No. _____

IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC and PFIZER INC.,

Petitioners,

—v.—

KIMBERLY KENT, ET AL.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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ISSUES PRESENTED FOR REVIEW

1. Whether, under the conflict preemption principles in *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341 (2001), federal law preempts state law to the extent that it requires the fact-finder to determine whether the defendant committed fraud on a federal agency that impacted the agency's product approval, where the agency—which is authorized by Congress to investigate and determine fraud—has not found any such fraud, and thus—as in *Buckman*—the state requirement would interfere with the agency's critical functions.

2. Whether, under the conflict preemption principles in *Buckman*, federal law preempts the provision in a Michigan statute that allows a product liability claim to be maintained against a manufacturer of an FDA-approved drug where, without an FDA finding of fraud on that agency, the fact-finder is required to make a finding under state law as to whether the manufacturer committed fraud-on-the-FDA and whether, in the absence of that fraud, the FDA would not have approved the drug.

LIST OF PARTIES TO THE PROCEEDINGS

Petitioners Warner-Lambert Company LLC and Pfizer Inc. were defendants in the district court and appellees in the court of appeals.

Respondents are the following 29 individuals who were plaintiffs in the district court and appellants in the court of appeals:

Kimberly Kent, Personal Representative of the Estate of Virginia Kent

Emmett Kent

Elizabeth M. Graham

Robert C. Graham

Connie Armstrong

Lauranane Bradley

Raymond Bradley, Sr.

Glenn Chandler

Billie Jo Flynt

Shelly Grotenhius

Judy Ann Hearn

Colleen Rose Herndon

Michael Herndon

Michael H. Kanakry

Mary Ann Kanakry

Julia Lynne Martin

Royal M. Martin

Janice L. Kimmel, Personal Representative of the Estate of Thea Martz

Mona Lorene Przytulski

David A. Rice, Personal Representative of the Estate of Robert Rice

Anita Louise Schultz

Richard P. Schultz

James Soukup, Personal Representative of the Estate of Barbara Soukup

Jennifer St. Pierre, Personal Representative of the Estate of Raymond St. Pierre

Donald R. Waun

Jean Waun

Linda Sherman

Stanley Sherman

Nancy Fisher, Individually and as Personal Representative of the Estate of Troy Fisher

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of the Court, Petitioners Warner-Lambert Company LLC and Pfizer Inc. state:

Warner-Lambert Company LLC is wholly owned by Pfizer Inc. Pfizer Inc. has no parent and no publicly held company owns more than 10% of its stock.

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Warner-Lambert Company LLC ("Warner-Lambert") and Pfizer Inc. ("Pfizer") petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit entered in this case on January 18, 2007.

OPINIONS BELOW

The court of appeals' opinion (Appendix ("App.") 1a-28a) is reported at 467 F.3d 85. The district court's order is unreported. The district court's order and the transcript in which the district court set forth its reasons supporting the order are reprinted at App. 29a-38a.

JURISDICTION

The court of appeals entered judgment on January 18, 2007. On February 12, 2007, the court of appeals denied a timely petition for rehearing. App. 39a-40a. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The basis for implied conflict preemption, which is at issue here, is the Supremacy Clause of the Constitution, which provides in relevant part: "[T]he laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2, reprinted at App. 41a.

The Second Circuit opinion below conflicts with a Sixth Circuit opinion in regard to preemption of a portion of a Michigan statute that makes proof of fraud-on-the-FDA a prerequisite to a product liability action.

The relevant sections of Michigan's product liability statute provide:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the [FDA], and the drug and its labeling were in compliance with the [FDA's] approval at the time the drug left the control of the manufacturer or seller.

MICH. COMP. LAWS § 600.2946(5), reprinted at App. 42a. An exception provides for manufacturer liability, if the manufacturer

> [i]ntentionally withholds from or misrepresents to the [FDA] information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act . . . and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted.

MICH. COMP. LAWS § 600.2946(5)(a), reprinted at App. 42a.

The relevant provisions of the Federal, Food, Drug, and Cosmetic Act ("FDCA") and related regulations are reprinted at App. 43a-192a and cited in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), where the Court held that state-law claims based on fraud-on-the-FDA conflict with FDCA provisions and therefore are impliedly preempted.

The pertinent statutory and regulatory provisions are as follows: FDA has a duty to ensure that "drugs are safe and effective" for their intended uses. 21 U.S.C. § 393(b)(2)(B). FDA regulates each step of the clinical

investigation process that precedes approval. *See generally* 21 U.S.C. § 355; 21 C.F.R. Parts 312, 314. A pharmaceutical company must submit a large volume of information for its "new drug application" ("NDA"). 21 U.S.C. § 355(b); 21 C.F.R. § 314.50. In reviewing clinical and scientific research to assess safety and effectiveness, "FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." 21 C.F.R. § 314.105(c). After approval, holders of NDAs are responsible for further reporting, 21 U.S.C. § 355(k), 21 C.F.R. §§ 314.80, 314.81, which the FDA reviews to decide whether to continue approval, 21 U.S.C.§ 355(e), 21 C.F.R. § 314.150.

