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Many states have enacted statutory limits on claims against manufacturers of drugs that comply with the Food and Drug Administration's approval and labeling regulations. Michigan's law, with an absolute bar to recovery in cases concerning FDA-approved drugs, is among the most restrictive.

A plaintiff can overcome the bar with proof that the manufacturer withheld required information that, if provided, would have caused the FDA not to approve or to withdraw approval for the drug.

In 2004, the U.S. Court of Appeals for the Sixth Circuit found that the showing required to overcome the Michigan defense is a fraud-on-the-FDA claim. Based on a U.S. Supreme Court decision that fraud-on-the-FDA claims are preempted by federal law, the Sixth Circuit said Michigan's fraud-on-the-FDA exception is likewise preempted. But the Second Circuit recently reached exactly the opposite conclusion. As explained below, the Sixth Circuit's analysis is the better-reasoned one.

Deconstructing *Desiano:* Why the Sixth Circuit Reached the Better Conclusion

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Many states, including Texas, New Jersey, Arizona, and Michigan, have enacted statutory limits on claims against pharmaceutical manufacturers that comply with the FDA's drug approval and labeling regulations.[1] Michigan's law is among the most restrictive. Michigan has an absolute statutory bar to recovery in product liability actions relating to use of

[1] *See, e.g.*, Tex. Civ. Prac. & Rem. Code Ann. § 82.007; N.J.S.A. §§ 2A:58C-4, 2A:58C-5; Ariz. Rev. Stat. Ann. § 12-701.

FDA-approved drugs.[2] However, that bar is overcome when the manufacturer is shown to have withheld required information that, if provided to the FDA, would have caused the agency not to approve or to withdraw approval for the drug.[3]

In 2004, the Sixth Circuit found in *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), that the showing required to overcome the Michigan defense is a fraud-on-the-FDA claim. The U.S. Supreme Court ruled in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), that fraud-on-the-FDA claims are preempted by federal law, so *Garcia* held that Michigan's fraud-on-the-FDA provision is likewise preempted, 385 F.3d at 965-66. Recently, the Second Circuit reached exactly the opposite conclusion in *Desiano v. Warner-Lambert & Co.*, No. 05-1705, 2006 U.S. App. LEXIS 25108 (2d Cir. Oct. 5, 2005). As explained below, *Garcia* is the better-reasoned decision.

Buckman

In *Buckman*, the plaintiffs asserted state law tort claims premised on the theory that, but for the defendants' alleged misrepresentations to the FDA to obtain approval of a medical device, the device would not have been approved, and the plaintiffs would not have been injured. The Supreme Court in *Buckman* rejected those claims: The ''plaintiffs' state-law fraud-on-the-FDA claims conflict[ed] with, and [we]re therefore preempted by, federal law.'' *Buckman*, 531 U.S. at 348 (footnote omitted).

In particular, ''the federal statutory scheme amply empowers the FDA to punish and deter fraud,'' and the FDA's ''somewhat delicate balance of statutory objectives'' could be ''skewed by allowing fraud-on-the-FDA claims under state tort law,'' *id.* at 348 (footnote omitted). ''[C]omplying with the FDA's detailed regulatory regime in the shadow of 50 states' tort regimes w[ould] dramatically increase the burdens facing potential applicants,'' *id.* at 350. State-law, fraud-on-the-FDA claims could ''cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court,'' thus creating ''an incentive to submit a deluge of information that the Administration neither wants nor needs,'' *id.* at 351. Private parties therefore cannot pursue fraud-on-the-FDA claims.

Michigan Compiled Laws § 600.2946(5)

The Michigan statute at issue in both *Garcia* and *Desiano*, Michigan Compiled Laws § 600.2946(5) (''M.C.L. § 2946(5)''), was enacted in 1995 and became effective in March 1996. It provides categorically that FDA-approved drugs are ''not defective or unreasonably dangerous'' and that manufacturers of FDA-approved drugs are ''not liable'' in product liability actions, M.C.L. § 2946(5); *see generally Taylor v. SmithKline Beecham Corp.*, 468 Mich. 1, 658 N.W.2d 127 (2003) (rejecting challenge to M.C.L. § 2946(5) under Michigan Constitution). Under an exception set forth in subsection (a) to M.C.L. § 2946(5), the absolute bar on recovery ''does not apply'' if the manufacturer ''[i]ntentionally withholds from or misrepresents to'' the FDA ''information that is required to be submitted'' under the Federal Food, Drug & 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,'' M.C.L. § 2946(5)(a).[4]

Garcia

Garcia involved the prescription pain reliever Duract, which allegedly caused liver damage. The manufacturer voluntarily withdrew Duract from the market. The *Garcia* plaintiff alleged that Duract caused her liver to fail, a claim that M.C.L. § 2946(5) barred unless an exception applied. The district court found that the exception provided in M.C.L. § 2946(5)(a) was a fraud-on-the-FDA claim that was preempted under *Buckman*. *Garcia v. Wyeth-Ayerst Labs.*, 265 F. Supp. 2d 825, 831-32 (E.D. Mich. 2003), *aff'd*, 385 F.3d 961 (6th Cir. 2004). Michigan law required severing the exception in M.C.L. § 2946(5)(a) and then applying the remaining liability bar created by M.C.L. § 2946(5), so the district court dismissed the plaintiff's claims, *id.*, 265 F. Supp. 2d at 832.

