[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 12-13263

D.C. Docket No. 8:10-cv-02885-JSM-TGW

ANDREA GUARINO,

Plaintiff - Appellant,

versus

WYETH, LLC,
SCHWARZ PHARMA, INC.,
TEVA PHARMACEUTICALS USA, INC.,

Defendants - Appellees,

Appeal from the United States District Court
for the Middle District of Florida

(June 25, 2013)

Before HULL, WILSON and FARRIS,* Circuit Judges.

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* Honorable Jerome Farris, United States Circuit Judge for the Ninth Circuit, sitting by designation.

WILSON, Circuit Judge:

Plaintiff Angela Guarino appeals the district court's dismissal of her claims against the brand-name manufacturers of the prescription drug Reglan, Wyeth LLC and Schwarz Pharma, Inc. (collectively, the "Brand Manufacturers"), and grant of summary judgment in favor of Teva Pharmaceuticals USA, Inc. (Teva), the manufacturer of its generic equivalent (metoclopramide), on her claims of negligence, strict liability, breach of warranty, misrepresentation and fraud, and negligence per se. Guarino alleges that she developed tardive dyskinesia after taking generic metoclopramide manufactured by Teva for a period of greater than 12 weeks, contrary to administrative guidance issued by the Food & Drug Administration (FDA). We conclude that Guarino's claims against Teva are preempted by federal law and that even if they were not preempted they would fail on the merits. We similarly conclude that Florida law recognizes no cause of action against the brand manufacturer of a drug when a plaintiff admits to having only taken the generic form of that drug. We affirm.

I. Background

The facts are largely undisputed. In May 2007, Guarino received a prescription for metoclopramide, a medication often sold under the brand name Reglan, used to treat symptomatic gastroesophageal reflux and recurrent diabetic gastric stasis. Guarino suffered from abdominal pain and various digestive

problems, and her doctor prescribed metoclopramide in the hope that it would alleviate her symptoms. She took the generic form of the drug from May through August of 2007 and alleges that, as a result of taking the drug for a period of time exceeding twelve weeks, she developed tardive dyskinesia. Tardive dyskinesia is a neurological disorder characterized by abnormal movements of the facial muscles, tongue and limbs. Because use of metoclopramide for prolonged periods is associated with tardive dyskinesia, the FDA has strengthened the warning label for the drug several times. In 2004, three years before Guarino was prescribed the medication, the FDA changed the label to explicitly provide that "[t]herapy should not exceed 12 weeks in duration." And in 2009, two years after Guarino took the medication, the FDA ordered a black box warning—its strongest—cautioning against taking the medication for over twelve weeks.

Guarino sued Teva and the Brand Manufacturers, alleging negligence, strict liability, breach of warranty, misrepresentation and fraud, and negligence per se. The gravamen of her claims was that the defendants failed to adequately warn medical providers of the risks associated with long-term use of metoclopramide. After Guarino filed her complaint, the Supreme Court decided *PLIVA, Inc. v. Mensing*, —— U.S. ——, 131 S. Ct. 2567, 2578 (2011), in which it held that because the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301–399f, mandates that generic manufacturers label their drugs identically to brand-name

drugs, lawsuits against generic manufacturers for failure to warn or for the inadequacy of the drug's labeling are preempted by federal law. The district court then granted Teva's motion to dismiss based upon *Mensing*, holding that Guarino's failure-to-warn claims against Teva were preempted. The district court next granted the Brand Manufacturers' motion for summary judgment, finding that because Guarino never took brand-name Reglan and only took generic metoclopramide, the Brand Manufacturers could not be liable to her because they did not manufacture or sell the product she ultimately used. This appeal followed.

II. Discussion

On appeal, Guarino primarily argues that her negligence claim against Teva is not preempted insofar as it alleges a "failure to communicate" the 2004 label change to medical providers. That is, she no longer claims that Teva's warning labels were themselves inadequate, but now contends that Teva is liable for failing to make medical providers aware of—i.e., failing to *communicate*—the change in labeling. Guarino also avers that the district court erred in granting summary judgment to the Brand Manufacturers on her misrepresentation claim, arguing that because the Brand Manufacturers knew that their warning labels would be relied upon by consumers of the generic formulations of their drugs, they can be held

liable for fraud and misrepresentation even though Guarino never consumed their product.[1] We address each argument in turn.

