IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
July 11, 2014
Lyle W. Cayce
Clerk

No. 12-31011

TINA JOHNSON,

Plaintiff – Appellant

v.

TEVA PHARMACEUTICALS USA, INCORPORATED; QUALITEST PHARMACEUTICALS, INCORPORATED; WYETH, L.L.C.; SCHWARZ PHARMA, INCORPORATED; ALAVEN PHARMACEUTICAL, L.L.C.; GENERICS BIDCO I, L.L.C., doing business as Qualitest Pharmaceuticals, Incorporated,

Defendants – Appellees

Appeal from the United States District Court
for the Western District of Louisiana

Before SMITH, DENNIS, and HIGGINSON, Circuit Judges.

HIGGINSON, Circuit Judge:

Tina Johnson filed this products liability suit against generic and brand-name manufacturers of the prescription drug metoclopramide. Johnson alleges that her long-term use of generic metoclopramide caused her to develop a neurological disorder known as tardive dyskinesia, and that manufacturers provided misleading and inadequate warnings as to the risks associated with long-term use of the drug. The district court dismissed Johnson's claims against the brand-name manufacturers under Rule 12(b)(6), granted judgment on the pleadings for the generic manufacturers under Rule 12(c), and denied

Johnson leave to amend her complaint. Because all of Johnson's claims are either preempted by federal law, not viable under Louisiana law, or otherwise fail to state a claim, we AFFIRM the district court's orders.

I. Background

Metoclopramide is a prescription drug approved by the Food and Drug Administration ("FDA") and available in both brand ("Reglan") and generic formulations. From July 2002 until March 2009, Johnson consumed generic metoclopramide to treat digestive problems. In prescribing metoclopramide, Johnson's physicians relied on the drug's warning labels, including the information contained in the drug's package inserts and the Physicians' Desk Reference. Johnson alleges that, as a result of her long-term use of generic metoclopramide, she developed tardive dyskinesia.

In March 2010, Johnson filed this suit against generic and brand-name manufacturers of metoclopramide, including Teva Pharmaceuticals, USA, Inc.; Qualitest Pharmaceuticals, Inc.; and Generics Bidco I, LLC ("Generic Defendants"), and also Wyeth, LLC; Schwarz Pharma, Inc.; and Alaven Pharmaceuticals, LLC ("Brand Defendants"). Johnson alleges that both Generic and Brand Defendants provided inadequate, misleading, and false warnings as to risks associated with long-term use of the drug. Johnson brought claims against Generic Defendants under the Louisiana Products Liability Act ("LPLA") for inadequate warning, design defect, and breach of express warranty. Johnson brought claims against Brand Defendants for breach of warranty, misrepresentation, fraud, and violation of the Louisiana Unfair Trade Practices Act ("LUTPA").

The district court granted Brand Defendants' motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) on the ground that Brand Defendants did not manufacture the generic metoclopramide consumed by Johnson. After dismissing the claims against Brand Defendants, the district court stayed the

claims against Generic Defendants pending the Supreme Court's decision in *PLIVA, Inc. v. Mensing*, —U.S.—, 131 S.Ct. 2567 (2011). Following *Mensing*, the district court granted Generic Defendants' motion for judgment on the pleadings under Rule 12(c), holding that Johnson's claims against Generic Defendants are preempted by federal law. The district court further denied Johnson's request to amend her complaint to add two additional claims and denied Johnson's motion for reconsideration. Johnson timely appealed.

II. Claims Against Generic Defendants

On appeal, Johnson contends that the district court erred in granting Generic Defendants' Rule 12(c) motion for judgment on the pleadings. Johnson further contends that the district court abused its discretion in denying her leave to amend her complaint.

