UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 15-1806

KIMMY MCNAIR; LARRY MCNAIR,

Plaintiffs – Appellants,

v.

JOHNSON & JOHNSON, a foreign corporation; JANSSEN PHARMACEUTICALS, INCORPORATED, a foreign corporation; ORTHO-MCNEIL PHARMACEUTICAL, INCORPORATED, a foreign corporation,

Defendants – Appellees.

Appeal from the United States District Court for the Southern District of West Virginia, at Charleston. John T. Copenhaver, Jr., District Judge. (2:14-cv-17463)

Argued: January 25, 2017 Decided: May 30, 2017

Before NIEMEYER, TRAXLER, and WYNN, Circuit Judges.

Question certified to the Supreme Court of Appeals of West Virginia by unpublished order. Judge Traxler prepared the order, in which Judge Niemeyer and Judge Wynn joined.

ARGUED: Richard David Lindsay, TABOR LINDSAY & ASSOCIATES, Charleston, West Virginia, for Appellants. John Winter, PATTERSON BELKNAP WEBB & TYLER LLP, New York, New York, for Appellees. **ON BRIEF:** Matthew C. Lindsay, TABOR LINDSAY & ASSOCIATES, Charleston, West Virginia, for Appellants. Daniel

R. Higginbotham, THOMAS COMBS & SPANN, PLLC, Charleston, West Virginia, for Appellees.

ORDER OF CERTIFICATION TO THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

TRAXLER, Circuit Judge:

Pursuant to West Virginia's Uniform Certification of Questions of Law Act, *see* W. Va. Code § 51-1A-1 *et seq.*, we hereby request that the Supreme Court of Appeals of West Virginia exercise its discretion to answer the following certified question of law:

> Whether West Virginia law permits a claim of failure to warn and negligent misrepresentation against a branded drug manufacturer when the drug ingested was produced by a generic manufacturer.

The answer to the foregoing question of West Virginia law may be determinative of the action presently before us. As set forth below, there appears to be no controlling precedent in West Virginia that directly addresses this issue or provides sufficient guidance for us to dispose of this question. In support of our request, we briefly describe the relevant facts and legal issues in the matter before us.

I.

This case involves the drug levofloxacin. The patent for this drug had been held by Janssen Pharmaceuticals and marketed under the trade name of Levaquin®.[1] Janssen produced the warnings that accompanied the distribution of Levaquin. When Janssen's

[1] The McNairs also named as defendants Ortho-McNeil Pharmaceutical, Inc., which originally held the patent for levofloxacin before transferring its assets to Janssen, and Johnson & Johnson, Janssen's parent company.

patent expired, other companies began manufacturing and distributing generic versions of levofloxacin. When they did so, federal law required the generic manufacturers to use the exact same warnings Janssen produced. No additions or subtractions were permitted by the generic manufacturers.

Kimmy and Larry McNair filed an action in West Virginia state court against Janssen Pharmaceuticals, alleging that in March 2012, Kimmy developed acute respiratory distress syndrome ("ARDS") after taking the drug levofloxacin, which had been given to her along with warning information prepared by Janssen. The McNairs assert that Janssen was aware that ARDS had been linked to the use of levofloxacin but negligently failed to include this fact in its warnings, knowing that this omission would exist not only in its own distribution of Levaquin, but also in the warnings accompanying the distribution of the generic versions. The McNairs' theory of liability is that even though Kimmy took a generic version manufactured by Dr. Reddy's Laboratories, Janssen had exclusive control of the content of the warnings that went out to the public and to health care providers for both the name brand drug and the generic forms and therefore Janssen is liable for injuries caused by the lack of warning that levofloxacin might induce ARDS.

Janssen removed the action to federal court on diversity grounds. *See* 28 U.S.C. § 1332(a)(1); 28 U.S.C. § 1441(b). Janssen then moved for summary judgment, arguing that it could not be liable for a drug it did not manufacture or distribute because, under West Virginia law, a "manufacturer's culpability in a product liability case is tied to conduct associated with designing or manufacturing a defective product." J.A. 70

(internal quotation marks omitted). The McNairs conceded that Janssen did not manufacture or distribute the generic drug that Kimmy ingested, but they nonetheless urged the district court to hold Janssen liable, alleging that Janssen alone made the decision to omit the warning about ARDS and no one else had the power to put it into the labeling.

