UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

August Term, 2005

(Argued: November 8, 2005 Decided: October 5, 2006
Amended: January 18, 2007)

Docket Nos. 05-1705-cv(L), 05-1743-cv(CON), 05-1745-cv(CON)

CAESAR DESIANO ET AL.,

Plaintiffs-Appellants,

– v.–

WARNER–LAMBERT & CO., ET AL,

Defendants-Appellees.

Before: FEINBERG, CALABRESI, and B.D. PARKER, *Circuit Judges*.

Appeal from grant of judgment on the pleadings in favor of Defendants-Appellees. The United States District Court for the Southern District of New York (Kaplan, J.) held that Michigan law shields pharmaceutical companies from products liability claims unless there is, *inter alia*, evidence that the drug company misrepresented or withheld material information in obtaining FDA approval for its drug. The court concluded that Michigan plaintiffs' claims could not be distinguished from the "fraud-on-the-FDA" claim found to be preempted by federal law in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). We disagree. A presumption against federal preemption of state law applies in the context of traditional common law claims preserved by states to protect the health and safety of their citizens. Moreover, a fraud-based exception to Michigan's immunity statute does not raise the same concerns that animated the Supreme Court's decision in *Buckman*. Vacated and remanded.

DAVID B. RODES, Goldberg, Persky & White, P.C.,

Pittsburg, PA (Vincent J. Carter, Girardi Keese, Los Angeles, CA; David R. Parker, Charfoos & Christensen, PC, Detroit, MI; Jerome D. Goldberg, Varjabedian Attorneys, Southfield, MI, *on the brief*), *for Plaintiffs-Appellants*.

DAVID KLINGSBERG, Kaye Scholer LLP (Wendy S. Dowse, *on the brief*), New York, NY, *for Defendants-Respondents*.

CALABRESI, *Circuit Judge*:

It has long fallen within the province of states to safeguard the health and safety of their citizens. *See Medtronic v. Lohr*, 518 U.S. 470, 475 (1996). Consonant with the "historic primacy of state regulation" of these matters, *see Medtronic*, 518 U.S. at 485, the power of states to govern in this field is considerable and undisputed. *See Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) ("The States traditionally have had great latitude under their police powers to legislate as 'to the protection of the lives, limbs, health, comfort, and quiet of all persons.'" (quoting *Slaughter-House Cases*, 16 Wall. 36, 62, 21 L.Ed. 394 (1873); *Thorpe v. Rutland & Burlington R. Co.*, 27 Vt. 140, 149 (1855)). Historically, common law liability has formed the bedrock of state regulation, and common law tort claims have been described as "a critical component of the States' traditional ability to protect the health and safety of their citizens." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 544 (1992) (Blackmun, J., concurring in part and dissenting in part). In recent years, some states, in exercising their traditional authority with respect to the pharmaceutical industry, have narrowed common law liability in order to insulate drug companies from burdensome litigation. *See generally* David G. Owen, *Special Defenses in Modern Products Liability Law*, 70 MO. L. REV. 1, 22-23 (2005). The case before us concerns a supposed conflict between federal law and the products liability regime of one such state.

In 1995, the State of Michigan enacted legislation immunizing drugmakers from products liability claims so long as the Food and Drug Administration ("FDA") approved the pharmaceutical product at issue. *See* Mich. Comp. Laws § 600.2946(5) (hereinafter "M.C.L. § 2946(5)"). Michigan's immunity scheme contains an exception that preserves liability if the pharmaceutical company withheld or misrepresented information that would have altered the FDA's decision to approve the drug. In 2001, in a case dealing with different legal rules and a different jurisdiction, the Supreme Court held that state "fraud-on-the-FDA" claims were impliedly preempted by federal law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). The question presented by this appeal is whether, under the rationale of *Buckman*, federal law also preempts traditional common law claims that survive a state's legislative narrowing of common law liability through a fraud exception to that statutory limitation. For the reasons below, we conclude that federal law does not preempt these state claims. We therefore vacate the District Court's grant of judgment on the pleadings and remand the case for further proceedings consistent with this opinion.

BACKGROUND

A. Michigan's Immunity Statute

Prior to its amendment in 1995, Michigan's products liability statute provided that "evidence showing compliance with governmental or industry standards was admissible in a products liability action in determining if the standard of care had been met." *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 130 (Mich. 2003). In describing the pre-amendment law, the Supreme Court of Michigan emphasized the limits on the probative value of this sort of evidence of compliance:

> We note that our Legislature has recently enacted a statute which provides that industrial and governmental standards are admissible in products liability actions [citing earlier version of M.C.L. § 600.2946]. The statute does not provide that such standards are conclusive. [We affirm the position] that compliance with

> governmental and industrial standards is admissible as evidence but is not conclusive as to whether the defendant was negligent or the product was defective.