We review a district court's ruling on a Rule 12(c) motion for judgment on the pleadings de novo, using the same standard applicable to a Rule 12(b)(6) motion to dismiss. *Gentilello v. Rege*, 627 F.3d 540, 543-44 (5th Cir. 2010). "To avoid dismissal, a plaintiff must plead sufficient facts to state a claim for relief that is plausible on its face." *Id.* at 544 (internal quotation marks and citation omitted). Additionally, we review a district court's ruling on a motion to amend for abuse of discretion. *Briggs v. Mississippi*, 331 F.3d 499, 508 (5th Cir. 2003). A district court does not abuse its discretion in denying leave to amend if amendment would be futile. *Id.*

a. Failure-to-Warn Claims

In her original complaint, Johnson brought a claim against Generic Defendants for inadequate warning under La. Rev. Stat. Ann. § 9:2800.57. Johnson alleges that generic metoclopramide was "unaccompanied by proper warnings regarding the serious risks associated with ingestion of the drug." The district court concluded that Johnson's claim is preempted by federal law in light of *Mensing*.

In *Mensing*, the Supreme Court held a similar failure-to-warn claim against generic manufacturers of metoclopramide preempted by federal law. *Mensing*, 131 S.Ct. at 2572. The Court reasoned that federal law demands that "generic drug labels be the same at all times as the corresponding brand-name drug labels." *Id.* at 2578. This is known as the "duty of sameness." *Id.* at 2576. "This duty of sameness is overlaid with the agency's pronouncement that 'Dear Doctor' letters (or other forms of warnings) from a generic manufacturer constitute labeling." *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 474 (5th Cir. 2014). Because federal law requires generic drug labels to be the same as brand-name labels, any state-law duty that requires generic manufacturers to use safer labels conflicts with the federal "duty of sameness" and is preempted by federal law. *Mensing*, 131 S.Ct. at 2577, 2578 ("Where state and federal law 'directly conflict,' state law must give way."); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 776-77 (5th Cir. 2013) ("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."); *see also Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 678 (5th Cir. 2014); *Lashley*, 750 F.3d at 747.

The crux of Johnson's failure-to-warn claim alleged in her original complaint appears to be that the warnings accompanying generic metoclopramide were inadequate and that Generic Defendants should have provided stronger warning labels. Because Generic Defendants were unable to provide stronger warnings as a matter of federal law, Johnson's failure-to-warn claim is preempted. *See Mensing*, 131 S.Ct. at 2578. Accordingly, the district court did not err in granting Generic Defendants' motion for judgment on the pleadings for this claim.

Johnson also requested leave to amend her complaint to add two additional failure-to-warn claims. First, Johnson requested leave to add a

claim alleging that Generic Defendants failed to adequately communicate the information contained in the FDA-approved label. In 2004, the FDA approved a label change to warn that "[t]herapy should not exceed 12 weeks in duration." *Mensing*, 131 S.Ct. at 2572. Johnson alleges that Generic Defendants are liable for failing to send "Dear Doctor" letters or similar communications to alert medical providers to the 2004 label change. This claim is controlled by *Morris* and *Lashley*, in which we held nearly identical claims preempted by federal law. *See Morris*, 713 F.3d at 777; *Lashley*, 750 F.3d at 474-75. In *Morris*, we wrote:

> *Mensing* forecloses such claims because failure to "communicate" extends beyond just a label change. To avoid liability, the manufacturer must take affirmative steps to alert consumers, doctors, or pharmacists of changes in the drug label. Because the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead. Under federal law, the inquiry is whether the brand-name manufacturers sent out a warning, not whether the proposed warning to be disseminated contains substantially similar information as the label. Because no brand-name manufacturer sent a warning based on the 2004 label change, the generic manufacturers were not at liberty to do so. As *Mensing* concluded, preemption is thus triggered since it would be impossible for [the generic manufacturer] to comply with both the state law duty to warn and the federal law duty of sameness.

Morris, 713 F.3d at 777 (internal citations omitted).

In this case, Johnson acknowledges that no brand-name manufacturer sent a warning based on the 2004 label change. Accordingly, Generic Defendants were not at liberty to do so. *See id.*; *Lashley*, 750 F.3d at 474-75; *see also Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013). *But see Teva Pharm. USA, Inc. v. Superior Court*, 158 Cal. Rptr. 3d 150, 161-64 (Cal. Ct. App. 2013). Following controlling precedent, we conclude that Johnson's

proposed claim is preempted by federal law, and the district court did not abuse its discretion in denying Johnson leave to add this claim.

