

# THOUGHTS ON THE RISE AND DECLINE OF THE IMPLIED PREEMPTION THEORY FOR STATE LAW DAMAGES CLAIMS

ALLISON M. ZIEVE\*

Over the past decade, and particularly over the past few years, implied preemption of state law damages claims has become a topic of significant interest to practicing lawyers and academics. Yet both damages claims and preemption doctrine—which has its roots in the Supremacy Clause of the United States Constitution<sup>1</sup>—have long been part of the legal landscape. This Article outlines how and why the topic has become such an important one and offers a consumer advocate’s perspective on the issue.

## I. IN THE BEGINNING

Traditional tort law principles recognize that federal approval of a product for marketing and compliance with federal requirements for product safety have a role to play, and a potentially very powerful role to play, in product liability cases. Consistent with this tradition, the current law in most states allows a manufacturer that is alleged to have sold a defective product to use compliance with federal standards or regulations as non-dispositive evidence that the product was not defective or that the manufacturer acted non-negligently.<sup>2</sup> A typical jury instruction might say, for example, that

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\* Allison M. Zieve is the director of Public Citizen Litigation Group, the litigating arm of the nonprofit consumer advocacy organization Public Citizen. Public Citizen Litigation Group attorneys have represented the plaintiffs on appeal or before the Supreme Court in many of the cases discussed in this essay, including *Warner-Lambert v. Kent*, *Riegel v. Medtronic, Inc.*, *Medtronic, Inc. v. Lohr*, *Fellner v. Tri-Union Seafood*, and *Wyeth v. Levine*, and they have represented the plaintiffs on the preemption issue in the district court in *Lockwood v. ConAgra Foods, Inc.* and *Hitt v. AriZona Beverage Co.* They have also participated as counsel for amicus curiae before appellate courts in other cases cited, such as *Holk v. Snapple*, *Colacicco v. Apotex*, and *Motus v. Pfizer*.

1. U.S. CONST. art. VI., para. 2.

2. RESTATEMENT (THIRD) OF TORTS § 4(b) (1998); accord 63B AM. JUR. 2d *Products Liability* § 2022 (2008) (“As a general rule, compliance with applicable federal standards is relevant but not conclusive evidence in a products liability case.”); see, e.g., IND. CODE § 34-20-5-1 (LexisNexis 2008); KAN. CIV. PROC. CODE ANN. § 60-

“Food and Drug Administration (FDA) approval, though not dispositive, may be considered to show whether a product is safe or not safe.”<sup>3</sup> Sometimes evidence of approval is given even greater weight, as in this pattern jury instruction from Kansas:

If a product was at the time of manufacture in compliance with administrative regulatory safety standards relating to design or performance, the product is not defective by reason of design or performance, unless the plaintiff proves that a reasonably prudent manufacturer could and would have taken additional precautions to design the product so as to be reasonably safe for the ordinary consumer who possesses knowledge common to the community as to the product’s characteristics.<sup>4</sup>

Over the past twenty years or so, manufacturers have argued with increasing success that regulatory approval or compliance is not only a defense on the merits—not only evidence that the product was not defective or that the label was adequate—but a defense that operates regardless of the merits of the underlying claim. In terminology that has become all too familiar to lawyers, academics, and consumer advocates interested in tort law, the manufacturers argue that federal approval *preempts* state law damages claims as a threshold matter, creating a bar to product liability suits. The argument for preemption is unrelated to whether a product has caused injury; it applies regardless of causation. The argument is not about whether the company or the consumer was at fault—it applies even if the company acted purposefully or negligently. The argument does not care about the nature of the injury or the extent

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3304 (West 2008); TENN. CODE ANN. § 29-28-104 (2008); UTAH CODE ANN. § 78B-6-703(2) (2008); Howard v. McCrory Corp., 601 F.2d 133, 138 & n.9 (4th Cir. 1979) (Maryland law); Salmon v. Parke, Davis & Co., 520 F.2d 1359, 1362 (4th Cir. 1975) (North Carolina law); Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1030 (D.N.J. 1988) (New Jersey law); Shell Oil Co. v. Gutierrez, 581 P.2d 271, 279–80 (Ariz. Ct. App. 1978); Hernandez v. Badger Constr. Equip. Co., 34 Cal. Rptr. 2d 732, 756 (Cal. Ct. App. 1994); Wagner v. Clark Equip. Co., 700 A.2d 38, 50 (Conn. 1997); Banks v. ICI Americas, Inc., 450 S.E.2d 671, 675 n.6 (Ga. 1994); Toner v. Lederle Labs., 732 P.2d 297, 311 n.12 (Idaho 1987); Malek v. Lederle Labs., 466 N.E.2d 1038, 1039–40 (Ill. App. Ct. 1984); Asbestos v. Bordelon, Inc., 726 So. 2d 926, 958 (La. Ct. App. 1998); MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 70–71 (Mass. 1985); Bennett v. Mallinckrodt, Inc., 698 S.W.2d 854, 859 (Mo. Ct. App. 1985); Brooks v. Beech Aircraft Corp., 902 P.2d 54, 63 (N.M. 1995); Sherman v. M. Lowenstein & Sons, Inc., 282 N.Y.S.2d 142, 143–44 (N.Y. App. Div. 1967); Gable v. Village of Gates Mills, 784 N.E.2d 739, 747–48 (Ohio Ct. App. 2003); Zacher v. Budd Co., 396 N.W.2d 122, 133–34 (S.D. 1986).

3. See, e.g., O’Neill v. Novartis Consumer Health, Inc., 55 Cal. Rptr. 3d 551, 556 (Cal. Ct. App. 2007).

4. PATTERN INSTRUCTIONS KANSAS 4TH CIVIL § 128.02 (2008).

of damages. The argument for preemption is that because the product is in compliance with federal regulations (or sometimes simply because the product is subject to federal regulation), the company cannot be held liable, no matter the facts of the case.

