

No. 08-6018

United States Court of Appeals for the Tenth Circuit

ANNABEL DOBBS, Individually and as
Personal Representative of the
Estate of Terry Dobbs, Deceased,
Plaintiff-Appellant,

v.

WYETH PHARMACEUTICALS,
Defendant-Appellee.

On Appeal from the United States District Court
for the Western District of Oklahoma,
Civil Action No. 05-cv-01762-D
Hon. Timothy D. DeGiusti

**Brief for *Amici Curiae* Product Liability Advisory Council, Inc.
and Chamber of Commerce of the United States of America in
Support of Appellee**

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Amicus Curiae The Products Liability Advisory Council, Inc., does not have a parent corporation, nor does any publicly held corporation own 10% or more of its stock.

Amicus curiae Chamber of Commerce of the United States of America (“the Chamber”) is a non-profit corporation organized under the laws of the District of Columbia; it has no parent corporation, and no publicly held company owns 10% or more of its stock.

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INTEREST OF THE *AMICI CURIAE*¹

The Product Liability Advisory Council, Inc. (PLAC) is a non-profit association with 105 corporate members representing a broad cross-section of American and international product manufacturers. These companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products. PLAC's perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector, from automobiles to electronics to pharmaceutical products.²

Since 1983, PLAC has filed over 850 briefs as *amicus curiae* in

¹ All parties have consented to the filing of this brief under Federal Rule of Appellate Procedure 29(a).

² A list of PLAC's corporate members is attached as Appendix A. Although appellee Wyeth is not a member of PLAC, Pfizer Inc. is a corporate member of PLAC, and has agreed to acquire Wyeth if certain conditions are met. *See* Wyeth Br. at i. But such membership is neither necessary nor sufficient to obtain PLAC's *amicus* support; PLAC chooses cases in which to participate on the basis of their jurisprudential importance, not whether they involve a PLAC member. For example, in only 24 of the 36 cases in which PLAC filed *amicus* briefs in 2008 was the party supported a PLAC member. And neither Pfizer nor Wyeth made a contribution to the fee paid for PLAC's brief (other than Pfizer having paid the same annual dues assessments paid by all corporate members of PLAC). Indeed, PLAC never accepts any sum of money or "donation" earmarked for an *amicus* brief.

various state and federal courts, including numerous briefs in this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability. Courts have “acknowledge[d] the assistance” of PLAC, have noted that PLAC’s briefs help “enrich[] the judicial decisionmaking process,” and have characterized PLAC’s briefs as “exceptionally well written” and “excellent.”³ Numerous other courts have quoted PLAC’s briefs or discussed the substantive position presented by PLAC.⁴

The Chamber of Commerce of the United States of America (Chamber) is the world’s largest business federation. The Chamber represents an underlying membership of more than three million com-

³ *Maillet v. ATF-Davidson Co.*, 407 Mass. 185, 186 n.1, 552 N.E.2d 95, 96 n.1 (1990); *Connerly v. State Pers. Bd.*, 37 Cal. 4th 1169, 1177, 129 P.3d 1, 6 (2006); *Gardner v. Honda Motor Co.*, 145 A.D.2d 41, 44, 536 N.Y.S.2d 303, 305 (1988); *Blankenship v. GM Corp.*, 185 W. Va. 350, 352, 406 S.E.2d 781, 783 (1991).

⁴ *See, e.g., United States v. GM Corp.*, 268 U.S. App. D.C. 278, 290, 291–92, 841 F.2d 400, 412, 413–14 (D.C. Cir. 1988); *Milwaukee Elec. Tool Corp. v. Superior Court*, 15 Cal. App. 4th 547, 559, 19 Cal. Rptr. 2d 24, 33 (1993); *Ayers v. Johnson & Johnson Baby Prods. Co.*, 117 Wash. 2d 747, 757, 818 P.2d 1337, 1342 (1992); *Smart v. Caterpillar, Inc.*, 170 Wis. 2d 732, 492 N.W.2d 190 (Ct. App. 1992); *Simpson v. GM Corp.*, 108 Ill. 2d 146, 149, 483 N.E.2d 1, 2, 90 Ill. Dec. 854 (1985).

panies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs—roughly 1600 to date—in cases that raise issues of vital concern to the nation’s business community. Like PLAC, membership in the Chamber is neither necessary nor sufficient to obtain the Chamber’s *amicus* support. The Chamber’s briefs have been described as “helpful”⁵ and “influential.”⁶

In sum, the *amici* bring a level of experience and exposure to legal and policy issues that is broader than any single party can offer.