The McNairs also pointed out that federal law precluded a suit against Dr. Reddy's Laboratories based on a lack of warning because the generic manufacturer was forbidden to change the warning in any way from that which Janssen prepared. Dismissal of the case against Janssen, which drafted the warning information to start with, would mean no one would ever be liable for the misinformation that allegedly caused Kimmy's injury.

The district court concluded that West Virginia law does not permit "a plaintiff who consumes a generic [to] instead sue the brand-name manufacturer that produced the [original] formula for the drug and warning label in the first instance." J.A. 107. The district court noted that this court twenty years ago "rejected 'the contention [under Maryland law] that a name brand manufacturer's statements regarding its drug c[ould] serve as the basis for liability for injuries caused by another manufacturer's drug.'" J.A. 107 (quoting *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994)). The district court further observed that every other circuit court of appeals to consider this issue had arrived at the same conclusion—a brand-name manufacturer cannot be held liable for injuries caused by the ingestion of a generic produced by a third party. Finally, having compared this weight of authority to West Virginia law, the district court held that

"[t]here is no reason to think the outcome would be any different under West Virginia law." J.A. 109. The court dismissed the McNairs' action, and they appealed.

II.

Pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), "drug manufacturers must gain approval from the United States Food and Drug Administration (FDA) before marketing any drug in interstate commerce." *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013); *see* 21 U.S.C. § 355(a). A company that creates and develops a new brand-name drug must submit a new drug application ("NDA") to obtain FDA approval. *See* 21 U.S.C. § 355(b). The Supreme Court has described the "process of submitting an NDA" as "both onerous and lengthy," *Bartlett*, 133 S. Ct. at 2471, requiring the presentation of complete reports of clinical trials and nonclinical studies, as well as any other relevant information regarding the effectiveness and safety of the new drug, *see* 21 U.S.C. § 355(b)(1); *Bartlett*, 133 S. Ct. at 2470-71. The manufacturer must also submit proposed labeling for the drug. *See* 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. §§ 314.50(c)(2)(i), (e). Before approving an NDA, the FDA must find that the new branded drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d). The FDA will reject the proposed labeling if "based on a fair evaluation of all material facts, such labeling is false or misleading in any particular." *Id.*; 21 C.F.R. § 314.105(b).

The approval process required of generic drugs is far less demanding. Once the patent expires for a pioneer drug, a pharmaceutical company seeking to market a generic version of the drug must submit an Abbreviated New Drug Application ("ANDA"), in

which they may "rely on the clinical studies performed by the pioneer drug manufacturer" instead of having "to prove the safety and effectiveness of its generic drug from scratch." *aaiPharma, Inc. v. Thompson*, 296 F.3d 227, 231 (4th Cir. 2002). All a generic manufacturer must show is that: (1) the generic drug is "chemically equivalent to the approved brand-name drug," (2) the generic drug is "bioequivalent" to the brand-name drug, and (3) "the labeling proposed for the new drug is the same as the labeling approved for the . . . brand-name drug." *Bartlett*, 133 S. Ct. at 2471 (internal quotation marks and alterations omitted); *see* 21 U.S.C. § 355(j)(2)(A)(ii)-(v).

After a drug is approved by the FDA, "the manufacturer is prohibited from making any major changes to the qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application. *Generic manufacturers* are also prohibited from making any unilateral changes to a drug's label." *Bartlett*, 133 S. Ct. at 2471 (emphasis added; internal citation and quotation marks omitted); *see* 21 C.F.R. §§ 314.94(a)(8)(iii); 314.150(b)(10) (approval for a generic drug may be withdrawn if the generic drug's label "is no longer consistent with that for [the brand-name] drug"). Federal law "require[s] that the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of sameness." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) (internal quotation marks omitted).

