

Nos. 09-993, 09-1039 & 09-1501

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In The  
**Supreme Court of the United States**

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PLIVA, INC., et al.,

*Petitioners,*

v.

GLADYS MENSING,

*Respondent.*

—◆—  
ACTAVIS ELIZABETH LLC,

*Petitioner,*

v.

GLADYS MENSING,

*Respondent.*

—◆—  
ACTAVIS, INC.,

*Petitioner,*

v.

JULIE DEMAHY,

*Respondent.*

—◆—  
**On Writ of Certiorari to the United States Courts  
Of Appeals for the Eighth and Fifth Circuits**

—◆—  
**BRIEF OF TORTS PROFESSORS MARY J. DAVIS,  
HEIDI LI FELDMAN, THOMAS C. GALLIGAN, JR.,  
MARK P. GERGEN, AND JON HANSON AS AMICI  
CURIAE IN SUPPORT OF RESPONDENTS**

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March 2, 2011

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**STATEMENT OF INTEREST OF *AMICI CURIAE*<sup>1</sup>**

*Amici* are law professors who regularly teach and write about the law of torts. Each has taught for 20 years or more and each has written extensively in the field. *Amici* have no stake in the outcome of this case other than their academic interest in the logical and rational development of the law. Because this case implicates fundamental tort law issues, *amici* believe that their unique perspective may assist the Court in resolving this case. The Appendix includes further biographical information.

**SUMMARY OF ARGUMENT**

Petitioners and their *amici* are unduly optimistic about the ability of the Food and Drug Administration (“FDA”) to protect the public from unreasonably dangerous drugs. The civil justice system complements FDA regulation of drugs. Even if the agency were adequately funded and staffed, and even if drug-makers always cooperated with the agency to ensure the safety and efficacy of drugs, tort liability would still be necessary to encourage drug-makers to provide adequate warnings about risks that are outside the agency’s purview when it approves a drug and

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<sup>1</sup> The parties consented to the filing of this brief. No counsel for a party authored this brief in whole or in part and no person other than *amici* and their counsel made a monetary contribution intended to fund its preparation or submission.

labeling. Tort liability also serves compensation and corrective justice interests that FDA regulation was never intended to serve.

Petitioners and their *amici* also have an unduly pessimistic view of the civil justice system. Mechanisms exist within it to protect drug-makers from spurious claims. State courts have struck a balance by adopting rules that shield a drug-maker from design-defect claims while holding a drug-maker liable if it fails to give adequate warning of a drug's risks. This facilitates getting new FDA-approved drugs on the market while using failure-to-warn liability to encourage dissemination of risk information and so enable health-care professionals and the public to make informed decisions about drugs. Other rules address specific arguments for preemption. Rules of evidence enable courts to screen out claims that lack a sound scientific basis. The hypothetical danger of drug-makers' inundating the public with warnings to avoid liability is dealt with by the learned intermediary doctrine, which enables drug-makers to satisfy the duty to warn by providing information to health-care professionals.

The American Law Institute ("ALI"), state courts, and state legislatures have grappled with arguments for and against requiring courts and juries to defer to FDA approval of a drug's labeling in developing the "regulatory compliance" defense. Many state statutes require some deference to FDA approval of a drug's labeling. Those rules would not shield petitioner here because the FDA never approved the long-term use of

metoclopramide. When the FDA did consider the risks of long-term use, moreover, it mandated that a much stronger boxed warning be added to the label.

This experience teaches that preemption is not an either-or proposition. A narrow rule of preemption is similar to a strong form of the common-law defense of regulatory compliance. This would make FDA approval of a warning regarding specific risk determinative of the reasonableness of the warning for that risk if the FDA considered all relevant information. A broad rule would make the FDA solely responsible for ensuring the adequacy of warnings of FDA-approved drugs by precluding all failure-to-warn claims regarding FDA-approved drugs. This would shield a drug-maker from liability even if it withheld relevant risk information from the FDA or otherwise failed to cooperate, and even with respect to risks that appear post-marketing or that involve “off-label” uses, which the FDA has no opportunity to consider. This would be a radical change from the status quo. This Court should leave it to Congress to tailor an appropriate preemption rule and to decide whether the rule should apply retroactively.

Respondents each brought a typical state-law failure-to-warn case. The elements of such a case are well-established in Louisiana, Minnesota, and nationwide. Pliva’s effort to impose an additional obligation on respondents – to prove what the FDA would have done if petitioners had fulfilled their obligations to recommend adequate warnings – is unpersuasive. It misconceives the elements of a failure-to-warn

case, misconstrues this Court's decision in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), and misconceives the nature of the causation inquiry. Respondents need not disprove petitioners' affirmative defenses as part of their affirmative cases.

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## ARGUMENT

### **I. Preemption of state-law tort claims based on FDA regulation of a generic drug is unwarranted because the civil justice system complements the FDA's regulation of drugs**

The civil justice system complements FDA regulation of generic drugs on two general dimensions. First, tort liability serves several important functions that FDA regulation of drugs – either brand-name or generic – was never intended to serve. Most of those functions involve compensating people who are injured, usually because a drug-maker failed to provide adequate warning of a drug's risks. Whether the civil justice system should be preempted from serving those compensatory functions raises fundamental questions of morality and policy. Second, tort liability complements the FDA's regulatory function. Whether the civil justice system should be preempted from serving that function turns on an assessment of the relative strengths of FDA regulation and civil liability as mechanisms for protecting people from unreasonably dangerous drugs.

Ultimately, both answers turn on whether society chooses to err on the side of over- or under-protecting the public from unreasonably dangerous drugs. State courts have struck a balance by eliminating barriers to the introduction of new drugs, relying on the FDA to keep unreasonably dangerous drugs off the market, while imposing failure-to-warn liability to encourage dissemination of risk information and thus enable health-care professionals and the public to make informed judgments about drugs.