A. The Generic Manufacturer

We first explain why Guarino's claims against Teva do not survive *Mensing* and are preempted by federal law. We then explain why, even if her claims against Teva were not preempted by federal law, they would fail in any event. "We review a district court's order dismissing a complaint de novo, taking all well-pleaded facts as true and construing them in the light most favorable to the nonmoving party." *Meyer v. Greene*, 710 F.3d 1189, 1194 (11th Cir. 2013).

1. Preemption

The Supremacy Clause of our Constitution establishes that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. In accordance with that principle, when state law conflicts with federal law, state law must give way. *See Odebrecht Const., Inc. v. Sec'y, Fla. Dep't of Transp.*, — F.3d —, No. 12-13958, 2013 WL 1862714, at *3 (11th Cir. May 6, 2013). "Conflict preemption . . . arises in instances where (1) compliance with both federal and state regulations is a physical impossibility, or (2) the

[1] Guarino only challenges the district court's dismissal of her negligence claim against Teva and grant of summary judgment for the Brand Manufacturers on her fraud and misrepresentation claim. She has abandoned all other claims. *See Holland v. Gee*, 677 F.3d 1047, 1066 (11th Cir. 2012).

challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Fresenius Med. Care Holdings, Inc. v. Tucker*, 704 F.3d 935, 939 (11th Cir. 2013) (internal quotation marks omitted).

In *Mensing*, the Supreme Court confronted a case involving the preemption of failure-to-warn claims against a generic manufacturer of metoclopramide. 131 S. Ct. at 2573. The plaintiffs in *Mensing* sued PLIVA after they ingested generic metoclopramide produced by PLIVA and later developed tardive dyskinesia. *Id.* Because "[f]ederal law . . . demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels," the Court held it would be impossible for generic drug manufacturers to unilaterally change their labels to comply with any duty to warn sounding in state law. *Id.* at 2578. State-law failure-to-warn claims against generic manufacturers were therefore preempted. *Id.* ("[I]t was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.").

Applying *Mensing* here, we agree with the district court that Guarino's claims against Teva are preempted by federal law. As explained in *Mensing*, generic manufacturers operate under a "duty of sameness," which requires that their labels be at all times identical to the brand-name label of the same drug. *Id.* at 2576. "Whether a warning is placed on the label on the bottle or in letters to distributors, any state law duty requiring generic manufacturers to act unilaterally

in this area is preempted by federal law." *Morris v. PLIVA, Inc.*, 713 F.3d 774, 776–77 (5th Cir. 2013) (per curiam). Because each of Guarino's claims against Teva is premised upon an allegedly inadequate warning, they are all preempted by federal law.

Guarino's attempt to elude *Mensing* by clothing her allegations as "failure-to-communicate" claims rather than failure-to-warn claims does not alter our analysis. No matter the garb in which she attempts to present them, Guarino's claims are at bottom allegations regarding Teva's failure to warn her of the dangers of long-term metoclopramide use, and they therefore cannot escape *Mensing*'s grasp. As the Fifth Circuit recently stated in rejecting the identical argument that "claims concerning a failure to communicate approved warnings" are not preempted: "On the contrary, *Mensing* forecloses such claims because failure to 'communicate' extends beyond just a label change." *Id.* at 777 (emphasis omitted); *see also Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011) (denying, on remand from the Supreme Court, plaintiff's motion for supplemental briefing arguing failure-to-communicate claim); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011), *cert. denied*, 132 S. Ct. 2103 (2012).

Were we to accept the failure-to-communicate theory, generic manufacturers such as Teva would need to take affirmative action to notify consumers, doctors, or pharmacists of FDA-approved changes to the drug label in order to avoid liability.

Yet "[b]ecause the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead." *Morris*, 713 F.3d at 777; *see Mensing*, 131 S. Ct. at 2576 ("[I]f generic drug manufacturers, but not the brand-name manufacturer, sent [additional communications such as 'Dear Doctor' letters], that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly misleading." (internal quotation marks omitted)). That fact is determinative here. We embrace the Fifth Circuit's reasoning and similarly reject the failure-to-communicate theory of liability, as it is preempted by federal law. *Morris*, 713 F.3d at 777 (explaining that "[u]nder federal law, the inquiry is whether the brand-name manufacturers sent out a warning," and "[b]ecause no brand-name manufacturer sent a warning based on the 2004 label change, the generic manufacturers were not at liberty to do so"); *see also Mensing*, 131 S. Ct. at 2576 ("[W]e conclude that federal law did not permit the Manufacturers to issue additional warnings through Dear Doctor letters.").[2] Where federal and state law

[2] The Sixth Circuit's recent decision in *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013), is not to the contrary. In *Fulgenzi*, the plaintiff alleged that the generic manufacturer failed to update its label when the brand manufacturer strengthened the Reglan warning; therefore, the claim against the generic manufacturer was not preempted because "not only could [the generic manufacturer] have independently updated its labeling to match that of the branded manufacturer . . . it had a federal duty to do so." *Id.* at 584. In the present case, Guarino does not allege that Teva failed to update its label once the Brand Manufacturers strengthened it, so *Fulgenzi* is inapplicable.

conflict, state law must yield. The district court did not err in concluding that Guarino's claims against Teva are preempted.

