No. 06-1498

IN THE
Supreme Court of the United States

WARNER-LAMBERT CO., LLC, ET AL.,

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 AMERICAN ASSOCIATION FOR JUSTICE AS AMICUS CURIAE SUPPORTING RESPONDENTS

KATHLEEN FLYNN PETERSON
1050 31st Street, N.W.
Washington, DC 20007
(202) 965-3500
President, American Association for Justice

FRANCINE A. HOCHBERG*
CENTER FOR CONSTITUTIONAL LITIGATION, P.C.
1050 31st Street, N.W.
Washington, DC 20007
(202) 944-2803
Counsel for Amicus Curiae

*Counsel of Record

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATORY MATERIALS

OTHER AUTHORITIES

INTEREST OF *AMICUS CURIAE*

The American Association for Justice ("AAJ"), formerly the Association of Trial Lawyers of America, respectfully submits this brief as *amicus curiae* in support of Respondents. This brief is filed with consent of all parties.[1]

AAJ is a voluntary national bar association whose trial lawyer members primarily represent individual plaintiffs in personal injury cases and other civil actions, including product liability cases. Throughout its 60-year history, the association has advocated both in courts and in Congress and state legislatures to preserve the protections for ordinary citizens afforded by the common law and to ensure that state tort claims, such as product liability claims, provide injured persons with effective legal recourse and remedies for wrongful injuries. By bringing such claims on behalf of people injured by pharmaceutical products, among others, and also by testifying before Congress about drug safety and the FDCA, AAJ's members have helped to ensure that the nation's consumers have access to safe and effective pharmaceuticals.

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[1] Letters of consent from both parties have been filed with the Clerk of Court. Pursuant to Rule 37.6, *amicus* states that no counsel for a party authored any part of this brief, nor did any person or entity other than *amicus*, its members, or its counsel make a monetary contribution to its preparation or submission.

SUMMARY OF THE ARGUMENT

1. The Court of Appeals for the Second Circuit correctly held that this Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), does not preempt the exemption to Michigan's statute shielding pharmaceutical manufacturers from products liability claims, Mich. Comp. Laws Ann. § 600.2946(5). Congress did not intend the FDCA to preempt state common law tort claims, such as those alleged by Respondents, none of which has as an element fraud or misrepresentation to the FDA. The application of Michigan's exemption in this case does not "inevitably conflict with the FDA's responsibility to police fraud," *Buckman*, 531 U.S. at 350, nor is there a "direct and positive conflict" between the exemption and the FDCA.

Michigan's statutory scheme is consistent with the FDCA. The State's conclusive statutory presumption that drug manufacturers are not liable for state products liability claims applies only to drug manufacturers who comply with FDA protocols; the exemption challenged here applies only in cases in which a drug manufacturer withheld information from or misrepresented information to the FDA during the drug approval process.

When a plaintiff does not proffer evidence of misconduct, a court will dismiss a plaintiff's products liability action. In a case such as Respondents', however, in which evidence of such wrongdoing exists, such evidence merely permits Respondents' state law tort claims to proceed. Unlike *Buckman,* evidence of wrongdoing in the FDA drug-approval process does not compose any part of any tort claim

alleged by Respondents, and will not factor in the subsequent litigation, nor will it impact, impel, or result in any further action by the FDA.

2. State tort claims, such as those brought by Respondents, work in concert with FDA regulation to ensure that the public has access to safe and effective drugs. As an FDA-commissioned Institute of Medicine Report noted, drugs approved by the FDA enter the market with incomplete safety profiles. The FDA, however, lacks adequate tools to address the postmarketing safety issues that inevitably result. The FDA lacks the authority to require postmarketing safety studies and does not systematically document reports of adverse reactions, which generally are submitted at the discretion of the drug manufacturer. Furthermore, the FDA is underfunded and overburdened, as a result of which the FDA's rate of prosecuting enforcement actions declined by sixty-six percent between 2000 and 2005.

Congress understood that litigation plays an essential role in identifying key information concerning drug safety and efficacy, as well as in providing remedies to consumers who suffer drug-related injuries. The Michigan exemption, which would permit tort claims to proceed against a drug manufacturer *only* in cases in which the manufacturer withheld or misrepresented information during the drug approval process, does not conflict with the FDCA and thus should not be held preempted under *Buckman*.

ARGUMENT

I. The Exemption to Michigan's Statute Shielding Drug Manufacturers From Liability Is Not Impliedly Preempted by the FDCA

All states provide legal remedies to consumers who are injured by unreasonably dangerous products, including pharmaceuticals. State legislatures have modified common law products liability to varying extents to serve a range of state interests.

Michigan law provides that a drug manufacturer whose product has received FDA approval cannot be liable in a products liability action, unless the manufacturer obtained that approval by withholding or misrepresenting information to the FDA. Mich. Comp. Laws Ann. § 600.2946(5); *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 130 (Mich. 2003). The statute's conclusive presumption of non-liability – and the exemption thereto at issue here – are valid exercises of state legislative authority. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (explaining that because health and safety are "primarily, and historically, . . . matter[s] of local concern," the "States traditionally have had great latitude under their police powers to legislate" on such matters) (quotations omitted). That Michigan chooses to presume that pharmaceutical manufacturers are not liable for product liability claims when the manufacturer has complied with FDA protocols – and to deny that presumption to those manufacturers who violate those procedures by willfully withholding information from, or

misrepresenting information to, the FDA – is entirely a matter of state rather than federal law. *See id*. It also is a function of the historic distribution of power between the States and federal government as separate sovereigns under our Constitution.

The Court of Appeals for the Second Circuit correctly held that the exemption to Michigan's statute shielding pharmaceutical manufacturers from products liability, Mich. Comp. Laws Ann. § 600.2946(5), is not impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). As the lower court noted, the claims at issue in *Buckman* were novel state-law claims alleging that a consulting company that helped a medical device manufacturer gain FDA approval for its device committed fraud on the FDA. By contrast, Respondents assert common law claims, including breach of implied and express warranties, negligence, and defective design and manufacturing claims. Pet. App. at 7a. Respondents' claims neither are "premised on fraud against the FDA," nor seek to hold a drug manufacturer liable under state law for alleged misrepresentations to the FDA. *Compare Buckman*, 531 U.S. at 345-47. Respondents' common law claims also are not themselves "preempted" by the FDCA, as were those alleged in *Buckman*. *See* Pet. App. at 19a.

