Nos. 08-5042, 08-5050

United States Court of Appeals for the Tenth Circuit

CANDACE MILLER AND GEORGE MILLER,

Plaintiffs-Appellants/Cross-Appellees,

v.

SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE,

Defendant-Appellee/Cross-Appellant.

On Appeal from the United States District Court
for the Northern District of Oklahoma,
Civil Action No. 4:03-cv-00393
Hon. Gregory K. Frizzell

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 103 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 various state and federal courts, including numerous briefs in this

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[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. Appellee GlaxoSmithKline is a corporate member of PLAC, 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. GlaxoSmithKline did not make a contribution to the fee paid for PLAC's brief (other than its 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.

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 companies and professional organizations of every size, in every industry

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[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).

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.

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 is-

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[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].").

sues 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 GlaxoSmithKline's brief, plaintiffs' 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 plaintiffs' 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's inquiry took into account (*see* Aplt. App. (9), at 2035), the FDA considered and rejected the specific labeling that plaintiffs argue should have been provided. Plaintiffs rely 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 GlaxoSmithKline's persuasive demonstration of the fallacies underlying plaintiffs' 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 plaintiffs' presentation of this case that, if accepted by this Court, could inappropriately narrow fed-

eral 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 plaintiffs' suggestion that conflict-preemption arguments like those raised by GlaxoSmithKline are novel and had no support from the FDA prior to 2002. *See* Pls.' Br. 23–27. 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 gov-

ernment regulatory 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-

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[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* Pls.' Br. at 29 ("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 plaintiffs here acknowledge that some assertions of conflict preemption survive after *Levine*,[10] they adopt an unduly broad reading of the holding in that case. *See, e.g.*, GlaxoSmithKline Br. at 50–52.

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-

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8 *See* Marcia Coyle, *High court's 'Wyeth' ruling on federal pre-emption 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* Pls.' Br. at 18 (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 32.

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 GlaxoSmithKline 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.* Pls.' Br. at 42 ("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 pre-empt 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 plaintiffs' 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 Plaintiffs' Protestations To The Contrary, The FDA Has Recognized The Existence of Conflict-Preemption Doctrines For Over 25 Years.

Another flimsy reed on which plaintiffs' anti-preemption arguments in this case are based is the assertion that the FDA opposed the concept of conflict preemption until the 2000s, *see* Pls.' Br. at 23, and, more specifically, that in 2002, "FDA began to take a position on preemption that was diametrically opposed to its traditional view." *See id.* This argument is both flatly inaccurate and legally irrelevant.

According to plaintiffs, the FDA's support for conflict preemption "began" only in September 2002, with the filing of an *amicus* brief supporting preemption in *Motus v. Pfizer* in the Ninth Circuit. *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 at 14–16 (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 at 17–27 (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).[11] 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/

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[11] The government's *amicus* brief in *Bernhardt* allowed that "in certain circumstances, a common law tort action may be brought alleging that a drug had insufficient warnings," *id.* at 11 & n.1, but it also cautioned that "were a court hearing a common law cause of action to issue a decree establishing a substantive requirement … that conflicted with [that] required by [federal law], the court-imposed requirement would be subject to conflict-preemption analysis." *Id.* at 11 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 491, 591 (1996) (plurality op.)). To the extent that a money judgment is premised on a determination "that the defendant has violated a state-law obligation" to provide a warning that federal law forbids, the state-law cause of action is preempted by federal law. *See Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008). After all, "common-law causes of action for negligence and strict liability do impose 'requirement[s].'" *Id.* at 1007.

nqd3zy). The *Motus* amicus brief that plaintiffs discuss, *see* Pls.' Br. at 23–24 & n.15, 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.[12]

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

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[12] 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 (9th Cir. 2004) (No. 02-55372), 2002 WL 32303084 (Sept. 10, 2002) (hereinafter *Motus* Brief), and that under the controlling regulations 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).

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 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).[13]

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[13] Other instances in which the FDA has acknowledged the existence of conflict preemption include, for example, 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."); and FDA, *Final Rule: Irradiation in the Production, Processing, and Handling of Food*, 51 Fed.

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 agency has recognized that conflict—or even whether the agency explicitly recognizes the conflict. *See Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 884 (2000) ("[T]he Court has never … required a specific, formal agency statement identifying conflict in order to conclude that such a conflict in fact exists."). 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. *See id.* at 884–85. Plaintiffs' 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.