Neither the FDA itself (with one since discredited<sup>2</sup> exception) nor any other official body has ever concluded that a general rule preempting failure-to-warn liability is needed to enable the agency to accomplish its mission with respect to either brand-name or generic drugs.<sup>3</sup>

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<sup>2</sup> In the preamble to a 2006 FDA regulation governing the content and format of prescription drug labels, the FDA – in a reversal of previous policy – declared that “FDA approval of labeling . . . preempts conflicting or contrary State law.” 71 FED. REG. at 3935. Two years ago, this Court resoundingly rejected the FDA’s attempt to preempt state law through its 2006 preamble. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1200-04 (2009). It did “not merit deference,” *id.* at 1201; its adoption was procedurally questionable, *id.*; and it was “at odds with what evidence we have of Congress’ purposes,” *id.*

<sup>3</sup> The 2000 proposed regulations on prescription drug labeling recognized this explicitly. The preamble stated: “FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.” 65 FED. REG. 81,082, 81,103 (Dec. 22, 2000).

**A. The civil justice system serves compensation and loss-spreading functions outside the scope of FDA regulation**

By compensating individuals harmed by drugs, tort law serves some ends that FDA regulation simply is not meant to serve. Most importantly, “preemption completely eliminates the corrective justice role that common law courts have played in this country since its founding.” THOMAS O. MCGARITY, *THE PREEMPTION WAR* 33 (Yale 2008). For much of this country’s history, the purpose of tort law was thought to be redressing moral wrongs, not regulation or deterrence. In the last half-century, it has come to be understood as also serving a regulatory function. But corrective justice or compensation remain important. See *Warriner v. Stanton*, 475 F.3d 497, 501 (3d Cir. 2007) (reaffirming that New Jersey’s tort policies consist primarily of compensation and deterrence); *Hannah v. Heeter*, 584 S.E.2d 560, 566 (W. Va. 2003) (“the three fundamentals of tort law are morality, compensation, and deterrence”) (internal quotation marks omitted). See generally Gary T. Schwartz, *Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice*, 75 TEX. L. REV. 1801 (1997). In Europe, civil liability generally is still understood to serve corrective justice. For this reason, there has been almost no movement in Europe to eliminate civil liability for

unreasonably dangerous products and to rely solely on administrative regulation of dangerous products.<sup>4</sup>

From the perspective of corrective justice, FDA approval of drug labeling is relevant only insofar as it establishes that a drug-maker is not morally blameworthy in failing to provide an additional warning. FDA approval of a label would be significant if the FDA advised a drug-maker that a particular warning was adequate regarding a specific risk. It would be decisive if the FDA forbade the drug-maker from providing an additional warning. Of course, neither of those is relevant in the present cases. Outside of those two situations, FDA approval is of no obvious relevance.

Compensation through strict liability also spreads losses. See, e.g., *New Texas Auto Auction Servs., LP v. Gomez De Hernandez*, 249 S.W.3d 400, 404 (Tex. 2008) (stating justifications for strict liability as “(1

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<sup>4</sup> The European Union (“EU”) generally has two tiers of administrative approval, at the EU level and the member-state level. See CHRISTOPHER HODGES, *EUROPEAN REGULATION OF CONSUMER PRODUCT SAFETY*, Ch. 4 (Oxford 2004). An industry position paper has cited “a very low level of compensation claims” as evidence of the success of the administrative system. *Id.* at 43. The 1985 European Directive on Product Liability § 4(1)(a) makes compliance with a regulation a defense. See SIMON WHITTAKER, *LIABILITY FOR PRODUCTS* 522 (Oxford 2005) (“This defence is not, of course, a defence of compliance with public standards (though such a defence has been suggested): it requires that the defect itself results from the regulatory standard.”).

compensating injured consumers, (2) spreading potential losses, and (3) deterring future injuries”); *Antone v. Greater Arizona Auto Auction*, 155 P.3d 1074, 1076 (Ariz. Ct. App. 2007) (“[T]he underlying justification for imposing strict liability is risk/cost spreading to those parties in the distribution chain that are best able to both bear the cost and protect the consumer from defective products.”), *review denied* (Ariz. Sept. 25, 2007). The loss-spreading justification is buttressed by the law and economics insight that the cost of accidents is minimized by imposing costs on “the ‘cheapest cost avoider’ or [the actor] who is in the best position to make the cost-benefit analysis between accident costs and accident avoidance costs and to act on that decision once it is made.” *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 548 (N.J. 1982) (citing Guido Calabresi & Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L.J. 1055 (1972)). See generally Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2071 (2000).

For a court or state legislature that held those views, an FDA cost-benefit determination would be irrelevant, even when the lawmaker is confident the FDA is right. *Schneider Nat’l, Inc. v. Holland Hitch Co.*, 843 P.2d 561, 580 (Wyo. 1992) (“The risk allocation concept means that strict liability is not based on ‘fault.’ Instead of considering each actor’s negligence or fault, the person most able to avoid accidents . . . is held liable for the cost of the accident.”) (citations omitted). The court or legislature would still want to

impose liability to spread losses resulting from risks that were worth taking.<sup>5</sup> Cf. *Bruesewitz v. Wyeth LLC*, No. 09-152, slip op. 3-5 (U.S. Feb. 22, 2011) (describing compensation system to spread losses resulting from vaccine risks). If the court or legislature thought there was a risk of regulatory error, then they would have an additional reason for imposing strict liability for it would increase their confidence that a company would warn of a risk if the benefits of the additional warning outweighed the cost.

The U.S. trend in products liability law has been away from strict liability and towards negligence-based liability, particularly for pharmaceutical design defects.<sup>6</sup> See Jane Stapleton, *Liability for Drugs in*

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<sup>5</sup> See *Wilson v. Piper Aircraft Corp.*, 577 P.2d 1322, 1333 (Or. 1978) (Linde, J., concurring) (“In a state where common law or legislation imposed absolute liability on a producer for certain kinds of harm in fact caused by his product, the fact that it had been thoroughly tested and approved for safety would be immaterial. But when liability is predicated on finding a design ‘dangerously defective,’ not ‘duly safe,’ or short of some similarly phrased standard of safety, then a careful comparison of that standard and the one attested to by the certificate becomes important.”).

<sup>6</sup> *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991), cites FDA regulation and the “unavoidably unsafe” nature of drugs as reasons not to impose strict liability. *Id.* at 90-92. This leaves to “courts to find liability under circumstances of inadequate warning, mismanufacture, improper marketing, or misinforming the FDA – avenues for which courts are better suited.” *Id.* at 99.