The federally mandated NDA process requires continual interaction between the FDA and the applicant about all aspects of the clinical trial program and the NDA. *See* 21 U.S.C. § 355; 21 C.F.R. Parts 312, 314; *see also* "The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective," FDA Consumer Magazine (July-August 2002), Pub No. FDA05 3242, as revised September 2005, available at http://www.fda.gov/fdac/features/2002/402_drug.html.

FDA has the power to conduct examinations and investigations concerning prescription drugs, 21 U.S.C. § 372, and the United States may enforce FDA's mandate by seeking injunctive relief, seizure of misbranded drugs, or criminal and civil penalties. 21 U.S.C. §§ 332-334.

FDA is empowered to investigate and punish fraud under 21 U.S.C. § 372. Citizens may report wrongdoing to the FDA and petition the agency to take action under 21 C.F.R. § 10.30. The FDA may pursue a wrongdoer under criminal statutes that proscribe false statements to

the federal government. *Buckman*, 531 U.S. at 349 (citing 18 U.S.C. § 1001). The agency also has authority to address fraud by seeking injunctive relief and civil penalties. 21 U.S.C. §§ 332, 333; *see also* 21 U.S.C. § 355(e)(5) (allowing FDA to withdraw drug approval where application contains any untrue statement of a material fact). FDA has established an enforcement policy concerning fraud in pre-market submissions that sets forth the remedies it may pursue. *See* Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy, 56 Fed. Reg. 46,191, 46,199-200 (Sept. 10, 1991); *see also* FDA Compliance Policy Guide § 120.100, "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," issued July 1, 1991 (announced in 55 Fed. Reg. 52,323 (Dec. 21, 1990)), available at http://www.fda.gov/ora/compliance_ref/cpg/cpggenl/cpg120-100.html. All lawsuits to enforce the FDCA's provisions "shall be by and in the name of the United States." 21 U.S.C. § 337(a).

STATEMENT OF THE CASE

The basis for federal jurisdiction in the district court is diversity. 28 U.S.C. § 1332. Respondents (hereinafter "Plaintiffs") are Michigan citizens, who are plaintiffs in product liability actions filed in Michigan state court against Petitioners Warner-Lambert and Pfizer (collectively "Warner-Lambert")[1], claiming injuries from a prescription drug, Rezulin, approved by FDA for treatment of diabetes. Warner-Lambert removed those actions to federal district court in Michigan. The Judicial Panel on Multidistrict Litigation established the Rezulin Multidistrict Litigation ("Rezulin MDL") pursuant to

[1] Warner-Lambert manufactured Rezulin while it was marketed from March 1997 to March 2000. Pfizer acquired Warner-Lambert in June 2000.

28 U.S.C. § 1407, and transferred these cases and others to the Rezulin MDL court in the Southern District of New York.[2]

In their state law product liability claims under the Michigan statute quoted above, several of the Plaintiffs allege that Warner-Lambert

> "knowingly concealed material facts about the safety and efficacy of Rezulin from the FDA, which would have prevented its approval and/or resulted in its earlier removal from the market." App. 337a, 344a, 354a.

The FDA approved Rezulin as safe and effective for use consistent with its labeling at all times while it was marketed. After FDA approved Rezulin for sale in March 1997, the FDA continually scrutinized the drug and its warning labels and maintained its approval status at all times until Warner-Lambert withdrew Rezulin in March 2000. Warner-Lambert withdrew the drug at FDA's suggestion because of adverse side effects and the advent of two new similar drugs in the same class that rendered Rezulin outmoded.[3] A number of physicians

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[2] The five cases at issue in this appeal were transferred to the Rezulin MDL. *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-1 (J.P.M.L. June 21, 2000) (*Kent*); *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-7 (J.P.M.L. Dec. 12, 2000) (*Graham*). *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-34 (J.P.M.L. October 11, 2001) (*Armstrong*); *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-56 (J.P.M.L. April 23, 2003) (*Sherman*); *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-69 (J.P.M.L. Apr. 23, 2004) (*Fisher*).

[3] *See* App. 7a; Center for Drug Evaluation and Research, Food and Drug Administration, Endocrinologic and Metabolic Drugs Advisory Committee Meeting Transcript ("EMDAC") at 82 (May 19, 2000), available at http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3615t1.pdf.

and patients sought to keep the drug on the market because of its therapeutic benefits in treating diabetes.[4]

Warner-Lambert moved for judgment on the pleadings on the ground that Plaintiffs could not establish, under the Michigan product liability statute, that Rezulin—as an FDA-approved drug—was "defective." Warner-Lambert further argued that a portion of the Michigan statute—which required plaintiffs to obtain a state law finding that Warner-Lambert had engaged in fraud-on-the-FDA without which the FDA would not have approved Rezulin—was impliedly preempted under *Buckman*. The motion relied on *Buckman's* holding that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law." 531 U.S. at 348. The motion also relied on *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), which applied *Buckman* to preempt the portion of the Michigan statute requiring a state law finding of fraud-on-the-FDA (where the FDA had not itself found fraud). *Garcia* also held that the remainder of the statute, which provided that FDA-approved drugs are not *defective* for purposes of Michigan products liability law, should be severed and enforced independently.

