No. 06-1498

IN THE
Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC
and PFIZER INC.,
Petitioners,
v.
KIMBERLY KENT, *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

BRIEF FOR RESPONDENTS

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January 11, 2008

QUESTION PRESENTED

A Michigan statute provides that a drug manufacturer is not liable to a patient injured by a drug if the FDA ("Food and Drug Administration") approved the drug for marketing and the drug and its labeling complied with the FDA's approval. The statute further provides that this defense does not apply if the defendant has intentionally withheld information from or misrepresented information to the FDA that was required to be submitted, and the FDA would not have approved the drug or would have withdrawn approval if the information had been accurately submitted. The question presented is

Whether federal regulation of drugs impliedly preempts application of the exception to the defense provided under the Michigan statute, while leaving the defense itself intact.

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INTRODUCTION

Traditional state tort law allows a manufacturer, alleged to have sold a defective product, to use compliance with federal standards or regulations as evidence that the product was not defective or that the manufacturer acted non-negligently. In most states, such evidence is not controlling. However, in 1995, Michigan enacted a statute providing that, with respect to drug manufacturers, federal approval and compliance with Food and Drug Administration ("FDA") approval requirements generally precludes liability for injuries caused by their products. The Michigan legislature chose not to extend this defense to situations in which it lacked confidence that the federal approval could be relied on as dispositive evidence that the manufacturer satisfied state-law duties of care. Accordingly, the statute also provides that, if a drug manufacturer did not comply with FDA disclosure requirements and the non-compliance affected the FDA's approval decision, the statutory defense does not apply.

Petitioner Warner-Lambert Company argues that the non-compliance exception to Michigan's statutory defense is preempted because it is premised on three showings or findings, each of which the company claims conflicts with the FDA's authority. Specifically, Warner-Lambert argues that the state law is preempted because it calls for consideration of what information the manufacturer was required to disclose and report, whether the company complied with those federal requirements, and whether the FDA would have refused to approve or withdrawn approval of the drug if the company had not misrepresented or omitted relevant information. The first two showings, however, are no different from those offered by *manufacturers* themselves in product liability cases involving injuries

caused by drugs, automobiles, and other regulated products. These two topics are also litigated in negligence per se cases, about which the Court in other federal preemption cases has expressed approval, not concern. The broad range of claims and defenses that have for decades involved the first two showings challenged by Warner-Lambert—and the notable lack of evidence that such claims and defenses have caused any impediment to the functioning of the federal regulatory scheme—belies Warner-Lambert's preemption argument as to these showings.

As for the finding of how the FDA would have reacted to a complete and honest disclosure, Warner-Lambert's argument turns on its misunderstanding that Michigan law is seeking to police compliance with FDA regulations. In fact, the statute seeks only to withhold a state-law defense from companies whose actions have negated the premise of the defense—that is, that regulatory approval provides a sound basis for concluding that a drug is not defective. Thus, contrary to Warner-Lambert's suggestion, a finding that the FDA would have withdrawn approval had the company made accurate disclosures is not equivalent to a finding that the company should be punished for lying to the agency. Rather, the finding only allows the case to pass the hurdle erected by the Michigan statute, so that the case may be litigated as a traditional common-law claim. Because the statute does not impose liability for "fraud on the FDA," Warner-Lambert's preemption arguments should be rejected.

STATEMENT OF THE CASE

The Regulatory Scheme

Under the Food, Drug, and Cosmetic Act ("FDCA"), a manufacturer seeking to market a new prescription

drug must first file a new drug application ("NDA") with the FDA. 21 U.S.C. § 355(a). The NDA must include, among other things, full reports of investigations conducted to determine the safety and effectiveness of the drug, a full description of manufacturing methods and controls for the drug, and samples of the proposed labeling to be used for the drug. *Id.* § 355(b)(1). The agency will approve the NDA unless it finds specified grounds for denying it, including that test results and other information fail to establish that the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," that there is a lack of "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," or that, "based on a fair evaluation of all material facts, such labeling is false or misleading in any particular." *Id.* § 355(d).

Because prescription drug labeling provides information used by clinicians to prescribe and administer an approved drug, the FDA's regulations describe in detail the proper form and content for labeling. *See generally* 21 C.F.R. Part 201. Once the agency approves a drug for marketing, the drug generally must be accompanied by labeling in the form approved by the FDA. *See* 21 C.F.R. § 314.70(b)(2)(v). However, a manufacturer must revise its labeling "to include a warning as soon as there is reasonable evidence of an association of a serious hazard" with the drug. *Id.* § 201.80(e). Some labeling changes require FDA pre-approval, but manufacturers are permitted to make revisions, without prior FDA approval, to

> add or strengthen a contraindication, warning, precaution, or adverse reaction; [and to] add or

> strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product[.]

Id. § 314.70(c)(6)(iii)(A), (C); *see also* 44 Fed. Reg. 37434, 37447 (1979) (revised warnings may be communicated by various means, including label changes and "Dear Doctor" letters).

"Many serious ADRs [adverse drug reactions] are discovered only after a drug has been on the market for years." Lasser, *et al.*, *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 JAMA 2215, 2218 (May 1, 2002). To monitor these adverse reactions, the FDA requires companies to submit an "adverse event report" within 15 days of a "serious and unexpected" experience. 21 C.F.R. § 314.80(c)(1). All other adverse drug experiences must be reported quarterly for three years after approval of an NDA and annually after three years have passed. *Id.* § 314.80(c)(2).

Factual Background

In July 1996, Warner-Lambert, through its Parke-Davis division, submitted to the FDA an NDA for a diabetes drug called troglitazone, to be marketed under the brand name Rezulin. Rezulin is in a category of drugs called glitazones. No other drug in that category had ever been approved by the FDA.

Even before Warner-Lambert submitted the NDA, it knew that the FDA was concerned about an association between Rezulin and liver toxicity. While aware as early as 1993 of Rezulin's potential harm to the liver, *see* Wilman, *Risk Was Known as FDA Okd Fatal Drug*, L.A. Times, Mar. 11, 2001, Warner-Lambert chose to omit

from its FDA submissions information that showed this concern to be valid.[1]

For example, at the FDA advisory committee meeting held in December 1996 to consider the Rezulin NDA, Randall Whitcomb, Warner-Lambert's vice president for diabetes research, stated that the occurrence of liver injury among Rezulin patients was "comparable to placebo." FDA, Transcript of Endocrinologic and Metabolic Advisory Committee Meeting, Dec. 11, 1996, at 152, *available at* http://www.fda.gov/ohrms/dockets/ac/96/transcpt/3255t2b.pdf; *see id.* at 147. In fact, the incidence of liver injury among patients who took Rezulin was more than three times higher than the incidence among patients who took a placebo. *See* Whitcomb & Watkins, *Hepatic Dysfunction Associated with Troglitazone*, 338 New Eng. J. Med. 916 (1998) (letter from Warner-Lambert acknowledging that clinical trial data showed Rezulin's association with liver injury); *Risk Was Known as FDA Okd Fatal Drug*, *supra* (quoting Whitcomb's deposition testimony in other cases). And although the company reported only one case of jaundice to the FDA Advisory Committee, it knew that at least four patients had suffered jaundice, and 12 had experienced potentially life-threatening liver toxicity. *Id.*; *see* Whitcomb & Watkins, *supra*, at 916. A physician who conducted early research on Rezulin

[1]The facts in the underlying cases were not developed below because the cases were dismissed on motions for judgment on the pleadings under Federal Rule of Civil Procedure 12(c), prior to litigation on the merits. The facts stated here—based on allegations in the complaints, publicly available sources, and two documents produced to lawyers in the multidistrict litigation of which respondents' cases are a part and filed as exhibits in other Rezulin cases—reflect what respondents will attempt to prove if the case proceeds.

later wrote that Warner-Lambert "deliberately omitted reports of liver toxicity and misrepresented serious adverse events experienced by [Rezulin] patients in their clinical studies." *Risk Was Known as FDA Okd Fatal Drug*, *supra* (quoting letter sent from company consultant to Senator Edward Kennedy).

