No. 06-1498

In the Supreme Court of the United States

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

v.

KIMBERLY KENT, ET AL.

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONERS

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QUESTION PRESENTED

Michigan law generally provides that a drug manufacturer is not liable in tort if the federal Food and Drug Administration (FDA) approved the drug, unless the manufacturer "[i]ntentionally withh[eld] from or misrepresent[ed] 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under the federal food, drug, and cosmetic act * * * and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted."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 Ann. § 600.2946(5). The question is:

Whether federal law preempts state law to the extent that it requires a court to determine whether a drug manufacturer committed fraud on FDA and whether FDA would have denied or withdrawn approval of a drug but for that fraud.

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INTEREST OF THE UNITED STATES

This case presents the question whether state law is preempted to the extent it requires a court to determine, as a prerequisite to the award of tort damages, whether a drug manufacturer committed fraud on the Food and Drug Administration (FDA). Resolution of that question will affect FDA's drug approval process and response to fraud on the agency.

STATEMENT

1. Under the Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. 301 *et seq.*, a drug manufacturer may not market a new drug unless it has submitted a new drug application to FDA and received the agency's approval. 21 U.S.C. 355(a). An application

must include extensive information about the composition, manufacture, and specification of the drug, any studies of the drug's pharmacological actions and toxicological effects in animals, any studies of the drug's bioavailability and pharmacokinetics in humans, any clinical investigations of the drug, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source." 21 C.F.R. 314.50(d); see 21 U.S.C. 355(b)(1). FDA maintains guidance documents on the format and content of applications to assist applicants in their preparation. 21 C.F.R. 314.50.

The applicant may meet with FDA for the purpose of "reaching agreement" on the design and size of clinical trials intended to form the primary basis of an effectiveness claim, 21 U.S.C. 355(b)(5)(B), and to discuss the presentation of supporting information, 21 C.F.R. 314.50(f)(4). Regulations also provide for a conference approximately 90 days after the application is filed and another conference at the conclusion of FDA's review. 21 C.F.R. 314.102(c) and (d). Those conferences provide an opportunity to resolve disagreements over scientific and medical matters, and meetings may be scheduled at other times to resolve disputes. 21 C.F.R. 314.102(e). There may also be communications by telephone and letter. All conversations, letters, and meetings "shall be appropriately documented" in FDA's files. 21 C.F.R. 10.65(e) and (f), 314.102(a).

FDA will approve a new drug application if it determines that the drug meets statutory standards for safety and effectiveness, manufacturing, and labeling. 21 C.F.R. 314.105(c). The regulations state that, while the same statutory standards apply to all drugs, the

wide range of drugs and the variety of their uses "demand flexibility in applying the standards." *Ibid.* Thus, FDA "is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." *Ibid.*

After a drug has been approved and marketed, the manufacturer must investigate and report to FDA any adverse events associated with use of the drug in humans, 21 C.F.R. 314.80, and must periodically submit any new information that may affect FDA's previous conclusions about the safety or effectiveness of the drug, 21 C.F.R. 314.81. FDA may withdraw approval of a drug if it finds, among other things, that the drug is unsafe or ineffective. 21 U.S.C. 355(e).

Federal law generally prohibits persons from making false or fraudulent statements of material fact to federal agencies. 18 U.S.C. 1001(a). In addition, the FDCA specifically provides for the withdrawal of approval of a drug if FDA finds that "the application contains any untrue statement of material fact," 21 U.S.C. 355(e); 21 C.F.R. 314.150(a)(2)(iv), and includes failing to submit required post-market information to FDA among its enumerated prohibited acts, 21 U.S.C. 331(e). The FDCA was recently amended specifically to prohibit the submission of false or misleading clinical trial information. 21 U.S.C. 331(jj)(3); see 42 U.S.C. 282(j)(5)(D).

The FDCA authorizes FDA to investigate violations of the Act, 21 U.S.C. 372, and to pursue a wide range of sanctions for any fraud it uncovers. The agency may withdraw approval of the drug, 21 U.S.C. 355(e), seek injunctive relief in certain circumstances, 21 U.S.C. 332, seize the drug if it is adulterated or misbranded, 21 U.S.C. 334, or pursue criminal prosecution of the manu-

facturer, 21 U.S.C. 333(a); 18 U.S.C. 1001, 1341. As recently amended, the FDCA also gives FDA authority to seek civil monetary penalties for submission of false or misleading clinical trial information. 21 U.S.C. 333(f)(3)(A).

FDA has instituted an administrative policy regarding appropriate measures for responding to false or misleading statements in drug applications. 56 Fed. Reg. 46,191, 46,199-46,200 (1991); see FDA, *Compliance Policy Guide* § 120.100 (1991) <http://www.fda.gov/ora/compliance_ref/cpg/cpggenl/cpg120-100.html>. FDA has also established a general process for citizens to petition FDA to take administrative action, 21 C.F.R. 10.30, which may be invoked by any person who believes a manufacturer has defrauded FDA. There is, however, no private right of action to enforce the FDCA. See *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 352 (2001). The United States has exclusive authority to enforce the Act's provisions, subject only to a limited exception for some actions by States (but not private parties). 21 U.S.C. 337(a).

2. Respondents are Michigan residents who were allegedly injured by Rezulin, a drug marketed by petitioners for the treatment of diabetes. Pet. App. 6a, 30a. FDA approved Rezulin in 1997. Petitioners withdrew it from the market three years later at FDA's request because of adverse side effects in patients taking the drug, see *id.* at 6a-7a, and FDA later withdrew its approval of the drug, 68 Fed. Reg. 1469 (2002).

Respondents filed suit alleging a variety of common-law torts, including breach of express and implied warranties, negligent misrepresentation, defective design, and defective manufacturing. Pet. App. 7a. Michigan law provides:

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

Mich. Comp. Laws Ann. § 600.2946(5). That provision does not apply if:

> [T]he defendant at any time before the event that allegedly caused the injury * * * [i]ntentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted under the [FDCA], and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted.

