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No. 06-1498

IN THE
Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC
and PFIZER, INC.,
Petitioners,

v.

KIMBERLY KENT, *et al.*,
Respondents.

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

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONERS

DIANE E. BIERI
Senior Vice President
and General Counsel
KATHRYN R. COLBURN
Assistant General Counsel
PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA
950 F Street, NW
Suite 300
Washington, D.C. 20004
(202) 835-3405

BERT W. REIN
Counsel of Record
WILLIAM S. CONSOVOY
BRENDAN J. MORRISSEY
WILEY REIN LLP
1776 K Street, NW
Washington, D.C. 20006
(202) 719-7000

Attorneys for Amicus Curiae

212604

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

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INTEREST OF AMICUS CURIAE [1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association that represents the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's members are dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. Member companies are the source of a majority of all new medicines that are discovered and marketed. New medicines accounted for 40 percent of the lifespan increase between 1986 and 2000. *See* Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence From Longitudinal, Disease-Level Data From 52 Countries, 1982-2001*, 21 (Nat'l Bureau of Econ. Research, Working Paper No. 9754, 2003). In the past decade alone, PhRMA's members invested approximately $300 billion to develop new medicines. *See* PhRMA, *Pharmaceutical Industry Profile 2007* 42 (2007).

PhRMA's members closely monitor legal issues that affect the entire industry, and PhRMA often offers its perspective in cases raising such issues. PhRMA has a particular interest in cases involving possible state-law interference with the comprehensive public health regulatory regime for prescription drugs administered

1. Pursuant to Rule 37.1 of the Rules of the Supreme Court of the United States, no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

by the Food and Drug Administration ("FDA"). PhRMA supports and endorses this Court's safeguarding of the "inherently federal" relationship between FDA and pharmaceutical manufacturers against state law intrusion based on alleged fraud on the FDA, *see Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), and submitted a brief *amicus curiae* supporting the grant of certiorari in this case. *See* Brief of the Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Petitioners, Warner-Lambert Co. v. Kent, No. 06-1498 (filed July 20, 2007). PhRMA strongly believes that the Second Circuit's decision was flawed in several respects and asks that this Court reverse the judgment of the court below under the reasoning of its decision in *Buckman*.

INTRODUCTION

In *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), this Court held that state law claims that authorized recovery against medical device and drug manufacturers where regulatory approval was allegedly procured through "fraud on the FDA" were preempted. The court below, however, upheld a "fraud on the FDA" claim framed as an exception to a Michigan affirmative defense that otherwise insulated FDA-approved drugs from product liability claims. The decision below cannot be squared with this Court's precedent and, if allowed to stand, would evade *Buckman*'s bar on state-law interference in the manufacturer-FDA relationship through only slightly more subtle means. The likely proliferation of state-law fraud on federal regulators litigation and the resulting interference with congressionally granted federal authority that would follow would significantly burden both the health care and judicial systems.

The Second Circuit ruled that because Respondents' causes of action were not grounded *solely* on a fraud-on-the-FDA theory, *Buckman* did not control. The court sought to bolster that contention by characterizing it as the position "the pharmaceutical industry" took in *Buckman*. The court was wrong on both counts. The conflict that drove this Court's preemption decision in *Buckman* arose from the state's assertion of power to review the regularity of FDA approvals under state law, not from the specific role that such review played in state litigation. The industry's position then, as now, is that such review would frustrate the objects and purposes of federal law and cannot be sustained under the Supremacy Clause. Thus, as in *Buckman*, liability here turns on Respondents' ability to prove as a matter of *state law* that Petitioners' FDA approval was obtained through fraud on the FDA. Allowing judges and juries to determine that issue would produce the same interference with FDA's regulatory mandate that led this Court to preempt fraud on the FDA actions in *Buckman*. That the Michigan statute uses the resolution of that question as a means of overcoming an otherwise available product liability defense cannot justify it constitutionally.

In addition, to shore up its faulty interpretation of *Buckman*, the Second Circuit wrongly invoked a "presumption against preemption." The presumption, which is of dubious constitutional heritage generally, has absolutely no place in conflict preemption cases where the rule of decision is provided by Article VI of the Constitution-not, as in express preemption cases, by an Act of Congress. Furthermore, the fact that the Michigan "legislative scheme" addresses product liability does not, as the Second Circuit asserted, alter this conclusion;

indeed, the claims in *Buckman* were allegedly framed within the States' traditional areas of tort action. States cannot obtain the benefit of the presumption by burying interference with an area of traditional federal control in an exception to an affirmative defense. The need to establish fraud on the FDA in order to obtain relief under state law rendered the presumption inapplicable in *Buckman*, and so it does here.

The Second Circuit also ignored the adverse practical consequences of allowing state-law "fraud on the FDA" to be litigated in case after case. Permitting this uniquely federal question to be incorporated into state law would defeat Congress's deliberate decision to grant FDA ample and exclusive authority to establish information filing requirements and police fraud on the agency. The interference that would necessarily flow from state "fraud on the FDA" litigation would disrupt FDA's ability to accomplish the tasks assigned to it by Congress.