In January 1997, the FDA approved Rezulin for use in combination with insulin or other diabetes drugs. JA 31. In May 1997, Warner-Lambert submitted a safety update indicating that, in liver function tests, no Rezulin patients showed liver enzymes in excess of three times the upper limit of normal.[2] JA 33. In August, approval was expanded to allow use of Rezulin as a stand-alone diabetes therapy. JA 32. The approval letter reiterated the reporting requirements imposed on manufacturers of approved drugs. *See* Letter from FDA to Parke-Davis Pharmaceutical Research, Aug. 4, 1997, *available at* http://www.fda.gov/cder/foi/nda/97/020720_s02_s03_s05ap.pdf. In October, an FDA medical officer complained to Warner-Lambert that, based on his review of clinical trial results, critical data about Rezulin's potential for liver toxicity had been omitted from the May report. JA 34. The company later admitted that 20 study participants had experienced liver enzyme elevations higher than it had reported to the FDA, including five whose elevated enzymes were significantly higher. *See* Whitcomb & Watkins, *supra*.

Although reports of serious adverse events started to flow in to the FDA, some FDA medical staff continued to support Rezulin. Rather than withdrawing approval, the FDA negotiated a series of labeling changes with Warner-Lambert, eventually resulting in five changes in

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[2] An elevated level of liver enzymes in the blood is an indication of liver damage.

the three years that the drug was on the U.S. market.[3] The first labeling change described the incidence of adverse effects on the liver as "rare." *See* Letter from Parke-Davis to Healthcare Professional, Oct. 28, 1997, *available at* http://www.fda.gov/medwatch/safety/1997/rezuli.htm (quoting labeling change). Each subsequent change recommended increasingly frequent liver monitoring.

On December 1, 1997, Glaxo Wellcome, which sold the drug in Britain, withdrew it from the market there because "the pace of liver injuries and deaths was by that point 'unacceptably high.'" JA 34-35. A few days later, as evidenced in an email produced in litigation (#QMET-022-0968), an FDA medical officer told Warner-Lambert that if the agency had known the true safety data when it was considering whether to approve Rezulin as a solo therapy, it would not have approved that use. That same month, the FDA requested that Warner-Lambert stop marketing Rezulin as a stand-alone therapy. *See* Wilman, *"Fast-Track" Drug to Treat Diabetes Tied to 33 Deaths*, L.A. Times, Dec. 7, 1998. Warner-Lambert resisted and did not do so until June 1999. *See* Letter from Parke-Davis to Healthcare Professional, June 17, 1999, *available at* http://www.fda.gov/medwatch/safety/1999/rezuhp.htm.

Warner-Lambert tried to conceal the extent of the danger posed by Rezulin not only from the FDA, but from physicians as well. For example, in February 2000, Warner-Lambert released a statement claiming that it believed that no liver-failure deaths were attributable to

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[3] At that time, the FDA did not have authority to dictate labeling changes. The statute has since been amended to augment the FDA's authority in this regard. *See* Pub. L. No. 110-85, 121 Stat. 823, § 901 (Sept. 27, 2007), *to be codified at* 21 U.S.C. § 355(o)(4).

Rezulin after the June 1999 label change. *See* Warner-Lambert, *Warner-Lambert responds to recent Rezulin media reports* (Feb. 24, 2000), *available at* http://web.archive.org/web/20001204094600/www.warnerlambert.com/press/release.asp?release=106. The FDA discredited that statement the next day, pointing to six instances of liver failure that post-dated June 1999, three of which resulted in the patients' deaths. Wilman, *Update*, L.A. Times, Feb. 29, 2000 (quoting FDA spokesperson).

In March 2000, Warner-Lambert stopped selling Rezulin in the United States altogether. HHS News, *Rezulin to be Withdrawn from the Market* (Mar. 21, 2000), *available at* http://www.fda.gov/bbs/topics/NEWS/NEW00721.html.

When the FDA was considering the Rezulin NDA and during the period when the drug was on the market, the FDA was aware that Rezulin presented potential risks. However, as one FDA medical officer noted in an email produced in the MDL (#REZ1006968), "one would have had to be 'clairvoyant' to predict the risk of liver failure from the NDA data, given the manner in which [the company] represented those data."

Respondents include 13 patients who suffered serious liver damage as a result of taking Rezulin, the estates of 6 patients who died from liver damage, and the spouses of 8 of these 19 patients. All respondents are Michigan residents.

The Michigan Statute

Respondents are plaintiffs in four separate suits, all brought in the Eastern District of Michigan but transferred to a multidistrict litigation in the Southern District of New York. *See* 28 U.S.C. § 1407. Throughout

litigation of the MDL and other Rezulin lawsuits, Warner-Lambert's defense has relied heavily on the FDA's approval of Rezulin, the company's interactions with the FDA, and its submissions to the FDA. For the MDL plaintiffs from Michigan, this defense poses a particular challenge.

Before 1995, Michigan allowed defendant-manufacturers in product liability cases to present evidence of compliance with government standards. Such compliance was admissible but not conclusive evidence that the defendant had acted non-negligently or that its product was not defective. *Owens-Allis Chalmers Corp.*, 325 N.W.2d 372, 375-76 (1982) (discussing then-current version of Mich. Comp. Laws § 600.2946). That approach is still followed in the vast majority of states. *See Restatement (Third) of Torts: Prods. Liab.* § 4 Reporters' Note, cmt. e (1998) ("*Restatement (Third)*").

In 1995, Michigan amended its product liability law to address drug manufacturers' liability in particular. The law now provides that evidence of FDA approval and compliance with the terms of the approval bars a claim for negligence or product defect, unless the drug was sold after the FDA withdrew approval. Mich. Comp. Laws § 600.2946(5); *see Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003) (statute provides "absolute defense to a products liability claim if the drug and its labeling were in compliance with the FDA's approval"). The Michigan statute contains two exceptions:

> This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
>
> (a) Intentionally withholds from or misrepresents to the United States food and drug administration

> information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.
>
> (b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

Mich. Comp. Laws § 600.2946(5) (citations omitted).

In providing a compliance-based defense, this statute is little different from the product liability law in most states, where a defendant may use compliance with federal law as evidence that a product was not defective. *Restatement (Third)* § 4 & Reporters' Note cmt. e. However, unlike in most jurisdictions, in Michigan that evidence is dispositive in a case against a drug manufacturer, unless the plaintiff can show either bribery or that the company did not disclose required information to the FDA and that, had it done so, the agency would not have approved or would have withdrawn approval of the product.

Proceedings Below

In the multidistrict litigation below, Warner-Lambert raised the defense set forth in the Michigan statute and moved to dismiss the Michigan cases on the ground that the paragraph (a) rebuttal to the statutory defense was impliedly preempted under the reasoning of *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and was severable from the rest of the statute. The district court agreed with Warner-Lambert and dismissed the Michigan cases. Pet. App. 38a.

On appeal, the Second Circuit reversed, finding that *Buckman* did not control the case and that the exception to the Michigan defense was not impliedly preempted. In *Buckman*, this Court considered whether the Medical Device Amendments to the FDCA impliedly preempt a state-law claim for "fraud on the FDA." There, plaintiffs injured by bone screws had alleged that the defendant had misrepresented the intended use of the screws to the FDA and that, had the defendant disclosed the actual intended use, the FDA would not have granted permission to market the product. The plaintiffs had contended that the fraud on the agency caused their injury and was itself actionable under state tort law. 531 U.S. at 343.

In this case, the Second Circuit first explained that the analysis here differs from that in *Buckman*. In *Buckman*, the presumption against preemption did not apply to a claim premised entirely on fraud on the agency because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." Pet. App. 16a (citing 531 U.S. at 347). In contrast, the Second Circuit noted, the Michigan statute does not create a new cause of action for fraud on the agency but rather places a condition on victims' ability to recover under preexisting state tort law—the very type of traditional state law at the heart of the presumption against preemption.

Turning to the merits of the preemption issue, the court of appeals found three meaningful differences between a rebuttal to a defense to claims under traditional state tort law and the fraud-on-the-FDA claim at issue in *Buckman*. First, the "source and 'vintage'" of the duty that the defendant is accused of breaching in tort cases such as this one are different from the source and vintage of the duty at issue in *Buckman*. Pet. App.

