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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

VICKI MARSH, THE ESTATE OF SHAY BLAIR, by personal representative Trisharla Brown, DAVID TIEFENTHAL, and THE ESTATE OF EDDIE A. MUNIZ, by personal representative Sheila Muniz,

Plaintiffs-Appellants,

v.

GENENTECH, INC. and XOMA (U.S.) LLC,

Defendants-Appellees.

Nos. 11-2373/ 2385/ 2417/ 2419

Appeal from the United States District Court
for the Western District of Michigan at Grand Rapids.
Nos. 1:11-cv-482; 1:11-cv-683; 1:11-cv-688; 1:11-cv-689;
Robert J. Jonker, District Judge.

Argued: July 20, 2012

Decided and Filed: September 6, 2012

Before: SILER and MOORE, Circuit Judges; VAN TATENHOVE, District Judge.[*]

COUNSEL

ARGUED: Alyson Oliver, KRESCH OLIVER PLLC, Southfield, Michigan, for Appellants. Richmond T. Moore, WILLIAMS & CONNOLLY LLP, Washington, D.C., for Appellees. **ON BRIEF:** Alyson Oliver, KRESCH OLIVER PLLC, Southfield, Michigan, for Appellants. Richmond T. Moore, Jennifer N. Wimsatt Pusateri, WILLIAMS & CONNOLLY LLP, Washington, D.C., for Appellees.

[*]The Honorable Gregory F. Van Tatenhove, United States District Judge for the Eastern District of Kentucky, sitting by designation.

OPINION

KAREN NELSON MOORE, Circuit Judge. Vicki Marsh, Shay Blair, David Tiefenthal, and the Estate of Eddie Muniz (collectively, "Marsh"), the plaintiffs in these consolidated products-liability actions, brought suit against drug manufacturers Genentech, Inc. and Xoma (U.S.) LLC (collectively, "Genentech") to recover for injuries allegedly sustained from use of the psoriasis medication Raptiva. The district court granted Genentech's motion to dismiss, holding that Genentech was entitled to immunity under the Michigan Products Liability Act (the Act) and that Marsh's claim that immunity did not apply was preempted by federal law. Because the allegations underlying Marsh's argument that immunity does not apply are essentially the type of claim that Supreme Court and Sixth Circuit precedent holds is preempted, we AFFIRM.

I. BACKGROUND

Genentech designed, manufactured, and sold the psoriasis medication Raptiva, which was approved by the federal Food and Drug Administration ("FDA") in 2003 and sold in the United States from 2003 until 2009. Raptiva works by suppressing T-cells to prevent them from migrating to the skin and causing psoriasis. Because T-cells help fight infections, however, their suppression has the potential to cause potentially life-threatening side effects. Following reports of adverse health effects, including a rare brain infection, in patients treated with Raptiva, Genentech voluntarily removed Raptiva from the market in 2009.

Marsh began using Raptiva in 2004 and subsequently suffered viral meningitis and a collapsed lung; she attributes these conditions to her use of Raptiva.[1] She brought suit against Genentech in 2011, alleging strict products liability under design-defect and failure-to-warn theories, negligence, breach of warranty, and fraud. She contends that,

[1]Blair and Tiefenthal used Raptiva in 2006-2008 and 2007-2008, respectively. Both developed lymphoma in 2008. Muniz used Raptiva in 2007 and died of kidney and liver failure later that year.

both prior to and after FDA approval of Raptiva, Genentech knew of dangerous side effects that it concealed from the public and did not include in the drug's label. Marsh also alleged that Genentech "intentionally and negligently failed to update statement of contraindications, warnings, precautions, and adverse reactions that Defendant affirmatively knew about" and "intentionally and negligently failed to comply with various but not limited to, 21 CFR 201, 21 CFR 202, 21 CFR 314.80, and 21 CFR 314.81." R.1 (Marsh Complaint) at ¶¶ 110–111 (PageID #27).[2]

Following a transfer of venue, Genentech moved to dismiss on the grounds that it was immune from suit under the state Act, which provides that drug manufacturers are not liable in products-liability actions if the allegedly dangerous drug and its label were approved by the FDA and were in compliance with the FDA's approval at the time that the drug left the manufacturer's control. *See* Mich. Comp. Laws § 600.2946(5). Marsh countered that Genentech was not entitled to immunity because it failed to submit updated safety information to the FDA after Raptiva had gone to market or otherwise comply with various FDA regulations regarding post-marketing reporting, which was a condition of FDA approval.