The Sixth Circuit affirmed, observing that M.C.L. § 2946(5) presented ''a somewhat different legal regime from the one invalidated in *Buckman*. The Michigan Legislature has provided for a general immunity for drug manufacturers with a specific exception for circumstances involving . . . fraud on the FDA rather than a specific cause of action for fraud on the FDA'' as in *Buckman*. 385 F.3d at 965-66 (footnote omitted). But the court found ''[t]his difference . . . immaterial in light of *Buckman*. As the 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' '' unless ''the FDA *itself* determines that a fraud had been committed,'' *id.* at 966 (citation omitted) (italics in original). Having found M.C.L. § 2946(5)(a) preempted, *Garcia* affirmed the district court's order dismissing the plaintiff's claims based on M.C.L. § 2946(5).

Desiano

Desiano involved the prescription diabetes drug Rezulin, which, like Duract, allegedly caused liver damage and was withdrawn from the market. In *Desiano*, Michigan residents sought to recover for liver injuries that allegedly resulted from using Rezulin. Acting as an MDL transferee court, the Southern District of New York interpreted Michigan law. Because Michigan is within the Sixth Circuit, the court found that *Garcia* was entitled to ''quite substantial deference'' under the Second Circuit's decision in *Factors Etc. Inc. v. Pro Arts Inc.*, 652 F.2d 278 (2d Cir. 1981) (''*Factors*''). Additionally, the trial court found M.C.L. § 2946(5)(a) preempted under *Buckman* unless the FDA itself found that it had been defrauded. Because there had been no such finding, M.C.L. § 2946(5) barred the *Desiano* plaintiffs' claims. *See* 2006 U.S. App. LEXIS 25108, at *10 (discussing district court's reasoning).

[2] Mich. Comp. Laws § 600.2946(5).

[3] *Id.* at § 600.2946(5)(a).

[4] The other exception to M.C.L. § 2946(5) applies when the manufacturer ''[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). That exception was not at issue in *Garcia* or *Desiano*.

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In an Oct. 5, 2006, opinion, the Second Circuit vacated and remanded.[5] Initially, *Desiano* found that the question before it was one of federal, not state, law and, thus, *Garcia* was entitled to no deference under *Factors*, 2006 U.S. App. LEXIS 25108, at *20. Turning to the preemption issue, *Desiano* found that the plaintiffs' claims were not preempted based on (a) the presumption against federal law preempting state law; (b) the traditional nature of the plaintiffs' state-law claims; and (c) the fact that M.C.L. § 2946(5) is an affirmative defense, *id.* at *20-36. By focusing on whether the plaintiffs' causes of action were preempted, rather than on whether M.C.L. § 2946(5)(a) was preempted, *Desiano* asked the wrong question, and, not surprisingly, reached the wrong result.

The 'Presumption Against Preemption'

Buckman held that, because ''[p]olicing fraud against federal agencies is hardly a 'field which the States have traditionally occupied,' . . . a presumption against federal pre-emption of a state law cause of action'' did not apply, 531 U.S. at 347 (internal citation omitted). *Desiano*, however, found that a presumption against preemption did apply because the *Desiano* plaintiffs' ''cause[s] of action''—for breach of warranty, negligence, strict liability, and the like—''cannot reasonably be characterized as a state's attempt to police fraud against the FDA.'' 2006 U.S. App. LEXIS 25108, at *24. Accordingly, *Desiano* applied ''an altogether different analysis from that in *Buckman*,'' *id.* at *25 (footnote omitted).

Desiano's conclusion that the plaintiffs' state-law causes of action were not fraud-on-the-FDA claims, while correct, misses the point. Of course the *Desiano* plaintiffs' breach of warranty, negligence, strict liability, and fraud claims were not themselves ''attempt[s] to police fraud against the FDA.'' But neither *Garcia* nor the *Desiano* district court found that the plaintiffs' causes of action were fraud-on-the-FDA claims, and neither court found the causes of action to be preempted under *Buckman*. It was not the plaintiffs' causes of action, but the exception to M.C.L. § 2946(5)'s rule of non-liability created by M.C.L. § 2946(5)(a), that was preempted. The plaintiffs' claims were not dismissed because they were preempted; rather, they were dismissed because M.C.L. § 2946(5) barred them. *See Garcia*, 385 F.3d at 965-66. Because M.C.L. § 2946(5)(a) applies only when a plaintiff shows that a manufacturer withheld information that, if provided, would have prevented or caused the withdrawal of FDA approval, M.C.L. § 2946(5)(a) is indistinguishable from the fraud-on-the-FDA claims at issue in *Buckman*.