20a (quoting *Buckman*, 531 U.S. at 352). Here, the state-law duties on which the plaintiffs premise their claims are all duties traditionally recognized by the common law; none is a "newly-concocted duty between a manufacturer and a federal agency." *Id.*

Second, in a fraud-on-the-FDA claim, proof of fraud is alone sufficient to impose liability because there are "no freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements." *Id.* 20a-21a. Thus, in *Buckman*, the fraud claims existed solely by virtue of the FDA disclosure requirements. In fact, on that basis, *Buckman* had expressly distinguished *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), in which the Court held that state product liability claims against a medical device manufacturer were not preempted, including claims premised on common-law duties that paralleled federal duties. Pet. App. 21a (citing *Buckman*, 531 U.S. at 352-53). Similarly, the Second Circuit reasoned, the complaints in this case allege "violations of common-law duties long-recognized by Michigan's tort regime." *Id.* "The pre-existing claims survive M.C.L. § 2946(5) because there is also evidence of fraud in FDA disclosures. But, unlike in *Buckman*, they are anything but solely based on the wrong of defrauding the FDA." *Id.*

Third, the Second Circuit observed that proof of fraud is not an element of a tort claim in Michigan and becomes relevant only if the drug manufacturer-defendant asserts FDA approval as a defense. Pet. App. 23a (citing *Taylor*, 658 N.W.2d at 131). Indeed, it is the defendant that first raises the issue of the FDA's findings and actions, in contrast to a fraud-on-the-agency claim, where the plaintiff injects the administrative proceedings into the litigation.

Finally, the Second Circuit cautioned against the breadth of Warner-Lambert's preemption argument. "Finding preemption of traditional common law claims where proof of fraud is not even a required element—but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law—would result in preemption of a scope that would go far beyond anything that has been applied in the past." Pet. App. 24a. Without explicit direction from Congress, the court was unwilling to invalidate "state common law claims merely because issues of fraud may arise in the trial of such claims." *Id.*

SUMMARY OF ARGUMENT

I. This case involves the scope of a state-law defense to traditional tort claims. The Michigan statute that establishes the defense and the showing needed to rebut it are elements of Michigan's tort system, which is not aimed at policing conduct before the FDA, but at redressing violations of duties of care owed by manufacturers to consumers. As *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), *Medtronic v. Lohr*, and other of this Court's cases make clear, where the state is exercising its historic authority to protect the health and safety of its citizens, a presumption against preemption applies.

II. In *Buckman*, this Court held that a state-law "fraud-on-the-FDA" claim conflicts with FDA regulation and, therefore, is impliedly preempted by federal law. "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." 531 U.S. at 348. That balance, the Court explained, "can be

skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* Here, respondents have not alleged a "fraud-on-the-FDA" claim. Rather, they seek to pursue only traditional damages claims based on tort theories that predate the federal drug laws. Such claims do not trigger the concerns at issue in *Buckman*. *See id.* at 352 (distinguishing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), on the ground that the claim in that case was based on traditional state tort law).

Relying primarily on *Buckman*, Warner-Lambert argues that the exception to § 600.2946(5) for instances in which a drug manufacturer has misled the FDA or failed to make required disclosures is subject to either field or conflict preemption. The company contends that consideration of evidence about what a manufacturer was required to disclose to the FDA, evidence showing whether a manufacturer complied with those requirements, and evidence about how the FDA would have reacted to honest and complete submissions each intrude on or pose an obstacle to the exercise of the FDA's authority. The first two showings, however, are unremarkable elements of a range of litigation—from negligence per se cases against regulated companies, to criminal cases against such companies. Moreover, the two showings are standard elements of the regulatory compliance defense available to manufacturers in product liability cases in all 50 states. The regularity with which these showings are made in state-law tort litigation—including by Warner-Lambert—belies the preemption claim.

As for the finding about how the FDA would have reacted if the company had made honest submissions, Warner-Lambert's preemption argument turns on the misunderstanding that Michigan is attempting to police compliance with FDA regulations. The Michigan

statute, however, is not an effort to enforce FDA regulations. Rather, the paragraph (a) deceit exception, like the paragraph (b) bribery exception, represents a decision to withhold a statutory defense where the premise of the defense—that FDA approval represents a fair and expert finding of safety and effectiveness—does not apply. Put differently, § 600.2946(5) reflects Michigan's judgment that a drug is not defective, as a matter of law, if it has FDA marketing approval, but that if circumstances, such as misrepresentation or bribery, eliminate the state's confidence that the approval can be relied on as dispositive evidence that the manufacturer satisfied state-law duties of care, then the state will not conclusively deem the product to be non-defective or the manufacturer's conduct to be non-negligent.

Warner-Lambert also relies on purported burdens imposed by the Michigan law. Yet the overwhelming majority of jurisdictions have long allowed manufacturers to show compliance with federal regulations as evidence of non-defect or non-negligence and allowed plaintiffs to rebut that evidence. This traditional framework would seem to raise the same risk of obstacles and burdens as Warner-Lambert describes with respect to the Michigan statute, but no obstacles or burdens have materialized.

III. If the Court holds that some or all of the paragraph (a) exception to § 600.2946(5) is preempted, the case must be remanded to allow the court below to consider whether the preempted portion is severable from the rest of the statute. This issue, which was briefed and argued below, presents a question under Michigan state law. Warner-Lambert did not include it in the question presented, but suggests in its brief that the Court reach out to decide it by deferring to the Sixth Circuit's decision in *Garcia v. Wyeth-Ayerst Labora-*

tories, 385 F.3d 961 (6th Cir. 2004), which held that paragraph (a) of § 600.2946(5) was preempted in most instances and was severable from the rest of subsection (5). However, whether this Court or the Second Circuit should defer to the Sixth Circuit's decision on this issue is not before the Court and is properly left to the Second Circuit on remand.

ARGUMENT

I. A PRESUMPTION AGAINST PREEMPTION APPLIES HERE.

This Court's decisions have repeatedly emphasized that "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Medtronic*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). In considering whether the first exception to Michigan's FDA-approval defense is impliedly preempted by federal law, the Second Circuit properly took as its starting point that "the presumption against federal preemption of state law obtains in the case before us." Pet. App. 18a.

A. Relying on *Buckman*, Warner-Lambert and its amici contend that the presumption does not apply here because, they say, the state has strayed beyond its traditional police-power role of creating remedies for people injured by unsafe products. They claim that the state has instead attempted to interfere with "the relationship between a federal agency and the entity it regulates," *Buckman*, 531 U.S. at 347, and hence, that no presumption against preemption applies.

As the Second Circuit recognized, Warner-Lambert's argument ignores fundamental differences between the claim in *Buckman* and the conditional defense made available by the Michigan law. The claim in *Buckman* was premised on the alleged violation of a duty owed to the FDA, not to the plaintiff. As this Court explained, the essence of the claim was that the manufacturer had "made fraudulent representations to the [FDA] in the course of obtaining approval to market" its products, *id.* at 343, and the Court thus aptly and repeatedly described the purported cause of action as a "'fraud-on-the-FDA claim." *Id.* at 347, 348, 350, 351. Such claims, the Court held, are not entitled to a presumption against preemption because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Id.* at 347 (quoting *Rice*, 331 U.S. at 230); *see also id.* at 353 (plaintiffs not "relying on traditional state tort law which had predated the federal enactments"). At the same time, *Buckman* expressly distinguished cases, such as *Silkwood*, 464 U.S. 238, in which issues of federal regulatory compliance arise in the context of state-law personal injury actions based on "traditional state tort law principles of the duty of care owed by" the defendant to the plaintiff. *Buckman*, 531 U.S. at 352; *see also id.* (distinguishing *Medtronic*, 518 U.S. at 481, in which the "claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements").

Here, unlike in *Buckman*—but as in *Silkwood* and *Medtronic*—the state law at issue is not an attempt to "police" conduct before the federal agency. Rather, the law is part of a traditional state tort system aimed at redressing violations of duties of care owed by drug manufacturers to the individuals who use their

products. The underlying basis of the claim against Warner-Lambert is its breach of the common-law duty of care. The challenged statute creates a defense (compliance with federal licensing requirements) to what might otherwise be a breach of that duty of care (marketing an unsafe product), and then limits that defense so that it is not improvidently extended to a defendant that did not in fact comply with the federal requirements. In other words, the law in question is neither aimed at regulating the conduct of manufacturers before the agency, nor premised on an underlying duty to comply with federal law. Rather, the Michigan law circumscribes the availability of a defense to an action aimed at enforcing state common-law duties devised to protect the health and safety of the public.