Ibid. Respondents allege that petitioners knowingly concealed material facts from FDA about the safety and efficacy of Rezulin—including post-approval adverse event reports of liver and heart damage and deaths associated with the drug—which would have prevented approval of Rezulin by FDA or resulted in its earlier removal from the market. Pet. App. 337a, 344a-345a, 353a-354a; J.A. 36, 43. FDA has not made such a determination.

3. The district court dismissed the complaints. Pet. App. 29a-38a. "The question," explained the court, "is whether the plaintiffs, assuming they have adequately pled fraud on the FDA, should be afforded an opportunity to try to prove it." *Id.* at 32a. The court answered that question in the negative because it understood this

Court's decision in *Buckman* to hold that "there can be no recovery on a theory of fraud on the FDA." *Id.* at 33a. The court also deferred to the Sixth Circuit's determination in *Garcia* v. *Wyeth-Ayerst Laboratories*, 385 F.3d 961 (2004), that the fraud-on-the-FDA exception is severable from the remainder of Section 600.2946(5). Pet. App. 33a-34a. Thus, the court concluded, FDA's approval of Rezulin triggered the bar to liability in Section 600.2946(5). *Id.* at 33a-34a, 36a.

4. The court of appeals reversed. Pet. App. 1a-28a. It acknowledged that *Buckman* "held that state 'fraud-on-the-FDA' claims were impliedly preempted by federal law." *Id.* at 4a (quoting *Buckman*, 531 U.S. at 348). But the court concluded that "three differences" between the Michigan statute and the state law in *Buckman* compelled a different result in this case. *Id.* at 18a. First, the court held that a presumption against preemption applies in this case, unlike in *Buckman*, because the "object" of the Michigan statute as a whole is to limit traditional tort liability, not to police fraud on the FDA. *Id.* at 18a-19a. Second, the court reasoned that, while the *Buckman* plaintiffs sought to recover based solely on a showing of fraud on the FDA, respondents assert "traditional" common-law tort duties under which liability is not based solely on fraud on the FDA. *Id.* at 20a-22a. Third, the court stated that, under the Michigan statute but not the state law in *Buckman*, fraud on the FDA is a "defense" rather than an "element" of a plaintiff's cause of action. *Id.* at 24a.

SUMMARY OF ARGUMENT

Michigan law is preempted to the extent it requires courts to determine whether a manufacturer defrauded

FDA and whether FDA would have denied or withdrawn approval of a drug but for the fraud.

A. In *Buckman*, this Court held that a state-law fraud-on-the-FDA claim conflicted with federal law and was therefore preempted. The Court explained that the relationship between a federal agency and the entities it regulates is inherently federal, and that state-law fraud-on-the-FDA claims would give applicants an incentive "to submit a deluge of information that the Administration neither needs nor wants, resulting in additional burdens on the FDA's evaluation of an application." 531 U.S. at 351. Because individual drugs differ, the information FDA wants and needs to review a particular drug varies from case to case, based on FDA's exercise of its expert judgment. Moreover, when FDA concludes that it has been defrauded, it has discretion under the FDCA to pursue those remedies that, in its judgment, best fit a violation. Permitting lay juries to second-guess the adequacy of a manufacturer's submission to FDA, and to impose damages (including punitive damages) based on their appraisal of any fraud, would interfere with FDA's exercise of its expert judgment.

B. Justice Stevens concurred in the result in *Buckman* because FDA had not determined "both that fraud ha[d] occurred and that such fraud require[d] the removal of a product from the market." 531 U.S. at 354. That rationale applies here because, as a predicate for imposing liability, the Michigan statute requires that FDA would have denied or withdrawn approval but for the fraud. Speculation by fact-finders about what FDA would have done in hypothetical circumstances invades the province of the agency. Moreover, a legal standard that turned on such speculation would inevitably lead parties to request burdensome and intrusive discovery

from FDA concerning its approval of a drug, and thereby divert the agency from its core public health mission.

C. The court of appeals attempted to distinguish *Buckman* by asserting that it involved a novel claim alleging only fraud on FDA, whereas this case involves a "traditional" tort. Pet. App. 19a. The Michigan statute is not "traditional," however, to the extent that, at bottom, it requires a determination of fraud on a federal agency. That inquiry is problematic whether it occurs as part of a stand-alone tort or in determining the applicability of an exception to a limitation. The state statute's requirement that a plaintiff prove the violation of a traditional tort duty *as well as* fraud on FDA does nothing to diminish the conflicts discussed above. Rather, it means only that those *other* aspects of the state-law claim may not give rise to preemption; it does not reduce the conflict, found in *Buckman*, between federal law and state-law determinations of fraud on FDA.

ARGUMENT

THE MICHIGAN STATUTE IS PREEMPTED UNDER *BUCKMAN* BECAUSE IT REQUIRES A FINDING OF FRAUD ON THE FDA AS A PREREQUISITE TO LIABILITY

Federal law preempts state laws that conflict with federal law, including those state laws that "stand[] 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). This Court held in *Buckman* that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law." 531 U.S. at 348. The Michigan statute at issue here is preempted because, just like the fraud-on-the-FDA claims in *Buckman*, it makes liability turn on

whether the defendant withheld information from or made misrepresentations to FDA and whether FDA would have approved or withdrawn its approval of the product if accurate information had been submitted.

