United States Court of Appeals
For the Eighth Circuit

No. 12-1674

Shirley J. Bell

Plaintiff - Appellant

v.

Pfizer, Inc.; Wyeth, LLC; Schwarz Pharma, Inc.;
Pliva USA; Alaven Pharmaceutical, LLC

Defendants - Appellees

Appeal from United States District Court
for the Eastern District of Arkansas - Pine Bluff

Submitted: November 15, 2012
Filed: June 14, 2013

Before RILEY, Chief Judge, WOLLMAN and MELLOY, Circuit Judges.

RILEY, Chief Judge.

Shirley J. Bell, a resident of Monticello, Arkansas, alleges she was injured by the prescription medication metoclopramide, which is available in both generic forms and under the brand-name Reglan. Bell sued in federal court under our diversity jurisdiction, see 28 U.S.C. § 1332(a)(1), alleging various causes of action against Pliva USA, the maker of the generic drug Bell took, and Wyeth, LLC (and its parent,

Pfizer, Inc.), Schwarz Pharma, Inc., and Alaven Pharmaceutical, LLC (brand defendants), the makers of Reglan at different times. Bell appeals the district court's adverse grant of summary judgment to the brand defendants and dismissal of her claims against Pliva. We affirm in part, reverse in part, and remand for further consideration.

I. BACKGROUND

In January 2008, Bell's physician prescribed the brand name drug Reglan to treat Bell's abdominal pain and epigastric problems. As permitted by Arkansas law, Bell's pharmacist substituted generic metoclopramide manufactured by Pliva for the brand name Reglan prescribed by Bell's physician. See Ark. Code Ann. § 17-92-503. Bell stipulated she only ingested generic metoclopramide and never took Reglan, and Bell does not claim to have taken any other product manufactured by the brand defendants. Bell continued to take metoclopramide as directed through December 2008.

Bell alleges she developed the neurological movement disorder tardive dyskinesia as a result of "long-term ingestion" of metoclopramide. In 2009, the United States Food and Drug Administration (FDA) required manufacturers of metoclopramide to change their label to include a black box warning about the risk of tardive dyskinesia from prolonged treatment. Bell faults the brand defendants and Pliva for not adequately informing her and her physician before 2009 of the known risks associated with long-term metoclopramide use.

On April 12, 2010, Bell filed this product liability action, asserting the following claims for relief against all defendants: negligence; strict liability; breach of warranties; misrepresentation, suppression of evidence, and fraud; and gross negligence.

On July 14, 2010, the brand defendants moved for summary judgment based on Bell's stipulation that she did not use their products. The district court granted the motion, concluding Bell could not maintain her claims under the Arkansas Product Liability Act of 1979 (APLA), Ark. Code Ann. § 16-116-101 et seq., which requires proof of product identification. Relying in part on Section III of our decision in Mensing v. Wyeth, Inc. (Wyeth), 588 F.3d 603, 612-14 (8th Cir. 2009) rev'd in part on other grounds sub nom. Pliva, Inc. v. Mensing (Mensing), 564 U.S. ___, 131 S. Ct. 2567 (2011), the district court also determined the brand defendants did not owe Bell any duty under Arkansas common law.

After the district court's summary judgment order, the Supreme Court issued its opinion in Mensing. In Mensing, the Supreme Court held federal law preempted "state tort-law claims based on certain drug manufacturers' alleged failure to provide adequate warning labels for generic metoclopramide," Mensing, 564 U.S. at ___, 131 S. Ct. at 2572, because it was "impossible" for a generic manufacturer "to comply with both their state-law duty to change the label and their federal law duty to keep the label the same," id. at ___, 131 S. Ct. at 2578. The Supreme Court reversed our judgment in Wyeth, but did not analyze the liability of a brand name manufacturer under these circumstances. Id. at ___, 131 S. Ct. at 2582. On remand, we reinstated Section III of our opinion in Wyeth, which addressed the claims against the brand name manufacturers. See Mensing v. Wyeth, Inc. (Wyeth II), 658 F.3d 867 (8th Cir. 2011).