As Warner-Lambert points out, the preemption argument here does not directly target the underlying tort claim, but rather the bounds of the state-law defense. However, as reflected by the *Restatement (Third)* § 4(b) and comment e, regulatory compliance defenses, and their limitation to cases in which the regulatory process is not "tainted" by the defendant's fraud, misconduct, or violation of regulatory requirements, are a traditional component of state tort-law systems. The existence of such defenses (and of conditions or limitations on them) does not transform the state's law into an improper effort to interfere with the federal regulatory regime any more than would state tort-law duties that parallel federal regulatory requirements, such as those that the Court unanimously approved in *Medtronic*, 518 U.S. at 495; *id.* at 513, and *Bates*, 544 U.S. at 447. Because the purpose and function of the state law, as in *Silkwood*, *Medtronic*, and *Bates*, is not to enforce duties owed to federal agencies, but rather to determine the availability of a remedy for common-law duties

owed by the defendant directly to the plaintiff, the presumption against preemption should apply here, as it did in those cases.

To be sure, application of the presumption against preemption does not turn on the subjective motivation of state lawmakers. *See* Pet. Br. 39. But viewed objectively, the "function," "operation," and "effect," *id.*, of the Michigan law are entirely different from those of the purported "fraud-on-the-FDA" claim in *Buckman*. Unlike that claim, the function of which was to enforce duties derived entirely from the federal-law regulator-industry relationship, the law here functions solely to limit liability for a breach of a traditional state-law tort duty. There is no basis for displacing the well-established presumption against federal preemption of such laws.

B. This Court has repeatedly applied the presumption against preemption to claims of implied conflict preemption, as well as implied field preemption and express preemption.[4]

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[4]*See, e.g.*, *Pharm. Research & Mfrs. Ass'n v. Walsh*, 538 U.S. 644, 661-62 (2003) (plurality opinion of Stevens, J., joined by Souter, Ginsburg & Breyer, JJ.) (in implied preemption case, starting with "presumption that the state statute is valid"); *id.* 680 n.4 (opinion of Thomas, J., concurring) (agreeing that presumption applied to implied preemption claim); *Johnson v. Fankell*, 520 U.S. 911, 918 (1997) (applying "our normal presumption against preemption" to claim that state statute barring interlocutory appeals impliedly conflicted with policies of 42 U.S.C. § 1983); *English v. General Elec. Co.*, 496 U.S. 72, 90 (1990) ("The 'teaching of this Court's decisions . . . enjoin[s] seeking out conflicts between state and federal regulation where none clearly exists.' *Huron Portland Cement Co. v. Detroit*, 362 U.S. 440, 446 (1960)."); *see also Medtronic*, 518 U.S. at 485 ("In all pre-emption cases, . . . we 'start with the assumption that the historic police powers of the States were

(continued...)

Nonetheless, amicus curiae Chamber of Commerce, but not Warner-Lambert or the United States, argues that the presumption against preemption should not apply in implied conflict preemption cases. The Chamber cites no authority rejecting application of the presumption in such cases. It relies principally on decisions that simply did not repeat that the presumption applied when they turned to address the issue of implied conflict preemption. *See* Chamber Br. 10 n.7.[5]

Moreover, the type of conflict preemption alleged here—where the defendant claims that the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), but does not claim that it is impossible to comply with both state and federal law—is very similar to field preemption in that it calls for a relatively open-ended assessment of the relationship of state law to allegedly

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[4](...continued)
not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'"). Five members of the Court in *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88 (1992) similarly made clear that the presumption applies to implied conflict preemption cases. *See id.* at 110 (Kennedy, J., concurring); *id.* at 115-16 (Souter, J., dissenting).

[5]The Chamber cites *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), in which the opinion of the Court did not discuss the presumption, apparently because it was overcome by a clear conflict between state law and federal policy. The Chamber (at 12) wrongly suggests that *Geier* stands for the proposition that the presumption has "no relevance to a conflict preemption analysis." However, the portion of the opinion on which the Chamber relies is not discussing the presumption, but rather the argument that, because the Motor Vehicle Safety Act contains a savings clause, a "special burden" should be imposed on automakers claiming preemption in tort claims. *Geier*, 529 U.S. at 872-74 (rejecting argument made by dissent at 898).

overriding federal policies that are implicit in what Congress has done. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000); *see also*, *e.g.*, *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 615-16 (1991) (holding that reasons for rejecting field preemption claim also dictate rejection of claim of implied conflict with objectives of federal legislation); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65-70 (2002) (weighing similar policy considerations in assessing conflict and field preemption). In fact, Warner-Lambert concedes that it makes little or no difference whether its argument is labeled one of "narrow" field preemption or conflict preemption. Pet. Br. 21-22. Therefore, just as in implied field preemption cases, the Court should be reluctant to infer a preemptive federal policy in cases involving claims of "obstacle" preemption in the absence of either express preemptive language or the impossibility of compliance with both state and federal law.

II. FDA REGULATION DOES NOT PREEMPT § 600.2946(5)(a).

A. *Buckman* Does Not Control The Outcome Here.

In *Buckman*, the plaintiffs' theory was that, without the fraudulent representation of the manufacturer's consultant Buckman, the FDA would not have cleared the device for marketing, the manufacturer therefore would not have had access to the market to promote its device for an unapproved use, and the plaintiffs then would not have suffered injury from the unapproved use of the device. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 827 (3d Cir. 1998). Holding that this "fraud-on-the-FDA" claim was preempted, this Court stated: "The conflict stems from the fact that the

federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Buckman*, 531 U.S. at 348. Summing up its reasoning, the Court stated: "[W]ere plaintiffs to maintain their fraud-on-the agency claims here, they would not be relying on traditional state tort law [that] had predated the federal enactments in question. On the contrary, the existence of these federal enactments is a critical element in their case." *Id*. at 353.

The same cannot be said here. First, respondents' claims, if successful, would not "punish and deter fraud against" the FDA. Rather, as in *Medtronic*, respondents' claims "arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not from the violation of FDCA requirements." *Id*. at 352. Second, the claims at issue existed prior to the FDCA and exist apart from the FDCA. The complaints do allege that Rezulin would not have been approved for sale if Warner-Lambert had not concealed from or misrepresented information to the FDA, but those allegations are for the purpose of rebutting the defense provided by § 600.2946(5), not for the purpose of seeking to impose liability for fraud on the agency. That is, the company's conduct with respect to the agency is at issue in the case, not because of the common-law claims alleged, but because the company has asserted FDA approval as a defense to liability under state law. *See Taylor*, 658 N.W.2d at 131 (§ 600.2946(5) provides defense to product liability claim). *Buckman* simply does not address this situation.

Warner-Lambert (at 45) incorrectly suggests that the elements of the claim alleged in *Buckman* "mirror" the elements that respondents must prove to prevail in their lawsuits here. In *Buckman*, however, the plaintiffs did not allege or seek to prove against Buckman the traditional elements of a common-law tort claim—a design defect, a failure to provide adequate warnings about risks associated with product, or a breach of warranty. Here, by contrast, respondents will not prevail unless they can prove the elements of those traditional claims —including existence of the relevant duties, breach of the duties, and injury resulting from the particular defects or breaches. *See* Pet. App. 336a, 343a, 353a; JA 35-38, 43.

Accordingly, a finding that the company had obtained FDA approval for Rezulin through misrepresentation or omission would not, as in *Buckman*, be a finding of liability. Rather, its effect would be only to put the case back in the position it would have been in had Warner-Lambert not invoked § 600.2946(5). For this reason, the concerns articulated in *Buckman*—that only the FDA should have responsibility for policing its approval process and for determining the appropriate sanction for failures to comply with FDA requirements—do not apply here.

B. The Exception To Michigan's Statutory Defense Is Not Impliedly Preempted.

That *Buckman* does not control here does not fully answer the question whether respondents' rebuttal to Warner-Lambert's FDA-compliance defense is preempted. The answer to that question is no. Warner-Lambert contends, however, first, that the FDA occupies the field of regulating compliance with federal disclosure obligations and that the Michigan statute

intrudes on this field, and, second, that the Michigan statute presents an obstacle to the uniform enforcement of the FDCA. Neither contention is correct.

