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 THE STATES OF KANSAS, *ET AL.* AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTIONS PRESENTED

Whether MICHIGAN COMP. LAWS § 600.2946(5)(a)—creating an exception to a state law statutory tort defense for drug manufacturers who have obtained approval of the federal Food and Drug Administration—is entitled to a presumption against preemption when challenged on the ground that it is impliedly preempted by federal law and, if so, whether the Petitioners have overcome that presumption?

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INTEREST OF THE *AMICI* STATES

The States have a paramount interest in their own tort laws, laws which are the result of the States' exercise of one of their most traditional police powers. Indeed, there is no general federal common law of torts, but there are 50 state tort systems. Even when federal law involves or implicates tort claims, federal law typically borrows and adopts state tort law. *See, e.g.*, 28 U.S.C. § 1346(b) (making the United States liable for the negligent torts of its employees "under circumstances where the United States, if a private person, would be liable to the claimant *in accordance with the law of the place where the act or omission*

occurred.") (emphasis added); *see also Molzof v. United States*, 502 U.S. 301, 305 (1992) ("the extent of the United States' liability under the FTCA is generally determined by reference to state law").

Tort law is one of the States' most traditional prerogatives, long exercised as a general State police power. Indeed, the common law of torts itself goes back centuries and, in this country, the development of the common law primarily has occurred in the state court systems.

Some states rely upon noncompliance with FDA requirements in defining the limits of tort liability in certain cases. Michigan does so by making noncompliance an exception to a general tort defense for manufacturers that have obtained FDA approval. MICH. COMP. LAWS § 600.2946(5), (5)(a). Other states rely upon noncompliance in another way, as an exception to a statutory bar on punitive damages claims that would otherwise apply to drug manufacturers that have obtained FDA approval. *See, e.g.*, ARIZ. REV. STAT. § 12-701; N.J. STAT. ANN. § 2A:58C-5C; N.D. CENT. CODE § 32-03.2-11(6), 7(a); OHIO REV. CODE ANN. § 2307.80(C); OR. REV. STAT. ANN. § 30.927; UTAH CODE ANN. § 78-18-2.

Several states accord a rebuttable presumption of nondefective design or of adequate warnings to FDA or other government approval, though not always with a noncompliance exception. *See, e.g.*, COLO. REV. STAT. § 13-21-403(1); IND. CODE ANN. § 34-20-5-1; KAN. STAT. ANN. § 60-3304(a); KY. REV. STAT. ANN. § 411.310(2); N.J. STAT. ANN. § 2A:58C-4; TENN. CODE ANN. § 29-28-104; TEX. CIV. PRAC. & REM. CODE § 82.007; UTAH CODE ANN. § 78-15-6(3).

Thus, many states have a direct interest in the question whether the Michigan noncompliance exception can be enforced. And, in any event, *all* the States have a substantial interest in the fundamental tort and preemption questions the case raises. *See, e.g.*, Catherine M. Sharkey, abstract for *The Fraud Caveat To Agency Preemption*, Nw. U. L. Rev., Vol. 102, No. 2, 2007, *available at* http://ssrn.com/abstract=1020722 (the *Warner-Lambert* case "raises a narrow doctrinal issue, but one that hits a raw federalism nerve, with correspondingly wide reverberations in products liability preemption jurisprudence").

Importantly, as the Second Circuit recognized and Petitioners and their *amici* agree, this case implicates once again the question in what circumstances a "presumption against preemption" applies to claims of federal preemption. The presumption is a first principle of great importance to the States, going to the very heart of federalism.

STATEMENT

1. Respondents, Michigan residents, sued Warner-Lambert Company LLC and Pfizer, Inc., in Michigan state court, asserting common law tort claims in connection with the Petitioners' product Rezulin, a drug marketed and sold for the treatment of Type-2 diabetes. The federal Food and Drug Administration (FDA) approved Rezulin in 1997. After it was documented that Rezulin caused adverse liver-related effects, Petitioners agreed to alter Rezulin labeling on several occasions between 1997 and 1999. In March 2000, Petitioners withdrew Rezulin from the market.