The exemption to Michigan's presumption of non-liability that Respondents' seek to apply here is not akin to those claims held preempted in *Buckman*. *Buckman*, 531 U.S. at 353. "In [*Buckman*], the fraud claims exist solely by virtue of the FDCA disclosure requirements." *Id.* Respondents' claims, by comparison, are not premised on "[p]olicing fraud

against" the FDA, nor do they exist "solely by virtue of the FDCA." *Compare id.*

The Michigan exemption reflects the legislature's decision to allow only a limited class of product liability claims to proceed against drug manufacturers. Those cases, in which evidence demonstrates that the drug manufacturer withheld information from, or misrepresented information to, the FDA, neither implicate this Court's ruling in *Buckman*, nor interfere with the FDA's policing of fraud. In fact, they are consistent with the FDA's anti-fraud provisions and reinforce the FDA's purposes by providing a further disincentive to drug manufacturers to breach FDA protocols, by withholding or misrepresenting information during the drug approval process. Compliance with FDA protocols confers nonliability in Michigan.

The Michigan exemption is a *precondition* to holding a drug manufacturer liable under Michigan's product liability laws, just as service of process is a precondition to suit. A judge's decision whether to apply the exemption and permit a plaintiff's state tort claims to proceed to trial neither implicates action by the FDA, nor interferes with FDA functions. The determination is based largely on the court's review of documents submitted to the FDA by the drug manufacturer or that have come to light post-marketing, and the ultimate FDA actions concerning the drug. *See, e.g.,* Liza Gibson, *GlaxoSmithKline to Publish Clinical Trials After US Lawsuit*, 328 Brit. Med. J. 7455 (Jun. 26, 2004) (discussing lawsuit brought by New York Attorney General alleging that drug manufacturer "engaged in 'repeated and persistent fraud' for concealing" results of clinical studies and citing company memo that it

would be "commercially unacceptable" to admit results). Such an inquiry would not burden the FDA.

A court's finding a drug manufacturer committed wrongdoing during the drug approval process sufficient to allow the lawsuit to proceed would have no legal consequences for the FDA. It does not override or replace a judgment by the FDA. It does not obligate the FDA to take action related to the finding. Most importantly, it does not itself result in liability for the drug-manufacturer defendant. It merely opens the door to the courtroom.

Applying Michigan's exemption in this way does not "inevitably conflict with the FDA's responsibility to police fraud," *Buckman*, 531 U.S. at 350, nor does it infringe or "direct[ly] and positive[ly] conflict" with the FDCA, as this Court held the claims did in *Buckman*. Application of the exemption neither renders compliance with the FDCA "a physical impossibility" nor "stands as an obstacle to the accomplishment and execution of the full purposes and objectives" of the FDCA. Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 228 (2000) (citations omitted). Instead, the Michigan exemption and the showing required by the statute are completely consonant with federal law.

By comparison, a finding by this Court that the Michigan exemption *is* preempted would interfere with Congress's purposes in enacting the FDCA. Allowing drug manufacturers, who have misrepresented or withheld information during the drug approval process, to avail themselves of a conclusive presumption of non-liability and thus be immune from suit would destroy a powerful,

complementary incentive to comply with FDA procedures and would limit FDA's access to crucial information. Such interference would impede the FDA's ability to fulfill its regulatory mission, as the agency itself recognizes.[2] *See* 71 Fed. Reg. 3922, 3936 (Jan. 24, 2006) (stating that state tort claims should not be preempted if "the [drug's] sponsor withheld material information" from the FDA).

II. Congress Did Not Intend the FDCA to Preempt State Tort Liability for Harm Caused by Unreasonably Dangerous Drugs

This Court should affirm the Second Circuit's decision that the application of Michigan's exemption to Respondents' claims does not conflict with and is not preempted by the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301, *et seq*. First, Congress did not intend the FDCA to preempt state tort claims. Congress intended to preserve traditional state tort claims to provide remedies for persons who wrongly suffered drug-related injuries and to supplement the FDA's regulatory authority. Second, Congress intended the FDCA to preempt state law only where state law poses a "direct and positive conflict" with the FDCA. The exemption to the Michigan statute does not pose a direct and positive conflict with the FDCA or undermine FDA's ability to police fraud.

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[2] This assumes for argument that the exemption is severable. Whether the exemption provision is severable is an open question, discussion of which is beyond the scope of this brief.

A. Congress Did Not Intend the FDCA to Preempt State Tort Claims

Congress's intent provides the "touchstone" in matters of federal preemption. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996). Courts ascertain that intent from the plain wording of a preemption provision, *Medtronic*, 518 U.S. at 484; *Cipollone*, 505 U.S. at 523-24, as well as from "both textual and legislative context" of the statute, *Medtronic*, 518 U.S. at 489-90; *Cipollone*, 505 U.S. at 519 n.16.

Petitioners urge the Court to hold that the application of the Michigan exemption is impliedly preempted under *Buckman*, thus barring Respondents' state law claims seeking remedies for drug-related injuries. The Michigan exemption, however, is an exemption to a statute enacted within Michigan's legislative prerogative in a "field which the States have traditionally occupied." *Medtronic*, 518 U.S. at 485; *compare Buckman*, 531 U.S. at 347. Because both the exemption to the Michigan statute and Respondents' underlying claims, unlike those at issue in *Buckman*, involve a "'field which the States have traditionally occupied,'" the Court "start[s] 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)); *Jones v. Rath Packing Co.*, 430 U.S. 519, 544-45 (1977) (Rehnquist, J., concurring).