1. Warner-Lambert argues that only the FDA can enforce compliance with the disclosure obligations imposed on drug companies, and that Michigan law requires three showings that intrude on the FDA's "field": (1) a showing of what Warner-Lambert was required to disclose to the FDA under the relevant federal standards, (2) a showing that the company failed to submit or misrepresented information required under the FDCA and applicable regulations, and (3) a showing that the FDA would not have approved the drug or would have withdrawn approval if the company had not withheld the information. According to Warner-Lambert (at 25, 28), each of these three showings is preempted because each involves the interpretation and application of federal statutes and regulations that are subject to exclusive federal oversight.

To begin with, this Court has long recognized the viability of state-law claims premised on the failure to comply with federal regulations. Thus, for example, in *Bates*, the Court unanimously held that "States are free to impose liability predicated on a violation of the federal standards" set forth in the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). *Bates*, 544 U.S. at 455 (Thomas, J., concurring in part and dissenting in part); *accord id.* at 447 (majority opinion). And the Court explained that a state-law duty equivalent to a federal duty "need not be phrased in identical language as its corresponding [federal] requirement." *Id.* at 454. Likewise, in *Medtronic*, the Court unanimously held that state-law claims that seek to enforce common-law requirements that parallel federal requirements are not preempted under the express preemption provision

of the Medical Device Amendments of 1976. 518 U.S. at 495; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

Although these cases involved interpretation of express preemption provisions, they are relevant here because one cannot show that state and federal requirements are equivalent without showing what the federal requirements are and what the defendant was required to do to satisfy them. Yet in neither case did the Court express any concern that such a showing would intrude on an occupied federal field or pose an obstacle to the operation of the federal regulatory scheme. To the contrary, in *Medtronic*, Justice O'Connor observed that "[w]here a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement 'different from or in addition to' requirements under federal law," and she noted no concern about the continued viability of such state-law claims. 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part); *see id.* at 495 (majority opinion). And in *Bates*, the Court observed that "[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of" the Federal Insecticide, Fungicide, and Rodenticide Act. 544 U.S. at 451.

Second, states have long allowed negligence per se claims premised on violations of federal law—which is essentially what *Bates* and *Medtronic* countenanced—and those claims necessarily require showing both what the federal requirements are and whether the defendant-company satisfied them. This Court, however, has expressed no concern about any "intrusive" effects of such claims. For example, in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308 (2005), the Court noted that "in garden variety state tort

law," "[t]he violation of federal statutes and regulations is commonly given negligence per se effect." *Id.* at 318 (citing *Restatement (Third) of Torts* § 14, Reporters' Note, p.195 cmt. a, Tent. Draft No.1 (Mar. 28, 2001)). And the Court noted that some states "treat a violation of a federal statute as evidence of negligence or . . . as creating a rebuttable presumption of negligence. Either approach could still implicate issues of federal law." *Id.* at 319 n.6 (citation omitted). While recognizing the "garden variety" nature of these claims, the Court expressed no concern about their viability or effect on the federal regulatory schemes. *See also Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804 (1986) (negligence per se claim against drug manufacturer based on manufacturer's violation of FDCA).[6]

Similarly, some federal-law cases require the sort of findings that Warner-Lambert contends intrude on the FDA's exclusive domain. For example, juries make fact findings in criminal prosecutions for violations of the FDCA and in civil cases stemming from FDA enforcement actions. *See* 21 U.S.C. §§ 331(b), 332, 334(b). And in patent litigation between private parties, a patent may be held unenforceable based on the holder's "inequitable conduct," a judicially created doctrine that turns

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[6]In *Merrell Dow*, which rejected federal question jurisdiction over a negligence per se claim premised on a violation of the FDCA, the Court noted that the petitioner's argument was, in effect, that the FDCA preempted state-court jurisdiction over the dispute. However, the Court quickly dismissed that argument. 478 U.S. at 815 & n.13. The dissenting Justices suggested that a negligence per se claim might be preempted, not because the claim would interfere with FDA regulation, but because a decision by Congress not to create a private cause of action might be intended to preclude private enforcement. *Id.* at 831 (Brennan, J., dissenting). *Bates* and *Medtronic* effectively—and unanimously—reject that suggestion.

on factual findings that the holder failed to disclose material information or submitted false material information with an intent to mislead the Patent and Trademark Office. *See Old Town Canoe Co. v. Confluence Holdings Corp.*, 448 F.3d 1309, 1332 (Fed. Cir. 2006); *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998).

Third, the Michigan statute only comes into play when the manufacturer asserts that it received FDA approval to market its drug and that it complied with the terms of that approval at the time the drug left its control. Mich. Comp. Laws § 600.2946(5). But to show that it complied with the terms of approval, the manufacturer must first show what obligations the FDA and the FDCA imposed on it when its drug was approved, and then show that it complied with those obligations. *See, e.g.*, Pet. Br. 13-14; *see also* Letter from FDA to Parke-Davis Pharmaceutical Research (Rezulin approval letter), *supra* p. 6 ("you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 [postmarketing reporting of adverse drug experiences] and 314.81 [other postmarketing reports]"). These showings, however, address the same topics as the first two showings that Warner-Lambert argues invade the federal field. Thus, it is the manufacturer, not the plaintiff, that in the first instance imports into the litigation the first two showings challenged by Warner-Lambert. If preemption bars a plaintiff's showing on these elements of the rebuttal to the Michigan statutory defense, then it must also preempt a defendant's showing that the defense applies. Conversely, if the defendant's compliance defense is not preempted—as the parties to this case and the United States assume—then those two aspects of the plaintiff's rebuttal are not preempted either.

Moreover, as noted above, every state allows a manufacturer to offer evidence of compliance with federal standards to show non-defect or non-negligence, although in the "overwhelming majority of jurisdictions" the evidence is not dispositive. *Restatement (Third)* § 4 Reporters' Note, cmt. e; *accord* 63B Am. Jur. 2d *Prods. Liab.* § 2022 (2007) ("As a general rule, compliance with applicable federal standards is relevant but not conclusive evidence in a products liability case.").[7] Therefore, if Warner-Lambert were correct that evidence about the relevant federal requirements and whether the defendant complied with those requirements improperly intrudes on the FDA's exclusive domain, defendants would lose the ability to present an important defense in product liability cases involving not only drugs, but also other regulated products, including pesticides, automobiles, and medical devices, and not only in Michigan cases, but in cases across the country.

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[7] *See, e.g.*, *Howard v. McCrory Corp.*, 601 F.2d 133, 138 & n.9 (4th Cir. 1979) (Maryland law); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1974) (North Carolina law); *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024 (D.N.J. 1988); *Brooks v. Beech Aircraft Corp.*, 902 P.2d 54, 63 (N.M. 1995); *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 675 n.6 (Ga. 1994); *Wagner v. Clark Equip. Co.*, 700 A.2d 38, 50 (Conn. 1997); *Toner v. Lederle Labs.*, 732 P.2d 297, 311 n.12 (Idaho 1987); *Zacher v. Budd Co.*, 396 N.W.2d 122, 133-34 (S.D. 1986); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70-71 (Mass. 1985); *Gable v. Gates Mills*, 784 N.E.2d 739, 748-49 (Ohio App. 2003); *Asbestos v. Bordelon, Inc.*, 726 So. 2d 926, 958 (La. App. 1998); *Hernandez v. Badger Constr. Equip. Co.*, 34 Cal. Rptr. 2d 732, 756 (Cal. Ct. App. 1994); *Bennett v. Mallinckrodt, Inc.*, 698 S.W.2d 854, 859 (Mo. App. 1985); *Malek v. Lederle Labs.*, 466 N.E.2d 1038, 1040 (Ill. App. 1984); *Shell Oil Co. v. Gutierrez*, 581 P.2d 271, 279-80 (Ariz. App. 1978); *Sherman v. M. Lowenstein & Sons, Inc.*, 282 N.Y.S.2d 142, 143-44 (N.Y. App. Div. 1967); Ind. Code § 34-20-5-1; Kan. Stat. Ann. § 60-3304(a); Tenn. Code Ann. § 29-28-104; Utah Code Ann. § 78-15-6.

Warner-Lambert's argument thus has very broad ramifications. Adopting it would turn the product liability law of every state upside-down by precluding not only plaintiffs' rebuttal to evidence of compliance with federal standards but the compliance defense itself.