⁵ See, e.g., *Kedy v. A.W. Chesterton Co.*, 946 A.2d 1171, 1179 n.8 (R.I. 2008); *Scott v. Cingular Wireless*, 161 P.3d 1000, 1004 (Wash. 2007).

⁶ David L. Franklin, *What Kind of Business-Friendly Court? Explaining the Chamber of Commerce’s Success at the Roberts Court*, 49 SANTA CLARA L. REV. 1019, 1026 (2009); see also *id.* (quoting a leading Supreme Court practitioner, Carter Phillips: “The briefs filed by the Chamber in that Court and in the lower courts are uniformly excellent. They explain precisely why the issue is important to business interests. Except for the Solicitor General representing the United States, no single entity has more influence on what cases the Supreme Court decides and how it decides them than the [Chamber].”).

This case, which is one of the first to address the scope of the preemption doctrine after *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), raises issues of considerable importance to PLAC, the Chamber, and their members; indeed, the two organizations combined have filed over 150 *amicus* briefs addressing all aspects of the preemptive effect of federal law and regulation. Many of *amici*'s members are governed by comprehensive federal safety regulations and statutes. Such uniform, national standards, mandated by Congress and developed by agencies with considerable expertise in the field, are vastly superior as a matter of both common sense and public policy to a system in which an agency's carefully designed standards may be supplanted or supplemented at will by trial courts or lay juries. *Amici*'s members, and ultimately the consumers of their products, benefit greatly both from the certainty and efficiency that come with federal uniformity and from the security of knowing that lay juries will not second-guess the safety decisions of expert, deliberative bodies such as the FDA. Accordingly, *amici* and their members have a strong interest in the proper resolution of this challenge to the authority of a federal agency under a detailed federal regulatory scheme.

INTRODUCTION AND SUMMARY OF ARGUMENT

As demonstrated by Wyeth's brief, plaintiff's arguments for reversing the district court's well-reasoned opinion are baseless and fail to refute the actual ground articulated by the district court for why plaintiff's state-law claims are preempted by federal law. Although it is true that the Supreme Court in *Levine* rejected the specific—and very broad—conflict-preemption arguments in the prescription drug arena put forth by the defendant and the FDA, the *Levine* decision in no way suggests that preemption is inappropriate here, where, as the district court explained (*see* Aplt. App. 1847–52, 1860), the FDA repeatedly considered and rejected the very warnings that plaintiff argues should have been provided. Plaintiff relies on a fanciful version of the factual record and a stilted interpretation of the legal standard articulated in *Levine* to argue to the contrary.

Given Wyeth's persuasive demonstration of the fallacies underlying plaintiff's specific arguments—and the appropriate role of *amici curiae*—we see no need to reiterate those arguments in this brief. There are, however, three themes to plaintiff's presentation of this case that, if

accepted by this Court, could inappropriately narrow federal preemption doctrine in ways that would affect cases far removed from this one.

In particular, this Court should affirmatively reject the proposition that *Levine* spells the end of the doctrine of conflict preemption. There is no support for that proposition in *Levine* itself, but that has not stopped much of the plaintiffs' bar from loudly and repeatedly claiming otherwise.

This Court also should give no credence to plaintiff's suggestion that conflict-preemption arguments like those raised by Wyeth are novel and had no support from the FDA prior to 2002. *See* Pl.'s Br. 14–17. While that argument would be legally irrelevant even if true, in fact the FDA has for more than a quarter century repeatedly acknowledged that its regulations and actions could conflict with, and hence preempt, state laws.

Finally, it is important for this Court to understand that *Levine* in no way undermines the argument that *in this case* the FDA's intentional effort to avoid overwarning with respect to modern antidepressants has preemptive effect. Overwarning is a major public health issue, and at least in situations like this one, in which the expert government reg-

ulatory agency carefully considered that risk in determining the appropriate level of warnings to provide with a product, the government's judgment as to the proper warnings must preempt state-law rules mandating additional warnings.

