No. 06-1498

JUL 30 2007

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

REPLY BRIEF IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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CORPORATE DISCLOSURE STATEMENT

Petitioners' Rule 29.6 Statements were set forth on page iv of their Petition, and there are no amendments to those statements.

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Respondents' brief does not challenge the sharp conflict between the decision of the Second Circuit below and that of the Sixth Circuit as to whether, under *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), federal law preempts a state statutory requirement that—as a predicate to liability involving an FDA-approved prescription drug—the finder of fact must determine if there was fraud-on-the-FDA. Allowing such state law findings inevitably interferes with the federal agency's authority and its relationship with the entities that it regulates.

In order to obscure the far-reaching federal preemption issues flowing from the Second Circuit's overly narrow reading of *Buckman,* respondents assert that the issues here are limited to this particular case and the Michigan statute. However, the consequences of allowing state law determinations of fraud-on-the-FDA, which were central to *Buckman,* transcend this case and the Michigan statute for the following reasons, which respondents fail to address:

- There are seven comparable statutes enacted in other states, one of which in Texas makes a state law finding of fraud-on-the-FDA a predicate for liability and six of which require such a finding to award punitive damages.

- Thousands of pharmaceutical product liability cases pending in Multidistrict Litigations will be impacted by the precedential effect of the Second Circuit's holding that *Buckman*'s conflict preemption only applies to stand-alone claims based solely on fraud-on-the-FDA.

- The issues raised in the Petition impact litigation where fraud on federal agencies other than FDA is raised, as illustrated by a Ninth Circuit decision, which involved a claim requiring proof of fraud on the EPA,

and which conflicts with the Second Circuit opinion below.

Under the circumstances, the Petition presents an ideal vehicle for resolving the circuit conflict and clarifying the scope of *Buckman*. Michigan's broad statutory scheme, like that of seven other states, poses an even greater threat to the integrity of the federal regulatory system than the isolated, stand-alone, fraud-on-the-FDA claim at issue in *Buckman*.

I. The Conflict Among the Circuits and With *Buckman* Will Have Far-Reaching Effects.

Respondents urge that "this case is unlikely to have far-reaching effects." Brief in Opposition to Petition for a Writ of Certiorari ("Resp. Br.") at 1. That contention ignores the adverse consequences to the FDA's regulatory process and health care that will ensue when courts adopt the Second Circuit's overly restrictive interpretation of *Buckman*'s conflict preemption holding. The far-reaching effects of the issues raised by the Petition are twofold: (i) resolving the circuit split will impact many cases beyond this case and the Michigan statute; and (ii) a reasoned interpretation of *Buckman,* as in the Sixth Circuit's decision is essential to avert the dire consequences to the FDA regulatory process that *Buckman* found would result from allowing state law fraud-on-the-FDA claims. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004).

Respondents contend that the issue raised by the Petition "is limited to Michigan drug-injury cases brought within the Second Circuit in which a plaintiff can make a showing of fraud on the FDA." Resp. Br. at 1. That argument fails to recognize that the issue of whether under *Buckman*'s rationale there is preemption of state law requirements for determining fraud-on-the-FDA

could arise in any circuit in which a case is filed by a Michigan plaintiff or—as in the instant case—where there is a transfer pursuant to MDL procedures. *See* 28 U.S.C. § 1407.

Moreover, the scope of *Buckman's* conflict preemption rule has in fact arisen in a number of other jurisdictions, with inconsistent lower court decisions, where plaintiffs sued under one of the seven other state statutes with comparable fraud-on-the-FDA requirements as a predicate to liability or punitive damages. Petition for a Writ of Certiorari ("Pet.") at 11-12. The circuit conflict also will cause plaintiffs in Michigan and the seven other states to forum shop in order to take advantage of the Second Circuit's decision, rather than the law of the circuit in which plaintiffs reside and their alleged injuries occurred.

The conflict between the Second and Sixth Circuit's interpretation of *Buckman* also impacts thousands of other pharmaceutical product liability cases pending across the country where fraud-on-the-FDA is being litigated under state law in a variety of contexts. Brief of the Product Liability Advisory Council as *Amicus Curiae* in Support of Petitioner ("PLAC Br.") at 11-16. In addition, resolving the circuit conflict affects cases alleging fraud on agencies other than FDA. Thus, conflicting approaches to the *Buckman* preemption issue will continue to arise in cases such as the Ninth Circuit's decision in *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2001), which inconsistently with the rationale of the Second Circuit here, found preemption of a state law claim requiring a determination of fraud on the Environmental Protection Agency. Pet. at 9.

Respondents also assert that the Michigan legislature may consider further legislation on the subject, but that only shows that Michigan and other state legislatures

around the country need guidance now from this Court, in light of the circuit split, on how far they can go in imposing state law requirements on matters relating to fraud on federal regulatory agencies.