As for the third enumerated showing—whether the failure to disclose was material to the FDA's approval—Warner-Lambert argues (at 26) that it is preempted because its "only effect" is to police and enforce compliance with FDA disclosure rules. Warner-Lambert is incorrect. Rather, as the Second Circuit explained, Pet. App. 18a n.5, the legislation's principal effect is (and the reason for its passage was) to reduce manufacturers' tort liability in light of a perceived increase in product liability litigation.[8] Like the exception for instances in which the drug's approval was tainted by bribery, *see* Mich. Comp. Laws § 600.2946(5)(b), the exception for instances in which the drug manufacturer obtained or maintained approval without complying with disclosure requirements does not function to police the regulatory process, but rather to ensure that the defense otherwise conferred under the new law does not extend to circumstances in which the state has insufficient confidence in the agency's approval to accord it dispositive legal weight. Yet even in those circumstances, far from punishing manufacturers, this element of the Michigan law provides that the defense is still available if the company's non-disclosure was not material.

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[8]There are no legislative reports on § 600.2946(5). The statute derived from a state senate bill, and the "Bill Analysis" by the Senate Fiscal Agency shows that the legislation was based the perception of an "explosion" in product liability litigation. Pet. App. 18a n.5 (quoting S. Fiscal Agency, SFA B. Analysis, Revised Enrolled Analysis, S.B. 344, H.B. 4508, at *1 (Jan. 11, 1996)).

For the same reason, the premise of Warner-Lambert's field preemption argument—that only the FDA can decide whether or not to enforce its regulations—is inapposite here. In *Buckman*, the plaintiffs sought damages *for* violation of federal law, based on an alleged causal connection between the violation of FDA requirements and the injury suffered. In contrast, § 600.2946(5) does not seek to enforce FDA requirements, and it does not punish manufacturers for noncompliance. Indeed, even where the manufacturer's non-disclosure did affect the FDA's decisionmaking, Michigan makes clear that the state does not seek to punish the company by providing that noncompliance with federal regulations "does *not* raise a presumption of negligence." Mich. Comp. Laws § 600.2946(4) (emphasis added). The Michigan statute simply provides that, as a matter of state law, manufacturers that complied with the requirements of FDA approval, including disclosure requirements, cannot be held liable in a product liability action, and manufacturers that did not comply with disclosure requirements can be—but only if they are otherwise liable under state common-law principles.

Put differently, respondents seek to impose liability because Warner-Lambert defectively designed its product and failed to warn of serious dangers inherent in its use. Because Warner-Lambert had obtained FDA approval to market Rezulin, respondents can pursue their claims under Michigan law only *if* the company made material misrepresentations to the FDA, but, unlike in *Buckman*, they are not seeking to impose liability *because* of those misrepresentations.

In this regard, the Michigan statute reflects not only the traditional rule allowing manufacturers to use regulatory compliance as evidence of non-defect; it also

reflects the traditional rule that when the approval process "was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that . . . approved the product, compliance with regulation is entitled to little or no weight." *Restatement (Third)* § 4 cmt. e; *cf.* 63B Am. Jur. 2d *Prods. Liab.* § 2022 (to be admissible as evidence of due care, federal safety standards for consumer products "must meet the threshold evidentiary showing of trustworthiness"). Indeed, the two are not distinct rules, but part and parcel of a single approach to the role of regulatory compliance in product liability cases. When a court has no confidence that the regulatory process "was full, fair, and thorough and reflected substantial expertise," *id.*, the basis for giving weight to the approval—not to mention dispositive weight—evaporates. The legislature's decision to withhold a defense in these circumstances does not intrude on the FDA's enforcement authority.

2. Warner-Lambert also argues that a determination that § 600.2946(5)(a) was satisfied—that is, that the FDA would not have approved Rezulin or would have withdrawn approval sooner if the company had not misrepresented or omitted relevant information—poses an obstacle to uniform enforcement of the FDCA. Warner-Lambert concedes that this conflict preemption argument is not really distinct from its field preemption argument, *see* Pet. Br. 21-22 & n.9, and its discussion of conflict preemption largely repeats arguments made elsewhere in its brief.

Nonetheless, in the guise of discussing conflict preemption, Warner-Lambert makes a few additional arguments. First, the company points out that the FDA never made a finding of fraud. Although that point is correct, Warner-Lambert fails to note that the FDA

rarely if ever makes such findings. *See* U.S. Br. 24 n.7 (citing 2 cases from past 10 years). Thus, the contention that a Michigan determination on this point would intrude on the FDA's "core functions," Pet. Br. 30, falls wide of the mark. Instead, as the United States explains, fraud investigations would divert resources from the agency's "core public health mission." U.S. Br. 24.

Warner-Lambert also argues that allowing findings about what the FDA would have done if the company's submissions had not misrepresented or omitted relevant information would upset "the delicate balance of statutory objectives" implicated in FDA decisionmaking. Pet. Br. 31 (quoting *Buckman*, 531 U.S. at 348). However, in the passage of *Buckman* quoted by Warner-Lambert, the Court was not discussing the effect on federal regulation of a litigation finding that the FDA would have made a different decision if the company had been honest with it. The Court was discussing the balance of objectives that the agency achieves through exercise of its power to punish and deter fraud against it, which the Court held could be "skewed" by allowing state-law liability for fraud on the FDA. Here, as discussed above, respondents are not seeking to hold Warner-Lambert liable for withholding information from and lying to the agency; their showing in this regard is aimed only at getting past Warner-Lambert's statutory defense so that they can litigate the question of liability based on traditional common-law elements.

Accordingly, cases cited by Warner-Lambert for the proposition that factfinders should not be able to "reformulate . . . technical balances reached by agencies," Pet. Br. 31, do not apply here. For example, in *Geier*, 529 U.S. at 881, cited by Warner-Lambert, the Court held that a claim seeking damages against an automaker for

failure to install an airbag was preempted, where the automaker had complied with a federal regulation that expressly provided automakers a choice about whether to install airbags because the agency sought a gradual phase-in of passive restraint devices. In *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 714 (1984), the Court held a state regulation prohibiting certain advertisements on cable television was preempted because the state "requirements directly conflict with" the agency's unambiguously expressed intent to preempt state regulation of signals carried by cable television systems. And in *Ray v. Atlantic Richfield*, 435 U.S. 151, 177 (1978), the Court held that federal regulation imposing size limitations on oil tankers preempted a more stringent Washington State regulation on this same topic. Here, the wisdom of a federal regulation is not at issue; Warner-Lambert does not allege a "direct conflict" of the sort at issue in *Capital Cities* and *Ray*, and the Michigan law does not ask factfinders to rethink a regulatory balance struck by the agency. Rather, the premise of § 600.2946(5) is that the balance struck by the agency's regulations is the right one.

Both Warner-Lambert and the United States argue that the showing under § 600.2946(5)(a) is preempted because a judge or jury should not be allowed to predict what the FDA would have done if Warner-Lambert had submitted accurate information. Although both rely on rely *Arkansas Louisiana Gas Co. v. Hall*, 453 U.S. 571 (1981) ("*Arkla*"), that case is inapposite. There, an award of damages would have effectively afforded the plaintiff a retroactive change in a filed rate for natural gas. However, the Natural Gas Act authorized only the Federal Power Commission to change rates and prohibited even the Commission from doing so retroactively. On this basis, the damages suit was held to

conflict with the Act. In contrast, the FDCA does not concern economic regulation of the drug and medical device industries. And whereas in *Arkla* the damages sought would have had an effect forbidden under the federal statute (a retroactive change in rates), the damages sought here (as in tort cases brought against drug companies in other states) would have no effect, retroactive or otherwise, on marketing approval under the FDCA.

The United States also cites *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981), but that case is not on point either. In *Kalo Brick*, the petitioner had sought and obtained permission from the Interstate Commerce Commission ("ICC") to stop rail service on a certain line. When the service stopped, the respondent sued the petitioner for damages resulting from the cessation of service. The Court held that the lawsuit was preempted because it required the state court to evaluate the reasonableness of closing the line, an evaluation Congress had assigned to the ICC. The Court pointed out that the Interstate Commerce Act offered administrative remedies but that the respondent had not availed itself of those remedies. Although the Act did not offer a private damages remedy, the available administrative remedies would have allowed the respondent to object to and seek reversal of the agency decision allowing cessation of service.