Upon Bell's request, the district court permitted Bell to amend her complaint to address the impact of Mensing on her failure to warn claims against Pliva. On November 7, 2011, Pliva filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12. On February 16, 2012, the district court granted Pliva's motion to dismiss, finding "ample authority supporting [Pliva's] position that Bell's newly-styled allegations remain, in essence, failure-to-warn claims that are barred by Mensing." Bell appeals.

II. DISCUSSION

A. Standards of Review

We review de novo the district court's grant of summary judgment, viewing all evidence and drawing all reasonable inferences in favor of the nonmoving party. See Crawford v. Van Buren Cnty., Ark., 678 F.3d 666, 669 (8th Cir. 2012). Summary judgment is required "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

We also review de novo the district court's grant of a motion to dismiss. See Murphy v. Aurora Loan Servs., LLC, 699 F.3d 1027, 1033 (8th Cir. 2012). Dismissal is proper where the plaintiff's complaint fails "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). "As part of this review we assume all factual allegations in the pleadings are true and interpret them 'in the light most favorable to the nonmoving party.'" Murphy, 699 F.3d at 1033 (quoting Cmty. Fin. Grp., Inc. v. Republic of Kenya, 663 F.3d 977, 980 (8th Cir. 2011)). "[W]e interpret Arkansas law in determining whether the elements of the offenses have been pled." Ashley Cnty., Ark. v. Pfizer, Inc., 552 F.3d 659, 665 (8th Cir. 2009) (quoting Moses.com Sec., Inc. v. Comprehensive Software Sys., Inc., 406 F.3d 1052, 1062 (8th Cir. 2005)) (internal marks omitted).

B. Bell's Motion to Supplement the Record

Before oral argument, Bell moved this court to allow her to supplement the record with additional evidence she acquired from the FDA's "website identifying various marketing and promotional materials that manufacturers of generic drugs have used to provide physicians and consumers with information about their products." Bell contends the additional evidence refutes Pliva's contention that "as a generic manufacturer it was prohibited by federal law from disseminating any labeling or information concerning its drug under any and all circumstances." Bell also asks to

supplement the record with her response to the brand defendants' motion for summary judgment to show she did not abandon certain claims.

We deny Bell's motion. Bell's district court brief is already part of the record we have reviewed. See Fed. R. App. P. 10(a)(1) (explaining the record includes all "the original papers and exhibits filed in the district court"). And we find no compelling reason to allow Bell to supplement the record with evidence available from the FDA long before the district court decided this case. See Fed. R. App. P. 10(e); Dakota Indus., Inc. v. Dakota Sportswear, Inc., 988 F.2d 61, 63 (8th Cir. 1993) (explaining our authority to enlarge the record when the interests of justice demand it, but noting we rarely exercise this narrow exception to the general rule that the appellate court only consider evidence contained in the record before the district court).

C. Brand Defendants

Although Bell admits she never ingested Reglan, Bell contends the brand defendants are liable for her injuries because the generic manufacturers copied the brand defendants' Reglan labeling. An "overwhelming majority of courts considering this issue," including the Eighth Circuit, have rejected Bell's theory of liability. Wyeth, 588 F.3d at 613; see also Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170 (4th Cir. 1994) ("There is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control.").

In Wyeth, this court, applying Minnesota law to claims nearly identical to Bell's, determined the manufacturers of brand name Reglan were not liable to a plaintiff who never ingested their products because the plaintiff's connection, if any, to the brand name manufacturers was too attenuated. Wyeth, 588 F.3d at 613-14 & n.9. In joining the majority of courts declining to hold "name brand manufacturers

liable for injuries caused by their competitors," id. at 613, we concluded the brand name manufacturers did not owe a duty of care to users of their competitor's generic products "necessary to trigger liability" under Minnesota law, id. at 614. Accord Foster, 29 F.3d at 171 ("We think to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far.").

Arkansas law compels the same result. Bell's claims against the brand defendants are product liability actions under Arkansas law. See Ark. Code Ann. § 16-116-102(5). Section 16-116-102(5) of APLA 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, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging, or labeling of any product." This broad language encompasses Bell's various claims regardless of her theory of recovery.