State superintendence of "fraud on the FDA," moreover, expressly invites state-law courts to second-guess FDA approval determinations. Michigan permits juries to determine for themselves, under state law, whether (1) there was a fraudulent misrepresentation or omission and (2) if that "fraud" would have led FDA to prevent the product from coming to market or remove an approved product from the market. These highly scientific and technical judgments have been delegated by Congress to an expert agency for a reason. Congress understood that judges and juries facing an injured plaintiff in a single case were not in a position to make complex scientific decisions with consequences that could

have a significant effect on public health for millions of Americans. FDA's expertise and judgment in this area, therefore, has always been entitled to considerable deference-deference that would be denied the agency under the Second Circuit's mistaken rationale.

Upholding the Second Circuit's decision could induce PhRMA's members to adopt a decidedly defensive posture before FDA. Uncertainty as to the scope of potential tort exposure for non-disclosure under state law would create an incentive for drug manufacturers to inundate FDA with information in an effort to ensure that they were not charged with "fraud" under state law for omitting from their approval applications information that a judge or jury later might find "material" to FDA's approval decision. Indeed, manufacturers would be compelled to make such submissions even if FDA expressed no interest in receiving the information since the agency would not be the ultimate arbiter of the fraud question. Manufacturers also would have reason to demand, in order to document these prophylactic submissions, formal and detailed responses from FDA. As explained in *Buckman*, a flood of filings would strain FDA's resources, restrict the agency's ability to effectively balance drug safety and efficacy, and generally undermine the inherently federal FDA-manufacturer relationship.

These constitutional and practical concerns led this Court to conclude in *Buckman* that any state law that required courts to adjudicate "fraud on the FDA" wrongly intruded into an inherently federal relationship

and created an obstacle to the accomplishment of Congress's objectives in the FDA approval process. The Michigan exception requires judges and juries to determine, as a matter of state law, whether FDA approval was procured through fraud. Only if the answer is yes may the case proceed. The Second Circuit's attempt to distinguish this reliance on fraud on the FDA for state remedy administration from the reliance confronted by the Court in *Buckman* utterly fails. For all of these reasons, PhRMA respectfully requests that the Court reverse the decision below.

ARGUMENT

I. *BUCKMAN* REQUIRES PREEMPTION OF THE "FRAUD ON THE FDA" EXCEPTION TO THE MICHIGAN STATUTORY DEFENSE.

A. The Michigan Exception Would Obstruct FDA's Supervision Of Federal Disclosure Requirements In The Same Way As The "Fraud On The FDA" Claim Struck Down In *Buckman*.

The case at bar presented the Second Circuit with a product liability claim against a pharmaceutical manufacturer under Michigan law. *See Desiano v. Warner-Lambert Co.*, 467 F.3d 85, 93 (2d Cir. 2006). Michigan law provides pharmaceutical manufacturers a complete defense against a product liability claim so long as the product at issue is distributed in accordance with FDA rules and regulations. *See* Mich. Comp. Laws § 600.2946(5). The Michigan affirmative defense does not apply, however, if the manufacturer commits material

fraud on the FDA. *See id.* § 600.2946(5)(a) ("This subsection does not apply" if the manufacturer "[i]ntentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted . . . and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted.").

The constitutional viability of this "fraud-on-the-FDA" exception to the Michigan statutory defense depends on the force and meaning of this Court's decision in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the plaintiffs brought state-law causes of action, alleging that a consultant to a medical device manufacturer had made "fraudulent representations" to FDA during the approval process. *See id.* at 343. According to the plaintiffs, "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." *Id*. This Court unanimously ruled that this state-law "fraud-on-the-FDA" claim conflicted with, and "therefore [was] impliedly pre-empted by, federal law." *Id.* at 348; *see also id.* at 353 n.1 (Stevens, J., concurring) (agreeing that "federal law 'pre-empts' this state-law fraud-on-the-FDA claim").

As this Court then explained, "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. The federal regime could not properly function "in the shadow of 50 States' tort regimes." *Id.* at 350. Indeed, allowing judges and juries to determine under state law

whether "fraud on the FDA" had occurred 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 351. Manufacturers therefore would be prompted to "submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." *Id.*

In the present case, even though Respondent's ability to recover for product liability under Michigan law also turns on a finding that Petitioners procured FDA approval through fraud, the Second Circuit rejected the applicability of *Buckman* and ruled that the exception to the Michigan statutory defense was not preempted. *See Desiano*, 467 F.3d at 93 (finding a "meaningful difference between the fraud-on-the-FDA claims struck down in *Buckman* and Appellants' claims under Michigan tort law"); *see also id.* at 94-95 (stating that, in contrast to *Buckman*, none of the claims "derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency"); *id.* at 95 (distinguishing *Buckman* because, in that case, "there were no free standing allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements"). As explained below, the Second Circuit's justifications for distinguishing *Buckman* do not pass muster. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004) ("Doubtless, *Buckman* prohibits a plaintiff from invoking the exceptions on the basis of *state court* findings of fraud on the FDA. Such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*.").