The Food, Drug, and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. § 301, *et seq.*,[3] does not contain a general express preemption provision for pharmaceutical products as codified. *Jones*, 430 U.S. at 537; *see also* 71 Fed. Reg. 3935 n.8. The legislative history of the FDCA, its amendments, and its predecessor the Pure Food and Drug Act of 1906, however, reflect Congress's intent that the FDCA not infringe on state common law causes of action.

In 1938, after the deaths of more than 100 people from elixir of sulfanilamide, Congress passed the FDCA, Institute of Medicine, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* 22, 152 (Alina Baciu, et al. eds. 2007) ("IOM Report"), to regulate producers of dangerous products and to protect consumers. *See United States v. Dotterweich,* 320 U.S. 277, 280, 282 (1943) (stating that House and Senate committee reports indicate that "[t]he purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection"); *see also 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States,* 340 U.S. 593, 596 (1951) (stating that Congress intended the FDCA to protect consumers); *United States v. Sullivan,* 332 U.S. 689, 696 (1948).

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[3] When the FDCA was enacted, Congress repealed the Pure Food and Drug Act of 1906, Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906), codified at 21 U.S.C. §§ 1-15 (1934) (repealed in 1938 by 21 U.S.C. § 329(a)). *See* Marden G. Dixon & Frank C. Woodside III, Drug Product Liability § 5.01 [1] (1982). Prior to the enactment of the Pure Food and Drug Act of 1906, "the States provided the primary and possibly the exclusive source of regulatory control over the labeling of foods and drugs." *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 782 (E.D. La. 2007).

"The act prohibited false therapeutic claims for drugs and for the first time required premarket notification of FDA by the sponsor for all new drugs. . . . [I]t did not require proof of efficacy." IOM Report, *supra*, at 22.

Congress considered including in the Act a private federal cause of action for damages caused by faulty or unsafe products regulated by the Act. *See* H.R. Rep. No. 73-6110, pt. 1, § 25 (1933) ("Liability for Personal Injuries – a right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this Act."). Notably, the Senate deleted this proposed private cause of action from the bill on the ground that it is unnecessary because "[a] common-law of right of action exists" in state law. Hearing on S. 1944 Before a Subcomm. of the Comm. on Commerce, 73d Cong. 2d Sess. 400, 403 (1933). *See also Consumer Fed'n of Am. v. Upjohn*, 346 A.2d 725, 731 (D.C. 1975) (explaining that private right of action was omitted from bill because "it would create an *unnecessary* federal action *duplicative of state remedies*" and concluding that Congress "*rejected* [] setting up a nationally uniform law for such" actions) (emphasis added); Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 924 & n.130 (1994).

A common law cause of action for negligence with respect to the manufacture and sale of medicines and related products was long-standing and widely recognized. *See, e.g., Boyd v. Coca Cola Bottling Works*, 177 S.W. 80, 81 (Tenn. 1915) (holding that drug, food, and beverage manufacturers owe a duty to those who consume their products and that "[a] tort is committed, a legal

right invaded, by practices which prejudice another's health"); *Thomas v. Winchester*, 2 Seld. 397, 1852 WL 4748 (N.Y. 1852) (holding a drug manufacturer liable for a patient's injury); *see also* Restatement (Third) of Torts Prod. Liab. § 2 (1998) (providing standards of liability when a product is defective).

That Congress passed the FDCA without a private right of action indicates that Congress intended state tort actions to be maintained both to provide "judicial recourse for those injured" by pharmaceutical products and to accomplish the purposes of the FDCA. *Compare Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("This silence [of Congress in enacting and amending the Atomic Energy Act] takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."). *See also Medtronic*, 518 U.S. at 487 (citing same in construing 21 U.S.C. § 360k(a) of the Medical Device Amendments).

In Europe, in the late 1950s and early 1960s, thousands of children were born with birth defects to mothers who had ingested thalidomide. IOM Report, *supra*, at 22, 152; *see also* Richard S. Jacobson & Jeffrey R. White, *David v. Goliath: ATLA and the Fight for Everyday Justice* 153-55 (2004). Thalidomide's approval by the FDA was pending when the adverse effects of the drug in Europe came to light. Because of this "near miss" – but for a delay in the approval process many thousands of children in the U.S. likely would have been born with disfiguring birth defects – Congress initiated

amendments to strengthen the FDCA in 1962.[4] *See* S. Rep. No. 1744, 87th Cong., 2d Sess., at 1 (1962) ("The purpose of the proposed legislation . . . is to strengthen and broaden existing laws in the drug field so as to bring about better, safer, medicine and to establish a more effective system of enforcement of the drug laws."); *see also* Jacobson & White, *supra*, at 153-55 (discussing ATLA members' representation of thalidomide victims and their role in Congressional hearings on strengthening the FDCA).

The 1962 Drug Amendments "shifted the burden of proof from FDA (which previously had to prove harm to keep a drug from being marketed) to manufacturers, who now were required to demonstrate both safety and efficacy prior to receipt of marketing approval." IOM Report, *supra*, at 152 (citation omitted). Nevertheless, the "FDA's ability to form judgments about the safety and efficacy of drugs depends upon the submission of data, usually from drug company sponsors, rather than on the use

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[4] In recent years, the FDA has not been so lucky in avoiding adverse events. Pharmaceutical companies are not required to report "adverse events identified in non-US marketing experience unless the events are 'serious and unexpected.'" Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 310 (Jan. 17, 2007). In 1995, Belgian authorities informed FDA that women who used diet drugs such as dexfenfluramine (Fen-Phen) had heart valve abnormalities. Because the FDA did not monitor reports of adverse effects made to its international counterparts, and the drug manufacturer did not provide case reports to the FDA, the FDA did not consider the earliest adverse events related to the drug. *Id.* Ultimately, the drug was withdrawn from the U.S. market after many consumers suffered injuries when Fen-Phen's "risk of causing cardiac valvulopathy and pulmonary hypertension was determined to outweigh its very modest capacity to promote weight loss." *Id.*

of data developed independently or on its own initiative." *Id.*

The 1962 amendments also clarified the FDCA's intended effect on state laws. Congress included language explicitly *restricting* the potential preemptive effect of federal law to cases of "direct and positive conflict": "Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating *any* provision of State law which would be valid in the absence of such amendments unless there is a *direct and positive conflict* between such amendments and such provision of State law." Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962) (emphasis added).