2. The Learned Intermediary Doctrine

Even if we were to hold that Guarino's claims against Teva were not preempted by federal law, they would fail on the merits. Under Florida law, "it is clear that the manufacturer's duty to warn of [a prescription drug's] dangerous side effects [is] directed to the physician rather than the patient." *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989). That is so because the prescribing physician, acting as a "learned intermediary" between the manufacturer and consumer of the drug, weighs the drug's benefits against its potential harms in deciding whether it is appropriate to the patient's course of treatment. *Id.* "The learned intermediary rule is a corollary to the rule that a manufacturer of prescription drugs or products discharges its duty to warn by providing the physician with information about risks associated with those products." *Christopher v. Cutter Labs.*, 53 F.3d 1184, 1192 (11th Cir. 1995). "Pharmaceutical manufacturers discharge their duty to warn the learned intermediary by way of a package insert which accompanies each vial of vaccine." *E.R. Squibb & Sons, Inc. v. Farnes*, 697 So. 2d 825, 827 (Fla. 1997) (internal quotation marks omitted); *see Buckner v. Allergan Pharms., Inc.*, 400 So. 2d 820, 822 (Fla. Dist. Ct. App. 1981) ("A manufacturer of a dangerous commodity, such as a drug, does have a duty to

warn but when the commodity is a prescription drug we hold that this duty to warn is fulfilled by an adequate warning given to those members of the medical community lawfully authorized to prescribe, dispense and administer prescription drugs." (footnote omitted)).

Guarino does not allege that Teva failed to update its label to incorporate the 2004 FDA label change. It is therefore undisputed that the metoclopramide furnished by Teva included a clear, unambiguous warning that "[t]herapy should not exceed 12 weeks in duration." Neither can Guarino argue that this warning was itself inadequate, because any claim based upon the content of the warning label is preempted pursuant to *Mensing*. *See* 131 S. Ct. at 2578 (explaining that "[f]ederal law . . . demand[s] that generic drug labels be the same at all times as the corresponding brand-name drug labels"). Teva thus satisfied its duty to provide Guarino's physician—the learned intermediary—with information regarding the risks of long-term metoclopramide use. In the present context, that is all Florida law requires. "Whether the physician in fact reads the warning, or passes its contents along to the recipient of the drug is irrelevant." *Farnes*, 697 So. 2d at 827 (internal quotation marks omitted); *see also Buckner*, 400 So. 2d at 823. Ultimately, then, it does not matter whether we treat Guarino's claims against Teva as preempted by federal law or on the merits, because under either mode of

analysis, the same result obtains: Guarino's claims against Teva must fail, and the district court properly granted Teva's motion to dismiss.

B. The Brand Manufacturers

Guarino submits that the district court erred in granting summary judgment for the Brand Manufacturers on the ground that Florida law does not permit the consumer of a generic drug to seek damages from the brand-name manufacturer if the consumer did not ingest the brand-name version of the drug. We review the district court's grant of summary judgment de novo, viewing the evidence and drawing all reasonable inferences in the light most favorable to the nonmoving party. *Latimer v. Roaring Toyz, Inc.*, 601 F.3d 1224, 1232 (11th Cir. 2010). Where, as here, the material facts are undisputed, the question reduces to a legal one, and summary judgment is appropriate if the Brand Manufacturers are entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552 (1986).