Second, Johnson requested leave to add a claim alleging that generic manufacturer Teva failed to incorporate the 2004 label change into its label until 2005. This claim is also controlled by *Morris*. *See Morris*, 713 F.3d at 777; *see also Lashley*, 750 F.3d at 475. In *Morris*, we observed that "it is logically incoherent to conclude that [the generic manufacturer] had a duty to apply the 2004 warning label when Appellants also assert repeatedly that no labels predating 2009 were adequate. Tort liability does not arise for failure to attach an inadequate label." *Morris*, 713 F.3d at 777. We further concluded that "a claim that [the generic manufacturer] breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted." *Id.* In light of *Morris*, we hold that the district court did not abuse its discretion in denying Johnson leave to add this claim.[1]

b. Design-Defect Claim

In her original complaint, Johnson also brought a claim against Generic Defendants for design defect under La. Rev. Stat. Ann. § 9:2800.56. Johnson alleges that "the foreseeable risks of serious harm posed by the drug far outweigh its alleged benefits." To establish a design-defect claim under Louisiana law, a plaintiff must show:

> (1) There existed an alternative design for the product that was capable of preventing the claimant's damage; and (2) The likelihood that the product's design would cause the claimant's

[1] Johnson's proposed failure-to-update claim fails for an additional reason: Johnson does not plausibly allege that Teva's one-year delay in updating its label caused her injuries. Johnson acknowledges that Teva updated its label in July 2005 and that she continued to take metoclopramide until March 2009. Thus, Johnson's doctors continued to prescribe, and she continued to ingest, the drug for almost four years after Teva updated its label. Johnson does not allege any facts indicating that her doctors would not have continued to prescribe, and she would not have continued to consume, metoclopramide had Teva updated its label in 2004 instead of 2005.

> damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

La. Rev. Stat. Ann. § 9:2800.56. The second prong involves a risk-utility analysis. *See Krummel v. Bombardier Corp.*, 206 F.3d 548, 551 (5th Cir. 2000). Louisiana law instructs courts, in conducting this risk-utility analysis, to consider whether the product contains an "adequate warning." *See* La. Rev. Stat. Ann. § 9:2800.56.

For the reasons articulated in *Bartlett*, Johnson's design-defect claim is preempted by federal law. *See Mut. Pharm. Co., Inc. v. Bartlett*, —U.S.—, 133 S.Ct. 2466 (2013) (holding a New Hampshire design-defect claim against generic manufacturers preempted by federal law). Federal law requires a generic drug to have the same chemical composition and labeling as its brand-name counterpart. *Id.* at 2471, 2475 ("[T]he FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based."). Johnson's state-law claim that Generic Defendants should have designed metoclopramide's composition or labeling differently conflicts with these federal requirements. *See id.* at 2475-77. Because Generic Defendants were unable to change metoclopramide's design as a matter of federal law, Johnson's design-defect claim is preempted. *See id.*; *see also Eckhardt*, 751 F.3d at 678-79; *Lashley*, 750 F.3d at 475-76.

Johnson contends that her design-defect claim is not preempted because Generic Defendants could have complied with their duties under both federal and state law by declining to sell metoclopramide. The Supreme Court rejected this "stop-selling" rationale in *Bartlett* as "incompatible with our pre-emption jurisprudence." *Bartlett*, 133 S. Ct. at 2477. "Our pre-emption cases presume

that an actor seeking to satisfy both his federal and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.*

Johnson further contends that her design-defect claim is distinguishable from those that courts have previously found preempted because Louisiana law allows liability for a design defect under the theory that there exists a safer alternative product, not just a safer alternative design. Even assuming this to be the case, Johnson's argument does not save her claim. Johnson did not allege the existence of a safer product in her complaint. Nor did Johnson move to amend on this ground.