The district court granted Warner-Lambert's motion for judgment on the pleadings, relying on *Garcia* and its application of *Buckman.* App. 29a-38a. The district court reasoned that "[i]f plaintiffs covered by the Michigan statute were able to litigate claims of fraud on the FDA in individual personal injury suits, whether in state courts or in federal courts, the potential would exist for the FDA's personnel to be drawn into those controversies on a case-by-case basis over and over again," resulting in "enormous" "interference with the proper discharge of

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[4] EMDAC, n. 3, *supra*, at 13-14, 17-27.

the mission that Congress created the FDA to perform." App. 35a-36a.

In direct conflict with *Garcia*, the Second Circuit reversed the district court decision. App. 1a-28a. The court relied on a presumption against preemption, citing *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996), even though *Buckman* had explicitly rejected that presumption for state law claims of fraud-on-the-FDA. The Second Circuit read *Buckman* narrowly so that it applied only to claims based "solely" on fraud-on-the-FDA, which in its view did not include claims requiring plaintiffs to prove the exception in the Michigan statute. The court of appeals also was dismissive of *Buckman's* concerns with the adverse impact that state law determinations of fraud-on-the-FDA could have on the FDA's internal operations and the regulatory process.

REASONS FOR GRANTING THE PETITION

The Second Circuit decision threatens to upset the basic understanding of preemption law that has informed this Court's decisions since *Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218 (1947), cited in *Buckman*, 531 U.S. at 347. As *Buckman* held, under this line of decisions there is no presumption against preemption of state law with respect to an issue that is not historically within a field occupied by the states, such as finding fraud on a federal agency that affected the agency's decision-making. *Id.* at 348. *Buckman* found that the FDA approval process was a "comprehensive scheme." The Court concluded that "[s]tate law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives," and would "cause applicants to fear that their disclosures to the FDA, although deemed

appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 348, 350, 351.

The circuit courts are sharply split in their application of *Buckman* and the preemption doctrine. The Second Circuit here confined *Buckman* to the narrow circumstance where a plaintiff has asserted a stand-alone cause of action for "fraud-on-the-FDA"—in essence a claim that is pleaded entirely on that theory. App. 19a-23a. A number of district courts as well as a state court have adopted a similarly narrow approach. *See*, *e.g.*, *Ackermann v. Wyeth Pharmaceuticals*, No. 4:05CV84, 2006 WL 354492, at *8 (E.D. Tex. Dec. 7, 2006); *In re: St. Jude Medical, Inc. Silzone Heart Valves Prods. Liab. Litig.*, No. MDL 01-1396, 2004 WL 45503, at *13 (D. Minn. Jan. 5, 2004); *Bryant v. Hoffman-LaRoche, Inc.*, 585 S.E.2d 723, 725 (Ga. Ct. App. 2003).[5]

The Sixth Circuit and Ninth Circuits, as well as the Third Circuit prior to *Buckman,* have taken a more functional approach—applying *Buckman* to preempt state law to the extent that it requires a plaintiff to establish a fraud on a federal agency, regardless of the technical nature of the pleading in which that requirement arises. This line of cases has looked to whether the state-law requirement—that the fact-finder make a determination as to whether a federal agency has been defrauded—would lead to the same impositions on the federal agency that concerned this Court in *Buckman*. As shown above, the Sixth Circuit's preemption decision in *Garcia* squarely conflicts with the Second Circuit decision here on this issue. Taking an approach like that of the Sixth Circuit, the Ninth Circuit has held that under "[t]he rationale articulated by the Supreme Court in *Buckman*,"

[5] All unpublished decisions cited herein are reprinted at App. 193a-331a.

plaintiff's claim for tortious interference with prospective business advantage was preempted where plaintiff would have to prove that defendant committed a fraud on the Environmental Protection Agency to prevail. *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1205-06 (9th Cir. 2001). The Third Circuit, in a decision that presaged *Buckman*, held that "[i]f a medical device manufacturer's claim that the MDA pre-empts a plaintiff's cause of action depends in the first instance upon proof that its Premarket Approval was not fraudulently obtained, courts would have to engage in the intrusive inquiry which we have demonstrated is forbidden." *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir. 1995).

Federal district courts and state courts have rendered holdings consistent with the Sixth, Ninth and Third Circuits' approach, and contrary to the Second Circuit's narrow view of *Buckman. See Webster v. Pacesetter*, 259 F. Supp. 2d 27, 36 (D.D.C. 2003) (plaintiffs precluded by *Buckman* from "arguing" that defendants failed to comply with FDA regulations in regard to design and labeling of medical device, where their claim was denominated as for common law failure to warn); *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 851 (W.D. Tex. 2001) (dismissed unclean hands defense to trademark infringement suit premised on alleged misbranding under the FDCA on ground that, citing *Buckman*, the defense as pleaded would have "require[d] interpretation and application of FDA regulations," which was better left to FDA to determine); *Baker v. St. Jude Medical, S.C., Inc.*, 178 S.W.3d 127, 138 (Tex. Ct. App. 2005) (common law fraud claims preempted where plaintiffs alleged that "St. Jude withheld, or unreasonably delayed, in providing the FDA with information that it had regarding adverse effects associated with Silzone heart valve"); *Ledbetter v. Merck & Co., Inc.*, No.

2005-59499, slip op. at 8 (Tex. Dist. Ct. Harris County Apr. 20, 2007) (held that federal law preempted portion of state statute that required that "in order to pursue a failure to warn case, plaintiffs must prove that required and material information was withheld from the FDA," and concluded that "[w]hether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same").

