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 OF THE PRODUCT LIABILITY ADVISORY COUNCIL AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

HUGH F. YOUNG, JR.
PRODUCT LIABILITY ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, Va 20191
(703) 264-5300

ROBERT N. WEINER
Counsel of Record
ARNOLD & PORTER LLP
555 12th St. NW
Washington, DC 20004
(202) 942-5000

Counsel for Amicus Curiae
Product Liability Advisory Council

212605

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

QUESTION PRESENTED

Whether, under the implied preemption principles of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), federal law preempts state law to the extent it permits or requires a fact-finder to speculate as to whether a defendant improperly disclosed information to the federal agency that materially affected the agency's decision to approve or not withdraw the drug.

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INTEREST OF *AMICUS CURIAE*[1]

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association with more than 120 corporate members representing a broad cross-section of American and international manufacturers. These companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products. PLAC's perspective reflects the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred of the leading product liability defense attorneys in the country are sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed over 800 briefs as amicus curiae in both state and federal courts, including 70 in this Court, presenting the viewpoint of product manufacturers seeking fairness and balance in the application and development of the law.

PLAC has a significant interest in this case as the issue before the Court affects manufacturers in regulated industries, particularly pharmaceutical and medical device companies. Those effects, moreover, extend far beyond Michigan, for the question presented here regarding federal preemption may also be critical

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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. A list of the Corporate Members of the Product Liability Advisory Counsel is included in the Appendix at 1a.

in tens of thousands of cases before state and federal courts. PLAC is well situated to address this question. The organization has filed *amicus* briefs in significant preemption cases, including *Wyeth v. Levine*, No. 06-1249, 2007 WL 1186615 (U.S. April 20, 2007), *Buckman Co. v. Plaintiffs' Legal Comittee*, 531 U.S. 341 (2001), *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Furthermore, the members of PLAC engage in commerce in all 50 states and the District of Columbia. They have faced the cross-pressures generated by divergent federal and state regulatory standards and common law rules. They have endured crushing burdens of litigation and borne liability merely for following the instructions of federal regulators. They understand – indeed, they have experienced – the practical consequences of state efforts to regulate the relationship of industries with their federal regulators. PLAC therefore can provide valuable insights on the issue before the Court.

STATEMENT

Respondents are citizens of Michigan. They sued Petitioners Warner-Lambert and Pfizer (collectively "Warner-Lambert") for injuries allegedly attributable to Rezulin, a drug manufactured by Warner-Lambert and approved by FDA for treatment of diabetes. Michigan law imposes liability on a manufacturer for injuries allegedly caused by an FDA-approved drug only 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) (2007) (citations omitted). Thus, in order to recover damages, respondents needed to demonstrate that Warner-Lambert knowingly concealed material facts about the safety and efficacy of Rezulin from FDA, and that knowledge of those facts would have led FDA either not to approve the drug or to remove it from the market.

Warner-Lambert sought judgment on the pleadings because this inquiry into fraud on the FDA mandated under Michigan law invades the Agency's exclusive authority to police its relationship with regulated companies. In support of this position, Warner-Lambert relied on the Sixth Circuit's conclusion that, under *Buckman*, federal law preempts this inquiry. *See Garcia v. Wyeth-Ayerst Laboratories,* 385 F.3d 961, 965-966 (6th Cir. 2004). The district court agreed. It found that litigation regarding fraud on the FDA would interfere with the Agency's enforcement efforts. Appendix to Petition for Writ of Certiorari ("Pet. App.") 35a-36a. The Second Circuit reversed. *Id.* at 1a-28a. Rejecting *Garcia*, the court held that *Buckman* would apply – and the predicted burdens on FDA would occur – *only* where plaintiffs advanced a stand-alone cause of action for fraud on the Agency, not where the claim was "merely" an indispensable prerequisite to liability on another ground. *Id.* at 16a-23a.

