

# DUE PROCESS PREEMPTED: STEALTH PREEMPTION AS A CONSEQUENCE OF AGENCY CAPTURE

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## INTRODUCTION

Proponents of widespread federal preemption are quick to portray our civil litigation system, established in the eighteenth century, as anachronistic when set against the backdrop of modern mass production and interstate and international marketing of goods and services by multinational corporations. These preemption proponents sympathize with manufacturers’ desire to predict, control, and predetermine judgments regarding product quality or defect, corporate conduct or misconduct, and truth or lies in marketing. They emphasize the value of the national uniformity that comes with determinations by federal agencies.<sup>1</sup> These values of

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1. This argument is frequently advanced in the context of a pro-business free-market stance. See, e.g., Daniel E. Troy & Rebecca K. Wood, *The Business of the Court: Federal Preemption at the Supreme Court, 2007–2008* CATO SUP. CT. REV. 257, 263–67 (2008). See generally Nancy L. Perkins et al., *Watters v. Wachovia: A Funda-*

uniformity and predictability are often frustrated by a system such as ours in which the substantive law in these areas is derived from state common and statutory law, and in which disputes are adjudicated by lay juries, instructed in state law by both federal and state judges. Yet in the view of consumers' advocates, this is all as it should be.<sup>2</sup>

The Supreme Court's March 4, 2009 decision in *Wyeth v. Levine*<sup>3</sup> is the culmination and reflection of many conflicting considerations. Among them is a cautionary tale of what can happen to our revered concepts of access to justice and compensation for harms negligently or intentionally committed when the will of Congress and the expectations of the people are bypassed. In this tale, bypass was effected by an agency (whose expertise is medical and scientific) that, encouraged by the industry it regulates and empowered by a political administration, preemptively opines on profound matters of substantive law without bothering to observe the necessities of constitutional due process.

The operating system established by the Constitution and its amendments, known by the shorthand of "federalism," has been viewed by manufacturers and their trade groups as an anomaly to be cured by absolute deference to the expertise of the *federal* agencies charged by Congress with regulating the relevant products or services uniformly throughout the entire nation.<sup>4</sup> However, legislative preemption is rare.<sup>5</sup> It is likely to remain so, given congressional—and traditional—reverence for the common law system, the importance of federalism, and the extreme political difficulty of legislating a complete system of substantive law, adjudicatory proce-

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*mental Approach to Federal Banking Law Preemption*, 27 REV. BANKING & FIN. L. 127 (2008) (discussing the balance of regulatory authority between the federal and state governments and the uniformity versus vulnerability of a system that completely defers to the presumptive expertise of a federal regulatory agency).

2. See, e.g., Associated Press, *Obama Undoes Bush-Era Policy That Undercut States*, S.F. CHRON., May 20, 2009 (reporting on positions of consumer and plaintiffs' advocates). See generally *High Court Dismisses FDA Preamble in Broad Rejection of Preemption*, 15 FDA WEEK 9 (2009).

3. *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (affirming the judgment of the Vermont Supreme Court awarding damages to plaintiff and respondent Diana Levine).

4. See, e.g., Lawrence S. Ebner, *Four Myths About Federal Preemption of State Tort Claims*, LEGAL BACKGROUNDER (Washington Legal Foundation, Washington D.C., June 5, 2009).

5. See, e.g., Sharon A. Kahn & Brian McCarthy, Note, *At-Will Employment in the Banking Industry Ripe for A Change*, 17 HOFSTRA LAB. & EMP. L.J. 195, 210 (1999) ("Explicit Congressional [sic] preemption of national banks is a rare occurrence.").

dure, and appropriate compensation. These features are already present in our litigation system, and Congress, with good reason, appears loath to duplicate or to supplant them.

A deep instinct preserves the check-and-balance system of state substantive law, as interpreted by state and federal courts, that provides compensatory and deterrent remedies which are determined with the participation of citizen fact-finders, and informed, but not foreclosed, by the opinions of regulatory agencies. This is a system that is neither perfectly consistent nor entirely predictable, but that trades perfect certainty for openness and flexibility. It avoids the extreme prejudice to consumers of an unbalanced, unilateral agency system in which those entrusted with regulating an industry bestow complete immunity from civil liability on those products they determine to be in initial compliance with agency standards. We have been reluctant, throughout our political and judicial history, to give the first, last, and only word on any issue that affects public health and safety, civil rights, or procedural due process exclusively to any one branch of government or its designees.<sup>6</sup> Rare indeed should be the situation in which a single agency is allowed to nullify this system of checks and balances, arrogate to itself the powers traditionally distributed among the legislative, executive and judicial branches, and reign unchecked in the area of its presumed expertise.

## I.

### THE BIRTH (AND DEATH) OF A PREAMBLE

The Supreme Court's 2009 decision in *Wyeth v. Levine* addressed a regulation issued by the Food and Drug Administration (FDA) governing the content and format for prescription drug labels.<sup>7</sup> As described in the Court's opinion, the preamble to that regulation "articulated a sweeping position on the [Food, Drug, and Cosmetic Act's (FDCA)] pre-emptive effect" that the Court characterized as a "conclusion" rather than a justification or even an "explanation."<sup>8</sup> Justice Stevens's opinion striking the preamble

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6. See Jennifer S. Hendricks, *Preemption of Common Law Claims and the Prospects for FIFRA: Justice Stevens Puts the Genie Back in the Bottle*, 15 DUKE ENVTL. L. & POL'Y F. 65, 97-98 (2004); see also Ernest A. Young, *Stalking the Yeti: Protective Jurisdiction, Foreign Affairs Removal, and Complete Preemption*, 95 CAL. L. REV. 1775, 1813-15 (2007).

7. *Wyeth*, 129 S. Ct. at 1187 (2009); see also Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (to be codified at 21 C.F.R. pt. 201, 314, 601).

8. *Wyeth*, 129 S. Ct. at 1201.

pegged the George W. Bush Administration's end-run around legislative, regulatory, and litigation due process for what it was: an attempt at preemption by agency fiat that, by overreaching, ultimately short-circuited its own preemptive intent.<sup>9</sup>

The drug manufacturer, Wyeth, seeking to shield itself from legal and financial responsibility for injuries it caused by its anti-nausea drug Phenergan,<sup>10</sup> argued that the FDA must be presumed to have established a specific labeling standard that leaves no room for different state law judgments. Its argument relied on the preemptive effect of an obscure preamble to a 2006 FDA regulation declaring that state law failure-to-warn claims threaten the FDA's statutorily prescribed role.<sup>11</sup> Although an agency regulation with the force of law can preempt conflicting state requirements,<sup>12</sup> respondent (the permanently injured Diana Levine<sup>13</sup>) and amici<sup>14</sup> ar-

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9. *See id.* at 1200–01.