The issue presented in this case is a specific manifestation of the split in the circuits and lower courts described above—whether federal law preempts the portion of a state statute that requires a fact-finder to make a determination concerning alleged fraud-on-the-FDA, absent a determination by the FDA on that issue. In *Garcia,* the Sixth Circuit had held that implied conflict preemption applied to the portion of the Michigan statute that authorized finders of fact to decide under state law—as a prerequisite to product liability claims—whether there was material fraud-on-the-FDA, unless the FDA itself had made such a finding. *Garcia* recognized that the powerful concerns expressed in *Buckman* were sparked by the intrusion of such a state law requirement on the FDA's regulatory process. Moreover, the Sixth Circuit held that those concerns are equally relevant whether they are raised in a state common law action for fraud-on-the-FDA or under a statutory exception to a provision that treats FDA drug approval as dispositive of product liability claims.

The Second Circuit took precisely the opposite position when it exalted form over substance to rule that the concerns expressed in *Buckman* somehow vanish because of the difference in the procedural posture in which a court under state law would be required to determine if there was material fraud-on-the-FDA. As a result, the Second Circuit adopted an unduly narrow reading of *Buckman* as

applying only to stand-alone claims that are in effect denominated as for fraud-on-the-FDA. In so ruling, the Second Circuit misread *Medtronic* and jettisoned a half century of preemption law culminating with *Buckman*. Indeed, the decision of the Second Circuit below is the most limited interpretation of *Buckman* to date and most egregiously ignores *Buckman*'s rationale.

Moreover, the Second Circuit's holding will interfere with the FDA's ability to perform its critical functions, which is precisely what this Court sought to avoid in *Buckman*. 531 U.S. at 349-51. Findings of fraud-on-the-FDA would inevitably disrupt the regulatory process by encouraging manufacturers to supply unnecessary information to the FDA for fear that the failure to do so will lead to state-law liability; by discouraging manufacturers from seeking approval for beneficial drugs that are not risk-free; by distorting the FDA's decision-making process to anticipate potential state-law review of that process; and by burdening FDA personnel who are ordered to testify as witnesses in state-law products liability cases concerning the FDA's decision-making process.

An additional reason for granting certiorari in this case is that the issues reach beyond the Michigan statute on which the Sixth and Second Circuit are in conflict. As part of tort reform efforts throughout the country, other states have enacted statutes limiting claims or damage recoveries for FDA-approved drugs unless the finder of fact determines under state law that there was fraud-on-the-FDA. Thus, Texas has enacted legislation, which—similar to the Michigan statute—provides for a presumption that FDA-approved warnings on pharmaceutical products are adequate, which can be rebutted if the plaintiff establishes fraud-on-the-FDA. *See* TEX. CIV. PRAC. & REM. CODE § 82.007. In addition, six states have a fraud-on-the-FDA exception to a rule bar-

ring punitive damages for FDA-approved drugs. *See* ARIZ. REV. STAT. § 12-701; N.J. STAT. ANN. § 2A:58C-5(c); 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. All of these statutes reflect a trend to limit state law product liability claims or recoveries where products have been approved and are regulated by the federal government.[6] Thus, the issue raised by this petition has a broad impact on other statutes. A Michigan appellate court, a Texas state court and federal district courts in Tennessee, Pennsylvania and Arizona have followed the Sixth Circuit decision in finding preemption of such state law requirements, while a district court in Texas adopted the formalistic approach of the Second Circuit here.[7] *See* discussion of *Garcia* in Point I, *infra*.

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[6] David G. Owen, *Special Defenses in Modern Products Liability Law*, 70 MO. L. REV. 1, 20 22 (2005).

[7] *See Duronio v. Merck & Co., Inc.*, No. 267003, 2006 WL 1628516, at *5 (Mich. Ct. App. June 13, 2006) (agreeing with the Sixth Circuit's decision in *Garcia* that the fraud on the FDA exception in MICH. COMP. LAWS § 600.2946(5)(a) is partially preempted by federal law); *Ledbetter v. Merck & Co., Inc.*, No. 2005-59499, slip op. at 9 (Tex. Dist. Ct. Harris County Apr. 20, 2007) (following *Garcia* and holding that the fraud on the FDA exception under Tex. Civ. Prac. & Rem. Code § 82.007 is preempted except where FDA has "made a determination that material and relevant information was either withheld or misrepresented concerning Vioxx"). *In re Aredia and Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760, 2007 WL 649266, *8, *9 n.17 (M.D. Tenn. Feb. 27, 2007) (New Jersey statute that "immunizes drug manufacturers from punitive damage liability *unless* the plaintiff can prove fraud on the FDA" is impliedly preempted unless the FDA itself finds fraud) (emphasis in original); *Henderson v. Merck & Co., Inc.*, No. 04-CV-05987-LDD, 2005 WL 2600220, *11 (E.D. Pa. Oct. 11, 2005) (following the "holdings of *Buckman* and *Garcia* and find[ing] that [the exceptions for fraud-on-the-FDA in the Michigan statute] are preempted by the FDCA in most situations"); *Kobar v. Novartis Corporation,* 378 F. Supp. 2d 1166, 1173 (D. Ariz. 2005) (both fraud on

State legislatures need direction from this Court on how they should conform their existing statutes or new legislation to federal preemption standards. The lower courts likewise need instruction on these preemption issues as they relate to the overlap between *Buckman* and *Medtronic*. Only this Court can provide the necessary guidance in this important area of federal constitutional law.