Over the past few years, defendant companies' preemption arguments have focused on conflict preemption theories, in particular the notion that state product liability claims pose an obstacle to federal regulation.<sup>5</sup> That focus, however, is a fairly recent development in product liability and unfair and deceptive trade practices cases. The argument was raised only rarely prior to 2002, and it did not become popular until 2006.<sup>6</sup> In the 1990s, express preemption became the favored defense of medical device, pesticide, and automobile companies.<sup>7</sup> The common thread in the express preemption cases was a consumer protection statute that established federal regulation of a category of products—cigarette labels, medical devices, pesticides, motor vehicles—that directly addressed preemption of state law.<sup>8</sup> The question in these cases was whether damages claims were preempted by statutory language explicitly stating that certain state “requirements” or “standards” are preempted. The argument that the preemption provisions barred damages claims seems to have been devised by lawyers for tobacco companies, who in the mid-1980s developed the argument that the express preemption provision of the Cigarette Labeling Act preempted failure-to-warn claims. The earliest reported decision discussing the tobacco companies' argument came in 1984.<sup>9</sup> The earliest reported decision involving the express preemption provision in the Medical Device Amendments came in 1987.<sup>10</sup>

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5. See *infra* Part II.

6. For examples of earlier cases in which the argument was made, see *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2002 WL 181972, at \*1 n.2 (S.D. Ind. Jan. 28, 2002) and *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1031–32 (S.D. Ill. 2001).

7. See, e.g., *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 867 (2000) (automobiles); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 481 (1996) (medical devices); *Grenier v. Vermont Log Buildings, Inc.*, 96 F.3d 559, 562 (1st Cir. 1996) (pesticides).

8. See, e.g., Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136v(b) (2006); Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1334 (2006); Medical Device Safety Act, 21 U.S.C. § 360k(a) (2006).

9. *Cipollone v. Liggett Group, Inc.*, 593 F. Supp. 1146, 1148–49, 1154, 1157, 1159 (D.N.J. 1984), *rev'd*, 789 F.2d 181 (3d Cir. 1986); *Roysdon v. R.J. Reynolds Tobacco Co.*, 623 F. Supp. 1189, 1190 (E.D. Tenn. 1985), *aff'd*, 849 F.2d 230 (6th Cir. 1988).

10. See *Tetuan v. A.H. Robins Co.*, 738 P.2d 1210, 1232–33 (Kan. 1987). *Tetuan* was a suit for damages arising from use of the Dalkon Shield, the intrauterine device that caused thousands of injuries and helped to motivate Congress to enact

In 1992, the Supreme Court decided *Cipollone v. Liggett Group, Inc.*,<sup>11</sup> a product liability case against a tobacco company, in which the question was whether a provision in the Public Health Cigarette Smoking Act of 1969 that preempted certain state “requirements” encompassed damages claims. The Court held that, as used in that Act, “requirements” could include damages claims and that certain damages claims were preempted by the provision.<sup>12</sup> After that, express preemption took off as a popular defense. Yet in the end, the plaintiffs did not fare too badly in the express preemption cases. With regard to vehicles and motor boats, the Supreme Court held that the relevant statutes do not expressly preempt damages claims;<sup>13</sup> with regard to medical devices and pesticides, the Supreme Court held that some but not all damages claims are expressly preempted.<sup>14</sup>

## II.

### THE RISE OF “OBSTACLE” PREEMPTION

After a decade of watching litigation over the scope of express preemption provisions, and having failed to push any bills through Congress to eliminate product liability suits, manufacturers started pressing an implied preemption theory. In the context of product liability law, the implied preemption doctrine asks whether the obligations imposed on manufacturers of federally regulated products are inconsistent with duties imposed by state common law. The implied preemption theory essentially is that the applicable federal regulation—whether a performance standard for an automobile or FDA marketing approval and labeling regulations for a device—es-

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the MDA. The court in *Tetuan* rejected the preemption argument. *Id.* Many of the early cases involving preemption under the MDA involved injuries caused by tampons, for which FDA regulations set forth specific required warning and testing requirements. *See* *Edmondson v. Int'l Playtex, Inc.*, 678 F. Supp. 1571 (N.D. Ga. 1987); *Ignace v. Int'l Playtex, Inc.*, No. 86-C-480-C, 1987 WL 93996, at \*5 (W.D. Wis. Aug. 14, 1987). As litigation over the subsequent two decades illustrates, the device companies later expanded their preemption theory to include all devices, no matter the extent of applicable regulation.

11. 505 U.S. 504 (1992).

12. *Id.* at 520–24 (plurality opinion); *id.* at 548–49 (Scalia, J., concurring in the judgment in part and dissenting in part).

13. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 69–70 (2002) (holding Boat Safety Act does not expressly preempt tort claims against motor boat manufacturers); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 868 (2000) (holding Motor Vehicle Safety Act does not expressly preempt tort claims against automakers).

14. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (medical devices); *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 452 (2005) (pesticides); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 491 (1996) (medical devices).

establishes both a floor and a ceiling for regulated products.<sup>15</sup> Accordingly, the argument goes, the regulatory scheme would be frustrated if manufacturers went beyond the federal requirements to provide better equipment than the relevant automobile safety standard or stronger warnings that the specific labeling approved for a medical device.

Automakers tried this approach concurrently with arguing about express preemption,<sup>16</sup> and occasionally medical device companies made the argument.<sup>17</sup> Before 2002, however, drug companies seldom made this argument. Soon after President George W. Bush took office, drug companies began to push an implied preemption theory, mostly in cases involving suicides allegedly associated with use of a type of antidepressants known as selective serotonin reuptake inhibitors, or SSRIs.<sup>18</sup> Most product liability cases about injuries from drugs are failure-to-warn cases based on inadequacies in the labeling, and the SSRI manufacturers focused their preemption arguments on the history of FDA review of the labeling of those drugs.<sup>19</sup> Their theory was that holding them liable for failing to comply with a state law duty to warn would be inconsistent with the FDA's careful review and approval of the labeling of SSRIs, and the agency's decision not to require the drug's label to warn about an increased risk of suicidality.<sup>20</sup>

After SSRI manufacturer Pfizer was successful in getting the FDA to file an amicus brief on its behalf in a product liability case,<sup>21</sup> the preemption argument quickly spread beyond antidepressants. Then in January 2006, the FDA restated the pro-preemption position taken in its amicus brief in a preamble to a new regulation about drug labeling that not only addressed antidepressants, but

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15. See generally William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547 (2007).

16. See, e.g., *Geier*, 529 U.S. 861. In the context of suits against automakers, defendants continue to make implied preemption arguments. See, e.g., *O'Hara v. General Motors Corp.*, 508 F.3d 753, 755 (5th Cir. 2007).

17. See, e.g., *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998).

18. See, e.g., *Dusek v. Pfizer Inc.*, No. Civ.A. H-02-3559, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004); *Motus v. Pfizer Inc.*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000), *aff'd*, 358 F.3d 659 (9th Cir. 2004).