Owens v. Allis-Chalmers Corp., 326 N.W.2d 372, 375-76 (Mich. 1982).

In 1995, Michigan's legislature amended the law in order to confer immunity upon drugmakers in product liability suits where the FDA had approved the drug in question. *See Taylor*, 658 N.W.2d at 130 ("The 1995 amendment of the statute . . . provided that compliance with federal governmental standards (established by the FDA) is conclusive on the issue of due care for drugs."). The relevant provision states:

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

M.C.L. § 2946(5). In addition to several qualifications not relevant to the case before us,[1] the immunity provision contains an important exception:

> This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
>
> (a) Intentionally withholds from or misrepresents to the United States food and drug administration 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 United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

[1] Michigan's law also states that the immunity "subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval." M.C.L. § 2946(5). And the immunity "does not apply if the defendant at any time before the event that allegedly caused the injury… [m]akes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug." M.C.L. § 2946(5)(b).

M.C.L. § 2946(5)(a) (internal citations omitted). Hence, under these provisions, so long as a drug company did not withhold or misrepresent information that would have affected the FDA's approval of a putatively harmful drug, the company can successfully defend itself against products liability litigation by establishing that its product received the FDA's approval and complied with the FDA's labeling and substantive requirements.

B. Procedural History

Appellants in this case are all Michigan residents alleging injuries caused by Rezulin, a drug marketed and sold by Appellees for the treatment of Type-2 diabetes. The FDA originally approved Rezulin in 1997. After adverse liver-related effects were documented in patients taking Rezulin, Appellees agreed to a series of label changes, which were authorized by the FDA on four occasions between November 1997 and June 1999. In March 2000, apparently at the FDA's request, *see Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 344 (2d Cir. 2003), Appellees withdrew Rezulin from the United States market.

The instant litigation began in state courts in Michigan and California. Appellants asserted various common law claims including, *inter alia*, breach of implied and express warranties, negligence, negligent misrepresentation, negligence *per se*, fraud, defective design, defective manufacturing, and loss of consortium. The drug companies removed the actions to federal court, and all of the claims were subsequently consolidated and transferred by the Judicial Panel on Multidistrict Litigation to Judge Lewis A. Kaplan in the Southern District of New York.

In the District Court, Appellees moved for judgment on the pleadings on the ground that liability was foreclosed under Michigan state law. To support their motion, Appellees emphasized *Buckman* and the Sixth Circuit's decision in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir.

2004), which held (on the basis of *Buckman*) that the "fraud" exception in Michigan's statute was impliedly preempted by two federal laws — the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, and the Medical Device Act ("MDA"), 21 U.S.C. §§ 360e(b)(1)(A)-(B) — and therefore had to be severed from the rest of the Michigan law.

The District Court agreed with Appellees, concluding that the immunity exception should be severed because under the reasoning of *Buckman*, it was preempted by federal law.[2] The court gave two reasons for its decision. First, the District Court believed that, although it was not "absolutely bound" by *Garcia*, the Sixth Circuit's reasoning was owed "quite substantial deference" under *Factors Etc., Inc. v. Pro Arts, Inc.*, 652 F.2d 278 (2d Cir. 1981), a decision by a panel of this circuit which stated that conclusive deference should be given to a federal court of appeals' interpretation of the law of a state within its circuit. Second, "apart from *Factors*," the District Court reasoned that "[i]f plaintiffs covered by the Michigan statute were able to litigate claims of fraud on the FDA in individual personal injury suits, whether in state courts or in federal courts, the potential would exist for the FDA's personnel to be drawn into those controversies on a case-by-case basis over and over again." Concluding that this would generate "a wholly impractical situation," the court held "that the exception in the Michigan statute is preempted, except where the plaintiff relies on a finding by the FDA, or in an action brought by the FDA, of material fraud in the new drug

[2] Before addressing the preemption issue, Judge Kaplan considered the choice-of-law question for those claims originally filed in California state court and concluded that there was "no serious argument for the application of California substantive law." In fact, the attorney representing those Michigan residents who filed suit in California conceded that he was the only tie his clients had to California. Moreover, Judge Kaplan observed that California's choice-of-law provisions required that the case be governed by the law of Michigan, where the plaintiffs reside and where the alleged injuries took place. None of the parties have challenged this finding on appeal.

approval process absent which approval would not have been granted." Hence, the court granted the drugmakers' motion for judgment on the pleadings and dismissed all of Appellants' complaints.