For the reasons above, the district court did not err in finding that Johnson's design-defect claim, as alleged in her complaint, is preempted by federal law. The district court properly granted judgment on the pleadings for Generic Defendants on this claim.

c. Express-Warranty Claim

Finally, Johnson brought a claim against Generic Defendants for breach of express warranty under La. Rev. Stat. Ann. § 9:2800.58. Johnson alleges that the metoclopramide manufactured by Generic Defendants was unreasonably dangerous because it did not conform to their express warranties about the product. As discussed above, federal law prohibited Generic Defendants from unilaterally altering the drug's composition or labeling. *See Bartlett*, 133 S.Ct. at 2471, 2475. Any modified or supplemental warranties by Generic Defendants would have run afoul of the "duty of sameness" identified in *Mensing*. "Any state law-based holding that the generic manufacturers should have acted differently with respect to warnings or should have ceased manufacturing these products because of insufficient warnings not only violates the duty of sameness but conflicts with FDA's exclusive authority to approve drugs and drug labels." *Morris*, 713 F.3d at 778 ("A breach of warranty claim that goes directly to the sufficiency of the generic manufacturers'

labeling is clearly unacceptable."); *see also Eckhardt*, 751 F.3d at 680; *Lashley*, 750 F.3d at 475-76; *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 479 (4th Cir. 2014); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1287-89 (10th Cir. 2013). Accordingly, the district court did not err in finding Johnson's breach-of-warranty claim preempted by federal law, and in granting judgment on the pleadings on this claim.

III. Claims Against Brand Defendants

Johnson next contends that the district court erred in dismissing her claims against Brand Defendants under Rule 12(b)(6). Johnson alleges that Brand Defendants are liable for providing false and misleading information and failing to warn medical providers as to the risks associated with long-term use of Reglan. Brand Defendants respond that Johnson's claims are barred by the Louisiana Products Liability Act ("LPLA") because Johnson never ingested Reglan manufactured by Brand Defendants, only generic metoclopramide.

In dismissing Johnson's claims, the district court reasoned that the LPLA provides the exclusive remedy against manufacturers in products liability suits under Louisiana law, and that Johnson could not maintain claims against Brand Defendants under the LPLA because Brand Defendants did not manufacture the generic metoclopramide that caused Johnson's injuries. The district court further reasoned that Johnson's claims also fail because "brand name drug manufacturers do not owe a continuing duty to consumers of the generic drug equivalent."

"We review a district court's decision on a 12(b)(6) motion de novo, accepting all well-pleaded facts as true and viewing those facts in the light most favorable to the plaintiff." *Stokes v. Gann*, 498 F.3d 483, 484 (5th Cir. 2007). To avoid dismissal, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

As a preliminary matter, Johnson moves to certify to the Louisiana Supreme Court the question of whether a brand-name manufacturer can be held liable for injuries caused by a plaintiff's ingestion of a generic product that was neither manufactured nor distributed by the brand-name manufacturer. We may certify a determinative question of Louisiana law to the Louisiana Supreme Court if there is "no clear controlling precedent" of that court. La. Rev. Stat. Ann. § 13:72.1. However, "[a]s a general proposition we are chary about certifying question of law absent a compelling reason to do so." *Jefferson v. Lead Indus. Ass'n, Inc.*, 106 F.3d 1245, 1247 (5th Cir. 1997). Standing alone, "the absence of a definitive answer from the state supreme court on a particular question is not sufficient to warrant certification." *Id.* "Neither is certification a proper avenue to change our binding precedent." *Id.* Furthermore, "[t]he court should be slow to honor a request for certification from a party who chose to invoke federal jurisdiction." *Id.* at 1248 (quoting 17A C. Wright, A. Miller, & E. Cooper, Federal Practice and Procedure § 4248 (2d ed. 1988)).