19. See, e.g., Brief of Defendant-Appellee and Cross-Appellant Pfizer Inc. at 19, *Motus v. Pfizer Inc.*, 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372 & 02-55498), 2002 WL 32303085.

20. See *id.*

21. Amicus Brief for the United States in Support of the Defendant-Appellee and Cross-Appellant, and in Favor of Reversal of the District Court's Order Denying Partial Summary Judgment to Defendant-Appellee and Cross-Appellant, *Motus*, 358 F.3d 659 (Nos. 02-55372 & 02-55498), 2002 WL 32303084.

also advocated for broad preemption of labeling claims with regard to any FDA-approved drug.<sup>22</sup> Not surprisingly, after the FDA issued this preamble, preemption became a standard theory for drug company defendants in product liability cases.<sup>23</sup> And just as the companies' arguments expanded, so did the FDA's theory. Whereas in 2006 the agency filed an amicus brief stating that, in its view, there would be no preemption in situations where the agency had not specifically considered the risk or labeling issue involved in a particular lawsuit,<sup>24</sup> a 2008 FDA amicus brief described a theory of preemption so broad as to bar most if not all labeling claims.<sup>25</sup>

The courts had mixed reactions to the FDA's position. Some stated that it warranted no deference and that FDA regulation does not preempt tort claims.<sup>26</sup> Others gave the FDA's views some level of deference—some a lot and some less—and held that a plaintiff's claims were preempted.<sup>27</sup>

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

23. See, e.g., *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M: 05-1699, 2006 WL 2374742, at \*2 (N.D. Cal. Aug. 16, 2006); *Perry v. Novartis Pharm. Corp.*, 456 F. Supp. 2d 678, 680 (E.D. Pa. 2006); *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964, 967–68 (D. Neb. 2006).

24. Letter from U.S. Dept. of Justice to Judge Stewart Dalzell, Eastern District of Pennsylvania (Sept. 21, 2006), available at <http://druganddevicelaw.net/FDA%20Amicus%20Briefs/Perry%20FDA%20amicus%20brief.pdf>.

25. Brief for the United States as Amicus Curiae Supporting Petitioner at 8–9, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249), 2008 WL 2308908.

26. See, e.g., *Jackson*, 432 F. Supp. 2d at 968 (D. Neb. 2006) (“The recent notice issued by the FDA claiming preemption is not persuasive.”).

27. *Colacicco v. Apotex Inc.*, 521 F.3d 253, 274–75 (3d Cir. 2008), vacated, 129 S. Ct. 1578 (2009) (concluding “(1) that an agency’s position concerning preemption need not be contained in a formal regulation in order to be considered, and (2) that such a position is subject to a level of deference approximating that set forth in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944),” and holding all claims preempted); *In re Bextra*, 2006 WL 2374742, at \*6 (stating that “[t]he FDA’s interpretation of the preemptive effect of its regulations is entitled to deference” and holding some claims preempted); *Weiss v. Fujisawa Pharm. Co.*, 464 F. Supp. 2d 666, 674 (E.D. Ky. 2006) (“FDA’s position has not been consistent and is therefore entitled only to *Skidmore* deference . . . . In particular, FDA’s position is persuasive insofar as it rejects failure-to-warn claims (1) based on conduct that allegedly occurred prior to and during the labeling approval process and (2) based on proposed warnings that FDA has specifically considered and rejected as scientifically unsubstantiated.”); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 525 (E.D. Pa. 2006), *aff’d*, 521 F.3d 253 (3d Cir. 2008), vacated, 129 S. Ct. 1578 (2009) (stating that “[t]he FDA’s view is critical to this Court’s analysis because Supreme Court precedent dictates that an agency’s interpretation of the statute and regulations it administers is entitled to deference” and holding all claims preempted).

### III. BROADENING INDUSTRY EFFORTS

The FDA's proactive approach to preemption with respect to drugs illustrates the George W. Bush Administration's effort to use the preemption doctrine to effect "tort reform," which companies and their advocates have had so little success achieving in Congress.<sup>28</sup> Not only the FDA, but also the National Highway Traffic Safety Administration (NHTSA), the Consumer Product Safety Commission (CPSC), and the Federal Railroad Administration (FRA) made pro-preemption statements during 2005–2008 in the commentary that accompanied the issuance of proposed and final rules in the Federal Register.<sup>29</sup> These preambles were not part of

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28. *See, e.g.*, Product Liability Reform Act of 1998, S. 2236, 105th Cong. (2d Sess. 1998); Product Liability Reform Act of 1997, S. 648, 105th Cong. (1st Sess. 1997); Common Sense Legal Standards Reform Act of 1995, H.R. 956 (1st Sess. 1995).

29. *See, e.g.*, Flammability (Open Flame) of Mattress Sets, 71 Fed. Reg. 13,472, 13,496–97 (Mar. 15, 2006) (to be codified at 16 C.F.R. pt. 1633) ("The Commission intends and expects that the new mattress flammability standards will preempt inconsistent state standards and requirements, whether in the form of positive enactments or court created requirements."); Reflectorization of Rail Freight Rolling Stock, 70 Fed. Reg. 144, 152 (Jan. 5, 2005) (to be codified at 49 C.F.R. pt. 224) ("With the exception of a provision directed at an essentially local safety hazard that is not inconsistent with a Federal law, regulation, or order, and that does not unreasonably burden interstate commerce, section 20106 will preempt any State or local law or regulatory agency rule covering the same subject matter as this final rule."); Federal Motor Vehicle Safety Standards; Door Locks and Door Retention Components, 72 Fed. Reg. 5385, 5397 (Feb. 6, 2007) (to be codified at 49 C.F.R. pt. 571) (claiming the newly enacted standard preempts state law under the National Traffic and Motor Vehicle Safety Act's express preemptive provision); Railroad Operating Practices: Handling Equipment, Switches and Derails, 71 Fed. Reg. 60,372, 60,404 (proposed Oct. 12, 2006) (to be codified at 49 C.F.R. pts. 217 & 218) ("This is a rule with preemptive effect. Subject to a limited exception for essentially local safety hazards, its requirements will establish a uniform Federal safety standard that must be met, and State requirements covering the same subject are displaced, whether those standards are in the form of State statutes, regulations, local ordinances, or other forms of State law, including State common law."); Passenger Equipment Safety Standards; Front-End Strength of Cab Cars and Multiple-Unit [MU] Locomotives, 72 Fed. Reg. 42,016, 42,028 (proposed Aug. 1, 2007) (to be codified at 49 C.F.R. pt. 238) ("FRA believes that it has preempted any State law, regulation, or order, including State common law, concerning the operation of a cab car or MU locomotive as the leading unit of a passenger train"); Railroad Operating Rules: Program of Operational Tests and Inspections; Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49,223, 49,245–46 (proposed Aug. 23, 2005) (to be codified at 49 C.F.R. pt. 571) (noting that 49 U.S.C. § 30103(b) provides for preemption of state law, and "[t]hus, all differing state statutes and regulations would be preempted" and that "any effort to impose either more stringent requirements or specific methods of compliance