The Second Circuit's central premise was that, unlike in *Buckman*, Respondents' legal claims were not "solely" grounded on a "fraud on the FDA" theory. *See Desiano*, 467 F.3d at 95 (concluding that "unlike the claims in *Buckman*, they are anything but based *solely* on the wrong of defrauding the FDA" and that "plaintiffs' complaints allege a wide range of putative violations of common law duties long-recognized by Michigan's tort regime"). Setting aside whether the distinction drawn by the Second Circuit is accurate, it is without a doubt immaterial. This Court's preemption decision in *Buckman* did not turn on whether fraud on the FDA was alone sufficient to trigger liability under state law. Indeed, the parameters of the state law at issue in *Buckman* were not clearly defined, and it is far from certain that a finding of fraud on the FDA would alone have been sufficient to impose liability on the defendant in that case. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 822 (3d Cir. 1998), *rev'd*, *sub nom. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) ("While it is clear that the plaintiffs' 'fraud on the FDA' claims are based on state rather than federal law, . . . the controlling state law of fraudulent representation in some cases may be different from that in other cases."). Rather, it was the consequences of allowing a plaintiff to prove as a matter of state law that the manufacturer had wrongly obtained FDA approval either by making affirmative misrepresentations or by withholding information from the agency that drove the decision in *Buckman*. *See id.* (explaining that the claim in *Buckman* was "drafted to track the elements of a common law cause of action for fraudulent misrepresentation") (citing Restatement (Second) of Torts § 525 *et seq.*); *see also Buckman*, 531 U.S. at 346-

47 (noting the claims at issue were "state-law causes of action claiming that petitioner and AcroMed made fraudulent representations to the FDA . . . and that, as a result, the devices were improperly given market clearance and were subsequently used to the plaintiffs' detriment"). On this ground, the case at bar and *Buckman* are indistinguishable.

In fact, none of the reasons articulated for finding preemptive conflict in *Buckman* depended in any way on the fact that the alleged fraud on the FDA was a stand-alone claim. *See id.* at 348 ("The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud."). Instead, the Court preempted the state-law cause of action because "the existence of these federal enactments [was] a critical element in [the plaintiffs'] case," *id.* at 353, and, accordingly, any state-law claim that interfered with the inherently federal relationship between regulated manufacturers and the FDA was foreclosed. *See id.* at 350 (explaining that "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants-burdens not contemplated by Congress in enacting the FDCA"); *id.* at 351 ("[F]raud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court.").

Here, just as in *Buckman*, liability under state law turns on whether the plaintiff can establish that Petitioners obtained FDA approval through fraud. *See Desiano*, 467 F.3d at 95. Michigan law unquestionably

forces courts to inquire into whether the manufacturer intentionally withheld from or misrepresented required disclosures to the FDA and whether that omission or misrepresentation would have altered FDA's decision to allow the drug to enter or remain on the market. *See* Mich. Comp. Laws § 600.2946(5)(a). This is the precise inquiry that was preempted in *Buckman*. *See Garcia*, 385 F.3d at 965-66 (recognizing that, although the Michigan statute "presents a somewhat different legal regime from the one invalidated in *Buckman*," the "difference . . . is immaterial in light of *Buckman*"); *see also Ledbetter v. Merck & Co.*, Nos. 05-59499 & 05-58543, 2007 WL 1181991 (Tex. Dist. Ct. Harris County Apr. 19, 2007) ("Whether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same. All of the federalism concerns expressed in *Buckman* still apply."); *Henderson v. Merck & Co.*, No. 04-CV-05987, 2005 WL 2600220, at *11 (E.D. Pa. Oct. 11, 2005) ("This Court follows the holdings of *Buckman* and *Garcia*, and finds that . . . [Sections] 600.2946(5)(a) and (b) are preempted by the FDCA in most situations.").[2]

2. Michigan law is clear that, when claiming an exception to an affirmative defense, the burden lies with the plaintiff to show all of the elements of fraud on the agency, and it is properly considered a "claim" that the plaintiff must make. *See Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003); *Feyz v. Mercy Memorial Hosp.*, 719 N.W.2d 1, 10 n.45 (Mich. 2006); *McNeil ex rel. McNeil v. Metinko*, Nos. 194595 & 194596, 1998 WL 2016585, at *1 (Mich. Ct. App. March 13, 1998). The Second Circuit's conclusion that the alleged fraud on the FDA will be raised based on a defendant's invocation of the statutory affirmative defense and "that it is not up to the plaintiff to prove

(Cont'd)

To bolster its faulty reading of *Buckman*, the Second Circuit announced that its conclusion was not different from "the position the pharmaceutical industry articulated at oral argument in *Buckman*." *Desiano*, 467 F.3d at 95. In particular, the court relied on a statement made by Buckman's counsel: "The plaintiffs don't claim that these devices were in any way defective. . . . Instead, the plaintiffs' sole claim in this case is the following. They assert that the Federal Food & Drug Administration was deceived into giving regulatory clearance to these devices." *Id.* at 95-96 (quoting Oral Argument Transcript, Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 2000 WL 1801621 (2000) (No. 98-1768) (hereafter "*Buckman* Transcript")); *see also id.* at 96 n.8 (concluding that "a second lawyer for the industry indicated that traditional tort remedies were *not* implicated by *Buckman*" because "[w]hen asked about what remedies an injured plaintiff would have under his theory of the case, the attorney responded: 'The *fraud* claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available[.]'") (quoting *Buckman* Transcript at *21).