2. Respondents' tort claims included breach of implied and express warranties, negligence, negligent misrepresentation, negligence per se, fraud, defective design, defective manufacturing, and loss of consortium. A Michigan statute provides a general defense to drug manufacturers when the FDA has approved the drug in question. MICH. COMP. LAWS § 600.2946(5). However, the Michigan statute further provides that the defense does not apply if a drug manufacturer withheld from or misrepresented to the FDA information required to be submitted in obtaining FDA approval and such information would have affected the FDA's decision. *Id.* at § 600.2946(5)(a). This "noncompliance" exception is the provision at issue here.

3. Petitioners removed the case to federal court. Later, this case and others were consolidated as multidistrict litigation in the Southern District of New York. The District Court dismissed the case, holding that federal law preempted the exception in the Michigan statute. The court relied on *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), in which this Court held that a state could not impose liability for "fraud on the FDA" with respect to a medical device that the FDA had approved. Further, the District Court relied on *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), which held that *Buckman* required preemption of the Michigan exception.

4. The Second Circuit reversed, concluding that *Buckman* did not require preemption of the Michigan exception for several reasons: first, *Buckman* is distinguishable from this case, because it involved a state law "fraud" claim premised solely and directly

on the defendant allegedly committing fraud on the FDA; second, a "presumption against preemption" applies here, because tort law is at the very core of traditional state police powers; and third, the Michigan statute is a defense to products liability claims, not an element of a plaintiff's claim.

SUMMARY OF THE ARGUMENT

1. At a constitutional minimum, a presumption against preemption generally applies in "implied" preemption cases involving one of the States' most traditional police powers, such as tort law. That presumption has special force when there is a convergence of three important factors, as in this case: (a) the area of law allegedly preempted is one at the core of traditional state police powers; (b) the area of law—tort law—is not one in which there is or has been a significant federal presence; and (c) the relevant federal statutes are lacking in any express congressional declaration of intent to preempt traditional state police powers.

The Court has recognized several reasons for a presumption in these and other circumstances. First, only such a presumption will adequately protect the federalism structure inherent in the constitutional design. Second, a presumption permits judges to avoid unnecessary and problematic guessing as to the preemptive "intent" of Congress when the relevant federal laws are silent regarding preemption. Third, a presumption against preemption reserves for Congress the primary power to determine when state law is preempted.

Contrary to some suggestions in *amici* briefs supporting the Petitioners, there is not a basis for distinguishing among types of implied preemption for

purposes of applying the presumption. Instead, as this Court has recognized and Petitioners acknowledge, there is not a rigid line between "conflict" and "field" preemption. Pet. Br. at 21 and n.9 (citing and quoting cases). Rather, these labels are different ways to describe what is the same—a potential conflict between federal and state law in a situation where Congress has not expressly preempted state law. *See, e.g.*, Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 263 (2000).

2. A presumption, when rebuttable, as in this context, is a starting point, not a final conclusion. Sometimes the presumption will be overcome, for example when state law inevitably and necessarily conflicts with federal law, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), or when there is a logical inconsistency between federal and state law, or it is literally impossible to comply with both federal and state law. But, with all due respect, the argument which the Petitioners and their *amici* should be making in this case is not that there is no presumption against preemption, but that it is overcome here. Instead, they miss the mark when they seek to rewrite this Court's jurisprudence by arguing that no presumption applies in this case, or indeed in any case.

3. A presumption is particularly appropriate here because the States are free to structure their tort law as they wish, without federal constitutional or statutory constraints. A State may choose to provide a defense to drug or medical device manufacturers from tort liability when FDA approval has been obtained (as Michigan did here), but as a matter of federalism and constitutional principle, the States

are not required to adopt that view. The greater power—to give drug manufacturers a defense—necessarily encompasses the lesser power to impose conditions on the defense.

The flaw in Petitioners' argument is the apparent assumption that FDA approval immunizes them from state tort liability as a matter of federal law, so that Michigan's noncompliance exception interferes with that purported federal immunity. But that is the wrong premise—FDA approval gives Petitioners no defense to or immunity from state tort claims other than that which a particular state may choose to grant as a matter of legislative grace.