ARGUMENT

I. This Court Should Affirmatively Reject The Suggestion That *Levine* Precludes All Conflict-Preemption Arguments.

A consistent theme in the commentary on *Levine* by the plaintiffs' bar and its supporters has been that the case spells the "death knell" to all conflict-preemption arguments,⁷ represents a "sea shift" in preemp-

⁷ See, e.g., David G. Savage, *Business Downturn: As the market tumbles, so does the corporate pre-emption defense*, ABA J., May 2009, at 22 (available at <http://tinyurl.com/dbbbgt>) ("The [*Levine*] ruling was greeted by some as a final verdict on the Bush administration's drive to kill off liability suits. 'The buzz among lawyers around town is that the Bush regulatory pre-emption agenda ran into a brick wall,' says Georgetown University law professor David Vladeck. The prior administration had not gone to Congress to change the law, he says, but instead tried to win pre-emption through agency pronouncement. '*Wyeth* looks to be the death knell of that,' he adds."); Beasley Allen, *U.S. Supreme court sides with consumers against preemption*, Mar. 19, 2009 (available at <http://tinyurl.com/r9mmoc>) ("The [*Levine*] ruling may be the death knell in the argument for preemption—an effort to protect corporations from state tort litigation."); see also Pl.'s Br. at 22 ("With respect to prescription drugs, the preemption war is effectively over.").

tion law,⁸ and applies across the board not only to specific conflict-preemption arguments in the prescription drug arena but to all forms of conflict preemption in all areas of federal regulation.⁹ Indeed, although plaintiff here acknowledges that some assertions of conflict preemption survive after *Levine*,¹⁰ she adopts an unduly broad reading of the holding in that case. *See, e.g.*, *Wyeth Br.* at 55–57.

But as a review of the opinion in *Levine* demonstrates, that case merely rejected the specific sweeping claim of preemption proposed by the defendant in that case, and clarified the narrower set of cases in which conflict preemption continues to exist, as it has for more than 200 years. As to “[i]mpossibility pre-emption”—the argument that “state-

⁸ *See* Marcia Coyle, *High court’s ‘Wyeth’ ruling on federal preemption a dramatic ‘sea shift,’* NAT’L L.J., Mar. 5, 2009 (available at <http://tinyurl.com/qz9qod>) (quoting plaintiffs’ attorney Sol Weiss).

⁹ *See* Kimberly Atkins, *Preemption ruling opens door to tort suits,* WIS. L.J., Mar. 23, 2009 (available at <http://tinyurl.com/cn89oq>) (quoting plaintiffs’ attorney David Frederick: “Because there are so many instances in which federal agency action butts up [against] state law action, I think this case will end up being a landmark decision in the area of implied preemption, and will have an enormous effect [beyond] drug litigation.”).

¹⁰ *See* Pl.’s Br. at 12 (acknowledging that “the Court seemed to hold open the possibility of preemption even without an attempt to add a warning pursuant to the CBE regulation,” if the manufacturer can “produce ‘clear evidence’ that FDA would have rejected” that warning) (quoting *Levine*, 129 S. Ct. at 1198); *id.* at 23–24.

law claims are pre-empted because it is impossible for [the defendant] to comply with both the state-law duties underlying those claims and its federal ... duties”—the Court noted that this is “a demanding defense”—not an *unavailable* one. 129 S. Ct. at 1196–99. Indeed, the Court clarified that a drug manufacturer like Wyeth could avail itself of this defense with respect to a failure-to-warn claim if it could demonstrate by “clear evidence” that “it was impossible for [it] to comply with both federal and state requirements.” *Id.* at 1198.