SUMMARY OF THE ARGUMENT

The questions presented in this case reflect a deep division among the lower courts, crystallized in the conflict between the Courts of Appeals for the Second and Sixth Circuits, regarding the scope of preemption under *Buckman*. Specifically, the courts have disagreed on whether FDA's regulation of drugs and medical devices preempts state tort claims that depend upon proof of fraud on the FDA, or whether it preempts only stand-alone claims for such fraud. The Sixth Circuit in *Garcia* followed *Buckman* in ruling that the Michigan statute, in making fraud against the FDA a prerequisite to liability for injuries attributable to an FDA-approved product, "inevitably conflict[s] with the FDA's responsibility to police fraud." *Buckman*, 531 U.S. at 350; s*ee Garcia*, 385 F.3d at 966. The court therefore held the statute preempted except where FDA itself has previously found a violation of its disclosure requirements, thereby obviating any inquiry on the subject in a tort case. *Garcia*, 385 F.3d at 966. The Second Circuit, addressing the same Michigan statute, came to the opposite conclusion. Misconstruing *Buckman*, the court rejected preemption because plaintiffs' claims were not *solely* for fraud on the FDA. Pet. App. 16a-23a.

The impact of the Second Circuit's misreading of *Buckman* extends far beyond Michigan, and far beyond even the other seven states that similarly specify fraud on the FDA as a precondition of liability or punitive damages in cases involving prescription drugs. Indeed, adoption of the court of appeals' approach could unleash plaintiffs in tens of thousands of pending cases – not to mention future ones – to seek damages against drug and

medical device manufacturers based on their dealings with FDA, even where FDA itself is entirely satisfied with the manufacturers' candor. Inevitably, the proliferation of cases linking liability to the adequacy of companies' disclosures to FDA will upset the "somewhat delicate balance of statutory objectives" FDA has struck in deterring and punishing fraud against the Agency. *Buckman*, 531 U.S. at 348. State law, not federal regulations, will define companies' duties to FDA. The Court should not allow this wholesale displacement of federal regulatory authority.

ARGUMENT

I. The Court of Appeals' Formalistic Approach Nullifies the Key Inquiry as to Whether Claims for Fraud on the FDA Interfere with FDA Regulation

A. Preemption Turns on the Impact of Fraud on the FDA Claims

In *Buckman*, plaintiffs allegedly injured by a medical device sought damages from the manufacturer and a consultant that assisted in obtaining FDA approval to market the device. This Court addressed charges that the consultant had "made fraudulent representations to [FDA] in the course of obtaining [FDA] approval" and that "such representations were at least a 'but for' cause" of the plaintiffs' injuries. 531 U.S. at 343. At the outset of the opinion, the Court determined that no presumption against preemption applied. The Court reasoned that "policing fraud" against federal agencies was not traditionally the role of the states. *Id.* at 347. To the contrary, the Court found that "the 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." *Id.* Thus, the plaintiffs could not claim the benefit of any presumption.

Having addressed this procedural prologue, the Court concluded that allegations of fraud on the FDA or of violations of FDA disclosure requirements "conflict with, and are therefore impliedly preempted by, federal law." *Id.* at 348. In the Court's judgment, such claims can interfere with the Agency's determinations regarding the disclosures it wants, when it wants them, and which inducements and sanctions to apply to that end. Illustrating the scope and complexity of those determinations, the Court set forth FDA's intricate disclosure requirements applicable to medical devices, including the obligation of applicants to submit prospective labeling and advertisements, explanations and data regarding the similarities between a proposed device and existing devices, and any additional information FDA seeks. *Id.* at 348-49. The requirements applicable in this case to prescriptions drugs are just as rigorous, if not more so. Before prescription drugs can be marketed, the sponsor must submit an extensive New Drug Application, including "full reports of investigations" into the safety and efficacy of the drug. 21 U.S.C. § 355(b)(1)(A) (2000). The requirements regarding what must be included in the New Drug Application are voluminous, detailed, and complex, resulting in submissions often running into the hundreds of thousands of pages. *See* Richard A. Merrill, *Human Tissues and Reproductive Cloning: New Technologies Challenge FDA*, 3 Hous. J. Health L. & Pol'y 1, 4 (2002) (noting the types and volume of information that must