The district court granted Genentech's motion to dismiss, holding that Genentech was immune from suit because neither statutory exception to immunity for drug manufacturers—that the manufacturer had defrauded or bribed the FDA—applied. Citing our decision in *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), the district court explained that federal law preempts tort claims premised on the Act's exceptions absent a finding by the FDA itself that the manufacturer had committed fraud or bribery. The district court concluded that, because Marsh had not alleged that the FDA had found that Genentech committed fraud, her claim was preempted. The district court subsequently denied Marsh's motion for reconsideration. Marsh timely appealed.

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[2]With the exception of factual allegations related to each plaintiff's use of Raptiva and adverse health effects, the four complaints are identical. We follow both the parties' briefs and the district court in citing Marsh's complaint.

On appeal, Marsh again contends that immunity does not apply because Genentech's failure to submit updated safety information rendered Raptiva non-compliant with the FDA's approval at the time it left Genentech's control. Because her claim is premised on non-compliance rather than the fraud exception, she argues that it is not preempted under *Garcia*. In addition, she characterizes this suit as the type of state-law tort claim that the Supreme Court held was not preempted in *Wyeth v. Levine*, 555 U.S. 555 (2009). Finally, Marsh argues that immunity is an affirmative defense and thus that the district court erred by not requiring Genentech to prove Raptiva's compliance with the FDA's approval after Marsh alleged non-compliance in the complaint.

In response, Genentech characterizes failure to submit safety update reports as a species of fraud that falls within the Act's first exception and is thus preempted absent a finding of fraud by the FDA. Alternatively, Genentech argues that Marsh's claim is preempted under *Garcia* regardless of how it is characterized.

II. JURISDICTION AND STANDARD OF REVIEW

We have jurisdiction over this diversity action pursuant to 28 U.S.C. § 1332. Both parties agree that Michigan law applies. We review the district court's grant of Genentech's motion to dismiss de novo. *Brown v. Cassens Transp. Co.*, 675 F.3d 946, 953 (6th Cir. 2012).

III. ANALYSIS

A. Implied Preemption and Michigan Products-Liability Law

Michigan's products-liability regime is statutory. A drug manufacturer or seller is not liable for injuries caused by the use of its products "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." Mich. Comp. Laws § 600.2946(5). As a matter of law, "a drug is not defective or unreasonably

dangerous" if such criteria are met. *Id.* Statutory immunity does not apply, however, if the manufacturer or seller:

> (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, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, 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.

or

> (b) Makes 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.

Id. The Michigan Supreme Court has described the Act's immunity provision as "an absolute defense to a products liability claim" premised on the determination that "compliance with federal governmental standards (established by the FDA) is conclusive on the issue of due care for drugs." *Taylor v. SmithKline Beecham Corp.*, 658 N.W.2d 127, 130–31 (Mich. 2003).

In *Garcia*, 385 F.3d at 965–66, we held that federal law impliedly preempts the Act's two exceptions.[3] In so holding, we relied on *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), in which the Supreme Court held that the federal Food, Drug, and Cosmetic Act ("FDCA") impliedly preempts state-law fraud-on-the-FDA claims.[4]

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[3]We also held that the Act's exceptions are not preempted when the FDA itself has determined that the manufacturer committed fraud or bribery. Because Marsh does not contend that the FDA made such a determination, this aspect of *Garcia* has no bearing on this case.