As noted by the district court, to prove her product liability claims under Arkansas law, Bell must show that a product manufactured or distributed by the brand defendants caused her injuries. See Chavers v. Gen. Motors Corp., 79 S.W.3d 361, 369-70 (Ark. 2002); Jackson v. Anchor Packing Co., 994 F.2d 1295, 1303 (8th Cir. 1993) (observing "plaintiffs in Arkansas must introduce sufficient evidence to allow a jury to find that more likely than not their exposure to a particular defendant's product was a substantial factor in producing their injuries"); Fields v. Wyeth, Inc., 613 F. Supp.2d 1056, 1060 (W.D. Ark. 2009) ("A basic requirement of products-liability actions under Arkansas law is product identification, i.e. that the actual product manufactured or distributed by the defendant caused injury to the plaintiff."). Because Bell never used Reglan the brand defendants manufactured, Bell cannot hold them liable under Arkansas law.[1]

[1]Bell argues, for the first time on appeal, that the brand defendants qualify as "manufacturers" of the metoclopramide Bell ingested because they are the exclusive "designer" of the product and the labeling. See Ark. Code. Ann. § 16-116-102(3)

Bell acknowledges "it is necessary to establish proximate cause by way of product identification" with respect to her strict liability and breach of warranty claims, but maintains her "negligence, misrepresentation, suppression of evidence and fraud claims do not require product identification." Bell provides no support under Arkansas law for the distinction she draws—a distinction that runs counter to the APLA's approach of treating all product liability actions consistently, regardless of the theory of recovery.

In fact, one of the cases on which Bell relies to attempt to show a negligence exception, Rogers v. Armstrong World Indus., Inc., 744 F. Supp. 901 (E.D. Ark. 1990), noted product identification was an element of strict products liability, breach of warranty, and negligence claims under Arkansas law. See id. at 904 ("[A]lthough the plaintiff relies on several theories of recovery, it is uncontroverted that under Arkansas law an essential element of each cause of action is that plaintiff's injuries were proximately caused by his exposure to the defendant's product."). Bell's recitation of the elements of misrepresentation and fraud under Arkansas law fails to persuade us the Arkansas Supreme Court would create an exception to the Arkansas product identification requirement to allow Bell to hold the brand defendants liable for injuries caused by their competitor's generic products.

Even if we were to ignore Arkansas's product identification requirement, Bell has also failed to establish the brand defendants "owed her a duty of care necessary to trigger liability" under Arkansas law. Wyeth, 588 F.3d at 614 (applying Minnesota law). "As a general rule, a manufacturer has a duty to warn the ultimate user of the risks of its product." West v. Searle & Co., 806 S.W.2d 608, 613 (Ark. 1991). Bell,

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("'Manufacturer' means the designer, fabricator, producer, compounder, processor, or assembler of any product or its component parts."). Though we are skeptical of Bell's new theory, "[a]bsent exceptional circumstances," not present here, "we cannot consider issues not raised in the district court." Shanklin v. Fitzgerald, 397 F.3d 596, 601 (8th Cir. 2005).

like the plaintiff in Wyeth, points to nothing in Arkansas law that supports extending such a duty of care to the customer of a competitor using a competing product. See Wyeth, 588 F.3d at 613-14 & n.9.

Bell argues her injuries were foreseeable and the brand defendants should be liable for misrepresentations to Bell and her physician about the safety of metoclopramide. We rejected those arguments in Wyeth as insufficient to show a duty under Minnesota law. See id. (reasoning "[t]he Reglan manufacturers intended to communicate with their customers, not the customers of their competitors" and concluding "holding name brand manufacturers liable for harm caused by generic manufacturers 'stretch[es] the concept of foreseeability too far'" (quoting Foster, 29 F.3d at 171)). Anticipating Arkansas law, we reach the same conclusion here. The district court did not err in determining Bell's claims against the brand defendants failed as a matter of law because Bell stipulated she had not ingested a product manufactured by the brand defendants.

D. Pliva

1. Hatch-Waxman Amendments and FDA Regulations

The labeling of prescription drugs is governed by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq. "[A] manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate." Mensing, 564 U.S. at ___, 131 S. Ct. at 2574. In 1984, Congress amended the FDCA to allow manufacturers of generic drugs to obtain "FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA." Id. at ___, 131 S. Ct. at 2574 (citing 21 U.S.C. § 355(j)(2)(A)). The amendments, commonly referred to as the Hatch-Waxman Amendments, permitted generic "manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." Id. at ___, 131 S. Ct. at 2574.