Appellants filed a timely appeal.

DISCUSSION

We review *de novo* a district court's dismissal of a suit pursuant to a motion for judgment on the pleadings. *See King v. Am. Airlines, Inc.*, 284 F.3d 352, 356 (2d Cir. 2002); *Burnette v. Carothers*, 192 F.3d 52, 56 (2d Cir. 1999). "In deciding a Rule 12(c) motion, we apply the same standard as that applicable to a motion under Rule 12(b)(6), accepting the allegations contained in the complaint as true and drawing all reasonable inferences in favor of the nonmoving party." *Burnette*, 192 F.3d at 56.

This appeal raises two separate and significant questions. First, under the rule in *Factors*, must we follow our sister circuit's holding in *Garcia* because the Sixth Circuit's decision involved the laws of Michigan, a state within its circuit? Second, even if we are not required to defer conclusively to *Garcia*, should we nonetheless conclude, applying the logic of *Buckman*, that Appellants' common law claims — preserved by Michigan's exception — conflict with, and are therefore preempted by, federal law?

I.

The District Court interpreted *Factors* to mean that, although it was not "absolutely bound" by the Sixth Circuit's ruling, *Garcia* was owed "substantial deference." Appellees advocate an interpretation of *Factors* that insists upon more than deference. They contend that, under *Factors*, we are not free to reach a conclusion contrary to *Garcia* unless a different result is compelled by prior or subsequent pronouncements of the Supreme Court of Michigan. For their part, Appellants

do not identify any contrary Michigan law to refute the *Garcia* court's decision that federal law preempts Michigan's immunity exception.[3] As a result, Appellees maintain that *Garcia* binds us to dismiss Appellants' suit. Appellees may be correct in their reading of *Factors*, when it applies. But like the District Court they misgauge the relevance of *Factors* to the case before us.

Factors involved a contract dispute governed exclusively by Tennessee state law. In that context, we held that a federal court exercising diversity jurisdiction should give "conclusive deference" to "a ruling by a court of appeals deciding the law of a state within its circuit." *Factors*, 652 F.2d at 279. We elaborated that conclusive deference was owed except in very narrow circumstances:

> We need not and do not conclude that the state law holding of the pertinent court of appeals is automatically binding upon the federal courts of all the other circuits. The ultimate source for state law adjudication in diversity cases is the law as established by the constitution, statutes, or authoritative court decisions of the state. A federal court in another circuit would be obliged to disregard a state law holding by the pertinent court of appeals if persuaded that the holding had been superseded by a later pronouncement from state legislative or judicial sources, or that prior state court decisions had been inadvertently overlooked by the pertinent court of appeals.

Factors, 652 F.2d at 283 (internal citation omitted). Because neither of these circumstances applied to the sister circuit's decision — *i.e.*, the court of appeals' decision had not been weakened by subsequent developments in state law, nor was the decision contrary to prior state precedent — the *Factors* court mandated deference:

> Where, as here, the pertinent court of appeals has essayed its own prediction of the course of state law on a question of first impression within that state, the federal courts of other circuits should defer to that holding, perhaps always, and at least in all situations except the rare instance when it can be said with conviction that the pertinent court of appeals has disregarded clear signals emanating from the state's highest court pointing toward a different rule.

[3] Appellants' arguments against preemption rely mainly on federal precedent. The only Michigan case they focus on, *Maki v. East Tawas*, 188 N.W.2d 593 (Mich. 1971), bears solely on severability, not preemption.

Factors, 652 F.2d at 283.

But *Factors* instructed us to defer conclusively to another circuit's judgment only when that court of appeals' decision addressed questions of *state* law from a state within that circuit. It asserted no obligation to defer to a foreign circuit's views on *federal* law. As to issues of federal law, we are permitted — indeed, required — to reach our own conclusions. *See Pan Am. World Airways, Inc. v. C. A. B.*, 517 F.2d 734, 741 (2d Cir. 1975) ("[W]e are not bound by the decision or the rationale of [another circuit] court."); *see also Colby v. J.C. Penney Co., Inc.*, 811 F.2d 1119, 1123 (7th Cir. 1987) ("We have an intermediate obligation to our sister federal courts of appeals. Bearing in mind the interest in maintaining a reasonable uniformity of federal law and in sparing the Supreme Court the burden of taking cases merely to resolve conflicts between circuits, we give most respectful consideration to the decisions of the other courts of appeals and follow them whenever we can. Our district judges should, of course, do likewise with regard to such decisions . . . . But neither this court nor the district courts of this circuit give the decisions of other courts of appeals automatic deference; we recognize that, within reason, the parties to cases before us are entitled to our independent judgment." (internal citation omitted)).