This Court found in *Buckman* such a direct and positive conflict in a fraud-based cause of action. However, extending *Buckman* to preempt the Michigan exemption would undermine the FDCA. As another federal district court has written, in rejecting a similar preemption argument:

> FDA's and [defendant]'s position [in favor of preemption] vitiates, rather than advances, the FDCA's purpose of protecting the public. That is, FDA and [defendant] invite the Court to find that in enacting the FDCA for the purposes of protecting public health, Congress not only declined to provide for a private cause of action but also eliminated the availability of common law state claims. This position contravenes common sense . . . .

In re Paxil Litig., No. 01-07937, 2002 WL 31375497 at *1 (C.D. Cal. Oct. 18, 2002).

The Court's inquiry here into whether application of the Michigan exemption to Respondents' claims is preempted under *Buckman* should not be "[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459 (2005) (Thomas, J., concurring in part and dissenting in part) (quoting *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)). Instead, the Court should reaffirm that "[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989) (internal quotation omitted).

Congress was fully aware of the existence – and usefulness – of state laws addressing drug safety and tort law remedies when it enacted and amended the FDCA. Congress, however, has *never* sought to preempt such actions.[5] As the former Commissioner of the Food and Drug Administration has written,

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[5] Congress recently amended the FDCA by enacting the Food & Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823 (2007). The sole preemption language included in the FDAAA precludes States or political subdivisions from "establish[ing] or continu[ing] in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database." 42 USCA § 282(d)

"Nothing in the statutes the FDA administers suggests that they eliminate state damages actions for pharmaceutical products. . . . And Congress *has not acted* to preempt or limit state damage actions, even though it has long been aware of tort litigation over drug products." David A. Kessler, M.D. & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. __ (forthcoming Jan. 2008) (emphasis added), *available at* http://lsr.nellco.org/georgetown/ois/papers/2/. Courts have noted that "[i]f Congress wants to take the extraordinary step of giving drug manufacturers immunity from personal tort actions, it would expressly state such intentions whether by statute or legislative history." *Merrell Dow Pharms., Inc. v. Oxendine*, 649 A.2d 825, 829 (D.C. 1994) (quoting *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1299-1300 (D. Minn.1988)) (ruling that FDCA did not preempt state tort law actions against manufacturers of prescription drugs).

This Court should decline to shield Petitioner from liability under Michigan law by preempting application of the Michigan exemption. Such a result would contradict Congress's intent in enacting the FDCA. Michigan's enactment of a conclusive presumption of non-liability for drug manufacturers, which bars all claims for drug-related injuries except those relating to drugs whose manufacturers misrepresented information to, or withheld information from, the FDA, is a legislative choice in a traditional state field of interest. Such legislation is Michigan's prerogative and should be respected by this Court.

B. No "Direct and Positive Conflict" Exists Between the Michigan Exemption and the FDCA

When Congress's express words provide "a reliable indicium of congressional intent with respect to state authority, there is no need to infer congressional intent to preempt state laws." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992). As discussed above, the FDCA "does not contain an express statement that Congress intended to displace state-law claims in the prescription drug context." *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d at 784. To the contrary, the 1962 Drug Amendments expressed Congress's intent that the FDCA *not* preempt state law "unless there is a *direct and positive conflict* between such amendments and such provision of State law." Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (emphasis added).

Congress inserted the "direct and positive conflict" language in the 1962 Drug Amendments to avoid claims of preemption and to leave state law in place except in cases in which it was impossible to comply with both state and federal laws. *Levine v. Wyeth*, --- A.2d ----, 2006 WL 3041078 at ¶27 (Vt. 2006), *petition for cert. filed* (U.S. Mar. 12, 2007) (No. 06-1249). *See also Southern Blasting Servs., Inc. v. Wilkes County, N.C.*, 288 F.3d 584, 590 (4th Cir. 2002) (interpreting statute disclaiming preemption except in cases of "direct and positive conflict" and explaining that state law is preempted *only* when it is in "*actual* conflict with federal law such that 'compliance with both federal and state regulations is a physical impossibility") (citing *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S.

707, 713 (1985) (internal quotation omitted)) (emphasis added).

Congress understood the "direct and positive conflict" language to ensure that federal law will not widely preempt state law in fields such as food and drug law where states have stronger laws and tort causes of action to remedy injuries. *Merrell Dow Pharms., Inc. v. Oxendine*, 649 A.2d 825, 828 n.3 (D.C. 1994) (citing 108 Cong. Rec. 21,083 (1962)). *See also Thrall v. Wolfe*, 503 F.2d 313, 317 (7th Cir. 1974) (interpreting statute with *identical* "direct and positive conflict" language and concluding, "The section was doubtless inserted for the purpose of avoiding a claim of preemption"); *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d at 784, 788-89 (discussing 1962 amendments; holding plaintiffs' claims not to be preempted by FDCA). Courts have held accordingly that this language in the 1962 Amendments "essentially removes from our consideration the question of whether common-law tort claims present an obstacle to the purposes and objectives of Congress." *Levine*, 2006 WL 3041078 at ¶ 27.

"For a direct and positive conflict to exist, the state and federal laws must be such that they 'cannot be reconciled or consistently stand together.'" *Southern Blasting Servs., Inc.*, 288 F.3d at 590; *see also Sinnot v. Davenport*, 63 U.S. 227, 243 (1859).

> [A] state[]'s imposition of additional requirements *above* a federal minimum is *unlikely* to create a direct and positive conflict with federal law. Rather, a conflict is more likely to occur when a state [] provides that compliance

> with a federal standard is not mandated, or when compliance with federal law actually results in a violation of local law.

