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File Name: 14a0134p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

In re: DARVOCET, DARVON, AND PROPOXYPHENE PRODUCTS LIABILITY LITIGATION.

YANISE GERMAIN, et al.,

Plaintiffs-Appellants,

v.

TEVA PHARMACEUTICALS, USA, INC., et al.,

Defendants-Appellees.

Nos.: 12-5368/ 5369/ 5370/ 5547/ 5596/ 5641/ 5840/ 5890/ 5893/ 5927/ 5928/ 5929/ 5930/ 5981/ 5993/ 6007/ 6094/ 6096/ 6103/ 6107/ 6109/ 6111/ 6112/ 6125/ 6126/ 6149/ 6245/ 6246/ 6247/ 6369/ 6380/ 6381/ 6391/ 6393/ 6394/ 6395/ 6396/ 6397/ 6402/ 6403/ 6405/ 6406/ 6408/ 6409/ 6421/ 6422/ 6423/ 6426/ 6427/ 6428/ 6431/ 6482/ 6503/ 6571/ 13-5058/ 5126/ 5175/ 5387/ 5449/ 5450/ 6116/ 6117/ 6118/ 6119/ 6120/ 6121/ 6123/ 6124

Appeal from the United States District Court
for the Eastern District of Kentucky at Covington.
No: 2:11-md-226—Danny C. Reeves, District Judge.

Argued: May 7, 2014

Decided and Filed: June 27, 2014

Before: SUHRHEINRICH, ROGERS, and SUTTON, Circuit Judges.

COUNSEL

ARGUED: Louis M. Bograd, CENTER FOR CONSTITUTIONAL LITIGATION, P.C., Washington, D.C., for Appellants. Jay P. Lefkowitz, KIRKLAND & ELLIS LLP, Washington, D.C., for Generic Appellees. Henninger S. Bullock, MAYER BROWN LLP, New York, New York, for Brand Appellees. **ON BRIEF:** Louis M. Bograd, CENTER FOR CONSTITUTIONAL LITIGATION, P.C., Washington, D.C., Richard W. Schulte, WRIGHT & SCHULTE, Dayton, Ohio, Dianne M. Nast, NAST LAW, LLC, Philadelphia, Pennsylvania, for Appellants. Jay P. Lefkowitz, John K. Crisham, KIRKLAND & ELLIS LLP, Washington, D.C., Lori G. Cohen, Victoria D. Lockard, GREENBERG TRAURIG LLP, Atlanta, Georgia, Mark S. Cheffo, Rachel B. Passaretti-Wu, Lincoln Davis Wilson, QUINN EMANUEL URQUART & SULLIVAN LLP, New York, New York, Bryan T. Pratt, SHOOK, HARDY & BACON L.L.P., Kansas City, Missouri, Carolyn Taylor, Tammara N. Tukloff, MORRIS POLICH & PURDY, LLP, San Diego, California, Summer H. McMillan, BAKER, DONELSON, BEARMAN,

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OPINION

SUHRHEINRICH, Circuit Judge. These appeals arise from a multidistrict litigation action consolidating sixty-eight claims against both generic and brand-name manufacturers for personal injuries related to the use of the drug propoxyphene (brand-name Darvocet or Darvon). Each plaintiff in this appeal (collectively "Plaintiffs") ingested the generic form of the drug (with one exception), and each plaintiff alleges that the manufacturers and sellers of the generic form ("Generic Manufacturers") continued marketing propoxyphene products after they knew or should have known the risks of the drugs exceeded their benefits. Most of the plaintiffs also seek to hold one or more of the manufacturers and sellers of the brand form ("Brand Manufacturers") liable for injuries, alleging that they made misrepresentations about propoxyphene, which led Plaintiffs' physicians to prescribe the generic equivalent of propoxyphene to Plaintiffs. The district court granted the various defendants' motions to dismiss or for judgment on the pleadings and entered final judgment in each case. We affirm the district court entirely, except for its holding regarding the claims in *Dickerson*, which we reverse and remand for further proceedings.

I. BACKGROUND

A. Statutory and Regulatory Background

Under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, drug manufacturers must gain approval from the United States Food and Drug Administration ("FDA") before marketing any drug in interstate commerce. § 355(a). A manufacturer seeking

approval to market a new drug must submit a New Drug Application ("NDA"), including "full reports of [all clinical] investigations," § 355(b)(1)(A), relevant nonclinical studies, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source." 21 C.F.R. §§ 314.50(d)(2) and (5)(iv) (2014). An NDA must also include "the labeling proposed to be used for such drug," 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. § 314.50(c)(2)(i) and "a discussion of why the [drug's] benefits exceed the risks under the conditions stated in the labeling," 21 C.F.R. §§ 314.50(d)(5)(viii); 314.50. The FDA may approve an NDA only if it determines that the drug is "safe for use" under "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d). In deeming a drug safe, the FDA makes a judgment that the drug's "expected therapeutic gain justifies the risk entailed by its use." *United States v. Rutherford*, 442 U.S. 544, 555 (1979).

Originally, the same rules applied to all drugs, including generic drugs, which are designed to be copies of a previously approved "reference listed drug" ("RLD"). Because the process of submitting an NDA is onerous, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly called the "Hatch-Waxman Act," to "'make available more low cost generic drugs by establishing a generic drug approval procedure.'" *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011) (citing H.R. Rep. No. 98-857, pt. 1, p. 14 (1984)). Under the Hatch-Waxman Act, a generic drug may be approved by an abbreviated new drug application ("ANDA") showing that the drug is equivalent to its RLD and that "the [safety and efficacy] labeling proposed . . . is the same as the labeling approved for the [brand-name] drug." 21 U.S.C. § 355(j)(2)(A)(v).

As a drug is used more widely under diverse conditions, new information regarding the risks and benefits of the drug may become available. All NDA (brand) and ANDA (generic) holders must monitor and review post-marketing adverse drug experience information, from all sources, and comply with FDA post-marketing report requirements. *See* §§ 355(j)(2)(A)(v); § 355(j)(4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7). If significant new adverse information comes to light, the FDA may withdraw approval of the drug, 21 U.S.C. § 355(e), or advise the manufacturer to remove the product from the market. Br. of U.S. as Amicus Curiae Supporting

Petitioner ("FDA Br."), *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013) (No. 12-142), 2013 WL 314460, at *5 (U.S. Jan 22, 2013). In other situations, new information changing the risk/benefit profile of the drug may be addressed through labeling changes. *Id*.

The FDA has created procedures by which manufacturers can make changes to a drug's approved labeling or other changes to an approved application. Drug manufacturers may submit either "Prior Approval Supplements," which require FDA approval before the proposed change may be implemented, or "Changes Being Effected" ("CBE") Supplements, under which the proposed change may be implemented before the FDA has acted on the supplemental application. 21 C.F.R. § 314.70(b), (c). While most changes to a drug's approved labeling must be requested through a Prior Approval Supplement, manufacturers may "add or strengthen a contraindication, warning, precaution, or adverse reaction" through a CBE supplement. *See* §§ 314.70(b)(1)(i), § 314.70(c)(6)(iii)(A).

Under current regulations, brand-name and generic manufacturers have different labeling responsibilities, even though both are authorized to use the label supplement procedures. 21 C.F.R. § 314.97. Generic manufacturers are subject to the requirement that their labeling match that of the RLD, *Mensing*, 131 S. Ct. at 2575, and may invoke the CBE process only "to match an updated brand-name label or to follow the FDA's instructions." *Id*. As a result, while a brand-name manufacturer is responsible for the accuracy and adequacy of its label, *see, e.g.*, 21 U.S.C. §§ 355(b)(1), (d), a generic manufacturer is responsible for ensuring that its warning label is the same as the brand-name's. *See, e.g.*, §§ 355(j)(2)(A)(v); § 355(j)(4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7). This is commonly known as the "duty of sameness."

B. Regulatory History of Propoxyphene

In 1957, the FDA approved propoxyphene for the treatment of mild to moderate pain, under the trade name Darvon, patented and manufactured by Eli Lilly and Company ("Lilly"). In 1972, Lilly obtained FDA approval to market a second product combining propoxyphene with acetaminophen, under the trade name Darvocet. Following passage of the Hatch-Waxman Act in 1984, several companies obtained approval to market generic versions of both Darvon and Darvocet. Lilly sold its NDAs for Darvon and Darvocet to NeoSan in 2002, which in turn sold them to Xanodyne in 2005.

Complaints about perceived risks associated with propoxyphene began in 1978 with a citizen petition by the Health Research Group, and have continued over the ensuing decades, including various clinical and non-clinical studies, post-marketing adverse event data, and the decision of the United Kingdom to withdraw propoxyphene from the market. In 2006, the Health Research Group again petitioned for withdrawal of the drug and presented to two FDA advisory committees. Those committees recommended withdrawing propoxyphene from the market, but the FDA did not follow the advisory committee's recommendation, determining that available data did not warrant market withdrawal.

Instead, the FDA ordered Xanodyne, then the NDA holder for Darvon and Darvocet, to change the approved propoxyphene label to include certain warnings on the drug's package insert, called "Black Box" warnings. The FDA also directed Xanodyne to undertake a clinical trial (the "Xanodyne study") to assess the risks of a particular cardiac complication in 2009. In November 2010, following review of the initial data generated by the Xanodyne study linking propoxyphene use to risk of heart rhythm abnormalities, the FDA determined that the risks of propoxyphene outweighed its benefits. Concurrently, the FDA asked all manufacturers to withdraw propoxyphene from the market, and the manufacturers complied. All Plaintiffs in these cases allege that they ingested propoxyphene products prior to the FDA's requested withdrawal of the drug in 2010. Plaintiffs also allege that they ingested propoxyphene products between the FDA's direction to conduct the Xanodyne Study in 2009 and its request to withdrawal the drug in 2010.

C. Supreme Court Landscape

The Supreme Court has explained the interplay between state tort law and FDA regulated products a number of times in recent years.

Three of these cases involved medical devices and vaccines. First, in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), patients injured from the implantation of orthopedic bone screws alleged that the manufacturer of the screws made fraudulent representations to the FDA. Rejecting those claims, the Court held that state law "fraud on the FDA" claims are impliedly preempted by the FDCA, because the federal government has exclusive jurisdiction to enforce the Act. *Id*. at 353. In 2008, the Court considered state law

claims by cardiac patients against the manufacturers of balloon catheters used in heart surgery, a type of medical device that receives premarket approval from the FDA. *Reigel v. Medtronic, Inc.*, 552 U.S. 312 (2008). Affirming the dismissal of the patients' claims, it held that state law claims challenging the safety or effectiveness of such devices are preempted by the Medical Device Amendments ("MDA") to the FDCA. *Id*. at 330. In 2011, the Court considered state law claims by the parents of a child injured after receiving a dose of diphtheria-tetanus-pertusis vaccine. *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011). It held that the National Childhood Vaccine Injury Act preempts all state design defect claims against the manufacturers of vaccines. *Id*. at 1075.

The other three cases dealt directly with labeling in the prescription drug context. In these cases, the Supreme Court's rulings have created different liability rules for generic drug manufacturers than for brand-name drug manufacturers. In *Wyeth v. Levine*, 555 U.S. 555 (2008), the Court held that state failure-to-warn claims against brand manufacturers are not preempted. It reasoned that brand manufacturers can unilaterally comply with both state and federal law obligations to add or strengthen label warnings through the CBE process when they become aware of new risks associated with their products. *Id*. at 581.

By contrast, in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the Court held that state failure-to-warn claims against generic manufacturers are preempted. The Court reasoned that because generic manufacturers are bound by the "duty of sameness" to copy the labels of their brand counterparts, they are unable to take unilateral action to adjust the labels even when they become aware of new information adjusting the drug's risk calculus. *Id*. at 2582. Last year, in *Mutual Pharmacy Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013), the Supreme Court reaffirmed *Mensing* and found that state "design defect" claims that turn on the adequacy of a drug's warnings are preempted by federal law as well. *Bartlett*, 133 S. Ct. at 2472. The *Bartlett* court rejected the "stop selling" theory, namely that a generic manufacturer could have avoided the conflict between state and federal law by refraining from selling the drug. *Id*. Thus, after *Mensing* and *Bartlett*, Plaintiffs cannot sue a generic manufacturer on a failure to warn claim or a state law design defect claim that turns on the adequacy of a drug's warnings. Notwithstanding, in an enigmatic footnote (hereinafter "Footnote 4"), the Court stated that it did not address "state

design-defect claims that parallel the federal misbranding statute." *Id*. at 2477 n.4. *Bartlett* will be discussed in more detail in the next section because it is central to Plaintiffs' appeals.