A. *Buckman* Bars Fraud-On-The-FDA Claims

The plaintiffs in *Buckman* alleged that the defendant had made false representations to FDA in the course of obtaining pre-market clearance under Section 510(k) of the FDCA, 21 U.S.C. 360(k), to market a medical device that was substantially equivalent to a predicate device already on the market. 531 U.S. at 343, 345-346; see *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 478-480, 492-494 (1996) (describing Section 510(k) pre-market clearance process). The plaintiffs sought damages under state tort law, seeking to establish the elements of common-law fraud by showing that false statements were made to FDA, that FDA relied on those statements in approving the product, and that the false statements caused plaintiffs injury because FDA would not have approved the device (and it therefore would not have been on the market and injured them) in the absence of the statements. See *Buckman*, 531 U.S. at 343, 345-346; *In re Orthopedic Bone Screw Prods. Liability Litig.*, 159 F.3d 817, 826-829 (3d Cir. 1998) (*Orthopedic Litig.*) (discussing Restatement (Second) of Torts § 310, at 103 (1965)), rev'd *sub nom. Buckman*, *supra*.

The Court first noted that "[p]olicing 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." *Buckman*, 531 U.S. at 347 (internal quotation marks and citation omitted). "To the contrary, the relationship between a federal agency and the entity it regu-

lates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Ibid.* Accordingly, any presumption against preemption was inapplicable. *Id.* at 347-348.

"Given this analytical framework," the Court held that the fraud-on-the-FDA claims conflicted with federal law and were therefore preempted. *Buckman*, 531 U.S. at 348. That conflict stemmed from the fact that the federal statutory scheme empowers FDA to punish and deter fraud against it, and FDA uses that authority to achieve a "somewhat delicate balance of statutory objectives" that could be skewed by allowing state-law fraud-on-the-FDA claims. *Ibid.* The Court pointed out that the Act and FDA's implementing regulations impose on applicants various requirements to disclose information to FDA, and at the same time give FDA various tools to detect, deter, and punish false statements made during the approval process—including investigatory powers, a citizen complaint process, criminal prosecutions, injunctive relief, and civil penalties. *Id.* at 348-349; see pp. 3-4, *supra* (discussing FDA's enforcement authorities with respect to drugs). The Court also noted that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with the Act's provisions. *Id.* at 349 n.4; see 21 U.S.C. 337(a).

The Court explained that the "variety of enforcement options" available exclusively to FDA affords it "flexibility" to make a measured response to suspected fraud against the agency in order to pursue difficult and sometimes competing objectives. *Buckman*, 531 U.S. at 349-350. In the Court's view, state-law fraud-on-the-FDA claims would "inevitably conflict" with FDA's responsi-

bility to "police fraud" consistently with its judgment and objectives. *Id.* at 350. Thus, for example, the prospect of fraud-on-the-FDA claims could deter would-be applicants from seeking approval by FDA of beneficial products because disclosure requirements in the approval process could expose them to liability under state law if the disclosures were found to be incomplete. To allow such claims also would cause applicants to fear that their disclosures to FDA would later be judged insufficient by a state court, which would create an incentive to submit much additional information that FDA neither needs nor wants, thereby burdening FDA and delaying the availability of the product. *Id.* at 350-351.

The Court noted that the fraud-on-the-FDA claims were not based on traditional state tort law principles concerning violation of a duty of care owed by the manufacturer to the plaintiffs, such as an alleged failure to use reasonable care in manufacturing the product. Instead, "the fraud claims exist[ed] solely by virtue of the FDCA disclosure requirements," and "the existence of these federal enactments is a critical element of [plaintiffs'] case." *Buckman*, 531 U.S. at 352-353. The Court concluded that this sort of litigation "would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme." *Id.* at 353.

B. Section 600.2946(5)(a) Is Preempted Under *Buckman*

Although the court of appeals pointed to differences between this case and *Buckman*, see Pet. App. 18a-24a, none of those differences is material. Michigan law explicitly makes liability turn on the very same determination that *Buckman* held to be preempted as a predicate to liability under state law. That inquiry exerts the

same "extraneous pull" here as in *Buckman* (531 U.S. at 353) and is equally preempted.[1]

The court of appeals perceived a material difference between the traditional state tort claims at issue here and the fraud-on-the-FDA claims at issue in *Buckman*. Pet. App. 19a-23a. But the claims in *Buckman* were also, at bottom, common-law tort claims, for fraud. See *Orthopedic Litig.*, 159 F.3d at 826-828. What was novel in *Buckman* was not the common-law nature of the underlying tort, but the plaintiffs' suggestion that they could recover in the absence of any duty between the plaintiffs and defendants if they could show fraud on the FDA. This Court found that theory of recovery preempted by federal law because premising liability on proof of fraud on the FDA impermissibly skewed the federal scheme. The decision proceeds on the assumption that, absent preemption, the conduct would violate a state common-law prohibition on fraud. This case, of course, involves not a plaintiff's novel effort to make out a common-law fraud action, but a statute that specifies that liability turns on proving fraud on the FDA.

Under Mich. Comp. Laws Ann. § 600.2946(5), in a product liability action against the manufacturer or seller of a drug, the drug is deemed not to be defective or unreasonably dangerous, and the manufacturer or seller is not liable, "if the drug was approved for safety and efficacy by [FDA], and the drug and its labeling

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[1] The questions presented in the petition ask only whether state law is preempted to the extent it requires a determination of fraud on FDA. See Pet. (i). The petition does not present the question whether or when FDA's approval of a drug impliedly preempts traditional state tort claims, and this brief expresses no view on that question. That question is presented in *Wyeth* v. *Levine*, petition for cert. pending, No. 06-1249 (filed Mar. 12, 2007).

were in compliance with [FDA's] approval at the time the drug left the control of the manufacturer or seller."[2] Section 600.2946(5) then specifies an exception that applies if the defendant, at any time before the event allegedly causing the injury, "[i]ntentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted under the [FDCA], and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws. Ann. § 600.2946(5)(a). That provision requires a court entertaining a state-law tort suit to make the same determination that was required and found preempted in *Buckman*. Indeed, the only differences between the inquiry here and in *Buckman* are that here (i) the inquiry is specified by statute, rather than representing an innovative plaintiff's theory of how to prove a common-law claim, and (ii) the inquiry arises not as a stand-alone sufficient basis for recovery, but as a limit on an immunity from liability. The first difference only strengthens the case for preemption, and the second is not material—the inquiry exerts an "extraneous pull" on the federal scheme no matter how it arises.