Southern Blasting Servs., Inc., 288 F.3d at 591-92 (emphasis added). *Compare Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 141 (1963) (holding that a California statute did not "'stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' . . . [because] there is neither such actual conflict between the two schemes of regulation that both cannot stand in the same area, nor evidence of a congressional design to preempt the field") (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)); *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947).

This Court should not hold that there is "a *direct and positive* conflict between [the 1962] amendments" to the FDCA and state law – the Michigan exemption for two reasons. First, the limited showing of misconduct necessary to satisfy the exemption does not amount to an "additional requirement[] above a federal minimum." *Southern Blasting Servs.*, 288 F.3d at 591. A plaintiff seeking to persuade a court that a defendant drug manufacturer's misconduct during the drug approval process falls within the exemption need only show that the defendant engaged in conduct already proscribed by federal law. The exemption does not amount to an "additional" or even a different requirement than the FDCA's. *See Medtronic*, 518 U.S. at 495 (holding that state law remedy does not impose an additional requirement but "merely provides another reason for manufacturers to comply with . . . federal law"). Second, the exemption

demonstrates that Michigan favors and indeed creates incentives for "compliance with federal law" rather than penalizes or discourages compliance with federal law because Michigan allows liability *only* in those cases in which drug manufacturers have not complied with federal law.

The Michigan exemption does not interfere with the federal regulatory scheme for prescription drugs, as did the claims at issue in *Buckman*. Rather, the exemption and federal regulations "consistently stand together." Moreover, the FDA has recognized that such an exemption is appropriate and consonant with its mandate. *See* Preamble to Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3936 (Jan. 24, 2006) (stating that state tort claims should not be preempted if "the [drug's] sponsor withheld material information" from the FDA).

III. Congress Intended State Tort Claims to Complement the FDA's Regulatory Authority

A. The FDA's Regulatory Structure and Its Limited Resources Create Safety and Information Gaps That Harm Consumers

The FDA's regulatory emphasis on new drug development and getting drugs to market, and its lack of authority over drugs and drug manufacturers postmarketing, creates safety and information gaps that Congress understood and anticipated would be filled by state tort claims, to some important extent. The FDA's regulatory scheme is consistent with

others created by Congress that rely on postmarketing liability not only to provide compensation for wrongful injuries but to inform and complement federal regulation. *See CSX Transp., Inc. v. Easterwood,* 507 U.S. 658, 668 (1993) (explaining state "negligence liability could just as easily complement" regulations under statute); *Silkwood,* 464 U.S. at 264 (Blackmun, J., dissenting) (stating that tort damages "complement the federal regulatory standards, and are an implicit part of the federal regulatory scheme"); *Larsen v. General Motors Corp.*, 391 F.2d 495, 506 (8th Cir. 1968) ("It is apparent that the National Traffic Safety Act is intended to be supplementary of and in addition to the common law of negligence and product liability."); *Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1493 (D. Kan. 1987) (state tort actions actually enhance the statutory goal of optimum vaccine safety).

The FDA's regulatory authority is "structured around the *premarketing* testing process; few tools are available for addressing *postmarketing* safety issues, short of the blunt instruments to respond to clear-cut adulteration and misbranding." IOM Report at 153 (emphasis added).[6] Postmarketing

[6] Relying on many of the Institute of Medicine's recommendations, Congress recently amended the FDCA to increase FDA's resources to ensure drug safety and its postmarketing power and authority. *See* Food & Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823 (2007); *see also* Bruce M. Psaty & David Korn, *Congress Responds to the IOM Drug Safety Report – In Full*, 298 JAMA 2185 (Nov. 14, 2007). Experts caution that even with the enactment of FDAAA, "drugs with unrecognized toxicity will reach the market." Psaty & Korn, *supra*, at 2187. FDAAA's ultimate success depends both on cooperation

safety issues, such as those for which Respondents seek remedies, however, are quite common: "Fifty-one percent of all [FDA] approved drugs elicit at least one serious type of adverse reaction that was not observed during premarketing clinical trials . . . 20 percent of new drug labels are modified with a black box warning; 3 to 4 percent of new drugs are withdrawn for safety reasons." Thomas N. Tiedt, *The Drug Safety System Conundrum*, 62 Food & Drug L.J. 547, 553 (2007).

Postmarketing safety issues arise because drugs enter the U.S. market with "incomplete safety profiles," IOM Report at 37. "Pre-approval testing generally is incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect subpopulations not included or adequately representing in the studies (*e.g.*, the elderly, ethnic minorities and pregnant women)." Kessler & Vladeck, *supra*, at 12 (citing IOM Report at 38). Premarketing clinical trials are highly managed and enroll patients who "generally have more homogenous medical histories" and represent a more limited demographic. Tiedt, *supra*, at 553. As a result, adverse drug reactions are constrained and more infrequent than they would be in a general population. *Id.* As an FDA-commissioned report by the Institute of Medicine explains:

> Preapproval trials typically are too small to detect even significant safety problems if they are rare. An adverse event (even a serious one) that occurs in less than one in 1,000 patients cannot

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between industry, academia and the FDA, and the FDA increasing its leadership and oversight. *See id.*

> be reliably detected except in the largest premarket trials but can pose a serious public health problem when hundreds of thousands or millions of people use the drug.

IOM Report at 37-38 (citations omitted). Unfortunately, changes to clinical trial protocols and their sizes likely will not prevent drugs from entering the market with incomplete safety profiles. As experts have explained, "[t]rials designed to test hypotheses about serious safety outcomes would in most cases require many more subjects than are needed for an efficacy endpoint." IOM Report at 106.