the regulations, and they do not have the force of law.<sup>30</sup> That is, damages claims are not preempted just because an agency says in a Federal Register notice that it thinks that claims are preempted. Nonetheless, this development—agencies offering broad and often unsolicited statements about preemption—was troubling because companies’ preemption arguments would have far less success in the courts if they were not supported by the agencies. The debate about whether to hold companies liable for injuries caused by their products really is one that belongs in Congress, the branch of government structured to be sensitive to state interests. But by inserting statements about preemption into Federal Register notices, unelected officials at the regulatory agencies and the Office of Management and Budget were attempting to effect broad “product liability reform,” while side-stepping both the legislative branch and open debate on the issue.

Encouraged by the government’s support of the conflict preemption theory, defendant manufacturers during the past eight years were increasingly creative in finding some regulatory hook on which to hang a preemption argument. Describing a few examples is perhaps the best way to show how far companies sought to extend preemption doctrine. I do not cite these cases to make any comment on their merits or who should ultimately prevail, but only as illustrations of the extent to which preemption theory was being stretched in recent years.

In one case, *Fellner v. Tri-Union Seafoods, L.L.C.*, a tuna company argued that it could not be held liable for failing to warn about the risk of mercury poisoning from eating too much tuna because several years earlier the FDA issued what it called a “consumer advisory” and “backgrounder” telling people that eating too much of some types of fish could be bad for pregnant women and children, but also saying that having some fish in your diet was

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would frustrate our balanced approach”); Federal Motor Vehicle Safety Standards; Designated Seating Positions and Seat Belt Assembly Anchorages, 70 Fed. Reg. 36,094, 36,101 (proposed June 22, 2005) (to be codified at 49 C.F.R. pt. 571) (“The proposed rule is not intended to preempt state tort civil actions, except that the determination in those actions of what is a ‘designated seating position’ would be governed by the definition and procedure contained in the Federal motor vehicle safety standards.”).

30. See *Nat’l Res. Def. Council v. Env’t Prot. Agency*, 559 F.3d 561, 564–65 (D.C. Cir. 2009) (“While preamble statements may in some unique cases constitute binding, final agency action susceptible to judicial review, *Kennecott Utah Copper Corp. v. Dep’t of Interior*, 88 F.3d 1191, 1222–23 (D.C. Cir. 1996), this is not the norm.”).

healthy.<sup>31</sup> The FDA advisory is available on the FDA's website and apparently was sent to some physicians' offices and clinics.<sup>32</sup> The company argued that allowing a suit for damages for failure to warn would conflict with the FDA's "approach" to the problem of mercury in tuna.<sup>33</sup> Notwithstanding the agency's very limited and informal "approach," the trial court held that the case was preempted.<sup>34</sup> However, the Third Circuit reversed,<sup>35</sup> and the Supreme Court denied the company's petition for certiorari.<sup>36</sup>

Another example of industry efforts to broaden preemption doctrine is a recent series of cases in which plaintiffs have brought claims under state unfair and deceptive trade practices laws against food and beverage manufacturers that label and promote their products as "all natural," when those products contain high fructose corn syrup, a highly processed sweetener.<sup>37</sup> The defendants have argued that these cases are preempted by federal regulations that address some aspects of statements on food or beverage labels and an FDA policy, pursuant to which the agency has said that it will not restrict use of the term "natural" and that it construes the word to mean "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food."<sup>38</sup> These arguments were made notwithstanding a provision of the federal food labeling law that "explicitly forecloses the possibility that state law would be impliedly preempted"<sup>39</sup> by stating that

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31. 539 F.3d 237, 241–42 (3d Cir. 2008).

32. U.S. ENVTL. PROT. AGENCY & U.S. FOOD AND DRUG ADMIN., WHAT YOU NEED TO KNOW ABOUT MERCURY IN FISH AND SHELLFISH, ADVICE FOR WOMEN WHO MIGHT BECOME PREGNANT, WOMEN WHO ARE PREGNANT, NURSING MOTHERS, AND YOUNG CHILDREN (2004), <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm110591.htm>.

33. See *Fellner*, 539 F.3d at 242.

34. *Fellner v. Tri-Union Seafoods, L.L.C.*, No. 06-CV-0688 (DMC), 2007 WL 87633, at \*6–7 (D.N.J. Jan. 29, 2007), *rev'd*, 539 F.3d 237 (3d Cir. 2008).

35. *Fellner*, 539 F.3d 237.

36. *Tri-Union Seafoods, L.L.C. v. Fellner*, 129 S. Ct. 1987 (2009).

37. See *Lockwood v. ConAgra Foods, Inc.*, 597 F. Supp. 2d 1028, 1030–34 (N.D. Cal. 2009) (rejecting express and implied preemption arguments in connection with challenge to "all natural" marketing practices); *Hitt v. AriZona Beverage Co.*, No. 08-809 WQH (POR), 2009 WL 449190, at \*4–6 (S.D. Cal. Feb. 4, 2009) (same).