10. As the Supreme Court decision describes the background of the case, after a clinician injected respondent Levine with Phenergan by the 'IV-push' method, whereby the drug is injected directly into a patient's vein, the drug entered Levine's artery instead, and she developed gangrene. Doctors amputated her forearm. Levine brought a tort action in Vermont state court, alleging, *inter alia*, that Wyeth had failed to provide an adequate warning about the significant risks of administering Phenergan by the IV-push method. The Vermont jury determined that Levine's injury would not have occurred if Phenergan's label included an adequate warning and awarded damages for her pain and suffering, substantial medical expenses, and loss of her livelihood as a professional musician. Declining to overturn the verdict, the trial court rejected Wyeth's argument that Levine's failure-to-warn claims were preempted by federal law because Phenergan's labeling had been approved by the FDA. The Vermont Supreme Court affirmed the lower court. *See id.*, 129 S. Ct. at 1190–94.

11. *See* Brief for Petitioner at 8, 11, 45, 50, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249).

12. *See Wyeth*, 129 S. Ct. at 1200 (citing *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000); *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985)).

13. As the Vermont Supreme Court opinion described the events, in April 2000 Ms. Levine received two injections of Wyeth's drug Phenergan at a health clinic to treat nausea resulting from a migraine headache. The second dose was administered by direct intravenous injection into her arm, a procedure known as "IV push." This "resulted in an inadvertent injection of Phenergan into an artery. As a result, the artery was severely damaged, causing gangrene. After several weeks of deterioration, plaintiff's hand and forearm were amputated." Ms. Levine alleged that Wyeth failed to warn adequately of the dangers of IV push injection. *Levine v. Wyeth*, 944 A.2d 179, 182 (Vt. 2006). As the Supreme Court opinion noted, Ms. Levine (a professional guitarist) alleged "substantial medical expenses and loss of her livelihood as a musician." *Wyeth*, 129 S. Ct. at 1191.

14. Amicus briefs were filed on behalf of petitioner Wyeth by the United States of America; Generic Pharmaceutical Association; Pharmaceutical Researchers and Manufacturers of American and Biotechnology Industry Organization; the

gued that the 2006 preamble involved no such regulation, but was merely an agency's assertion that state law is an obstacle to achieving its statutory objectives.

The *Wyeth* court held that where, as in the case of the challenged preamble, Congress has not authorized a federal agency to preempt state law directly, the weight the courts should accord the agency's explanation of state law's impact on the federal scheme depends on its "thoroughness, consistency, and persuasiveness."<sup>15</sup> This standard was previously articulated in a series of federal (including Supreme Court) decisions.<sup>16</sup>

The plaintiffs argued that the FDA's 2006 preamble simply did not merit deference. In the view of the plaintiff and amici, the preamble, which effectively immunized all drugs receiving FDA marketing approval (even those subsequently recalled) from tort actions for compensatory and punitive damages brought by those harmed, could not, consistent with principles of due process, be allowed to perform its intended function. The plaintiff thus challenged the preamble as inherently suspect in light of the FDA's failure to offer interested parties notice or opportunity for comment on the preemption question.<sup>17</sup> That failure was not only at odds

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United States Chamber of Commerce; the Product Liability Advisory Council, Inc.; DRI-The Voice of the Defense Bar; the Generic Pharmaceutical Association; John E. Calfee et al., (economists and economic professors); American College of Emergency Physicians; and the Washington Legal Foundation. Amicus briefs for Respondent Levine included briefs for the Former FDA Commissioners Dr. Donald Kennedy and Dr. David Kessler; members of Congress; the New England Journal of Medicine; the California Medical Association; forty-seven states (including Vermont); the National Conference of State Legislatures; the American Association for Justice; the Center for State Enforcement of Antitrust and Consumer Protection Laws, Inc.; Constitutional and Administrative Law Scholars; the Constitutional Accountability Center; Consumer Union of the United States; the Citizens Commission on Human Rights; and the Senior League. See 2006 U.S. Briefs 1249 (Lexis).

15. *Wyeth*, 129 S. Ct. at 1201.

16. See Brief of Amicus Curiae Constitutional and Administrative Law Scholars in Support of Respondent at 34-46, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249) (citing *United States v. Mead Corp.*, 533 U.S. 218 (2001); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000)). As the Court noted in *Wyeth v. Levine*, "The weight we accord the agency's explanation of State law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness." *Wyeth*, 129 S. Ct. at 1201.

17. As respondent's amicus, NCSL stated in its brief:

Moreover, the question of whether a federal agency can, without a grant of authority to preempt from Congress, dictate preemption as a matter of agency policy has significant fiscal implications for State governments. Consumers' injuries do not simply vanish, nor are they magically healed, when the claims

with the available evidence regarding congressional purposes; it also reversed the longstanding position that state law is a complementary form of drug regulation without providing a reasoned explanation. In its opinion in *Wyeth*, the Supreme Court agreed, bluntly characterizing the preamble as “inherently suspect” and holding that it did “not merit deference.”<sup>18</sup>

The 2006 preamble was thus declared dead on arrival at the Supreme Court. Yet, in the intervening three years between its birth and demise the preamble wreaked havoc in American pharmaceutical litigation. Many, but not all, courts gave deference to the preamble and dismissed claims seeking compensatory and punitive damages for deaths and injuries attributed to dangerously defective drugs.<sup>19</sup> The preemptive preamble defense was even attempted in cases in which changes were initially approved by the FDA but later recalled and withdrawn from the market.<sup>20</sup> Many thousands of plaintiffs found themselves out of court, without remedy for their injuries and losses, because the preamble not only declared their tort claims null and void but also provided no alternative administrative remedies to compensate tort victims.<sup>21</sup>

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are preempted. Instead, the costs of their injuries are paid by insurers, borne by the individuals themselves, and, if the injured consumers cannot pay and are uninsured, State governments may pay (in whole, or with matching federal funds) for medical expenses and disability payments. These and other social costs, and the countervailing impact on States' economies of consumer litigation, have been the focus of much debate and legislation in the States. This vital decision-making process is a key part of our co-operative system of Federalism.

Brief of the National Conference of State Legislatures as Amicus Curiae Supporting Respondents at 2, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249) (hereinafter Brief of Amicus Curiae NCSL).

18. *Wyeth*, 129 S. Ct. at 1201.

19. See, e.g., *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 523–38 (E.D. Pa. 2006), *aff'd*, 521 F.3d 253 (3d Cir. 2008). But see *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 273–74 (E.D.N.Y. 2007); *In re Vioxx Prod. Liab. Litig.*, 501 F. Supp. 2d 776, 786–88 (E.D. La. 2007).