[4]As relevant for this case, federal law impliedly preempts a state law if the state law "creates an unacceptable 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Wyeth*, 555 U.S. at 563–64 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). The Supreme Court has identified two "cornerstones of . . . pre-emption jurisprudence": "First, the purpose of Congress is the ultimate touchstone in every pre-emption case. Second, in all pre-emption cases, and particularly in those 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." *Id.* at 565 (internal quotation marks, citations, and alterations omitted).

The plaintiffs in *Buckman* brought suit against a medical-device manufacturer under state law, alleging that the manufacturer had made fraudulent representations to the FDA in the course of the approval process and that, as a result, the device was improperly placed on the market. 531 U.S. at 346–47. The Court held that such claims are preempted because they interfere with the federal regulatory scheme for the approval of drugs and medical devices, *id.* at 348–50, and because they implicate the "inherently federal" issue of "the relationship between a federal agency and the entity it regulates," *id.* at 347. Indeed, because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,'" the traditional presumption against preemption did not apply. *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

The FDCA sets forth a "comprehensive scheme" of disclosure requirements as part of the approval process. *Id.* at 348. Along with these requirements, the FDCA empowers the FDA to investigate and penalize fraud in a manufacturer's disclosures or elsewhere in the approval process. *Id.* at 348–49. The Court viewed these provisions of the FDCA as evidence that Congress intended exclusively federal enforcement. *Id.* at 352. State-law fraud-on-the-FDA claims would thus "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives" by allowing state courts to rule on the adequacy of a manufacturer's disclosures. *Id.* at 350. These claims could also interfere with the FDA's approval process, because the possibility that "disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court" could lead manufacturers to oversubmit information and thus burden the evaluation process. *Id.* at 351.

At its core, a fraud-on-the-FDA claim implicates "the relationship between a federal agency and the entity it regulates," a relationship that is "inherently federal in character." *Id.* at 347. Moreover, the basis for the claim is violation of a federal statute or regulation. Unlike a common-law tort claim, these "fraud claims exist solely by virtue of the FDCA disclosure requirements." *Id.* at 352–53. The alleged wrong is

inadequate disclosure to a federal agency rather than breach of the common-law duty to use reasonable care. *Id.*

Following *Buckman*, we held in *Garcia* that suits against drug manufacturers under Michigan law in which the plaintiff seeks to defeat immunity by invoking the Act's fraud exceptions are equivalent to fraud-on-the-FDA claims and are thus preempted. *Garcia*, 385 F.3d at 965–66.[5] Even though, under Michigan law, fraud on the FDA is an exception to a grant of immunity to the manufacturer rather than a stand-alone cause of action, it nonetheless ultimately "requir[es] proof of fraud committed against the FDA" to succeed. *Id.* (internal quotation marks omitted). *Garcia* thus essentially requires treating a plaintiff's fraud arguments against manufacturer immunity as a threshold "claim" that can be preempted.[6] We subsequently held that *Garcia* applied to claims that the manufacturer misrepresented or withheld information about a drug from the FDA after the FDA had approved it. *In re Aredia & Zometa Prods. Liab. Litig.*, 352 F. App'x 994, 995 (6th Cir. 2009) (unpublished opinion) (holding that such claims are preempted under the FDCA "unless some federal agency has already found the requisite fraud on the FDA").

Subsequent to *Buckman* and *Garcia*, the Supreme Court again dealt with the implied preemptive effect of the FDCA on state-law tort claims against drug manufacturers. In *Wyeth*, 555 U.S. at 558–59, the Court held that a state-law failure-to-warn claim premised on the inadequacy of a brand-name drug's label was not preempted simply because the FDA had approved the label. The manufacturer could still be liable under state law for failing to update the drug's label based on newly acquired information. *See id.* at 571. Because Congress has not provided a federal cause of