Nor did the Court reject the validity of conflict-preemption arguments based on the ground that the plaintiff’s state-law claims would “obstruct the purposes and objectives of federal drug labeling regulation.” *Id.* at 1199; *cf.* Pl.’s Br. at 38 (“Impossibility preemption is rare in prescription drug cases. Obstacle preemption is essentially nonexistent.”). Rather, the *Levine* Court held that the defendant’s *specific* preemption argument “relie[d] on an untenable interpretation of congressional intent and an overbroad view of an agency’s power to preempt state law” absent congressional authorization. *Id.* The Court thus rejected the argument that FDA approval of a drug label, *standing*

alone, establishes both a floor and a ceiling for the warnings a state could mandate for that drug. *Id.*

Neither of these holdings suggests that the conflict-preemption doctrine is dead; indeed, “it has been settled that state law that conflicts with federal law is without effect” “since [the Court’s] decision in *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 427 (1819).” *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (internal quotation marks omitted). Nothing in the majority’s opinion in *Levine* is to the contrary. In fact, Justice Thomas refused to join the majority opinion in *Levine*—instead concurring in the judgment—precisely *because* he could not “join the majority’s implicit endorsement of far-reaching implied pre-emption doctrines.” 129 S. Ct. at 1205 (Thomas, J., concurring).

If the plaintiffs’ bar were correct as to the meaning of *Levine*, the majority in that case would not have had to engage in a painstaking review of the regulatory record of the drug at issue. *See* 129 S. Ct. at 1192. The principal difference between the majority and the dissent in *Levine* was over the regulatory record and whether the FDA had rejected the change that Vermont said had to be made in the label, *see id.* at 1222–25 (Alito, J., dissenting)—not over the scope of conflict preemption. As

noted above, only Justice Thomas would have rejected the long-settled view on that issue.

Amici thus urge the Court, regardless of how it rules on the specific preemption issues presented by plaintiff's appeal, to reaffirm the continuing vitality of the federal conflict-preemption doctrine, a legal principle whose heritage traces back to the Supremacy Clause—and one that is crucial to the sensible regulation of numerous industries.

II. Despite Plaintiff's Protestations To The Contrary, The FDA Has Recognized The Existence of Conflict-Preemption Doctrines For Over 25 Years.

Another flimsy reed on which plaintiff's anti-preemption arguments in this case are based is the assertion that the FDA opposed the concept of conflict preemption until the 2000s, *see* Pl.'s Br. at 14, and more specifically until “[p]olitical forces within FDA began an active attempt to change the historical view [that FDA regulations set forth only minimum safety standards] in 2002.” *See id.* at 17. This argument is both flatly inaccurate and legally irrelevant.

According to plaintiff, the FDA's support for conflict preemption “began” with the filing of an *amicus* brief supporting preemption in *Motus v. Pfizer* in the Ninth Circuit, in September 2002. *See id.* But in fact,

the government filed at least three briefs supporting conflict-preemption arguments with respect to the FDA under President Clinton as well. *See* Br. for United States as *Amicus Curiae*, *Buckman Co. v. Pls.’ Legal Comm.*, 531 U.S. 341 (2001), No. 98-1768, 2000 WL 35746614 (June 7, 2000); Br. for United States as *Amicus Curiae*, *Buckman Co. v. Pls.’ Legal Comm.*, 531 U.S. 341 (2001), No. 98-1768, 2000 WL 1364441 (Sept. 13, 2000); Statement of Interest of United States, *Bernhardt v. Pfizer, Inc.*, 2000 WL 1738645 (S.D.N.Y. Nov. 22, 2000), No. 00 Civ. 4042 LLM (Nov. 13, 2000) (available at <http://tinyurl.com/q6fg3z>). And the FDA filed at least one *amicus* brief arguing for conflict preemption as long ago as 1992. *See* Statement of Interest of United States, *Biffle v. Eli Lilly & Co.*, No. 91-02496-A (Dallas County, Tex. D. Ct.) (Feb. 25, 1992) (available at <http://tinyurl.com/nqd3zy>). The *Motus* *amicus* brief that plaintiff discusses, *see* Pl.’s Br. at 17–18, is merely the first FDA brief addressing conflict preemption that *also* happened to involve failure-to-warn claims with respect to a modern antidepressant drug.¹¹

¹¹ It is also worth noting that the government’s *amicus* brief in *Motus* was filed by the Department of Justice, not the FDA, *see* Br. for *Amicus Curiae* United States at 25, *Motus v. Pfizer, Inc.*, 358 F.3d 659

Indeed, in 2004, five former FDA general counsel—representing both Republican and Democratic Administrations stretching back to 1972—submitted a letter to Congress defending the submission of *amicus* briefs by the FDA under the George W. Bush administration, noting the government’s history of submitting such *amicus* briefs and explaining that “[t]here is a greater need for FDA intervention [in litigation] today because plaintiffs in courts are intruding more heavily on FDA’s primary jurisdiction than ever before.” 150 Cong. Rec. E1505, E1506, 2004 WL 1639246 (July 22, 2004).