In contrast, here, respondents had no administrative remedies to pursue. Petitioning the FDA to remove Rezulin from the market would not remedy or ameliorate the liver injuries already suffered by respondents; and, besides, Rezulin has been off the market since March 2000. Furthermore, at the time of Rezulin's approval, patients had no basis for objecting to or

seeking reversal of the FDA's approval decision because they could not have known then that their physicians would prescribe Rezulin and that they would suffer injury as a result. Moreover, *Kalo Brick* left open the question whether a state-law claim would be preempted if the federal agency were empowered to rule on an issue but had not done so. *Id.* at 327 ("But we need not decide whether a state-court suit is barred when the Commission is empowered to rule on the underlying issues, because here the Commission has actually addressed the matters respondent wishes to raise in state court."). Here, as the United States's brief emphasizes (at 5, 21), the FDA has never made a finding about whether its approval decision would have been different if the company had not misrepresented and omitted information about adverse events, and the agency is not intending to do so.

Although the United States makes a brief plea for deference, U.S. Br. 25, its view is not entitled to weight here because the statement of the agency's position lacks the requisite formality. *See United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (degree of deference due to government depends on, among other things, formality and consistency of government's position). The United States relies on *Medtronic*, 518 U.S. at 496, but that case does not support deference to the position stated in the government's brief in this case. In *Medtronic*, the Court was interpreting the scope of an express preemption provision and deferred to the agency's *regulation*—not to its amicus brief—because of the "unique role" that Congress gave the agency in determining the scope of preemption, as exhibited by both the particular language of the preemption provision and a related provision giving the FDA authority to exempt certain state laws from preemption.

Id. (citing 21 U.S.C. § 360k(a) & (b)). In contrast, here, the United States seeks deference to the position stated in an amicus brief, not to an FDA regulation, and no statutory provision exists giving the FDA a direct role in interpreting the scope of preemption in this context.

In addition, deference is unwarranted because, just last year, the United States advocated a contrary position. *See Mead Corp.*, 533 U.S. at 228. In a failure-to-warn case brought by the parents of an injured child against a prescription drug manufacturer, the FDA argued that a judge presiding in such a case should begin by making the determination whether the FDA would have rejected the warning sought by the plaintiff on the ground that it would render the product misbranded or that it was unsubstantiated. Br. of U.S. as Amicus Curiae at 11, *Perry v. Novartis Pharms.*, 456 U.S. 678 (E.D. Pa. 2006) (Civ. No. 05-5350). The FDA stated that determining whether tort liability for failure to warn would conflict with the accomplishment of federal objectives "require[s] an analysis of the agency's actions and the actions that are alleged to give rise to liability." *Id.* And the FDA suggested that "the court must ask" how the agency would have reacted if the company had proposed a particular warning. *Id.* In other words, just last year, the FDA argued that, in tort cases against drug manufacturers, courts *must* make findings about how the FDA would have reacted if a manufacturer had presented it with different information (there, a new warning and information to support it). For this reason as well, the United States's argument here that such findings conflict with the federal regulatory scheme deserves no weight. *See Bates*, 544 U.S. at 449, 451-52 (giving no weight to agency's view on preemption in light of agency's flip-flop).

3. Warner-Lambert also argues that allowing litigation to address the findings required to rebut the Michigan defense would increase burdens on manufacturers. Yet, as discussed above, the product liability law of every state allows defendants to present evidence of federal compliance as a defense and allows plaintiffs to present evidence to counter that defense, and this traditional tort-law scheme would seem to create the same burdens and incentives that Warner-Lambert purports to fear from the Michigan statute. Throughout the nearly 70 years during which the FDA has regulated the marketing of prescription drugs, drug companies have not only survived but prospered in the face of any burdens posed by tort law. In any event, the company does not argue that state and federal law impose inconsistent burdens on manufacturers, and thus its argument on this point is not a basis for preemption.

In a related argument, Warner-Lambert contends that the exception to the Michigan statute "would" encourage companies to submit to the FDA large amounts of information that the FDA "neither wants nor needs." Pet. Br. 27 (quoting *Buckman*, 531 U.S. at 351). The Michigan statute, however, has been in effect since 1995 (and the Sixth Circuit did not issue its decision in *Garcia* holding the exception usually preempted until 2004); four states passed statutes immunizing manufacturers of approved prescription drugs from punitive damages unless the plaintiff could show that the company made misrepresentations or failed to submit relevant information to the FDA in 1987, and two others passed similar statutes in 1989.[9] Warner-Lambert offers

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[9]Ariz. Rev. State. Ann. § 12-701 (enacted in 1989); N.D. Cent. Code § 32-03.2-11 (enacted in 1987); N.J. Stat. Ann. § 2A:58C-5(c) (continued...)

no evidence that the FDA is receiving excessive and unwanted quantities of information attributable to these laws. Moreover, the Food and Drug Administration Amendments Act of 2007 requires drug companies to provide information about clinical trials and their results in a publicly accessible registry. *See* Pub. L. No. 110-85, § 801, *to be codified at* 42 U.S.C. § 282. The public's increased access to this information greatly alleviates any concern about how plaintiffs will prove what information a drug manufacturer had and whether it disclosed this information.

Furthermore, the exception expressly applies only to non-disclosure of information that is "*required* to be submitted under the [FDCA]." Mich. Comp. Laws § 600.2946(5)(a). In addition, the exception is limited to instances where non-disclosure had a demonstrable effect on FDA decisionmaking. *Id.* Both of these features ensure that the statute does not encourage manufacturers to flood the FDA with immaterial information because submission of such information would not help a manufacturer to defend against the non-compliance exception. And again, unless such submissions interfere with the agency's ability to accomplish its objectives, this contention is not a basis for preemption. Warner-Lambert cites *Buckman* for this point, but there, the Court noted that "a deluge of information that the [FDA] neither wants nor needs" could delay the streamlined 510(k) review process. 531 U.S. at 351. That statement does not apply here, where the NDA process is not "comparatively speedy," *id.*, and

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[9](...continued)
(enacted in 1987); Ohio Rev. Code Ann. § 2307.80 (enacted in 1987); Or. Rev. Stat. § 30.927 (enacted in 1987); Utah Code Ann. § 78-18-2 (enacted in 1989).

requires far more significant submissions. *See supra* p. 3; Pet. Br. 5 & n.1.

Warner-Lambert suggests that juries cannot be trusted to distinguish immaterial omissions from material ones, but its distrust is an insufficient basis for ousting state law. Juries make fact findings in criminal prosecutions and civil cases arising from FDA enforcement actions, as discussed above. *See supra* p. 26; *cf. Bates*, 544 U.S. at 452 ("[L]ay juries are in no sense anathema to FIFRA's scheme: In criminal prosecutions for violations of FIFRA's provisions, juries necessarily pass on allegations of misbranding.") (citation omitted). Furthermore, drug companies, even some who sold notoriously dangerous products, are often able to prevail in jury trials. *See*, *e.g.*, Associated Press, *Major victory for Merck in N.J. Vioxx trial* (Nov. 3, 2005), *available at* http://www.msnbc.msn.com/id/9910674/. And Warner-Lambert's insinuation that juries are improperly swayed by plaintiffs' arguments and cannot be trusted to evaluate evidence objectively is refuted by Department of Justice statistics, which show that plaintiffs win only 44 percent of state-court trials in product liability cases and 43 percent of federal-court trials in such cases. DOJ Bureau of Justice Statistics, *Tort Trials and Verdicts in Large Counties*, *2001*, at 4 Table 3 (Nov. 2004); DOJ Bureau of Justice Statistics, *Federal Tort Trials and Verdicts*, *2002-03*, at 1 (Aug. 2005).[10]

The history of tort litigation against drug manufacturers also belies the theory that the Michigan statute will distort FDA decisionmaking or burden FDA

[10]The Bureau of Justice Statistics reports are available at http://www.ojp.usdoj.gov/bjs/pub/pdf/ttvlc01.pdf and http://www.ojp.usdoj.gov/bjs/pub/pdf/fttv03.pdf.

personnel who are asked to testify in product liability cases. Tort litigation against drug companies has coexisted with the FDCA since 1938. And the "overwhelming majority of jurisdictions hold that compliance with product safety regulation is relevant and admissible on the question of defectiveness, but is not necessarily controlling." *Restatement (Third)* § 4 Reporters' Note, cmt. e. The Restatement (Second) took a similar approach. *Restatement (Second) of Torts* § 288C (1965) ("Compliance with . . . an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions."). Yet neither Warner-Lambert nor the United States has offered evidence suggesting that the FDA's ability to fulfill its mission has been adversely affected by state tort litigation. To be sure, the Michigan statute has an additional element not found in other jurisdictions—the showing of how the FDA would have reacted to the information if properly disclosed. Yet it is not obvious why that additional element would add a burden not posed by the traditional compliance defense, or why the plaintiffs would try to force current FDA medical officers to testify, presumably against the FDA's wishes, when there are so many former FDA medical officers potentially available. *See* FDA, *FDA Science and Mission at Risk*, *Report of the Subcomm. on Science and Technology* at 4 (Nov. 30, 2007) (discussing unusually high turnover rate in FDA science staff). In sum, evidence about the existence of federal standards and approvals, and argument about compliance with standards and conditions of approval, have long been a part of product liability litigation.[11]

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[11]Although Warner-Lambert states that the Court need not address the question whether the Michigan provision would be (continued...)