Respondents surmise that the impact of the Second Circuit's decision will be limited because "plaintiffs will be unable to make a colorable claim of fraud-on-the-FDA in run-of-the-mill cases, and the issue will likely be limited to groups of cases" such as those involving the drugs Rezulin or Vioxx. Resp. Br. at 2-3. As set forth in the Petition and the amicus briefs, numerous plaintiffs have made such colorable claims under state law, which are being actively litigated in state and federal courts. The Vioxx cases alleging fraud-on-the-FDA number in the thousands, as do Multidistrict Litigations involving other drugs and medical devices. PLAC Br. at 12-13.

Moreover, the threshold for plaintiffs to allege fraud-on-the-FDA is not high. A new drug application is a massive submission, and there are continuing submissions after approval. Pet. at 3; Brief for the Pharmaceutical Research and Manufactuers of America as *Amicus Curiae* Supporting Petitioners ("PhRMA Br.") at 11 n.3. In light of hindsight, plaintiffs can easily assert that some piece of information was omitted or should have been stated differently in submissions to FDA before or after drug approval. Any such simple allegation will launch the case down the path that *Buckman* has proscribed in order to protect the integrity of the FDA's regulatory function. Under the Second Circuit's holding, any case in which such allegations are made, other than in the context of a stand alone fraud-on-the-FDA claim, must proceed through discovery to the point where a fact-finder will have to determine under state law whether the defendant committed fraud-on-the-FDA.

In addition to the numerous cases that are affected by the circuit split, the Second Circuit's decision threatens to unleash the untoward consequences from conflicts with the FDA regulatory process that this Court in *Buckman* sought to avert. Thus, the Second Circuit's decision now provides a road map for plaintiffs to evade *Buckman's* preemption ruling simply by pleading their state-law allegations of fraud-on-the-FDA so that the claims are not "solely" based on such fraud. Further exacerbating the impact of the Second Circuit's ruling is its invitation to state legislatures and courts to enact and enforce legislation that makes a state law determination of fraud-on-the-FDA a prerequisite to liability or punitive damages recovery.

In sum, the Petition and the amicus briefs provide overwhelming support for the widespread impact of the Second Circuit's overly narrow interpretation of *Buckman* and the conflict with the Sixth Circuit as well as with the Ninth Circuit and numerous lower court decisions addressing state law requirements of proof of fraud-on-the-FDA and other federal regulatory agencies.

II. No "Showing", Beyond the Findings in *Buckman*, Is Necessary to Conclude That State Law Requirements to Determine Fraud-on-the-FDA Will Conflict with the Federal Regulatory System.

Respondents argue that "Petitioners have made no showing" that the issues implicated by the Michigan statute will have any disruptive effect on FDA. Resp. Br. at 4. To the contrary, that "showing" derives from *Buckman*'s conclusions that state law decisions on fraud-on-the-FDA inevitably conflict with the federal regulatory regime. No further showing is required to conclude that the FDA is entrusted by Congress with exclusive author-

ity to police fraud on the agency, and that state law determinations of fraud-on-the-FDA would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." 531 U.S. at 349-350. As *Buckman* established, state law litigation of the issue of fraud-on-the-FDA undermines the "flexibility" that is "a critical component" of FDA's ability, entrusted to it by Congress, to "pursue[ ] difficult (and often competing) objectives" on complex scientific and medical issues relating to the safety and efficacy of drugs and medical devices. *Id.* at 349.

Respondents assert that "it is not apparent" how the FDA or its regulatory processes would be hurt by state juries' "ill-informed" speculation as to how FDA would react to certain information. Resp. Br. at 3. In so arguing, respondents fail to recognize that *Buckman* has identified the adverse impact that such "ill-informed" speculation would have on the integrity of FDA regulation. For example, it was apparent to this Court that in order to protect themselves from what states might require to avoid fraud-on-the-FDA, 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." 531 U.S. at 351. The same concerns could delay or deter applications for new drugs and devices to the detriment of health care. *Id.*

Respondents also cite to the Second Circuit's conclusion that the inducement to overburden the FDA with excessive data to satisfy state law requirements could also occur where "a court or jury is *allowed to consider* evidence of fraud against the FDA . . . ." App. 25a (emphasis in original) cited in Resp. Br. at 3. Respondents have added a gloss omitted from the Second Cir-

cuit's formulation to the effect that under the common law rule, "such matters are admissible *but not necessarily determinative*." Resp. Br. at 3 (emphasis added). *See* Pet. at 22-23. That is not the case with the Michigan statute and comparable statutes in seven other states, which require a determination under state law that fraud-on-the-FDA occurred. In that circumstance, the consequences to the regulatory process set forth in *Buckman* would likely occur. Under the reasoning of this Court, statutes requiring such determinations "conflict with, and are therefore impliedly preempted by, federal law." 531 U.S. at 348.