These cases have left consumers of both generic and brand-name prescription drugs with few avenues for relief. In this case, Plaintiffs have raised a wrongful marketing claim based on the parallel misbranding theory against the Generic Manufacturers, seizing upon Footnote 4 in *Bartlett*. To date, the only federal appellate court to consider this cause of action has held that these types of claims are impliedly preempted. *Lashley v. Pfizer, Inc.*, 12-60861, 2014 WL 661058, *4 (5th Cir. Feb. 21 2014). Plaintiffs also raise other sundry state law causes of action which they globally assert were adequately pled and not preempted.

Plaintiffs suing the Brand Manufacturers proceed on a misrepresentation theory, namely that the Brand Manufacturers can be held liable to consumers of generic drugs based on statements made to prescribing physicians. There is a lopsided split of authority on this question. A few courts recognize such a cause of action, reasoning that physician reliance on these statements is foreseeable to brand manufacturers. *See, e.g., Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 705 (D. Vt. 2010) (holding name brand manufacturers may be held liable by consumers of generic drugs for representations made to prescribing physicians under Vermont law). However, almost every court has rejected this theory, reasoning that a brand manufacturer does not owe a duty to a consumer unless the consumer actually used the brand manufacturer's product. *See* Victor E. Schwartz et. al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 Fordham L. Rev. 1835, 1857-58 (2013) [hereinafter "Schwartz et al."] (cataloging cases following the majority trend).

D. Proceedings Below

After the FDA's 2010 decision to pull all propoxyphene products from the market, several plaintiffs initiated actions against both brand and generic manufacturers of propoxyphene. In 2011, the Judicial Panel on Multi-district Litigation consolidated all federal cases in a multi-district litigation in the United States District Court for the Eastern District of Kentucky. All defendants moved to dismiss under Federal Rule of Civil Procedure 12(b)(6).

Plaintiffs raised three sets of claims against the Generic Manufacturers: (1) wrongful marketing, (2) failure-to-warn claims, and (3) various remaining state law claims including breach of express and implied warranty, fraud, misrepresentation, and consumer protection. The district court dismissed each of Plaintiffs' claims against the Generic Manufacturers. The district court held that Plaintiffs' wrongful marketing claims were preempted by *Mensing* because they are based on the allegedly defective design of the drug which Generic Manufacturers could not change under the "duty of sameness." It found that Plaintiffs' failure-to-warn claims were not adequately pled under *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), and suggested that such claims would also be preempted under *Mensing*. The district court found the express and implied warranty, fraud, and misrepresentation claims preempted in accordance with *Mensing* because they related to the sufficiency of the warnings, and the statutory negligence claim preempted under *Buckman* because there is no private right to enforce the FDCA.

The district court also dismissed all claims against the Brand Manufacturers for failure to state a claim on which relief could be granted. Following "the overwhelming majority of courts," it concluded that the Brand Manufacturers could not be held liable to plaintiffs who consumed other manufacturers' drugs even for alleged misrepresentations.

These sixty-eight appeals, involving the laws of twenty-two states, timely followed. This Court stayed briefing for several months after the Supreme Court granted certiorari in *Bartlett*.

II. STANDARD OF REVIEW

We review de novo a district court's decision to grant a motion to dismiss for failure to state a claim under Rule 12(b)(6). *CBC Co., Inc. v. Equifax, Inc.*, 561 F.3d 569, 571 (6th Cir. 2009) (citations omitted). Judgments on the pleadings under Rule 12(c) are also reviewed de novo. *Roger Miller Music, Inc. v. Sony/ATV Publ'g, LLC*, 477 F.3d 383, 389 (6th Cir. 2007) (citations omitted).

When evaluating a motion to dismiss under Rule 12(b)(6), the Court must determine whether the complaint alleges "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The plausibility standard is met "when the plaintiff pleads factual

content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). It requires "more than a sheer possibility that a defendant has acted unlawfully." *Id*.

III. ANALYSIS

A. Claims Against Generic Manufacturers

Plaintiffs argue that the district court erred in dismissing (1) their wrongful marketing, (2) failure-to-warn claims, and (3) various remaining state law claims against the Generic Manufacturers. They note that the district court rendered its decision prior to the Supreme Court's decision in *Bartlett* and this Court's decision in *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013), and maintain that *Bartlett* mandates reinstatement of Plaintiffs' wrongful marketing and various remaining state law claims, and that *Fulgenzi* requires reinstatement of their failure-to-update claims. They also contend that their failure-to-warn claims were adequately pled. For the reasons stated below, we disagree and affirm.

1. Wrongful Marketing Claims

Plaintiffs' central claim in these consolidated appeals is that the Generic Manufacturers wrongfully marketed an unreasonably dangerous product that caused them injury. Plaintiffs assert that Generic Manufacturers' conduct in continuing to sell propoxyphene, when they knew or should have known that its risks outweighed its utility, is actionable under a variety of legal theories including, strict liability design defect, negligent design, negligent marketing, and breach of implied warranty. The district court held that the foregoing claims are premised on the allegedly defective design of propoxyphene, and would be preempted under *Mensing* because federal law prohibited the Generic Manufacturers from changing the design of the drug. The district court rejected Plaintiffs' "stop selling" argument, calling it an "oversimplified solution" that would render conflict preemption largely meaningless because it would make most conflicts between state and federal law illusory.

On appeal, Plaintiffs argue that their wrongful marketing claims are not preempted and should be reinstated in light of *Bartlett*. Specifically, they claim that the Supreme Court identified an exception to the preemption of state law design defect claims in *Bartlett*: "parallel

misbranding claims." *Bartlett*, 133 S. Ct. at 2477 n.4, and that their wrongful marketing claim presents the "parallel misbranding" exception.

Plaintiffs' argument requires us to answer the following three questions: (1) Is there a parallel misbranding exception to *Mensing* and *Bartlett* preemption?; (2) What does a parallel misbranding claim look like under both federal and state law?; (3) Did Plaintiffs properly plead such claims?

However, before we take up that task, we must decide a preliminary procedural question of whether Plaintiffs forfeited their ability to argue the parallel misbranding theory.

a. Forfeiture

The Generic Manufacturers argue that Plaintiffs have forfeited their "parallel misbranding" theory on appeal by failing to raise it before the district court. Plaintiffs respond that the issue of the Generic Manufacturers' federal preemption defense was litigated below, as was the stop selling argument, and the allegation that the Generic Manufacturers' conduct violated federal misbranding requirements.

"The general rule is that the circuit court will not address issues on appeal that were not raised and ruled upon below." *Meade v. Pension Appeals & Review Comm.*, 966 F.2d 190, 194 (6th Cir. 1992) (citations omitted). However, we may address a claim that has not been ruled on by the district court in exceptional circumstances. *Id*. This general policy is justified by two main policy goals: "First, the rule eases appellate review by having the district court first consider the issue. Second, the rule ensures fairness to litigants by preventing surprise issues from appearing on appeal." *Rice v. Jefferson Pilot Fin. Ins. Co.*, 578 F.3d 450, 454 (6th Cir. 2009) (quoting *Scottsdale Ins. Co. v. Flowers*, 513 F.3d 546, 552 (6th Cir. 2008)).

Plaintiffs did not expressly raise their "parallel misbranding" theory below. Their failure to do so is not surprising, given that the Supreme Court had not yet decided *Bartlett*. Nonetheless, Plaintiffs properly presented the issue of a stop selling exception to impossibility preemption and alleged that the Generic Manufacturers sold misbranded drugs. As a result, the district court considered this issue under then-existing jurisprudence and even anticipated the Supreme Court's rejection of the "stop selling" argument. Furthermore, because briefing of

these appeals was stayed for several months after the Supreme Court granted certiorari in *Bartlett*, Generic Manufacturers cannot say that they were surprised that this issue appeared on appeal. Accordingly, we find that Plaintiffs did not forfeit their right to argue their "parallel misbranding" argument on appeal.

Now, we turn to the first question of whether a state parallel misbranding claim escapes preemption. This requires us to examine *Bartlett* and Footnote 4.

b. Bartlett and Footnote 4

In *Bartlett*, the Supreme Court overturned a judgment for the plaintiff on a state law design defect claim. It found the state law claim preempted because New Hampshire law required the generic manufacturer defendant either to alter the design of its generic drug or to strengthen the warnings on its label, both actions prohibited by federal law. *Bartlett*, 133 S. Ct. at 2475-76. "Because it is impossible for [the generic manufacturer] and other similarly situated manufacturers to comply with both state and federal law, New Hampshire's warning-based design-defect cause of action is preempted with respect to FDA-approved drugs sold in interstate commerce." *Id*. at 2477. In holding that the claim was not preempted, the First Circuit reasoned that the generic manufacturer could escape the impossibility of complying with both its federal and state law duties by not selling the drug. The *Bartlett* majority rejected the "stop-selling theory" as "incompatible with our preemption jurisprudence," noting that "[o]ur 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*.

Despite these clear pronouncements, the Court included the following in a footnote:

> We do not address state design-defect claims that parallel the federal misbranding statute. The misbranding statute requires a manufacturer to pull even an FDA-approved drug from the market when it is "dangerous to health" even if "used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j); *cf. Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447, 125 S. Ct. 1788, 161 L.Ed.2d 687 (2005) (state-law pesticide labeling requirement not pre-empted under express pre-emption provision, provided it was "equivalent to, and fully consistent with, [federal] misbranding provisions"). The parties and the Government appear to agree that a drug is misbranded under federal law only when liability is based on new and scientifically significant information that was not before the FDA.

> Because the jury was not asked to find whether new evidence concerning sulindac that had not been made available to the FDA rendered sulindac so dangerous as to be misbranded under the federal misbranding statute, the misbranding provision is not applicable here. *Cf.* 760 F. Supp. 2d 220, 233 (D.N.H.2011) (most of respondent's experts' testimony was "drawn directly from the medical literature or published FDA analyses").

Id. at 2477 n.4. As noted, Plaintiffs in this case have advanced their "parallel misbranding" argument in light of this footnote, arguing that it outlines an exception to *Mensing* and *Bartlett* preemption and that their wrongful marketing claims fall under this theory.

This Court is one of the first appellate courts faced with the "parallel misbranding" theory of generic drug manufacturer liability. Academics, commentators, and even the parties to this case are not clear on what precisely Footnote 4 means and what its impact might be.[1]

Footnote 4's genesis provides some perspective. In *Bartlett*, the FDA argued in an amicus brief that *Mensing*'s preemption analysis applied only to claims that turn on the adequacy of the drug labeling. The FDA distinguished those claims from "pure" design defect claims, which it argued are preempted unless they "parallel the FDCA's drug 'misbranding' prohibition." FDA Br., *Bartlett*, 2013 WL 314460, at *23 (citation omitted). The FDA continued: "[A] manufacturer has a federal duty not to market a drug if, *inter alia*, it is 'dangerous to health' when used as provided in the labeling. A state-law duty not to market the drug in the same circumstances would not conflict with federal law if it appropriately accounted for [the] FDA's role under the FDCA." *Id*. The *Bartlett* Court responded to this argument in Footnote 4, remarking that its holding "[does] not address state design defect claims that parallel the federal misbranding statute." *Bartlett*, 133 S. Ct. at 2477 n.4. It is not clear whether this language implies that an exception for "parallel misbranding" claims actually exists.

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[1] *See, e.g.*, Alyssa E. Lambert, *Supreme Court Expands Preemption to Design Defect Claims*, FDA to Release New Generic Labeling Rule, Am. Ass'n for Justice (July 11, 2013), *available at* http://www.justice.org/cps/rde//justice/hs.xsl/21443 htm (quoting Bograd, counsel for Plaintiffs, "Footnote 4 may just be a red herring . . . But the Court acknowledged that there might not be preemption of state design defect claims where you have new, scientifically valid info that the drug was not safe"); Anand Agneshwar and Anna K. Thompson, *Drug Design Defect Claims Post-Bartlett*, Law360 (Apr. 8, 2014), *available at* http://www.law360.com/articles/525656/drug-design-defect-claims-post-bartlett [hereinafter "Agneshwar and Thompson"].

This possibly thorny issue need not be resolved today because, even if such a claim does exist under federal and state law, Plaintiffs' claims fail for a simpler reason: Plaintiffs failed to plead such a claim.

c. Plaintiffs' "Parallel Misbranding" Claims Recast and *Iqbal*

Whether or not the "parallel misbranding" exception exists, our inquiry is whether Plaintiffs' wrongful marketing claims recast in light of the "parallel misbranding" exception alleged sufficient facts in order to survive a motion to dismiss. We ask whether the complaint alleges "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (2009) (quoting *Twombly*, 550 U.S. at 555).