To be sure, States generally have authority to carve out exceptions from state-law tort duties, as well as limi-

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[2] While that provision specifies both a state-law rule of decision (that the drug is not defective or unreasonably dangerous) and an immunity from liability by reference to actions of FDA under the FDCA, it is not preempted. Just as it is common and often unproblematic for state law to borrow federal law for a standard of care, see, *e.g., Medtronic*, 518 U.S. at 490; a State's decision to borrow federal law as a rule of decision or immunity, *vel non*, does not create a preemption issue (although there could be circumstances where such a state-law immunity provision would frustrate the objects of a federal scheme and therefore be preempted).

tations on those exceptions. But contrary to the court of appeals' belief (see Pet. App. 18a-19a), it does not follow that the substantive terms on which Michigan has chosen to carve out such an exception are automatically entitled to a presumption against preemption. In particular, that presumption "is not triggered when the State regulates in an area where there has been a history of significant federal presence," *United States* v. *Locke*, 529 U.S. 89, 108 (2000), or "where the interests at stake are 'uniquely federal' in nature," *Buckman*, 531 U.S. at 347 (quoting *Boyle* v. *United Techs. Corp.*, 487 U.S. 500, 504-505 (1988)). Because "the relationship between a federal agency and the entity it regulates is inherently federal," *Buckman* held that "no presumption against pre-emption obtain[ed] in th[at] case." *Id.* at 347, 348.

The court of appeals sought to distinguish *Buckman*'s rejection of a presumption against preemption on the ground that Michigan is seeking to "regulat[e] matters of health and safety." Pet. App. 19a (quoting *Buckman*, 531 U.S. at 348). But again, the question here is not whether traditional tort claims are preempted; it is whether the portion of the Michigan statute that requires a finding of fraud on FDA is preempted. Under *Buckman*, the presumption against preemption has no application to that non-traditional feature of the statute, just as it had no application to the non-traditional means of proving fraud at issue in *Buckman*. 531 U.S. at 347; see, *e.g.*, *Nathan Kimmel, Inc.* v. *DowElanco*, 275 F.3d 1199, 1205 (9th Cir. 2002).

The court of appeals may have assumed that the presumption against preemption must apply to a cause of action as a whole, as opposed to one aspect of the case, but there is no basis for that assumption. In *Boyle*, for example, this Court held that the presumption against

preemption did not apply to the question of under what circumstances government contractors have a "defense" to state tort suits. 487 U.S. at 504. There, as here, the state tort as a whole related to health and safety, but the presumption against preemption did not apply to a specific issue implicating uniquely federal interests.

As we demonstrate at greater length below, "[g]iven this analytical framework," *Buckman*, 531 U.S. at 348, Section 600.2946(5)(a) is preempted, just as the fraud-on-the-FDA claims in *Buckman* were preempted.

1. The Michigan statute is preempted because it requires courts and juries, as a predicate to awarding damages, to determine whether an applicant defrauded FDA

a. In *Buckman*, this Court explained that "the relationship between a federal agency and the entity it regulates is inherently federal in character," and "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration." 531 U.S. at 347, 348. While *Buckman* involved a medical device, as opposed to a drug, there is no meaningful distinction between drugs and devices in this respect.

As explained above, there is a general prohibition against making false statements to federal agencies. 18 U.S.C. 1001. In addition, the FDCA authorizes FDA to withdraw approval of a drug because of fraud, 21 U.S.C. 355(e), and expressly labels as prohibited conduct the failure to comply with post-approval reporting requirements regarding new safety or efficacy information, 21 U.S.C. 331(e). FDA has authority to investigate suspected fraud by a manufacturer seeking drug approval, 21 U.S.C. 372, and to pursue a wide range of sanctions for any fraud it uncovers, including withdrawal of approval, 21 U.S.C. 355(e), injunctive relief, 21 U.S.C. 332,

seizure, 21 U.S.C. 334, civil monetary penalties, 21 U.S.C. 333(f)(3)(A), and criminal prosecution, 21 U.S.C. 333(a); 18 U.S.C. 1001, 1341. "FDA thus has at its disposal a variety of enforcement options." *Buckman*, 531 U.S. at 349 (footnote omitted).

FDA uses its authority "to punish and deter fraud against the Administration, and * * * to achieve a somewhat delicate balance of statutory objectives," and this "balance * * * can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Buckman*, 531 U.S. at 348. For example, *Buckman* observed that the prospect of fraud-on-the-FDA claims could deter manufacturers from even submitting products for approval because the federal requirements for disclosure to FDA could expose them to state tort liability. *Id.* at 350-351. Also, "fraud-on-the-FDA claims 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. Applicants would then have an incentive to submit information that FDA neither wants nor needs, resulting in additional burdens on FDA's evaluation of an application and delays in the approval process and the introduction of the product into the market. *Ibid.*

Of course, Michigan law also requires proof of violations of traditional state-law tort duties owed by a manufacturer to a user of the product that exist independently of the federal regulatory scheme. Issues concerning fraud on FDA—and what FDA would have done if accurate information had been submitted—arise in connection with an immunity from traditional liability that the State has elected to afford. But the conflict is the same as with the stand-alone fraud-on-the-FDA claims in *Buckman*, because in both instances damages may be

awarded only if a court finds that information was withheld or misrepresented to FDA and that FDA would have disapproved the product or withdrawn it sooner if it had received accurate information. See pp. 27-29, *infra*.[3]

b. Section 600.2946(5)(a) also threatens to upset the balance struck by the FDCA and implementing regulations in affording FDA broad discretion to oversee the application process and respond to misrepresentations or omissions of information. The regulations set forth detailed requirements concerning the information manufacturers must submit to the agency, both during the approval process and after a drug has been marketed. See 21 C.F.R. 314.50, 314.80, 314.81; pp. 1-3, *supra*. Those regulations seek to clarify the requirements for manufacturers while relieving the agency of the burden of evaluating unnecessary information.