Respondents also assert that a preemption ruling under which only the FDA can determine if there was fraud on the agency would impose greater burdens on the FDA than allowing state courts to share that responsibility. Resp. Br. at 4. Congress has mandated the FDA's exclusive authority to police fraud on the agency and to allow citizens to file petitions bringing such fraud allegations to the FDA's attention. *Buckman*, 531 U.S. at 349. Any burdens on the FDA that this authority entails were contemplated by Congress. But, as *Buckman* held, preemption is warranted where conflicting duties would result from requiring applicants to "comply[ ] with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes." *Id.* at 350.

III. The Preemption Issues Raised by this Petition Are Not Dependent on State Law.

Respondents argue that the preemption issues raised by this Petition are "inextricably intertwined with consideration of whether the fraud-on-the-FDA exception is severable from the" remainder of the Michigan tort reform statute, which is governed by Michigan law. Resp. Br. at 4-5. This argument puts the cart before the

horse. The Michigan statute precludes liability for alleged injury from FDA-approved prescription drugs, with an exception where there is a state law finding of fraud-on-the-FDA. The question of whether the exception is severable from the remainder of the statute is not reached unless the exception's requirement to prove fraud-on-the-FDA is first held to be preempted.

Michigan law regarding severance has nothing to do with the conflict between the Sixth Circuit and the Second Circuit. Rather, the circuits differed in their interpretation of the scope of preemption under *Buckman*, particularly whether—as the Second Circuit held—*Buckman* is narrowly limited to stand-alone fraud-on-the-FDA claims, or whether—as the Sixth Circuit recognized—the consequences of state law fraud-on-the-FDA determinations are the same irrespective of the formal procedural context in which state courts are required to make that determination.

Accordingly, resolution of the issues raised by the Petition is not dependent on whether the Second Circuit properly deferred to the Sixth Circuit's construction of Michigan law,[1] or whether the Sixth Circuit properly applied Michigan law to sever the preempted portion of the state statute. This Court is not being asked to rule on any Michigan state law issues.

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[1] Even the Second Circuit did not premise its interpretation of *Buckman* on the argument respondents make here. Rather, citing *Factors Etc., Inc. v. Pro Arts, Inc.*, 652 F.2d 278 (2d Cir. 1981), it accepted the Sixth Circuit's ruling on Michigan law regarding severance. App. 14a; *see MacGregor v. State Mut. Life Assurance Co. of Worcester, Mass.*, 315 U.S. 280, 281 (1942) (per curiam) (accepting interpretation of Michigan law by Sixth Circuit).

IV. The Second Circuit's Decision Below Squarely Conflicts with *Buckman*.

Respondents quote *Buckman* to the effect that "the existence of these federal enactments [relating to FDA regulation] is a critical element in their [plaintiffs'] case." Resp. Br. at 13 quoting *Buckman*, 531 U.S. at 352-53. The same is true of the Michigan statute at issue here. Respondents cannot proceed with their product liability claims involving the FDA-approved prescription drug Rezulin without proving under state law that there was fraud-on-the-FDA.

Contrary to respondents' assertion (Resp. Br. at 13-14), the Petition meaningfully challenges the three grounds on which the Second Circuit sought to distinguish *Buckman*. *See* Pet. at 19-26; *see also* PhRMA Br. at 3-11. First, the Second Circuit erred in applying a presumption against preemption. As *Buckman* explained, the presumption does not apply because policing fraud on a federal agency is not within the states' historical functions. *Buckman*, 531 U.S. at 347-48; Pet. at 19-20. Second, the decision below to limit *Buckman* to stand-alone claims based "solely" on fraud-on-the-FDA would provide an open door to avoiding the conflict preemption mandated by this Court, and lead to the adverse consequences described in *Buckman*. Pet. at 21-22. Third, by narrowly interpreting *Buckman* to apply only to affirmative claims in a complaint and not to state law requirements to determine fraud-on-the-FDA in other procedural contexts, the Second Circuit put form over substance and exposed the federal regulatory process to unacceptable interference in the ways that *Buckman* depicted. Pet. at 23-26.

In sum, the direct conflict between the Second and Sixth Circuit, which respondents have not challenged, should be resolved by a grant of certiorari. Otherwise,

the Second Circuit's holding will lead to the conflicts between state law and the FDA's regulatory process found by this Court in *Buckman*, which in turn will have serious and widespread consequences in other cases regarding other state statutes.

CONCLUSION

The petition for a writ of certiorari should be granted.

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