Thus, if a state chooses to create a defense not recognized at common law, it also may impose conditions on or limits to that defense. So long as the States do not effectively impose a tort law duty based on FDA processes and decisions, *see Buckman*, federal law does not impliedly preempt traditional state products liability law.

The practical effect of finding preemption here may be that States decline to accord FDA approval of new drugs any special legal significance in tort cases. Indeed, the States may choose not to create a defense for drug manufacturers under any circumstances. If the greater power—to provide manufacturers a defense from liability—does not include the lesser (to impose conditions on such a defense), then some States that currently have statutory defenses may well decide to alter or repeal them. Others are less likely to adopt such defenses at all.

4. Finally, the Michigan noncompliance exception does not affect the evidence generally admissible in traditional state law products liability actions.

Evidence of a manufacturer's knowledge of the risks its product poses, including what the manufacturer disclosed or failed to disclose to government regulators, generally is relevant and admissible in traditional products liability actions alleging negligence, design defect, and failure to warn.

The common law rule is that obtaining government approval or complying with government regulation is relevant evidence but not, in and of itself, a tort defense and does not create immunity. Michigan, by statute, departed from that rule, creating a defense in cases where drug manufacturers have obtained FDA approval. Michigan's noncompliance exception to that defense, however, follows the common law tradition of not treating government approval as a complete defense to tort liability. Rather, the States have a strong interest in protecting their citizens from negligence, defectively designed products, and products with inadequate warnings.

Michigan's choice—as a matter of policy—to provide a statutory defense to drug manufacturers who have obtained FDA approval, while also creating an exception in cases where the defendant has not fully complied with regulators' requirements and expectations, does not affect or expand the evidence that typically would be relevant and admissible in state law products liability actions. Preempting Michigan's exception would not bar the admission of evidence regarding a manufacturer's knowledge of the risks its product poses.

Ultimately, the Michigan statute here no more conflicts with federal law nor frustrates federal purposes than does the unquestioned state common law tort rule that government approval of a product

is not a defense in and of itself. Consequently, this Court need not and should not read *Buckman* to require preemption of the Michigan exception. Rather, tort liability for negligence, defective design, and failure to warn involves one of the States' most traditional police power prerogatives, is not an area in which there is a history of significant federal presence, and Congress has not declared an intent to preempt such state tort law.

* * * * *

Concurrent and overlapping federal and state regulation of the same activities is an inherent feature of our constitutional design. The structure of the Constitution demands no less; indeed, the framers purposely created federalism. The States readily acknowledge that federal power is supreme within its sphere when properly exercised. But a presumption against preemption is a proper mechanism for giving effect to the constitutional design, particularly when one of the core state law police powers is at issue.

ARGUMENT

I. AT A CONSTITUTIONAL MINIMUM, A PRESUMPTION AGAINST PREEMPTION APPLIES WHEN FEDERAL LAW IS ALLEGED TO PREEMPT ONE OF THE STATES' MOST TRADITIONAL POLICE POWERS—TORT LAW, THERE IS NO HISTORY OF SIGNIFICANT FEDERAL PRESENCE, AND THERE IS NO CONGRESSIONAL EXPRESSION OF INTENT TO PREEMPT STATE LAW.

A. A Presumption Against Preemption Serves Important Constitutional Purposes In Cases Involving The Most Traditional State Powers.

1. This Court has said 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, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (emphasis added) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). "In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest." *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 449 (2005). Thus, "[w]ith rare exception, [the Court has] found preemption only when a federal statute commanded it, when a conflict between federal and state law precluded obedience to both sovereigns, or when a federal statute so completely occupied a field that it left no room for additional state regulation." *Watters v. Wachovia Bank, N.A.*, 550 U.S. ___, ___,

127 S. Ct. 1559, 1585-86 (2007) (Stevens, J., dissenting) (internal citations omitted).[1]

a. The States readily acknowledge that federal power is supreme within its sphere, as the Supremacy Clause of Article VI declares. And it is true that the Tenth Amendment, reserving to the States and the people powers not granted to the Federal Government, does not itself preclude preemption of state law when the Federal Government has properly exercised its powers under the Constitution.