Every court in Florida to consider the question has concluded that the brand manufacturer of a prescription drug cannot be held liable for injuries suffered by consumers who ingested only the generic form of a drug. *See Metz v. Wyeth LLC*, 830 F. Supp. 2d 1291, 1293 (M.D. Fla. 2011) ("The vast majority of courts, in Florida and elsewhere, that have addressed the issue now before the Court have consistently held that consumers may not bring claims for negligence, fraud, strict

liability, misrepresentation, or breach of warranty against a brand name pharmaceutical manufacturer when the consumers only ingested generic versions of the drug manufactured by third parties."); *Howe v. Wyeth Inc.*, No. 8:09-CV-610-T-17AEP, 2010 WL 1708857, at *3 (M.D. Fla. Apr. 26, 2010); *Levine v. Wyeth Inc.*, 684 F. Supp. 2d 1338, 1343 (M.D. Fla. 2010); *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-21586, 2009 WL 4924722, at *2 (Fla. Cir. Ct. Dec. 21, 2009); *Sharp v. Leichus*, No. 2004-CA-0643, 2006 WL 515532, at *2 (Fla. Cir. Ct. Feb. 17, 2006), *aff'd*, 952 So. 2d 555 (Fla. Dist. Ct. App. 2007) (per curiam) (affirming without written opinion). As one court explained, "[i]t is well-settled under Florida law that a plaintiff may only recover from the defendant who manufactured or sold the product that caused the injuries in question." *Sharp*, 2006 WL 515532, at *2. We see no reason to doubt this interpretation of the law. *Bravo v. United States*, 577 F.3d 1324, 1326 (11th Cir. 2009) (per curiam) ("[W]e are bound to follow an intermediate state appellate court unless there is persuasive evidence that the highest state court would rule otherwise." (internal quotation marks omitted)); *see McMahan v. Toto*, 311 F.3d 1077, 1080 (11th Cir. 2002). At any rate, no Florida court has recognized a potential cause of action against a brand manufacturer by the consumers of a generic product, and considerations of comity and federalism counsel that we proceed gingerly when venturing into uncharted waters of state substantive law. *See Douglas Asphalt Co. v. QORE, Inc.*, 657 F.3d

1146, 1154 (11th Cir. 2011) ("It is not the function of federal courts to expand state tort doctrine in novel directions absent state authority suggesting the propriety of doing so."). We therefore decline to manufacture such a claim out of whole cloth here.

Although Guarino suggests that the Florida Supreme Court's decisions in *Conley v. Boyle Drug Co.*, 570 So. 2d 275 (Fla. 1990), and *Engle v. Liggett Group, Inc.*, 945 So. 2d 1246 (Fla. 2006) (per curiam), support her novel theory of liability under Florida law, those decisions are actually to the contrary. In *Conley*, the court did permit liability based upon a manufacturer's market share where it was impossible to determine which pharmaceutical manufacturer had actually produced the drug ingested by the plaintiff. 570 So. 2d at 281–83. But the court also made abundantly clear that "an individual defendant may exculpate itself from liability by proving by a preponderance of the evidence that it did not produce or market the type of [pharmaceutical drug] taken by the plaintiff's mother." *Id.* at 286; *see also id.* ("Where a plaintiff can identify a specific tortfeasor as causing her injury and traditional remedies are thus available, we see no reason for resort to a remedy based on the concept of risk contribution."). Thus, and because it affirmatively provides for no liability when we know with certitude that a given manufacturer did not produce the allegedly dangerous product, *Conley* does not cut in favor of liability here, but against it.

Engle offers no solace either. In *Engle*, the Florida Supreme Court affirmed the reversal of judgments against certain cigarette manufacturers in part because "it [was] undisputed that the Liggett defendants did not manufacture or sell any of the products that allegedly caused injury to the individual plaintiff representatives." *Engle*, 945 So. 2d at 1276. Guarino suggests that her case is different from *Engle* because one of her claims sounds in fraud rather than negligence or products liability, but we are not persuaded. Even if we accepted that reading of the law—which we do not—it remains that nothing in *Engle*, *Conley*, or otherwise actually supports the theory upon which Guarino premises her case: that a fraud claim against a defendant known *not* to have manufactured the allegedly offensive product is cognizable under Florida law.[3] And as a matter of fact, we think the better reading of those cases is that the Florida courts have expressly rejected such a view. *See Dietrich*, 2009 WL 4924722, at *2 ("*Engle* and *Conley* are only two more recent cases in a long and unbroken line of Florida authority holding that a product manufacturer cannot be liable, regardless of the claim or theory asserted, when the plaintiff did not use or consume that manufacturer's product."); *see also*

[3] Guarino suggests that the Third District Court of Appeal's decision in *Rey v. Philip Morris, Inc.*, 75 So. 3d 378 (Fla. Dist. Ct. App. 2011), *review denied*, 99 So. 3d 944 (Fla. 2012), supports her view of liability. We disagree. *Rey* permitted a claim of civil conspiracy against a tobacco company to proceed despite the fact that the plaintiff had only used a coconspirator's product. *Id.* at 381–82. "The law of civil conspiracy is striking in its extension of liability to a co-conspirator which may not have caused any direct injury to the claimant." *Id.* at 383. In other words, conspiracy is different. Guarino has not brought a civil conspiracy claim in this case, so the reasoning employed in *Rey* is simply inapposite.