This obligation does not change in the context of transferred cases. In *Menowitz v. Brown*, 991 F.2d 36 (2d Cir. 1993) (per curiam), we considered securities fraud claims that had been consolidated and transferred to the Southern District of New York only to be dismissed as untimely under our circuit's limitations guidelines. One set of claims, however, had originally been filed in the Southern District of Florida and would have been timely under the statute of limitations applicable under the Eleventh Circuit's rule (which would have borrowed Florida's "blue sky" limitations period). Thus, the question presented was "whether Second Circuit doctrine directs

application of the Eleventh Circuit limitations rule to such a transferred action." *Menowitz*, 991 F.2d at 40. We stated that "[r]esolution of this question turns on whether the choice of the applicable limitations period is properly understood as a matter of state or of federal law." *Id.* Were it an issue of state law, we indicated that "a transferee court applies the substantive state law, including choice-of-law rules, of the jurisdiction in which the action was filed." *Id.* But since we concluded that the proper statute of limitations applicable to a federal claim was a matter of federal law, we disregarded the Eleventh Circuit's approach to the federal issue and opted instead to follow our own. In so doing, we emphasized that, even in the transfer context, a court of appeals must develop its own circuit law on federal questions; it cannot mechanically adopt the reasoning and conclusions of its sister circuits:

> We have previously held that a transferee federal court should apply its interpretations of federal law, not the constructions of federal law of the transferor circuit. . . . [F]ederal courts comprise a single system applying a single body of law, and no litigant has a right to have the interpretation of one federal court rather than that of another determine his case. . . .
>
> [U]ntil the Supreme Court speaks, the federal circuit courts are under duties to arrive at their own determinations of the merits of federal questions presented to them; . . . [I]f a federal court simply accepts the interpretation of another circuit without [independently] addressing the merits, it is not doing its job.

Id. (internal citations and quotation marks omitted).

The problem, therefore, with the District Court's decision and with the position taken by Appellees is that both fail to appreciate that this appeal — unlike the Tennessee contract dispute in *Factors* — is not governed primarily, and certainly not exclusively, by state law. Rather, the question of whether federal law impliedly preempts part of Michigan's statutory scheme depends on significant issues of federal law including, *inter alia*, the meaning of Supreme Court precedents, *e.g.*, *Buckman*, and the scope of federal statutes, *e.g.*, FDCA. As a result, in resolving this appeal, we

operate under twin mandates with respect to the Sixth Circuit's opinion in *Garcia*. On the one hand, under *Factors*, we are bound to follow *Garcia*'s conclusions as to questions of Michigan state law. On the other hand, under *Menowitz*, we are obligated to answer independently questions of federal law, applying only the usual intercircuit regard for the Sixth Circuit's analysis of these federal issues.

Accordingly, the central question presented by this appeal — *i.e.*, whether federal law preempts Michigan's immunity exception — is controlled by the decision in *Garcia* only to the extent that the Sixth Circuit's conclusion rested solely on findings as to state law. *Garcia* did begin with an explanation of state law:

> [M.C.L. § 2946(5)] presents a somewhat different legal regime from the one invalidated in *Buckman*. The Michigan legislature has provided a general immunity for drug manufacturers with a specific exception for circumstances involving, *inter alia,* fraud on the FDA rather than a specific cause of action for fraud on the FDA.