be submitted to gain approval of a New Drug Application). In addition, extensive and complex regulations, supplemented by published FDA guidances and draft guidances, govern the reporting of adverse drug events that occur once the drug is on the market. *See, e.g.*, 21 C.F.R. § 314.80 (2002); GUIDANCE FOR INDUSTRY, POSTMARKETING ADVERSE EXPERIENCE REPORTING FOR HUMAN DRUG AND LICENSED BIOLOGICAL PRODUCTS: CLARIFICATION OF WHAT TO REPORT, Aug. 1997, 1997 WL 33793759; GUIDELINE FOR INDUSTRY, CLINICAL SAFETY DATA MANAGEMENT: DEFINITIONS AND STANDARDS FOR EXPEDITED REPORTING, March 1995, 1995 WL 17210961; Draft GUIDANCE FOR INDUSTRY: PROVIDING REGULATORY SUBMISSIONS IN ELECTRONIC FORMAT – POSTMARKETING PERIODIC ADVERSE DRUG EXPERIENCE REPORTS, June 2003, 2003 WL 24014276; GUIDANCE FOR INDUSTRY, E2C CLINICAL SAFETY DATA MANAGEMENT: PERIODIC SAFETY UPDATE REPORTS FOR MARKETED DRUGS, May 1997, 1997 WL 33793832; GUIDANCE FOR INDUSTRY, GOOD PHARMACOVIGILANCE PRACTICE AND PHARMACOEPIDEMIOLOGIC ASSESSMENT, March 2005, 2005 WL 3628217.

To enforce these disclosure requirements, FDA has at its disposal provisions "aimed at detecting, deterring, and punishing false statements. . . ." *Buckman*, 531 U.S. at 349. FDA has authority to investigate suspected fraud, 21 U.S.C. § 372 (2000), and citizens may report wrongdoing and petition the Agency to act, 21 C.F.R. § 10.30 (2002). The remedies available to FDA at the time of *Buckman* included injunctive relief against fraud, 21 U.S.C. § 332 (2000), or seizure of the product, *id.* § 334. In addition, the Food, Drug, and Cosmetic Act ("FDCA") has long mandated that "failure to establish

or maintain any record, or make any report, required" by FDA regulations is subject to criminal prosecution, *id.* §§ 331(e), 333(a), as are false statements to the Agency, 18 U.S.C. § 1001 (2000). The statute, moreover, grants FDA authority *not* to use these tools, or to use less formal ones, as it seems fit. *See* 21 U.S.C. § 336 (FDA not required "to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever [FDA] believes that the public interest will be adequately served by a suitable written notice or warning."). In sum, as the Court found in *Buckman*, the "federal statutory scheme amply empowers the FDA to punish and deter fraud," and FDA uses "this authority . . . to achieve a somewhat delicate balance of statutory objectives. The balance sought by the [Agency] can be skewed by allowing fraud-on-the-FDA claims under state tort law."[2] 531 U.S. at 348.

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[2] FDA has long recognized the potential of product liability litigation to upset the post-marketing reporting scheme on which it relies so heavily. In considering proposed regulations on reporting, FDA expressed concern about the prospect that state product liability law could operate at cross-purposes with its reporting requirements. *See, e.g.*, Safety Reporting Requirements for Human Drug and Biological Products, 68 Fed. Reg. 12,405, 12,418 (proposed March 14, 2003) ("FDA is concerned that [product] liability misuse of [voluntary] reports could imperil the credibility and functionality of this critical public health reporting system."); Protecting the Identities of Reporters of Adverse Events and Patients; Preemption of Disclosure Rules, 59 Fed. Reg. 3,944 (proposed January 27, 1994) (codified at 21 C.F.R. § 20) (discussing FDA's proposed regulation to prohibit the disclosure of the identities of reporters of adverse events and patients in product liability and other litigation).

The Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 ("FDAAA"), is also relevant in determining whether the Second Circuit's approach will upset FDA's delicate balance of statutory objectives. FDAAA gives FDA additional tools to regulate prescription drugs – strengthening FDA's authority, allowing it greater flexibility, and mandating intensive consultation with regulated companies. As of March 25, 2008, FDA can require post-approval studies of prescription drugs and specify the timetable for the completion of those studies, *see* 21 U.S.C.A. § 355(o) (2007), demand labeling changes, *see id.*, require changes in the overall Risk Evaluation and Mitigation Strategy now required for many drugs, *see id.* § 355-1(g), and impose substantial civil penalties for failure to comply with these or other commands, *see id.* § 333(f). Moreover, the FDAAA bolsters the ability of citizens to have a role in the balancing of regulatory objectives, while recognizing that, within the broad confines of the Administrative Procedure Act, the decisions are solely FDA's. The Act deems a citizen petition to FDA to be denied and appealable if FDA fails to act on it within 180 days after filing. *See id.* § 355(q).