To obtain approval for a generic drug, the manufacturer generally must show the generic drug is "bioequivalent" to the brand name drug and has the same active ingredients, route of administration, dosage, and strength. 21 U.S.C. § 355(j)(2)(A). The generic manufacturer must also "'show that the [safety and efficacy] labeling proposed . . . is the same as the labeling approved for the [brand-name] drug.'" Mensing, 564 U.S. at ___, 131 S. Ct. at 2574 (quoting 21 U.S.C. § 355(j)(2)(A)(v)) (alterations in Mensing). This federal duty of "sameness" regarding the warning label is "ongoing." Id. at ___, 131 S. Ct. at 2575. FDA regulations permit "changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions." Id. at ___, 131 S. Ct. at 2575-76 (deferring to the FDA's interpretation of its change process and regulations).

The federal labeling regulations also apply to letters providing "additional warnings to prescribing physicians and other healthcare professionals" (Dear Doctor letters), which must be "'consistent with and not contrary to [the drug's] approved . . . labeling.'" Id. at ___, 131 S. Ct. at 2576 (quoting 21 C.F.R. § 201.100(d)(1)) (alterations in Mensing). Letters containing "substantial new warning information would not be consistent with the drug's approved labeling" and, if sent by the generic manufacturer but not the brand name manufacturer, "would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" Id. at ___, 131 S. Ct. at 2576 (quoting 21 C.F.R. § 314.150(b)(3)).

2. Preemption

The Supremacy Clause of the United States Constitution establishes federal law as "the supreme Law of the Land." U.S. Const., art. VI, cl. 2. State law that directly conflicts with federal law "must give way." Mensing, 564 U.S. at ___, 131 S. Ct. at 2577. "[S]tate and federal law conflict where it is 'impossible for a private party to

comply with both state and federal requirements.'" Id. at ___, 131 S. Ct. at 2577 (quoting Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)).

In Mensing, the Supreme Court found it impossible for Pliva and other generic manufacturers of metoclopramide "to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." Id. at ___, 131 S. Ct. at 2578. As such, the Supreme Court held federal law preempts "state tort-law claims based on certain drug manufacturers' alleged failure to provide adequate warning labels for generic metoclopramide." Id. at ___, 131 S. Ct. at 2572. In so holding, the Supreme Court rejected this court's conclusions that the generic manufacturers could have satisfied their state law duties without violating federal law by (1) proposing a label change to the FDA that it could impose, (2) suggesting the FDA send a warning letter, or (3) by suspending sales of the product, Wyeth, 588 F.3d at 608-11. See Mensing, 564 U.S. at ___, 131 S. Ct. at 2576-77; Wyeth II, 658 F.3d at 867 (vacating the sections of our opinion in Wyeth addressing those issues); but see Mensing, 564 U.S. at ___, 131 S. Ct. at 2587 n.8 (Sotomayor, J., dissenting) (finding it unnecessary to consider whether generic manufacturers "could not show impossibility because federal law merely permitted them to sell generic drugs [but] did not require them to do so").

In light of the decision in Mensing, the district court permitted Bell to amend her complaint against Pliva. Bell's amended complaint again asserted claims for negligence; strict liability; breach of warranties; misrepresentation, suppression of evidence, and fraud; and gross negligence. Finding "ample authority supporting [Pliva's] position that Bell's newly-styled allegations remain, in essence, failure-to-warn claims that are barred by Mensing," the district court dismissed Bell's claims with prejudice.