This ongoing duty of sameness makes it impossible for a generic manufacturer to comply with any state law duty to strengthen the warnings on its labels. And, "where it is impossible for a private party to comply with both state and federal requirements," then

state law is preempted to the extent it conflicts with federal law. *Id.* at 618 (internal quotation marks omitted); s*ee Bartlett*, 133 S. Ct. at 2477 ("Because it is impossible for [the manufacturer of a generic drug] . . . to comply with both state and federal law, New Hampshire's warning-based design-defect cause of action is pre-empted with respect to FDA-approved drugs sold in interstate commerce."); *see also Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 476 (4th Cir. 2014). But while a state law failure-to-warn claim against a generic manufacturer is preempted, such claims are *not preempted* as to the warnings on a brand-name drug distributed by a brand-name manufacturer, which can "unilaterally strengthen its warning." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

III.

With these principles in mind, we turn to the question at issue in this case—whether, under West Virginia law, a brand-name manufacturer can be held liable on a failure-to-warn claim where the plaintiff ingested a generic substitute and therefore has no remedy against the manufacturer of the generic drug. The Supreme Court of Appeals of West Virginia has not decided this issue, and the parties reasonably disagree as to how the Supreme Court of Appeals would resolve the question.

The McNairs argue that under West Virginia products liability law, a manufacturer can be held liable where the product at issue was defective when it left the manufacturer. *See Dunn v. Kanawha County Bd. of Educ.*, 459 S.E.2d 151, 157 (W. Va. 1995) ("Product liability law in this State permits a plaintiff to recover where the plaintiff can prove a product was defective when it left the manufacturer and the defective product was the proximate cause of the plaintiff's injuries."). The McNairs describe the product

at issue in this case as the generic levofloxacin Mrs. McNair ingested and its accompanying warning label, which Janssen produced. The McNairs contend that under the FDCA, brand-name manufacturers are solely responsible for the content of the branded drug's label, which, in turn, establishes the content of the generic drug's label as a result of the "sameness" requirement. The warning label produced by Janssen, the McNairs argue, contained inadequate warnings and, thus, was defective when it left the generic manufacturer.

Moreover, the McNairs argue that the "duty of sameness" results in physicians relying upon Janssen's warning label when prescribing the generic drug and individuals doing the same when deciding to ingest the generic drug, giving rise to Janssen's responsibility to warn those physicians and consumers adequately. The McNairs note that this responsibility is all the more important due to state laws, like that in West Virginia, which compel pharmacists to fill prescriptions for brand-name drugs with generic equivalents. *See, e.g.*, W. Va. Code § 30-5-12b(b) ("A pharmacist who receives a prescription for a brand name drug . . . shall substitute a less expensive generic name drug . . . unless in the exercise of his or her professional judgment the pharmacist believes that the less expensive drug is not suitable for the particular patient [or] . . . the prescribing practitioner indicates that . . . a specific brand name drug is medically necessary."). The McNairs allege that Janssen failed to warn consumers of the generic drug of the risk of ARDS, proximately causing Mrs. McNair's injury. Thus, the McNairs ask us to find that Janssen can be held liable under West Virginia law because Janssen was solely responsible for the inadequate warning label that accompanied the generic

levofloxacin, and the generic manufacturer was powerless to change it, rendering the product that injured Mrs. McNair defective when it left the manufacturer.

The McNairs' theory of liability is not entirely without support. A few courts have held that the brand-name manufacturer may be liable for failure to warn when the plaintiff's injury was caused by the generic drug, basing their decisions largely on the foreseeability of physicians' and patients' reliance upon the brand-name manufacturer's warning label. *See Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 320–21 (Cal. Ct. App. 2008) (holding that, under California law, the brand-name manufacturer owes a duty of care to patients who ingest the generic drug);[2] *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010) (concluding, under Vermont law, that brand-name manufacturers owe a duty of care to physicians who prescribe and patients who ingest the generic drug); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 676–77 (Ala. 2014) (holding that a brand-name manufacturer could be liable for failure to warn claims brought by plaintiffs who ingested the generic drug), *superseded by statute*, Ala. Code § 6-5-530(a) ("In any civil action for personal injury, death, or property damage caused by a product, regardless of the type of claims alleged or the theory of liability asserted, the plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product.").