These statements should not have been attributed to the "pharmaceutical industry"; they were instead advanced by the Petitioner in *Buckman*-a consulting

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(Cont'd)
fraud as an element of his or her claim," *see Desiano v. Warner-Lambert Co.* 467 F.3d 85, 96 (2d Cir. 2006), thus coyly, but unsuccessfully, sidesteps the dispositive question—*i.e.*, which party bears the ultimate burden of proof. The Second Circuit did not—and could not—dispute that the ultimate fraud burden resides with the plaintiff under Michigan law.

company for medical device manufacturers-and by the United States government. *See id.* at 95; *Buckman* Transcript at *3-4, 21. PhRMA, which does represent "the pharmaceutical industry," in fact filed an *amicus curiae* brief in *Buckman*. *See* Brief of the Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Petitioner, Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2000) (No. 98-1768). The positions taken in that brief are in complete accord with the position taken here. *See id.* at 6 (explaining that federal law "require[d] preemption of state-law standards that permit[ted] the states to scrutinize the FDA approval process and second-guess the validity of FDA approval determinations" and that "[t]hese standards, whether imposed through common-law causes of action or statutory schemes, would impermissibly disrupt the intended uniformity and certainty of the federal approval regime, and could lead to reduced availability of important medical products"); *id.* at 14 (taking the position that "[t]he integrity of the FDA approval regime requires preemption of state-law standards-including respondents' 'fraud on the FDA' claims-that permit ad hoc (or systematic) challenges to the validity of FDA approval decisions").

Moreover, the Second Circuit completely mischaracterizes the arguments advanced by Buckman's counsel at oral argument. Counsel stated that "the plaintiffs' sole claim" was fraud on the FDA and that the plaintiffs did not claim that the devices were defective. *Buckman* Transcript at *3-4. Counsel did not argue that these distinctions were in any way material to the question before the Court, and certainly did not suggest that the case should come out any differently if

fraud on the FDA were only one part of a claim or a "necessary proof" element of a case. That issue was not before the Court, and the *Buckman* Petitioner would have had no reason to draw such a distinction. Indeed, portions of the argument before the Court omitted from the Second Circuit's discussion of this issue make clear that Buckman's position would have been the same even if the claim at issue was not based "solely" on fraud on the FDA:

> So this lawsuit is, in other words, a direct attack under State law on the decision of the Federal Food & Drug Administration[.] . . . [I]t means that a jury applying State law would have to decide such issues as, what sorts of disclosures have to be made to the Food & Drug Administration[?] What did the FDA know[?] Was the FDA deceived in any way in granting regulatory clearance?

Buckman Transcript at *4; *see also id.* at *9 ("[T]he point that I was simply making is the sorts of inquiries that a State judge or jury would have to make if this State law claim were allowed to proceed are inquiries that would delve heavily into the intricacies of the Federal regulatory process[.]").

Moreover, the United States, arguing in support of the Petitioner in *Buckman*, articulated exactly the point being made by the Petitioner and by PhRMA here: "[I]nsofar as they would be asserting an essential element of the claim . . . that the FDA was defrauded, that is an area of exclusive Federal concern, and the State common law cause of action would be preempted."

Id. at *21. Put simply, the record does not support any contention that the pharmaceutical industry conceded in *Buckman* the validity of a law such as the one at issue here. The Second Circuit's contrary makeweight is unsustainable.

B. The Second Circuit Erred In Applying A Presumption Against Preemption In This Case.

This Court, at times, has endorsed a "presumption against preemption" under which the review of a federal statute "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." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, (1947); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 523-24 (1992) ("[W]e must fairly but-in light of the strong presumption against pre-emption-narrowly construe the precise language of § 5(b) and we must look to each of petitioner's common-law claims to determine whether it is in fact pre-empted."). The court below found that a presumption against preemption applied in this case. *See Desiano*, 467 F.3d at 93 ("[T]he presumption against federal preempt-ion of state law obtains in the case before us."). The Second Circuit's invocation of a "presumption" in the case at a bar was deeply flawed for at least two reasons.

First, a presumption against preemption has no legitimate role in conflict preemption cases. When Congress exercises its Article I power to occupy an area of commerce, or to foreclose state activity in a traditional area of state concern, without regard to a conflict of commands or purposes, principles of federalism might

properly counsel requiring a clear legislative articulation of the bounds of that foreclosure. *See*, *e.g.*, *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 813-14 (1997) (invoking a "presumption against preemption" to determine "the scope of the state law that Congress understood would survive" (citations and internal quotations omitted)); *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963) (explaining that the "principle to be derived from" past Supreme Court "decisions is that federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons-either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained."). That invocation of the "presumption" essentially supplies guidance in cases where it is unclear whether Congress intended to trump state law by positive enactment. *See*, *e.g.*, *Cipollone*, 505 U.S. at 518 ("This presumption reinforces the appropriateness of a narrow reading of § 5.").