Because individual drugs differ, the information FDA needs in order to review a particular drug will vary from case to case. Cf. *Merck KGaA* v. *Integra Lifescis. I, Ltd.*, 545 U.S. 193, 207 (2005) (discussing "the uncertainties that exist with respect to * * * what research

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[3] In *Buckman*, the Court focused on the adverse impact that fraud-on-the-FDA claims could have on the Section 510(k) pre-market clearance process for medical devices, which is designed to be comparatively streamlined and speedy. See 531 U.S. at 348-351. This case involves the submission of new drug applications, which entails a far more comprehensive review than under Section 510(k). The preemption question under *Buckman* should be answered as a general matter, however, and should not turn on the procedures that are applicable to the particular product under the FDCA. The basic point of *Buckman*—that FDA is charged with striking a balance between keeping unsafe products off the market and making efficacious products available to patients and doctors that should not be skewed by state law—applies to all of FDA's approval processes under the FDCA.

to include in" a new drug application). FDA "is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." 21 C.F.R. 314.105(c). Because of the complexity of the analysis, an applicant may request a meeting with FDA for the purpose of "reaching agreement" on the design and size of the drug's clinical trials, 21 U.S.C. 355(b)(5)(B), and to discuss the presentation of information, 21 C.F.R. 314.50(f)(4). FDA "usually communicates often with sponsors about scientific, medical, and procedural issues that arise during the review process. Communications may take the form of telephone conversations, letters, faxes or meetings." FDA, *The CDER Handbook* 24 (1998) <http://www.fda.gov/cder/handbook/handbook.pdf>. Permitting lay juries to second-guess the adequacy of a manufacturer's submissions of information to FDA in that ongoing process would interfere with FDA's expert judgment on what information it wants and needs.

Moreover, in situations where FDA concludes that omissions or misrepresentations occurred, the FDCA gives FDA "complete discretion" to pursue those remedies that, in the agency's judgment, best fit a violation and the overall purposes of the Act. *Heckler* v. *Chaney*, 470 U.S. 821, 835 (1985). Notwithstanding fraud, FDA may decide that a drug's health benefits counsel against removing it from the market or imposing a severe administrative penalty, and that other sanctions are more appropriate. Awards of damages (including punitive damages) based on state-law determinations of fraud on

the FDA would interfere with FDA's determination of the appropriate remedy.[4]

In these respects, Section 600.2946(a)(5) "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Davidowitz*, 312 U.S. at 67, in conferring authority and discretion on FDA to tailor the application process and choose the appropriate remedies for violations of disclosure requirements. Cf. *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 372-374 (2000).

If a State established its own administrative agency to monitor whether regulated entities were withholding or misrepresenting information to FDA, and to impose monetary remedies upon a finding that FDA would have acted differently if accurate information had been submitted, the conflict between that state law and the federal interests would be manifest. As *Buckman* reflects, there likewise is a conflict when monetary remedies are imposed in state-law tort litigation on that basis.

2. The Michigan statute is preempted because it requires courts to determine whether FDA would have denied or withdrawn approval if it had received accurate information

a. There is an additional reason why the Michigan statute is preempted. As the *Buckman* concurrence

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[4] Some state statutes condition the availability of *punitive* damages on a finding that information was withheld from or misrepresented to FDA. See Pet. Br. 11-12 & n.6. Conditioning the availability of punitive damages on that basis would have a particularly acute impact on FDA's oversight of the approval process and selection of remedies for misrepresentation. Cf. *Credit Suisse Sec. (USA) LLC* v. *Billing*, 127 S. Ct. 2383, 2396 (2007) (noting that threat of treble damages would make it impossible for the agency to police fine distinctions between forbidden conduct and closely related conduct that was affirmatively encouraged).

explained, "an essential link in the chain of causation that [a plaintiff] must prove in order to prevail is that, but for [defendant's] fraud, the allegedly defective [product] would not have reached the market." 531 U.S. at 353 (Stevens, J., concurring in the judgment). In the absence of a determination by FDA "both that fraud has occurred and that such fraud requires the removal of a product from the market," plaintiffs could not "establish a necessary element of their claim." *Id.* at 353 n.1, 354. Without such action by FDA, the state law would require a difficult inquiry into "a counterfactual situation" and "second-guessing [of] the FDA's decisionmaking" by state courts and juries. *Id.* at 354.

This Court has long accorded preemptive effect to a federal administrative decision that has neither been rescinded by the agency nor set aside by a federal court in accordance with the procedures for review established by Congress. In *Arkansas Louisiana Gas Co.* v. *Hall*, 453 U.S. 571, 578-579 (1981) (*Arkla*), for example, this Court held that a state contract action was preempted by the Federal Power Commission's (FPC's) approval of a filed rate different from the one provided by contract. Although the state supreme court had determined that the FPC would have approved the higher rate as reasonable had the circumstances of the case been brought to its attention, this Court held that "the Commission alone is empowered to make that judgment, and until it has done so, no rate other than the one on file may be charged." *Id.* at 581. By awarding damages based on a determination of what the FPC *might* have done, the state court "usurped a function that Congress has assigned to a federal regulatory body." *Id.* at 582;

see *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 326 (1981).[5]

Like the state law in *Buckman*, the Michigan statute requires a determination that "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 Ann. § 600.2946(5)(a). FDA has never made such a determination. To be sure, three years after FDA approved the application for Rezulin, it asked petitioners to take the drug off the market, and FDA later withdrew its approval for safety-related reasons. See Pet. App. 6a-7a; 68 Fed. Reg. 1469 (2002). FDA did not, however, rely on a finding of fraud in doing so. See 68 Fed. Reg. at 1469. Indeed, when FDA withdraws approval of a drug, it normally does so for reasons other than fraud, including, as with Rezulin, that newly available information revealed that the drug was not as safe or effective as the agency previously thought. See 21 U.S.C. 355(e). Therefore, federal law precludes a state rule—whether as an element of a claim or of a defense—that turns on whether FDA would have denied approval or withdrawn it sooner if it had received accurate information.