Nor was the FDA’s pre-2002 recognition of conflict preemption limited to *amicus* briefs. For example, in 1995 the FDA clarified that FDA confidentiality regulations conflicted with, and hence preempted, a state-law rule mandating the disclosure of the identity of anyone who reported an “adverse event” associated with a drug or device to the agency. *See* FDA, *Final Rule: Protecting the Identities of Reporters of*

(9th Cir. 2004) (No. 02-55372), 2002 WL 32303084 (Sept. 10, 2002) (hereinafter *Motus* Brief), and that under well-established government rules that *amicus* brief, like all federal *amicus* briefs filed in a federal court of appeals, had to be approved by the Solicitor General. *See* 28 C.F.R. 0.20(c).

Adverse Events and Patients, 60 Fed. Reg. 16,962, 16,963–66 (Apr. 3, 1995). As the agency explained,

Although Congress did not expressly preempt State law in this area, the agency finds Federal preemption to be appropriate because such State or local laws, rules, regulations, or other requirements would impede FDA’s ability to monitor product safety after approval to ensure that human drug products, biologics, and medical devices are safe and effective for their intended uses.

Id. at 16,963.

Similarly, in a 1997 final rule governing mammography standards, the agency explained that its new rule would require facilities to transfer mammography films to other facilities upon the patient’s request, and noted that “[w]ere a State to enact a law that conflicts with this regulation or if ... such laws currently do exist, those State laws would be preempted.” FDA, *Quality Mammography Standards*, 62 Fed. Reg. 55,852, 55,932 (Oct. 28, 1997).

In fact, the FDA has acknowledged the possibility of conflict preemption for more than 25 years. In 1982, the FDA determined that state requirements for pregnancy/nursing warnings with respect to over-the-counter drugs were preempted by federal law because “FDA

believes that differing State OTC drug pregnancy-nursing warning requirements would prevent accomplishment of the full purpose and objectives of the agency in issuing the regulation and that, under the doctrine of implied preemption, these State requirements are preempted by the regulation as a matter of law.” FDA, *Final Rule: Pregnant or Nursing Women; Delegations of Authority and Organization; Amendment of Labeling Requirements for Over-the-Counter Human Drugs*, 47 Fed. Reg. 54,750, 54,756 (Dec. 3, 1982).¹²

Of course, the question whether a specific state rule—statutory or common law—conflicts with, and hence is preempted by, federal law will rarely if ever depend on the length of time that the relevant federal

¹² Other instances in which the FDA has acknowledged the existence of conflict preemption include, *e.g.*, FDA, *Tamper-Resistant Packaging Requirements for Certain Over-the-Counter Human Drug and Cosmetic Products*, 47 Fed. Reg. 50,442, 50,447 (Nov. 5, 1982) (promulgating national packaging standards for over-the-counter drugs and explaining that “FDA intends that the regulations issued in this document preempt State and local packaging requirements that are not identical to it in all respects”); FDA, *Final Rule: Food Labeling; Declaration of Sulfiting Agents*, 51 Fed. Reg. 25,012, 25,016 (July 9, 1986) (“The agency does not use its authority to preempt State requirements unless there is a genuine need to stop the proliferation of inconsistent requirements between FDA and the States.”); FDA, *Final Rule: Irradiation in the Production, Processing, and Handling of Food*, 51 Fed. Reg. 13,376, 13,392 (Apr. 18, 1986) (“The test of whether a State activity is preempted by Federal law and regulations is whether the State activity conflicts with and stands as an obstacle to the Federal program.”).

agency has recognized that conflict—or even whether the agency explicitly recognizes the conflict. Preemption will depend on the regulation at issue as applied to the facts at issue, not whether the agency has explicitly stated its intent to preempt. Plaintiff’s argument in this respect thus would have no merit even if its factual basis were true. But given the frequency with which the plaintiffs’ bar has sought to paint federal preemption in the prescription drug arena as a recent invention, and given the significance some courts might place on such a fact were it to be true, *amici* believe that it is important to demonstrate the fallacious nature of this argument.