*the U.S. and EU: Rhetoric and Reality*, 26 REV. LITIG. 991 (2007).<sup>7</sup> But, as Professor Rabin has observed:

More than a half century after *Escola* [*v. Coca Cola Bottling Co.*, 150 P.2d 436 (Cal. 1944)], the courts still have not reached a consensus on which rationale [compensation or regulation] should prevail. The divide is defined by those courts (and commentators) that would limit design defect and inadequate warning liability to some version of risk-benefit analysis, contrasted with those that would recognize a consumer expectations rationale, as well.

Rabin, 88 GEO. L.J. at 2071.

In particular, while it is now a minority position, some courts apply the “hindsight test” to determine whether a product was defective or, in the case of an FDA-approved drug, whether there was inadequate

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<sup>7</sup> The gist of Professor Stapleton’s argument is that the Europeans should learn from the U.S. experience and move away from a view that, at least rhetorically, treats liability for defective products, including drugs, as being strict. The leading European case on the character of liability is *A v. National Blood Authority*, [2001] 3 All ER 289 (Q.B.). It involves claims by Hemophiliacs given transfusions of blood infected by Hepatitis C. The court held the defendant liable, although the defendant was not negligent in failing to screen against Hepatitis C given the state of the art when the claims arose. The court interpreted the Product Liability Directive as intended to “achieve a higher and consistent level of consumer protection throughout the Community and render recovery of compensation easier, and uncomplicated by the need for proof of negligence.” *Id.* at 310-11.

warning. The “hindsight test” assesses whether a product was defective – or, in the case of an FDA-approved drug, whether a warning was adequate – taking account of information that arose after a product was marketed. See *Sternhagen v. Dow Co.*, 935 P.2d 1139, 1147 (Mont. 1997); DAVID G. OWEN, PRODUCTS LIABILITY LAW § 8.7 (2005). A court that applies the hindsight test will hold a drug-maker liable if risks that became apparent only in hindsight warranted an additional warning. The court would not second-guess the FDA’s decision not to require a warning for the agency does not have the benefit of hindsight.

Congress could decide that the interest in compensation is insufficient to justify maintaining failure-to-warn liability as a complement to FDA regulation. Congress has not done so here. On the contrary, post-Vioxx legislation expressly ratifies a regulatory requirement that drug-makers warn the public of risks of which they are aware without waiting for FDA action.<sup>8</sup> This requirement is a linchpin of civil liability because it demonstrates that FDA-approved warnings are not a ceiling on a drug-maker’s duty to warn.

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<sup>8</sup> See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(a), 121 Stat. 823, 925-26 (codified at 21 U.S.C. § 355(o)(4)(I)) (“2007 FDA Amendments Act”).

**B. The civil justice system regulates decisions and activities outside the purview of the FDA's approval of a drug and its labeling**

Tort liability also has regulatory value. Sometimes it is a safeguard against regulatory failure. The FDA sometimes fails to protect the public from unreasonably dangerous drugs. The Vioxx experience is instructive:

The picture that the Vioxx experience paints of FDA regulation of pharmaceutical products is one of an agency that has been very accommodating to the regulated industry in approving new and potentially highly beneficial drugs but not especially adept at detecting adverse side effects once these drugs are in use. At the same time, the pharmaceutical industry has been very aggressive in pushing potential “blockbuster” drugs through the approval process, and it has not been particularly forthcoming with the agency and the public when it comes upon warning signs of potential adverse outcomes. . . . Dr. David J. Graham . . . called the Vioxx episode “a profound regulatory failure,” and he pessimistically concluded that “FDA as currently configured is incapable of protecting America against another Vioxx.”

MCGARITY, *supra* at 16.

Regulatory failure has many causes, some of which this Court recognized in *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 & nn.11-12 (2009). The FDA is

inadequately funded and staffed, it may be subject to regulatory capture, drug-makers may withhold relevant information, and they may resist FDA action. But even if the agency were adequately funded and staffed, and drug-makers always worked hand-in-hand with the agency to ensure the safety and efficacy of drugs, failure-to-warn liability would still be warranted to encourage drug-makers to warn about risks that are outside the purview of the FDA's decision when it approves a new drug and its labeling. For this reason, state courts and legislatures generally agree that regulatory approval of conduct should shield an actor from liability only regarding risks that were considered in approving the conduct. These reasons for maintaining failure-to-warn liability are independent of the quality of the FDA's analysis in approving a drug and its labeling.

- 1. The civil justice system creates the incentive system by which post-marketing risk information comes to light**

Approval of a new drug is typically based on limited clinical studies involving relatively small populations and relatively short time periods. "Once the drug enters the marketplace, risks that are relatively rare, that manifest themselves only after an extended period of time, or that affect vulnerable subpopulations, begin to emerge. These are often not risks foreseen by the drug's manufacturer or the FDA and, for that reason, are not addressed on the label."

David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 466 (2008) (footnote omitted). “[F]ully one-half the adverse effects of newly marketed drugs are not discovered until after the drugs have been on the market for a while.” MCGARITY, *supra* at 237-38.

Historically, the FDA has expended vastly more resources evaluating new-drug applications than monitoring adverse events for existing drugs. See Kessler & Vladeck, 96 GEO. L.J. at 485. Doctor Kessler and Professor Vladeck describe new tools and resources given to the FDA by the 2007 FDA Amendments Act to strengthen the agency’s post-approval surveillance. *Id.* at 487-90.<sup>9</sup> But they conclude “it remains to be seen whether this increased surveillance will help the agency to recognize emerging safety problems more quickly.” *Id.* at 490. Some problems are endemic. It is difficult for the FDA to assess adverse reaction reports when it “does not know how many people are using the drug or have information about their conditions.” *Id.* And it takes time for the FDA to take effective action, particularly if its information is inconclusive and a drug-maker resists.<sup>10</sup>

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<sup>9</sup> These include express statutory authority to update labeling and to order new clinical trials, something the FDA had done in the past depending on the cooperation of drug-makers.

<sup>10</sup> An FDA advisory panel recommended in early 2001 that the Vioxx label warn about the cardiovascular risk. This

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While concerns with post-marketing risk information are relevant for all drugs, the issue is particularly important for generic drugs. By definition, generic drugs are those that have been available in the marketplace for years, and are thus drugs for which post-marketing risk information is more likely to be significant.