The FDAAA also imposed additional obligations on manufacturers to make disclosures to FDA – obligations that plaintiffs in cases like this one undoubtedly will seek to refashion, supplement, and enshrine in state law duties, enforced by lay juries. Companies must report the results of clinical trials, 42 U.S.C.A. § 282(j) (2007), submit adverse events occurring in those trials, *id.*, submit detailed information on the methodology, targeted population, and design of new trials, *id.*, provide periodic reports on post-marketing clinical trials,

21 U.S.C.A. § 355(o), and prepare periodic assessments of the company's risk evaluation and minimization strategy, *id.* § 355-1(d). A Michigan plaintiff thus could argue that her case can proceed because, for example, the defendant did not report clinical results as the new statute and implementing regulations require, or did not submit proper adverse event reports from those trials, or did not provide the requisite explanations of the methodology used, and so on. And, of course, the plaintiff would herald each dereliction as the tipping point, suppressing the critical piece of information that would have led FDA to withhold its approval of the drug.

Even before these elaborate new requirements, when explaining how state fraud on the FDA claims could overrun the careful regulatory lines FDA had drawn, the Court in *Buckman* worried 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 or the MDA." *Buckman*, 531 U.S. at 350. Companies, the Court predicted, will fear that "their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 351. That fear will fuel an "incentive to submit a deluge of information that the Administration neither wants nor needs."[3] *Id.* FDAAA has amplified the cause for concern.

[3] For example, in 1997, FDA stated that it did not wish to receive adverse event reports unless there was an identifiable patient and reporter, a suspect drug and an adverse event, "because reports without such information make interpretation of their significance difficult, at best, and impossible, in most

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B. The Court of Appeals Overemphasized the Procedural Format of Fraud on the FDA Claims

In reading *Buckman,* the Second Circuit appeared to fixate on this Court's observation that the plaintiffs there were not "relying on traditional state tort law which had predated the federal enactments in question," and that, to the contrary, "the existence of these federal enactments [was] a critical element in their case." *Id.* at 353. The court of appeals thus distinguished *Buckman* on the ground that it involved a *cause of action* specifically for fraud on the FDA, while in this case the Michigan statute "merely" incorporates the fraud charge as a prerequisite to traditional tort liability. *See* Pet. App. 18a ("M.C.L. § 2946(5) did not invent new causes of action premised on fraud against the FDA."). Even on its own terms, this distinction is illogical. Just as the fraud on the FDA claims in *Buckman* existed "*solely* by virtue of the FDCA disclosure requirements," Pet. App. 21a

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instances." ADVERSE DRUG REACTION REPORTING REGULATIONS WORKING GROUP, GUIDANCE FOR INDUSTRY, POSTMARKETING ADVERSE EXPERIENCE REPORTING FOR HUMAN DRUG AND LICENSED BIOLOGICAL PRODUCTS: CLARIFICATION OF WHAT TO REPORT, Aug.1997, 1997 WL 33793759. And FDA has discouraged reporting of adverse events derived from "planned contacts and active solicitation" unless they are "serious" or "unexpected." *Id.* at 3-4. Indeed, when proposing changes in the adverse event reporting system in 2003, FDA carefully calculated the additional staffing, down to the FTE, that expansion of the reporting requirements would entail. *See* Safety Reporting Requirements for Human Drug and Biological Products, *supra* n.2, 68 Fed. Reg. at 12456.

(quoting *Buckman*, 531 U.S. at 353), under the Michigan statute, claims against a manufacturer for injuries allegedly caused by an FDA-approved drug can exist *solely* by virtue of the FDCA disclosure requirements. In the words of the Michigan Supreme Court, "the Legislature has determined that a drug manufacturer or seller that has *properly* obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie." *Taylor v. SmithKlineBeecham, Inc.*, 658 N.W.2d 127, 131 (Mich. 2003). Thus, unless the manufacturer violated FDCA requirements, the plaintiff has no claim.

To avoid this common sense conclusion, the court of appeals posited that the cause of action here "cannot reasonably be characterized as a state's *attempt* to police fraud against the FDA." Pet. App. 18a (emphasis added). Rather, the court held, the "*object* of the legislative scheme was . . . to regulate and restrict when victims could continue to recover under preexisting state products liability law[,]" *id*. (emphasis added), and "the *goal* of preventing or punishing fraud against the FDA in [no] way *motivated* Michigan legislators," *id.* at 18a n.5 (emphasis added). Based on this assessment of legislative intent, the court of appeals concluded that *Buckman* was inapplicable and the presumption against preemption, controlling. *Id.* at 27a-28a.