Conley, 570 So. 2d at 286 (explaining that the market-share theory of liability "may not be used in conjunction with allegations of fraud, breach of warranty or strict liability"). We discern no error in the district court's grant of summary judgment in favor of the Brand Manufacturers.

Our conclusion is fortified by the fact that the overwhelming national consensus—including the decisions of every court of appeal and the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product. *See, e.g.*, *Bell v. Pfizer, Inc.*, — F.3d —, No. 12-1674, 2013 WL 2661189, at *3–4 (8th Cir. June 14, 2013) (rejecting negligence, misrepresentation, and fraud claims against the brand manufacturer of metoclopramide, and explaining that that "[a]n overwhelming majority of courts considering this issue . . . have rejected [plaintiff's] theory of liability" (internal quotation marks omitted)); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 182–83 (5th Cir. 2012) (per curiam), *petition for cert. filed*, 81 U.S.L.W. 3519 (U.S. Mar. 7, 2013) (No. 12-1093); *Smith*, 657 F.3d at 423–24 ("The plaintiffs' argument—that the name-brand defendants' liability stems from the fact that the regulatory structure governing name-brand and generic drugs makes it foreseeable that patients and their physicians will rely on the name-brand labels to use and prescribe generic drugs—has been rejected by all but one of the courts that have

considered it."); *Mensing*, 658 F.3d at 867 (expressly reinstating the portion of the opinion holding that brand-name manufacturers cannot be held liable under Minnesota law for damage caused by generic drugs); *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170–71 (4th Cir. 1994); *Gardley-Starks v. Pfizer, Inc.*, — F. Supp. 2d —, No. 4:10-CV-099-SA-JMV, 2013 WL 139900, at *5 (N.D. Miss. Jan. 10, 2013) ("The Court concludes that Mississippi law, consistent with the vast majority of courts to consider this issue, would not recognize a cause of action—however styled—against a brand manufacturer for injuries caused by use of its competitors' generic product."); *see also id.* at *5 n.4 (noting the defendants' citation to "sixty-six decisions applying the law of twenty-three different jurisdictions holding that brand-name manufacturers of a drug may not be held liable under any theory for injuries caused by the use of a generic manufacturer's product"). *But see Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010); *Wyeth, Inc. v. Weeks*, — So. 3d —, No. 1101397, 2013 WL 135753, at *19 (Ala. Jan. 11, 2013), *reh'g granted* (June 13, 2013); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 310 (Cal. Ct. App. 2008). Although only the law of Florida controls the outcome here, the cases denying recovery to plaintiffs bringing claims identical to those we confront in this case are legion, and this mountain of authority steels us in our determination that Florida law does not recognize a claim against the brand manufacturer of a prescription drug when the

plaintiff is known to have consumed only the generic form. We find no error in the district court's grant of summary judgment in favor of the Brand Manufacturers.

III. Conclusion

We affirm the district court's dismissal of Guarino's claims against Teva as preempted by federal law and because, preemption aside, the learned intermediary doctrine prevents Guarino from stating a claim upon which relief can be granted under Florida law. We similarly affirm the district court's grant of summary judgment in favor of the Brand Manufacturers because Florida law does not permit an injured consumer to recover from the brand manufacturer of a prescription drug if the consumer is known to have ingested only the generic form of that drug. We are mindful that the disposition of this case may leave Guarino and those similarly situated without a remedy in cases such as these, but as federal judges we are bound merely to interpret and apply the law as promulgated by Congress and the political divisions of government. *See Mensing*, 131 S. Ct. at 2581–82 (acknowledging "the unfortunate hand that federal drug regulation has dealt [the plaintiffs] and others similarly situated," but noting that "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre" (internal quotation marks omitted)); *see also id.* at 2592 (Sotomayor, J., dissenting) ("If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings. . . . If, however, she takes a generic drug, as occurs 75

percent of the time, she now has no right to sue."). Thus, and insofar as Guarino seeks redress for her injuries, such redress lies with Congress or the Florida legislature, not with this Court.

AFFIRMED.