20. See, e.g., *In re Vioxx Prod. Liab. Litig.*, 501 F. Supp. 2d at 780–81 (denying defendants' motion for summary judgment on preemption grounds).

21. See, e.g., Note, *New Evidence on the Presumption Against Preemption: An Empirical Study of Congressional Responses to Supreme Court Preemption Decisions*, 120 HARV. L. REV. 1604, 1623–24 (2007) (describing how courts' consideration of consequences of preemption often aligns with the presumption against preemption); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933–34 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601). When state law tort claims are preempted, injured patients' damages suits are dismissed with prejudice, leaving them without any source of compensation for the medical expenses, lost wages, personal injuries, and emotional distress they and their families suffer when medical products fail. Prior to

Because of the vast amount of damage done by the preamble during its brief reign, the tale of its genesis bears repeating and needs remembering.

Any agency, once captured by the industry it is entrusted to regulate, may be hijacked or used as the mouthpiece for that industry, and may become the vehicle for the industry-friendly political objectives of any executive administration. The tale of the 2006 preamble teaches the satisfying lesson that usurped power will not necessarily remain unchecked if the judiciary ultimately does its job. But there is no reason to believe, despite the change of administration and shift in political alignment resulting from the 2008 election, that the preamble is a one-off: political strategies do not tend to the unique, and even a short period of success, like the three years of litigation advantage enjoyed by the pharmaceutical industry at the expense of state tort law, may be deemed sufficient justification and incentive to try it again.

## II.

### THE FDA'S HISTORICAL POSITION AND 2000 STATEMENT THAT PREEMPTION WAS NOT IMPLICATED BY AGENCY LABELING RULES

Courts have held that Congress specifically rejected a proposal to include a federal private right of action for damages because Congress recognized that such actions already existed under state common law when it enacted the Food, Drug, and Cosmetic Act (FDCA) in 1938.<sup>22</sup> In 1962, when Congress passed amendments to the FDCA, it added a provision stating that:

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the Supreme Court's *Wyeth* decision, many pharmaceutical personal injury cases were dismissed as preempted by FDA regulation. *See, e.g., Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009). The *Wyeth* decision has appreciably reduced the risk of preemption dismissals in many other pharmaceutical cases. *See, e.g., Demahy v. Actavis, Inc.*, No. 08-31204, 2010 WL 46513, at \*1 (5th Cir. Jan. 8, 2010) ("While not directing our result, [*Wyeth*] shadows our conclusion that the federal regulatory regime governing generics is also without preemptive effect."). As Demahy observes, "the bar to a finding of preemption is set even higher" when "federal law provides no remedy for an injured consumer." *Id.* at \*4. As to medical device cases, preemption is still the norm. *See, e.g., In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147 (D. Minn. 2009) (dismissing the tort claims of more than 1000 plaintiffs), *appeal docketed*, No. 09-2290 (8th Cir. June 5, 2009).

22. *See In re Paxil Litig.*, No. CV 01-07937, 2002 WL 31375497 at \*1 (C.D. Cal. Oct 18, 2002) ("FDA and [defendant] invite the Court to find that in enacting the FDCA for the purposes of protecting public health, Congress not only declined to provide for a private cause of action, but also eliminated the availability of com-

[n]othing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.<sup>23</sup>

For nearly 40 years thereafter, the FDA consistently took the position that its labeling requirements represented *minimum standards* that did not preempt state law.<sup>24</sup>

The FDA has historically and consistently recognized that product liability litigation asserting state law claims serves an important role in protecting the public.<sup>25</sup> In doing so, the FDA acknowledged that compliance with agency labeling requirements does not supplant state tort doctrines, such as the manufacturer's continuing duty to warn as new risks are discovered. The FDA has noted that "drug labeling does not always contain the most current information and opinion available to physicians about a drug because advances in medical knowledge inevitably precede formal submission of proposed new labeling by the manufacturer and approval by FDA."<sup>26</sup>

For example, in 1998, when issuing regulations addressing pharmacists' provision of written patient information ("Medication Guides") for certain types of prescription drugs, the FDA stated that its regulations established only *minimum standards* that posed no actual or anticipated conflict with state law and that were not intended to preclude the imposition of additional labeling requirements.<sup>27</sup> Even though Medication Guides are subject to intense regulatory oversight by the FDA,<sup>28</sup> the agency reaffirmed its anti-preemption stance, and properly rejected comments from the

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mon law state claims. This position contravenes common sense, and the Court declines the invitation.") (internal citation omitted); Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 924 (1994).

23. 21 U.S.C. § 301.

24. David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-To-Warn Claims*, 96 GEO. L.J. 461, 474 (2008).

25. See, e.g., 44 Fed. Reg. 37,447 (citing *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522 (Or. 1974)).

26. *Id.* at 37,435.

27. Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998) (codified in 21 C.F.R. pts. 201, 208, 314, 601, 610); see also *Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989); *Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 431–32 (D. Vt. 2008).

28. See, e.g., *Kellogg*, 612 F. Supp. 2d at 431–32.

pharmaceutical industry calling for the preemption of state labeling requirements. In doing so, the agency stated that “FDA regulations establish the minimal standards necessary, but were not intended to preclude states from imposing additional labeling requirements. States may authorize additional labeling, but they cannot reduce, alter, or eliminate FDA-required labeling.”<sup>29</sup>

Executive Order 13132, “Federalism,” issued on August 4, 1999, was designed to prevent runaway or captured agencies from preempting state law or circumventing federalism by fiat.<sup>30</sup> This executive order states that “[n]ational action limiting the policymaking discretion of the States shall be taken only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance.”<sup>31</sup> The executive order also outlined several “Special Requirements for Preemption.”<sup>32</sup> This section requires that federal agencies restrict any regulatory preemption of state law to the minimum level necessary;<sup>33</sup> that *prior to* publication federal agencies shall consult with appropriate state and local officials in an effort to avoid the possibility of conflict between state law and federal interests;<sup>34</sup> and that “when an agency proposes to act through adjudication or rule-making to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.”<sup>35</sup> The executive order specifies the due process required: “no agency shall promulgate any regulation that has federalism implications and that preempts State law, unless the agency, prior to the formal promulgation of the regulation . . . consulted with State and local officials early in the process of developing the proposed regulation.”<sup>36</sup>

The FDA acknowledged these principles and procedures in 2000 when it published its proposed drug-labeling rule—the same rule before the courts in *Wyeth v. Levine*—declaring as follows:

FDA has analyzed this proposed rule in accordance with Executive Order 13132: Federalism. The Order requires Federal agencies to carefully examine actions to determine if they con-

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29. 63 Fed. Reg. at 66,384 (codified in 21 C.F.R. pts 201, 208).

30. Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999).