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.").

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

As plaintiffs stress, 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; Pls.' Br. at 26–27. 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, GlaxoSmithKline has demonstrated (by providing "clear evidence," 129 S. Ct. at 1198) that the FDA "would not have approved," *id.*, the warning plaintiffs say should have been given in this case. *See* GlaxoSmithKline Br. at 40-49. But GlaxoSmithKline only adverts 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* GlaxoSmithKline Br. at 56; *see also*, *e.g.*, *Motus* Br., 2002 WL 32303084 at 23–24.[14]

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

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[14] 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 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).

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 dangers 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).[15]

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[15] 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*

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.

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 assess-

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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).

ing the warnings that should be utilized for Paxil 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, GlaxoSmithKline 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 GlaxoSmithKline's brief, the judgment below should be affirmed.

Respectfully submitted.

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Dated: September 11, 2009.

APPENDIX:
CORPORATE MEMBERS OF THE PRODUCT LIABILITY ADVISORY COUNCIL

as of 9/11/2009

3M
A.O. Smith Corporation
ACCO Brands Corporation
Altec Industries
Altria Client Services Inc.
American Suzuki Motor Corporation
Andersen Corporation
Anheuser-Busch Companies
Arai Helmet, Ltd.
Astec Industries
BASF Corporation
Bayer Corporation
Beretta U.S.A Corp.
BIC Corporation
Biro Manufacturing Company, Inc.
BMW of North America, LLC
Boeing Company
Bombardier Recreational Products
BP America Inc.
Bridgestone Americas Holding, Inc.
Briggs & Stratton Corporation
Brown-Forman Corporation
Caterpillar Inc.
Chrysler LLC
Continental Tire North America, Inc.
Crown Equipment Corporation
Daimler Trucks North America LLC
The Dow Chemical Company
E.I. DuPont De Nemours and Company
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, Inc.
Estee Lauder Companies
Exxon Mobil Corporation
Ford Motor Company
Genentech, Inc.
General Electric Company
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Harley-Davidson Motor Company
Hawker Beechcraft Corporation
The Heil Company
Honda North America, Inc.
Hyundai Motor America
Illinois Tool Works, Inc.
International Truck and Engine Corporation
Isuzu Motors America, Inc.
Jarden Corporation
Johnson & Johnson
Joy Global Inc., Joy Mining Machinery
Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.
Koch Industries
Kolcraft Enterprises, Inc.
Kraft Foods North America, Inc.

Leviton Manufacturing Co., Inc.
Lincoln Electric Company
Magna International Inc.
Mazak Corporation
Mazda (North America), Inc.
Medtronic, Inc.
Merck & Co., Inc.
Microsoft Corporation
Mitsubishi Motors North America, Inc.
Mueller Water Products
Newell Rubbermaid Inc.
Nintendo of America, Inc.
Niro Inc.
Nissan North America, Inc.
Novartis Pharmaceuticals Corporation
PACCAR Inc.
Panasonic
Pfizer Inc.
Porsche Cars North America, Inc.
Purdue Pharma L.P.
Remington Arms Company, Inc.
RJ Reynolds Tobacco Company
Schindler Elevator Corporation
SCM Group USA Inc.
Senco Products, Inc.
Shell Oil Company
The Sherwin-Williams Company
Smith & Nephew, Inc.
St. Jude Medical, Inc.
Subaru of America, Inc.
Synthes (U.S.A.)
Terex Corporation
Textron, Inc.
TK Holdings Inc.
The Toro Company
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Watts Water Technologies, Inc.
Whirlpool Corporation
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a) the undersigned counsel for the *amici curiae* hereby certifies as follows:

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 4853 words, excluding the parts of the brief exempted by Fed. R. App. R. 32(a)(7)(B)(iii); and

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced type-face using Microsoft Word 2007 in 14-point Century Schoolbook.

Dated: September 11, 2009.

/s David M. Gossett
David M. Gossett

Counsel for the Amici Curiae

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, scan engine 91.2.0.30, virus definitions last updated 9/10/2009), and, according to that program, is free of viruses.

Dated: September 11, 2009.

/s David M. Gossett
David M. Gossett

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CERTIFICATE OF SERVICE

I hereby certify that on September 11, 2009, I:

(1) Sent to the Clerk via overnight delivery one signed original and seven copies of this brief;

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