Garcia, 385 F.3d at 965-66 (internal footnote omitted). Under *Factors*, therefore, we must accept the Sixth Circuit's conclusion that M.C.L. § 2946(5) *does not* create a new cause of action for misleading the FDA. And that holding guides our review of the federal issues before us.[4]

[4] It should be noted that *Factors*, a case involving Tennessee state law, was decided in 1981. At that time, the Tennessee Supreme Court did not accept certified questions. *See Holt by Holt v. Hypro, a Div. of Lear Siegler, Inc.*, 746 F.2d 353, 354 (6th Cir. 1984) ("We[, the Sixth Circuit,] are somewhat puzzled by the [Tennessee] statute as it applies to minors injured by products over ten years old, and we sought to certify the question to the Tennessee Supreme Court. That Court has now advised us that they do not have the judicial power to accept certified questions. We are left to divine the meaning of the Tennessee Legislature on our own."). In fact, it was not until 1989 that Tennessee adopted a certification rule. *See* Tennessee Supreme Court Rule 23 ("The Supreme Court may, at its discretion, answer questions of law certified to it by the Supreme Court of the United States, a Court of Appeals of the United States, a District Court of the United States in Tennessee, or a United States Bankruptcy Court in Tennessee.") (made effective February 17, 1989). It may well be, therefore, that *Factors* would not foreclose us from certifying a question of state law to the relevant state court, even where the pertinent federal court of appeals has provided its interpretation.

We need not, and hence do not, however, decide in this case the significance of *Factors* when certification is available and appropriate. Certification to Michigan is available. *See* Michigan Court Rule 7.305(B)(1) ("When a federal court, state appellate court, or tribal court considers a question that Michigan law may resolve and that is not controlled by Michigan Supreme Court precedent, the court may on its own initiative or that of an interested party certify the question to the Michigan

After issuing this interpretation of M.C.L. § 2946(5), the Sixth Circuit turned to issues of federal law. And, on the basis of *its* understanding of the Supreme Court's decision in *Buckman*, the Sixth Circuit concluded that the difference it had just identified — between those preexisting common law claims that survived M.C.L. § 2946(5) and those arising under a specific cause of action for fraud-on-the-FDA, like those invalidated in *Buckman* — was "immaterial." *See Garcia*, 385 F.3d at 966 ("As the [Michigan] district court properly found, '*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.'").

Nothing in *Factors* requires that we adopt the Sixth Circuit's reading of *Buckman*. On the contrary, because *Garcia*'s conclusions as to preemption depended on its analysis of federal (and not state) law, we must decide for ourselves whether Michigan's surviving common law cause of action is implicitly preempted by federal law under the rationale of *Buckman*. It is to this question that we, therefore, now turn.

II.

In *Buckman*, the Supreme Court considered whether federal law — specifically, the FDCA and the MDA — preempted state "fraud-on-the-FDA" claims. The plaintiffs in *Buckman* contended that a medical device manufacturer had obtained FDA approval for its product only after making fraudulent misrepresentations to the federal agency. Claiming that the FDA would not have approved the device but for these misrepresentations, the plaintiffs sought damages under California state law. The Court began by stating what is undoubtedly true that "[p]olicing

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Supreme Court."). But *Garcia*'s holding that the state law at issue in this case does not *create* a new cause of action is so clearly correct, both on its face, and in view of the relationship of the current statute to the previous Michigan law (which allowed defendants to introduce evidence of compliance with government standards, *Taylor*, 658 N.W.2d at 130), that certification would not be appropriate.

fraud against federal agencies is hardly a field which the States have traditionally occupied." *Buckman*, 531 U.S. at 347 (internal citation and quotation marks omitted). As a result, the presumption against federal preemption of a state law cause of action did not apply to fraud-on-the-FDA claims. *Id.*

In the absence of any presumption against preemption, the Court found that fraud-on-the-FDA claims conflicted with, and were therefore impliedly preempted by, federal law. "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. In other words, *policing fraud on the FDA* through a tort action could interfere with how the FDA might wish to police that kind of fraud itself.

The *Buckman* Court went on to express its concern that the potential conflict between federal law and the competing regulatory regimes of 50 states would unduly burden drug companies seeking to obtain FDA approval for their products. The Supreme Court worried that these companies, fearful of state liability, would file "a deluge of information" that the FDA does not require, thereby burdening the federal agency as well. *Id.* at 351. But the Court ended by emphasizing that the plaintiffs' claims before it were not rooted in traditional state law, and were instead derivative of federal law:

> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of . . . federal enactments is a critical element in their case.

Id. At 353. For these reasons, the Court invalidated the plaintiffs' fraud-on-the-FDA claims as impliedly preempted by federal law.

Echoing the conclusion of the Sixth Circuit, Appellees argue that, notwithstanding *Garcia*'s statement that M.C.L. § 2946(5) did not create "a specific cause of action for fraud on the FDA," *Garcia*, 385 F.3d at 966, there is no meaningful difference between the fraud-on-the-FDA claims struck down in *Buckman* and Appellants' claims under Michigan tort law. We disagree. There are three differences between the nature of the claim which M.C.L. § 2946(5) exempts from abolition and the claim in *Buckman*. Given the bases of *Buckman*'s holding, each of these is crucial.