31. *Id.* § 3(b).

32. *Id.* § 4.

33. *Id.* § 4(c).

34. *Id.* § 4(d).

35. *Id.* § 4(e).

36. *Id.* § 6(c)(1).

tain policies that have federalism implications or that preempt State law. . . .

FDA is publishing this proposed rule to revise its regulations governing the format and content of labeling for human prescription drug products. . . . [T]his proposed rule does not pre-empt State law.

Accordingly, FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.<sup>37</sup>

Having expressly stated that the proposed new labeling rules did not implicate federalism or preempt state law, the FDA did not seek or receive comments on the federalism implications of preemption.

### III. THE FDA IS CAPTURED AND ISSUES A HOSTAGE STATEMENT

In 2001 a new Chief Counsel of the FDA, Daniel Troy, was appointed. Mr. Troy had represented pharmaceutical and other industries in lawsuits against the FDA.<sup>38</sup> Once appointed, Mr. Troy publicly called for industry representatives to suggest cases in which the FDA could advocate for preemption.<sup>39</sup> The FDA subsequently began filing amicus briefs whose arguments mirrored the preemptive opinion later expressed in the 2006 preamble. No such position had ever been advocated in the over ninety-year history of the FDA.

Then a funny thing happened. On December 30, 2005, the Executive Branch Liaison for the National Conference of State Legislators (NCSL) received a call from FDA intergovernmental staff.<sup>40</sup> The FDA staffer informed her that the agency planned to finalize its long-dormant labeling rule in early January 2006 and would be

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37. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000) (to be codified at 21 C.F.R. pt. 201).

38. See generally Stacey Schultz, *Mr. Outside Moves Inside: Daniel Troy Fought the FDA for Years; Now He's Helping to Run It*, U.S. NEWS & WORLD REPORT, March 16, 2003, available at [http://health.usnews.com/usnews/health/articles/030324/24\\_fda.htm](http://health.usnews.com/usnews/health/articles/030324/24_fda.htm) (last visited Nov. 4, 2009).

39. James T. O'Reilly, *U.S. Food and Drug Regulation in Its First Century and Beyond*, 93 CORNELL L. REV. 939, 953–54 (2008).

40. Affidavit of Susan Parnas Frederick at 1 (attached to Brief for Nat'l Conference of State Legislatures as Amici Curiae Supporting Respondents), *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249).

including a statement preempting state laws. This was, to put it mildly, a surprise. NCSL's counsel immediately asked to be placed in touch with the FDA's general counsel's office and asked for a copy of this proposed "policy statement." She also asked that the consultation process under Executive Order 13132 occur and asked for the notice-and-comment period to be reopened.<sup>41</sup>

NCSL counsel then received a call from the office of the FDA's general counsel, and, as she states in her affidavit:

I was informed by Mr. Randy Luttig that NCSL could not review this proposed language in advance of its publication, that this telephone call constituted the consultation under Executive Order 13132, and that the comment period was closed and would not be reopened to permit NCSL to submit comments on the new language.

In a follow-up conversation with FDA staff, I was informed that the FDA considers the requirement of Executive Order 13132 satisfied, and was again told I would not be able to review a copy of the proposed "policy statement." I subsequently learned that FDA had received and accepted numerous late, non-public, comments from industry on the proposed regulation.<sup>42</sup>

Thereafter, without further rulemaking or public notice, the FDA simply attached a "preamble" to its January 24, 2006 Final Rule on labeling that had not, prior to its publication, seen the light of day. The FDA attempted to explain away its failure to follow the requirements of Executive Order 13132 in this statement:

FDA sought input from all stakeholders on new requirements for the content and format of prescription drug labeling through publication of the proposed rule in the Federal Register. Although the proposed rule did not propose to preempt state law, it did solicit comment on product liability issues. FDA received no comments on the proposed rule from State and local governmental entities.<sup>43</sup>

Those from whom the FDA supposedly did solicit comment were neither described nor identified.<sup>44</sup> With this as its only justifi-

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41. *Id.* at 1–2.

42. *Id.* at 2.

43. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3969 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 214, 601) (emphasis in original).

44. *See generally id.* The FDA does indicate responsiveness to concerns of unidentified "manufacturers" regarding "product liability implications" and addressed these by stating "such product liability claims would be preempted." *Id.* at

caution, the FDA stated that it “believe[d] that it ha[d] complied with all of the applicable requirements under Executive Order 13132 and ha[d] determined that this final rule is consistent with the Executive Order.”<sup>45</sup>

The FDA’s failure to describe those from whom it purported to have solicited comments would lead directly to the preamble’s demise at the hands of the Supreme Court, which considered the preamble as “inherently suspect” in light of the agency’s failure to offer interested parties notice or opportunity for comment on the preemption question.<sup>46</sup> The agency’s willingness to lie about its compliance with the comment requirement was a telling symptom of its extreme and ultimately self-destructive “capture” by the very group it was meant to police—drug manufacturers—and the corollary betrayal of the group it was created to protect—the drug-consuming public.<sup>47</sup>

Shortly after the FDA published its preamble, ranking members of the House and Senate wrote to the FDA objecting to it.<sup>48</sup> They criticized the FDA for attempting to “reverse[ ] a long-standing FDA policy of permitting complementary State activities intended to protect consumers from unsafe drugs.”<sup>49</sup> Their letter noted the due process end-run: “[N]either affected state and local entities, nor the general public were given an opportunity to comment” because the FDA “provided no opportunity for dissenting

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3933. No identification of entities from whom anti-preemption comments were sought or received was included, and support for the preemption position referred to arguments made in FDA amicus briefs. *Id.* at 3934–35.

45. *Id.* at 3,969.

46. *Wyeth v. Levine*, 129 S. Ct. 1187, 1201 (2009).

47. See Carl Tobias, *FDA Regulatory Compliance Reconsidered*, 93 CORNELL L. REV. 1003, 1009–10 (2008) (discussing judicial concerns about “agency capture” as applied to the FDA). Voices within the FDA itself have cast this as a failure of resources. The FDA’s own blue-ribbon panel agreed that the agency was not up to the task of ensuring public safety, stating that, “the scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the . . . regulatory system, and hence the safety of the public.” FDA SCIENCE BOARD, *FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY FOOD AND DRUG ADMINISTRATION SCIENCE BOARD 2* (2007).

48. See, e.g., Letter from Edward M. Kennedy and Christopher J. Dodd to Michael O. Leavitt (February 23, 2006); Letter from Henry A. Waxman, John D. Dingell, and Sherrod Brown to Michael O. Leavitt (February 23, 2006) (on file with the Annual Survey of American Law), available at <http://dodd.senate.gov/index.php?q=node/3381>.