That said, all preemption cases implicate federalism and respect for the constitutional role of the States as sovereign entities. *Cf. Alden v. Maine*, 527 U.S. 706, 713 (1999). Thus, "because the States are independent sovereigns in our federal system, [the Court has] long presumed that Congress does not cavalierly pre-empt state law causes of action." *Lohr*, 518 U.S. at 485. Rather, "the fact that the [Tenth] Amendment was included in the Bill of Rights should nevertheless remind the Court that its [preemption] ruling affects the allocation of powers among sovereigns. Indeed, the reasons for adopting

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[1] The application of a presumption against preemption when interpreting federal statutes that expressly declare an intent to preempt some aspects of state law has been criticized. *See, e.g., Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 544 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part); *Bates,* 544 U.S. at 457 (Thomas, J., joined by Scalia, J., concurring in the judgment in part and dissenting in part). But such criticism of a presumption in "express" preemption cases has been accompanied by calls for a narrow approach to "implied" preemption, with no suggestion that a presumption should not apply generally in "implied" preemption cases. *See, e.g., Bates*, 544 U.S. at 459.

that Amendment are precisely those that undergird the well-established presumption against preemption." *Watters*, 550 U.S. at ___, 127 S. Ct. at 1585 (Stevens, J., dissenting).

Because "[t]he purpose of Congress is the touchstone of pre-emption analysis," *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992), a presumption against preemption operates much like the "clear statement" rule that applies in the Tenth and Eleventh Amendment contexts. *See, e.g., Gregory v. Ashcroft*, 501 U.S. 452, 457-61 (1991) (discussing clear statement rule in the Tenth Amendment and preemption contexts); *Seminole Tribe of Florida v. Florida*, 517 U.S. 44, 55-56 (1996) (the clear statement rule in the immunity context "arises from a recognition of the important role played by the Eleventh Amendment and the broader principles that it reflects"); *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 238-39 (1985); *Quern v. Jordan*, 440 U.S. 332, 345 (1979). A presumption is not a constitutional *bar* to federal preemption, but it does require Congress to be clear about its intent. Thus, a presumption reserves for Congress the primary role in deciding when federal statutes preempt traditional state law.

b. The justifications for a presumption against preemption are at their zenith in this case. Indeed, "implied" preemption is at best an ambiguous and uncertain doctrine. Accordingly, members of the Court regularly have warned against expansive notions of implied preemption, describing the "Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption," *Bates*, 544 U.S. at 459

(Thomas, J., joined by Scalia, J., concurring in the judgment in part and dissenting in part); *see also Camps Newfoundland/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 617 (1997) (Thomas, J., dissenting), and cautioning that implied preemption is not "[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in the judgment).

Judicial caution is particularly proper here for three reasons. First, this case involves one of the States' most traditional police powers—tort law. "The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Bates*, 544 U.S. at 449.

Second, although this Court has indicated that a presumption "is not triggered when the State regulates in an area where there has been a history of significant federal presence," *United States v. Locke*, 529 U.S. 89, 108 (2000); *see also Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71, 88 (2006); *Buckman*, 531 U.S. at 347-48, that circumstance is not present here. The federal government does not have a history of regulating tort law, either generally or with respect to drugs.

The federal government for the better part of the twentieth century has played a role in regulating food and drug products, but it largely did so in conjunction with a widely-recognized choice by Congress not to

preempt traditional state tort law liability principles. That fact is driven home by the absence of any federal cause of action or remedies for those injured by harmful food and drugs subject to FDA regulation.

Policing fraud on federal agencies is neither the purpose, the goal, nor the effect of the Michigan statute, *cf. Buckman*, 531 U.S. at 347 ("Policing fraud against federal agencies" is not a state prerogative); instead, the Michigan statute regulates tort law liability rules and defenses. Establishing tort liability principles is one of the most traditional exercises of the States' general police powers.

Third, all parties and *amici* acknowledge that there is no express preemption provision applicable in this case. Thus, a finding of preemption in this case cannot rest on the "express intent" of Congress, further confirming the wisdom and propriety of applying a presumption against preemption.