Bell contends the district court erred in dismissing all of her claims based on impossibility preemption. According to Bell, "[i]t is clear from the [Mensing] Court's

decision that the preemption found to exist applies **only** to allegations that a generic manufacturer should have unilaterally changed the content of its metoclopramide label"—leaving many of Bell's state law claims viable, including many of her failure to warn claims. In support, Bell relies on Bartlett v. Mut. Pharm. Co., 678 F.3d 30, 37-38 (1st Cir. 2012), cert. granted sub nom., Mut. Pharm. Co. v. Bartlett, 568 U.S. ___, 133 S. Ct. 694 (2012), in which the First Circuit determined the FDCA did not preempt the plaintiff's design defect claim against the manufacturer of a generic drug. The First Circuit acknowledged some "tension not with the holding but with part of [Mensing's] rationale," but determined Mensing was "a limited departure from . . . a general no-preemption rule" as stated in Wyeth v. Levine, 555 U.S. 555 (2009). Id. at 38 (acknowledging "the developing split in the lower courts" regarding Mensing's reach and stating "it is up to the Supreme Court to decide whether [Mensing's] exception is to be enlarged to include design defect claims").[2]

In contrast to Bell's unduly narrow view of Mensing, Pliva broadly contends "[t]he *only* authority the district court needed to reach its conclusion . . . was the Supreme Court's decision in Mensing." Pliva contends the district court correctly determined Bell's claims are all "premised on a failure to warn" and thus barred by the preemption analysis in Mensing.

While we agree with the district court that the vast majority of Bell's allegations in her amended complaint set forth preempted failure to warn claims, we are unable to conclude, at this point, that Bell's design defect and breach of implied warranty claims, other than those based on an inadequate warning or labeling, are "in essence,

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[2]The First Circuit may have its wish. On November 30, 2012, the Supreme Court granted certiorari to determine whether federal law preempts "state law design-defect claims targeting generic pharmaceutical products." See Mut. Pharm. Co., 568 U.S. at ___, 133 S. Ct. at 694. The answer to that question may affect Bell's non-warning claims against Pliva, but need not delay our disposition of this appeal under the circumstances.

failure-to-warn claims that are barred by Mensing." Pliva asserts "the Mensing complaint raised the very same claims Ms. Bell asserts here—and more" and suggests the Supreme Court in Mensing categorically rejected all of Bell's claims.[3] But a key distinction exists between Mensing's claims and Bell's. Mensing did not contest the trial court's characterization of her claims as asserting failure to warn claims "at the core." Wyeth, 588 F.3d at 605. Bell does. At this stage, we must accept Bell's allegations as true and construe them in her favor. See Murphy, 699 F.3d at 1033.

In challenging Bell's critique of the "ample authority" upon which the district court relied in dismissing Bell's claims, Pliva asserts the courts in the cited cases, like those in "the overwhelming decisions issued by courts around the country in [Mensing's] wake," found claims similar to Bell's (1) preempted by Mensing, (2) failed to state a claim upon which relief could be granted, or (3) barred under applicable state law. See, e.g, Demahy v. Schwarz Pharma, Inc., 702 F.3d 177, 186 (5th Cir. 2012) (observing "[p]ost-Mensing . . . a seeming majority of federal district courts to consider other state-law tort claims have found them to be preempted . . . failure-to-warn claims under different names" and "other courts have specifically held . . . design defect claims against generic metoclopramide manufacturers to be preempted based on Mensing"). Pliva contends the courts in those cases rejected the same arguments Bell makes here.

Yet that is precisely the analysis that is missing in this case. Because the district court construed Bell's claims as failure to warn claims, we do not have the benefit of the district court's analysis of whether Bell's non-warning design defect and breach of implied warranty claims adequately state viable claims under Arkansas law.

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[3]Noting Mensing pled fourteen causes of action, including strict liability, negligent failure to warn, breach of warranty, misrepresentation, fraud, unfair trade practices, false advertising, and consumer fraud, Pliva points out the Supreme Court in Mensing stated "federal law preempts *these lawsuits*," not just Mensing's failure to warn claims. Mensing, 564 U.S. at ___, 131 S. Ct. at 2581.

Those questions are best addressed first in the district court. See Beckon, Inc. v. AMCO Ins. Co., 616 F.3d 812, 820 (8th Cir. 2010) (declining to affirm on alternative ground not considered by the trial court without expressing any opinion on the merits). We also leave for the district court to consider in the first instance whether Pliva has met its burden of establishing impossibility preemption or any other defense with respect to those claims. See Levine, 555 U.S. at 573 ("Impossibility pre-emption is a demanding defense."). We reverse the district court's dismissal of Bell's non-warning design defect and breach of implied warranty claims and remand for further consideration.