This distinction, however, misgauges the focus of *Buckman.* There is no hint in *Buckman* or in the long line of precedent on conflict preemption that preemption – through application of a presumption or otherwise – turns on a state's intent to regulate. Nor does the question whether 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 (1941), depend on whether the state intended it to do so. To hold otherwise would mean that states can override and obstruct federal law so long as they are merely negligent in doing so. In other words, while insisting that Congress would not "cavalierly" override state law, *Medtronic, Inc. v. Lohr*, 518 U.S. at 483, the court of appeals would encourage states to be cavalier in obstructing federal law. If intent were the litmus test for preemption, *Buckman* would have been a dead letter from the day it was written. This Court instead adopted a functional approach. As in prior preemption cases, it focused on the effects of state law rather than the intent behind it. *See, e.g., Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363 (2000) (Massachusetts law restricting State purchases from companies doing business with Burma preempted because it obstructed accomplishment of Congress' objectives under Foreign Operations, Export Financing, and Related Programs Appropriations Act); *Geier v. American Honda Co.*, 529 U.S. 861 (2000) (state tort law preempted because it obstructed accomplishment of objectives of the Department of Transportation under the National Traffic and Motor Vehicle Safety Act of 1966); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64-65 (2002) (state tort law not implicitly preempted by the Federal Boat Safety Act of 1971 where they served "the Act's more prominent objective" rather than obstructing its operation).

Moreover, to the extent that analysis of preemption should consider the "traditional" reach of tort claims, which was so critical to the court of appeals' approach, an embedded prerequisite of fraud on the FDA in a

traditional cause of action, as in this case, is no more rooted in common law doctrine than the stand-alone claim in *Buckman.* In discussing the traditional objects of tort law, the Court's point in *Buckman* was that liability there did not hinge, as is traditionally the case, on the defendant's communications with the plaintiffs, their doctors or the public, but rather on the defendant's communications with FDA. The point was relevant because, whatever authority the state may have to regulate the relationship between pharmaceutical companies *and the public* – itself an important question before this and other courts – the state cannot regulate the relationship between pharmaceutical companies *and FDA*. *Buckman*, 531 U.S. at 350. The distinction is crucial in this case. The issue here is not whether a plaintiff could allege negligence *per se* under state law based on the violation of an FDA rule regarding product labeling. Although such a claim could well be preempted, particularly if it conflicted with FDA's reading of the requirements, at least liability under state law would turn on an FDA rule governing communications with physicians, not communications with the Agency. In this case, liability under the Michigan statute hinges on Warner-Lambert's communications and relationship with FDA, allowing state law to define a manufacturer's duties to FDA. That is precisely what *Buckman* barred.

Furthermore, in shifting the focus from the impact of state law to the motivation behind it, and from practical consequences to procedural formality, the court of appeals shortchanged this Court's concern – which should be heightened with the enactment of FDAAA – that the burden of satisfying discordant common law duties and FDA requirements would lead applicants to

inundate the Agency with unwanted and unhelpful information. *Buckman*,. 531 U.S. at 351. To be sure, the court of appeals did touch on this concern. Pet. App. 24a-26a. The court inferred that pharmaceutical companies would continue to have incentives to flood FDA with unwelcome disclosures so long as fact-finders in tort cases can consider evidence of fraud against the Agency and react to that evidence in assessing liability and punitive damages. *Id.* at 24a-25a. Therefore, permitting plaintiffs to prove fraud on the FDA when rebutting a statutory defense to liability would not, in the court's uncorroborated judgment, amplify those incentives. *Id.* Only stand-alone claims of fraud against the FDA would markedly increase the incentives. *Id.* In other words, the court surmised that because "anything goes" short of a cause of action for fraud on the FDA, only the incremental impact of such a cause of action for fraud could have constitutional significance.