A. *Presumption Against Preemption*

First, the presumption against federal preemption of state law obtains in the case before us. In *Medtronic*, the Supreme Court explained that "because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic*, 518 U.S. at 485. In *Buckman*, the Court held that this presumption did not apply *because* "*[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." Buckman*, 531 U.S. at 347 (internal citation and quotation marks omitted) (emphasis added).

In the case before us, instead, the cause of action (which survives the changes made by M.C.L. § 2946(5)) cannot reasonably be characterized as a state's attempt to police fraud against the FDA. And, significantly, *Garcia* did not so characterize it. Rather, as *Garcia* recognized, M.C.L. § 2946(5) did not invent new causes of action premised on fraud against the FDA. The object of the legislative scheme was rather to regulate and restrict when victims could continue to recover under preexisting state products liability law.[5]

[5] We also have found no evidence that the goal of preventing or punishing fraud against the FDA in any way motivated Michigan legislators to enact the statutory framework in question. M.C.L. § 2946(5) grew out of Michigan Senate Bill 344; the "Bill Analysis," produced by the state Senate

The Michigan legislature's desire to rein in state-based tort liability falls squarely within its prerogative to "regulat[e] matters of health and safety," which is a sphere in which the presumption against preemption applies, indeed, stands at its strongest. *See Buckman*, 531 U.S. at 348 (citing *Medtronic*, 518 U.S. at 485 as governing "situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,'" and contrasting these to the case before it). As a result, while there may be reasons to override that presumption, the existence of the presumption in the instant case requires an altogether different analysis from that made in *Buckman*.[6]

B. Traditional Common Law Liability

Second, Appellants here are not pressing "fraud-on-the-FDA" claims, as the plaintiffs in *Buckman* were understood by the Supreme Court to be doing. They are, rather, asserting claims that sound in traditional state tort law. In *Buckman*, the Supreme Court mentioned two characteristics of preempted "fraud-on-the-FDA" claims that distinguish them from claims sounding in preexisting common law.

The *Buckman* Court suggested that the source and "vintage" of the *duty* the drug maker is accused of breaching in "fraud-on-the-FDA" claims is different from the source and "vintage" of the duty that obtains in traditional tort claims. On this basis, the *Buckman* Court distinguished

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Fiscal Agency, suggests that the main impetus driving the legislation was a desire to limit the liability of drug makers under state tort law. *See generally* S. Fiscal Agency, SFA B. Analysis, Revised Enrolled Analysis, S.B. 344, H.B. 4508, at *1 (Jan. 11, 1996) ("According to many, over the past several decades there has been an explosion of product liability litigation, resulting in unfair and excessive judgments against manufacturers and sellers. . . . In Congress and state legislatures, a number of proposals have been advanced to reduce manufacturers' and sellers' exposure to liability.").

[6] This fact also substantially diminishes the persuasive effect of the federal law analysis made in *Garcia*, since the Sixth Circuit's holding in *Garcia* was based on the assumption that no presumption against preemption applied.

the plaintiff's unpreempted claims in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), from those before it and wrote: "Silkwood's claim was not based on any sort of fraud-on-the-agency theory, but on traditional state tort law principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant." *Buckman*, 531 U.S. at 352.

Significantly, all of the claims advanced by Appellants in this case are premised on traditional duties between a product manufacturer and Michigan consumers. None of them derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency. As a result, were we to conclude that Appellants' claims were preempted, we would be holding that Congress, without any explicit expression of intent, should nonetheless be taken to have modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers. We see no reason, nor can we identify any precedent, to justify such a result.[7]

The second difference between common law actions and "fraud-on-the-FDA" claims, suggested in *Buckman*, is that in FDA-fraud cases, proof of fraud against the FDA is *alone sufficient* to impose liability. In *Buckman*, there were no freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements. And *Buckman* explicitly distinguished *Medtronic* on this ground. *Medtronic*, the *Buckman* Court said, involved a "common-law negligence action against the manufacturer of an allegedly defective" product:

> [T]he *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not *solely* from the violation of FDCA requirements. In the present case, however, the fraud claims exist *solely* by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read

[7] This may be seen as another way of saying that, unlike the situation in *Buckman*, the presumption against preemption is at its strongest in the instant case.