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[5]We also held that the fraud exceptions are not preempted "when the federal agency itself determines that fraud marred the regulatory-approval process." *Garcia*, 385 F.3d at 966. Accordingly, "claims based on federal findings of bribery or fraud on the FDA" can defeat manufacturer immunity under the state Act. *Id.*

[6]At oral argument, Marsh cited the Second Circuit's opinion in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2007), *aff'd by an equally divided court sub nom. Warner-Lambert Co. v. Kent*, 552 U.S. 440, 441 (2008), which held that the Michigan Act's exceptions were not preempted because, unlike in a stand-alone fraud-on-the-FDA claim, plaintiffs' claims under the Act are traditional tort claims that do not contain fraud as an element. We are, of course, bound by our own published precedent in *Garcia* to the contrary.

action for consumers harmed by unsafe drugs, state-law failure-to-warn claims provide "an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 579.

B. Compliance With FDA Approval

Marsh would protest that the above analysis is an irrelevant detour, because she does not invoke the Act's fraud exception. Instead, her argument that immunity does not apply is premised on Genentech's alleged non-compliance with the terms of the FDA's approval of Raptiva. Whatever vitality this distinction might have in other circumstances, the nature of Marsh's allegations of non-compliance does not take this case outside of *Garcia*'s precedential reach.

As described above, the state Act provides immunity from liability if "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." Mich. Comp. Laws § 600.2946(5). The Act does not define "compliance with [FDA] approval," and the parties have not cited, and we have not found, any Michigan caselaw interpreting this requirement.

The nature of Marsh's allegations of non-compliance is somewhat obscure, but she seems to allege that Genentech failed to comply with the FDA's post-marketing reporting requirements. The complaint alleges that Genentech "intentionally and negligently failed to update statement of contraindications, warnings, precautions, and adverse reactions that Defendant affirmatively knew about" and "intentionally and negligently failed to comply with various but not limited to, 21 CFR 201, 21 CFR 202, 21 CFR 314.80, and 21 CFR 314.81." R.1 at ¶¶ 110–111 (Page ID #27). Marsh contends that these failures constitute non-compliance with the FDA's approval because, as part of its application for approval of Raptiva, Genentech signed FDA Form 356h, which requires the applicant to certify as follows:

> "I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindicaitons [sic], warnings, precautions or adverse reactions in the draft labeling. I

> agree to submit safety update reports as provided for by regulation or as requested by the FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications. . . ."

Id. ¶ 108 (Page ID #27).

Such allegations do not fit comfortably within the statutory language requiring compliance for immunity to apply. Marsh's complaint alleges that *Genentech* did not comply with the terms of the FDA approval by failing to update its application or submit safety reports, not that "the drug and its labeling" did not comply. Mich. Comp. Laws § 600.2946(5); *see also Taylor*, 658 N.W.2d at 129–30 (explaining that the Act limits a manufacturer's liability when "the drug at issue was . . . labeled in compliance with FDA standards"). Put another way, the statutory language suggests that immunity requires substantive compliance with FDA approval, but Marsh essentially alleges procedural non-compliance. Marsh does not allege that the dose of Raptiva she received was adulterated or that its label varied from the label that the FDA approved.[7]

Moreover, failure to submit reports to the FDA that the FDA requires is arguably a species of fraud on the agency under the state Act. Indeed, the Michigan Act's fraud exception specifically encompasses at least some of the misconduct Marsh alleges—a manufacturer "[i]ntentionally withhold[ing] from . . . the [FDA] information concerning the drug that is required to be submitted under the [FDCA]" when the FDA "would have