49. Letter from Henry A. Waxman, John D. Dingell, and Sherrod Brown to Michael O. Leavitt, *supra* note 48.

views to be heard.”<sup>50</sup> The legislators also attacked the very foundation of the FDA’s analysis, which they claimed abrogated the roles and powers of the legislative and judicial branches, accusing the FDA of relying on “misleading characterizations of the governing statute and irrelevant cases, while ignoring contrary legislative history.”<sup>51</sup>

The NCSL, an organization representing the interest of the states’ legislatures in preserving the states’ role in America’s system of federalism, voiced similar objections, stating in a formal letter to the Secretary of Health and Human Services that the FDA’s radical shift in position, combined with its refusal to go through the legally required notice-and-comment process, constituted “an abuse of agency process and a complete disregard for our dual system of government. . . . It is unacceptable that [the] FDA would not permit the states to be heard on language that has a direct impact on state civil justice systems nationwide.”<sup>52</sup>

The FDA was intended to function as an independent regulatory agency deploying its medical and scientific expertise to protect the health and safety of the public. However, it has come under increasing fire from the medical profession itself (a constituency with undoubtedly relevant expertise), for its inability, through lack of funding and otherwise, to regulate the products of pharmaceutical laboratories and safeguard the public health effectively.<sup>53</sup> Whether or not such criticism is warranted, the FDA is without the legal authority or expertise to regulate, much less nullify, the legislative and judicial products of the states. Announcements of preemption made without expertise, authority, or due process should warrant no deference.

As noted by former Commissioner David Kessler, subsequent to the FDA’s issuance of the preamble, Congress passed and the President signed the FDA Amendments Act of 2007, which did not include a preemption provision.<sup>54</sup> The Act instead included a “rule of construction” that the FDA’s new authority over labeling did not

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50. *Id.*

51. *Id.*

52. See Letter from Steven J. Rauschenberger, Assistant Senate Minority Leader, Illinois President, NCSL to Mike Leavitt (Jan. 13, 2006) (on file with the author).

53. As the *New England Journal’s* editors have now expressly stated, the FDA’s current preemptive position is also a threat to the broad-based expertise and patient-responsive role of the medical profession. See, e.g., Gregory D. Curfman, et al., *Why Doctors Should Worry About Preemption*, 359 *NEW ENG. J. MED.* 1, 1–3 (2008) (editorial by NEJM editors, criticizing FDA position in this case).

54. Kessler & Vladeck, *supra* note 24, at 467–70.

relieve manufacturers of their current responsibilities to provide up-to-date safety information and did *not* affect their ability and responsibility to do so without first securing the FDA's approval.<sup>55</sup> As Commissioner Kessler notes, the pharmaceutical industry unsuccessfully sought a preemption provision; when they failed to secure one, opponents of the bill criticized it as "a definite boon to trial lawyers."<sup>56</sup> Whether it was or was not a "definite boon" to the competing constituencies of consumers, their lawyers, or the pharmaceutical companies and theirs, or whether it assisted or facilitated the state legislatures and courts that have long considered and balanced the interests of these constituencies in the system of tort law, the FDA Amendments Act definitely did *not* authorize preemption.<sup>57</sup>

The 2006 preamble on which Wyeth premised its preemption arguments in its campaign to overturn the jury verdict in favor of Diana Levine was thus not part of the FDA regulation, and it demonstrably did not go through the formal notice-and-comment process. Although the Supreme Court has sometimes given deference to an agency's interpretive rules—rules that do not have the force of law, but that set forth the agency's understanding of a law which Congress has authorized that agency to interpret via the regulatory process or enforce<sup>58</sup>—in the case of the preamble, the FDA did not purport to issue an interpretive rule, as Congress had not authorized the FDA to preempt or replace state tort law. Instead, the FDA stated its belief on a legal question, in language resembling a lawyer's or a lobbyist's advocacy position.<sup>59</sup>

#### IV. THE PREAMBLE UNDER FIRE

Respondent Diana Levine and those amici who supported an anti-preemptive interpretation of the preamble argued that, even if the Court were to view the preamble as an interpretive rule, no deference could be given to it without fundamentally undermining

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55. FDA Amendments Act of 2007 § 901(a), Pub. L. No. 110-85, 121 Stat. 825, 925–26 (codified at 21 U.S.C. § 301); Kessler and Vladeck, *supra* note 24, at 468.

56. Kessler & Vladeck, *supra* note 24, at 468 n. 27.

57. *Id.*

58. *See, e.g.*, *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (holding that the Secretary of Labor's interpretation of the salary-basis test is controlling unless "plainly erroneous or inconsistent with the regulation").

59. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934, 3969 (Jan. 24, 2006) (to be codified at 21 C.F.R. pt. 201, 314, 601).

our system of federalism. The NCSL amicus brief (which was submitted by the author), for example, urged a denial of deference to the preamble out of concern that the member states' traditional authority over the products liability claims and recoveries by their citizens—i.e., their position “on the front line of the policy decisions about ‘Tort Reform’”—and the extensive work many states had completed in the field, including enactments that both approved and rejected preemption, had been negated by the preamble without due process or due regard for federalism.<sup>60</sup> The amici for respondents urged three reasons for denying deference to the preamble and its preemption manifesto:

1. The FDA failed to give state authorities any meaningful notice or opportunity to comment and participate in the proceedings as required by executive order 13132. The preamble's method of creation instead sought to preempt due process. The FDA's flagrant violation of a binding executive order designed to safeguard the system of federalism should not be enabled by the Court.

2. The FDA's procedural violation was exacerbated by the FDA's lack of congressional authority to determine the preemptive effect of drug labeling rules on state law causes of action. The FDA simply attempted to seize, in a manner never countenanced by preemption jurisprudence, the states' sovereign authority over their own tort law, in order to assist a special interest (the pharmaceutical industry). Respect for federalism requires the Court to reject the executive branch's effort to impose preemption absent clear congressional authorization and appropriate respect for procedural norms.

3. When an agency has radically and suddenly changed its longstanding views, as the FDA did in the preamble, is unable or unwilling to explain its profound change in view, and proceeds in a manner that demonstrates that external pressure or politics, rather than independent agency expertise, is the source of the new view, the agency's arguments for administrative preemption should be rejected. The NCSL brief implored that “preemption cannot be allowed to be implied based upon political decisions by the Executive Branch acting alone.”<sup>61</sup>

The NCSL and other amici argued that the FDA failed to comply with the unambiguous and mandatory directive of Executive Order 13132, and that no sensible or reasoned excuse was provided by the FDA for its failure to consult with appropriate state officials.

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60. Brief of Amicus Curiae NCSL, *supra* note 17, at 1.

61. *Id.* at 15–16.