III. This Case Demonstrates The Importance Of Preemption In Failure-To-Warn Cases When Overwarning Is A Significant Concern.

As plaintiff stresses, the Supreme Court in *Levine* rejected the FDA’s position that the mere fact of FDA approval of a drug manufacturer’s warning label is preemptive of state-law failure-to-warn claims—and in so doing the Court declined to defer to the FDA’s regulatory proclamation on the subject (FDA, *Final Rule: Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products* (the “Preemption Preamble”), 71 Fed. Reg. 3922, 3934

(Jan. 24, 2006)). *See* 129 S. Ct. at 1201–03; Pl.’s Br. at 20–21. But importantly, in so holding the *Levine* Court did not reject all of the *reasons* that the FDA and the defendant gave for why state-law failure-to-warn claims might, at least in certain circumstances, conflict with the FDA’s regulation of a drug’s labeling. In particular, notwithstanding *Levine* it remains the case that overwarning is a major concern in the prescription drug arena. *Amici* believe that it is important for this Court, in deciding this case, to be aware of the very real risks that can be posed by such overwarning.

Here, Wyeth has demonstrated (by providing “clear evidence,” 129 S. Ct. at 1198) that the FDA “would not have approved,” *id.*, the warning plaintiff says should have been given in this case. But Wyeth only advertises in passing to a significant part of the *reason* why the FDA would not have approved that warning—that the Agency was afraid that overwarning might have discouraged people who needed modern antidepressants from taking the drugs. *See* Wyeth Br., at 43; *see also*, *e.g.*, *Motus* Br., 2002 WL 32303084 at 23–24.¹³

¹³ In fact, there is evidence suggesting that there was a significant increase in youth-suicide rates in 2003. This is approximately the same time as publicity suggesting that antidepressant drugs could make

As the FDA explained in its brief in *Motus*, “[u]nder-utilization of a drug based on dissemination of scientifically unsubstantiated warnings, so as to deprive patients of beneficial, possibly lifesaving treatment, could well frustrate the purposes of federal regulation as much as over-utilization resulting from a failure to disclose a drug’s scientifically demonstrable adverse effects.” *Motus Br.*, 2002 WL 32303084 at 23. The FDA has repeatedly reiterated this point, including in other *amicus* briefs and most notably in the Preemption Preamble. *See* 71 Fed. Reg. at 3935 (additional warnings “can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use”).

Indeed, the Eighth Circuit acknowledged this precise risk—in the context of a failure-to-warn case involving the labeling of a medical device approved by the FDA—in *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) (en banc). The Eighth Circuit identified “a number of sound reasons why the FDA may prefer to limit warnings on product labels.” *Id.* at 796. These include the fact that “[w]arnings about dan-

young people suicidal led to a decrease in the number of antidepressant prescriptions. *See* Bruce Bower, *SSRI use declines, youth suicides rise*, SCIENCE NEWS, Sept. 22, 2007, at 190 (available at 2007 WLNR 19567659).

gers with less basis in science or fewer hazards could take attention away from those that present confirmed, higher risks,” *id.*, and the concern that “[a] label with many varied warnings may not deliver the desired information to users.” *Id.*; *see also, e.g., Finn v. G.D. Searle & Co.*, 35 Cal. 3d 691, 701, 677 P.2d 1147, 1153 (1984).¹⁴

None of these concerns is likely, however, to motivate—or even be considered by—a jury that is asked to decide a state failure-to-warn claim. All that such a jury would be called upon to determine is whether the content of the defendant’s label satisfied the defendant’s state-law duty to warn of the *particular* risk allegedly encountered by the *particular* plaintiff. If the jury answers that question in the negative, liability is almost certain to attach, regardless of the potential impact that the addition of that warning might have on *other* warnings with respect to other risks or on *other* patients’ ability or willingness to use the product.

¹⁴ The FDA recently issued draft guidelines on presenting risk information to physicians and consumers, which note these risks and demonstrate more generally the sophisticated nature and empirical foundation of the agency’s analysis of warnings. *See FDA, Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion; Draft Guidance*, at 2 n.5 (May 2009) (available at <http://tinyurl.com/m2w7sa>); *FDA, Draft Guidance for Industry on Presenting Risk Information in Prescription Drug and Medical Device Promotion; Availability*, 74 Fed. Reg. 25,245 (May 27, 2009).