The FDA Amicus Brief and Footnote 4 of *Bartlett* indicate the minimum that a plaintiff must show in order to avoid preemption on a design defect claim under the "parallel misbranding" exception: (1) allege a cause of action for misbranding under state law, (2) identify the "new and scientifically significant information that was not before the FDA," and (3) demonstrate that the FDA would have found the drug to be misbranded in light of this new information in order to "appropriately account for the FDA's role under the FDCA." FDA Br., *Bartlett*, 2013 WL 314460 at *24; *Bartlett*, 133 S. Ct. at 2477 n.4.

Plaintiffs in this case do not allege sufficient facts to establish a claim under the "parallel misbranding" theory. In the first place, Plaintiffs fail to identify specific wrongful marketing claims from the states at issue that parallel, *i.e.*, have elements identical to, a federal misbranding claim under 21 U.S.C. § 352(j). But, even if we assume for purposes of argument that the states at issue have mirror image state law claims, Plaintiffs cannot state such a claim because they do not point to "new and scientifically significant information" that the Generic Manufacturers possessed that was not before the FDA.

Plaintiffs list as "new information": the 1978 Citizen Petition, various subsequent clinical and non-clinical studies, post-marketing adverse event data, and the decision of the UK and European regulatory agencies to withdraw propoxyphene, culminating in the FDA Advisory Committee's recommendation against the continued marketing of propoxyphene products. But this is not "new information" because it was before the FDA. Critically, the FDA did not follow

the Advisory Committee's recall recommendation in July 2009, instead requiring Xanodyne to conduct a safety study and imposing new labeling requirements. Plaintiffs submit only information that was considered, reviewed, and rejected by the FDA. That the FDA approved continued marketing of propoxyphene in July 2009, notwithstanding the information Plaintiffs submit, is fatal to their misbranding claim before that time.[2]

Post-July 2009, Plaintiffs submit as "new information" that the initial data from the Xanodyne study confirmed the safety risks of propoxyphene, resulting in the FDA's conclusion that the safety risks of the drug outweighed its benefit. But the Generic Manufacturers did not have access to, and thus had no ability to evaluate, that study. In fact, the FDA's revised risk/benefit determination was contemporaneous with its request for market withdrawal after completing its own independent review of the Xanodyne study's proprietary data in late 2010. Thus, Plaintiffs have not pled sufficient "new and scientifically significant information that was not before the FDA" in order to satisfy the requirements of a "parallel misbranding" claim (if such exists) to survive Generic Manufacturers' motion to dismiss.

In short, Plaintiffs' wrongful marketing claim stacks assumptions into a house of cards. It asks us to assume that parallel misbranding claims survive *Mensing* and *Bartlett* preemption, to assume what a parallel misbranding claim consists of, and to assume such claims exist in the states at issue. At a minimum, the house collapses based on their deficient pleading. The district court did not err in dismissing Plaintiffs' wrongful marketing claims.

2. Failure-to-Warn Claims

Plaintiffs admit that the central thrust of their complaints is premised on the Generic Manufacturers alleged wrongful marketing theory. But, they also argue that certain of their claims based on the Generic Manufacturers' failure-to-warn prescribing physicians about propoxyphene's risks should be allowed to proceed. Particularly, Plaintiffs contend that at least some of the Generic Manufacturers can be held liable because they allegedly failed to timely

[2]In this way, this case parallels *Bartlett* itself, wherein the Supreme Court did not find the parallel misbranding theory applicable. In *Bartlett*, the FDA had ordered new labeling for the drug at issue upon completion of a comprehensive safety review and its conclusion that the drug should not be removed from the market. *Bartlett*, 133 S. Ct. at 2477 n.4.

implement certain changes to their product labeling after the NDA holder Xanodyne changed its labeling in 2009, and because those Manufacturers otherwise failed to send "Dear Doctor" Letters to healthcare providers regarding propoxyphene's risks. The district court dismissed these claims as inadequately pled under *Iqbal*, noting that the complaints failed to: (1) identify which of the Generic Manufacturers allegedly failed to make the label changes, (2) elaborate on the allegation of untimeliness (e.g. length of delay or why it was unreasonable), or (3) explain how the alleged failure to update injured the plaintiffs. The district court also suggested that such claims would be preempted under *Mensing*. We affirm.

a. "Failure-to-Update" Claim

Plaintiffs' principal failure-to-warn claim alleged that the Generic Manufacturers did not update their labeling to include "Black Box" warnings even though the FDA had ordered all propoxyphene manufacturers to do so. After the district court issued its decision, this Court ruled in *Fulgenzi* that "failure-to-update" claims against generic manufacturers are not preempted. *See Fulgenzi*, 711 F.3d 578 (6th Cir. 2013). Nonetheless, Plaintiffs' claims falter because they did not plead them properly.

The complaints plead, in relevant part that "[u]pon information and belief, the Generic [Manufacturers] did not timely implement the Black Box warning." The complaints add that "[h]ad . . . Plaintiff and her prescribing physicians . . . been adequately advised of the risks associated with the use of Propoxyphene Products, Plaintiff would not have been prescribed or would not have filled prescriptions for Propoxyphene Products, would not have ingested or would have stopped ingesting them, and would not have suffered injuries resulting from those ingestions."

As an initial matter, the complaints fall short because they plead the Generic Manufacturers' failure to implement the black box warning "upon information and belief." To survive a motion to dismiss, a complaint must plead "facts" that create a "plausible inference" of wrongdoing. *Iqbal*, 556 U.S. at 682. The mere fact that someone believes something to be true does not create a plausible inference that it is true. *See, e.g.*, *Twombly*, 550 U.S. at 551 (finding a complaint insufficient even though it said, "Plaintiffs allege upon information and belief that [defendants] have entered into a contract, combination or conspiracy to prevent competitive

entry . . . ."); *16630 Southfield Ltd. P'ship v. Flagstar Bank*, 727 F.3d 502, 506 (6th Cir. 2013) (finding a series of "upon information and belief" claims insufficient, because the plaintiffs "have merely alleged their 'belief'").

Plaintiffs respond that, under an exception to this principle, information-and-belief pleading is permissible when "the facts are peculiarly within the possession of the defendant." *Arista Records, LLC v. Doe 3*, 604 F.3d 110, 120 (2d Cir. 2010). Even assuming the existence of such an exception, it does not help Plaintiffs here. The Generic Manufacturers are not "peculiarly" in possession of the facts about whether a box of propoxyphene contains a package insert bearing the updated Black-Box warnings. Rather, the plaintiff would know best what box of propoxyphene she bought and whether that box contains a particular package insert. To the extent Plaintiffs want to find out about the Generic Manufacturers' actions, they could for instance file a Freedom of Information Act request with the FDA to request a copy of Generic Manufacturers' labels from the period at issue.

Even putting aside the words "upon information and belief," the complaints still fail. The complaints' allegation of wrongdoing – "the Generic [Manufacturers] did not timely implement the Black Box warning" – does not identify *which* Generic Manufacturers did not timely implement the warnings. And the complaints' allegation of causation – "Had . . . Plaintiff and her prescribing physicians . . . been adequately advised of the risks associated with the use of Propoxyphene Products, Plaintiff . . . would not have suffered injuries" – does not identify whose failure to implement the warnings caused the injuries.

Plaintiffs suggested at oral argument that these allegations refer to all of the Generic Manufacturers. In order for this theory to work, we would have to interpret the complaint as alleging: (1) the plaintiff ingested every single generic version of propoxyphene available, (2) every single generic version of propoxyphene contributed to the plaintiff's injuries, and (3) points (1) and (2) are true with respect to each of the plaintiffs in this case. Common sense suggests that Plaintiffs never meant to allege this scenario.

Beyond the complaints' failure to identify the responsible defendant, it falls short for another reason. Under *Iqbal*, "conclusory statements" or "naked assertions devoid of further factual enhancement" do not insulate a complaint from a motion to dismiss. *Iqbal*, 556 U.S. at

678 (citations omitted). And even before *Iqbal*, complaints had to "give the defendant fair notice of . . . the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957).

The complaint in this case does not give the Generic Manufacturers "fair notice . . . of the grounds upon which it rests," or offer the "factual enhancement" necessary to pass *Iqbal*. It asserts without elaboration Plaintiffs' belief that the Generic Manufacturers failed to update their warnings, providing no factual basis for that belief. As the district court noted, the belief is "pure conjecture." The complaint is thus akin to Iqbal's conclusory allegation that Ashcroft acted out of discriminatory motive, *see* 556 U.S. at 680-81 (holding that the plaintiff's complaint failed to state a claim for purposeful and unlawful discrimination), and to Twombly's conclusory allegation that Bell Atlantic conspired with its competitors, *see* 550 U.S. at 557 (holding that plaintiff's complaint failed to state a claim under Section 1 of the Sherman Act).

For these reasons we affirm the district court's dismissal of failure-to-update claims.

b. "Failure-to-Communicate" Claim

In a footnote, Plaintiffs contend that the district court erred in dismissing their "failure-to-communicate" claims, arguing that the Generic Manufacturers should have sent "Dear Doctor" Letters to healthcare professionals regarding propoxyphene's risks. "'[I]t is a settled appellate rule that issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.'" *United States v. Johnson*, 440 F.3d 832, 846 (6th Cir. 2006) (quoting *United States v. Elder*, 90 F.3d 1110, 1118 (6th Cir.1996)); *see also Carter v. Toyota Tsusho Am., Inc.*, 529 F. App'x 601, 612 n.2 (6th Cir. 2013) ("Generally, an argument raised in a footnote without further development is deemed waived."). Because Plaintiffs fail to develop this argument further than this footnoted reference, it is forfeited.

In any event, Plaintiffs' argument fails on the merits. In *Mensing*, the Supreme Court held that generic manufacturers cannot send "Dear Doctor" Letters unless their brand counterparts do so first because "if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly misleading." *Mensing*, 131 S. Ct. at 2576 (citation and internal quotation marks omitted). In other words, generic manufacturers

cannot violate the duty of sameness. The only two federal appellate courts to consider this issue have rejected "failure-to-communicate" claims similar to those Plaintiffs advance. *Morris v. PLIVA*, 713 F.3d 774, 777 (5th Cir. 2013) ("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 . . . the generic manufacturers were not at liberty to do so."); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013) ("Because the duty of sameness prohibits the generic manufacturers from taking such actions unilaterally, they are dependent on brand-names taking the lead. That fact is determinative here. We . . . reject the failure-to-communicate theory of liability, as it is preempted by federal law.") (citing *Morris*, 713 F.3d at 777). We agree with our sister circuits' analysis, and find Plaintiffs' "failure-to-communicate" claim preempted.

c. "Failure-to-Warn" Claims against Mylan

Plaintiffs next argue that the district court erred in dismissing their failure-to-warn claims against Generic Manufacturer Mylan because the FDA designated Mylan's ANDA product as the reference listed drug holder for certain strengths of propoxyphene after the Brand Manufacturer for those strengths left the market.[3] Plaintiffs assert that as a result of the RLD designation, Mylan is subject to failure-to-warn liability under the standard for Brand Manufacturers in *Levine*, rather than the standard for Generic Manufacturers under *Mensing*.

The FDA recently addressed this issue, confirming that RLD-designation does not alter the obligations of generic manufacturers. Although it declared that RLD designees generally must submit labeling changes when new safety information warrants, it made clear that this rule does not apply to RLD designees whose drug was approved pursuant to an ANDA:

> Under existing FDA regulations, ANDA holders cannot make labeling changes through the formal supplement process under 21 CFR 314.70 in all circumstances in which NDA holders can because an ANDA's labeling must be the same as the NDA RLD's labeling. Accordingly the *changes-being-effected* supplement process under 21 CFR 314.70(c) is not expressly available to ANDA holders

[3]Mylan was the RLD holder for the combination product of 100 milligrams of propoxyphene napsylate and 650 milligrams of acetaminophen.

> except to match the RLD labeling or to respond to FDA's specific request to submit a labeling change under this provision.

FDA, Center for Drug Evaluation and Research, *Guidance for Industry: Safety Labeling Changes–Implementation of Section 505(o)(4) of the FD&C Act*, at 7 n.10 (July 2013), *available at* http://1.usa.gov/1cF0bdk. This makes sense because, as the Supreme Court recognized in *Mensing*, the FDCA and implementing regulations recognize only two categories of drug applications: NDAs, which are fully subject to the CBE process set forth in 21 C.F.R. § 314.70, and ANDAs, which are not subject to the CBE process given the duty of sameness. *Mensing*, 131 S. Ct. at 2574 (citing 21 U.S.C. § 355(b)(1), (d) (responsibilities of NDA holders) & 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7) (responsibilities of ANDA holders)). Indeed, "[r]eference listed drug" merely "means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application." 21 C.F.R. § 314.3; *see also* 21 C.F.R. § 314.94(a)(3) ("The listed drug will be the drug product selected by the agency as *the reference standard for conducting bioequivalence testing.*") (emphasis added). Thus, merely becoming an RLD holder does not empower a generic manufacturer to independently change the drug's warning label.