The FDA's arguably tautological explanation, that it need not consult with the state and local governments because it received no comments from them on preemption (after having told state and local government in 2000 that the proposed regulations did not preempt state law), would be comical if it were not so nakedly undemocratic.

As the NCSL brief described:

Section 4(d) of Executive Order 13132 *requires* all agencies to consult with appropriate State and Local officials whenever an agency foresees the possibility of a conflict between state law and a federally protected interest within the agency's area of regulatory responsibility. Section 4(e) . . . further specifies that, when an agency proposes to act through adjudication or rulemaking to preempt state law, it *shall provide* all affected state and local officials with notice and an opportunity to comment and participate in the proceedings.<sup>62</sup>

The states thus argued that they had a reasonable basis to rely upon the executive order, and to expect that the executive branch would not engage in an end-run around due process to avoid what it knew to be unfavorable input and opposition. When the FDA issued its proposed drug labeling rule in 2000, it stated quite clearly in its notice of rulemaking that "this proposed rule does not preempt State law."<sup>63</sup> This unequivocal statement was consistent with the FDA's longstanding position on preemption.<sup>64</sup> The FDA's express message to the public, and to state and local officials, was that the proposed rule would not preempt or otherwise impact state law, effectively silencing interested parties during the notice-and-comment period by assuring them that federalism issues were not at stake. Without too much exaggeration, in light of the 2006 preamble's attempt (and temporary success) at absolute preemption, the FDA could itself be accused of "failure to warn."

The process by which the preamble was inserted without due notice, or due process, improperly placed expediency above respect for state governments. In its mission to implement the peculiar interest of a pressure group, the FDA disrupted the balance of powers and the system of checks and balances among the branches of our federal government, and between the federal and state governments that are the structural and functional bedrocks of our sys-

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62. *Id.* at 16–17.

63. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000) (to be codified at 21 C.F.R. pt. 201).

64. *See* *Wyeth v. Levine*, 129 S. Ct. 1187, 1202–03 (2009).

tem.<sup>65</sup> Unbalanced and unchecked, the preamble exalts the bureaucratic processes of the executive branch and subordinates the legislative and judicial branches of both the federal government, and the states themselves, without any constitutional basis or justification.

The preamble disregarded the clear intent of Congress to defer to the traditional role of the states in this area.<sup>66</sup> State tort laws have historically been the primary compensatory mechanism for negligence and product liability.<sup>67</sup> This system has been developed over two centuries and would have been destroyed had the Court deferred to the preamble.<sup>68</sup> No federal agency has ever fully occupied an area of the compensatory tort system without an explicit act of Congress. Such acts have been rare and usually provide for comprehensive adjudicatory procedures.<sup>69</sup> The preamble met neither requirement.<sup>70</sup> In the eyes of tort law's traditional enactors and guardians, it was nihilism, not preemption.

In the preamble, the FDA attempted, ultimately unsuccessfully, to preempt Congress, and to do so secretly, dispensing with the notice-and-comment requirements. This is a low-water mark in agency integrity and a rejection of due process that is likely unprecedented in the annals of federal regulation. It was, deservedly, short-lived, but wreaked havoc in the courts while it lasted.

While the executive branch is entitled to assert any position it wishes, it cannot do so through a legal process that fails to afford state governments the respect they are due under constitutional

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65. See *Gregory v. Ashcroft*, 501 U.S. 452, 457–59 (1991) (describing federalism).

66. See David C. Vladeck, *FDA Preemption, Wyeth, Congress, and a Crystal Ball*, 32 *HAMLIN L. REV.* 707, 719 (2009); see also Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 *Fed. Reg.* 3922, 3934–35 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

67. See Philip H. Corboy & Todd A. Smith, *Federal Preemption of Product Liability Law: Federalism and the Theory of Implied Preemption*, 15 *AM. J. TRIAL ADVOC.* 435, 451 (1992).

68. See Betsy J. Grey, *The New Federalism Jurisprudence and National Tort Reform*, 59 *WASH. & LEE L. REV.* 475, 519–20 (2002).

69. This did occur, uniquely, with respect to vaccines. See *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 251, 255–56 (3d Cir. 2009) (affirming the grant of summary judgment in favor of Wyeth, the manufacturer of the diphtheria-pertussis-tetanus (DPT) vaccine, and discussing the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-22(a)–(b), which expressly preempts design defect claims).

70. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 *Fed. Reg.* at 3933–36.

guarantees of federalism.<sup>71</sup> There was no emergency or any other supposed exigency at issue in 2006 to justify the hidden process used to create the preamble.<sup>72</sup> The procedural failure to give meaningful notice—the preamble’s stealth preemption—is fatal to its preemptive goal.<sup>73</sup> For the Supreme Court to have held otherwise would deprive state and local governments of important historical rights without giving them any voice in the proceedings, while rewarding what was essentially a bait-and-switch by the FDA. The FDA’s new 2005–2006 views, as expressed in the preamble, are therefore entitled to no deference.

Congress has never delegated to the FDA authority to determine the preemptive effect of drug labeling rules on state law causes of action. To the contrary, Congress specifically declined to provide a federal damages remedy in the FDCA because state law damages remedies were available, and Congress subsequently added a savings clause.<sup>74</sup> Congress can hardly be said to have authorized the FDA to supersede the damages remedies traditionally provided by the states, let alone to have made a “plain statement” of intent to preempt.

Congress expressly rejected a proposal to include a federal private right of action in the legislation creating the FDA itself, the FDCA, because “a common law right of action already exist[ed].”<sup>75</sup> There are no provisions within the FDCA delegating authority to the FDA to determine the preemptive effect of drug labeling rules on state law causes of action. There is only one logical conclusion: Congress did not confer upon the FDA the power to legislate for itself and unilaterally determine whether its drug labeling regulations preempt state law. Therefore, the FDA’s proposed preempt-

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71. Exec. Order No. 13,132: Federalism, 64 Fed. Reg. 43,255, 43,257–58 (section 6) (Aug. 4, 1999) .

72. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3933–36 (only explanation for reversal of position on preemption is that “[s]ince the proposed rule was published, FDA has learned of several instances in which product liability lawsuits have directly threatened the agency’s ability to regulate”).

73. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1201 (2009) (declining to give deference to preamble in light of “procedural failure” to give “notice or opportunity for comment” to states); cf. *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (“thoroughness evident” in agency’s consideration of the issue is a factor in assessing its “power to persuade”) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

74. See Brief of Amici Curiae Vermont et al. in Support of Respondent at 31, *Wyeth*, 129 S. Ct. 187 (No. 06-1249).

75. See Brief of Amici Curiae Members of Congress in Support of Respondent at 9, 31, *Wyeth*, 129 S. Ct. 187 (No. 06-1249).

tion analysis was an ultra vires political statement which exceeded the scope of the FDA's congressional authority and, in the view of state tort laws' protectors, was due no deference from the Court.