This approach is legally unfounded, factually unsupported, and logically circular. The legal flaw underlying this derisory estimate of the impact of litigating fraud on the FDA in Michigan was the court's failure to appreciate that the Michigan statute requires such proof in every case. The factual error in the court's rationale was its reliance on the type of *faux* empiricism that this Court rejected in *Geier v. American Honda, Inc.*, 529 U.S. 861 (2000). The petitioners in *Geier* asked the Court "to calculate the precise size of the 'obstacle,' with the aim of minimizing it, by considering the risk of tort liability and a successful tort action's incentive-related or timing-related compliance effects." *Id.* at 882. The Court declined the invitation because, among other things, the calculations, as here, "rest[ed] on

speculation" and were "unpersuasive." *Id.* at 882-83. And the court's logical fallacy was in assuming the conclusion that virtually any litigation of fraud on the FDA short of a stand-alone cause of action was constitutionally permissible, such that making fraud on the FDA a prerequisite to liability could contribute only marginally to any regulatory overload. Pet. App. 24a-26a. The issue of what claims are permissible short of a stand-alone cause of action for fraud on the FDA was a key question presented for judicial decision. Assuming the answer to that question was circular.

The assumption, moreover, was not consistent with *Buckman.* The Court there did not license all claims, other than a stand-alone cause of action, that depend upon fraud on the FDA. Rather, the Court held that where "the existence of these federal enactments [FDA disclosure requirements]" is a "critical element" in the plaintiffs' case, the plaintiffs' claims are preempted. *Buckman*, 531 U.S. at 353. A federal enactment can be a "critical element" in the plaintiffs' case without being the exclusive tenant in its own cause of action. This Court has recognized as much in cases finding federal jurisdiction where an issue of federal law is lodged within a state claim. In *Grable & Sons Metal Prods., Inc. v. DARUE Engineering & Mfg.*, 545 U.S. 308, 314 (2005), the Court applied a practical, functional test for determining if such a claim arises under federal law – whether the "state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any

congressionally approved balance of federal and state judicial responsibilities." Here, plaintiffs' claim clearly raises a federal issue, and considering it would indeed disturb the congressionally approved balance of federal and state responsibilities under the FDCA, by obstructing FDA's enforcement scheme.

The Second Circuit's cramped focus on pleading to avoid the standard clearly articulated in *Buckman* invested the procedural context of that case with far more significance than this Court intended, and far more significance than makes good sense. *Buckman* addressed a cause of action for fraud on the FDA because that was the claim against the petitioner – who was a consultant, not a manufacturer.[4] Nevertheless, in discussing the potential impact of claims of fraud on the FDA, this Court explicitly addressed "applicants," that is the manufacturers who apply for FDA approval of their products. They – unlike consulting companies – not only get sued for fraud on the FDA, but also routinely face claims of negligence, strict liability, fraud, and breach of warranty. *See Buckman*, 531 U.S. at 350; *see, e.g.*, Restatement (Third) of Torts: Product Liability § 6 (1997) (discussing liability for design and manufacturing

[4] That *Buckman* involved a consultant, rather than a manufacturer, was happenstance. The original trial court order held that identical fraud on the FDA claims against medical device manufacturers were preempted. *In re Orthopedic Bone Screw Products Liability Litigation*, MDL-1064, 1997 WL 305257, at *3 (E.D. Pa. March 28, 1997), *rev'd*, 159 F.3d 817 (3d Cir. 1998), *rev'd*, 531 U.S. 341 (2001). Because plaintiffs asserted no other cause of action against the consultant, they obtained an order under Fed. R. Civ. P. 54(b) permitting an interlocutory appeal against her, but not against the manufacturers.

defects); William A. Drier, *Liability for Drug Advertising, Warnings, and Frauds*, 58 Rutgers L. Rev. 615, 636 (2006) (noting that manufacturers also often face claims for violations of state consumer fraud statutes and other laws).

Thus, under the reasoning of the court below, in a multi-count complaint against a manufacturer, if a plaintiff alleges fraud on the FDA in a separate count, the claim would pose the threat that concerned this Court, skewing the "delicate balance of [FDA's] statutory objectives," *Buckman*, 531 U.S. at 348, and thus would be preempted. But if the plaintiff embedded precisely the same allegations in the other counts for negligence or strict liability, they would not have the same effect and hence would not be preempted. Form is thus more important than substance. As this Court said many years ago in dismissing a comparably flawed argument, "[t]o state the proposition is to refute it." *Howard v. Illinois Cent. R.R. Co.*, 207 U.S. 463, 502 (1908).