We conclude that certification is not warranted in this case. Our conclusion is informed by a number of considerations, including this court's prior decision in *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177 (5th Cir. 2012), *cert. denied*, 134 S.Ct. 57 (2013); the numerous other decisions interpreting Louisiana law on this subject;[2] Johnson's decision to file suit in federal court; and the text of the LPLA.

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[2] *See, e.g.*, *Whitener v. PLIVA, Inc.*, No. 10-1552, 2014 WL 1276489, at *6-7 (E.D.La. Mar. 27, 2014); *Cooper v. Wyeth, Inc.*, No. 09-CV-929, 2010 WL 4318816, at *2-3 (M.D.La. Oct. 26, 2010); *Craig v. Pfizer, Inc.*, No. 3:10-00227, 2010 WL 2649545, at *2-4 (W.D.La. May 26, 2010); *Washington v. Wyeth, Inc.*, No. 3:09-CV-01343, 2010 WL 450351, at *2 (W.D.La. Feb. 8, 2010); *Morris v. Wyeth, Inc.*, No. 09-0854, 2009 WL 4064103, at *2-5 (W.D.La. Nov. 23, 2009); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 35 (La. Ct. App. 2008).

Turning to the merits of Johnson's appeal, our prior decision in *Demahy* resolves Johnson's claims against Brand Defendants. In *Demahy*, we addressed nearly identical claims brought by a consumer of generic metoclopramide against brand-name manufacturers, including claims for misrepresentation, fraud, and violation of LUTPA. *Demahy*, 702 F.3d at 180-81. Demahy appealed the district court's denial of her Rule 59(e) motion for relief from the district court's dismissal of her claims against the brand-name manufacturers in light of the Supreme Court's decision in *Mensing*. *Id.* at 182. We affirmed the district court's ruling. In doing so, we reasoned that prior to *Mensing*, Louisiana law did not provide liability against brand-name manufacturers for injuries caused by a plaintiff's ingestion of a generic product, and that nothing in *Mensing* altered this conclusion. *Id.* at 182-84. We wrote:

> The Louisiana Products Liability Act ("LPLA") provides that it is the exclusive remedy for products liability suits, stating that "[a] claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in this Chapter." La. Rev. Stat. Ann. § 9:2800.52. Under the LPLA, recovery is not available against a manufacturer if the manufacturer did not produce the offending product. Thus, according to pre-*Mensing* Louisiana caselaw, Demahy's claims against [the brand-name manufacturers] fail because they did not manufacture the medication she actually consumed.

Id. at 182-83 (internal quotation marks and citations omitted). We further explained that "the Supreme Court's decision in *Mensing* had no effect on Louisiana state law." *Id.* at 184.

Following *Demahy*, we conclude that Johnson's claims against Brand Defendants are foreclosed by the LPLA. Brand Defendants, like the brand-name manufacturers in *Demahy*, are "manufacturers" within the LPLA's exclusivity provision. *See* La. Rev. Stat. Ann. § 9:2800.52 ("A claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in this Chapter."); *see also* La. Rev.

Stat. Ann. § 9:2800.53 (defining "manufacturer" as, *inter alia*, "a person or entity who is in the business of manufacturing a product for placement into trade or commerce"). Johnson argues that Brand Defendants are not "manufacturers" under the LPLA because they did not manufacture the product Johnson consumed. However, we rejected this same argument in *Demahy*. *See Demahy*, 702 F.3d at 183 n.4 ("Demahy argues that the LPLA . . . does not apply to her claims because Wyeth and Schwarz are not 'manufacturers,' given that they have no connection to the product she actually consumed. This argument is unavailing. The vast majority of decisions have held that the LPLA broadly applies to all suits involving injuries from products, and these decisions rejected the argument that common law tort claims can still be brought for injuries stemming from products under facts nearly identical to those in the current case."); *see also Lashley*, 750 F.3d at 477 ("This argument fails because brand defendants are, indeed, manufacturers—and were they not, there would be no relationship on which to presume liability (since they did not design the drug).").