2.a. Contrary to the suggestions of some *amici* in this case, there is no basis for this Court to distinguish between "conflict" and "field" preemption in applying a presumption against preemption. Conflict and field preemption are not separable and distinct concepts, neither theoretically nor practically, as this Court has recognized and Petitioners concede. *See, e.g., English v. Gen. Elec. Co.*, 496 U.S. 72, 79 n.5 (1990) (the categories are not "rigidly distinct" and "field pre-emption may be understood as a species of conflict pre-emption"); *Gade*, 505 U.S. at 104 n.2 (1992) (plurality opinion) (recognizing that the Court could describe the situation presented as either one of "conflict" or "field" preemption); *id.* at 115-16 (Souter, J., dissenting) (acknowledging that conflict preemption

may in practical effect be the same as or similar to field preemption); Pet. Br. at 21 and n.9.

Rather, federal law "conflicts" with state law when federal law "occupies the field" in which a state law purports to operate. Vice versa, federal law always "occupies the field" to the extent it is in actual "conflict" with state law. Thus, "field" and "conflict" preemption are two sides of the same coin. The state sovereignty concerns that favor a presumption against preemption are equally strong no matter which label one attaches to the situation. *Cf. Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874 (2000) ("We see no grounds, then, for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case.")

b. Contrary to the suggestion of Petitioners and their *amici*, applying a presumption against preemption broadly instead of narrowly in implied preemption cases *simplifies*, rather than complicates, the preemption analysis. A rule that a presumption against preemption applies in cases involving the most traditional of state police powers, no history of significant federal presence in the area, and no express congressional declaration of intent to preempt is relatively clear and simple. Thus, with all due respect, the Court's decisions indicating that the presumption generally applies are correct. *See, e.g., Lohr*, 518 U.S. at 485 ("In all pre-emption cases" a presumption against preemption applies.)

A presumption against preemption may be overcome by an inevitable conflict between federal and state law, logical inconsistency between the two, or the impossibility of complying with both. Even so,

the presumption applies, and proponents of preemption bear the heavy burden of persuading a court that a conflict requiring preemption inevitably and necessarily exists.

3. The States have a paramount interest in their own tort law. There is no general federal common law of torts, but there are 50 state tort systems. Indeed, when federal law involves or implicates tort claims, it typically borrows state tort law. *See, e.g.*, 28 U.S.C. § 1346(b) (making the United States liable for the negligent torts of its employees "under circumstances where the United States, if a private person, would be liable to the claimant *in accordance with the law of the place where the act or omission occurred*.") (emphasis added); *see also Molzof*, 502 U.S. at 305 ("the extent of the United States' liability under the FTCA is generally determined by reference to state law").

Tort law is one of the States' most traditional prerogatives, long exercised as a general State police power. This Court has upheld state tort law in the face of preemption claims even when there was a strong federal interest in the subject matter and a State imposed substantial *punishment* for noncompliance with state tort law requirements. *See Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984) (upholding $10 million state law punitive damage award involving a federally-regulated nuclear power plant).

There may be no area of public safety, health, and welfare regulation that is more a traditional province of the States than tort law. The Court has suggested that Congress may lack even the *power* to regulate certain matters where the States' sovereign interests

are strong and the federal interest is tenuous. *See, e.g, United States v. Lopez*, 514 U.S. 549, 561 n.3 (1995) (state primacy in criminal law generally), *United States v. Morrison*, 529 U.S. 598, 615-16 (2000) (overly expansive commerce power would improperly permit Congress to regulate traditional state domestic relations law).

The reasoning of such cases supports the principle that federal statutes that do not even purport to preempt state law should not be read to preempt implicitly one of the most traditional areas of state police power regulation—tort liability and remedies. "[F]ederalism canons like the *Rice* presumption [against preemption] in particular, are legitimate ways of giving effect to underenforced constitutional principles. Such canons also perform the important function of buttressing political and procedural checks on national power and, as a result, reduce the need to rely on substantive constitutional limitations." Ernest A. Young, *Federal Preemption and State Autonomy*, in FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 249, 265 (R. Epstein & M. Greve, eds. 2007).