Every federal court to consider this issue has held that FDA's designation of a generic manufacturer's drug as the RLD does not subject an ANDA product to NDA, or brand-name, status or requirements. *See, e.g., Morris*, 713 F.3d at 777-78 ("[W]e agree with the district court's analysis, in rejecting this claim, that it assumes, without authority, that the FDA considered [the ANDA holder designated by FDA as the RLD] to be a brand manufacturer with the requisite duty to unilaterally change its product's labeling simply because the FDA designated [that ANDA holder's generic drug] as the RLD.") (internal quotation marks omitted); *Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1348 (N.D. Ga. 2012) ("Plaintiff has not shown that Mylan's manufacture of one RLD converted Mylan into [a] brand name drug manufacturer with the right to use the CBE process to change the label of any of its drugs or how listing [the drug] as an RLD converted [it] into a brand name drug"); *Cooper v. Wyeth, Inc.*, No. 09-cv-929-JJB, 2012 WL 733846, *9 (M.D. La. Mar. 6, 2012) ("Plaintiffs point to no authority authorizing the FDA to elevate the duties of generic ANDA drug to the level of a brand name NDA drug simply

because the FDA chooses that generic as the comparison model for bioequivalency measurements arising from the processing of subsequent ANDAs.").

After examining the relevant regulations, we find that the status of an ANDA holder's product as the RLD for a given prescription drug product does not alter the ANDA holder's obligations. Therefore, we affirm the district court's rejection of the Plaintiff's RLD theory against Mylan.

3. Remaining State Law Claims

Plaintiffs argue that the district court erred in dismissing their remaining state law claims including breach of express and implied warranty, misrepresentation, fraud, consumer protection, and statutory negligence. A prior panel of this Court rejected similar claims, including breach of warranty, fraud, and misrepresentation under Tennessee law in *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 391-96 (6th Cir. 2013), finding them preempted under *Mensing* and *Bartlett*. We reach the same result here.

a. Breach of Express and Implied Warranty Claims

Plaintiffs argue that the district court improperly dismissed their breach of warranty claims. They allege that the Generic Manufacturers expressly warranted that propoxyphene "had been adequately tested" and "was safe and effective for pain management" on the products' labeling. Plaintiffs also claim that in selling propoxyphene, Generic Manufacturers impliedly warranted that their product was safe and effective. The district court held that the express warranty claims are attacks on Generic Manufacturers' labeling, and the implied warranty claims were attacks on Generic Manufacturers' product design, both preempted under *Mensing*.

The alleged express warranty includes provisions on Generic Manufacturers' label. As discussed above, the duty of sameness required Generic Manufacturers to conform their labeling to that of the brand-name drugs. *Mensing*, 131 S. Ct. at 2577-78. Therefore, federal law prohibited Generic Manufacturers from modifying any "express warranty" contained in the labeling. In *Smith*, this Court rejected a similar argument regarding warranty claims, finding them preempted. *Smith v. Wyeth*, 657 F.3d 420, 423 (6th Cir. 2011) (finding all claims

preempted, including plaintiffs' warranty claims in their supplemental brief).[4] Plaintiffs cite three cases outside the prescription drug context in support of their argument, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (holding that the Federal Cigarette Labeling and Advertising Act did not preempt state law damages actions), *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005) (holding that the Federal Insecticide, Fungicide, and Rodenticide Act did not preempt plaintiffs' state law claims), and *Altria Group, Inc. v. Good*, 555 U.S. 70 (2008) (holding that the Federal Cigarette Labeling and Advertising Act did not preempt plaintiffs' state law claims), where the Supreme Court found express warranty claims not preempted. These cases are inapplicable; not only do they not consider the FDCA, but they involve express, rather than conflict, preemption. The district court did not err in dismissing Plaintiffs' express warranty claims.

The alleged implied warranty stems from Generic Manufacturers' continuing to market their propoxyphene products after 2009. These claims are based on the allegedly defective design of the drug: Plaintiffs allege that the Generic Manufacturers knowingly or negligently marketed and sold defectively designed propoxyphene products without adequate warnings and thus impliedly warranted that the products were safe and effective. As discussed above, Generic Manufacturers were bound by their "duty of sameness" and powerless to change the design of propoxyphene. *Mensing*, 131 S. Ct. at 2575. Additionally, the district court appropriately rejected Plaintiffs' "stop selling" argument, anticipating *Bartlett*. *Bartlett*, 133 S. Ct. 2466. Therefore, the district court correctly concluded that Plaintiffs' implied warranty claims are preempted as well.

b. Fraud, Misrepresentation, and Consumer Protection Claims

Plaintiffs contend that the district court erred in dismissing their fraud, misrepresentation, and consumer protection claims. They argue that while federal law may have prohibited the

[4]Three other courts of appeals have also concluded that breach of warranty claims against generic manufacturers are preempted. *Schrock*, 727 F.3d at 1289 ("In advancing their warranty claims, the Schrocks allege that [generic manufacturer] had a duty under state law to alter either the composition or the labeling, as broadly defined by the FDA, of its generic metoclopramide. Because [generic manufacturer] could not have taken either action under federal law, we conclude these claims are preempted."; *Guarino*, 719 F.3d at 1247-50 (finding all claims, including breach of warranty, based on allegedly inadequate warning and thus preempted); *Morris*, 713 F.3d at 778 (holding any claim that alleges generic manufacturers "should have acted differently with respect to warnings" is preempted).

Generic Manufacturers from adding warnings to their drug labels without FDA approval, it does not compel them to make misrepresentations about their products. These claims all challenge label content, and Plaintiffs do not identify any representations made other than those contained in the FDA-approved labeling. As above, the Generic Manufacturers could not have corrected any alleged misrepresentation without violating federal law because they were required to conform their labeling to that of the brand-name drugs. These claims are preempted under *Mensing*, and the district court did not err in dismissing them. *Mensing*, 131 S. Ct. at 2577-78.[5]

c. Statutory Negligence Claims

Plaintiffs argue that the district court wrongly dismissed their claims for statutory negligence. The district court found that these claims are premised on Generic Manufacturers' alleged violation of federal law, and therefore preempted by *Buckman*. Plaintiffs maintain that their statutory negligence claims do not seek to enforce federal statutory and regulatory requirements, but assert only state law causes of action.

Plaintiffs' statutory negligence complaints list a number of federal regulations, mostly related to labeling or misbranding, that the Generic Manufacturers allegedly violated. As the district court correctly concluded, these claims are premised on the Generic Manufacturers' alleged violation of federal standards for the sale of prescriptions set forth in the FDCA. In *Buckman*, the Supreme Court recognized that because the FDA has the exclusive power to enforce the FDCA there is no private right to enforce the statute. *Buckman*, 341 U.S. at 350-53. Since the conduct that Plaintiffs allege gives rise to their statutory negligence claims is the Generic Manufacturers' violation of the FDCA, the district court properly dismissed those claims, and we affirm.

d. Derivative Claims

Plaintiffs concede that their derivative claims for wrongful death, survivorship, unjust enrichment, loss of consortium, and punitive damages stand or fall with the underlying claims on

[5]In a footnote, Plaintiffs also argue that their fraud, misrepresentation, and consumer protection claims are not preempted because they parallel the misbranding statute. As discussed above in Section A.1., Plaintiffs' misbranding theory fails in its entirety.

which they rest. Because the district court correctly dismissed the underlying claims, it did not err in dismissing their derivative claims and we affirm.

B. Claims Against Brand Manufacturers

1. Misrepresentation Claims

The district court dismissed Plaintiffs' products liability claims against the Brand Manufacturers, reasoning that, in the twenty-two states implicated, it is settled law that the plaintiff must assert that the defendant's product caused the plaintiff's injury. Because Plaintiffs did not allege that they ingested drugs marketed, sold, or manufactured by the Brand Manufacturers, their claims could not succeed. Plaintiffs do not appeal that holding. Plaintiffs appeal only the dismissal of their misrepresentation claims against Brand Manufacturers, which they characterize as a separate theory of recovery in which identification of the defendant's specific product is not required.[6]

Plaintiffs' misrepresentation arguments against the Brand Manufacturers proceed as follows: physicians reasonably and foreseeably relied on representations by Brand Manufacturers in writing prescriptions for generic propoxyphene because they understand that generic drugs are required by federal law to be bioequivalent to, and labeled the same as, RLDs. State laws permit, and sometimes require, pharmacists to fill prescriptions with generic medications. Thus, they argue, it was reasonably foreseeable to Brand Manufacturers that physicians would rely on their representations in prescribing generic propoxyphene.

The district court dismissed Plaintiffs' misrepresentations for two reasons. First, it held that under the laws of the twenty-two states at issue, because these misrepresentation claims stem from personal injuries allegedly caused by a product (a drug), they are in fact product liability claims. Construed as such, Plaintiffs' "misrepresentation" claims would fail for the same reason their "product liability" claims did: Plaintiffs did not allege that they were injured by the Brand Manufacturers' product. Second, the district court found that even if the misrepresentation

[6]Plaintiffs raised several other theories in the district court. Because they appeal only the dismissal of their misrepresentation claim, all other theories of recovery are forfeited on appeal. *See Johnson*, 440 F.3d at 845-46 (holding that an appellant forfeits all issues not raised and argued in initial brief on appeal) (citations omitted).

claims could be seen as distinct and separate from product liability claims, they would fail because Plaintiffs could not establish that the Brand Manufacturers owed them a legal duty.

We must analyze whether Plaintiffs' misrepresentation claims would stand under the laws of each implicated state, as required per *Erie*. *See Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938) (holding that a federal court sitting in diversity is bound to follow the law of the forum state). When sitting in diversity, federal courts are required to apply the substantive law of the states in which they reside. *Erie R.R.*, 304 U.S. at 78. On questions of state law, this Court is bound by the rulings of the state supreme court. *Bradley v. Gen. Motors Corp.*, 512 F.2d 602, 604–05 (6th Cir. 1975). "When there is no state law construing a state statute, a federal court must predict how the state's highest court would interpret the statute." *United States v. Simpson*, 520 F.3d 531, 535 (6th Cir. 2008). If the state's highest court has not yet addressed the issue presented, we must predict how the court would rule by looking to all available data, including decisions of the states' appellate courts. *Allstate Ins. Co. v. Thrifty Rent-A-Car Sys., Inc.*, 249 F.3d 450, 454 (6th Cir. 2001) (citations omitted). While not binding, this Court may turn to decisions of its sister circuits and lower federal courts interpreting state law for guidance. *See Andrew v. Bendix Corp.*, 452 F.2d 961, 963 (6th Cir. 1971) (looking to decisions of sister circuits and federal district courts for guidance interpreting state law).

Furthermore, federal courts must be cautious when making pronouncements about state law and "'[w]hen given a choice between an interpretation of [state] law which reasonably restricts liability, and one which greatly expands liability, we should choose the narrower and more reasonable path.'" *Combs v. Int'l Ins. Co.*, 354 F.3d 568, 577 (6th Cir. 2004) (citing *Todd v. Societe Bic, S.A.*, 21 F.3d 1402, 1412 (7th Cir. 1994) (en banc)) (other citations omitted).

There are two analytical avenues by which a state's highest court would determine whether Plaintiffs have stated viable misrepresentation claims against Brand Manufacturers under applicable state law: (1) Plaintiffs' claims may be construed as strict "product liability" claims under the state's tort regime regardless of whether they are articulated as sounding in negligence and fraud, or (2) even if they are seen as distinct and separate from product liability claims under a state's law, whether a duty exists between Brand Manufacturers and users of generic drugs that can give rise to liability. Thus, first, if a state's highest court would construe

Plaintiffs' misrepresentation claims as "product liability" claims under the tort law of that state, they were properly dismissed. In the twenty-two states implicated by the Brand Manufacturers' motion to dismiss, it is well-settled law that the "threshold requirement of any products-liability claim is that the plaintiff assert that the defendant's product caused the plaintiff's injury."[7] This is known as the "product identification requirement." Because Plaintiffs did not ingest the Brand Manufacturers' drugs, their "misrepresentation" claims would fail if a state's highest court would construe them as product liability claims under applicable state law. Second, even if a state's highest court would not construe Plaintiffs' claims as "product liability" claims, the claims were still properly dismissed if we predict that such courts would hold that the Brand Manufacturers do not owe users of generic drugs a duty that can give rise to liability.