The case of Rezulin (troglitazone), the drug at issue here, is not an isolated example of these systemic failures. *See, e.g.,* IOM Report at 17 ("Alosetron was withdrawn . . . Troglitazone, propulsid, cerivastatin, rofecoxib, and valdecoxib have been withdrawn."); *see also* Amalia M. Issa, *et al.*, *Drug Withdrawals in the United States: A Systematic Review of the Evidence and Analysis of Trends*, 2 Current Drug Safety 177 (Sept. 2007) (finding that a mean of 1.5 drugs per year (or twenty drugs) were withdrawn since 1993). The clinical trial of Rezulin involved 2510 patients who received Rezulin; an additional 475 patients received placebo. Paul B. Watkins, M.D., *Hepatic Dysfunction Associated with Troglitazone*, 338 New Eng. J. Med. 916-17 (Mar. 26, 1998). Of the patients taking rezulin, 48 (1.9%) had abnormal liver tests, meaning that they had enzyme elevations of more than three times the upper limit of normal. *Id.* Some patients' "enzyme elevations were more than 20-fold greater than normal and [] several patients developed severe liver failure." Aaron S. Kesselheim & Jerry Avorn,

The Role of Litigation in Defining Drug Risks, 297 JAMA 308, 310 (Jan. 17, 2007). During the clinical trial, twenty patients withdrew from the trial and stopped receiving Rezulin because of their abnormal "liver-chemistry values." *Id.*

The "FDA's ability to form judgments about the safety and efficacy of drugs *depends* upon the submission of data, usually from drug company sponsors, rather than on the use of data developed independently or on its own initiative." IOM Report at 152. Thus, although the adverse effects occurred during the Rezulin trial, because Petitioner "did not acknowledge this clinically important difference until more than a year after the drug was marketed," the FDA could not evaluate the adverse reactions and the drug's risks. Kesselheim & Avorn, *supra*, at 309-10. Moreover, when Petitioner presented the data to the FDA, Petitioner "minimized its presentation of [these] adverse effects by not considering the reason patients dropped out of placebo-controlled clinical trials." *Id.* (citation omitted).

The adverse effects, which occurred in only a limited number of patients at the clinical trial stage, were amplified – and thus more prevalent – once Rezulin went on the market, where it was used reportedly by more than one million patients. David Willman, *'Fast-Track' Drug to Treat Diabetes Tied to 33 Deaths*, L.A. Times, Dec. 6, 1998 at A1; *see also* Kessler & Vladeck, *supra*, at 12-13 (citing William B. Schultz, *How to Improve Drug Safety*, Washington Post, Dec. 2, 2004; *In re Vioxx Prods. Liab. Litig.*, 2007 U.S. Dist. LEXIS 43867 (E.D. La. July 3, 2007)). After the first Rezulin-related deaths were reported in 1997, an "FDA medical officer, Dr. Robert I. Misbin, estimated that more than 12,000 Rezulin

users would experience some liver injury. Misbin also advised his superiors that 2,000 of those patients might die . . . ." *Id.* At the time of its withdrawal, the FDA had conclusively linked 91 liver failures to the pill and reports cited Rezulin as a suspect in 391 additional deaths. David Willman, *The New FDA How a New Policy Led to Seven Deadly Drugs*, L.A. Times, Dec. 20, 2000, at A1. The safety limitations of a drug are compounded when a drug manufacturer does not report or acknowledge adverse events during the clinical trial phase to the FDA, as occurred here, Kesselheim & Avorn, 297 JAMA at 310, and in the case of Paxil, among others, Gibson, *supra*, at 7455.

Congress anticipated and the FDA and other government agencies recognize that "FDA approval does not represent a lifetime guarantee of safety and efficacy." IOM Report at 2. Indeed, it cannot. "While only a few thousand patients are exposed to the new drug in aggregate before approval, millions of patients, many of whom have significantly more complex medical histories than those studied prior to approval, will ultimately use the drug in intended as well as untested circumstances" after the drug is on the market. Tiedt, *supra*, at 553. Thus, many more adverse events occur once a drug is on the market. *See, e.g.,* IOM Report at 17 (listing drugs), 109-10 (same and describing flaws in FDA's system for identifying and addressing such adverse events);

The FDA lacks a systematic means of collecting reports of adverse reactions, *id.* at 109, and what procedures exist are plagued by conflicts of interest, Tiedt, *supra*, at 553. Under the FDCA, at the time of Respondents' suit, "the detection, evaluation, and timely reporting of postmarketing

safety issues [were entrusted] to the pharmaceutical industry." Bruce M. Psaty & David Korn, *Congress Responds to the IOM Drug Safety Report – In Full*, 298 JAMA at 2185.[7] More than "90 percent of the adverse reaction reports submitted to FDA come from the new drug's marketer, who may have an inherent economic conflict of interest in drug safety decisions." Tiedt, *supra*, at 554 (citation omitted). The drug manufacturer has a disincentive to "acknowledge a risk or [] to implement studies to quantify the risk." *Id.* In fact, investigators from the FDA's Center for Drug Evaluation and Research stated that "there are strong disincentives for companies . . . to identify safety problems with licensed drugs quickly and efficiently. . . . Seeking out and sharing bad news about a product are unlikely to increase business." *Id.* (citations omitted).

That FDA approval does not indicate that the drug is necessarily safe and effective has become even more true since Congress enacted the Prescription Drug User Fee Act of 1992 ("PDUFA"), which sought to expedite agency decision-making by requiring that drug review be completed in 180 days. IOM Report at 154-55. As the FDA has struggled to meet PDUFA's goals, it has become "hard or close to impossible for [] reviewers to pursue safety concerns as carefully as they would in a less frenetic setting." *Id.* at 155 (citations omitted). Moreover, PDUFA's fee structure has contributed to commentators' and regulators' concerns that the FDA "has been 'captured' by industry it regulates [and] that the

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[7] The FDAAA of 2007 has sought to change this by giving the "FDA the authority to require postmarketing studies to identify or assess potential serious risks." Psaty & Korn, *supra* at 2185.

agency is less willing to use the regulatory authority at its disposal." *Id.*

Of most profound concern for safety and efficacy is that once the FDA has approved a drug, it has "few tools" to regulate drugs after they are released on the market. FDA has "limited authority after marketing" and is unable "to enforce implementation and fulfillment of important and necessary postmarketing commitments . . . ." *Id.* at 156 (citation omitted). As discussed above, FDA lacks "the authority to mandate further collection of data to better define adverse effects or to ensure compliance with suggested alterations in marketing practices." Kesselheim & Avorn, *supra*, 308. It also lacks authority to require postmarketing studies except in very limited cases (accelerated approval); of those requested, "47% of annual reports on studies that were due were not submitted to FDA." IOM Report at 156. According to the Office of the Inspector General, "FDA has no recourse when sponsors do not make progress or do not report on their commitments." *Id.* (citations omitted).