Accordingly, the consequences of adopting Warner-Lambert's preemption argument would be far broader than the effect on the Michigan statute and would threaten principles of product liability law in every state—principles that benefit both plaintiffs and defendants. As the court below stated, adopting Warner-Lambert's view "would result in preemption of a scope that would go far beyond anything that has been applied in the past." Pet. App. 24a. But for the reasons explained above, Warner-Lambert's view is incorrect, and the decision below should be affirmed.

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[11](...continued)
preempted if the FDA had made a fraud finding, the United States (at 23-24) argues that preemption would bar a plaintiff's showing under the Michigan statute *even if* the FDA had found fraud. The United States's argument on this point is *not* that the Michigan statute would, in such instances, conflict with any FDA determination or intrude on the FDA's judgment about how to enforce its regulations. Rather, it argues that, as a practical matter, allowing injured patients to rely on FDA fraud findings to get past the hurdle imposed by § 600.2946(5) *might* motivate potential plaintiffs to file citizen petitions asking the FDA to make fraud findings, which the FDA does not typically make, and that processing such petitions would be burdensome. The United States does not explain the connection between these speculative concerns and the preemption doctrine. After all, federal law affirmatively allows citizens to file such petitions. *See* 5 U.S.C. § 553(e); 21 C.F.R. § 10.30. Moreover, the FDA's purported concerns are unfounded. More than three years ago, the Sixth Circuit held that § 600.2946(5)(a) is preempted except when the FDA has made a finding of fraud. *Garcia*, 385 F.3d at 966. Notably, the United States does not offer any evidence of a deluge of citizen petitions—or *any* citizen petitions—filed since then by Michigan patients requesting that the FDA make such findings.

III. IF THE COURT HOLDS THAT SOME OR ALL OF § 600.2946(5)(a) IS PREEMPTED, THE CASE SHOULD BE REMANDED FOR CONSIDERATION OF SEVERABILITY.

The decision below is correct and should be affirmed. However, if the Court disagrees, this case must be remanded to the Second Circuit for consideration of whether the preempted portion of the statute is severable. For example, if this Court holds that the final clauses of paragraph (a), which require a finding about how the FDA would have reacted to an honest submission, are preempted, the lower court must determine whether those clauses are severable from the remainder of paragraph (a) and/or from subsection (5) in its entirety. If this Court holds that all of paragraph (a) is preempted, the lower court must determine whether paragraph (a) is severable from the rest of subsection (5) or whether all of subsection (5) is therefore invalid. Severability was briefed and argued below, but because the Second Circuit held that no part of paragraph (a) is preempted, it did not reach the issue.

Michigan law, through Mich. Comp. Laws § 8.5, expressly addresses severability, explaining that a determination that one portion of an act is invalid will not invalidate remaining portions that can nonetheless be given effect. "To be capable of separate enforcement, the valid portion of the statute must be independent of the invalid sections, forming a complete act within itself. After separation of the valid parts of the enactment, the law enforced must be reasonable in view of the act as originally drafted." *Pletz v. Sec'y of State*, 336 N.W.2d 789, 809 (Mich. App. 1983) (severing invalid portions of statute where remainder consistent with intent of the legislature); *see also Maki v. East Tawas*, 188 N.W. 2d 592, 595 & n.1 (Mich. 1971) (striking

down, rather than limiting scope of, statutory provision where "we cannot determine how [the legislature] would have voted had they" faced the choice). Because the severability question that will arise here if the Court finds some or all of paragraph (a) preempted is a question of state law, a remand would be required to allow the lower court to address the issue or, possibly, to certify the question to the Michigan Supreme Court.

Below, Warner-Lambert relied primarily on *Garcia* as support for the argument that paragraph (a) of § 600.2946(5) is severable, and it urged the Second Circuit to defer to that Sixth Circuit decision. That argument, which Warner-Lambert reprises very briefly here, *see* Pet. Br. 50 n.18, is insufficient to avoid a remand for four reasons. First, Warner-Lambert did not include severability in the question presented, and thus the severability issue, including whether *Garcia* binds either this Court or the Second Circuit on this point, is not before the Court.

Second, Warner-Lambert (at 50 n.18) cites cases for the proposition that this Court usually defers to or "leaves undisturbed" the decision of a regional court of appeals on a state-law issue where a case comes to the Court from that court of appeals. It cites no authority for reversing a court of appeals' decision based on another court's state-law ruling in another case.

Third, the argument about whether the Second Circuit should or would defer to the Sixth Circuit is based largely on interpretation and application of a Second Circuit case, *Factors Etc., Inc. v. Pro Arts, Inc.*, 652 F.2d 278 (2d Cir. 1981). In that case, the Second Circuit deferred to a state-law holding of a federal court of appeals in which the relevant state was located, but noted that the holding was not binding because the

ultimate source of authority for adjudicating state-law issues in diversity cases "is the law as established by the constitution, statutes, or authoritative court decisions of the state." *Id.* at 283. The degree to which one federal court of appeals (or this Court) should defer to another on a question of state law is not fairly encompassed in the question presented here, yet Warner-Lambert's primary argument in favor of severability would require resolution of this question. The Second Circuit's case law gives ample deference to the views of the home circuit, and that court can give the Sixth Circuit's views any weight that the Second Circuit determines it deserves. The case should be remanded to enable the Second Circuit to apply its law in the first instance.

Fourth, *Garcia*'s consideration of severability was based on its own conclusion about the scope of pre-emption. Specifically, *Garcia* had held that all of paragraph (a) is preempted, except where the FDA has made a finding of fraud. 385 F.3d at 966. Below, Warner-Lambert argued that this holding was correct. *See* Br. for Appellees, No. 05-1705(L) at 28 n.10, filed July 27, 2005. Here, Warner-Lambert urges the Court not to address whether the Michigan law is preempted in circumstances where the FDA has found that the company made material representations that affected the FDA's decisionmaking. Pet. Br. 37. And the United States urges the Court to hold the statute preempted even in such cases. U.S. Br. 23. Unless the Court addresses this circumstance and agrees with *Garcia* on the point, there will be no basis for deferring to the Sixth Circuit's holding on severability, for the Sixth Circuit did not address the question whether § 600.2946(5) can survive without any exception for instances where the FDA has actually made a finding of fraud. Similarly, if the Court holds that the portion of

paragraph (a) that requires a finding about what the FDA would have done if presented with accurate information is preempted, but that the rest of paragraph (a) is not preempted, its preemption holding will differ from the holding in *Garcia*. In that circumstance as well, there will be no basis for deferring to the Sixth Circuit's holding on severability, premised on a different conclusion about the scope of preemption.

Finally, if paragraph (a) is preempted in its entirety, it is not severable from the remainder of the statute. Michigan enacted § 600.2946(5) to reduce the amount of product liability litigation against drug manufacturers, but, at the same time, the state legislature made clear, through the plain language of the statute, that it did not want to extend immunity in cases where the drug approval was tainted. Therefore, through two exceptions—one for drug manufacturers who misrepresented information to or omitted information from the FDA (paragraph (a)) and one for manufacturers who bribed an FDA official (paragraph (b))—the legislature withheld the statutory defense from manufacturers who obtained or maintained marketing approval through dishonest means. To sever one exception from the statute, thereby conferring irrebutable immunity on a category of manufacturers that the legislature plainly did not intend to protect, would not be "reasonable in view of the act as originally drafted." *Pletz*, 336 N.W.2d at 809.

CONCLUSION

The decision of the United States Court of Appeals for the Second Circuit should be affirmed.

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January 11, 2008