Before turning to our state-by-state *Erie* analysis, we note that an overwhelming majority of courts, in at least fifty-five decisions from twenty-two states,[8] have rejected "the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug." *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994). These courts have arrived at this conclusion through either or both of the analytical avenues specified above, but often do not neatly indicate which route they are selecting. Some of these courts maintain that regardless of the label a generic consumer plaintiff might use (*e.g.* misrepresentation), she has effectively brought a product liability action and cannot circumvent the product identification requirement of applicable state product liability law. *See, e.g., Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643 (W.D.N.C. 2010) (holding that although

[7] *See, e.g.*, *Smith*, 657 F.3d at 423 (applying Kentucky law); *Barnes v. Kerr Corp.*, 418 F.3d 583, 588-89 (6th Cir. 2005) (applying Tennessee law); *Johannsen v. Zimmer, Inc.*, 3:00CV2270 (DJS), 2005 WL 756509, *7 (D. Conn. Mar. 31, 2005); *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 92 (D. Md. 1989); *Sherman v. Sunsong Am., Inc.*, 485 F. Supp. 2d 1070, 1078 (D. Neb. 2007); *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 633 (E.D.N.C. 2009); *Baughman v. Gen. Motors Corp.*, 627 F. Supp. 871, 874 (D.S.C. 1985); *Ashworth v. Albers Med., Inc.*, 410 F. Supp. 2d 471, 476 (S.D. W. Va. 2005); *Chavers v. Gen. Motors Corp.*, 79 S.W.3d 361, 369-70 (Ark. 2002); *Sharp v. Leichus*, No. 2004-CA-0643, 2006 WL 515532 (Fla. Cir. Ct. 2006); *Hoffman v. AC&S, Inc.*, 548 S.E.2d 379, 382 (Ga. Ct. App. 2001); *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324, 328 (Ill. 1990); *Bryant-Poff, Inc. v. Hahn*, 453 N.E.2d 1171, 1172-73 (Ind. 1983); *Stanley v. Wyeth, Inc.*, 991 So.2d 31, 34-35 (La. Ct. App. 2008); *Abel v. Eli Lilly & Co.*, 343 N.W.2d 164, 170 (Mich. 1984); *Gorman-Rupp Co. v. Hall*, 908 So. 2d 749, 757 (Miss. 2005); *Diel v. Flintkote Co.*, 204 A.D.2d 53, 53 (N.Y. App. Div. 1994); *Sutowski v. Eli Lilly & Co.*, 696 N.E.2d 187, 190-93 (Ohio 1998); *Kirkland v. Gen. Motors Corp.*, 521 P.2d 1353, 1365 (Okla. 1974); *DeWeese v. Anchor Hocking Consumer & Indus. Prods. Grp.*, 628 A.2d 421, 423 (Pa. Super. Ct. 1993); *Gaulding v. Celotex Corp.*, 772 S.W.2d 66, 68 (Tex. 1989); *Macias v. Saberhagen Holdings, Inc.*, 282 P.3d 1069 (Wash. 2012).

[8] *See* Doc. 1274 at PageID #38266.

plaintiffs' claims were "masked in various legal theories, they [were] premised on a single claim of product liability" and therefore fell under North Carolina's product liability statute). Other courts note that no matter whether they find that the misrepresentation cause of action is distinct from a product liability claim, a brand name defendant owes no duty of care to consumers of the generic bioequivalent of its product. *Foster*, 29 F.3d at 171.

A minority of courts have held the opposite, first finding generic consumers' common law claims distinct from product liability claims and then concluding that brand manufacturers owe a duty to avoid causing injury to generic consumers that can give rise to liability. *See, e.g.*, *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 309 (Cal. Ct. App. 2008); *Kellogg*, 762 F. Supp. 2d at 709; *Wyeth, Inc. v. Weeks*, No. 1101397, 2013 WL 135753, at *19 (Ala. Jan. 11, 2013); *Dolin v. SmithKline Beecham Corp.*, 12-C-6403, 2014 WL 804458, at *9 (N.D. Ill. Feb. 28, 2014). Courts in the minority recognizing this duty find generic consumers' injurious reliance foreseeable; brand manufacturers know or should know that a significant number of patients whose doctors rely on their product information for brand name drugs are likely to have generic drugs dispensed to them.

Applying Kentucky law in *Smith*, 657 F.3d at 424 and Tennessee law in *Barnes v. Kerr Corp.*, 418 F.3d 583, 588-89 (6th Cir. 2005), this Court concluded that generic consumers in those states could not maintain an action against brand manufacturers, in line with the majority of courts nationwide. Every circuit court of appeals that has addressed the issue is in accord. *See Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1282 (10th Cir. 2013) (holding that brand-name drug manufacturers owe no duty to consumers of generic drugs under Oklahoma law); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1251 (11th Cir. 2013) (holding that a brand manufacturer of prescription drugs cannot be held liable for injuries suffered by consumers who ingested only the generic form of a drug under Florida law); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092-94 (8th Cir. 2013) (holding that brand name manufacturers cannot be held liable for injuries caused by products they did not manufacture under Arkansas law); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 183-84 (5th Cir. 2012) cert. denied, 134 S. Ct. 57 (U.S. 2013) (finding plaintiff could not pursue any claim, regardless of theory, under Louisiana law against brand drug manufacturer because they did not manufacture the medication plaintiff actually consumed);

Foster, 29 F.3d at 168 (4th Cir. 1994) (applying Maryland law and holding name-brand drug manufacturer not liable under negligent misrepresentation theory).

After conducting a state-by-state *Erie* analysis, we conclude that the highest courts in each of the 22 implicated states would not recognize Plaintiffs' misrepresentation claims under their respective state laws. That analysis is provided in Appendix A to this opinion. Thus, we affirm the district court's dismissal of Plaintiffs' misrepresentation claims against the Brand Manufacturers.

2. Plaintiffs who Ingested Mylan Products Allegedly Manufactured by Lilly

Ten plaintiffs assert that they ingested products manufactured by a specific generic manufacturer, Mylan Pharmaceuticals, Inc. ("Mylan"). They claim that it is plausible that Lilly made those products pursuant to a 1994 supply agreement Lilly had with Mylan, under which Lilly manufactured generic propoxyphene for Mylan. These plaintiffs seek to hold Lilly liable in its capacity as a generic manufacturer. The district court granted Lilly's motion for judgment on the pleadings, holding that the plaintiffs failed to state a claim on which relief could be granted. The district court correctly dismissed all ten plaintiffs' claims.

The plaintiff in *Hunsucker* did not allege ingestion of a Mylan product. She alleged that she "cannot determine the Defendant and/or other entity that manufactured, marketed, distributed and/or tested the particular Propoxyphene Product that caused Plaintiff's harm." RE302, PageID #6524. Her failure to allege whose product she ingested is fatal to her claim under the law of Mississippi, the state in which she resides. *Gorman-Rupp Co. v. Hall*, 908 So. 2d 749, 757 (Miss. 2005) (noting that attributing a product to a defendant is an essential element of a product liability claim under Mississippi tort law).

The plaintiff in *Marston* alleged in her amended complaint that she ingested a product manufactured by Lilly for Mylan beginning in 2003, after Lilly had divested its NDAs. Therefore, her claims against Lilly are preempted, failing for the same reasons that the Plaintiffs' other claims against the Generic Manufacturers do. After the divestiture, Lilly had no more power to change the label than did Mylan. Because Lilly was no different than the other Generic

Manufacturers at the point the *Marston* plaintiff allegedly may have taken their product, the district court did not err in dismissing their claim.

The plaintiff in *Chavez* alleged in his amended complaint that he ingested a generic propoxyphene product that was allegedly manufactured by Lilly for Mylan during the time that Lilly held the NDA for the drug. Since Lilly possessed the NDA, he argues, it had the power to change the brand-name label, thereby triggering a required change in the generic label. Because Lilly had the power to effectively change the generic label, he persists, there is no conflict under *Bartlett* or *Mensing* meaning Lilly could satisfy both its state-law duty to warn and its "duty of sameness" under federal law. *Mensing*, 131 S. Ct. at 2575.

The district court properly dismissed *Chavez*'s claims against Lilly, finding them "'too attenuated' to allow the Court to draw the reasonable inference that Lilly was liable for the misconduct alleged." RE2054, at PageID #65114 (citing *Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 556). Chavez inherently argues that Lilly, as the NDA-holder for propoxyphene, owed a duty to the consumers of another company's product because Lilly had a supply agreement with that company. In turn, Chavez seeks to hold a brand manufacturer responsible as a generic manufacturer based on powers it held as a brand manufacturer. The claims would be dismissed under *Mensing* and *Bartlett* if they were asserted against a generic manufacturer and would be dismissed on product identification grounds if they were asserted against Lilly as a brand manufacturer under Michigan law. Chavez cannot create a viable claim by combining two other, untenable claims. The district court did not err in dismissing his complaint against Lilly.

The remaining seven plaintiffs, in *Cool*, *Daughtry*, *Freeland*, *Harper*, *LeJeune*, *Sapp*, and *Zickefoose*, who claim that they used a Mylan medication allege "upon information and belief" that following Lilly's 2002 divestiture of its NDAs for propoxyphene products, Lilly continued to manufacture generic propoxyphene products for certain generic drug companies. However, none of those plaintiffs specifically allege Lilly manufactured the Mylan product they ingested. In all the states in which these plaintiffs reside, a necessary part of their claims against Lilly is to specifically allege that the defendant's product caused their harm. *See, e.g., Holbrook v. Rose*, 458 S.W.2d 155, 157 (Ky. Ct. App. 1970) (Kentucky law); *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 92 (D. Md. 1989) (Maryland law); *Napier v. Osmose, Inc.*, 399 F. Supp. 2d 811,

814 (W.D. Mich. 2005) (Michigan law); *Gorman-Rupp Co.*, 908 So.2d at 757 (Mississippi law); *Sutowski v. Eli Lilly & Co.*, 696 N.E.2d 187, 190 (Ohio 1998) (Ohio law); *Gaulding v. Celotex Corp.*, 772 S.W.2d 66, 68 (Tex. 1989) (Texas law); *Meade v. Parsley*, 2009 WL 3806716 at *3 (S.D. W.Va. 2009) (West Virginia law). Because these Plaintiffs' allegations are insufficient to state a claim on which relief can be granted, the district court did not err in dismissing them and we affirm.

3. Claims in *Dickerson*

Mrs. Dickerson alleges that her husband, who died of heart problems, used "Darvocet (brand name), Darvon 65 (brand name), Propo-N/Apap 100-65 (generic) for pain management for nearly 38 years, dating back to September of 1970." She further alleges that "[a]s a result of ingesting those drugs, [her husband] suffered from [heart problems] . . . and an eventual cardiac death." She sued Lilly, among others.

The district court dismissed the claim against Lilly because Mrs. Dickerson did not adequately plead that her husband used a drug manufactured by Lilly. We disagree. She alleged that her husband used "Darvocet (brand name)" and "Darvon 65 (brand name)" – drugs manufactured by Lilly. While a different part of the complaint refers to "generic and/or brand-name drugs," this part of the complaint does not say "or." Besides, the complaint says that Dickerson used propoxyphene starting in 1970 – a time when the only propoxyphene available was Lilly's. The complaint thus adequately alleges use of brand name drugs.

Lilly adds that even if Mrs. Dickerson alleged that her husband used a Lilly drug, she never alleged that a Lilly drug injured him. We also disagree. After saying Mr. Dickerson used "Darvocet (brand name), Darvon 65 (brand name), [and] Propo-N/Apap 100-65 (generic)," the complaint alleges that "those drugs" caused his heart problems. We reverse the district court's dismissal of the Dickerson complaint.

IV. CONCLUSION

The judgment of the district court is affirmed in all respects, except for its holding regarding the claims in *Dickerson*, which are reversed.

V. APPENDIX

A. State-By-State Analysis of Claims against Brand Manufacturers

1. Arkansas

The Eighth Circuit has held that no matter the theory alleged, claims against brand defendants arising from the ingestion of generic drugs are product liability actions under Arkansas Law. *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092 (8th Cir. 2013). It reasoned that the Arkansas Product Liability Act broadly defines "product liability action" to include "all actions brought for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, . . . warning, instruction, marketing, packaging, or labeling of any product," and that "broad language encompasses [a plaintiff's] various claims regardless of her theory of recovery." *Id.* (citing Ark. Code Ann. § 16–116–102(5)). Because the plaintiffs in *Bell* could not satisfy the product identification requirement necessary to state a product liability claim, their claims could not survive a motion to dismiss. *Id*. at 1093. The Eighth Circuit added that, even if it ignored the product identification requirement, the plaintiff failed to demonstrate brand defendants owed generic consumers a duty necessary to trigger liability under Arkansas law. *Id*. at 1093.