38. Food Labeling: Nutrition Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993).

39. *New York State Rest. Ass'n v. New York City Bd. of Health*, 509 F. Supp. 2d 351, 355 (S.D.N.Y. 2007) (discussing the Nutrition Labeling and Education Act of 1990).

the statute “shall not be construed to preempt any provision of State law, unless such provision is expressly preempted” by the statute.<sup>40</sup> Moreover, the FDA acknowledged as long ago as 1991, when setting forth the policy on the use of “natural,” that the term is used in ways that confuse and mislead consumers.<sup>41</sup> The FDA has acknowledged that a definition would abate that problem, but has declined to issue a regulation defining the term “natural” “[b]ecause of resource limitations and other agency priorities.”<sup>42</sup> As the Third Circuit recently explained, there can be no preemption without federal law to do the preempting.<sup>43</sup> Accordingly, three of the four district courts that have ruled in these “natural” cases have rejected the preemption argument.<sup>44</sup> The only district court to find preemption (the first of the cases decided) was reversed on appeal.<sup>45</sup>

My last example is a case decided by the Texas Supreme Court. The question in the case was whether CPSC regulations about child-resistant lighters preempted damages claims brought on behalf of a six-year-old child who was severely burned when her five-year-old brother lit her dress with a disposable Bic lighter.<sup>46</sup> According to the CPSC, if a lighter cannot be lit by eighty-five percent of the children who try, the lighter can be marketed as “child-resistant.”<sup>47</sup> The plaintiff in this case argued, among other things, that although the lighter passed that test, a reasonable manufacturer would have

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40. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353 (1990); see 21 U.S.C. § 343-1 note (2006).

41. Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421, 60466.

42. Food Labeling: Nutrition Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993).

43. *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 254 (3d Cir. 2008) (“State law is not preempted whenever an agency has merely ‘studied’ or ‘considered’ an issue; state law is preempted when federal *law* conflicts with state law.”); see also *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 549–51 (2008) (finding state unfair and deceptive trade practices action not preempted where Federal Trade Commission suspended proposed rulemaking to require disclosure of cigarettes’ tar and nicotine contents after manufacturers submitted a voluntary agreement to disclose the contents).

44. Compare *Covington v. Arizona Bev. Co.*, No. 08-21894, slip op. at 6–12 (S.D. Fla. Sept. 11, 2009), and *Lockwood v. ConAgra Foods, Inc.*, 597 F. Supp. 2d 1028, 1030–34 (N.D. Cal. 2009), and *Hitt v. AriZona Beverage Co.*, No. 08-809 WQH (POR), 2009 WL 449190, at \*4–6 (S.D. Cal. Feb. 4, 2009), with *Holk v. Snaple Beverage Corp.*, 574 F. Supp. 2d 447 (D.N.J. 2008), *rev’d*, 575 F.3d 329 (3d Cir. 2009).

45. *Holk*, 575 F.3d 329 (3d Cir. 2009).

46. *Bic Pen Corp. v. Carter*, 251 S.W.3d 500 (Tex. 2008).

47. 16 C.F.R. § 1201.3 (2009).

made the lighter safer because more effective child-resistant lighters were on the market.<sup>48</sup> So the plaintiff's theory of the case seemed to track the traditional consideration of federal standards in products cases, like the jury instructions mentioned earlier. Express preemption was not an issue because although the Consumer Product Safety Act has a preemption provision, it also has a savings clause that states that CPSC standards and regulations do not preempt common law claims.<sup>49</sup> The Texas Supreme Court held, however, that the damages claims were impliedly preempted because allowing state law to impose liability for not making a safer lighter would conflict with the CPSC's determination that its testing protocol set the appropriate balance between safety and other concerns.<sup>50</sup>

One frustrating aspect of the preemption jurisprudence is that the courts that find conflict preemption have fairly consistently approached the preemption arguments as if the traditional state law civil justice system did not exist.<sup>51</sup> This approach is remarkable because damages claims against manufacturers of approved drugs, medical devices, and automobiles are not *new* remedies. The availability of damages claims preexisted all of our regulatory statutes, including the Food, Drug, and Cosmetic Act,<sup>52</sup> the Medical Device Amendments of 1976,<sup>53</sup> and the National Traffic and Motor Vehicle Safety Act,<sup>54</sup> and they have coexisted with those laws for decades. There is no evidence that manufacturers have had difficulty complying with federal requirements while also being held accountable to patients under state law for injuries caused by their products.

Nonetheless, this tendency to talk about what "would" happen if consumers injured by drugs, medical devices, automobiles, or other regulated products "could" sue for damages is revealing. Manufacturers' use of "would" is a clever tactic, whereby they shift

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48. *Bic Pen Corp.*, 251 S.W.3d at 506.

49. 15 U.S.C. §§ 2072(c), 2074(a) (2006).

50. 251 S.W.2d at 508–09.

51. *See, e.g.*, Transcript of Oral Argument at 43, *Warner-Lambert v. Kent*, 552 U.S. 440 (2008) (No. 06-1498) (question from Justice Breyer: "Now, is that the law in most places? Where the FDA has approved a drug for use and the doctor follows the label and the label is all okay, is it the case that somebody can come in and say, despite that, this drug is on balance harmful, and I get compensation? This is a serious question. I'm not sure how it works.").

52. 21 U.S.C. §§ 301–99 (2006).

53. Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

54. 49 U.S.C. §§ 30101–70 (2006).

the landscape to suggest that plaintiffs are the ones seeking to do something new and questionable, when in fact the status quo allows the lawsuits and preemption would be the major sea change. And when judges speak of what “would” happen if tort claims could go forward against manufacturers of regulated products, they reveal, perhaps, a lack of familiarity with the history of product liability cases, which allows us to see not just what “would” happen but what *does* happen when these cases are litigated.<sup>55</sup> Or perhaps they buy into the defendants’ framing of the case, which is often presented as if the ruling on preemption is the ultimate ruling on the merits, and thus as if a finding for the plaintiff on preemption is a finding that the plaintiff wins the case.

#### IV. CONSUMER PERSPECTIVE

The attempt to transform federal compliance from evidence that is relevant to a merits defense into the basis for a legal preemption defense has been bad for consumers for a number of reasons. To begin with, the preemption discussion must proceed from a recognition that people will be injured by regulated products because, even in the best of circumstances, regulation simply cannot guarantee safety. And the best of circumstances rarely exist. To get back to the FDA example, two recent independent government reports have described dangerous shortcomings in FDA oversight of drug safety.<sup>56</sup> And a National Academies of Sciences’ Institute of Medicine report, prepared at the FDA’s request and released in September 2008, found that the nation’s drug safety system is impaired by “serious resource constraints that weaken the quality and quantity of the science that is brought to bear on drug safety; an organizational culture in [the FDA] that is not optimally functional;

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55. *See, e.g.*, *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 122 (2d Cir. 2006) (“In fact, it is unclear what a manufacturer of a PMA-approved medical device *would* do when faced with such a jury verdict on a plaintiff’s common law claims, given that the manufacturer *would* nonetheless be unable to make any modifications affecting the device’s safety and effectiveness without obtaining further FDA approval. Moreover, it is certainly conceivable that different juries *would* reach conflicting verdicts about the same medical devices . . .”) (emphasis added), *aff’d*, 552 U.S. 312 (2008).