I. THE SECOND CIRCUIT'S DECISION BELOW IS IN CONFLICT WITH THE SIXTH CIRCUIT, AND WITH THE RATIONALE OF THIS COURT IN *BUCKMAN,* AS WELL AS THE THIRD AND NINTH CIRCUITS IN ANALAGOUS CASES, AS TO WHEN A STATE LAW REQUIREMENT OF A FINDING OF FRAUD ON A FEDERAL AGENCY IS IMPLIEDLY PREEMPTED.

Buckman—In *Buckman*, this Court held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law." 531 U.S. at 348. *Buckman* is one of a series of decisions in which the Court has charted a course between federal preemption and proper state authority. Thus, *Buckman* began its analysis by explaining that "[p]olicing fraud against federal agencies is hardly 'a field which the states have traditionally occupied . . . .' " *Id.* at 348 (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). In *Rice,* the Court applied an "assumption" against superseding state powers because states had for

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the-FDA claim and statute requiring plaintiff to prove fraud to avoid punitive damages "place state courts, as finders of fact," in the position of deciding what role the withheld information would have had in the "FDA's complicated approval process."). *But see Ackermann v. Wyeth Pharmaceuticals*, No. 4:05CV84, 2006 WL 354492, at *8 (E.D. Tex. Dec. 7, 2006) (plaintiff's evidence of fraud on the-FDA rebuts presumption of no liability and does not in itself establish liability).

years regulated warehouses while the federal government had only recently decided to regulate them under a new statute. *Rice*, 331 U.S. at 330. The Court there found that comprehensive federal regulation overcame the "assumption." *Id.* at 236. In contrast, where the interests at stake are "uniquely federal" in nature, the conflict with the state need not be "as sharp" because of a concern that "the application of state law would 'frustrate specific objectives' of federal legislation." *Boyle v. United Technologies Corp.,* 487 U.S. 500, 504, 507 (1988) (finding preemption of common law design defect claim involving military equipment where federal law only authorized such a claim on a limited basis), cited in *Buckman,* 531 U.S. at 347.

Applying these well-established principles, this Court in *Buckman* explained that no presumption against preemption applies where "the relationship between a federal agency and the entity it regulates is inherently federal in character . . . ." 531 U.S. at 347. As the Court further explained, permitting fraud-on-the-FDA determinations under state law would frustrate the "flexibility [that] is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Id.* at 349. In addition, it would "inevitably conflict with the FDA's responsibility to police fraud consistently with the [FDA's] judgment and objectives." *Id.* at 350. Furthermore, allowing fraud-on-the-FDA claims would "dramatically increase the burdens facing potential applicants" in a manner "not contemplated by Congress," and create an "incentive" for manufacturers "to submit a deluge of information that the [FDA] neither wants nor needs" for "fear that their disclosures to the FDA, although deemed appropriate by the [FDA], will later be judged insufficient in state court." *Id.* at 350-51.

The same rationale precludes application of the Michigan statute (and similar state statutes) to the extent that those statutes require plaintiffs to prove fraud-on-the-FDA as a condition of recovery under state law. As with the Medical Device Amendments to the FDCA at issue in *Buckman*, the FDCA "sets forth a comprehensive scheme" for determining if an applicant is entitled to new drug approval. *Buckman*, 531 U.S. at 348. Therefore, as in *Buckman*, petitioner's dealings with FDA and the "very subject matter of petitioner's statements" to FDA were "dictated by that statute's provisions," and the relationship between petitioner and the FDA is inherently federal in character. *Id.* at 347-48. Thus, as in *Buckman*, no presumption against preemption applies.

Moreover, the FDCA, regulatory and other statutory provisions—described in *Buckman* as "aimed at detecting, deterring, and punishing false statements" during the approval process—are equally relevant here. *Id.* at 349. As described in *Buckman*, "citizens may report wrongdoing and petition the agency to take action." *Id.* (citing 21 C.F.R. § 10.30). The FDA and the federal government make extensive use of the provisions cited in *Buckman,* 531 U.S. at 349, to investigate and sanction fraud-on-the-FDA.[8] In the interactive drug regulatory

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[8] *See e.g.,U.S. v. Barile*, 286 F.3d 749 (4th Cir. 2002) (criminal prosecution for false statements to FDA); *U.S. v. Prigmore*, 243 F.3d 1 (1st Cir. 2001) (prosecution for conspiring to defraud FDA); *U.S. v. Leichter*, 96 F. Supp. 2d 5 (D. Mass. 2000) (conspiracy to defraud FDA); FDA News P03 92, *Louisiana Ophthalmologist Fined $1.1 Million by FDA For Clinical Study Violations* (Nov. 5, 2003), available at http://www.fda.gov/bbs/topics/NEWS/2003/NEW00972.html; Michelle Meadows, *Company Gets a Guilty Reading in Glucose Monitor Case*, FDA CONSUMER MAGAZINE (March April 2001), available at http://www.fda.gov/fdac/departs/2001/201_irs.html (pharmaceutical manufacturer pleaded guilty to misdemeanor charges and agreed to pay $60 million in criminal and civil fines for *inter alia*, filing false or misleading information).