Traditional Common Law Liability

Desiano articulated two additional grounds for distinguishing *Buckman*; both rested on the nature of the duties involved in the cases. Initially, *Desiano* observed that, because the *Desiano* plaintiffs' claims rested ''on traditional duties'' and not, as in *Buckman*, ''on a newly-concocted duty between a manufacturer and a federal agency,'' finding them preempted would ''be holding that Congress, without any explicit expression of intent, . . . modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers,'' 2006 U.S. App. LEXIS 25108, at *27.

Again, however, in asking whether the plaintiffs' causes of action were preempted, rather than whether the exception in M.C.L. § 2946(5)(a) was preempted, *Desiano* asked the wrong question. Michigan's Legislature surely ''modified . . . traditional state law duties between pharmaceutical companies and their consumers'' by enacting M.C.L. § 2946(5). That legislative choice was the basis upon which both *Garcia* and the *Desiano* district court dismissed the claims before them.

Desiano also distinguished *Buckman* because ''in FDA-fraud cases, proof of fraud against the FDA is *alone sufficient* to impose liability,'' while the *Desiano* ''plaintiffs' claims . . . [we]re not premised principally (let alone exclusively) on a drug maker's failure to comply with federal disclosure requirements,'' *id.* at *28 (italics in original). Rather, the *Desiano* plaintiffs ''allege[d] a wide range of putative violations of common law duties long-recognized by Michigan's tort regime,'' *id.* at *29.

Once again, the Second Circuit is correct that the *Desiano* plaintiffs needed to show more than fraud on the FDA to recover on their underlying causes of action, but those causes of action were not what was preempted. Instead, *Garcia* and the *Desiano* district court found that the exception created by M.C.L. § 2946(5)(a) was preempted. M.C.L. § 2946(5)(a), like the claims at issue in *Buckman*, is ''premised principally [and] . . . exclusively[] on a drug maker's failure to comply with federal disclosure requirements,'' *id.* at *28.

Immunity as an Affirmative Defense

Desiano's final basis for distinguishing *Buckman* was that ''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,'' and is ''germane *only* if a defendant company chooses to assert an affirmative defense made available by the Michigan Legislature in M.C.L. § 2946(5),'' *id.* at *31 (italics in original) (*citing Taylor v. SmithKline Beecham Corp.*, 468 Mich. 1, 658 N.W.2d 127 (2003)). Thus, *Desiano* found that ''the Michigan law in question 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,'' *id.* at *32.

It is true that Michigan's tort law did not impose an obligation on the *Desiano* plaintiffs to establish fraud on the FDA as ''an *element* of [their] products liability claim[s].'' And M.C.L. § 2946(5) is indeed ''a defense that drug makers may invoke, if they so decide.'' But the preemption analysis cannot turn on the label attached to the plaintiff's obligation to show fraud on the FDA or whether that showing is an ''element'' of a claim. Once M.C.L. § 2946(5) is invoked, a plaintiff seeking to avoid the statute's liability bar under subsection (a) may recover if, and only if, he or she establishes that the defendant defrauded the FDA.

[5] In a prior appeal that arose from the Rezulin MDL proceedings, the Second Circuit vacated and remanded the district court's order dismissing health benefit providers' claims to recover amounts paid for Rezulin. *Desiano v. Warner-Lambert Co.*, 326 F.3d 339 (2d Cir. 2003). Circuit Judge Calabresi, who was the only Circuit Judge on both panels, wrote both opinions. The 2003 *Desiano* decision included a recitation of those plaintiffs' allegations concerning the circumstances surrounding the FDA's approval of Rezulin that, if established, might cause a fact finder to conclude that M.C.L. § 2946(5)(a) applied.

Fraud on the FDA is the exclusive issue framed by M.C.L. § 2946(5)(a), which is why, as *Garcia* and the *Desiano* district court found, it is preempted. Plaintiffs invoking M.C.L. § 2946(5)(a) would upset the FDA's ''somewhat delicate balance of statutory objectives'' as surely as the plaintiffs in *Buckman* did. *Buckman*, 531 U.S. at 348. The plaintiffs 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'' and create ''an incentive to submit a deluge of information that the Administration neither wants nor needs,'' *id.* at 351. Further, once M.C.L. § 2946(5)(a) is found to be preempted, *Garcia*'s finding that Michigan law required severing M.C.L. § 2946(5)(a) and applying M.C.L. § 2946(5)'s liability bar would control under the Second Circuit's decision in *Factors*. Thus, as the *Desiano* district court correctly found, M.C.L. § 2946(5) required dismissing the *Desiano* plaintiffs' claims.

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