## **2. The civil justice system regulates “off-label uses” that largely fall outside the scope of FDA regulation**

Drugs often are prescribed for “off-label use,” meaning a use not approved by the FDA. It is estimated that “40-60% of prescriptions were written for off-label uses” and that “50% of cancer treatment drugs, 80-90% of drugs used to treat rare diseases, and 80% of drugs used in the pediatric field are prescribed off-label to patients.” James O’Reilly & Amy Dalal, *Off-Label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs*, 12 ANNALS HEALTH L. 295, 298 (2003). The contentious issue regarding FDA

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recommendation was based on a study that showed a correlation but Merck argued there was another cause. “Merck vigorously resisted this suggestion, arguing that the gastrointestinal benefits of Vioxx outweighed any cardiovascular risk. After fourteen months of negotiations, Merck and the agency compromised” on a diluted warning. The FDA acted quickly to take Vioxx off the market once it received the results of a more conclusive study in September 2004. See MCGARITY, *supra* at 7-8.

regulation of off-label uses has been whether and to what extent drug-makers may promote off-label uses or educate physicians and the public about off-label uses. The FDA can warn about an unreasonably risky off-label use, and can ask a drug-maker to stop marketing a drug when it learns of unreasonably dangerous off-label uses. But this occurs after the fact, sometimes tragically so.

Fen-Phen is a case in point. Fenfluramine was combined with Phentermine to create a dietary suppressant that did not induce asleep. The popular press reported 1992 study results that found Fen-Phen users lost 30 pounds on average in 9 months. It was off to the races. By 1996, physicians had written over 5 million Fen-Phen prescriptions. The FDA never approved the combination. By the time the FDA asked Wyeth in 1997 to stop marketing Fen-Phen and a sister drug, Redux, an estimated 45,000 women had already been harmed. See Sue McGrath, *Only a Matter of Time: Lessons Unlearned at the Food and Drug Administration Keep Americans at Risk*, 60 FOOD & DRUG L.J. 603, 613-16 (2005); ALICIA MUNDY, DISPENSING WITH THE TRUTH (St. Martin's 2001).

Because Reglan and metoclopramide were approved only for short-term use, these cases involve an “off-label use” of a drug – indeed, a common “off-label use” that was well-known to the drug-makers.

### **3. The civil justice system regulates unexamined risks that the FDA never considered**

Petitioners and their supporting *amici* argue that respondents' failure-to-warn claims should be preempted based on the FDA's approval of Reglan's short-term use years before. Ultimately, the FDA examined the risks of long-term use of metoclopramide and in 2009 finally required a "Boxed Warning." See Resp. Br. 10-11 (describing warning). That action, of course, occurred several years after the events at issue here.

There is no suggestion that the FDA considered the risks of long-term usage when it approved Reglan. Indeed, its approval of the drug only for short-term use is clear evidence that it did not. There is accordingly no more reason to find preemption here on the basis of the FDA's approval of Reglan than there was to find preemption in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), when this Court refused to find preemption based on the FDA-approved labeling of Phenergan when the FDA had not considered the risks of IV-push administration of the drug.

## **II. Preemption of state-law tort claims based on FDA regulation of a drug is unnecessary because the civil justice system defers to FDA expertise and protects drug-makers from spurious claims**

Petitioners and their supporting *amici* seek to portray a range of terrible consequences if generic

drug-makers are held responsible under state tort law for their failures. Not surprisingly, in the real world – where state-law failure-to-warn claims have long been available – those consequences have not materialized. State courts and legislatures recognize the need for an appropriate balance. They recognize the great good that drugs can do but also the accompanying risks. And they respect the FDA’s expertise in regulating drugs and deciding which risks merit warnings. But they have steadfastly refused to grant total immunity to drug-makers from failure-to-warn liability in the absence of an FDA decision that the specific risk in question did not warrant warning. Only one state legislature, Michigan, has taken that step. Petitioners ask this Court to do something that neither Congress, nor any other state legislature, nor any state court has thought prudent.

**A. Tort law already defers to FDA’s expertise in drug approval**

Over the last half century, tort law has evolved to a position in which courts largely cede to the FDA the authority to decide whether a new drug should be allowed on the market. Drug-makers face a risk of liability only for failing to warn of a drug’s risks. Professor Owen summarizes the story:

Whether and how prescription drugs in particular should be treated differently from other types of products has consumed more time and effort, and resulted in the gnashing of more teeth, than about any other

particular issue in all of products liability law. In addition to featuring two prominent Restatement provisions – comment k to § 402A of the Restatement (Second) of Torts and § 6(c) of the Third Restatement, the drug design defect story wends through two of the most prominent cases in products liability law history – *Feldman v. Lederle Laboratories* and *Brown v. Superior Court*. The issue is complex, involving the learned intermediary doctrine, product category liability, state of the art, the battle for supremacy between the consumer expectations and risk utility tests of liability for design defectiveness, the never-ending struggle between negligence and strict liability, how design and warning defect notions fit together, federal preemption, and, at bottom, whether drugs in fact are different from other types of products, and whether they should be treated differently by products liability law.

OWEN, *supra* at 549.

Professor Owen refers to an ongoing debate over when and how FDA-approved drugs should be shielded from products liability claims in general and design-defect claims in particular. The issue emerges only after true strict liability (sometimes referred to as absolute liability) is rejected in favor of negligence-based liability. Once this choice has been made, drugs are the paradigmatic example of what has come to be called an “unavoidably dangerous” product. This is a product – like a cigarette, a gun, or a knife – that must be dangerous if it is to perform its intended

function. Products liability law generally is open to a claim that an unavoidably dangerous product should be designed more safely so it could serve its intended function with reduced risk.

Commentators debate whether the law should permit a claim that a product was so dangerous, and of so little utility, that it is wrong to sell the product even if it can be made no safer while performing its intended function. While that is hotly contested, there is a consensus that FDA-approved drugs should be shielded from both types of claims. The FDA, better than a judge or jury, can decide whether the benefits of a new drug sufficiently outweigh the risk to justify placing the drug on the market, and whether the design of a drug can be tweaked to realize the benefits with reduced risk.