process, as in *Buckman*, "flexibility" is a "critical component of the framework under which the FDA pursues difficult (and often competing) objectives." *Id.* at 349. Superimposing state law determinations of any sort on top of "the FDA's detailed regulatory regime. . . will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA . . . ." *Id.* at 350. Such burdens could discourage applicants from filing for approval of beneficial drugs that are not risk-free, and cause applicants to submit a deluge of information not wanted by FDA to assure that their submissions will not "later be judged insufficient in state court." *Id.* at 351. Plainly, these concerns arise under any state law that makes a finding of fraud-on-the-FDA a prerequisite to establishing liability under the state's tort law, when the FDA is empowered to make its own potentially inconsistent findings in regard to any such alleged fraud. Whether the requirement of a finding of fraud-on-the-FDA is called an "element" of the state-law claim or a "threshold prerequisite" is irrelevant to the vital institutional concerns expressed in *Buckman*.

The concurring opinion in *Buckman* suggested, as an accommodation between state and federal interests, that the conflict between the FDCA regulatory scheme and state tort fraud actions vanishes if the FDA has exercised its statutory power to find that fraud by an applicant induced it to approve a drug. As Justice Stevens stated, if "the FDA had determined that petitioner had committed fraud," plaintiffs' "state law fraud claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation but would be grounded in the agency's explicit actions," and would not lead to "second-guessing the FDA's decision making or overburdening its personnel." 531 U.S. at 354. Once the FDA decides that there has been fraud, the burdens on the

administrative process and perverse incentives to drug applicants no longer pertain. This same accommodation was adopted by *Garcia* and ignored by the Second Circuit. It is as valid for the Michigan statutory exception's requirement as it was for the common law fraud-on-the-FDA claims in *Buckman.* In both procedural settings, "an essential link in the chain of causation that respondent must prove in order to prevail is that, but for petitioner's fraud, the allegedly defective [medical product] would not have reached the market." 531 U.S. at 353.

The Sixth Circuit decision in Garcia—*Garcia* applied *Buckman* to find partial preemption of what in reality is a statutory fraud-on-the-FDA claim, stemming from the exception in the Michigan statute that allows a product liability claim only where the fact-finder concludes that the defendant made intentional misrepresentations to FDA without which FDA would not have approved the medication. 385 F.3d 961. The "Michigan legislature has provided a general immunity for drug manufacturers with a specific exception for circumstances involving, *inter alia*, fraud on the FDA rather than a specific cause of action for fraud on the FDA. This difference, however, is immaterial in light of *Buckman*." *Id.* at 965-66 (footnote omitted). In both instances, "a plaintiff asks a state court to find bribery or fraud on the FDA." *Id.* at 967. Under the statute, a plaintiff must establish the exceptions to the immunity in the statute for FDA approved drugs "on the basis of *state court* findings of fraud on the FDA." *Id.* at 966 (emphasis in original). The Sixth Circuit concluded: "Such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*." *Id.* at 966. For Plaintiff's here, as in *Buckman*, "the existence of these federal enactments is a critical element in their case." 531 U.S. at 353. Accordingly, *Buckman's* conclusion is fully applicable in the circumstances here, *i.e.*, that "this sort

of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore preempted by that scheme." *Id.*

The Sixth Circuit was careful to avoid reading *Buckman* too broadly, for it recognized that "the same concerns do not arise when the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process" and, therefore, in that circumstance, the Michigan statutory exception is not impliedly preempted. *Garcia*, 385 F.3d at 966 (emphasis in original). At bottom, the FDA is the appropriate forum for deciding, through its mandated procedures, whether it was deceived by a fraud by the applicant. Because a potential plaintiff may seek an FDA finding of fraud that has materially affected its decision-making, the partial preemption found by the Sixth Circuit does no more than recognize the FDA's primary jurisdiction over a claim of fraud on the agency. *See* 21 C.F.R. § 10.25(b) ("FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate . . . .").

Plaintiffs in *Garcia* had offered no proof of fraud. They did not seek to satisfy the statutory exception but rather to use *Buckman* to persuade the court to overturn the entire immunity provision including the exception. Instead, the Sixth Circuit held that under Michigan law, while the exception was partially preempted, the statutory immunity for FDA-approved drugs should be preserved. *Garcia*, 385 F.3d at 967. As the court explained, "the Michigan legislature would have preferred the situation where drug manufacturers would enjoy immunity in the absence of a federal finding of . . . fraud on the FDA" to "the situation urged by the Plaintiff where drug manufacturers would enjoy no immunity at all." *Id.* The court of appeals relied on the Michigan severance provisions to support this holding. *Id.* at 966-67. Because

the State of Michigan is in the Sixth Circuit, that court's interpretation of the Michigan statute is entitled to deference. Its decision to find partial preemption is a federal question that was correctly decided under *Buckman*.[9]

A Michigan appellate court adopted *Garcia's* "holding that the fraud on the FDA exception is preempted by federal law unless the FDA itself determines that it was defrauded," and also agreed with its Michigan law holding regarding severance of the preempted portion of the statute. *Duronio v. Merck & Co., Inc.*, No. 267003, 2006 WL 1628516, at *5 (Mich. Ct. App. June 13, 2006). *Accord*, *Zammit v. Shire US, Inc.*, 415 F. Supp. 2d 760 (E.D. Mich. 2006).