b. As the *Buckman* concurrence suggests, and the district court stressed, a contrary result would not only entail intrusive "second-guessing [of] the FDA's decisionmaking," it would also "overburden[] its personnel." 531 U.S. at 354; see Pet. App. 35a-36a; see also U.S. Amicus Br. at 28-30, *Buckman*, *supra*. Parties would

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[5] The *Arkla* Court "save[d] for another day the question whether the filed rate doctrine applies in the face of fraudulent conduct." 453 U.S. at 583 n.13. The *Buckman* concurrence took the next step by recognizing that only the federal agency can determine whether it was defrauded. See 531 U.S. at 353-354 & n.1.

likely seek discovery from FDA concerning whether a manufacturer misrepresented or withheld information that it was required to submit to FDA, as well as discovery concerning the agency's internal deliberations, including agency officials' states of mind and the courses of action they might have taken under various hypothetical scenarios. The United States' position is that employees of the federal government are immune from third-party subpoenas issued in private litigation, that testimony must be sought under an agency's Touhy regulations, see generally *United States ex rel. Touhy* v. *Ragen*, 340 U.S. 462 (1951), and that an agency's denial of a request for testimony by agency employees is subject to review only in federal court and only under the arbitrary or capricious standard of the Administrative Procedure Act (APA), 5 U.S.C. 706(2)(A). The lower federal courts, however, have taken divergent views on issues concerning third-party subpoenas when issued by a federal court to federal employees. Compare, *e.g.*, *Comsat Corp.* v. *National Sci. Found.*, 190 F.3d 269, 277-278 (4th Cir. 1999) (applying APA standard), with *Exxon Shipping Co.* v. *United States Dep't of Interior*, 34 F.3d 774, 778-780 (9th Cir. 1994) (holding that agency is protected only by court's discretion to limit discovery under Federal Rules of Civil Procedure 26 and 45).

Nor would the undesirable consequences abate if the courts ultimately accepted the government's position on when its officials can be required to testify. Parties would still be free to challenge any refusal to testify under the APA. In one recent products liability class action, *Walson* v. *Merck & Co.*, No. 3:04-cv-00027-GPM-DGW (S.D. Ill.), FDA devoted approximately 1,300 employee hours to producing approximately 40,000 pages of documents in response to a third-party subpoena.

Private litigation such as this would divert FDA's resources and create a substantial potential for distorting its mission.

c. While an FDA decision finding fraud and withdrawing its approval of the product would overcome preemption under the rationale of the *Buckman* concurrence, a rule that made preemption turn on the presence or absence of a decision by FDA could create its own potential for interference with the federal scheme. See 12/4/2000 Oral Arg. Tr. 20-21, 23-25, *Buckman*, *supra* (argument of the United States).[6]

The federal government alone has responsibility to determine the appropriate remedy under the FDCA when it approved a product and later learned of misrepresentations that might have led it not to approve the product. See pp. 18-19, *supra*. The addition of potential damages liability in an uncertain amount under state law to the consequences ensuing from FDA's own remedy under the FDCA would skew FDA's exercise of its discretion under the FDCA. Cf. *Credit Suisse Sec. (USA) LLC* v. *Billing*, 127 S. Ct. 2383, 2396 (2007). In addition, if FDA were the gatekeeper for private tort liability, it could anticipate numerous petitions filed by prospective tort plaintiffs urging the agency to make a finding of fraud. The disposition of such petitions might prove every bit as burdensome for the agency as state-court litigation concerning whether FDA was defrauded. Par-

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[6] We note that, in a preamble to a recent rule, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3936 (2006), FDA provided examples of state-law claims that in its view are preempted under current doctrine by its approval of a drug, including some claims for failure to warn "unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning."

ties would presumably seek extensive information from FDA, pursuant to the agency's Touhy regulations and the Freedom of Information Act, 5 U.S.C. 552, to support or defend against such an assertion. And it could be difficult for FDA to respond to numerous such petitions within the 180-day regulatory timeframe. See 21 C.F.R. 10.30(e)(2).

While FDA takes suggestions of fraudulent representations very seriously, it does not have a process for considering allegations or making explicit findings of fraud in the abstract. Citizen petitions must seek specific types of administrative action, such as withdrawal of a drug's approval, not merely a finding of fraud. See 21 C.F.R. 10.30(b). And even if FDA chose to grant such a petition, it would not necessarily premise the withdrawal on a formal finding of fraud. When FDA suspects fraud, it often reaches a settlement with the applicant in which the applicant pays a fine or takes corrective action (such as changes in labeling) without admitting liability. Thus, FDA does not presently have a system to process routine requests to make findings of fraud in service of private litigation, and any expectation that it do so "would exert an extraneous pull" on FDA, *Buckman*, 531 U.S. at 353, and divert its resources away from its core public health mission.[7]

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[7] When necessary and appropriate, the government has secured formal relief, including criminal convictions, against drug or device manufacturers who defrauded the agency. See, *e.g.*, FDA, *Enforcement Story* (last modified Aug. 7, 2003) <http://www.fda.gov/ora/about/enf_story/archive/2001/ch6/default.htm> (corporate officers sentenced to 15 months of imprisonment for fraudulent submission to FDA); John Henkel, *Investigators' Reports*, FDA Consumer, Nov.-Dec. 1997, at 38 (drug company criminally convicted for, among other things, submitting false statements to FDA in annual reports for approved drugs).