In short, the Sixth Circuit was correct in *Garcia* when it recognized that tort liability predicated on "state *court findings* of fraud on the FDA," will "raise the same inter-branch-meddling concerns that animated *Buckman*." 385 F.3d at 966. Those concerns arise regardless of the procedural vehicle for those findings.

II. Allowing Fraud on the FDA Claims Could Allow Plaintiffs to Circumvent Virtually Any Preemption Claim

If the Second Circuit's decision were allowed to stand, sophisticated counsel could negate express or implied preemption in almost every case simply by alleging that the Agency action on which the defendant relies was procured by fraud. With regard to express preemption, for example, *Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006), *cert. granted*, (U.S. Jun. 25, 2007) (No. 06-179), would be essentially moot. This Court granted review in *Riegel* to decide whether the Medical Device Amendments expressly preempt tort claims involving medical devices subject to premarket approval ("PMA") if the suits seek to impose requirements different from or in addition to those dictated by FDA. *Id.* But under the Second Circuit's reasoning, Plaintiffs could simply claim that, in securing approval of the PMA or a PMA Supplement, the manufacturer concealed the truth from FDA. That would allow a case to go forward and would render the express preemption provision in the Medical Device Amendments virtually inoperative. The ruling in *In re Medtronic, Inc. Implantable Defibrillators Litigation,* 465 F. Supp. 2d 886 (D. Minn. 2006), highlights the problem. The MDL court there, addressing the same issue presented in *Riegel*, rejected express preemption based largely on the plaintiffs' evidence, "which *if believed*, tends to show that [Medtronic] withheld critical information from the FDA while seeking the PMA Supplement approval for its newly-designed battery." *Id.* at 895 (emphasis added). Because the plaintiffs there raised a disputed issue of fact, the court denied summary judgment. Presumably,

had Medtronic moved earlier to dismiss on the pleadings, the court would have denied that motion as well based entirely on the allegations in the complaint. The court's rationale, which paralleled that of the court of appeals here, would make fraud on the FDA a reliable detour around the MDA's express preemption provision.

Indeed, blazing such a facile path around the express preemption provision would effectively nullify *Buckman* itself. If PMA-approved devices are subject to express preemption, a claim of fraud on the FDA would become an essential prerequisite to liability in virtually every product liability case involving such a device. Compared to the rare circumstance of a stand-alone fraud on the FDA claim against a non-manufacturer at issue in *Buckman*, such a result would engender a far greater level of interference with the Agency than the Court found problematic in that case.

Moreover, on this approach, plaintiffs in pharmaceutical litigation could potentially circumvent preemption even where FDA expressly ordered a manufacturer to do or say exactly what plaintiffs challenge, or forbade the manufacturer from saying or doing what the plaintiffs demand. *Dowhal v. SmithKline Beecham Consumer Healthcare, Inc.*, 88 P.3d 1 (Cal. 2004), though it involved an over-the-counter product, illustrates the type of problems that would arise. In that case, an individual plaintiff claimed that a drug manufacturer had a duty under California law to label its nicotine patch with warnings that FDA had specifically considered and rejected as scientifically unsubstantiated. The California Supreme Court found that federal law preempted the claim. *Id.* at 3. If the

Second Circuit's position prevailed, however, the individual plaintiff in such a case, like thousands of plaintiffs in cases pending in state and federal courts now, would likely include in her complaint allegations that the manufacturer concealed required information from FDA. On the court of appeals' reasoning, those allegations would likely survive dismissal and perhaps summary judgment. The burdens of defending such a case are substantial, the efforts of manufacturers to avoid them could well have the impact that *Buckman* feared, undercutting FDA's regulatory efforts.

In sum, the Second Circuit's logic allows virtually any collateral attack under state law on FDA determinations – even where the fraud on the FDA allegations are a "critical element" of the plaintiffs' case, even where, as in *Grable,* the plaintiffs' claim requires resolution of this federal issue – so long as the attack is encapsulated in a cause of action labeled as something other than a stand-alone fraud on the FDA claim. On the court of appeals' standard, *Buckman* would wither in the face of procedural machinations. Indeed, the court of appeals' ruling would resurrect form pleading, where using (or avoiding) the right "magic words" potentially would dictate whether state law standards can govern a company's relationship with FDA. As this Court predicted in *Buckman,* the multitude of fraud on the FDA claims, in assorted procedural packaging, would disrupt the Agency's "measured approach" to enforcement and precipitate a flood of unsolicited information to FDA, interfering with the Agency's congressionally mandated responsibilities. This is exactly the result the Court in *Buckman* sought to avoid.