> to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that *any* violation of the FDCA will support a state-law claim.

Buckman, 531 U.S. at 352-53 (emphasis added) (internal citation omitted).

As in *Medtronic*, the plaintiffs' claims in the case before us "parallel federal safety requirements" but are not premised principally (let alone exclusively) on a drug maker's failure to comply with federal disclosure requirements. On the contrary, the plaintiffs' complaints allege a wide range of putative violations of common law duties long-recognized by Michigan's tort regime. These pre-existing common law claims survive under M.C.L. § 2946(5) because there is also evidence of fraud in FDA disclosures. But, unlike the claims in *Buckman*, they are anything but based *solely* on the wrong of defrauding the FDA. Given *Buckman*'s explanation of *Medtronic*, *Buckman* cannot be read as precluding such preexisting common law liability based on other wrongs, even when such liability survives only because there was *also* evidence of fraud against the FDA.

Significantly, this reading of *Buckman* reflects the position the pharmaceutical industry articulated at oral argument in *Buckman*. Thus, the industry's presentation to the Supreme Court began by stressing the unusual and narrow claim before the *Buckman* Court:

> The plaintiffs in this case are people who underwent back surgery in which particular medical devices were used. They brought this suit under State law to recover for injuries allegedly caused by their — by these devices, but this is a very unusual form of State law product liability action. The plaintiffs don't claim that these devices were in any way defective. There's no claim here of manufacturing defect. There's no claim here of design defect. The plaintiffs also don't claim that the surgeons who used these devices did anything wrong. There's no claim here of medical malpractice.
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> Instead, the plaintiffs' sole claim in this case is the following. They assert that the Federal Food & Drug Administration was deceived into giving regulatory clearance to these devices, that, absent this deception, these devices would never have been on

> the market, and that, if the devices had never have been on the market, they wouldn't have been used in their surgeries and they wouldn't have suffered any injuries.

Oral Argument Transcript, *Buckman*, 531 U.S. 341, 2000 WL 1801621, at *3-4 (2000) (No. 98-1768). [8]

C. Immunity as Affirmative Defense

Third, and once more unlike *Buckman*, the Michigan Supreme Court has indicated that proof of fraud against the FDA is not even an *element* of a products liability claim like the one here brought. The existence of properly-obtained FDA approval becomes germane *only* if a defendant company chooses to assert an affirmative defense made available by the Michigan legislature in M.C.L. § 2946(5). *See Taylor*, 658 N.W.2d at 131. Thus, in *Taylor*'s discussion of M.C.L. § 2946(5), Michigan's highest court offered this characterization of the statute: "[A] manufacturer or seller of a drug that has been approved by the FDA has an absolute *defense* to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller." *Id.* (emphasis added). And, throughout its opinion, the *Taylor* court spoke of the *defendant's* references to the *FDA's* findings, suggesting again that it is the defendant that must invoke the FDA's decision to approve its drug if it wishes to insulate itself from liability, *Taylor*, 658 N.W.2d at 134. We take this to mean that the Michigan law in question

[8] Similarly, a second lawyer for the industry indicated that traditional tort remedies were *not* implicated by *Buckman*. When asked about what remedies an injured plaintiff would have under his theory of the case, the attorney responded: "The *fraud* claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available . . . ." *Id.* at 21 (emphasis added). In the case before us, Appellants have asserted precisely "negligent design, negligent manufacturing, [etc.] . . ." and claim only that the Michigan exclusion from liability does not apply to their traditional tort law claims because there was *also* fraud on the FDA.

does no more than create a defense that drug makers may invoke, if they so decide, and that it is not up to the plaintiff to prove fraud as an element of his or her claim.

Finding preemption of traditional common law claims where fraud is not even a required element — but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law — would result in preemption of a scope that would go far beyond anything that has been applied in the past. Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect. *See Medtronic*, 518 U.S. at 485 ("[P]articularly in [circumstances] in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the *clear and manifest* purpose of Congress.'" (internal citations omitted) (emphasis added)).

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The *Buckman* Court did, however, mention practical concerns with allowing "fraud-on-the-FDA" suits to go unpreempted. Specifically, it said that permitting such suits would result in a deluge of information that could swamp FDA administrators. The *Garcia* court, in applying *Buckman* to a suit like the one before us, made reference to these same concerns. But these worries, if deemed controlling, would prove too much. They would result in preemption of a scope that no one is contemplating, let alone advocating.