The Court has "long presumed that state laws—particularly those such as the provision of tort remedies to compensate for personal injuries, that are within the scope of the States' historic police powers—are not to be pre-empted by a federal statute unless it is the clear and manifest purpose of Congress to do so." *Geier*, 529 U.S. at 894 (2000) (Stevens, J., dissenting, joined by Souter, J., Thomas, J., and Ginsburg, J.). "Because we are unlikely to jettison the post-New Deal interpretation of the Commerce Clause, it becomes both necessary and

legitimate for courts to formulate 'compensating adjustments' to protect the federal balance under modern circumstances." Young, *Federal Preemption*, at 266.

The Supremacy Clause is not a means for asking the federal judiciary to impose tort reform on the States. *Geier*, 529 U.S. at 894 (Stevens, J., dissenting). Applying a presumption against preemption—at least in cases that involve the most traditional areas of state police powers, no history of significant federal presence, and no express declaration by Congress of an intent to preempt traditional state law—respects the States' constitutional role as sovereigns. Lastly, a presumption respects the role of Congress in such matters as well: "[t]he signal virtues of this presumption are its placement of the power of preemption squarely in the hands of Congress, which is far more suited than the Judiciary to strike the appropriate federal/state balance (particularly in areas of traditional state regulation), and its requirement that Congress speak clearly when exercising that power." *Id.* 529 U.S. at 907 (Stevens, J., dissenting).

B. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), Does Not Control Here.

1. The *only* claim at issue in *Buckman* was a fraud claim, and it was against a consultant, not the product manufacturer. The Court's opinion is clear that traditional products liability claims such as negligence, design defect, and failure to warn were not at issue (and could not have been, given that the defendant was not the manufacturer). Thus, *Buckman* was an unusual and unique tort case, with

"fraud on the FDA" an essential element of the claim against a consultant who was the *sole* defendant.

In *Buckman*, "fraud on the FDA" was *the dog*; here, Michigan's noncompliance exception is *the tail*, not the dog, as the Second Circuit recognized. Respondents' causes of action under Michigan law are based "on traditional state tort law principles of the duty of care owed by" drug manufacturers, *Buckman*, 531 U.S. at 352, and "rely[] on traditional state tort law which had predated" the FDA's approval process. *Id.* at 353.

2. What distinguishes this case further from *Buckman* is that here Petitioners are seeking a defense or an immunity that neither the common law nor federal law recognizes. If a state, like Michigan, chooses to create a tort defense not recognized at common law, *see* Part II, *infra*, there is no apparent reason why that state cannot also set the terms and conditions of that defense, including any limits or exceptions to it. When a defense to state tort liability is a matter of legislative grace—a pure policy decision not dictated by either federal preemption or the common law—the greater power to create the defense necessarily includes the lesser power to set the terms and conditions of the defense.

Perhaps in some states the creation of such a defense may be challenged as violating state constitutional provisions, like those that require a remedy by due course of law or other guarantees, as in fact happened in Michigan with this very statute. *See Taylor v. Smithkline Beecham Corp.*, 658 N.W. 2d 127 (Mich. 2003). But that is a matter for state supreme courts to decide—a question of state law. *See, e.g.*, David Schuman, *The Right to a Remedy*, 65

TEMPLE L. REV. 1197 (1992). The FDA-related statutes do not contain any express preemption provision that grants *federal immunity* to drug manufacturers who obtain FDA approval. Nor is anyone claiming here that the FDA statutes preempt the States from making a policy decision to create a tort defense on the basis of FDA approval.

3. Read fairly and objectively, *Buckman* can be understood in at least two ways, so that both Petitioners and Respondents can find aspects of the opinion that support their positions in this case, just as the Sixth and Second Circuits did. But, at the end of the day, what tips the scale in favor of a narrower reading of *Buckman* is the fact that Respondents' claims here are typical and traditional state tort actions, unlike the *sole* claim and *unique* defendant in *Buckman*. Further unlike *Buckman*, the Michigan provision is an exception to a tort defense created as a matter of legislative policy, a defense not recognized at common law. The noncompliance exception itself follows the common law tradition and is a logical exception to the statutory defense.