V.  
THE PREAMBLE'S ABOUT-FACE ON PREEMPTION  
UNDERMINED ITS ENTITLEMENT  
TO DEFERENCE

Assuming that the FDA had the requisite congressional authority to determine the preemptive scope of its regulations, the plaintiff's position was that judicial deference would nevertheless be unwarranted, because the preamble reversed the FDA's longstanding position against preemption.<sup>76</sup> The Supreme Court had previously held that an agency's assertions of preemption that reversed prior longstanding agency policy are entitled to little or no weight by the courts.<sup>77</sup> The FDA's abrupt change in position regarding the preemptive scope of its drug labeling requirements reversed an anti-preemption policy which spanned decades, including an express statement by the FDA in 2000 that: "this proposal does not preempt state law."<sup>78</sup> During this time, numerous courts throughout the country relied on the FDA's interpretation of its regulations while continuing to develop and refine a substantial body of state common law. Notably, the final rule did not amend any of the regulations upon which these courts have relied in finding no preemption. The FDA's abrupt change in position unnecessarily disrupted

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76. As also noted by several courts that were presented with the 2006 preamble as the basis for preemption, "FDA's current view of the preemptive effect of its labeling regulations is a 180-degree reversal of its prior position." *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M:05-1699 CRB, 2006 WL 2374742 at \*8 (N.D. Cal. Aug. 16, 2006). Some courts therefore rejected the preamble and the FDA's claims of preemption. *See, e.g., In re Vioxx Prod. Liab. Lit.*, 501 F. Supp. 2d 776 (E.D. La. 2007) (noting change in prior position and refusing to give the preamble either *Auer* or *Chevron* deference).

77. *See, e.g., Bates v. Dow Agrosociences, LLC*, 544 U.S. 431, 449 (2005). *Bates* held that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 (2006), a federal statute governing the safety of pesticides, did not preempt state common law tort claims. In *Bates*, the Court rejected arguments made by the government in amicus briefs and chastised the EPA for engaging in the same policy flip-flop at issue in *Wyeth*: "The notion that FIFRA contains a nonambiguous command to preempt the types of tort claims that parallel FIFRA's misbranding requirements is particularly dubious given that just five years ago the United States advocated the [opposite interpretation]." *Id.*

78. Draft Guidance for Industry on the Content and Format for Labeling for Human Prescription Drugs and Biological Products, 65 Fed. Reg. 81082, 81103 (2000).

not only its own longstanding principles, but also those of stare decisis.

As the preamble's foes argued, ultimately, the FDA's preamble was simply an unwarranted and arbitrary change in position without any concomitant change in the law, as to which the Supreme Court should grant no deference.<sup>79</sup> And as it turned out, the Court did not.

## VI. THE *WYETH V. LEVINE* DECISION DELIVERS THE COUP DE GRÂCE

The Supreme Court was unimpressed with Wyeth's argument that Diana Levine's tort claims were preempted because they interfered with Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives.<sup>80</sup> The opinion states: "[W]e 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 preempt state law."<sup>81</sup> Wyeth contended that the FDCA established both "a floor and a ceiling" for drug regulation. That is, once the FDA has approved a drug's label, no state law verdict may deem it inadequate, directly or indirectly, "regardless of whether there is any evidence that the FDA has considered the stronger warning at issue."<sup>82</sup> Of course, there is no federal system of compensatory law that would provide a substitute for the invalidated state law verdict, a point never emphasized (understandably) by Wyeth. This unstated consequence did not escape the notice of the Court, however:

The most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary. Building on its 1906 Act, Congress enacted the FDCA to bolster consumer protection against harmful products. Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers.<sup>83</sup>

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79. *See, e.g.*, Brief of Amicus Curiae NCSL, *supra* note 17, at 29.

80. *See id.*

81. *Wyeth v. Levine*, 129 S. Ct. 1187, 1199 (2009).

82. *See id.*

83. *Id.* at 1199–1200 (internal citations omitted).

As the Court noted pointedly, Congress has never acted expressly to preempt prescription drug suits.<sup>84</sup> The Court did not accept Wyeth's position that the preamble sufficed to preempt, but instead reiterated its classic statement that "the weight we accord the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness."<sup>85</sup> The Supreme Court delivered its own verdict: "Under this standard, the FDA's 2006 preamble does not merit deference."<sup>86</sup> Why? Because, when the FDA finalized the proposed rule it announced in December 2000 (at the time explaining that it would not "preempt State law"), it did so "without offering States or other interested parties notice or opportunity for comment" and "articulated a sweeping position" on "pre-emptive effect in the regulatory preamble. The agency's views on state law are inherently suspect in light of this procedural failure."<sup>87</sup>

The Court's opinion contains further condemnation of the preamble, saying it is "at odds with what evidence we have of Congress' purposes, and it reverses the FDA's own long-standing 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."<sup>88</sup> The Court observed the following:

[T]he FDA's 2006 position plainly does not reflect the agency's own view at all times relevant to this litigation. Not 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, it cast federal labeling standards as a floor upon which States could build and repeatedly disclaimed any attempt to pre-empt failure-to-warn claims.<sup>89</sup>

As the Court observed, there has been good reason why "the FDA traditionally regarded state law as a complementary form of

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84. *Id.* at 1200 ("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. But despite its 1976 enactment of an express preemption provision for medical devices, Congress has not enacted such a provision for prescription drugs.") (internal citations omitted).

85. *Id.* at 1201 (citing *United States v. Mead Co.*, 533 U.S. 218 (2001); *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

86. *Wyeth*, 129 S. Ct. at 1201.

87. *Id.*

88. *Id.*

89. *Id.* at 1201-02.

drug regulation.”<sup>90</sup> Here, the Court recognized the limited resources with which the FDA must do its work:

The FDA 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. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA’s premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.<sup>91</sup>

## VII. CONCLUSION

As the Court observed, the FDA’s 2006 preamble represented “a dramatic change in position.”<sup>92</sup> In the interim between the issuance of the 2006 preamble, and the 2009 issuance of the Supreme Court’s *Wyeth v. Levine* decision, however, the preamble’s drama had tragic consequences. While not universally honored by the lower courts, it drove motions for dismissal and summary judgment at the expense and to the lasting prejudice of many thousands of injured consumers and the families of thousands more who were killed by unsafe drugs. The revival of such claims presents obvious practical and legal problems. Substantial judicial resources were consumed in grappling with the preemptive intent of the preamble. Confusion and inconsistency were created in state tort law as interpreted by federal and state torts, and many claims were foreclosed on the technical ground of preemption without the opportunity to be adjudicated on their merits.