As a result, the LPLA provides Johnson's exclusive remedy against Brand Defendants, and Johnson's non-LPLA claims are barred. *See Demahy*, 702 F.3d at 183. To the extent that Johnson's complaint can be construed as bringing claims against Brand Defendants under the LPLA, these claims fail because "recovery is not available under LPLA against a manufacturer if the manufacturer did not produce the offending product." *Id.* at 182; *see also Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 260-61 (5th Cir. 2002); *Jefferson*, 106 F.3d at 1252. Therefore, consistent with *Demahy*, we hold that Johnson's claims against Brand Defendants fail under Louisiana law because Brand Defendants did not manufacture the medication Johnson consumed.

Also consistent with *Demahy*, we conclude that, even if the LPLA did not apply, Johnson has not established that Brand Defendants owed Johnson a

duty of care. *See Demahy*, 702 F.3d at 183 n.4 ("[E]ven if the LPLA did not apply, Demahy's tort claims would fail since [the brand-name manufacturers] did not manufacture the generic product giving rise to Demahy's claims, and thus owed Demahy no duty of care."); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34-35 (La. Ct. App. 2008) ("[A] name brand drug manufacturer owes no legal duty to the consumer of a generic equivalent of its drug."); *Fricke v. Owens-Corning Fiberglas Corp.*, 618 So. 2d 473, 475 (La. Ct. App. 1993); *see also Solomon v. Walgreen Co.*, 975 F.2d 1086, 1089 (5th Cir. 1992) ("This court is *Erie*-bound to apply state law as it currently exists, and may not change that law or adopt innovative theories of recovery."). Thus, to the extent that Johnson's claims rely on a duty of care, these claims fail for an additional reason as well.[3]

Accordingly, we perceive no error in the district court's dismissal of Johnson's claims against Brand Defendants.

IV. Conclusion

For the foregoing reasons, we AFFIRM the district court's grant of Generic Defendants' motion for judgment on the pleadings, grant of Brand

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[3] Our decision is consistent with other circuit decisions that have held (under the laws of several different states) that brand-name manufacturers are not liable for injuries caused by a plaintiff's ingestion of generic products. *See Eckhardt*, 751 F.3d at 681-82; *see, e.g.*, *Lashley*, 750 F.3d at 476-78 (finding no liability under Mississippi and Texas law); *Guarino v. Wyeth*, LLC, 719 F.3d 1245, 1252 (11th Cir. 2013) (same under Florida law); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1282-85 (10th Cir. 2013) (same under Oklahoma law); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 401-06 (6th Cir. 2013) (same under Tennessee law); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092-93 (8th Cir. 2013) (same under Arkansas law); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423-24 (6th Cir. 2011) (same under Kentucky law), *cert. denied*, 132 S.Ct. 2103 (2012); *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170-71 (4th Cir. 1994) (same under Maryland law). *But see Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 705-09 (D. Vt. 2010); *Wyeth, Inc. v. Weeks*, —So.3d—, 2013 WL 135753, at *19 (Ala. Jan. 11, 2013), *reh'g granted* (June 13, 2013); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 311-18 (Cal. Ct. App. 2008).

Additionally, to the extent that Johnson makes an argument on appeal based on the Louisiana Constitution, Article I, Section 22, Johnson waived this argument by failing to raise it in the district court. *See AG Acceptance Corp. v. Veigel*, 564 F.3d 695, 700 (5th Cir. 2009). We decline to consider this substantive argument for the first time on appeal.

Defendants' motion to dismiss, and denial of leave to amend. We further DENY Johnson's motion for certification.

AFFIRMED.