Guided by our sister circuit, we likewise predict that the Arkansas Supreme Court would construe Plaintiffs' misrepresentation claims as product liability claims that fail for lack of product identification under Arkansas law. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Arkansas law.

2. Connecticut

There are no state or federal court cases interpreting Connecticut law on this particular question. The Connecticut Product Liability Act ("CPLA") defines "product liability claim" to include all claims for "personal injury, death, or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of any product." Conn. Gen. Stat. § 52-572m(b). Courts construe this language broadly to reach "all conduct which affects the safety of a product prior to its entry into the stream of commerce." *Oliva v. Bristol-Myers Squibb Co.*, CIVA305CV00486

(JCH), 2005 WL 3455121, *7 (D. Conn. Dec. 16, 2005) (citing *Rodia v. Tesco Corp.*, 527 A.2d 721 (Conn. App. Ct. 1987)). Because Plaintiffs bring a personal injury claim allegedly caused by a defective product, their claims are within the scope of the CPLA and require product identification. *See Johannsen v. Zimmer, Inc.*, No. 3:00CV2270, 2005 WL 756509, *10 (D. Conn. Mar. 31, 2005) ("Plaintiff's [common law] fraud claim is explicitly one arising out of his personal injuries as allegedly caused by inaccurate or fraudulent marketing, packaging or labeling," and therefore excluded by the CPLA).

Plaintiffs allege that their claims survive under another statute, the Connecticut Unfair Trade Practices Act ("CUTPA"). They note that the Connecticut Supreme Court has held that CUTPA claims are not necessarily excluded by the CPLA if they are "either for an injury not caused by the defective product, or if the party is not pursuing a claim for personal injury, death or property damage." *Gerrity v. R.J. Reynolds Tobacco Co.*, 818 A.2d 769, 774 (Conn. 2003) (citation omitted). Nonetheless, where a personal injury claim is based on the use of an allegedly defective product under the guise of CUTPA, "the purported CUTPA claim would be revealed to be nothing more than a product liability act claim dressed in the robes of CUTPA." *Id*. at 775 (citation omitted). Because Plaintiffs are pursuing an action for personal injury or death based on injuries caused by an allegedly defective prescription drug, their purported CUTPA claims are product liability claims.

We predict that if the Connecticut Supreme Court were directly faced with this question under Connecticut Law, it would find that Plaintiffs' claims are product liability claims within the scope of the CPLA that do not survive under CUTPA. Accordingly, the district court did not err in dismissing Plaintiffs claims against the Brand Manufacturers arising under Connecticut law because Plaintiffs did not allege that they ingested a product manufactured by the Brand Manufacturers.

3. Florida

Florida courts have summarily dismissed misrepresentation claims by generic drug consumers against brand manufacturers. In *Sharp v. Leichus*, No. 2004-CA-0643, 2006 WL 515532 (Fla. Cir. Ct. 2006), a Florida Circuit Court dismissed fraud/intentional misrepresentation, negligent misrepresentation, and fraud-by-concealment claims against a brand

manufacturer when a plaintiff ingested a drug manufactured and sold by a generic competitor. *Id*. at *2. The court found it clear that such claims are in fact "product liability" claims, under which a plaintiff may only recover from the defendant who manufactured or sold the product that caused his or her injury. *Id*. Federal courts applying Florida law have followed *Sharp*'s holding on this point. *Guarino*, 719 F.3d at 1251 ("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.") (citations omitted).

We predict that the Florida Supreme Court would construe Plaintiffs' misrepresentation claim as a product liability claim that fails for lack of product identification under Florida law. Thus, the district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Florida law.

4. Georgia

Although there are no state cases, the Northern District of Georgia has considered and rejected misrepresentation claims against brand-name drug manufacturers where the plaintiffs ingested only generic drugs. *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1358 (N.D. Ga. 2008). The *Swicegood* court noted that under Georgia law, plaintiffs must prove that the defendant manufactured or distributed the product that caused plaintiff's injury in order to be held liable under a product liability theory. *Hoffman v. AC&S, Inc.*, 548 S.E.2d 379 (Ga. Ct. App. 2001); *see also* O.C. G.A. § 51-1-11(b)(1). Further, the *Swicegood* court maintained that brand manufacturers do not owe generic consumers a duty that could give rise to liability under *Georgia* law for their alleged misrepresentations. Permitting negligence claims against one manufacturer for injuries caused by a competitor's products would reflect an "'unprecedented departure from traditional Georgia tort law.'" *Swicegood*, 543 F. Supp. 2d at 1357 (citing *Starling v. Seaboard Coast Line R. Co.*, 533 F.Supp. 183, 193 (S.D. Ga. 1982)).

Guided by the Northern District of Georgia's decision, we predict that the Georgia Supreme Court would either construe Plaintiffs' misrepresentation claims as product liability claims that fail for lack of product identification or that Brand Manufacturers did not owe Plaintiffs a duty that could give rise to liability under Georgia law. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Georgia law.

5. Illinois

The Northern District of Illinois considered wrongful death claims by a generic consumer against a brand name drug manufacturer in *Dolin v. SmithKline Beecham Corp.*, 12 C 6403, 2014 WL 804458 (N.D. Ill. Feb. 28, 2014). In *Dolin*, the plaintiff brought a wrongful death action against brand-name manufacturer GlaxoSmithKline after her husband committed suicide. He had ingested the generic form of the anti-depressant Paxil. The court considered the brand manufacturer's motion for summary judgment on plaintiff's product liability and common law negligence claims. It granted the motion as to the plaintiff's strict product liability claims, finding that such claims cannot be asserted against non-manufacturers or those outside the manufacturer's distributive chain. But, breaking from the majority of courts nationwide, it found plaintiff's negligent misrepresentation claims and product liability claims based on negligence sufficient to withstand the summary judgment motion. *Id*. at *10-11.

The *Dolin* court reasoned that under Illinois state law, plaintiff's common law negligence claims need not be construed as product liability claims simply because a "product" caused the injury. As a result, it applied four factors to determine whether the brand name manufacturer and the generic consumer had a sufficiently strong relationship to give rise to a legal duty of care: "(1) the reasonable foreseeability of the injury; (2) the likelihood of the injury; (3) the magnitude of the burden of guarding against the injury; and (4) the consequences of placing that burden on the defendant." *Id*. at *4-5 (citing *Simpkins v. CSX Transp., Inc.*, 965 N.E.2d 1092, 1096 (Ill. 2012)). As a result of FDA regulations requiring generic manufacturers to mirror brand name labels and drug composition, the court found it foreseeable that negligence in design or warning labels by brand manufacturers would cause injury to generic consumers. Further, it found the burden on brand manufacturers in updating their warning labels to be minimal. Thus, the court concluded that brand manufacturers had a duty that could give rise to liability in Illinois. *Dolin*, 2014 WL 804458 at *4-*6. Resolving this legal duty sufficient for both negligent misrepresentation and product liability claims based on a negligence theory, it denied the brand manufacturer's summary judgment motion as to those claims. *Id*. at *13.

We disagree with the *Dolin* court's holding. While Illinois does not have a product liability statute, its case law indicates that Plaintiffs' misrepresentation claims would be

construed as product liability claims and fail for lack of product identification. Under Illinois law, a plaintiff must "identify the supplier of the product and establish a causal connection between the injury and the product." *York v. Lunkes*, 545 N.E.2d 478, 480 (Ill. App. Ct. 1989) (citation omitted); *see also Smith v. Eli Lilly & Co.*, 560 N.E.2d 324, 328 (Ill. 1990) ("[I]t is obvious that to hold a producer, manufacturer, or seller liable for injury caused by a particular product, there must first be proof that the defendant produced, manufactured, sold, or was in some way responsible for the product.") (citation omitted). But, even if Plaintiffs' misrepresentation claims were not construed as product liability claims, applying the same factors, we predict that the Illinois Supreme Court would not recognize brand manufacturers owed generic consumers a duty that can give rise to liability.

First, the generic consumers' injuries are not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand manufacturers have no control. Schwartz et. al. at 1865. Congress made the public policy decisions to lower barriers of entry for generic drugs, as has the Illinois state legislature in enacting laws to require certain prescriptions be filled with available generics. *Id*. at 1870-71. Using these laws as the basis of supplying the duty element for tort liability stretches foreseeability too far. Additionally, the *Dolin* court failed to properly account for the magnitude of brand manufacturers' burden of guarding against the injury; and the consequences of placing that burden on the brand manufacturers. *Dolin*, 2014 WL 804458 at *6 ("But there is nothing yet in the record here to suggest that [the Brand Manufacturers' burden] is so grave as to warrant finding that GSK owed no duty of care to Plaintiff."). Courts in the majority note the traditional reticence against imposing liability on a manufacturer for injuries caused by their competitor's products. *Foster*, 29 F.3d at 171. Further, there are grave health policy consequences associated with recognizing brand manufacturer liability in these situations including higher priced brand name drugs and fewer innovative drugs. Schwartz et al. at 1870-71.

As a federal court predicting state law, we are also guided by this Court's decision in *Combs*. *See Combs*, 354 F.3d at 577 (quoting *Todd*, 21 F.3d at 1412) ("'[G]iven a choice between an interpretation of [state] law which reasonably restricts liability, and one which greatly expands liability, we should choose the narrower and more reasonable path.'"). The

potential for wide-ranging ramifications on Illinoisans' health and welfare should we recognize a duty in this case renders the narrower path the proper choice.

We predict that the Illinois Supreme Court would either construe Plaintiffs' misrepresentation claims as product liability claims that fail for lack of product identification or that Brand Manufacturers did not owe Plaintiffs a duty that could give rise to liability under Illinois law. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Illinois law.

6. Indiana

There are no state or federal court cases interpreting whether generic consumers may hold brand manufacturers liable for their injuries under Indiana law. Indiana has a statute, the Indiana Product Liability Act ("IPLA"), which governs all actions that are "brought by a user or consumer" against a "manufacturer or seller" for "physical harm caused by a product . . . regardless of the substantive legal theory." Ind. Code Ann. § 34-20-1-1 (2014). The Indiana Supreme Court has allowed actions that do not fall within these provisions to proceed under the common law. *Vaughn v. Daniels Co. (West Va.), Inc.*, 841 N.E.2d 1133, 1144 (Ind. 2006) ("the PLA now applies to all negligence claims brought against a 'manufacturer' of a defective product by a 'user' or 'consumer.' The PLA is explicit that it does not govern other claims."). In order to determine whether a novel duty exists in a particular case, the Indiana Supreme Court balances three factors: "(1) the relationship between the parties, (2) the reasonable foreseeability of harm to the person injured, and (3) public policy concerns." *Webb v. Jarvis*, 575 N.E.2d 992, 995 (Ind. 1991).

With this precedent in mind, we must predict whether the Indiana Supreme Court would recognize a duty if faced with this precise question. We begin with this Court's precedent in *Combs*, guiding us to choose the interpretation of state law that reasonably restricts liability over one that greatly expands liability where the state's highest court has not spoken. *Combs*, 354 F.3d at 577 (quoting *Todd*, 21 F.3d at 1412). From there, we take up the three factors in *Webb*. First, the party's relationship, we note that the generic consumers were injured by a product that the Brand Manufacturers did not manufacture, and, as already noted, courts are reluctant to impose "competitor liability." *See, e.g.*, *Foster*, 29 F.3d at 171. Second, the generic

consumers' injuries are not the foreseeable result of the Brand Manufacturers' conduct, but of the laws over which the Brand Manufacturers have no control. Using federal and Indiana state laws designed to increase the availability of generic drugs as the basis of supplying the duty element for tort liability stretches foreseeability too far. *See* Schwartz et al. at 1870-71. Further there are grave health policy consequences associated with recognizing brand manufacturer liability in these situations including higher priced brand name drugs and fewer innovative drugs. *Id*. Taken together, we predict that the Indiana Supreme Court would decline to recognize that brand manufacturers owe generic consumers a duty of care that could give rise to liability. Thus, the district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Indiana law.

7. Kentucky

This Court has already determined that claims by consumers of generic drugs against brand manufacturers cannot survive under Kentucky law. *Smith*, 657 F. 3d at 424 (affirming judgment for brand defendants' favor on all claims asserted against them). We may not overrule the published decision of a prior panel. *Gilliam v. Mitchell*, 179 F.3d 990, 994 (6th Cir. 1999). Thus, the district court did not err in dismissing Kentucky Plaintiffs' misrepresentation claims against the Brand Manufacturers.