The debate has been over precisely when and how an FDA-approved drug should be shielded from a design-defect claim. Cf. *Bruesewitz, supra*. Some courts adopted a categorical rule precluding design-defect claims for FDA-approved drugs. That approach was taken in *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988), and adopted in cases such as *Grundberg v. Upjohn Co., supra*.<sup>11</sup> Others took a case-by-case

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<sup>11</sup> The *Grundberg* court summarized the justification:

We find this extensive regulatory scheme capable of and appropriate for making the preliminary determination regarding whether a prescription drug's benefits outweigh its risks. The structured follow-up program imposed by law ensures that drugs are not

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approach under which the judge makes a preliminary determination whether a drug was defective as marketed or as designed. This is the approach taken in *Feldman v. Lederle Laboratories*, 479 A.2d 374 (N.J. 1984), and adopted and amplified in cases such as *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827 (Neb. 2000). This takes the issue out of the hands of the jury. The Restatement (Third) of Torts: Products Liability § 6(c) (1998) straddles the two approaches by allowing a claimant to proceed with a design-defect claim only if the foreseeable risks are so great, and foreseeable benefits so small, that no health-care professional would prescribe the drug “for any class of patients.” This “leaves a very small window for design defect claims for prescription drugs, a window so tiny that almost no drug claim could fit through it.” OWEN, *supra* at 557.

The upshot is that courts generally have ceded to the FDA the power to determine whether a new drug should be placed on the market as designed, so long as the drug-maker is not aware of risks that it fails to disclose to the FDA. While ceding this ground, courts have retained failure-to-warn liability. Thus, the

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placed on the market without continued monitoring for adverse consequences that would render the FDA's initial risk/benefit analysis invalid. Allowing individual courts and/or juries to continually reevaluate a drug's risks and benefits ignores the processes of this expert regulatory body and the other avenues of recovery available to plaintiffs.

813 P.2d at 97.

Utah Supreme Court observed in *Grundberg*, 813 P.2d at 99: “Relying on the FDA’s screening and surveillance standards enables courts to find liability under circumstances of inadequate warning, mis-manufacture, improper marketing, or misinforming the FDA – avenues for which courts are better suited.” This compromise facilitates getting new drugs to market while using failure-to-warn liability to encourage dissemination of information about risks to enable health-care professionals and the public to make informed decisions about drugs.

**B. This Court’s decision in *Daubert* and the “learned intermediary doctrine” protect defendants from unjustified liability**

Other judicially developed doctrines address specific policy arguments for preemption. One argument raises the specter of unsophisticated juries overriding the FDA based on junk science. Eighteen years ago, this Court, in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), interpreted Federal Rules of Evidence 702 to empower trial judges to screen proffered expert scientific testimony to ensure that the testimony meets basic standards of scientific validity and reliability. Professor Owen observes: “Post-Daubert, the federal district courts, exercising their newly appointed ‘gatekeeper’ function, have scrutinized expert testimony more closely, often holding rigorous pre-trial ‘Daubert hearings’ – that are often outcome determinative – to determine

the admissibility of proffered expert testimony.” David G. Owen, *A Decade of Daubert*, 80 DENV. U. L. REV. 345, 362 (2002). While counts vary, it is estimated that a majority of states now apply a similar standard. See OWEN, *supra* at 376.

Another argument raises the specter of drug-makers responding to the risk of liability by overwhelming consumers with warnings. This is avoided by the “learned intermediary” doctrine, which shields makers of prescription drugs from claims for failure to warn the public.<sup>12</sup> One codification of the doctrine states:

[A prescription] drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that [prescription] drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that [prescription] drug is to be given directly to the ultimate user of it.

Ohio Rev. Code Ann. § 2307.76(C).

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<sup>12</sup> “The doctrine was first recognized in case law over 50 years ago, and since that time has been recognized and applied in nearly all jurisdictions in the country.” Richard B. Goetz & Karen R. Growdon, *A Defense of the Learned Intermediary Doctrine*, 63 FOOD & DRUG L.J. 421, 421 (2008).

### **C. The regulatory compliance defense protects defendants from unjustified liability**

The American Law Institute (ALI), state courts, and state legislatures have grappled with whether and when civil courts and juries should defer to regulatory approval of allegedly negligent conduct in considering what has come to be called the regulatory compliance defense. A broad consensus holds that regulatory approval of conduct should shield an actor from negligence liability only if the regulator considered the specific risk in question when it approved the conduct.

#### **1. The evolving ALI views**

Over the last generation, the ALI has slowly moved towards a position that treats regulatory approval of allegedly negligent conduct as a basis for taking the issue of negligence away from the jury if the regulator considered the specific risk in question and decided that additional precautions were not worth taking.

While stating the traditional common-law position that statutes and regulations set a floor and not a ceiling on what is reasonable conduct, Restatement (Second) of Torts § 288C (1965) briefly acknowledges in Comment *a* the possibility that a court may treat a statute or regulation as determinative of what is reasonable conduct:

[A] legislative or administrative minimum does not prevent a finding that a reasonable man would have taken additional precautions where the situation is such as to call for them. . . . Where there are no such special circumstances, the minimum standard prescribed by the legislation or regulation may be accepted by the triers of fact, or by the court as a matter of law, as sufficient for the occasion. . . .

More recent Restatements expand on when a court may take the issue of the unreasonableness of conduct or the defectiveness of a product away from the jury because of legislative or regulatory approval of the conduct or product. Restatement (Third) of Torts: Products Liability § 4 (1998) explains in Comment e:

Occasionally, after reviewing relevant circumstances, a court may properly conclude that a particular product safety standard set by statute or regulation adequately serves the objectives of tort law and therefore that the product that complies with the standard is not defective as a matter of law. Such a conclusion may be appropriate when the safety statute or regulation was promulgated recently, thus supplying currency to the standard therein established; when the specific standard addresses the very issue of product design or warning presented in the case before the court; and when the court is confident that the deliberative process by which the safety standard was established

was full, fair, and thorough and reflected substantial expertise. Conversely, when the deliberative process that led to the safety standard with which the defendant's product complies was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that promulgated the standard or certified or approved the product, compliance with regulation is entitled to little or no weight.

Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 16 (2005), after canvassing the situations in which compliance is not a defense, explains in Comment *f* when compliance may be a defense:

*Statutory compliance as a limitation on liability.* While the Comments above explain the rule to the effect that compliance with statutes is usually no more than evidence of nonnegligence, the observations in the Comments suggest the rule's own limits. When the statute directly addresses the particular safety problem before the court, when the statutory scheme evidently seeks to identify all the precautions called for by the general negligence standards in § 3, and when the particular case involves no unusual circumstances, the court may conclude that the actor's compliance with the statute shows that the actor's conduct does not lack reasonable care. In reaching this conclusion, the court can take into account several factors,

including the evident thoroughness of the statute and the desirability of a uniform liability standard that can simplify litigation and provide parties with appropriate guidance as to what precautions are expected of them.

ALI's Reporters' Study, *Enterprise Responsibility for Personal Injury* (1991), goes furthest towards endorsing a strong defense of regulatory compliance. After stating that, at a minimum, regulatory compliance should create a presumption of non-negligence and should shield an actor from punitive damages, the study goes on to recommend "making regulatory compliance a complete bar to tort liability once certain carefully-defined conditions have been satisfied respecting the regulation." *Id.* at 110. One condition is that "[t]he agency must have addressed the specific risk at issue in the case at hand, and must have made an explicit judgment about what type of legal controls are appropriate." *Id.* That condition is not satisfied here because the FDA never addressed the specific risk of long-term use of Reglan or metoclopramide.

## **2. The regulatory compliance defense in the courts**

Courts endorsing a regulatory compliance defense limit it to cases in which the regulator considered the specific risk at issue when approving the challenged conduct. Justice Linde expressed the requirement pithily in a concurring opinion in *Wilson v. Piper Aircraft*, 577 P.2d at 1334-35:

[I]t should be defendant's burden to show that a governmental agency has undertaken the responsibility of making substantially the same judgment that the court would otherwise be called on to make; and if so, it should then be plaintiff's burden to show that the responsible agency has not in fact made that judgment with respect to the particular "defect" at issue.

One leading case, *Ramirez v. Plough, Inc.*, 863 P.2d 167 (Cal. 1993), involved a challenge to the labeling of a non-prescription drug. The plaintiff claimed it was negligent to market children's aspirin in California without a warning in Spanish of the risk of Reye's Syndrome. The California Supreme Court, affirming summary judgment for the defendant, found the FDA's decision not to require a Spanish-language warning conclusive on the issue of negligence: "[T]he FDA has concluded that despite the obvious advantages of multilingual package warnings, the associated problems and costs are such that at present warnings should be mandated only in English." *Id.* at 175.<sup>13</sup> In other words, court ruled for the defendant only because it concluded that the FDA

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<sup>13</sup> The bases for this conclusion were that the FDA required Spanish-language warnings on medicine sold in Puerto Rico and other territories where the predominant language was Spanish, 863 P.2d at 174, and the FDA had experimented with foreign-language package inserts but concluded that the cost outweighed the benefits, *id.* at 175.

had considered the relevant cost and benefits and decided the cost outweighed the benefits.

### **3. State legislation**

State legislatures have moved cautiously in making regulatory approval of conduct or a product a defense to a claim that the conduct was unreasonable or the product was defective. Regulatory approval of conduct or a product is generally relevant under state statutes only if the regulator specifically addressed the risk at issue in a case, and the approval creates only a presumption of non-negligence and non-defectiveness. Only Michigan has enacted a statute that shields a drug-maker from liability for failure to warn about risks that the FDA did not consider in approving a drug and its labeling. Some states have enacted statutes that make FDA approval of a drug and labeling a general shield to liability for punitive damages, even with regards to risks not considered by the FDA.

**Presumption of non-negligence and non-defectiveness.** A significant number of states have enacted statutes that provide for a rebuttable presumption of non-negligence and non-defectiveness if a regulator approves of conduct or a product. Some of the statutes are general while some apply only to FDA-approved drugs and labeling. See Ark. Code Ann. § 16-116-105; Colo. Rev. Stat. § 13-21-403; Fla. Stat. § 768.1256(1); Ind. Code § 34-20-5-1; Kan. Stat. Ann. § 60-3304(a) (enacting Model Uniform Product

Liability Act § 108(A)<sup>14</sup> verbatim); Mich. Comp. Laws § 600.2946(4); N.J. Stat. Ann. § 2A:58C-4 (warning or instruction in compliance with regulatory approval under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act); N.D. Cent. Code § 28-01.3-09; Tenn. Code Ann. § 29-28-104; Tex. Civ. Prac. & Rem. Code Ann. § 82.007.<sup>15</sup>

The rebuttable presumption is not toothless. *Schultz v. Ford Motor Co.*, 857 N.E.2d 977 (Ind. 2006), holds that the jury is told of the presumption. That invites the jury to defer to an agency if it is uncertain about whether a product was unreasonably dangerous. One court went further and endorsed instructing the jury that regulatory compliance is “strong and substantial evidence” of non-negligence and non-defectiveness. *Lorenz v. Celotex Corp.*, 896 F.2d 148, 149 (5th Cir. 1990) (Texas law).

Louisiana and Minnesota have not enacted such legislation. Even if one had, however, the presumption would not have applied in either of these cases because the FDA did not approve Reglan or metoclopramide for the long-term use on which respondents’ claims are based. The presumption applies only if “the specific injury causing aspect of the product

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<sup>14</sup> The Model Uniform Product Liability Act was published by the Department of Commerce in 1979. See 44 FED. REG. 62,714 (Oct. 31, 1979).

<sup>15</sup> Wash. Rev. Code § 7.72.050(1) merely provides that the trier of fact may consider evidence of compliance. This was to reverse a Washington case holding that the evidence was not admissible.

conformed to or was in compliance with the legislative or administrative regulatory standard.” *Alvarado v. J.C. Penney Co.*, 735 F. Supp. 371, 373 (D. Kan. 1990) (quoting comments to Model Uniform Product Liability Act § 108). See also *Ehlis v. Shire Richwood, Inc.*, 233 F. Supp. 2d 1189, 1198-99 (D.N.D. 2002) (holding the presumption does not apply to an “off-label” use because the use was not approved by the FDA), *aff’d*, 367 F.3d 1013 (8th Cir. 2004).