This problem is exacerbated by the case-by-case process of common-law adjudication. Later judges or juries cannot reconsider outcomes reached in earlier cases. Thus, a trier of fact cannot decide that a warning added in response to an earlier verdict is unnecessary or inappropriate. Nor do judges and juries know how many warnings will be vying for limited reader attention.

That is precisely the role of the FDA—and this concern is precisely what the agency grappled with over a twenty-year period when assessing the warnings that should be utilized for Effexor and other modern antidepressants. As the Eighth Circuit has emphasized, “[i]t would be difficult for a jury focused on a single case to take into account ‘the cumulative, systemic effects’ of a series of verdicts. In contrast, the FDA possesses a broader perspective.” *Brooks*, 273 F.3d at 797 (quoting Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167, 2175 (2000)). Even where a judge or jury is aware of potential overwarning, it can do little to prevent the problem. See James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 302 (1990). As the Supreme

Court recently emphasized in a decision finding preemption in the medical device arena, “tort law[] applied by juries” produces distorted results because it fails to emulate the cost-benefit analysis that an expert agency would employ. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008) (“A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.”).

While the *Levine* Court discounted the FDA’s position that the *mere fact* of FDA review of a drug label necessarily means that the agency engaged in a careful balancing of risks and benefits, including the risks of overwarning, Wyeth has demonstrated that this case is one in which the FDA did undertake, over many years, *precisely* that balancing endeavor. Given this, preemption of conflicting state-law warnings is plainly appropriate.

CONCLUSION

For the foregoing reasons, as well as those in Wyeth’s brief, the judgment below should be affirmed.

Respectfully submitted.

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Dated: July 27, 2009.

**APPENDIX:
CORPORATE MEMBERS OF THE
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as of 7/27/2009

3M	The Dow Chemical Company
A.O. Smith Corporation	E.I. DuPont De Nemours and Company
ACCO Brands Corporation	Eli Lilly and Company
Altec Industries	Emerson Electric Co.
Altria Client Services Inc.	Engineered Controls Interna- tional, Inc.
American Suzuki Motor Corpo- ration	Estee Lauder Companies
Andersen Corporation	Exxon Mobil Corporation
Anheuser-Busch Companies	Ford Motor Company
Arai Helmet, Ltd.	Genentech, Inc.
Astec Industries	General Electric Company
BASF Corporation	GlaxoSmithKline
Bayer Corporation	The Goodyear Tire & Rubber Company
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Biro Manufacturing Company, Inc.	Hawker Beechcraft Corporation
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Boeing Company	Honda North America, Inc.
Bombardier Recreational Prod- ucts	Hyundai Motor America
BP America Inc.	Illinois Tool Works, Inc.
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Briggs & Stratton Corporation	Isuzu Motors America, Inc.
Brown-Forman Corporation	Jarden Corporation
Caterpillar Inc.	Johnson & Johnson
Chrysler LLC	Joy Global Inc., Joy Mining Ma- chinery
Continental Tire North Ameri- ca, Inc.	Kawasaki Motors Corp., U.S.A.
Crown Equipment Corporation	Kia Motors America, Inc.
Daimler Trucks North America LLC	Koch Industries

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Medtronic, Inc.	Vermeer Manufacturing Com- pany
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Pursuant to Fed. R. App. P. 32(a) the undersigned counsel for the *amici curiae* hereby certifies as follows:

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Dated: July 27, 2009.

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CERTIFICATE OF DIGITAL SUBMISSION

The undersigned certifies that, (1) all required privacy redactions have been made; (2) the native PDF format version of this brief that was filed using the ECF filing system is an exact copy of the hard copies of this brief that are being submitted to the Clerk; and (3) the native PDF format version of this brief that was filed using the ECF filing system was scanned for viruses with the most recent version of Symantec Antivirus (version 10.1.4.4000, virus definitions last updated 7/26/2009), and, according to that program, is free of viruses.

Dated: July 27, 2009.

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CERTIFICATE OF SERVICE

I hereby certify that on July 27, 2009, I:

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