[7]The complaint's C.F.R. citations support this view of Marsh's allegations. Sections 314.80 and 314.81 set forth post-marketing reporting requirements. Section 201 governs labeling, which would seem more relevant, but that section has seven subparts and seventy-one subsections, and Marsh does not specify with which regulation therein Genentech failed to comply. In her response to Genentech's motion to dismiss, Marsh attempted to clarify, stating that "Plaintiffs allege ***post-marketing*** failure to warn" and "21 C.F.R. 201 covers warnings and therefore, a failure to warn is a failure to comply with 21 C.F.R. 201." R.15 at 16 (Pl.'s Resp. to Defs.' Mot. to Dismiss) (Page ID #100). If Marsh means failure to warn consumers or physicians with an adequate label, this action does not constitute non-compliance if the FDA has approved the label. If she means failure to "warn" the FDA by reporting new safety information, she is essentially reiterating her allegation of non-compliance with the FDA's reporting requirements. Section 202 poses a similar problem; that section governs advertising, which, like the regulations governing post-marketing reporting, does not go to the issue of whether a drug itself complies with the terms of FDA approval.

withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws § 600.2946(5)(a).[8]

If Marsh's allegations do constitute non-compliance within the meaning of the Act, her "claim" that immunity does not apply triggers the same concerns that animated *Buckman* and *Garcia*. Marsh alleges that Genentech failed to submit updated safety information to the FDA as required of all applicants by FDA Form 356h and generally applicable FDA regulations, and thus relies on "federal enactments [a]s a critical element in [her] case." *Buckman*, 531 U.S. at 353. Moreover, this alleged wrong was perpetrated upon the agency, and thus implicates the "inherently federal" relationship described in *Buckman*. *Id.* at 347. Finally, Marsh's suit would require a court to rule on the adequacy of Genentech's post-marketing disclosures to the FDA, which is the kind of "inter-branch[]meddling" that concerned the Court in *Buckman*. *See Garcia*, 385 F.3d at 966. The FDA regulates post-marketing reporting, requiring manufacturers to report, inter alia, "adverse drug experience information," 21 C.F.R. § 314.80(c), and "significant new information . . . that might affect the safety, effectiveness, or labeling of the drug product," *id.* § 314.81(b)(2)(i). The FDA also has the discretionary authority to withdraw approval of a drug based on failure to submit these reports. *Id.* §§ 314.80(j), 314.81(d). Having a court determine whether any non-disclosed information "'may reasonably affect the statement of contraindications, warnings, precautions or adverse reactions in the draft labeling,'" R.1 at ¶ 108 (Page ID #27) (quoting FDA Form 356h), would both usurp the agency's role and go beyond the court's institutional expertise.[9]

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[8]The district court interpreted Marsh's argument as an allegation of fraud. Marsh's contention on appeal that the district court ignored the Act's requirement of compliance with the FDA's approval or held that immunity does not apply only if non-compliance was intentional rather than negligent stems from a misreading of the district court's opinion. The district court never held that a drug's compliance with FDA approval is not a condition precedent to immunity for the manufacturer under the Act, but instead concluded that Marsh was not alleging non-compliance. Nor did the district court hold that only intentional fraud, rather than negligence, could result in a finding of non-compliance. Such a holding would be incorrect. Because the district court did not believe that the non-compliance element was implicated, however, its ruling did not address what is required for a showing of non-compliance.

[9]Because the only alleged act of non-compliance in this case is the manufacturer's failure to comply with generally applicable requirements of disclosure to the agency, we take no position as to whether an allegation of substantive non-compliance that is unique to the terms of approval of a particular drug or that more directly involves a consumer, such as a chemical variance or an inaccurate label, would be preempted under *Garcia*.

We also note that, as in *Garcia*, a claim of non-compliance based on failure to submit safety

The fact that Marsh's substantive claims sound in negligence and strict products liability would not enable her to avoid preemption, because so did the claims in *Garcia*. Marsh alleges that Raptiva was "defective and unreasonably dangerous," R.1 ¶ 128 (Page ID #30), but Michigan has concluded that a drug that is approved by the FDA and is in compliance with that approval is, as a matter of law, "not defective or unreasonably dangerous," Mich. Comp. Laws § 600.2946(5). In order to reach her substantive claim under Michigan law, Marsh must first defeat immunity, and, as noted above, *Garcia* essentially treats this task as a threshold claim that can be preempted. Although Marsh's allegations of failure to report are a "claim" against immunity rather than the substantive basis of her tort claim, *Garcia* conflates the two for preemption purposes; under *Garcia*, the nature of Marsh's underlying substantive claim is immaterial to the preemption analysis.