JAMES L. DENNIS, concurring in part, dissenting in part:

Although I concur in the majority opinion's disposition of Plaintiff-Appellant Tina Johnson's claims against the generic manufacturers, I respectfully dissent from the resolution of Johnson's claims against the brand-name drug manufacturers because I would grant Johnson's motion to certify the question of state law to the Louisiana Supreme Court. Johnson seeks certification to the Louisiana Supreme Court of the question whether, under Louisiana law, a brand-name drug manufacturer may be held liable for harm caused by a consumer's use of the generic manufacturer's equivalent product—a drug that was not directly manufactured by the brand-name pharmaceutical corporation but, as the Supreme Court has explained, must contain labeling and warnings identical to that of the brand-name product under the "duty of sameness." *PLIVA Inc. v. Mensing*, 131 S. Ct. 2567, 2574-75 (2011). The question of whether Louisiana law imposes such liability should be certified to the Louisiana Supreme Court because it implicates significant public policy concerns with potentially grave ramifications, is dispositive as to Johnson's claims against the brand-name defendants, and there is no Louisiana Supreme Court case law available to guide our analysis and only scant lower state court authority that is called into doubt by *Mensing*. *See In re Katrina Canal Breaches Litig.*, 613 F.3d 504, 509 (5th Cir. 2010) ("[C]ertification may be advisable where important state interests are at stake and the state courts have not provided clear guidance on how to proceed." (quoting *Free v. Abbott Labs., Inc.*, 164 F.3d 270, 274 (5th Cir. 1999))); *see also Jesco Const. Corp. v. NationsBank Corp.,* 278 F. 3d 444, 448 (5th Cir. 2001) ("We have [certified a question] in the past when we determined that the issue carried 'tremendous consequences' . . . [or] widespread ramifications . . . .") (internal citations omitted).

The Louisiana Supreme Court has never addressed the extent of brand-name manufacturers' liability to consumers of the generic equivalents. There is only one Louisiana Court of Appeals case on point and it's questionable whether its reasoning stands today. In *Stanley v. Wyeth, Inc.,* 991 So. 2d 31 (La. App. 1st Cir. 2008), the Court of Appeal of Louisiana, First Circuit, held that the plaintiff failed to state a claim against the brand-name manufacturers for negligent misrepresentation because brand defendants do not owe a duty to consumers of the generic equivalent. *Id.* at 33. In holding that brand-name defendants owe no duty to consumers of the generic equivalent, the *Stanley* court reasoned that "a manufacturer cannot reasonably expect that consumers will rely on the information it provides when actually ingesting another company's drug." *Id.* at 34. The court in *Stanley* therefore based its holding on pre-*Mensing* assumptions: that consumers of generic drugs do not rely upon the brand-name manufacturer's representations or warnings as to the risks of harm to consumers, and that a generic manufacturer's "acceptance" of the brand-name manufacturer's label, is something of a choice. *Id.* Such reasoning is belied by *Mensing's* holding that, under federal law, a generic manufacturer's label and communications *must* be the same as the brand-name equivalent, and the generic manufacturer is *prohibited* from unilaterally communicating to consumers any message different than that communicated by the brand name manufacturer. Thus, it is perfectly foreseeable, if not inevitable, that, post-*Mensing,* consumers of generic drugs and their physicians will rely exclusively upon the brand-name manufacturer's label to assess the safety risks of the generic drug equivalent. *Mensing* thus calls *Stanley*—the sole Louisiana Court of Appeal decision on this issue—into

question.[1] Accordingly, the majority's *Erie* guess that, under Louisiana law, a brand-name manufacturer is not liable to a consumer of the generic equivalent for failure to warn rests primarily on a single Louisiana Court of Appeals case, that, after *Mensing*, is questionable, if not erroneous. There is absolutely no post-*Mensing* state law authority on the current state of Louisiana law.

Without any authoritative guidance from Louisiana courts, the majority's opinion completely closes the courthouse doors to Louisiana consumers injured by inadequately labeled generic pharmaceutical products. By declining to certify the question to the Louisiana Supreme Court and affirming the district court's decision below, both generic and brand-name pharmaceutical companies are essentially immunized from private suits by consumers of generic drugs, who make up an overwhelming majority of pharmaceutical consumers. Today, "nearly 8 in 10 of prescriptions are filled with generic drugs. The use of generic drugs is expected to grow over the next few years as a number of popular drugs come off patent through 2015." *See Facts About Generic Drugs*, U.S. FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm (last visited July 9, 2014). The threat of private suits for damages provides substantial incentives to pharmaceutical manufacturers to effectively warn consumers of the safety risks associated with consumption of their products. The majority eviscerates