Where, however, the exercise of state authority would impose duties inconsistent with federal mandates or obstruct the objects and purposes of federal law, preemption arises directly from Article VI of the Constitution. The relevant Congressional intent relates to how Congress expects the federal regime to operate-an issue to which the presumption has no relevance. *See Chicago & Nw. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (explaining that conflict preemption analysis entails "essentially a two-step process of first ascertaining the construction of the two statutes and then determining the constitutional question whether they are in conflict") (citations and

quotations omitted); *Fla. Lime*, 373 U.S. at 142-43 ("A holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce."). Thus, for example, this Court determined the objects of National Highway Traffic Safety Administration's passive restraint regulation without regard to any presumption. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874-75 (2000) ("In a word, ordinary pre-emption principles, grounded in longstanding precedent apply." (internal citation omitted)). Having given appropriate deference to the operation of the federal regimes, the Court properly secured them from state interference. *See id.* at 875-86.

As this Court explained, if "the state law regulates conduct that is actually protected by federal law . . . pre-emption follows not as a matter of protecting primary jurisdiction, but as a matter of substantive right." *Brown v. Hotel & Rest. Employees and Bartenders Int'l Union Local 54*, 468 U.S. 491, 503 (1984). In this context, unlike with respect to Congressional preemption by exclusion, any substantive federalism concerns were resolved when the Framers chose to make federal law supreme. *See id.* at 503 (explaining that when "the issue is one of an asserted substantive conflict with a federal enactment, then '[t]he relative importance to the State of its own law is not material . . . for the Framers of our Constitution provided that the federal law must prevail'") (quoting *Free v. Bland*, 369 U.S. 663, 666 (1962)); *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 769 (11th Cir. 1998) (explaining that under the Supremacy Clause "[t]he relative importance to the State of its own law is not

material when there is a conflict with a valid federal law, for any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield") (citations and quotations omitted).

Indeed, inquiry into the "intent" of Congress to limit state authority is an unnecessary enterprise when preemption turns on whether the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67-68 (1941); *see also* Howard L. Dorfman, Vivian M. Quinn, & Elizabeth A. Brophy, *Presumption of Innocence: FDA's Authority to Regulate the Specifics of Prescription Drug Labeling and the Preemption Debate*, 61 Food & Drug L.J. 585, 603 (2006) ("Regardless of intent, if a conflict is found, 'local law [will be] pre-empted.'" (quoting *Chicago & Nw. Transp. Co.*, 450 U.S. at 317)).[3] "[O]ne can assume that Congress or an agency ordinarily would not intend to permit a significant conflict." *Geier*, 529 U.S. at 885 ("To insist on a specific expression of . . . intent to pre-empt . . . would be in certain cases to tolerate conflicts that . . . Congress . . . is most unlikely to have intended."); *see also City of New York v. FCC*, 486 U.S. 57, 64 (1988) (explaining that "a narrow focus on Congress' intent to supersede state law [is] misdirected, for [a] pre-emptive regulation's

3. *See also id.* at 609 (explaining that "even if such intent was a necessary element, Congress undeniably has shown that it intends ordinary conflict-preemption principles to apply to FDA's actions under the FDCA."). "Section 202 of the 1962 Amendments to the FDCA expressly invalidates any state law that creates a 'direct and positive conflict' with any amendments to the FDCA." *Id.* (quoting Pub. L. No. 781, 76 Stat. 779 (1962)).

force does not depend on express congressional authorization to displace state law.") (citations and quotations omitted). Imposing a requirement on Congress to clearly express an intent to "conflict" preempt a contrary state law cannot be justified given the unmistakable choice that the Supremacy Clause represents.[4] For this most basic reason, the Second Circuit's invocation of the presumption against preemption was ill-advised in this instance.

Second, the court below erred even assuming *arguendo* that the presumption could extend to any conflict preemption case. This Court has made quite clear that the presumption cannot sustain "fraud on the FDA" litigation. *See Buckman*, 531 U.S. at 347 ("Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,'" such as to warrant a presumption against finding federal preemption of a state-law cause of action) (quoting *Rice*, 331 U.S. at 230). "[T]he relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law. . . . Accordingly . . . no presumption against pre-emption obtains in this

4. This Court at one point acknowledged that whether a presumption applies in the context of conflict preemption remains an open question. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 374 n.8 (2000). To the extent this question remains open after *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 906 (2000) (Stevens, J., dissenting) (objecting to the Court's decision to eschew the presumption against preemption in favor of "ordinary experience-proved principles of conflict pre-emption"), the Court should firmly announce that the presumption has no place in conflict preemption jurisprudence.

case." *Buckman*, 531 U.S. at 347-48 (internal citations and quotations omitted)). Nevertheless, the Second Circuit invoked the presumption here because, in its mistaken view, "the object of the legislative scheme" in this case was "to regulate and restrict when victims could continue to recover under preexisting state products liability law," which it considered to be within Michigan's traditional regulation of health and safety. *Desiano*, 467 F.3d at 94.

