curiae Supporting Petitioner, \textit{supra} note 73. I do not suggest that the lawyers in the Solicitor General’s Office knew about the disagreement within the FDA, much less that they were obligated to respond to the House Staff Report shedding light on that disagreement. I imagine, however, that the Report engendered some measure of discomfort among the highly professional lawyers in the Office.

\textsuperscript{157} As noted, the majority in \textit{Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.}, rejected NHTSA’s effort to further delay the introduction of air bags because its justification “runs counter to the evidence” and “is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” 463 U.S. 29,
whether there is much left of Geier after Wyeth. Justice Stevens’ opinion for the Wyeth Court (and recall that Justice Stevens led the dissent in Geier, criticizing the “‘free-form judicial policymaking’” undertaken by the majority) limits Geier to its facts.\(^\text{159}\) And intervening decisions, especially the Court’s recent ruling in Altria Group, Inc. v. Good,\(^\text{160}\) have refused to sustain implied preemption claims. It may be that Geier is the first casualty of Wyeth.

**B. Wyeth and the Demise of the Bush Administration’s Regulatory Implied Conflict Preemption Campaign**

Outside of the drug arena, the impact of Wyeth may be felt first in preemption claims based on the Bush Administration’s regulatory preemption campaign. In my view, the analytical framework the Court employs in Wyeth consigns those preemption claims to almost certain judicial rejection. There are several reasons for this conclusion. To start with, Wyeth first focuses on whether there is any indicium of a congressional intent to preempt. The Court found the FDA’s position flawed because, rather than finding a congressional intent to oust state law, the Court found a congressional intent to preserve state law.\(^\text{161}\)

The same is true of the statutes administered by NHTSA, CPSC, and FRA.\(^\text{162}\) The organic statutes of these agencies either do not contain express preemption provisions, or, if they do, have savings clauses that explicitly preserve state tort law.\(^\text{163}\) Thus there is no statutory basis to distinguish preemption claims these agencies make from the claim the Court rejected in Wyeth. Nor can the agencies defend their claims on the ground of administrative consistency. Wyeth found that the FDA’s about-face on preemption was a danger signal that something was amiss. Again, the same difficulty will confront the other agencies, since they too have previously taken the position that their regulatory actions did not preempt state law.\(^\text{164}\)

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\(^{159}\) Wyeth v. Levine, 129 S. Ct. 1187, 1203.


\(^{161}\) Wyeth, 129 S. Ct. at 1196.

\(^{162}\) See Funk et al., supra note 45.

\(^{163}\) Id.

\(^{164}\) Id.
Just as important is Wyeth’s demand for evidence of frustration of federal objectives and its unwillingness to defer to mere assertions of possible interference. One clear conclusion to draw from Wyeth is that the Court wants evidence that state-law is in fact interfering with the agency’s ability to do its job. Wyeth lost because neither it nor the FDA could produce evidence of actual interference. The courts are likely to demand the same from other agencies. This factor too will undercut pro-preemption arguments, because the agencies have all long engaged in regulation with state law as a backdrop to their regulatory efforts, without evidence of actual interference. The FDA had no answer to the Court’s “why now” question; as the Court pointed out, FDA regulation and state tort law had co-existed for decades. What had changed to transform complementary co-existence into obstacle preemption? The FDA’s inability to provide a plausible answer to that question undermined its case. It is hard to imagine any of the other agencies having a better answer.

Finally, the Wyeth Court was troubled by the FDA’s failure to provide any sort of public proceeding in formulating its new, pro-preemption position. Indeed, the Court said that the FDA’s new position was “inherently suspect” because it failed to provide “States or other interested parties notice or opportunity for comment.” And none of these agencies gave the public notice or an opportunity to comment on their new preemption positions; each simply announced their new positions on regulatory preemption and argued that notice was not required. Wyeth thus appears to deal a body blow to the Bush Administration’s regulatory preemption campaign.

C. Wyeth Reinvigorates the Role of Tort Law

Perhaps the ultimate irony of Wyeth is that instead of becoming a symbol of the retrenchment of tort law, as Wyeth’s supporters expected, Wyeth may come to stand as a symbol of the reaffirmation of tort litigation as a valuable complement to federal regulation. After all, Wyeth rejects emphatically the idea that federal regulation shifts the ultimate responsibility for ensuring that a product is reasonably safe for its intended use on to the federal government. That responsibility, says the Court, falls squarely on the shoulders of the manufacturers, who have superior access to information about their

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165 Wyeth, 129 S. Ct. at 1198–1200.
166 See Vladeck, The FDA and Defe
167 Wyeth, 129 S. Ct. at 1201.
168 Statement of David C. Vladeck, supra note 45, at 179 n.13.
product's performance in the market, and for that reason "bear[]
responsibility for the content of [their] label[s] at all times."169

Wyeth also underscores the important role that tort law plays in
providing information about product hazards that might escape the
attention of regulators, or come to the regulators' attention well after
the manufacturer is alerted to the risk.170 The Court points out that tort
litigation "provide[s] incentives for drug manufacturers to disclose
safety risks promptly" as a means of avoiding adverse tort rulings.171
The Court also makes clear that it values the compensatory function
of tort law, not just as an aid to those injured by drugs that prove to be
unsafe, but to "motivate injured persons to come forward with
information" about those risks.172 The Court's focus on the
informational role tort litigation serves was not inadvertent. To the
contrary, the Court was using it to underscore the point that federal
preemption comes at a cost—not just to the unfortunate person, like
Diana Levine, who is injured through no fault of her own—but to
society as a whole. Society benefits when injured people like Diana
Levine stand up and use the courts not just to redress their own
grievances, but also to alert regulators, doctors, and patients that a
widely used drug like Phenergan poses an unreasonable risk of
grievous harm.173

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169 Wyeth, 129 S. Ct. at 1198.
170 Id. at 1202.
171 Id.
172 Id.
173 As a post-script, it bears noting that on September 16, 2009, the FDA ordered
manufacturers of the drug to place a "black box" warning on its label urging caution in
administering the drug because of the risks of gangrene and amputation. See, e.g., Gardiner
Harris, F.D.A. to Require Strict Warning on Anti-Nausea Drug, N.Y. TIMES, Sept. 18, 2009, at
B6; Linda A. Johnson, FDA requires strong amputation warning on sedative, ASSOCIATED