[1] I acknowledge that, as discussed in Part III of the majority opinion, our court has previously rejected an argument that *Mensing* altered Louisiana law. *Demahy*, 702 F.3d at 183. The *Demahy* decision, however, relies upon our court's and federal district courts' opinions interpreting Louisiana law and nowhere cites any authoritative Louisiana Supreme Court case. *Id.* (citing, *inter alia, Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 260-61 (5th Cir. 2002), and *Possa v. Eli Lilly & Co.*, No. 05-CV-1307, 2006 WL 6393160 (M.D. La. May 10, 2006), for the proposition that "recovery is not available against a manufacturer if the manufacturer did not produce the offending product").

this incentive for brand-name manufacturers, who control the content of the warning labels and communications to the public for both brand and generic drug equivalents, and thus will have "tremendous consequences" for the health and safety of consumers of pharmaceutical products in Louisiana. *Jesco*, 278 F.3d at 448.

Tort claims against the manufacturer of drugs that allegedly inadequately warn the consumer as to potential risks are common. Given the nature of the parties involved,—Louisiana has many consumers of generic drugs but is home to few, if any, drug manufacturers—cases raising this issue will invariably be litigated in federal court, pursuant to diversity jurisdiction. *See* 28 U.S.C. §§ 1332, 1441. Therefore, by denying Johnson's motion to certify the question to the Louisiana Supreme Court, the majority ensures that federal courts facing the issue will continue down this uncharted path of attempting to interpret a true "creature of state law," *Rubino v. Lynaugh*, 845 F.2d 1266, 1275 (5th Cir. 1988), in the absence of any authoritative precedent, effectively barring the Louisiana Supreme Court the opportunity to articulate the meaning of its own tort law relating to the health and protection of Louisiana citizens, and thereby offending basic principles of comity.

Lastly, as Johnson notes in her motion to certify, an identical question was recently certified to the Alabama Supreme Court by the United States District Court for the Middle District of Alabama. Despite federal precedent interpreting Alabama law as precluding liability for brand-name defendants, once the question was certified, the Alabama Supreme Court concluded, contra to the earlier federal court decisions, that brand-name defendants *are liable* to consumers of the generic equivalent product for failing to provide adequate warnings. The Alabama Supreme Court discussed *Mensing* and its implications in concluding that under Alabama law, "a brand-name drug

company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company." *Wyeth, Inc. v. Weeks*, No. 11-01397, 2013 WL 135753 (Ala. Jan. 11, 2013), *reh'g granted* (June 13, 2013). The Alabama Supreme Court's answer to the certified question rejected federal courts' contrary decisions applying Alabama law, which had "held that Alabama law does not allow a person who consumed a generic version of a brand-name drug to sue the brand-name manufacturer based on fraudulent misrepresentation." *Id.* at *9-10 (discussing and rejecting, for example, *Overton v. Wyeth, Inc.,* No. CA 10-0391, 2011 WL 1343392 (S.D. Ala. 2011) (unpublished), because the *Overton* court's "conclusion that a generic manufacturer becomes responsible for its own warning label . . . is incorrect" in light of *Mensing*). The Louisiana Supreme Court should be afforded the same opportunity, particularly given the lack of a state Supreme Court case and the significant impact that this panel's decision will have on Louisiana citizens' ability to seek redress for serious bodily injury caused by the consumption of an allegedly inadequately labeled generic drug.

In conclusion, because there is no precedent from the Louisiana Supreme Court on this case-dispositive issue, the prior Louisiana case law is based on reasoning now undermined by *Mensing*, and the question implicates significant public policy concerns with potentially severe ramifications for the people of Louisiana, I respectfully dissent from the majority opinion's resolution of Johnson's claims against the brand-name manufacturers and would grant Johnson's motion to certify the question to the Louisiana Supreme Court.