As noted above, *see supra* § I.A., that Michigan labeled the "fraud on the FDA" liability trigger as an exception to an affirmative defense is immaterial. Whether a presumption applies cannot turn, as the Second Circuit would have it, on whether the state common law allows a claim specifically targeted to fraud on the FDA or whether a state has incorporated "fraud on the FDA" into a broader product liability statute. Indeed, under the Second Circuit's myopic view of the *Buckman* Court's presumption discussion, states could make fraud on the agency a convenient tool for asserting power to set aside or ignore relevant federal requirements so long as a finding of irregularity was not the sole basis for liability under state law. *See* Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. of Tort Law, Issue 1, Article 5 (2006) (criticizing *Desiano* for making "a huge deal out of the pedigree of the state law cause of action when the dominant concern of the Supreme Court was the entanglement of the FDA in state litigation, which remains the same no matter how state law tees up the plaintiff's cause of action"). Because Michigan law attempts to regulate an inherently federal relationship,

its "fraud on the FDA" exception cannot be entitled to any presumption against preemption.

It is important for the Court to recognize that whether the presumption against preemption should apply in this case is not an academic issue. There can be no question that the presumption infected the Second Circuit's ruling throughout. *See Desiano*, 467 F.3d at 95 & n.7 (framing its refusal to allow Congress "without any explicit expression of intent . . . to have modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers" as "another way of saying that, unlike the situation in *Buckman*, the presumption against preemption is at its strongest in the instant case"); *see also id.* at 96 ("Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect." (citations omitted)); *id.* at 98 (contrasting *Buckman* by stating that "[t]he appeal before us presents a very different set of circumstances, one in which there is a clear presumption against preemption of long-standing common law claims"). The Second Circuit's mistaken reliance on a presumption against preemption itself warrants reversal and counsels this Court to reiterate the presumption's limited applicability.

* * *

In sum, this Court's decision in *Buckman*, in PhRMA's view, stands for the correct proposition that state-law liability against a pharmaceutical manufacturer

may not depend in any way on a finding of fraud on the FDA. FDA simply cannot function properly under a regime where it shares authority with state agents over fraud in the approval process, whether stated as a cause of action or an exception to state law immunity. Such a state of affairs would interfere with FDA's ability to fulfill its mandate and would obstruct the comprehensive federal drug approval regime Congress put in place under FDCA. The Michigan exception is preempted under *Buckman*.

II. THE SECOND CIRCUIT'S RULING OBSTRUCTS EXECUTION OF REGULATORY OBJECTIVES ENTRUSTED TO FDA BY CONGRESS.

A. FDA's Authority To Control Disclosure And Police Fraud Would Be Obstructed By Michigan's Statutory Scheme.

Allowing state courts to pursue "fraud on the FDA" questions undermines the disclosure and enforcement flexibility Congress entrusted to FDA. *See Buckman*, 531 U.S. at 348. FDA's main task with regard to the marketing of pharmaceuticals is to ensure that "drugs are safe and effective" for their intended uses. 21 U.S.C. § 393(b)(2)(B). In seeking FDA approval for a new drug, manufacturers must submit volumes of information with their new drug applications. *See* 21 U.S.C. § 355(b)(1); *see also* 21 C.F.R. § 314.50 (stating that an application "is required to contain reports of all investigations of the drug product sponsored by the applicant, and all other information about the drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source," including,

among other things, proposed labeling, drug chemistry, scientific rationale for the drug, drug marketing history, pharmacology and toxicology, human pharmacokinetics and bioavailability, microbiology, clinical results and statistical analysis, environmental impact, and benefit and risk considerations); *id.* § 312.21 (setting forth the procedure for clinical trials); *id.* § 314.200 *et seq.* (providing for hearings before the agency where FDA proposes to deny a new drug application). Even after approval, manufacturers are under a continuing obligation to keep records of and report further clinical experience and other pertinent information. 21 U.S.C. § 355(k); *see also* 21 C.F.R. § 314.80 (adverse drug experiences); *id.* § 314.81 (field alert reports, annual reports, advertising, and notice of withdrawal from market). Each of these disclosure obligations requires a careful balance between utility and burden.

Because the reliability of these constant interactions between the agency and those it regulates is central to the agency's congressional mandate, FDA was granted a variety of tools to police fraud on the agency in the approval process. *See Buckman*, 531 U.S. at 349 ("Accompanying these disclosure requirements are various provisions aimed at detecting, deterring, and punishing false statements made during this and related approval processes."). First, FDA is empowered to investigate fraud. *See* 21 U.S.C. § 372(a)(1). Once FDA has determined that it has been defrauded, FDA, in its unfettered discretion, may seek injunctive relief, 21 U.S.C. § 332, civil penalties, *id.* § 333(g)(1)(A), or criminal prosecution, *id.* § 333(a). FDA also may have a prescription drug removed from the marketplace. *Id.* § 334(a)(1). Thus, as this Court recognized in

Buckman, the FDCA makes clear that the authority and discretion to take action against a drug manufacturer for noncompliance with the FDCA or FDA regulations rests exclusively with the United States government. *See Buckman*, 531 U.S. at 349 n.4; *see also* 21 U.S.C. § 337(a) (providing, with limited exceptions not pertinent here, "[a]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States").