8. Louisiana

The Fifth Circuit and a number of federal courts construing Louisiana law have rejected claims by generic drug consumers against brand manufacturers. *Demahy*, 702 F.3d 177; *see, e.g., Cooper v. Wyeth, Inc.*, No. 09-CV-929, 2010 WL 4318816, *2-3 (M.D. La. Oct. 26, 2010); *Johnson v. Teva Pharms. USA, Inc.*, No. 3:10-cv-00227, 2010 WL 3271934, *3 (W.D. La. Aug. 16, 2010). The *Demahy* court noted that the Louisiana Product Liability Act ("LPLA") "broadly applies to all suits involving injuries from products" including alleged common law claims against defendants who did not "manufacture" the product in question. *Demahy*, 702 F.3d at 183 n.4 (citing La. Rev. Stat. Ann. §9:2800.52). Because plaintiffs in that case could not prove product identification, their claim failed. Even if the LPLA did not apply, the Fifth Circuit concluded, plaintiff's "tort claims would fail since [the brand defendants] did not manufacture the generic product giving rise to [the plaintiff's] claims, and thus owed [the plaintiff] no duty of

care." *Id*. It noted that 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 . . . ." *Id*. (citations omitted).

Guided by our sister circuit's decision, we predict that the Louisiana Supreme Court would either construe Plaintiffs' misrepresentation claims as product liability claims under the LPLA that fail for lack of product identification or that Brand Manufacturers did not owe Plaintiffs a duty that could give rise to liability under Louisiana law. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Louisiana law.

9. Maryland

The Fourth Circuit has rejected claims by generic drug consumers against brand defendants for alleged negligent misrepresentation under Maryland law. *Foster*, 29 F.3d at 168. Surveying prior product cases applying Maryland law, the Court found that a plaintiff "seeking to recover for an injury by a product to demonstrate that the defendant manufactured the product at issue" *Id*. (citations omitted); *see also Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 92 (D. Md. 1989) (noting it is "axiomatic" that plaintiff must "prove that the defendant manufacturer made the product that caused plaintiff's injury"); *Jensen v. Am. Motors Corp.*, 437 A.2d 242, 247 (Md. Ct. Spec. App. 1981) ("Regardless of the recovery theory, the plaintiff in product litigation must satisfy three basics from an evidentiary standpoint: 1) the existence of a defect; 2) the attribution of the defect to the seller; and 3) a causal relation between the defect and the injury.").

Guided by our sister circuit's decision, we predict that the Maryland Court of Appeals would construe Plaintiffs' misrepresentation claims as product litigations that fail for lack of product identification. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Maryland law.

10. Michigan

There are no state or federal court cases interpreting whether generic consumers may hold brand manufacturers liable for their injuries under Michigan law. The Michigan Revised

Judicature Act of 1961 includes a provision defining "product liability actions" as those "based on a legal or equitable theory of liability brought for . . . injury to a person . . . caused by or resulting from the production of a product." Mich. Comp. Laws §600.2945(h). Michigan courts require that plaintiffs in product liability actions prove that the defendant manufactured the injury-causing product. *Abel v. Eli Lilly & Co.*, 343 N.W.2d 164, 170 (Mich. 1984) (noting that "the threshold requirement of any products liability action is identification of the injury-causing product and its manufacturer"). Nonetheless, the statute does not clearly foreclose or permit common law actions against non-manufacturers for misrepresentations based on injuries from products. Thus, the question is whether Brand Manufacturers' owed generic consumers a duty of care that could give rise to liability for their alleged misrepresentations. The Michigan Supreme Court has said that whether a defendant owes a plaintiff a duty depends on "the relationship between the parties, the nature and foreseeability of the risk, and any other considerations that may be relevant on the issue." *Buczkowski v. McKay*, 490 N.W.2d 330, 334 (Mich. 1992).

With this precedent in mind, we must predict whether the Michigan Supreme Court would recognize a duty owed by brand manufacturers to consumers of generic drugs. We begin with this Court's precedent in *Combs*, guiding us to choose the interpretation of state law that reasonably restricts liability over one that greatly expands liability where the state's highest court has not spoken. *Combs*, 354 F.3d at 577 (quoting *Todd*, 21 F.3d at 1412). From there, we take up the three factors in *Buczkowski*. First, regarding the party's relationship, the generic consumers were injured by a product that the Brand Manufacturers did not manufacture, and as already noted, courts are reluctant to impose "competitor liability." *See, e.g.*, *Foster*, 29 F.3d at 171. Second, the generic consumers' injuries are not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand manufacturers have no control. Using federal and Michigan state laws designed to increase the availability of generic drugs as the basis of supplying the duty element for tort liability stretches foreseeability too far. *See* Schwartz et al. at 1870-71. Finally, there are grave health policy consequences associated with recognizing brand manufacturer liability in these situations, including higher priced brand name drugs and fewer innovative drugs. *Id*. Taken together, we predict that the Michigan Supreme Court would decline to recognize that brand manufacturers owe generic consumers a duty of care

that could give rise to liability. Thus, the district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Michigan law.

11. Mississippi

The Fifth Circuit and federal district courts construing Mississippi law have rejected claims attempting to impose liability on brand defendants when plaintiffs ingested only generic pharmaceutical products. *Lashley*, 2014 WL 661058, at *4; *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 604 (N.D. Miss. 2013), *reconsideration denied*, 2013 WL 5423951 (N.D. Miss. Sep. 26, 2013); *Wash. v. Medicis Pharms. Corp.*, No. 3:12-cv-126, 2013 WL 496063, *5 (S.D. Miss. Feb. 7, 2013). The *Lashley* court noted that the Mississippi Products Liability Act ("MPLA") applies "in any action for damages caused by a product" and requires a plaintiff to prove that it was the defendant's product that caused the injury. *Lashley*, 2014 WL 661058 at *4 (citing Miss. Code Ann. § 11-1-63; *Monsanto Co. v. Hall*, 912 So.2d 134, 136-37 (Miss. 2005)). Because the plaintiff did not ingest the brand manufacturers' product, the court held that he had not established a duty of care that could give rise to liability. *Id*. (citing *Moore ex rel. Moore v. Miss. Valley Gas Co.*, 863 So.2d 43, 46 (Miss. 2003) ("[I]t is incumbent upon the plaintiff in any products liability action to show that the defendant's product was the cause of the plaintiff's injuries.")).

Guided by our sister circuit's decision, we predict that the Mississippi Supreme Court would construe Plaintiffs' misrepresentation claims as a product liability claim under the MPLA that fails for lack of product identification. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Mississippi law.

12. Nebraska

There are no state or federal court cases interpreting whether generic consumers may hold brand manufacturers liable for their injuries under Nebraska law. Nebraska has a statute defining a "product liability action" as "any action brought against a manufacturer, seller, or lessor of a product, regardless of the substantive legal theory or theories upon which the action is brought, for or on account of personal injury [or] death." Neb. Rev. Stat. §25-21, 180. It limits product liability claims based on the doctrine of strict liability to "the manufacturer of the

product or part thereof claimed to be defective." Neb. Rev. Stat. § 25-21, 181. The District of Nebraska, construing Nebraska law, has held that claims against a product manufacturer for injuries allegedly caused through use of a product are "product liability actions" under the statute, no matter the theory alleged. *BNSF Ry. Co. v. L.B. Foster Co.*, 917 F. Supp. 2d 959, 966-67 (D. Neb. 2013) (explaining plaintiff's negligent misrepresentation, fraudulent misrepresentation, and fraudulent concealment claims "merely reframe[] its product liability action" and treating claims as product liability claims under Nebraska law). Characterized as product liability actions, Plaintiffs' claims would fail for lack of product identification. *See Sherman*, 485 F. Supp. 2d at 1078.

However, if the Nebraska Supreme Court were to characterize Plaintiffs' misrepresentation as actionable under the common law, the question would become whether the Brand Manufacturers owed generic consumers a duty that could give rise to liability. In order to determine whether defendants owe plaintiffs a duty in a novel situation, Nebraska courts follow the Restatement (Third) of Torts. Under that regime, actors must "exercise reasonable care" when their conduct creates a risk of harm, but courts may decide a defendant has "no duty" in exceptional cases when a countervailing policy warrants denying or limiting liability. *A.W. v. Lancaster Cnty. Sch. Dist. 0001*, 784 N.W.2d 907, 918 (2010) (citing Restatement (Third) of Torts: Phys. & Emot. Harm § 7 (2010)). First, Brand Manufacturers' conduct did not create the risk of harm that caused plaintiffs' injuries, rather the Congressional and Nebraska state laws designed to increase the availability of generic drugs did. *See* Schwartz et al., at 1870-71. Second, there are grave health policy consequences associated with recognizing brand manufacturer liability in these situations including higher priced brand name drugs and fewer innovative drugs. *Id*. The potential ramifications for Nebraskans' health and welfare make this an exceptional case that would warrant denying liability.

We predict that the Nebraska Supreme Court would either construe Plaintiffs' misrepresentation claims as product liability claims under the Nebraska statute defining product liability actions that fail for lack of product identification, or that the Brand Manufacturers did not owe the Plaintiffs a duty that could give rise to liability under Nebraska law. The district

court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Nebraska law.

13. New York

The Northern District of New York and the Supreme Court of the State of New York for New York County, construing New York law, have rejected claims attempting to impose liability on brand defendants when plaintiffs ingested only generic pharmaceutical products. *Goldych v. Eli Lilly & Co.*, No. 5:04-cv-1477, 2006 WL 2038436, *2 n.3 (N.D.N.Y. July 19, 2006); *Weese v. Pfizer*, No. 153742/12, 2013 N.Y. Misc. LEXIS 4761 (N.Y. Sup. Ct. Oct. 8, 2013).

Goldych involved several common law claims, including negligent misrepresentation, against brand manufacturer Eli Lilly by a plaintiff whose husband committed suicide after ingesting the generic equivalent of Prozac. The Northern District held that "a brand name manufacturer cannot be held liable to a plaintiff allegedly injured by another company's generic bioequivalent." *Goldych*, 2006 WL 2038436, *6. It reasoned that despite the asserted theories, plaintiffs had effectively brought a product liability suit and thus could not circumvent the product identification requirement of New York product liability law. *Id*. at *1 n.3.

Weese involved claims against brand name manufacturer Pfizer by a mother, who had ingested generic Zoloft, after her daughter was born with birth defects. *Weese*, 2013 N.Y. Misc. LEXIS 4761, at 1. The Supreme Court held that any duty a brand defendant has "in connection with its own products and labels" does not extend "to products and labeling over which it has no control, even if those products and labels mirror its own, because it has done nothing toward putting them in the hands of consumers." *Id*. at 3-4.

We predict that the New York Court of Appeals would construe Plaintiffs' misrepresentation claims as a product liability claim that fails for lack of product identification, or alternatively that the Brand Manufacturers did not owe Plaintiffs a duty that could give rise to liability. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under New York law.

14. North Carolina

Two North Carolina federal courts, construing North Carolina law, have held that misrepresentation claims by users of generic drugs against brand name manufacturers are prohibited. *Couick*, 691 F. Supp. 2d at 646; *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 634 (E.D.N.C. 2009). In *Couick*, the court dismissed several claims, including misrepresentation, by consumers of the generic version of Reglan against two brand name manufacturers. It held that although the plaintiffs' claims were "masked in various legal theories, they [were] premised on a single claim of product liability" and, therefore, fell under North Carolina's product liability statute. *Couick*, 691 F. Supp. 2d at 645 (citing N.C. Gen. Stat. §§99B-1(3)). The statute states that any personal injury action "caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling of any product" is a product liability action. *Id*. Because the plaintiffs could not satisfy the product identification requirement, the court dismissed their claims. Faced with similar facts, the *Stoddard* court concluded that under North Carolina law, brand name manufacturers "may not be held liable for injuries stemming from the use of another manufacturer's generic bioequivalent." *Stoddard*, 630 F. Supp. 2d at 634.

Guided by these decisions, we predict that the North Carolina Supreme Court would construe Plaintiffs' misrepresentation claims as product liability claims that fail for lack of product identification, or alternatively that the Brand Manufacturers did not owe Plaintiffs a duty that could give rise to liability. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under North Carolina law.

15. Ohio

The Southern District of Ohio rejected misrepresentation claims by generic consumers against brand drug manufacturers. In *Hogue v. Pfizer*, Inc., 893 F. Supp. 2d 914, 915 (S.D. Ohio 2012), the court considered claims by plaintiffs who ingested generic Reglan against the brand-name manufacturer under Ohio Law. The court noted that the Ohio Product Liability Act ("OPLA") expressly "abrogate[s] all common law product liability claims or causes of action," and defines a product liability action as those where the alleged injuries arise from the

"formulation" of the product or "[a]ny warning or instruction, or lack of warning or instruction, associated with that product." *Id*. at 917 (citing Ohio Rev. Code §§ 2307.71(B), 2307.71(A)(13)(b)). Further, the OPLA requires proof that the defendant manufactured "the actual defective product in the product liability claim." *Id*. (citing Ohio Rev. Code § 2307.71(C)). Looking to Ohio case law interpreting the OPLA, the *Hogue* court observed that while active fraud claims can exist outside the statute, the "OPLA does abrogate fraud claims arising from a duty to warn." *Id*. at 918 (citing *Glassner v. R.J. Reynolds Tobacco Co.*, 223 F.3d 343, 348-49 (6th Cir. 2000)). Thus, it held that the plaintiffs' claims fell under the OPLA and were subject to its product identification requirement.