56. U.S. GEN. ACCOUNTABILITY OFFICE, GAO-06-402, IMPROVEMENT NEEDED IN FDA’S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS, (2006), *available at* [www.gao.gov/cgi-bin/getrpt?GAO-06-402](http://www.gao.gov/cgi-bin/getrpt?GAO-06-402); COMM. ON THE ASSESSMENT OF THE U.S. DRUG SAFETY SYS., INST. OF MED. OF THE NAT’L ACADS., *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (2006), *available at* [http://www.nap.edu/openbook.php?record\\_id=11750&page=R1](http://www.nap.edu/openbook.php?record_id=11750&page=R1).

and unclear and insufficient regulatory authorities particularly with respect to enforcement.”<sup>57</sup> FDA employees report similar problems. Responding to surveys, employees have expressed discomfort with the pressure they feel to approve new drugs.<sup>58</sup> In a survey released in the summer of 2006, sixty percent of FDA employees who responded knew of cases “where commercial interests have inappropriately induced or attempted to induce the reversal, withdrawal or modification of FDA determinations or actions.”<sup>59</sup> Moreover, experience suggests that the FDA’s shortcomings undermine public health. In recent years, several drugs have been forced from the market for safety reasons—in some cases, long after the FDA became aware that the drug was causing serious harm. The diabetes drug Rezulin and the pain reliever Vioxx provide two well-known examples.<sup>60</sup> Thus, experience shows that regulatory approval is not a guarantee of safety; inevitably, some people will be injured by regulated products.

Proceeding from that premise, the most obvious consequence of the preemption defense for consumers is that, when the defense is successful, consumers are cut off from even the possibility of recovering any compensation for injury caused by regulated products. The defense leaves no room for consideration of what a reasonable manufacturer would have done in a particular situation. It leaves no room for factual distinctions between individual cases. It sweeps away traditional common law approaches to assessing fault and liability.

Furthermore, damages suits advance public health in several ways. First, product liability lawsuits help to uncover information that can lead to safer products. Material produced in litigation can help the public and the FDA to identify problems with particular drugs and can add to physicians’ and the public’s understanding of

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57. COMM. ON THE ASSESSMENT OF THE U.S. DRUG SAFETY SYS., *supra* note 56, at 4.

58. UNION OF CONCERNED SCIENTISTS, VOICES OF SCIENTISTS AT FDA: PROTECTING PUBLIC HEALTH DEPENDS ON INDEPENDENT SCIENCE (2006), available at [http://www.ucsusa.org/assets/documents/scientific\\_integrity/fda-survey-brochure.pdf](http://www.ucsusa.org/assets/documents/scientific_integrity/fda-survey-brochure.pdf); Janet Rehnquist, Dep’t of Health and Human Servs., FDA’S REVIEW PROCESS FOR NEW DRUG APPLICATIONS 9–17 (2003), available at <http://oig.hhs.gov/oei/reports/oei-01-01-00590.pdf>.

59. UNION OF CONCERNED SCIENTISTS, *supra* note 58, at 2.

60. Brooke A. Masters & Marc Kaufman, *Painful Withdrawal for Makers of Vioxx; Pulling of Arthritis Drug Raises Questions on Marketing, Safety Risks*, WASH. POST, Oct. 18, 2004, at A1; David Willman, *The Rise and Fall of the Killer Drug Rezulin*, L.A. TIMES, June 4, 2000, at A1.

the risks of the products and flaws in the regulatory system.<sup>61</sup> The same is true with respect to other types of products. For example, suits against automakers led to disclosure of important information about the Ford/Firestone rollover problem.<sup>62</sup>

Second, by deciding up front that the industry cannot be held accountable to consumers, preemption eliminates an important motivation for companies to make their products as safe as possible.

Third, and related to the prior point, the broad conflict preemption arguments espoused over the past several years ignore the reality that knowledge and technology are constantly advancing. For example, knowledge of a drug's risks, particularly long-term risks, is never complete at the time of initial marketing approval. In fact, only half of a drug's serious hazards are known and documented in the *Physicians' Desk Reference* seven years after the drug's approval.<sup>63</sup> Products liability lawsuits help to protect patients from drugs with undisclosed risks because the potential for being held liable for harm caused by their products provides a powerful incentive for drug companies to revise labeling in a timely manner, to improve products as soon as a defect is identified, and to remove from the market older products that do not provide the safety that newer ones offer.

A similar point is illustrated by motor vehicle regulation. Once issued, a vehicle safety standard issued by the National Highway Traffic Safety Administration (NHTSA) usually remains in place for many years, even decades. Technology, however, does not stand still. Therefore, while it might have made sense to issue a particular standard at a given point in time, one year later or the year after that, automakers may know that the standard is not adequate to protect safety and that a safer alternative is achievable. At that point, it makes little sense to allow the company to hide behind the regulatory standard as a shield from liability. For example, NHTSA only recently updated a roof crush resistance standard for passen-

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61. See, e.g., David Brown, *Maker of Vioxx Is Accused of Deception*, WASH. POST, Apr. 16, 2008, at A1 (discussing article from the *Journal of the American Medical Association* evaluating information found in Vioxx discovery documents); Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. AM. MED. ASS'N 308, 309 (2007) (offering several examples).

62. Megan Stack, *Ford, Firestone Settle Woman's Tire Lawsuit*, CJ ONLINE, Jan. 9, 2001, [http://www.cjonline.com/stories/010901/bus\\_tiresuit.shtml](http://www.cjonline.com/stories/010901/bus_tiresuit.shtml); Jay Weaver, *Judge Cancels Order Sealing Firestone Files*, MIAMI HERALD, Sept. 30, 2000, at 4B.