The availability of this range of regulatory options "is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349. State-law enforcement of fraud on the FDA, in contrast, would operate in a vacuum, divorced from any obligation or incentive to balance the goal of full disclosure against other worthy (and sometimes competing) policy objectives. State law fraud-on-the-FDA litigation thus would have the perverse and destructive effect of allowing states to determine the regulatory cost of FDA drug approvals. FDA's mission undoubtedly would be hindered under such a system of divided and unaccountable authority. For this reason, among others, this Court determined in *Buckman* 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." *Id.* at 350.

The Second Circuit not only ignored the force of *Buckman* here, but appeared to go a step further by sanctioning a state law finding of fraud on the FDA even where FDA itself had specifically ruled that no such fraud had occurred. *Compare Dowhal v. SmithKline*

Beecham Consumer Healthcare, 88 P.3d 1, 9 (Cal. 2004) (preempting state law cause of action where "FDA has rejected plaintiff's claim that his data justify a different warning, and defendants do not claim to have any additional data"). This simply cannot be correct. *See* Epstein, *supra*, at 7 (explaining that *Buckman* "held unanimously . . . that no tort plaintiff could bring any tort action that made an evaluation of FDA conduct the subject of state court proceedings, with their extensive pre-trial discovery by way of both interrogatories and deposition"). If the Second Circuit reached the proper result, FDA is essentially powerless to regulate the flow of information from the manufacturers it comprehensively regulates. Given the broad responsibility conferred on FDA under FDCA, this result is constitutionally unacceptable.

B. FDA's Expert Scientific Drug Approval Determinations Should Not Be Second Guessed Under State Law.

The need to resolve materiality in state law fraud-on-the FDA litigation will undermine FDA's ability to make operative the scientific determinations that Congress entrusted to the agency. To determine whether a drug is safe and effective based on its intended use, FDA requires that new drug applications include the data necessary for the agency to reach an informed decision. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (explaining that "[u]nder the Act and FDA regulations, the agency makes approval decisions based . . . on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of

use prescribed, recommended, or suggested in the labeling" (citation omitted)). FDA exercises critical scientific judgment, taking into account the entire file and, often, the advice of expert advisory committees to determine whether a new drug application should be approved, and if so, under what labeling conditions. FDA has made this clear in congressional testimony:

> Every time the scientists on our staff allow a new drug to come on the market, they have to take the sum total of scientific knowledge that they can muster about the drug, and reach a conclusion as to whether or not the good that that drug will do, the lives it will save or the suffering that it will prevent, outweighs the known side effects.

Drug Industry Antitrust Act: Hearing Before the Antitrust Subcomm. on Antitrust, 87th Cong. 135 (1962).

Judges and juries evaluating state-law "fraud on the FDA" claims would be required to predict whether the information allegedly withheld or misrepresented during the NDA approval process would have changed FDA's actions. Judges and juries are not in a position to evaluate the scientific "materiality" of information not submitted to FDA; indeed, they are ill equipped to comprehend the manner in which FDA implements its policies and practices, why certain types of information may be probative and why others may not, and how the agency's institutional experience impacts its evaluation. *Cf.* 21 U.S.C. § 355(n) (directing FDA to convene panels consisting of experts from a number of scientific disciplines to assist in making safety and efficacy

determinations). This background knowledge is beyond the ken of jurors or judges even in isolation, let alone within the context of a particular lawsuit filled with a litany of other complicating variables. *See Reeves v. AcroMed Corp.*, 44 F.3d 300, 307 (5th Cir. 1995) ("Given the FDA's central role in reviewing and approving devices under the MDAs, the FDA is in the best position to decide whether AcroMed withheld material information from the agency and, if so, the appropriate sanction.").[5]

For these reasons, FDA's expert judgments are entitled to considerable deference in federal court actions. Congress has explicitly delegated rulemaking power to FDA, and FDA's interpretations of the FDCA are "binding in the courts unless procedurally defective, arbitrary or capricious in substance, or manifestly contrary to the statute." *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001) (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1984)). And, express delegation aside, an agency "charged with applying a statute necessarily make[s] all sorts of interpretive choices" for which "courts have looked to the degree of the agency's . . . relative

5. FDA's judgment also extends to the development of the submission criteria themselves; those outside the agency are simply not equipped to determine, for instance, whether data should be presented in a certain way or how clinical trials must be organized in order to best present the information needed to make safety and efficacy determinations. Therefore, even courts attempting to follow FDA's regulations and guidelines would be disrupting FDA's framework, as ex post facto interpretations of FDA statutes, regulations, and guidelines are not guaranteed to be in line with FDA's considered judgment.

expertness" to determine "[t]he fair measure of deference to an agency administering its own statute." *Id.* (citing *Aluminum Co. of Am. v. Cent. Lincoln Peoples' Util. Dist.*, 467 U.S. 380, 390 (1984)). FDA, which makes a range of scientific judgments, is the paradigmatic expert agency. *See Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 653-54 (1973) ("The determination whether a drug is generally recognized as safe and effective . . . necessarily implicates complex chemical and pharmacological considerations" and is "peculiarly suited to initial determination by the FDA."); *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995) ("[FDA's] judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us.").