The Michigan statute has neither the purpose nor the effect of regulating the FDA and those who make applications to the agency. Quite the contrary, the statute "implicat[es] federalism concerns and the historic primacy of state regulation of matters of health and safety." 531 U.S. at 348. The noncompliance exception follows the common law regarding products liability cases, as further explained below. Thus, the Michigan noncompliance provision fits comfortably within the scope of the States' traditional police power to define tort law within their borders.

II. MICHIGAN'S NONCOMPLIANCE PROVISION DOES NOT AFFECT THE EVIDENCE ADMISSIBLE IN STATE LAW PRODUCTS LIABILITY ACTIONS.

A. Tort law long has endorsed the rule that government approval of a product or compliance with government regulation generally does not create tort law immunity. *See, e.g.*, W. Page Keeton, *et al.,* PROSSER AND KEETON ON THE LAW OF TORTS, § 36, p. 233 (5th ed. 1984) ("Such a standard is no more than a minimum, and it does not necessarily preclude a finding that the actor was negligent in failing to take additional precautions"); *see also* RESTATEMENT (SECOND) OF TORTS § 288 C (1965).

Instead, "[u]nder the common law, the defendant's compliance with a statute is not in itself a defense to a negligence action." Dan B. Dobbs, THE LAW OF TORTS, § 373, p. 1033 (2000) (footnote omitted). Importantly for this case, "[t]he common law rule in products cases is the same—evidence of compliance with statute or regulation is relevant to judgments about the product's alleged design or warning defects and hence admissible but not by any means conclusive." *Id.* at 1033-34 (footnotes omitted).

One reason for the common law rule is that "[f]requently, regulations are intended to provide a floor or a minimum level of safety, not an optimal level or a ceiling on safety precautions." *Id.* at 1034. Another reason is that "even if legislatures and regulatory agencies are not 'captured' by the industries they regulate, statutes and regulations may reflect the heavy influence of the regulated industry as much as judicious concerns with safety." *Id.* Yet another reason is that "[m]ost federal law is

regulatory in nature; regulators are not likely to think through tort issues when they formulate rules that may be appropriate from an administrative viewpoint but not from a tort law viewpoint." *Id.* For these reasons and others, the common law does not treat government approval as creating a defense to, or immunity from, products liability actions.

B.1. The view that government approval is not conclusive regarding product safety and creates no tort immunity continues strongly to this day. Section 4 of the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998) provides as follows:

> § 4. Noncompliance and Compliance with Product Safety Statutes or Regulations
>
> In connection with liability for defective design or inadequate instructions or warnings:
>
> (a) a product's noncompliance with an applicable product safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation; and
>
> (b) a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, *but such compliance does not preclude as a matter of law a finding of product defect.*

Emphasis added; *see also id.* § 6 (defining potential liability of prescription drug manufacturers for manufacturing defects, design defects, and inadequate warnings).

Several members of the Court recognized and discussed these very principles in an earlier preemption case, *Geier v. Am. Honda Motor Co.,* 529 U.S. 861 (2000). The dissenting opinion in *Geier* made the explicit point that Honda's compliance with federal regulations regarding airbags in motor vehicles presumably would be admissible to respond to claims of negligence and defective design, but "would not provide Honda with a complete defense on the merits." 529 U.S. at 892 (Stevens, J., dissenting). The *Geier* dissent further recognized that evidence of compliance with regulatory standards "would presumably weigh against an award of punitive damages," *id.* at 893, but would not bar or preempt such an award under state tort law principles. *Id.* (citing *Silkwood v. Kerr-McGee Corp.*).

That discussion in *Geier* is an accurate description of the common law of torts generally, and no state but Michigan grants drug manufacturers a defense to all tort liability by virtue of obtaining FDA approval of a drug. Rather, in the "overwhelming majority of jurisdictions," RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 Reporters' Note, cmt. e, evidence of FDA approval would not be conclusive and would not create a complete defense to, or immunity from, tort claims.