63. Karen E. Lasser, et al., *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 J. AM. MED. ASS'N 2215, 2218 (2002).

ger cars that was first issued more than thirty-seven years ago.<sup>64</sup> Technology had changed tremendously during that time. Yet in 2005, when NHTSA proposed a new standard for roof strength, it said that the new standard should preempt damages claims.<sup>65</sup> In this case, we did not even need to wait years to see whether a stronger roof is achievable. Most cars already met the proposed standard, and some already exceeded it.<sup>66</sup>

So today, it is often feasible to design a product or to revise a label to provide a level of safety greater than the level required by a 1990 safety standard or to make a product safer than the version approved in 1995, for example. Yet if compliance with the relatively old standard or the fact of the approval preempts damages claims, then an injured consumer can never show that the design (or indeed the standard) was outdated or that a reasonable manufacturer would have known that the approved warning was inadequate. Suppose that the FDA approved a drug and its labeling in 2003, but that the manufacturer received adverse event reports in 2004 showing that the product was causing an unanticipated adverse reaction or that physicians were misunderstanding something stated on the label. The manufacturer does not raise the issue with the FDA—it neither seeks to change its label unilaterally nor asks the FDA for approval of a new label. Eventually, the information will get out; the label will be revised or the drug withdrawn from the market. The question remains, though, what about the injured patients? Who bears the cost of the injuries? Historically, that question has been for a jury to decide, but the preemption doctrine is based on the notion that this question must be answered as a matter of law and in favor of the defendant.

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64. *See* 49 C.F.R. § 571.216 (2008). Aside from non-substantive changes, the roof crush resistance standard issued in December 1971 was in effect until July 13, 2009. *See* Standard No. 216a; Roof crush resistance; Upgraded standard, 74 Fed. Reg. 22,347, 22,384–87 (May 12, 2009).

65. Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49223, 49245–46 (proposed Aug. 23, 2005).

66. The commentary accompanying issuance of the final rule receded from the position that NHTSA had stated when the proposed rule was issued:

After considering the public comments on the proposal and considering today's final rule, NHTSA has reconsidered the tentative position presented in the NPRM [notice of proposed rulemaking] and do not currently foresee any potential State tort requirements that might conflict with today's final rule.

Without any conflict, there could not be any implied preemption.

Federal Motor Vehicle Safety Standards; Roof Crush Resistance; Phase-In Reporting Requirements, 74 Fed. Reg. 22,348, 22,382 (May 12, 2009).

V.  
THE DECLINE OF “OBSTACLE” PREEMPTION

The Bush Administration’s effort to preempt state law damages claims suffered two recent and significant setbacks. First, Barack Obama won the 2008 presidential election, and all expect that the agencies’ efforts will now be cut back considerably, if not cease altogether. Two early indications are NHTSA’s final roof crush rule<sup>67</sup> and NHTSA’s March 29, 2009 Notice of Intent, which stepped back from the agency’s prior statement that federal corporate average fuel economy (CAFE) standards preempted state fuel economy standards, although it deferred a definitive statement on the agency’s position.<sup>68</sup> Then on May 12, 2009, President Obama issued a memorandum to the heads of the executive branch agencies in which he criticized the agencies’ practice under the prior administration of “announc[ing] that their regulations preempt State law, including State common law, without explicit preemption by the Congress or an otherwise sufficient basis under applicable legal principles.”<sup>69</sup> The memorandum instructs the agencies to limit statements of preemption to narrow circumstances and “to review 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.”<sup>70</sup>

Second, on March 4, 2009, the Supreme Court issued its decision in *Wyeth v Levine*, which asked whether FDA marketing approval of a drug impliedly preempted an injured patient’s failure-to-warn claim against the drug manufacturer.<sup>71</sup> The Court’s decision soundly rejects the preemption preamble issued by the Bush Administration’s FDA in 2006, and it seems to resolve the issue of what weight a court should accord an agency’s statement about preemption—little to none.

The story of the *Wyeth* case starts in 2000, when Diana Levine went to a clinic for treatment of a migraine headache. A physician

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67. *Id.*

68. Notice of Intent for Corporate Average Fuel Economy Standards; Effect Upon State Laws and Regulations, 74 Fed. Reg. 11,993 (Mar. 20, 2009).

69. Memorandum from Barack Obama, President of the United States, to Heads of Executive Departments and Agencies (May 20, 2009), *available at* [http://www.whitehouse.gov/the\\_press\\_office/Presidential-Memorandum-Regarding-Preemption](http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption).

70. *Id.*

71. 129 S. Ct. 1187 (2009).

assistant at the clinic gave her one drug for the pain and another drug, Phenergan, for nausea. The physician's assistant injected the Phenergan through a method called "IV-push." Unlike administration by IV-drip, where the drug is delivered to the vein through a hanging IV bag, IV-push means that the drug is injected into the vein from a syringe. Unfortunately, either the syringe nicked Ms. Levine's artery or the drug escaped from the vein and came into contact with arterial blood. As a result, gangrene set in, eventually requiring amputation of Ms. Levine's arm. Phenergan's label warned that the drug can cause gangrene when it comes into contact with arterial blood. However, although this risk is much higher if the drug is administered by IV-push, as opposed to an IV-drip or an intramuscular injection, the label did not warn about the increased risks associated with IV-push. After her arm was amputated, Ms. Levine sued Wyeth, the drug's manufacturer, alleging state law claims of failure to warn and strict liability.<sup>72</sup>

Wyeth moved for summary judgment, arguing that Ms. Levine's failure-to-warn claims were preempted under both conflict preemption and field preemption theories. The district court denied the motion.<sup>73</sup> After a four day trial, the jury returned a verdict for Ms. Levine and awarded her \$7,400,000.<sup>74</sup> In a post-trial motion for judgment as a matter of law, Wyeth again argued preemption, and the court again denied the motion.<sup>75</sup> The Vermont Supreme Court affirmed,<sup>76</sup> and the Supreme Court of the United States granted Wyeth's petition for certiorari.<sup>77</sup>

The Supreme Court affirmed.<sup>78</sup> First, the Court considered Wyeth's argument that state law claims were preempted because it would have been "impossible" for the company to comply with both the state law duties underlying Ms. Levine's claims and federal labeling requirements.<sup>79</sup> Noting that FDA regulations allow companies to revise their labels in light of information acquired after

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72. *Id.* at 1191-92.

73. *Levine v. Am. Home Prods., Inc.*, No. 670-12-01 Wncv, 2003 WL 25648135 (Vt. Super. Ct. Dec. 23, 2003), *aff'd sub nom.* *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006), *aff'd* 129 S.Ct. 1187 (2009).

74. *See Levine v. Am. Home Prods., Inc.*, No. 670-12-01, 2004 WL 5456809, at \*1 (Vt. Super. Ct. Jul. 30, 2004), *aff'd sub nom.* *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006), *aff'd* 129 S. Ct. 1187 (2009).