Under the Second Circuit's ruling, however, FDA approval decisions would be subject to limitless second-guessing under state law based on ostensibly unconsidered information. State law findings that FDA approvals were wrong clearly would obstruct FDA's execution of federal responsibilities under the FDCA. *See Warner-Lambert Co. v. Heckler*, 787 F.2d 147, 152-53 (3d Cir. 1986) (scientists and experts outside the agency cannot make a final determination of safety and efficacy of drugs because FDA must itself review the opinions of outside experts regarding safety and efficacy according to "well-established principles of scientific investigations") (citing *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 619 (1973)). Attempting to avoid such inconsistency by referring materiality issues to the FDA is not contemplated by Michigan law and, even if possible, would allow state tort actions to dictate FDA's regulatory agenda to the detriment of its federal mission.

C. State-Law Litigation Of Fraud On The FDA Would Improperly Interfere With The Inherently Federal Relationship Between FDA And Drug Manufacturers.

State superintendence over federal fraud claims would impose burdens on potential applicants and on FDA that directly contradict the expressed will of Congress. *See Buckman*, 531 U.S. at 350 ("[C]omplying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants-burdens not contemplated by Congress in enacting the FDCA and the MDA."). Plaintiffs seeking judicial relief under state law will seek to expand the category of information "required to be submitted" to its outer limits. This almost certainly would induce a reaction from drug manufacturers, who might "fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *See id.* at 351 ("Applicants would . . . have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application."). The disruptive practical consequences of fraud on the FDA litigation on FDA operations is yet another reason to preclude it.

FDA's scarce resources could easily be overwhelmed if every piece of potential raw data or speculative theory related to a drug, a clinical trial, or an adverse drug event were reported to the agency. *See*, *e.g.*, *Horn v. Thoratec Corp.*, 376 F.3d 163, 178 (3d Cir. 2004) (observing that excessive risk-oriented regulation "can harm the

public health . . . by encouraging 'defensive labeling' by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments"). In addition, manufacturers would have good reason to demand from FDA detailed and formal responses to these defensive filings in order to document these interactions in the event of future fraud-on-the-FDA litigation. This Court thus appropriately recognized that litigating fraud-on-the-FDA claims "would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme." *Buckman*, 531 U.S. at 353. Under the FDCA, responsibility rests with FDA-not the States-to balance the need for material information against the burden of excessive disclosure in the drug approval process. State law litigation of fraud on the FDA both wrongly asserts state legal authority to determine "inherently federal" disclosure requirements and improperly distorts the practical administration of the FDA's disclosure regime.

Fraud on the FDA litigation would have other inevitable and disruptive consequences on FDA's operations. State law discovery on the information conveyed or not conveyed to FDA could involve FDA employees who engaged in scientific discussions with applicants and FDA internal records. Litigants could seek to extract testimony from FDA officials and Advisory Committee members on what they relied upon in making approval decisions and how they might have reacted to additional or modified disclosures. Ironically, as appropriate state deference to FDA's scientific judgments increased either, as here, under state legislation or by application of conflict preemption

principles, *see*, *e.g.*, *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 537 (E.D. Pa. 2006) (finding that "assigning a duty to include a warning different from GSK's approved label inherently conflicts with the FDCA"), fraud on the FDA allegations would correspondingly proliferate to the detriment of FDA's mission.

Respondents have candidly acknowledged that, given any opportunity to introduce a fraud on the FDA issue under state law, FDA will be under siege. *See* Brief in Opposition to the Petition for Writ of Certiorari at 3-4, Warner-Lambert Co. v. Kent, No. 06-1498 (filed July 20, 2007). According to Respondents, permitting the Michigan exception to survive when "FDA had determined that petitioner had committed fraud . . . and had then taken the necessary steps to remove the harm-causing product from the market", *see Buckman*, 531 U.S. at 354 (Stevens, J. concurring); *Garcia*, 385 F.3d at 966, will turn loose a flood of Citizens Petitions seeking to force FDA to act. This Court has stressed the importance of the enforcement discretion accorded to FDA under FDCA. *See Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (concluding that FDCA's "enforcement provisions . . . commit complete discretion to the Secretary to decide how and when they should be exercised"). Incorporation of fraud-on-the FDA issues into state law, whether as an issue to be independently determined under the Second Circuit's decision or as a precondition to liability under the Sixth Circuit's decision in *Garcia*, would unduly impair FDA's enforcement discretion and allocation of resources. This Court thus should make clear that fraud on the FDA issues have no proper decisional role under state law and that any state action whose success relies upon a determination of fraud on the FDA should be preempted.

CONCLUSION

For all of the foregoing reasons, and for the reasons set forth in the Petitioner's brief, the Court should reverse the decision of the United States Court of Appeals for the Second Circuit.

Respectfully submitted,

DIANE E. BIERI
Senior Vice President
and General Counsel
KATHRYN R. COLBURN
Assistant General Counsel
PHARMACEUTICAL RESEARCH
AND MANUFACTURERS
OF AMERICA
950 F Street, NW
Suite 300
Washington, D.C. 20004
(202) 835-3405

BERT W. REIN
Counsel of Record
WILLIAM S. CONSOVOY
BRENDAN J. MORRISSEY
WILEY REIN LLP
1776 K Street, NW
Washington, D.C. 20006
(202) 719-7000

Attorneys for Amicus Curiae