The Obama Administration acted decisively, shortly after the issuance of *Wyeth v. Levine*, to prevent a repeat of the preamble scandal. On May 20, 2009, President Obama issued a “Memorandum for the Heads of Executive Departments and Agencies/Subject: Preemption” which, inter alia, prohibits the inclusion “in regulatory preambles statements that the department or agency in-

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90. *Id.* at 1202.

91. *Id.*

92. *Id.* at 1203.

tends to preempt State law through the regulation except where preemption provisions are also included in the codified regulation.”<sup>93</sup> The Memorandum also reaffirms “the principles outlined in Executive Order 13132” and requires a retrospective review of “regulations issued within the past 10 years that contain statements in regulatory preambles or codified provisions intended by the department or agency to preempt State law, in order to decide whether such statements or provisions are justified under applicable legal principles governing preemption.”<sup>94</sup> Any such provisions are to be eliminated: “Where the head of a department or agency determines that a regulatory statement of preemption or codified regulatory provision cannot be so justified, the head of that department or agency should initiate appropriate action, which may include amendment of the relevant regulation.”<sup>95</sup>

The most uncompromising affirmation of the sanctity of federalism pervades Justice Thomas’ opinion concurring in *Wyeth*. Justice Thomas stakes out the high ground of federalism:

In order to ensure the protection of our fundamental liberties, the Constitution establishes a system of dual sovereignty between the States and the Federal Government. The Framers adopted this constitutionally mandated balance of power, to reduce the risk of tyranny and abuse from either front, because a federalist structure of joint sovereigns preserves to the people numerous advantages, such as a decentralized government that will be more sensitive to the diverse needs of a heterogeneous society and increase[d] opportunity for citizen involvement in democratic process. Furthermore, as the Framers observed, the ‘compound republic of America’ provides a double security . . . to the rights of the people because the power surrendered by the people is first divided between two distinct governments, and then the portion allotted to each subdivision among distinct and separate departments.<sup>96</sup>

Indeed Justice Thomas’ defense of federalism is a *tour de force* critique of the Supreme Court’s “entire body” of “purposes and

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93. Memorandum From the White House Office of the Press Sec’y to the Heads of Executive Departments and Agencies (May 20, 2009) (on file with the Annual Survey of American Law), *available at* <http://www.whitehouse.gov/the-press-office/Presidential-Memorandum-Regarding-Preemption>.

94. *Id.*

95. *Id.*

96. *Wyeth v. Levine*, 129 S. Ct. 1187, 1205 (Thomas, J., concurring) (internal citations and quotation marks omitted).

objectives preemption jurisprudence [as] inherently flawed.”<sup>97</sup> Justice Thomas would eliminate the doctrine entirely:

Because such a sweeping approach to pre-emption leads to the illegitimate—and thus, unconstitutional—invalidation of state laws, I can no longer assent to a doctrine that pre-empts state laws merely because they stan[d] as an obstacle to the accomplishment and execution of the full purposes and objectives of federal law. . . .<sup>98</sup>

It appears that President Obama and Justice Thomas stand together, albeit from opposite ends of the political and philosophical spectrum, as foes of preemption.

Yet the battle of preemption is not over. As Justice Stevens noted in *Wyeth*, Congress did expressly act to preempt lawsuits concerning medical devices, and legislation will be required to restore access to the courts to compensate and deter harms arising from defective medical devices.<sup>99</sup> Judicial sympathy for preemption has been driven in part by distain for, or distrust of, juries, or at least for a stated preference to rely upon experts rather than lay people for assessments of risk and responsibility. It is sometimes argued that juries do not consider both sides of the risk/benefit analysis, because they only see the dead and injured and not the many benefited by drugs. These arguments will continue to be made, and they have some, albeit limited, logical appeal.

However they do not square with the facts of litigation. Juries do indeed hear, incessantly, about the benefits of the drugs implicated in product liability trials: defendants’ experts testify as to the relative numbers of those benefited and harmed by the drug at issue to demonstrate that the former far outnumber, and outweigh, the latter.<sup>100</sup> Moreover, it is a medical reality that juries are made up of lay people who are also drug consumers, who have been benefited by many drugs, and who rely upon drugs and their manufacturers to maintain and restore their health.

It is only fitting, in our society founded upon a social contract of reciprocal rights, liberties, and responsibilities, that the purchasers and consumers of drugs have a say in the risk/benefit analysis,

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97. *Id.* at 1211 (internal quotation marks omitted).

98. *Id.* at 1217 (internal quotation marks omitted).

99. *See id.* at 1200 (opinion of the court). The proposed Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. (2009), would amend the FDCA to restore liability under state law.

100. *See*, for example, the drug manufacturers’ experts’ testimony as described in the ruling on *Daubert* motions in *In re Bextra & Celebrex Mktg., Sales Practices, & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166 (N.D. Cal. 2007).

determining, on the basis of the facts before them, presented by vigorous and expert adversaries, and assisted by expert witnesses, whether the risk/benefit balance has been observed by the defendant, or whether it must be restored through compensation to the victim. This can be a scary system (for plaintiffs as well as defendants), but it has been refined by innovations such as the parties' selection of bellwether trials to flesh out the issues, predict the merits, and set values for claims, without trying hundreds or thousands of claims ad infinitum.<sup>101</sup> It is a testament to the fairness of the trial system and a rebuttal to the derogation of juries as hostile to manufacturers and coddling to consumers that plaintiffs do not invariably win such systematically selected bellwether trials; such trials present risks to both sides.<sup>102</sup>

Federalism is and always has been an uncomfortable system. The check-and-balance system was designed neither for comfort nor for speed. Accordingly, it invariably frustrates litigants and courts. More greatly to be feared, and assiduously to be avoided, however, is the alternative presented, albeit temporarily, by the 2006 preamble: A system in which bureaucrats, insulated from direct access by citizens or effective oversight by Congress, are allowed to usurp all judicial and legislative roles in the course of immunizing from civil liability the manufacturers whose products they approve for marketing. Such "mission creep" can result in mission failure where the public health and safety is concerned, and, if it recurs, the damage to our jurisprudence of federalism, and to the common law itself, may be incalculable.

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101. See generally Eldon E. Fallon et al., *Bellwether Trials in Multidistrict Litigation*, 82 TUL. L. REV. 2323 (2008).

102. See, e.g., *id.* at 2335–36 (describing the bellwether trial process in the Vioxx federal and state litigation, under various states' laws: six bellwether trials were conducted in the Vioxx federal MDL, "only one of which resulted in a verdict for the plaintiffs," while "approximately thirteen additional cases were tried before juries in state courts in New Jersey, California, Texas, Alabama, Illinois, and Florida" with mixed results).