In terms of deluging the FDA, there is little difference between (a) causes of action, like the instant one, where proof of fraud against the FDA is not the basis of the cause of action but is necessary to negate a limitation on state liability, and (b) causes of action where proof of fraud

against the FDA is permitted but not conclusive (as it was under the precursor to the Michigan law at issue here, *see supra*, and as it presumably is in most states in the country). So long as a court or jury is *allowed to consider* evidence of fraud against the FDA in an ordinary common law tort suit, and so long as juries are likely to react to such evidence, there will be substantial inducements on the pharmaceutical industry to provide the federal agency with just the kind of information that troubled the *Buckman* and *Garcia* Courts. Requiring such evidence when a plaintiff seeks to counter a statutory defense from liability would not significantly alter that incentive. Only when proof of fraud is by itself *sufficient* to impose liability — and indeed is the sole basis of liability (as it was in *Buckman*) — does the incentive to flood the FDA appreciably escalate.

In other words, the incentive to supply additional data to the 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. It follows that under *Garcia*'s reading of *Buckman*, unless a state barred the submission of evidence of fraud against the FDA in run of the mill tort cases, the policy concerns that *Buckman* expressed in a very narrow context would seemingly justify invalidating any product liability suit brought against a drugmaker. We do not believe *Buckman* meant to go anywhere near so far.[9]

[9] Since we heard oral argument in this case, the FDA issued a final rule governing the content and format of drug product labeling. *See* 71 Fed. Reg. 3922 (Jan. 24, 2006). In the amended regulation, the FDA announced its view that FDA labeling requirements preempt state law claims that impose additional or different requirements: "[The] FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law." *Id.* at 3934. In so doing, the FDA apparently confined its view that state claims undermine federal law to circumstances "when [state laws] purport to compel a firm to include in labeling or advertising a statement that [the] FDA has considered and found scientifically unsubstantiated." *Id.* at 3935.

Although any statement by a federal agency carries persuasive weight, the FDA's recent pronouncement does not ultimately affect our analysis in this case. The FDA's statement concerns only preemption of state laws that impose additional *labeling* requirements. Appellants' claims rest on far broader allegations, *e.g.*, defective design and manufacturing.

To the extent that the FDA's statement might bear peripherally on the claims asserted in this

III.

Because of its important role in state regulation of matters of health and safety, common law liability cannot be easily displaced in our federal system. *Buckman* underscored this fact, finding implied preemption of a newly-fashioned state cause of action only where (1) no presumption against federal preemption obtained, and (2) the cause of action, by assigning liability *solely* on the basis of fraud against the FDA, imposed significant and distinctive burdens on the FDA and the entities it regulates. The appeal before us presents a very different set of circumstances, one in which there is a clear presumption against preemption of long-standing common law claims. In the presence of this presumption, because Michigan law does not in fact implicate the concerns that animated the Supreme Court's decision in *Buckman*, and because Appellants' lawsuits depend primarily on traditional and preexisting tort sources, not at all on a "fraud-on-the-FDA" cause of action created by state law, and only incidentally on evidence of such fraud, we conclude that the Michigan

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case, it is not clear what, if any, deference would be owed to the FDA's view. Assertions of implied preemption arguably originate in statutory ambiguity as to which an agency's interpretations may be accorded deference. *See generally Chevron U.S.A, Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984). And — at least in a field of regulation in which no presumption against preemption applies — we recently indicated that we will give *Chevron* deference to an agency's regulation even though its interpretation has the resultant effect of preempting state law. *See Wachovia Bank, N.A. v. Burke*, 414 F.3d 305, 314-15 (2d Cir. 2005).

But, whatever deference would be owed to an agency's view in contexts where a presumption against federal preemption does apply, it is arguable that an agency cannot supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against preemption. *Cf. Alexander v. Sandoval*, 532 U.S. 275, 291 (2001) ("Agencies may play the sorcerer's apprentice but not the sorcerer himself."). Because we find that a presumption against preemption applies in the instant case, it may also be argued that even in the face of an FDA statement asserting preemption, the common law claims preserved by Michigan's immunity exception cannot be preempted by federal law absent a clear statement from Congress. In any event, since no such FDA statement dealing with Appellants' claims has been made, the question of its effect, were one to issue, is not before us.

immunity exception is not prohibited through preemption. It follows that common law liability is not foreclosed by federal law, and Appellants' claims should not have been dismissed.

For the foregoing reasons, we VACATE the District Court's grant of judgment on the pleadings, and we REMAND the case to the District Court for further proceedings