The recurring nature of the issue presented by the conflict between *Garcia* and the Second Circuit is illustrated by the decisions cited in note 7, *supra*, addressing preemption of analogous state statutes, which followed the Sixth Circuit, and another that adopted the narrow view of the Second Circuit in finding no preemption of an analogous provision in a Texas statute.

The Second Circuit's Decision Below—The Second Circuit essentially rejected this Court's rationale in *Buckman* at every step of its opinion. App. 1a-28a.

First, the Second Circuit applied a presumption against federal preemption because the "Michigan legislature's desire to rein in state-based tort liability falls squarely within the prerogative to 'regulat[e] matters of public health and safety . . . .' " App. 19a. This argument flies in the face of *Buckman* and this Court's preemption case law discussed in that opinion, which hold that there is no presumption against preemption when

[9] The Sixth Circuit's interpretation of Michigan law is controlling in other circuits. *Factors Etc., Inc. v. Pro Arts, Inc*., 652 F.2d 278 (2d Cir.1981), cited by the court of appeals below at App. 11a.

the state legislates regarding "the relationship between a federal agency and the entity it regulates," which relationship is "inherently federal in character." *Buckman*, 531 U.S. at 347. This case is sharply distinguishable from the state law claims in *Medtronic*, on which the Second Circuit relied (App. at 21a-22a), all of which predated the federal regulatory enactments, and did not interfere in any way with regulatory oversight over fraud investigations and enforcement.

Moreover, the Second Circuit's analysis is flawed because it treats Michigan's purpose as decisive, whereas *Buckman* focuses on the conflict with federal regulatory authority in an inherently federal area, without regard to the state's purpose. In addition, the Second Circuit's assertion fails to acknowledge that *Garcia* allows the state to "rein in" tort liability *and* to have an exception for fraud-on-the-FDA where the FDA has found fraud on the agency. The Sixth Circuit limited its preemption holding to cases where the fact-finder in a state-law action is required to find fraud-on-the-FDA as a condition to liability. That results in a state intrusion into "policing" fraud against a federal agency because, according to *Buckman*, the FDA has exclusive authority to decide whether there was a fraud on the agency and what consequences should follow.

The court below latched onto *Buckman*'s reference to the state law claim there being "solely" based on defrauding the FDA. But under the Michigan statute, product liability claims can succeed *only* if there is fraud-on-the-FDA—without which FDA would not have approved or would have withdrawn approval of the drug—*and* the product is proved defective. It is not sensible to suggest that by imposing the very same requirement of fraud-on-the-FDA and adding another requirement, a state law interferes with the FDA's regulatory policies any less than does

a statute requiring only fraud-on-the-FDA. The consequences to the federal regulatory process of a dual state/federal regime for finding fraud, and whether the fraud impacted regulatory approval, make this a difference without a distinction. *Buckman's* preemption rationale applies to all state law litigation of fraud-on-the-FDA, whether by statute or by a common law fraud claim.

Next, the court below purported to distinguish *Buckman* on the ground that plaintiffs here did not assert "fraud-on-the-FDA" claims. App. 19a-23a. However, preemption in *Buckman* did not turn on the *name* given to the state law requirement, but on the requirement itself and its intrusion into the FDA's exclusive authority over whether an applicant committed fraud against the agency. Furthermore, the court below wrongly concluded that the Sixth Circuit had "gutted" plaintiffs' traditional state law claims. App. 20a. The Michigan legislature—not the Sixth Circuit—altered the state's product liability regime.

The narrow procedural focus of the Second Circuit below is evident in its statement that under the Michigan statute, "FDA approval becomes germane *only* if a defendant company chooses to assert an affirmative defense made available by the Michigan legislature . . . ." App. 23a (emphasis in original). This statement is off the mark for two reasons. First, *Garcia* held—under Michigan law—that to invoke the exception, "*plaintiff* asks a court to find bribery or fraud on the FDA," 385 F. 3d 966 (emphasis added). The Michigan Supreme Court has characterized the fraud-on-the-FDA statutory exception as a "claim" that plaintiff must "make." *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003). Secondly, all of the concerns in *Buckman* remain whether FDA approval is raised as part of a plaintiff's prima facie case—as is

implicit in Plaintiffs' allegations here that fraud-on-the-FDA led to its approval of Rezulin—or, as a defense.

Moreover, where, as here, Plaintiffs alleged fraud-on-the-FDA in order to satisfy the statute's requirement, it follows that such fraud is an element of their state law claims. Furthermore, because the statutory requirement to prove fraud-on-the-FDA arises whenever there is an FDA-approved drug, which is a matter of public record and indisputable, it is immaterial whether that requirement is characterized as part of plaintiff's claim or as a rebuttal to a defense.

If a state created its own administrative agency to monitor and sanction fraud-on-the-FDA, the conflict between the state system and the federal interest would be unquestioned. *Buckman* held that this conflict is not lessened because the state seeks to regulate fraud through private litigation. Indeed, judicial intervention in the FDA regulatory process is likely to be even more intrusive as different state courts and juries potentially make different findings on what is required in the federal regulatory process, on when applicants have not satisfied those requirements, and on whether any omissions would have caused the federal agency to deny approval.