**A shield against punitive damages.** Several states statutorily shield drug-makers from punitive damages if a drug is manufactured and labeled in accordance with FDA approval. See Ariz. Rev. Stat. § 12-701; N.J. Stat. Ann. § 2A:58C-5(c); N.D. Cent. Code § 19-02.1-26(1); Ohio Rev. Code Ann. § 2307.80(C); Or. Rev. Stat. § 30.927; Utah Code Ann. § 78B-8-203. Typically, the shield is removed if a manufacturer knowingly withholds relevant information from the FDA. Unlike the presumption, these statutes do not require that the FDA have considered the specific risk at issue. See, e.g., Ariz. Rev. Stat. § 12-701.

**The Michigan statute.** In 1995, Michigan enacted a statute providing

a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration’s

approval at the time the drug left the control of the manufacturer or seller.

Mich. Comp. Laws § 600.2946(5). The statute was upheld in *Taylor v. SmithKline Beecham Corp.*, 658 N.W.2d 127 (Mich. 2003).

The statute is unique in its breadth. It shields a drug-maker from any liability based on a theory of negligence or products liability if the FDA approved the drug. Unlike the regulatory compliance defense and the rebuttable presumption statutes, the defense is not limited to claims involving risks actually addressed by the FDA. There is no exception for risks that appear post-marketing. And there is no exception for “off-label” uses the FDA never approved. The only exceptions in the statute are if (i) a company intentionally withholds information that it is required to submit under federal law that would have led the FDA not to approve the drug, or to withdraw approval, and (ii) an FDA official is bribed. Mich. Comp. Laws § 600.2946(5)(a)-(b).

### **III. This Court should leave it to Congress to craft appropriate preemption rules**

Preemption is not a simple either-or proposition. A narrow preemption rule is similar to a strong form of the regulatory compliance defense. It would make FDA approval of drug labeling determinative of non-negligence and non-defectiveness if the FDA considered the specific risk at issue in a case and concluded the labeling provided sufficient warning with respect

to that risk. A state could still impose strict liability that was independent of negligence in failing to give additional warning. In addition, liability would not be precluded if the FDA did not consider the relevant risk in approving the drug and labeling. Thus, a drug-maker would be subject to liability if (as in this case) it had reason to know the labeling was deficient based on post-marketing risk information (e.g., information demonstrating the risk of tardive dyskinesia associated with metoclopramide use) if the FDA had not yet considered whether that information justified additional warning. A drug-maker would similarly be liable for failure to warn about “off-label” uses not approved by the FDA (as in this case, since the FDA did not approve long-term use of metoclopramide). And a drug-maker would be liable if the FDA did not consider the specific risk at issue (as in this case). Additional exceptions might also be made for cases in which a drug-maker withholds relevant risk information to the FDA or unduly influences the FDA’s decision.

A broad form of preemption might be similar to the Michigan statute. It would shield a drug-maker from all claims regarding an FDA-approved drug and labeling so long as the drug-maker complied with the FDA’s orders. A claim would be precluded even if the FDA did not consider, and could not have considered, the relevant risk when approving labeling. While the Michigan statute makes exception for cases in which a drug-maker withholds crucial risk information, or

in which a drug-maker bribes an FDA official, one could dispense even with those exceptions.

Intermediate possibilities exist. For example, a narrow form of preemption could be supplemented by a rule precluding a state from imposing strict liability. Or drug-makers could be shielded from punitive damages.

Ideally, Congress or, in the absence of congressional action, state legislatures should choose among alternative preemption rules because the choice turns on fundamental questions of morality and policy on which there is deep disagreement, as well as contestable empirical assumptions. The choice only obliquely turns on views of the relative strengths and weaknesses of the FDA and courts in regulating drug warnings.

In particular, Congress can best weigh the interests in corrective justice and compensation, which justify civil liability, against the concerns for litigation cost and error, and the interest in national uniformity, which justify preemption. The political branches are also in the best position to give due weight to the fundamental federalism concerns that would be raised by any effort to preempt such basic and well-established state-law tort principles. Finally, institutional concerns point to Congress. Congress can legislate rules that resolve predictable boundary-drawing problems. This Court can resolve only the particular case before it. It would require a series of

cases to define even the most general contours of preemption.

A possible alternative might be to have the FDA rule on a case-by-case basis, as it approves a particular drug and labeling, whether, and the extent to which, preemption of civil liability is warranted. The agency has done this in the past by rulemaking in specific situations when it deemed it warranted.<sup>16</sup>

Congress should also decide whether a preemption rule applies retroactively or prospectively. It has long been understood that FDA approval of a drug and labeling does not shield a drug-maker from failure-to-warn liability, particularly for risks that the FDA did not consider in approving the labeling. This understanding may have helped persuade FDA officials to approve a drug and its labeling because they knew they were not solely responsible for protecting the public from unreasonably dangerous drugs. Certainly they would not have thought the legal system expected them to be omniscient and to anticipate post-marketing risks and off-label uses. Giving retroactive preemptive effect to decisions that were made in reliance on the understanding that they would not preempt state law is a radical step that warrants the kind of careful consideration that Congress is in the best position to provide.

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<sup>16</sup> Examples are collected at 71 FED. REG. at 3935.

**IV. Federal law does not alter the elements of a state-law failure-to-warn case by imposing an additional burden on respondents to disprove petitioners' defenses as part of their affirmative case**

Respondents have each brought a typical state-law failure-to-warn case. The elements of such a case are well established. Each respondent must show that she was injured by metoclopramide manufactured by the relevant defendant, that the metoclopramide was sold with inadequate warnings, and that her injuries were caused by the absence of adequate warnings. See, e.g., Restatement (Third) of Torts: Products Liability § 6 (1998); OWEN, *supra* § 11.4.