CONCLUSION

The court of appeals elevated formalism above common sense. Its misreading of *Buckman* allows state law claims to intrude on an exclusively federal domain, so long as they are dressed right for the occasion. In so doing, the court of appeals' ruling threatens to disrupt FDA's careful balance of regulatory objectives. This Court should reverse that ruling.

Respectfully submitted,

HUGH F. YOUNG, JR.
PRODUCT LIABILITY ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, Va 20191
(703) 264-5300

ROBERT N. WEINER
Counsel of Record
ARNOLD & PORTER LLP
555 12th St. NW
Washington, DC 20004
(202) 942-5000

Counsel for Amicus Curiae
Product Liability Advisory Council

APPENDIX

APPENDIX — CORPORATE MEMBERS OF THE PRODUCT LIABILITY ADVISORY COUNCIL AS OF 11/5/2007

3M
A.O. Smith Corporation
Altec Industries
Altria Corporate Services, Inc.
American Suzuki Motor Corporation
Andersen Corporation
Anheuser-Busch Companies
Appleton Papers, Inc.
Arai Helmet, Ltd.
Astec Industries
BASF Corporation
Bayer Corporation
Bell Sports
Beretta U.S.A Corp.
BIC Corporation
Biro Manufacturing Company, Inc.
Black & Decker (U.S.) Inc.
BMW of North America, LLC
Boeing Company
Bombardier Recreational Products
BP America Inc.
Bridgestone Americas Holding, Inc.
Briggs & Stratton Corporation
Brown-Forman Corporation
CARQUEST Corporation
Caterpillar Inc.
Chevron Corporation
Chrysler LLC
Continental Tire North America, Inc.
Cooper Tire and Rubber Company

Appendix

Coors Brewing Company
Crown Equipment Corporation
The Dow Chemical Company
E & J Gallo Winery
E.I. DuPont De Nemours and Company
Eaton Corporation
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, Inc.
Estee Lauder Companies
Exxon Mobil Corporation
Ford Motor Company
Freightliner LLC
Genentech, Inc.
General Electric Company
General Motors Corporation
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Harley-Davidson Motor Company
The Heil Company
Honda North America, Inc.
Hyundai Motor America
Illinois Tool Works, Inc.
International Truck and Engine Corporation
Isuzu Motors America, Inc.
Jarden Corporation
Johnson & Johnson
Johnson Controls, Inc.
Joy Global Inc., Joy Mining Machinery
Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.

Appendix

Koch Industries
Kolcraft Enterprises, Inc.
Komatsu America Corp.
Kraft Foods North America, Inc.
Lincoln Electric Company
Lyondell Petrochemical Company
Magna International Inc.
Mazda (North America), Inc.
Medtronic, Inc.
Merck & Co., Inc.
Michelin North America, Inc.
Microsoft Corporation
Mine Safety Appliances Company
Mitsubishi Motors North America, Inc.
Nintendo of America, Inc.
Niro Inc.
Nissan North America, Inc.
Nokia Inc.
Novartis Consumer Health, Inc.
Novartis Pharmaceuticals Corporation
Occidental Petroleum Corporation
PACCAR Inc.
Panasonic
Pfizer Inc.
Porsche Cars North America, Inc.
PPG Industries, Inc.
Purdue Pharma L.P.
Putsch GmbH & Co. KG
The Raymond Corporation
Raytheon Aircraft Company
Remington Arms Company, Inc.
Rheem Manufacturing

RJ Reynolds Tobacco Company
Sanofi-Aventis
Schindler Elevator Corporation
SCM Group USA Inc.
Shell Oil Company
The Sherwin-Williams Company
Smith & Nephew, Inc.
St. Jude Medical, Inc.
Sturm, Ruger & Company, Inc.
Subaru of America, Inc.
Synthes (U.S.A.)
Terex Corporation
Textron, Inc.
TK Holdings Inc.
The Toro Company
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
TRW Automotive
UST (U.S. Tobacco)
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Watts Water Technologies, Inc.
Whirlpool Corporation
Wyeth
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.