Finally, the Second Circuit brushed aside *Buckman*'s emphasis on "practical concerns" that would adversely impact the regulatory process, because—according to the Second Circuit—the same concerns purportedly would arise if a state court or jury were allowed to consider evidence of fraud-on-the-FDA. App. 24a. That possibility was as true in *Buckman* as it is here. To avoid disastrous effects on the regulatory process, *Buckman* has been properly applied so that evidence in the trial of common law or statutory claims "will be excluded outright when it is offered only to show that the FDA was misled, or that information was intentionally concealed

from the FDA." *Bouchard v. American Home Products Corp.,* 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002). Moreover, the exception in the Michigan statute goes beyond allowing evidence of fraud-on-the-FDA, and in addition permits state law findings of fraud and materiality, which can be inconsistent with the FDA's position.

II. THE CIRCUIT SPLIT WILL LEAD TO CONSEQUENCES TO THE FEDERAL REGULATORY SCHEME, WHICH *BUCKMAN* SOUGHT TO AVOID.

By opening the door to inevitable inconsistencies between state and FDA determinations of fraud on the agency, the Second Circuit's decision will have a negative impact on the FDA's drug review process and its administration of the FDCA, which in turn will interfere with the FDA's mission to protect public health. *See Buckman,* 531 U.S. at 350. The FDA has "complete discretion" in addressing possible statutory or regulatory violations. *See Heckler v. Chaney*, 470 U.S. 821, 835 (1985). Under the Second Circuit's decision, state law findings of fraud-on-the-FDA might conflict not only with those of other states, but also with FDA's own determinations. For example, if the FDA denied a Citizen Petition asking the agency to find that an applicant committed fraud-on-the-FDA, a state court or jury could—under the Michigan statute—second guess FDA's finding. If FDA found no fraud, any state law decision that found fraud, pursuant to statute or at common law, would undermine public confidence in the FDA, thereby creating havoc in the regulatory process. *See Garner v. Teamsters*, 346 U.S. 485, 490-91 (1953) ("multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law").

Moreover, allowing state law determinations of fraud-on-the-FDA would distort the behavior of regulated entities, which up to now could base their interactions with the agency on federal requirements alone rather than those of numerous state courts. Under the FDCA and FDA regulations, the applicant must closely cooperate with FDA to determine how clinical trials are to be run and what data must be submitted. Superimposing a state law regime based on litigation in civil court actions will grind that interactive process to a halt if—at each of the many steps in the process—companies must consider not merely what FDA asks but what the states might have wanted the FDA to have. Moreover, state law determinations of fraud-on-the-FDA could distort the FDA's internal decision-making by tempting it to anticipate and respond to state court decisions. The FDA's control over clinical trials and related approval requirements is sufficiently complex today, that no additional expense, delay or confusion is warranted from state sources. *See Buckman*, 531 U.S. at 351. Indeed, the cost of research and development of a new drug, including the FDA approval process, has been estimated at $802 million.[10]

Furthermore, as the district court recognized in its opinion below, the Michigan statute threatens to embroil FDA in state court litigation. App. 35a-36a. Litigants naturally will seek out the best evidence of whether an agency has been defrauded and the impact of that fraud on approval. Plaintiffs and defendants will seek discovery on whether there was fraud and whether absent the fraud, the FDA would have withheld approval of the drug, or would have withdrawn its approval. This will necessitate combing through thousands of pages of NDA

[10] Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 JOURNAL OF HEALTH ECONOMICS 151, 166 (2003).

material, followed by burdensome questioning of FDA personnel. Intrusive discovery into federal agency officials' states of mind, and the courses of action that agency officials might have taken under hypothetical scenarios long after the fact, would divert FDA resources from the central purpose assigned by Congress.

Nor would FDA personnel necessarily be shielded from testifying. FDA can decline to permit its employees to testify about their official duties, pursuant to 21 C.F.R. § 20.1. But courts do not always honor FDA's decisions in this regard. *See, e.g., In re Vioxx Prods. Liab. Litig.* 235 F.R.D. 334 (E.D. La. 2006) (denying FDA motion to quash deposition subpoena for FDA official). Moreover, if agency officials do not testify, juries would then be free to speculate on the key issues of fraud and what the agency might have done absent the fraud, which might conflict with the FDA's own judgment.

Notably, the Second Circuit ruling is at odds not just with a sister circuit, but with the circuit having the most direct responsibility for hearing claims arising under Michigan statutory law. The conflict in circuits should be resolved so that Michigan residents are not encouraged to sue in a distant forum within the Second Circuit, which they could do—given nationwide jurisdiction over pharmaceutical manufacturers—to nullify the sound decision of the Sixth Circuit. The conflict also will inject forum shopping considerations into the MDL process, which today handles much of the pharmaceutical product liability litigation.

This Court should clarify the law for state legislatures, state courts and lower federal courts by granting this petition and ruling that federal law preempts any state law to the extent it requires a fact-finder, in the absence of a fraud finding by the FDA, to determine under state

law whether a pharmaceutical manufacturer has committed a fraud-on-the-FDA that resulted in approval of a prescription drug. The disruption of the FDA administrative and regulatory process that *Buckman* sought to avoid will reappear if this conflict is not resolved by a sensible and functional application of this Court's preemption pronouncements.

CONCLUSION

The petition for a writ of certiorari should be granted.

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Dated: May 10, 2007