Guided by the *Hogue* court's analysis of Ohio products liability statutory and case law, we predict that the Ohio Supreme Court would construe Plaintiffs' misrepresentation claims as product liability claims that fail for lack of product identification. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Ohio law.

16. Oklahoma

The Tenth Circuit affirmed two federal district courts construing Oklahoma law and rejecting the notion that a brand name drug manufacturer can be held liable when the plaintiff ingested only the manufacturer's competitors' drugs. *Schrock*, 601 F. Supp. 2d at 1266; *Schrock v. PLIVA USA, Inc.*, CIV-08-453-M, 2011 WL 6122768 (W.D. Okla. Dec. 8, 2011) *aff'd sub nom. Schrock v. Wyeth, Inc.*, 727 F.3d 1273 (10th Cir. 2013). These courts noted that for both strict liability and negligence theories of liability, Oklahoma courts require a relationship between the defendant company and the product at issue. *Schrock*, 727 F.3d 1273, 1282 (10th Cir. 2013) (citing *Kirkland v. Gen. Motors Corp.*, 521 P.2d 1353, 1362 (Okla. 1974) (holding that to prevail on strict liability claim for a defective product, plaintiff must show the product was defective when it left the defendant's "possession and control"); *Spence v. Brown–Minneapolis Tank, Co.*, 198 P.3d 395, 401 (Okla. Civ. App. 2008) (rejecting a negligence claim premised on an injury caused by a product because the defendant "had nothing to do with the manufacture" of the product at issue and did not "occupy a relationship which gives rise to a legal obligation.")). It determined that the plaintiffs and brand manufacturers did not have such a recognized relationship. The *Schrock* court also found the plaintiff's claims unsupported by

decisions rendered by lower courts in Oklahoma, federal district court decisions interpreting Oklahoma law, or appellate decisions in other states with similar legal principles. *Id*. at 1284 (citing *Wade v. EMCASCO Ins. Co.*, 483 F.3d 657, 666 (10th Cir. 2007)). From these sources, it predicted the Oklahoma Supreme Court would not recognize plaintiffs' misrepresentation theory of liability against brand manufacturers.

Guided by our sister circuit's analysis of Oklahoma tort law, we predict that the Oklahoma Supreme Court would find that Brand Manufacturers did not owe Plaintiffs a duty that could give rise to liability under Oklahoma law. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Oklahoma law.

17. Pennsylvania

The Eastern District of Pennsylvania dismissed claims by generic consumers against brand manufacturers in *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 543 (E.D. Pa. 2006) *aff'd*, 521 F.3d 253 (3d Cir. 2008) *vacated and remanded on other grounds*, 556 U.S. 1101 (2009). In *Colacicco*, the plaintiff brought an action against both a brand manufacturer, GlaxoSmithKline, and generic manufacturer, Apotex Corp., alleging that his wife committed suicide after ingesting the generic equivalent of Paxil. The court held that, under Pennsylvania law, "a name brand drug manufacturer does not owe a legal duty to consumers of a generic equivalent of its drug." *Id*. at 538-39. Because there was no guidance from prior courts, the *Colacicco* court looked to public policy and various factors the Pennsylvania Supreme Court instructs should be weighed in order to determine whether a duty exists in a particular case under Pennsylvania law, including: "(1) the relationship between the parties; (2) the social utility of the actor's conduct; (3) the nature of the risk imposed and foreseeability of the harm incurred; (4) the consequences of imposing a duty upon the actor; and (5) the overall public interest in the proposed solution." *Id*. (citing *Althaus ex rel. Althaus v. Cohen*, 756 A.2d 1166, 1169 (Pa. 2000)). Persuaded by the *Foster* opinion, the court realized that the Fourth Circuit touched on these factors and adopted its holding. In its view, imposing liability on brand manufacturers "would be to stretch the concept of foreseeability too far" and would be contrary to Pennsylvania public policy not to inhibit new and effective prescription drugs. *Id*. at 541-42 (citing *Foster*, 29 F.3d at 171).

Guided by the Eastern District's analysis of Pennsylvania tort law, we predict that the Pennsylvania Supreme Court would find that Brand Manufacturers did not owe Plaintiffs a duty that could give rise to liability under Pennsylvania law. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Pennsylvania law.

18. South Carolina

The District of South Carolina rejected claims, including misrepresentation, by generic drug consumers against brand name manufacturers under South Carolina law. *Fisher v. Pelstring*, 4:09-CV-00252-TLW, 2010 WL 2998474, *8 (D.S.C. July 28, 2010). The *Fisher* court began by looking to how other courts within its circuit resolved this issue under Maryland, North Carolina, and West Virginia law respectively. *Id*. at *2-3 (citing *Foster*, 29 F.3d at 171 (applying Maryland law); *Stoddard*, 630 F. Supp. 2d at 631 (applying North Carolina law); *Couick*, 691 F. Supp. 2d at 643 (applying North Carolina law); *Meade v. Parsley*, 2009 WL 3806716 (S.D. W.Va. 2009) (applying West Virginia law). Each of those courts concluded that, under applicable state law, brand manufacturers could not be liable for generic consumers' injuries, either because of lack of product identification or lack of a duty of care. *Id*. at *3-*6. From there, the *Fisher* court looked to prior cases applying South Carolina law in comparable contexts, noting that a "crucial element of each claim under South Carolina law is that the defendant owe the plaintiff a duty of due care." *Id*. at *8 (citing *Hurst v. Sandy*, 494 S.E.2d 847, 852 (S.C. Ct. App. 1997)). It ultimately held that plaintiffs could not establish that the brand manufacturers owed them a duty because they did not manufacture or sell the products allegedly responsible for their injuries. *Id*.

Guided by the *Fisher* court's analysis of South Carolina law, we predict that the South Carolina Supreme Court would find that Brand Manufacturers did not owe Plaintiffs a duty that could give rise to liability under South Carolina law. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under South Carolina law.

19. Tennessee

This Court has already determined that claims by consumers of generic drugs against brand manufacturers cannot stand under Tennessee law. *Strayhorn*, 737 F.3d at 405. We may

not overrule the published decision of a prior panel. *Gilliam*, 179 F.3d at 994. Thus, the district court did not err in dismissing Tennessee Plaintiffs' misrepresentation claims against the Brand Manufacturers.

20. Texas

The Fifth Circuit and federal district courts construing Texas law have rejected claims attempting to impose liability on brand defendants when plaintiffs ingested only generic pharmaceutical products. *Lashley*, 2014 WL 661058, at *5; *see, e.g., Eckhardt v. Qualitest Pharm. Inc.*, 889 F. Supp. 2d 901 (S.D. Tex. 2012); *Phares v. Actavis-Elizabeth LLC*, 892 F. Supp. 2d 835, 844 (S.D. Tex. 2012); *Del Valle v. Pliva, Inc.*, No. 11-CV-113, 2012 WL 4747259 (S.D. Tex. Sept. 12, 2012); *Finnicum v. Wyeth, Inc.*, 708 F. Supp. 2d 616, 619-21 (E.D. Tex. 2010); *Burke v. Wyeth, Inc.*, No. G-09-82, 2009 WL 3698480, *3 (S.D. Tex. Oct. 7, 2009). The *Lashley* court noted that under Texas law, a product liability action is broadly defined as "any action against a manufacturer or seller for recovery of damages arising out of personal injury . . . allegedly caused by a defective product whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories." *Lashley*, 2014 WL 661058, at *5 (citing Tex. Civ Prac. & Rem. Code Ann. § 82.001(2)). It found that in product liability law actions, "the plaintiff must prove that the defendants supplied the product which caused the injury." *Id*. (citing *Gaulding v. Celotex Corp.*, 772 S.W.2d 66, 68 (Tex. 1989) (other citations omitted)). Further, the court noted that, in Texas, "a drug manufacturer enjoys a rebuttable presumption that it is not liable for failure to warn if the FDA has approved 'the warnings or information' accompanying the product alleged to have harmed the plaintiff." *Id*. at *6 (citing *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 374 (5th Cir. 2012) (quoting Tex. Civ. Prac & Rem. Code § 82.007(a)(1)). Because the brand defendants did not manufacture the generic drug that allegedly caused plaintiffs injuries, and because brand defendants' labels were approved by the FDA, the *Lashley* court found they could not be held liable under Texas law.

Guided by our sister circuit's decision, we predict that the Texas Supreme Court would construe Plaintiffs' misrepresentation claims as product liability claims that fail for lack of

product identification. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Texas law.

21. Washington

There are no state or federal court cases interpreting whether generic consumers may hold brand manufacturers liable for their injuries under Washington law. However, a Pennsylvania state court construing Washington law held that a plaintiff who used only a generic pharmaceutical product could not recover against the manufacturer of the brand name pharmaceutical product. *Madden v. Teva Pharms.*, No. 0087, 2012 WL 4757253, *12 (Pa. C.P., 1st Dist., Oct. 1, 2012). In *Madden*, a physician prescribed the sedative-hypnotic Ambien for the plaintiff in Washington, the plaintiff had the prescription filled with the generic version of Ambien in California, and the plaintiff was injured after sleep-driving in California. The plaintiff brought an action against the brand manufacturer and generic manufacturer in Pennsylvania, the state where the generic manufacturer is headquartered. The Court of Common Pleas of Pennsylvania conducted a conflict of laws analysis and determined that Washington's laws should apply to the claims against the brand manufacturer, because the alleged representations that formed the basis of that complaint occurred there. *Id*. at *8-*9.

The *Madden* court noted that under the Washington Product Liability Act ("WPLA"), a "product liability claim includes . . . but is not limited to, any claim or action previously based on . . . misrepresentation." *Id*. at *9 n.4 (citing Wash. Rev. Code. §7.72.010(4)). It looked to Washington Supreme Court cases construing the WPLA as "provid[ing] the exclusive remedy for product liability claims in Washington" and "subsum[ing] virtually all prior causes of action" including claims for negligence and negligent misrepresentation. *Id*. at *7-*8 (citing *Wash. Water Power Co. v. Graybar Elec. Co.*, 774 P.2d 1199, 1202-03 (Wash. 1989)). Under the WPLA, product liability claims can only be brought against the manufacturer or seller of the relevant product. Wash. Rev. Code. §7.72.010(1)-(4). Because the claims against the brand manufacturer were product liability actions, and because the brand manufacturer did not manufacture the product that caused the plaintiff's injury, the court rejected the claims.

Guided by the *Madden* decision and the clear terms of the WPLA, we predict that the Washington Supreme Court would construe Plaintiffs' misrepresentation claims as a product

liability claim under the WPLA that fails for lack of product identification. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers that arise under Washington law.

22. West Virginia

The Southern District of West Virginia, construing West Virginia law, has rejected claims attempting to impose liability on brand manufacturers where plaintiffs ingested only generic drugs. *Meade*, 2009 WL 3806716, at *3. The *Meade* court looked to its court of appeals' decision in *Foster*, and the line of cases from states within the Fourth Circuit, holding brand manufacturers not responsible for misrepresentations when a generic manufacturer's product caused the plaintiffs' injury. *Id*. at *2. It noted that even though "*Foster* was based in Maryland product liability law, West Virginia law does not yield a different result." *Id*. at *3. Citing cases from the Supreme Court of Appeals of West Virginia, the *Meade* court noted that West Virginia law requires that the defendants manufacture, sell, or distribute the product that injured the plaintiffs. Because the generic consumers' complaint failed to satisfy this product identification requirement, it failed. *Id*. (citing *Dunn v. Kanawha Cnty. Bd. of Educ.*, 459 S.E.2d 151, 157 (1995); *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 677 (1979)). The *Meade* court also held that plaintiffs failed to establish that brand manufacturers owed them a duty of care because under West Virginia law plaintiffs cannot recover from non-manufacturers for injuries caused by a defective product. *Id*. at *3.

Guided by the *Meade* court, we predict that the West Virginia Supreme Court of Appeals would construe Plaintiffs' misrepresentation claims as product liability claims that fail for lack of product identification, or alternatively that the Brand Manufacturers did not owe Plaintiffs a duty that could give rise to liability. The district court did not err in dismissing Plaintiffs' claims against the Brand Manufacturers arising under West Virginia law.