Finally, Marsh attests that her claim, like the failure-to-warn claim in *Wyeth*, complements rather than conflicts with the FDA's regulatory regime and thus survives preemption. This argument confuses the validity of her substantive claim with the validity of her argument that immunity does not apply. Marsh is correct that *Wyeth* preserves a role for state law in post-marketing enforcement of drug safety; as a general matter, FDA approval of a drug label does not preempt a state common-law failure-to-warn suit premised on the claim that the FDA-approved label is nonetheless inadequate. *See Wyeth*, 555 U.S. at 558–59. Absent the Michigan Act's immunity provision, Marsh could bring such a claim. *Wyeth* does not help plaintiffs in Michigan, however. Although preemption principles do not foreclose state-law failure-to-warn claims once the FDA has approved a drug, Michigan law does so. Absent a successful "claim" that immunity does not apply, the Act prevents Michigan plaintiffs from recovering on the type of claim brought by the plaintiff under Vermont law in *Wyeth*.

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update reports would not be preempted if the FDA itself had found that the manufacturer had failed to report.

C. Affirmative Defense

Marsh argues that immunity is an affirmative defense and thus that the district court should have required Genentech to prove that the dose of Raptiva that Marsh received was in compliance with the FDA's approval when it left Genentech's control before granting immunity to Genentech. Marsh does not cite any authority for the proposition that immunity under the Act is an affirmative defense, but we will assume for present purposes that it is.

If immunity is an affirmative defense, a defendant manufacturer would normally bear the burden of proving that the FDA approved the allegedly defective drug and that the drug was in compliance with that approval when it left the manufacturer's control. A motion to dismiss can be premised on an affirmative defense, however, if "the plaintiff's own allegations show that a defense exists that legally defeats the claim for relief." 5B Charles Alan Wright, Arthur Miller, Mary Kay Kane & Richard Marcus, Federal Practice & Procedure § 1357 at 713 (3d ed. 2004). Here, Marsh's complaint quoted the Act's immunity provision and preemptively alleged non-compliance in order to defeat immunity. After setting forth the allegations that Genentech failed to submit updated safety information, the complaint concludes that "[a]s Raptiva was not in compliance with the United States food and drug administration's approval at the time it left the control of the Defendant, Mich. Comp. Laws § 600.2946(5) will not shield the Defendants from liability in this action." R.1 at ¶112 (Page ID #28) (capitalization omitted). In her response to Genentech's motion to dismiss, Marsh references these allegations and states that she "has pled that Raptiva was not in compliance with its approval at the time it left Defendants control." R.15 at 13 (Page ID #97).

Although the fact that "the plaintiff merely has anticipated the defendant's answer and tried to negate a defense he believes his opponent will attempt to use against him" is generally not enough to merit dismissal based on an affirmative defense, 5B Wright & Miller, Federal Practice & Procedure § 1357 at 713, Marsh anticipated the defense of immunity in a way that shows that her response to the defense lacks merit.

The complaint makes clear that Marsh could not defeat Genentech's arguments for immunity.

IV. CONCLUSION

The State of Michigan has decided to limit the availability of tort remedies against drug manufacturers. As a federal court sitting in diversity, we are of course required to apply Michigan law. We are also bound by our precedent interpreting that law. Even characterized as non-compliance, Marsh's "claim" that Genentech is not entitled to immunity under the Act triggers the same concerns that animated *Buckman* and *Garcia*—it is premised on violation of federal law, implicates the relationship between a federal agency and the entity it regulates, and asks the court to assume a role usually held by the FDA—and is thus preempted. We AFFIRM the judgment of the district court.