FDA's "resources for postmarketing drug safety work are especially inadequate and [] resource limitations have hobbled the agency's ability to improve" and perform such work. IOM Report at 193. The FDA's lack of resources and authority to induce marketers to perform postmarketing safety studies, and its incomplete system for collecting reports on adverse events, necessitates that an additional mechanism exist to ensure that the drugs on the market are safe and effective. This role is filled primarily by litigation and the civil justice system. *See generally* Kesselheim & Avorn, *supra*, at 308-311. Because of litigation's crucial role in

"uncover[ing] important and previously unavailable data about major adverse events," *id.* at 308, and providing a remedy to patients who suffer drug-related injuries, of which Congress was aware, *see supra* at 11-12, 16, the Court should not preempt application of the Michigan exemption to Respondents' claims under *Buckman*. Such an action not only would bar Respondents' state tort law claims but those of all Michigan residents who have suffered drug-related injuries from drugs produced by manufacturers who wrongly misrepresented or withheld information during the drug approval process.

B. State Tort Liability Provides a Necessary and Intended Complement to Regulation in Achieving Congress's Goal of Safe and Effective Pharmaceuticals

Litigation is crucial to ensure the safety and effectiveness of drugs because, as Congress recognized, FDA approval is not a guaranty of safety or efficacy and the FDA historically has lacked the tools to fully and adequately regulate drugs after they are on the market. The FDA's reach is enormous, regulating products that represent roughly 25 percent of all consumer spending in the United States. Institute of Medicine, Challenges for the FDA: The Future of Drug Safety, Workshop Summary (2007). In other words, FDA regulates "approximately $1 trillion in consumer products or 25 cents of every consumer dollar expended in this country annually." FDA Subcommittee on Science & Technology, *FDA Science & Mission at Risk* 1 (Nov. 2007). Yet, as the FDA itself has concluded, it has

"serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." *Id.* at 2-3. The FDA is underfunded and overburdened, Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. Mich. J.L. Reform 461, 496 (1997), as a result of which the FDA's rate of prosecuting "enforcement actions [] declined by sixty-six percent between 2000 and 2005," U.S. House of Rep., Comm. on Gov. Reform, *Prescription for Harm: The Decline in FDA Enforcement Activity* 8-9 (Jun. 2006) (Minority Report prepared for Rep. Henry Waxman).

Congress intended the civil justice system to supplement regulation, *see supra* at 11-12, 16. Litigation has fulfilled this purpose. *See In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571, 575 (E.D.N.Y. 2007) ("[L]awyers and their clients often find themselves serving as drug safety researchers of last resort.") (quotation omitted). Litigation has "helped the medical community reassess drugs by bringing to light new information about adverse effects" and "[i]n both the premarketing and postmarketing stages, lawsuits have helped uncover important and previously unavailable data about major adverse events." Kesselheim & Avorn, *supra*, at 308. Additionally, the "legal system [has] played an important role in spurring change in regulatory or corporate procedures, as well as extending knowledge about drug risks by adding to the evidence available for evaluation by physicians, patients, and regulators." *Id.* at 310.

Product liability claims, such as those alleged by Respondents, work in concert with federal regulation, allowing the marketplace to provide an

added financial incentive for manufacturers to make their products safe and effective as mandated by the FDA. See John W. Wade, *On the Nature of Strict Tort Liability for Products,* 44 Miss. L.J. 825, 826 (1973); (Pet'r App. at 25a-26a). Regulation and liability, in fact, are understood by this Court to be complementary. *See, e.g., CSX Transp., Inc.,* 507 U.S. at 668 (explaining state "negligence liability could just as easily complement" regulations under statute); *Silkwood,* 464 U.S. at 264 (Blackmun, J., dissenting) (stating that tort damages "complement the federal regulatory standards, and are an implicit part of the federal regulatory scheme").

By assessing risk retrospectively, product liability helps to compensate consumers for imperfect information. Steven P. Croley & Jon D. Hanson, *Rescuing the Revolution: The Revived Case for Enterprise Liability*, 91 Mich. L. Rev. 683, 707-08 (1993); *see also* W. Kip Viscusi, *Reforming Products Liability* 66 (1991) ("The purpose of products liability is to fill the gaps left by market imperfections and to replicate the incentives that would have been generated had markets been functioning perfectly.") State tort claims fulfill this role directly, by providing remedies to people who suffer adverse reactions to drugs, and also indirectly, by creating financial incentives for pharmaceutical companies to make their products safer and to provide more reasonable warnings to the FDA and to consumers about the dangers those products pose. As the former Chief Counsel of the FDA, Margaret Jane Porter, has written, "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection." Margaret J. Porter, *The Lohr*

Decision: FDA Perspective and Position, 52 Food & Drug. L.J. 7, 11 (1997).

State tort claims, including Respondents' claims, further the purposes of the FDCA, as discussed above. As the Supreme Court said in *Bates* about a statutory scheme similar to the FDCA, "[p]rivate remedies . . . seem to aid, rather than hinder, the functioning of FIFRA . . . . [T]ort suits can serve as a catalyst in this process." 544 U.S. at 451.

Bates is consistent with numerous prior decisions holding that common law claims do not conflict with federal law because they merely exert incidental regulatory pressure on manufacturers. *See, e.g.*, *English v. Gen. Elec. Co.*, 496 U.S. 72, 85-86 (1990) (upholding employee whistleblowers state law claim for intentional infliction of emotional distress against nuclear industry employer because effect of damage awards was not direct or substantial enough to warrant preemption); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 186 (1988) (upholding nuclear worker's state workers compensation claim based on violation of state safety regulation on the ground that compensation award imposes only acceptable incidental regulatory pressure, not unacceptable "direct regulatory authority"); *see also Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1542 (D.C. Cir. 1984) ("Compliance with both federal and state law cannot be said to be impossible. Chevron can continue to use the EPA-approved label and can at the same time pay damages to successful tort plaintiffs such as Mr. Ferebee").