3. 2004 Label Change

In 2004, the FDA approved the brand name Reglan manufacturer's request to add bolded statements to the Reglan label indicating usage should not exceed twelve weeks. Pliva did not implement the 2004 change in the label for its generic metoclopramide products. Bell alleges her claims that Pliva's failure caused her injuries "survive an impossibility preemption analysis." In support, Bell directs our attention to Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 584 (6th Cir. 2013), in which the Sixth Circuit concluded Mensing did not preempt the plaintiff's argument, under Ohio law, "that PLIVA's warning was inadequate *to the extent* that it did not include the language contained in the updated Reglan label from 2004."

The district court determined Bell did "not have a federal private cause of action" based on Pliva's failure to incorporate the 2004 brand name label change into its label in light of Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 (2001) (holding state law "fraud-on-the-agency" claims are impliedly preempted by the FDCA). The district court further determined Pliva's failure to incorporate the label change did not vitiate Pliva's preemption defense because Arkansas adhered to the learned intermediary doctrine.

As adopted in Arkansas, the learned intermediary doctrine "provides an exception to the general rule that a manufacturer has a duty to warn the ultimate user of the risks of its products." Kowalski v. Rose Drugs of Dardanelle, Inc., 378 S.W.3d 109, 120 (Ark. 2011). "'[A] drug manufacturer may rely on the prescribing physician to warn the ultimate consumer of the risks of a prescription drug. The physician acts as the 'learned intermediary' between the manufacturer and the ultimate consumer.'" Id. (quoting West, 806 S.W.2d at 613). In applying the doctrine to prescription drugs, the Arkansas Supreme Court explained (1) the patient relies on her physician's independent medical judgment that the drug is appropriate—not on the manufacturer, (2) "it is virtually impossible in many cases for a manufacturer to directly warn each patient," and (3) imposing "a duty to warn the user directly would interfere with the relationship between the doctor and the patient." Id.

With respect to the relationship between the patient, the physician, and the pharmaceutical manufacturer,

> the patient must look to the physician, for it is only the physician who can relate the propensities of the drug to the physical idiosyncracies of the patient. "It is the physician who is in the best position to decide when to use and how and when to inform his patient regarding risks and benefits pertaining to drug therapy." W. Keeton, R. Keeton, & D. Owen, Prosser and Keeton on Torts § 96, at 688 (5th ed. 1984).

Id. (quoting McKee v. Am. Home Prods., Corp., 782 P.2d 1045, 1050-51 (Wash. 1989) (en banc)).

In light of the circumstances in this case, the district court did not err in concluding Bell could not state a viable claim based upon Pliva's failure to incorporate the 2004 change into its label. "Under the learned intermediary doctrine, the manufacturer's failure to provide the physician with adequate warnings of the risks associated with a particular prescription product 'is not the proximate cause of a

patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated.'" Ehlis v. Shire Richwood, Inc., 367 F.3d 1013, 1016 (8th Cir. 2004) (quoting Christopher v. Cutter Labs., 53 F.3d 1184, 1192 (11th Cir. 1995)).

Bell's physician prescribed Reglan—not generic metoclopramide manufactured by Pliva. Bell admits that in prescribing Reglan, her physician relied on information published in the brand defendants' "package inserts and/or the Physicians' Desk Reference . . . or otherwise disseminated by" the brand defendants. "'Thus, the causal link between [Bell's] injury'" and Pliva's admitted failure to incorporate the 2004 label change, if any, was broken because Bell's "'prescribing physician had "substantially the same" knowledge as an adequate warning from the manufacturer should have communicated to him.'" Id.

Because Bell's physician prescribed Reglan and relied on its labeling, there is nothing to indicate Pliva's failure to update its warning affected Bell's physician's prescribing decision or Bell's injury in any way. Because there is no causal link between Pliva's failure to incorporate the 2004 labeling change and Bell's injury, the district court's dismissal of that claim was not error, regardless of whether Mensing preempted that claim.

III. CONCLUSION

We affirm the district court's summary judgment in favor of the brand defendants and dismissal of Bell's claims based upon Pliva's alleged failure to warn and failure to incorporate the 2004 label change. We reverse the district court's prejudicial dismissal of Bell's non-warning design defect and breach of implied warranty claims and remand for further proceedings consistent with this opinion.