3. FDA's position that the Michigan statute conflicts with federal law is entitled to deference

Any lingering doubt should be resolved by deference to FDA's expert judgment. Congress delegated to FDA authority to administer the process of approving drugs for marketing, monitoring the safety and effectiveness of drugs after they have been marketed, deciding whether to withdraw approval, and determining whether the agency was defrauded and, if so, what remedies to impose. See pp. 1-4, *supra*. As this Court explained in *Medtronic*, FDA's role in administering the drug-approval process makes it "uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" 518 U.S. at 496 (quoting *Davidowitz*, 312 U.S. at 67); see *Geier* v. *American Honda Motor Co., Inc.*, 529 U.S. 861, 883 (2000).

C. The Court Of Appeals' Grounds For Distinguishing This Case From *Buckman* Are Without Merit

The court of appeals sought to distinguish *Buckman* on the ground that it involved a novel claim alleging only fraud on the FDA, whereas, the court of appeals asserted, this case involves a "traditional" tort to which fraud on the FDA is relevant to a defense. Pet. App. 19a-24a. None of the asserted distinctions embedded in the court's description detracts from the fact that the Michigan statute makes liability turn on the very determination that *Buckman* bars.

1. The court of appeals reasoned that respondents' claims are "premised on traditional [tort] duties," not "a newly-concocted duty between a manufacturer and a federal agency." Pet. App. 20a. But there is no material difference between the claims here and in *Buckman*.

Respondents allege claims that *sound* traditional, such as negligence, defective design, and breach of warranty. See *id.* at 7a. But although the fraud-on-the-FDA claim in *Buckman* sounded novel, at bottom, it was a plaintiff's innovative effort to make out a common-law fraud action (against a defendant other than a manufacturer). And, of course, preemption resulted not from the novelty of the claim, but from the fact that liability turned on an inquiry that frustrated the federal scheme. Michigan law is no different.

Under the Michigan statute, "a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable," if, among other things, FDA approved the drug and was not defrauded into doing so. Mich. Comp. Laws Ann. § 600.2946(5). That is not a "traditional" law, and more to the point it calls for the same problematic inquiry that was at issue in *Buckman*. Genuinely traditional tort suits are not preempted under *Buckman* because they do not require a determination that a federal agency was defrauded. But Section 600.2946(5) is preempted precisely because it requires such a finding as a predicate for liability.

Thus, the question is not whether a claim relies on a traditional-*sounding* duty, but whether the particular suit interferes with a federal prerogative. See, *e.g.*, *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225, 231 (1964) ("Just as a State cannot encroach upon the federal patent laws directly, it cannot, under some other law, such as that forbidding unfair competition, give protection of a kind that clashes with the objectives of the federal patent laws."); see also *American Airlines, Inc.* v. *Wolens*, 513 U.S. 219, 227-228 (1995) (state fraud claims); *Arkla*, 453 U.S. at 573, 580-582 (breach-of-con-

tract action); *Kalo Brick*, 450 U.S. at 323-324, 326-327 (negligence claim).

2. The court of appeals also emphasized that "proof of fraud against the FDA [wa]s *alone sufficient* to impose liability" in *Buckman*, whereas here, a plaintiff must prove more, such as negligence. Pet. App. 20a-21a. The court of appeals also expressed the view that respondents' traditional tort claims "cannot reasonably be characterized as a state's attempt to police fraud against the FDA." *Id.* at 18a. But it is the Michigan statute, not traditional tort claims, that is the proper focus of the preemption inquiry, just as *Buckman* focused on the novel fraud-on-the-FDA theory, rather than a common-law fraud action in the abstract.

In *Buckman,* the Court characterized the claims as "[p]olicing fraud" on the FDA, 531 U.S. at 347, in "inevitabl[e] conflict" with "FDA's responsibility to police fraud" itself, *id.* at 350. The FDCA "leaves no doubt that it is the Federal government rather than private litigants who are authorized to file suit for noncompliance," *id.* at 349 n.4, and allowing private damage actions based solely on violations of the FDCA would conflict with Congress's decision not to provide a private right of action under the FDCA, see *Merrell Dow*, 478 U.S. at 810, 812. While respondents' tort claims, in the abstract, may not be directed at "policing fraud" against FDA, the overlay of Section 600.2946(5)(a) on those tort claims results in the same impermissible intrusion into FDA's oversight of the approval process and its exercise of enforcement discretion as the specific claims in *Buckman*.

Moreover, a plaintiff's need to prove something *in addition to* fraud on the FDA, such as negligence—as well as causation, injury, and damages, which the

Buckman plaintiffs also had to prove—does nothing to eliminate the conflict that results from a state-law requirement that a court make the determination that *Buckman* prohibits as a predicate for liability.[8] Although "[i]n some cases * * * [an] entire body of state law * * * conflicts and is replaced by federal rules," "[i]n others, the conflict is more narrow, and only particular elements of state law are superseded." *Boyle*, 487 U.S. at 508. In *Boyle*, for example, plaintiffs brought a state tort suit for defective design and repair of a Marine helicopter that had crashed, killing the servicemen inside. *Id.* at 502. This Court did not hold that the state tort claims were preempted in their entirety, but instead held that state law was preempted on the specific question of under what circumstances government contractors are immune from state tort liability. *Id.* at 512.

Similarly, in *Arkla*, the state court determined both that the federal commission would have approved a different rate *and* that the plaintiff was entitled to that rate under state contract law. 453 U.S. at 573-575. In that circumstance as in this one, proving an additional element (breach of contract) did not eliminate the conflict. See *Howard* v. *Lyons*, 360 U.S. 593, 597 (1959) (state tort claim subject to specific federal privilege defense). And, of course, in *Buckman*, the Court did not invalidate any aspect of the common law of fraud beyond invalidating the plaintiffs' fraud-on-the-FDA theory.

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[8] Indeed, there may be substantial overlap between the common-law duty and the inquiry into whether FDA would have denied or withdrawn approval but for the fraud. Products liability claims typically require a showing that a product is unreasonably dangerous, see, *e.g.*, *Crews* v. *General Motors Corp.*, 253 N.W.2d 617, 619 (Mich. 1977), and FDA's decision to approve a drug likewise turns in large part on whether the drug is safe, 21 U.S.C. 355(d).

