

No. 08-2265

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**United States Court of Appeals for the Seventh Circuit**

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BONNIE J. MASON and WILLIAM L. MASON,

*Plaintiffs-Appellants,*

v.

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,

*Defendant-Appellee.*

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On Appeal from the United States District Court  
for the Central District of Illinois,  
Civil Action No. 05-cv-1252  
Hon. Michael M. Mihm

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**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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**CIRCUIT RULE 26.1 DISCLOSURE STATEMENT**

Appellate Court No: \_\_\_\_\_

Short Caption: \_\_\_\_\_

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party or amicus curiae, or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

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(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

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(3) If the party or amicus is a corporation:

i) Identify all its parent corporations, if any; and

\_\_\_\_\_

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

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Attorney's Signature:  /s Kenneth S. Geller Date: \_\_\_\_\_

Attorney's Printed Name: \_\_\_\_\_

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes \_\_\_\_\_ No \_\_\_\_\_

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Attorney's Signature:  /s David M. Gossett Date: \_\_\_\_\_

Attorney's Printed Name: \_\_\_\_\_

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Attorney's Signature:  /s Hugh F. Young Date: \_\_\_\_\_

Attorney's Printed Name: \_\_\_\_\_

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Attorney's Signature:  /s Robin S. Conrad Date: \_\_\_\_\_

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Attorney's Signature:  /s Amar D. Sarwal Date: \_\_\_\_\_

Attorney's Printed Name: \_\_\_\_\_

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## INTEREST OF THE *AMICI CURIAE*<sup>1</sup>

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.<sup>2</sup>

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

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<sup>1</sup> Pursuant to Federal Rule of Appellate Procedure 29, this brief is conditionally filed and accompanied by a motion for leave to file the brief. Counsel for appellee has consented to the filing of this brief but counsel for the appellants has refused to consent.

<sup>2</sup> A list of PLAC's corporate members is attached as Appendix A. Appellee GlaxoSmithKline (GSK) 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 *amicus* briefs filed by PLAC in 2008 was the party supported a PLAC member. And GSK made no contribution to the fee paid for PLAC's brief other than 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.”<sup>3</sup> Numerous other courts have quoted PLAC’s briefs or discussed the substantive position presented by PLAC.<sup>4</sup>

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-

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<sup>3</sup> *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).

<sup>4</sup> *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”<sup>5</sup> and “influential.”<sup>6</sup>

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.

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<sup>5</sup> 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).

<sup>6</sup> 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 GSK's brief, plaintiffs' arguments for reversing the district court's well-reasoned opinion are baseless and bear almost no relationship to the actual grounds 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 Wyeth and the FDA, the *Levine* decision in no way suggests that preemption is inappropriate here, where, as the district court explained, the FDA repeatedly considered and rejected the very warnings 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 GSK'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 federal preemption doctrine in ways that would affect cases far removed from this one.

In particular, this Court should affirmatively reject plaintiffs' implicit argument 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' claim that conflict-preemption arguments like those raised by GSK are novel and had no support from the FDA prior to the start of the George W. Bush Administration. 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 SSRI's has preemptive effect. Overwarning is a major public health issue, and at least in situations like this one, in which the expert government 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,<sup>7</sup> represents a "sea shift" in preemp-

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<sup>7</sup> 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.").

tion law,<sup>8</sup> 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.<sup>9</sup> Indeed, although plaintiffs here acknowledge that some assertions of conflict preemption survive after *Levine*,<sup>10</sup> they title that same section of their brief “The Supreme Court Has Concluded That Prescription Drug Failure To Warn Claims Are Not Preempted.” Pls.’ Br. at 23.

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

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<sup>8</sup> 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).

<sup>9</sup> 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.”).

<sup>10</sup> See Pls.’ Br. at 24 (acknowledging that preemption argument will succeed if the manufacturer can “present ‘clear evidence’ that the FDA would ‘have prohibited [the manufacturer] from adding a stronger warning’”) (quoting *Levine*, 129 S. Ct. at 1198–99 & n.6) (alteration in Plaintiffs’ Brief).

years. As to “[i]mpossibility pre-emption”—the argument that “state-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. Rather, the *Levine* Court held that Wyeth’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 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 President George W. Bush’s election in 2000, and more specifically until Dan Troy became Chief Counsel of the FDA in August 2001. *See* Pls.’ Br. at 18–20. Indeed, plaintiffs go so far as to entitle the very first section of their Argument “Mr. Troy Goes to Washington.” *Id.* at 18. This argument—besides being an inappropriate ad hominem attack—is both flatly inaccurate and legally irrelevant.

According to plaintiffs, the FDA conflict-preemption “story” “begins” 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 plaintiffs discuss, see Pls.’ Br. at 18–19, is merely the first FDA brief addressing conflict preemption that *also* happened to involve failure-to-warn claims with respect to an SSRI drug.<sup>11</sup>

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<sup>11</sup> 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) (listing Dan Troy and other FDA lawyers as “of

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

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counsel”), 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 (then Theodore Olson). See 28 C.F.R. 0.20(c).



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 ob-

jectives 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).<sup>12</sup>

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. Preemption will depend on the regulation

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<sup>12</sup> 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.”).

at issue as applied to the facts at issue, not whether the agency has explicitly stated its intent to preempt. 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.

### **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. But importantly, in so holding the *Levine* Court did not reject all of the *reasons* that the FDA and

Wyeth 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, GSK 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. But GSK only alludes 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 SSRIs from taking the drugs. *See* GSK Br., at 42–43; *see also, e.g., Motus Br.*, 2002 WL 32303084 at 23–24.<sup>13</sup>

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<sup>13</sup> 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).

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 dangers with less basis in science or fewer hazards could take attention away from those that present confirmed, higher risks,” *id.*, and the con-

cern 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).

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 assessing the warnings that should be utilized for Paxil and other SSRIs. 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, GSK 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 GSK’s brief, the judgment below should be affirmed.



Respectfully submitted.

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Dated: June 3, 2009.

## APPENDIX A

### Corporate Members of the Product Liability Advisory Council *as of 6/1/2009*

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

Leviton Manufacturing Co., Inc.  
Lincoln Electric Company  
Magna International Inc.  
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.  
Nokia Inc.  
Novartis Pharmaceuticals  
Corporation  
PACCAR Inc.  
Panasonic  
Pfizer Inc.  
Porsche Cars North America,  
Inc.  
Purdue Pharma L.P.  
Remington Arms Company, Inc.  
Rheem Manufacturing  
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.  
TRW Automotive  
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 4,488 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 typeface using Microsoft Word 2007 in 14-point Century Schoolbook.

Dated: June 3, 2009.

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**CIRCUIT RULE 31(e)(1) CERTIFICATION**

The undersigned hereby certifies that, pursuant to Circuit Rule 31(e), this brief has been filed electronically.

Dated: June 3, 2009.

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