As the Supreme Court has frequently observed, tort law often informs regulatory decisions,

and the FDA has often acted in response to information that has come to light in state damages action." Kessler & Vladeck, *supra*, at 21 (citing *Bates*, 544 U.S. at 451; Karen E. Lasser, *et al.*, *Timing of New Black Box Warnings & Withdrawals for Prescription Medications*, 287 JAMA 2215, 2218 (2002); Kesselheim & Avorn, *supra,* at 310.

The FDA recognized that its regulatory efforts benefited from and were supplemented by state product liability litigation. The FDA

> view[ed] that its regulatory efforts could coexist with state-law damages claims by consumers injured by drugs. As the agency saw it, state-law [] litigation *did not* interfere with the agency's regulatory efforts. . . . State damages litigation helps uncover and assess risks that are not apparent to the agency during a drug's approval process. Until recently, in the FDA's view, this "feedback loop" enabled the agency to better do its job. The agency also wanted to avoid the "harsh implications" of eliminating judicial recourse for consumers injured by dangerous drugs.

Kessler & Vladeck, *supra*, at 3 (emphasis added) (citing Porter, *supra*, at 9); FDA, *Prescription Drug Product Labeling: Medication Guide Requirements*, 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998) (requiring Medication Guides for products that are deemed to pose significant public health concern) ("FDA does not believe that the evolution of state tort law will cause the development of standards that would be at

odds with the agency's regulations."); FDA, *Final Rule, Labeling & Prescription Drug Advertising; Content & Format for Labeling of Human Prescription Drugs*, 44 Fed. Reg. 37,434, 37,437 (Jun. 26, 1979) ("It is not the intent of the FDA to influence the civil tort liability of the manufacturer . . . .")).

Recently, however, the FDA has shifted its position radically and has argued that state litigation and federal regulation are antagonistic and mutually exclusive. The Solicitor General writing as amicus curiae in support of Petitioners asserts in this case that "[t]he federal government alone has responsibility to determine the appropriate remedy under the FDCA when it approved a product and later learned of misrepresentations that might have led it not to approve the product." (SG Br. at 32.)

This position overstates the FDA's enforcement authority and misconstrues the Michigan statute. After a drug is approved, "unless a case meets the *statutory* definition of fraud or misbranding or the high threshold for proving imminent hazard to the health of the public, FDA's regulatory and enforcement options generally lie at the ends of the spectrum of regulatory actions: do nothing or precipitate the voluntary withdrawal of the drug."[8] IOM Report at 157. FDA often declines to take formal action against a drug manufacturer who has engaged in conduct that might fall within the Michigan exemption and instead negotiates

[8] The IOM Report notes that "[w]ithdrawals are almost always voluntary rather than mandated by FDA. According to its statute, FDA can institute recalls *only* for devices and baby formula." IOM Report at 157 n.1.

"softer remedies" with drug manufacturers. *Id.* Michigan does not impose remedies for a drug-maker's misrepresentations to the FDA; it merely vitiates the conclusive presumption of nonliability that the State itself conferred.

This Court should not defer to the FDA's position as articulated by the Solicitor General, because the Michigan statutory scheme is traditional legislation concerning state tort law, which FDA has long tolerated. *See* Resp. Br. at 10, 25-31. When an agency changes its position it is entitled to less deference. *See National Fed'n of Fed. Employees, Local 1309 v. Dep't of Interior*, 526 U.S. 86, 109-10 (1999); *see also Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 418 (1993) ("On the other hand, the consistency of an agency's position is a factor in assessing the weight that position is due. As we have stated: "An agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a consistently held agency view.") (citing *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446, n.30 (1987) (quoting *Watt v. Alaska*, 451 U.S. 259, 273 (1981))). "How much weight should be given to the agency's views in such a situation, and in particular where its shifts might have resulted from intervening and possibly erroneous judicial decisions and its current position from one of our own rulings, will depend on the facts of individual cases." *Good Samaritan Hosp.*, 508 U.S. at 418.

Instead, this Court should reaffirm the FDA's long-standing position that state tort claims such as Respondent's advance the FDCA's goal of consumer protection and the regulatory objective of prompt and effective warnings of serious health risks. And, this

Court should decline to extend *Buckman* to preempt application of the conclusive Michigan statutory exemption, which unlike *Buckman* does not create a state-law cause of action or inquiry into fraud on the FDA, but merely allows evidence of wrongdoing in the drug approval process to defeat Michigan's conclusive statutory presumption of non-liability for drug manufacturers.

A finding that the Michigan exemption is preempted would be inconsistent with Congress's intent in establishing and continuing the FDA's regulatory scheme. It also would undo the Michigan legislature's decision to reward drug-makers who comply with FDA's requirements by limiting their liability and to force those who do not to defend the safety of their products in court, consistent with the FDA's mandate. The FDA has stated that it is the latter state tort law claims that should be maintained: State tort claims should not be preempted if "the [drug's] sponsor withheld material information" from the FDA. 71 Fed. Reg. 3922, 3936 (2006). That position, restated so recently, recognizes that state tort liability complements the FDA in its mission. The FDA's job would be made only more difficult if the Court preempts the Michigan exemption and confers non-liability on drug-makers who withhold or misrepresent material information during the drug approval process.

CONCLUSION

For the foregoing reasons, Amicus urges this Court to affirm the decision of the Court of Appeals for the Second Circuit.

Respectfully submitted,

FRANCINE A. HOCHBERG*
CENTER FOR CONSITUTIONAL
LITIGATION, P.C.
1050 31st Street, N.W.
Washington, DC 20007

Date *Counsel for Amicus Curiae*

*Counsel of Record