And the problem in *Buckman* was that the plaintiffs' theory required them to prove fraud on the FDA, *not* the happenstance that plaintiffs' theory required them to prove little else.

Consistent with these principles, other courts of appeals have recognized that *Buckman* is not limited to circumstances where liability is premised *solely* on fraud on a federal agency. See, *e.g.*, *Garcia* v. *Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004) (Section 600.2946(5)(a) preempted); *Kimmel*, 275 F.3d at 1206 (preemption because fraud on federal agency was a "critical element of [plaintiff's] state-law case").[9]

3. The court of appeals "presum[ed]" that, "in most states in the country," evidence of fraud on a regulatory agency is "permitted but not conclusive." Pet. App. 25a. Further presuming that federal law does not preempt the introduction of evidence of fraud on FDA in such circumstances, the court reasoned that "the incentive to supply additional data to FDA under the Michigan law before us is no greater than the incentive that exists whenever evidence of what a company submitted, or failed to submit, to the FDA is admissible and probative of liability." *Ibid.* Thus, the court of appeals concluded, the Michigan statute does not conflict with federal law. *Ibid.*

That analysis is flawed. At the outset, it assumes that juries generally consider evidence of fraud on fed-

[9] If the exception to immunity is not severable under state law, Section 600.2946(5) is invalid as a whole, and petitioner has no state-law immunity based on FDA's approval of the drug. The United States takes no position on that state-law question because severability analysis is not relevant to the federal preemption question presented here, and the court of appeals did not reach it. Cf. *Garcia*, 385 F.3d at 966-967 (holding that the fraud-on-the-FDA provision is severable from the remainder of Section 600.2946(5)). Cf. p. 12 n.1, *supra*.

eral agencies. It is true that, under the Restatement (Third) of Torts: Products Liability § 4(b) (1998) (Restatement), a jury may consider evidence of "a product's compliance with an applicable product safety statute or administrative regulation" as part of a broader inquiry into whether a product is defective, but that such evidence is entitled to "little or no weight" if "the deliberative process that led to the safety standard with which the defendant's product complies was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that promulgated the standard or certified or approved the product." *Id.* § 4 cmt. e.

In practice, however, relatively few reported cases have involved evidence of fraud on an agency under the Restatement approach (and the court of appeals cited none). And the Restatement emphasizes that "questions of federal preemption are beyond [its] scope." Restatement § 4 cmt. e. At a minimum, there is less incentive to deluge FDA with information in light of the Restatement than in light of the decision below because the question of fraud on the FDA is not dispositive under the Restatement. The conflict with federal law also is not as sharp because the Restatement approach does not require a finding of fraud or that the federal agency would have disapproved the product in the absence of fraud. But regardless of how preemption and related issues might play out in *that* context, there is clearly preemption where, as here and in *Buckman*, findings that FDA was defrauded and that FDA would have disapproved or withdrawn its approval of a product in the absence of fraud are legally mandated predicates for recovery.

4. The court of appeals also found it relevant that fraud on the FDA is not an "element" of respondents' claims, but instead rebuts a defendant's reliance on the "affirmative defense" of FDA approval. Pet. App. 23a-24a. That distinction, too, is immaterial.

At the outset, it is not clear that fraud on the FDA is only relevant to an affirmative defense. Section 600.2946(5)(a) states that "a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable," if, among other things, FDA approved the drug and was not misled. The defective or unreasonably dangerous nature of a product is ordinarily an element of a products liability claim. See, *e.g.*, *Crews* v. *General Motors Corp.*, 253 N.W.2d 617, 619 (Mich. 1977). And respondents' complaints affirmatively allege fraud on the FDA. Pet. App. 337a, 344a, 354a; J.A. 33, 36, 43. The court of appeals relied on the Michigan Supreme Court's description of the statute as providing an "absolute *defense*." Pet. App. 23a (quoting *Taylor* v. *Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (2003)). But *Taylor* did not fully consider whether Section 600.2946(5) is relevant to a plaintiff's prima facie case or an affirmative defense—or whether the plaintiff bears the burden of proof on the exception once the defendant invokes the general rule of non-liability—because the issue there was whether the statute is constitutional. See *Taylor*, 658 N.W.2d at 137.

In any event, there is no reason why a state-law label would matter for conflict preemption purposes. All that matters is that the state statute requires a determination of fraud on FDA as a predicate to liability, and therefore conflicts with federal law under *Buckman*. Whatever label Michigan might place on the inquiry, "courts would have to engage in the [same] intrusive

inquiry which * * * is forbidden." *Michael* v. *Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir.), cert. denied, 516 U.S. 815 (1995). Any "attempt to reexamine the FDA's approval under state law standards, however pleaded, is pre-empted." *Ibid.*

The court of appeals appears to have been influenced by the fact that Section 600.2946(5), as a whole, benefits drug manufacturers by providing a defense to an otherwise traditional tort claim. See Pet. App. 18a-19a. While that question may have some relevance to the state-law severability question that is not before the Court, see p. 29 n.9, *supra*, it does not affect the reality that liability ultimately turns on the fraud-on-the-FDA inquiry and that inquiry is preempted under *Buckman*. Depending on the answer to the severability question, the finding of preemption may ultimately help the plaintiffs or the defendants. But the preemption inquiry does not turn on whether the law is "pro-defendant." In *Mackey* v. *Lanier Collection Agency & Service, Inc.*, 486 U.S. 825, 830 (1988), the Court held that the Employee Retirement Income Security Act of 1974, 29 U.S.C. 1001 *et seq.*, preempted a state statute that singled out federal benefit plans for *favorable* treatment because "[l]egislative 'good intentions' do not save a state law" that intrudes on the federal sphere. Preemption does not exist to help particular parties; it exists to protect the federal sphere from interference by the States.

CONCLUSION

The judgment of the court of appeals should be reversed.

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