In Louisiana (the relevant state for respondent Demahy), legislation defines the elements of a product liability failure-to-warn claim against a manufacturer. See La. R.S. 9:2800.54 & .57. Under the applicable statute a “claimant bears the burden of establishing that the manufacturer did not use ‘reasonable care’ to provide the claimant, or another, with an adequate warning and that the failure to do so proximately caused the claimant’s injuries.” FRANK L. MARAIST & THOMAS C. GALLIGAN, JR., LOUISIANA TORT LAW 15-30 (2004 & Supp. 2010). Louisiana also recognizes and applies the “learned intermediary” doctrine. La. R.S. 9:2800.53(8); MARAIST & GALLIGAN, *supra* at 15-36. Thus, the Louisiana failure-to-warn claim is a garden variety failure-to-warn claim based in negligence (failure to use reasonable care) and requires that the plaintiff prove causation.

In Minnesota (the relevant state for respondent Mensing), a plaintiff in a failure-to-warn claim must similarly establish the defendant's knowledge of the dangers, that the warnings provided were inadequate, and that the lack of an adequate warning caused the plaintiff's injuries. See *Tuttle v. Lorillard Tobacco Co.*, 377 F.3d 917, 924 (8th Cir. 2004) (applying Minnesota law); *Erickson v. American Honda Motor Co.*, 455 N.W.2d 74, 77-78 (Minn. Ct. App. 1990).

The elements of a failure-to-warn case are so clearly established in Louisiana, Minnesota, and nationwide that petitioner Pliva concedes that "in a typical failure-to-warn case" a plaintiff "needs to show only that (a) the drug is responsible for his or her injuries and (b) the existing warning's alleged inadequacy proximately caused the drug use that precipitated those injuries." Pliva Br. 51.

Pliva seeks to avoid its concession by arguing that these are not typical cases, and that the intricacies of federal law impose an additional obligation on respondents to prove, as part of their affirmative case, what the FDA would have done if petitioners had recommended adequate warnings. See *id.* If Pliva is making an argument about preemption, it is incorrect under *Wyeth*. If Pliva is making an argument about state law and proving causation, it is both wrong and irrelevant.

Pliva's attempt to redefine the elements of a failure-to-warn case misstates products liability law in a fundamental way. As this Court clearly recognized in *Wyeth*, once a plaintiff has established an

affirmative case, the burden is on the defendant to show that under federal law it could not have complied with its state-law duty to warn. See 129 S. Ct. at 1198-99.

Pliva attempts to distinguish *Wyeth* with the argument that Wyeth could have complied with its state-law duty-to-warn requirement (using the CBE procedure) whereas petitioners here cannot comply (because the CBE procedure is claimed to be unavailable to them). See Pliva Br. 51. Even if the premise were correct, Pliva's argument is circular. The burden was on Wyeth because it was seeking to rely on an affirmative defense, not because this Court first concluded that it could comply with both federal and state requirements. Under Pliva's proposed rule, the allocation of the burden would depend on whether or not a party would be able to carry the burden.

Although *Wyeth* did not involve a generic drug, it is nevertheless instructive. This Court expressly noted that the FDA retained its authority to reject labeling changes made through the CBE procedure. Having noted that truism, the *Wyeth* Court continued:

[A]bsent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements. \* \* \* Wyeth has offered no such evidence.

*Id.* at 1198; see also *id.* at 1199 (“Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements.”). Thus the *Wyeth* Court did not require a plaintiff seeking to avoid preemption to prove that the FDA would have approved a CBE change. Here, requiring respondents to prove what the FDA would have done if the petitioners had recommended appropriate warnings or “Dear Doctor” letters would be akin to requiring the *Wyeth* plaintiff to prove the FDA would not have rejected a change in the Phenergan label. The Court did exactly the opposite.

Pliva also misconceives the nature of the causation inquiry. The burden is on each respondent to show a sufficient causal connection between the inadequate warnings and her own injury. Each respondent has made sufficient allegations to survive petitioners’ motions to dismiss or for summary judgment. Indeed, those motions do not deny the basic causal connection which involve issues of state tort law, not federal preemption. Petitioners do not argue that an adequate warning would have made no difference in how the physician prescribed the drug, which is the relevant causation inquiry. Rather, they argue that it would have been impossible for petitioners to give adequate warnings. Whether this is characterized as a preemption defense or a regulatory compliance defense, it is not an element as to which the plaintiff bears the burden under state law. Pliva points to no basis in federal law for its radical proposal to shift the burden to the plaintiff to disprove

the defendants' affirmative defenses as part of her affirmative case. Consistent with *Wyeth*, proof that the FDA would have rejected a recommendation to give an adequate warning is part of petitioner's affirmative defense. As in *Wyeth*, petitioners have "offered no such evidence." *Id.* at 1198.

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## CONCLUSION

The judgments of the Courts of Appeals for the Eighth and Fifth Circuits should be affirmed.

Respectfully submitted,

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March 2, 2011

## APPENDIX

More detailed biographical information about each of the *amici* is as follows:

Mary J. Davis is the Stites & Harbison Professor of Law at the University of Kentucky College of Law. She is co-author of a leading Products Liability case-book and is currently co-authoring a treatise in the field. She has written extensively on the topic of federal preemption of common law damages actions, particularly regarding products liability. She has taught torts and products liability for twenty years.

Dr. Heidi Li Feldman is a faculty member at Georgetown University Law Center. Since beginning her career as a law professor in 1991, she has taught torts; product liability; and tort law and federalism. Her scholarship includes articles on *Daubert* and the silicone breast implant litigation; issues of causation in mass torts; and the marketing practices of the pharmaceutical industry.

Thomas C. Galligan, Jr., is President and a professor at Colby-Sawyer College. From 1986 to 1998, he was a professor at LSU's Paul M. Hebert Law Center. From 1998 to 2006, he was the dean of the University of Tennessee College of Law. He is the author or co-author of many books and articles on torts and his scholarship has been extensively cited by courts and scholars. He has testified before Congress and the Louisiana legislature on issues related to torts and product liability.

## App. 2

Professor Mark P. Gergen currently teaches at Boalt Hall School of Law, University of California at Berkeley. He has taught and written on the entire spectrum of the law of obligations: contracts, torts, and restitution. He was the reporter for *Restatement (Third) of Torts: Economic Torts and Related Wrongs*.

Jon Hanson is the Alfred Smart Professor of Law at Harvard Law School, where he has been writing about and teaching courses on tort law and products liability law (among other topics) for the last twenty years.

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