B.2. Furthermore, there is no express preemption provision in the relevant FDA statutes. As one well-respected tort law scholar puts it, "[f]ood and drugs are regulated heavily, but with no obvious preemptive intent." Dobbs, THE LAW OF TORTS, § 373, p. 1033 (footnote omitted). Thus, FDA approval of a new drug does not preempt general state tort law, nor does it create a defense to liability as a matter of

federal law. Rather, unless and until Congress declares otherwise, the legal significance, if any, of evidence of FDA approval of a new drug in state law products liability actions is determined by the law of each state.

States need not and generally do not immunize drug manufacturers from potential state tort liability based on FDA approval. Instead, because traditional products liability theories include concepts such as negligence, defective design, and failure to warn, the question of what a manufacturer knew or should have known about the risks its product posed often is central to a plaintiff's case under state tort law. Evidence addressing that question may well include documents and other materials submitted to, or withheld from, government regulators.

Some states, such as Kansas for example, direct that evidence of government approval or compliance with government regulation creates a rebuttable presumption of nondefectiveness or adequate warnings. *See* KAN. STAT. ANN. § 60-3304(a). But, at the same time, such States generally are clear that any presumption is rebuttable; it remains open to plaintiffs to prove "that a reasonably prudent seller could and would have taken additional precautions." *Id.* Evidence of product risks of which a drug manufacturer knew or should have known will be admissible to rebut the effect of evidence regarding government approval.

In other words, evidence that drug manufacturers failed to disclose risks that an FDA-approved drug poses is relevant and admissible in state law products liability actions generally, FDA approval notwithstanding. And such evidence might well

include information and documents that were or were not provided to the FDA, both prior to and following the approval of the drug. Even without a noncompliance statutory provision, evidence of manufacturers' knowledge and disclosures—or lack thereof—is relevant in traditional products liability actions under state tort law, and generally admissible.[2]

Thus, Michigan's noncompliance exception does not affect the kind of evidence that is already relevant and admissible in products liability actions under state law generally. To put it another way, Michigan's exception embodies traditional common law tort principles.

That Michigan chose—as a matter of policy—to provide a statutory defense to drug manufacturers who have obtained FDA approval, while it at the same time created a noncompliance exception, results in no significant change, if any, in the evidence that typically would be relevant and admissible in products liability actions. The Michigan statute no more conflicts with federal law nor frustrates federal purposes than does the unquestioned common law rule that government approval of a product does not create tort immunity.

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[2] In any event, there is no bar to the States permitting or authorizing traditional products liability actions for damages, or even state law "fraud" claims, based on an FDA finding of fraud. In that instance, state law unquestionably "would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme." *Buckman*, 531 U.S. at 354 (Stevens, J. joined by Thomas, J., concurring in the judgment).

As the Court stated many years ago in another preemption case, "[n]o doubt there is tension between the conclusion that [certain] regulation is the exclusive concern of the federal law and the conclusion that a state may nevertheless award damages based on its own law of liability." *Silkwood*, 464 U.S. at 256. A presumption against preemption is not a constitutional bar to federal preemption of state law when Congress clearly expresses an intent to preempt. But given the federalism that our Constitution created, a presumption is essential to respecting state sovereignty and inherent in our system, at least in cases involving (1) the most traditional areas of state police power, such as tort law, (2) no history of significant federal presence in such an area, and (3) no express declaration by Congress of its intent to preempt such traditional state tort law.

Importantly, a presumption permits the courts to leave the ultimate resolution of doubtful and unclear cases where such a determination belongs—in Congress. Only by reserving for Congress the primary role in preemption cases will "the right of the State courts to establish the [tort] liability of the persons involved in the normal way [be] maintained." *Silkwood*, 464 U.S. at 253 (internal citation omitted).

CONCLUSION

The Second Circuit correctly held that a presumption against preemption applies in this case and that federal law does not implicitly preempt Michigan's noncompliance exception to a statutory defense based on FDA approval of a drug. The judgment below should be affirmed.

Respectfully submitted,

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January 14, 2008

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