[2] The rule announced in *Conte* is at issue in a separate appeal pending before the Supreme Court of California. *H. (T.) v. Novartis Pharm. Corp.*, 371 P.3d 241 (Cal. 2016).

Our court addressed this issue well before the Supreme Court decided *Mensing* and *Bartlett*, which preempted state-law failure to warn and design defect claims against generic drug manufacturers. In *Foster v. American Home Products Corporation*, we held that under Maryland law, "a name brand manufacturer cannot be held liable on a negligent misrepresentation theory for injuries resulting from use of another manufacturer's [generic substitute]." 29 F.3d 165, 167 (4th Cir. 1994). *Foster*'s reasoning, in large part, was that

> a manufacturer of generic products is responsible for the accuracy of labels placed on its products. Although generic manufacturers must include the same labeling information as the equivalent name brand drug, *they are also permitted to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval. 21 C.F.R.§ 314.70 (1993).* The statutory scheme governing premarketing approval for drugs simply does not evidence Congressional intent to insulate generic drug manufacturers from liability for misrepresentations made regarding their products, or to otherwise alter state products liability law. Manufacturers of generic drugs, like all other manufacturers, are responsible for the representations they make regarding their products.

Id. at 170 (emphasis added). Of course, after *Mensing* and *Bartlett*, it is no longer the case that generic manufacturers can alter FDA-approved labels. *See Drager*, 741 F.3d at 476 ("[*Mensing* and *Bartlett*] establish that under the FDCA a generic may not unilaterally change its labeling or change its design or formulation."). This court has not revisited the question presented today since *Foster*.

Nonetheless, as the district court recognized, even after *Mensing* and *Bartlett*, the overwhelming weight of federal precedent favors no liability against the brand-name manufacturer, leaving plaintiffs who ingest generic drugs with no legal recourse for injuries caused by inadequate warning labels or defective drug designs. *See, e.g.*,

Johnson v. Teva Pharm. USA, Inc., 758 F.3d 605, 616 n.3 (5th Cir. 2014) ("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."); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1286 (10th Cir. 2013) (predicting the Oklahoma Supreme Court would not hold that "brand-name manufacturers can be held liable for injuries caused by their generic counterparts"); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1253 (11th Cir. 2013) ("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."); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 405 (6th Cir. 2013) ("The plaintiffs have presented no authority indicating that manufacturers of a brand-name drug have a duty under Tennessee law to consumers of the brand-name manufacturers' competitors, and we are loath to expand Tennessee's substantive law without direction from the Tennessee Supreme Court."); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1093 (8th Cir. 2013) ("Because Bell never used . . . the brand defendants manufactured, Bell cannot hold them liable under Arkansas law.").

IV.

For us to decide this issue, we would have to speculate as to how the Supreme Court of Appeals of West Virginia would rule in an area of law where it has not spoken directly and where its precedent leaves open the possibility that brand-name manufacturers may be liable for failure to warn when a plaintiff ingests the generic drug. Therefore, pursuant to the certification process provided by the State of West Virginia,

we seek guidance from the Supreme Court of Appeals of West Virginia on the controlling question of West Virginia law, which we identify as follows:

> Whether West Virginia law permits a claim of failure to warn and negligent misrepresentation against a branded drug manufacturer when the drug ingested was produced by a generic manufacturer.

We acknowledge that the Supreme Court of Appeals of West Virginia may reformulate the question. All of the parties in this matter are represented by counsel, whose names and addresses are provided hereunder.

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V.

Accordingly, pursuant to the privilege made available under West Virginia law as described above, we hereby order: (1) that the question set forth herein be certified to the Supreme Court of Appeals of West Virginia for answer; (2) that the Clerk of this Court transmit to the Supreme Court of Appeals of West Virginia, under the official seal of this Court, a copy of this Order of Certification; and (3) that the Clerk of this Court forward in addition the original or copies of the record before this Court, in all or in part, as requested by the Supreme Court of Appeals of West Virginia, any and all such requests

being effective upon notification by ordinary means from the Clerk of the Supreme Court of Appeals of West Virginia.

QUESTION CERTIFIED