75. *Id.*

76. *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006).

77. *Wyeth v. Levine*, 128 S. Ct. 1118 (2008).

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

79. *Id.* at 1196.

approval, the Court rejected this theory.<sup>80</sup> The Court also rejected the argument that revising the label would have rendered the drug misbranded.<sup>81</sup> The Court explained that a drug is not misbranded simply because a manufacturer has altered an FDA-approved label.<sup>82</sup> Moreover, the Court stated that “the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning . . . is difficult to accept.”<sup>83</sup> Accordingly, the Court held that “absent clear evidence that the FDA would not have approved a change to Phenergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.”<sup>84</sup>

Next, the Court turned to Wyeth’s theory that Ms. Levine’s inadequate warning claim was preempted because the state law duties underlying it would obstruct the objectives of federal drug labeling regulation.<sup>85</sup> The Court rejected this theory as well, stating that it “relies on an untenable interpretation of congressional intent and an overbroad view of an agency’s power to pre-empt state law.”<sup>86</sup> The Court disagreed with the notion that federal law establishes both a floor and a ceiling for drug regulation, finding that “all evidence of Congress’[s] purposes is to the contrary.”<sup>87</sup>

Aside from the very powerful rejection of the conflict preemption argument, *Wyeth* is significant for the lack of deference it gave the FDA. The Court stated that the FDA’s 2006 preamble “does not merit deference.”<sup>88</sup> Noting that the FDA had stated when it issued the proposed rule that the regulation would not preempt state law, but then “articulated a sweeping position” asserting preemption when it issued the final rule, the Court stated that the “agency’s views on state law are inherently suspect in light of this procedural failure.”<sup>89</sup> The Court also stated that “the preamble is at odds with what evidence we have of Congress’[s] purposes, and it reverses the FDA’s own longstanding position without providing a reasoned explanation.”<sup>90</sup> Using strong language, the Court stated not only that the FDA’s preamble did not merit *Chevron* deference or even *Skid-*

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80. *Id.* at 1196–99.

81. *Id.* at 1197.

82. *Id.*

83. *Id.*

84. *Id.* at 1198.

85. *Id.* at 1199.

86. *Id.*

87. *Id.*

88. *Id.* at 1201.

89. *Id.*

90. *Id.*

*more* deference,<sup>91</sup> it stated that the FDA's position "is entitled to no weight."<sup>92</sup> Similarly, the Court found that the government's amicus brief was "undeserving of deference," as its explanation of federal drug regulation "departs markedly from the FDA's understanding at all times relevant to this case."<sup>93</sup>

In dismissing the FDA's views, the Court distinguished the FDA's position in *Wyeth* from the government's position in *Geier v. American Honda Motor Co.*<sup>94</sup> In *Geier*, holding that the Motor Vehicle Safety Act impliedly preempted state law product liability claims premised on the lack of airbags in the plaintiff's automobile, the Court relied extensively on the Federal Register notice and preamble that accompanied issuance of NHTSA's passive restraint rule.<sup>95</sup> Yet the Court did not find preemption based on what NHTSA had said about *preemption* during the rulemaking—in fact, the agency had not addressed preemption in the rulemaking. Rather, the Court looked to what the agency had said about the substantive purposes of the rule, and it found that allowing the case to go forward would frustrate that purpose. In contrast, with regard to drug labeling regulation, the FDA's commentary directly addressed preemption and suggested that *Geier* gave it authority to say, not what the agency hoped to achieve by fashioning the regulation as it did, but what the effect of that standard would be on consumers' ability to sue for injury. The government and industry had sought to use *Geier* as support for a general proposition that the courts should defer to an agency's views on preemption.<sup>96</sup> *Wyeth* rejects that proposition.<sup>97</sup>

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91. When Congress, in enacting a statute, has left a gap for an agency to fill, thereby delegating to the agency authority to elucidate a specific provision of the statute, courts will defer to the agency's interpretation of the provision if that interpretation is "reasonable." *Chevron U.S.A., Inc. v. Nat'l Res. Def. Council*, 467 U.S. 837, 843–44 (1984). Where Congress has not delegated such authority to the agency, the weight accorded to the agency's views "will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

92. *Wyeth*, 129 S. Ct. at 1204.

93. *Id.* at 1203 n.13.

94. 529 U.S. 861 (2000).

95. *Id.* at 877–80.

96. See Brief for Petitioner at 48, 50 n.22, *Wyeth*, 129 S. Ct. 1187 (No. 06-1249), 2008 WL 2273067; Brief for the United States as Amicus Curiae Supporting Petitioner, *supra* note 25, at 26.

97. *Wyeth*, 129 S. Ct. at 1203.

## VI. CONCLUSION

After *Wyeth*, defendants will likely try these broad “frustration of purpose” or “obstacle” theories of preemption with considerably less frequency. Courts will likely accept them even less often. For example, if the FDA’s regulation of drugs, which is much more extensive than its regulation of food, does not ever preempt or almost never preempts state common law duties, it is hard to see how FDA regulation of foods could form the basis for preemption in any but the most unusual instances. As for drug cases, the question now is the same question that in some ways started us down this road about eight years ago: What about SSRI cases? Is there preemption in those cases? My personal view is no, but I have no prediction about what the lower courts will say.

Returning to preemption concerns more generally, many members of Congress are aware of and concerned about the expansion of preemption jurisprudence. Bills to overturn the *Riegel* decision are pending in the House and in the Senate,<sup>98</sup> and a number of pending bills include provisions intended to make clear that state law claims do not pose an obstacle to Congress’s purpose with respect to the subject matter of those bills, thereby forestalling broad conflict preemption arguments.<sup>99</sup>

As *Wyeth* recognizes, conflict preemption is not a choice that an agency gets to make. Conflict preemption occurs where, as a matter of fact, an entity cannot comply with both state and federal law or state law actually interferes with the operation of federal law. Whether or not an administration favors tort reform as a matter of policy should be largely irrelevant. The policy decision belongs to Congress.

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98. See Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. (2009); Medical Device Safety Act of 2009, S. 540, 111th Cong. (2009).

99. See, e.g., Consumer Financial Protection Agency Act of 2009, H.R. 3126, 111th Cong. § 141 (2009); Hardrock Mining and Reclamation Act of 2009, S. 796, 111th Cong. § 308 (2009).