PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 12-1259

ARTHUR L. DRAGER, as personal representative for the Estate of Shirley Gross,

Plaintiff – Appellant,

v.

PLIVA USA, Inc.,

Defendant – Appellee,

and

PFIZER, Inc.; WYETH, Inc.; WYETH PHARMACEUTICALS, Inc.; SCHWARZ PHARMA, Inc.; TEVA PHARMACEUTICALS USA, Inc.,

Defendants.

Appeal from the United States District Court for the District of Maryland, at Greenbelt. Alexander Williams, Jr., District Judge. (8:10-cv-00110-AW)

Argued: December 12, 2013 Decided: January 28, 2014

Before SHEDD, DUNCAN, and DAVIS, Circuit Judges.

Affirmed by published opinion. Judge Duncan wrote the opinion, in which Judge Shedd and Judge Davis joined.

ARGUED: Louis Martin Bograd, CENTER FOR CONSTITUTIONAL LITIGATION, PC, Washington, D.C., for Appellant. Michael David Shumsky, KIRKLAND & ELLIS LLP, Washington, D.C., for Appellee.

ON BRIEF: Terrence J. Donahue, Jr., MCGLYNN GLISSON & MOUTON, Baton Rouge, Louisiana, for Appellant. Joseph P. Thomas, Linda E. Maichl, Jeffrey Peck, ULMER & BERNE, LLP, Cincinnati, Ohio; Jay P. Lefkowitz, John K. Crisham, KIRKLAND & ELLIS LLP, Washington, D.C., for Appellee.

DUNCAN, Circuit Judge:

Appellant Arthur Drager, as personal representative of the estate of Shirley Gross, seeks reversal of the district court's denial of Gross's request to amend her complaint and its dismissal of her state common law tort claims against appellee PLIVA USA, Inc. for injuries sustained as a result of her use of a drug it manufactured. Drager contends on appeal that the proposed amendments were not futile and that Gross's state tort claims are not preempted by the requirements of the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301 et seq., ("FDCA"). For the reasons that follow, we affirm.

I.

In 2006, Gross was prescribed Reglan, a brand of metoclopramide, a drug used to treat gastroesophageal reflux disease and other ailments. Gross followed a ten-month course of generic metoclopramide, produced by appellee PLIVA, from March 2006 to January 2007. As a result of Gross's long-term use of metoclopramide, she developed permanent injuries including the movement disorders tardive dyskinesia and akathisia.

On January 15, 2010, Gross filed suit against PLIVA and brand-name Reglan producers, including Pfizer, Inc., alleging state law claims of negligence, breach of warranty, fraud and

misrepresentation, strict liability, and failure to warn. Pursuant to Gross's stipulation that she ingested only PLIVA's generic metoclopramide, the district court dismissed her claims against the brand name manufacturers on November 9, 2010. The district court stayed further proceedings against PLIVA, the only remaining defendant, on April 7, 2011, pending the Supreme Court's decision in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

After Mensing was decided, holding that FDCA labeling requirements preempted state failure-to-warn laws, see id. at 2577-78, the stay was lifted and PLIVA filed a motion for judgment on the pleadings. It contended that pursuant to Mensing, Gross's claims were preempted by the FDCA because of the impossibility of PLIVA's compliance with both that statute and the alleged state law duties. In her response to PLIVA's motion, Gross requested that the district court allow her to amend her complaint to include allegations that PLIVA violated a state law duty by failing to update its warnings to include changes made by brand name manufacturers in 2004. On November 22, 2011, the district court granted PLIVA's motion, holding under the reasoning of Mensing that all of Gross's state law claims were preempted by FDCA requirements applicable to generic drug manufacturers. The district court also denied leave to amend on the ground that the proposed amendments would be futile

under Maryland law. Gross filed a motion to alter or amend the judgment, which the district court denied on January 27, 2012. During the pendency of this action, Gross passed away and Drager continued the case on behalf of her estate. The district court's November 22 and January 27 orders form the basis of Drager's appeal.

II.

We review de novo a district court's ruling on a motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c). Butler v. United States, 702 F.3d 749, 751 (4th Cir. 2012). The standard of review for Rule 12(c) motions is the same as that under Rule 12(b)(6). Id. at 751-52. Therefore, a motion for judgment on the pleadings "should only be granted if, after accepting all well-pleaded allegations in the plaintiff's complaint as true and drawing all reasonable factual inferences from those facts in the plaintiff's favor, it appears certain that the plaintiff cannot prove any set of facts in support of his claim entitling him to relief." Edwards v. City of Goldsboro, 178 F.3d 231, 244 (4th Cir. 1999). A Rule 12(c) motion tests only the sufficiency of the complaint and does not resolve the merits of the plaintiff's claims or any disputes of fact. Butler, 702 F.3d at 752.

Under Federal Rule of Civil Procedure 15(a)(2), the "'grant or denial of an opportunity to amend is within the discretion of the district court.'" Scott v. Family Dollar Stores, Inc., 733 F.3d 105, 121 (4th Cir. 2013) (quoting Foman v. Davis, 371 U.S. 178, 182 (1962)). Consequently, we review the district court's denial of a motion to amend for abuse of discretion. Nourison Rug Corp. v. Parvizian, 535 F.3d 295, 298 (4th Cir. 2008). A district court's denial of leave to amend is appropriate when "(1) 'the amendment would be prejudicial to the opposing party;' (2) 'there has been bad faith on the part of the moving party;' or (3) 'the amendment would have been futile.'" Scott, 733 F.3d at 121 (quoting Laber v. Harvey, 438 F.3d 404, 426-27 (4th Cir. 2006)).

We may affirm on any ground supported by the record regardless of the ground on which the district court relied. United States v. Moore, 709 F.3d 287, 293 (4th Cir. 2013).

III.

A.

Drager contends on appeal that the district court's denial of leave to amend was an abuse of discretion because Gross's proposed allegations would have stated a cause of action under Maryland law. However, Drager concedes that Gross never filed a motion to amend her complaint or a proposed amended complaint

with the district court. Regardless of the merits of the desired amendment, a district court does not abuse its discretion "by declining to grant a motion that was never properly made." Cozzarelli v. Inspire Pharms., Inc., 549 F.3d 618, 630-631 (4th Cir. 2008) (finding no abuse of discretion where plaintiffs requested leave to amend in a response but did not file a motion to amend or a proposed amended complaint).

Consequently, we affirm the district court's denial of leave to amend and hold that none of Drager's claims regarding PLIVA's alleged failure to update its warnings are before us on appeal. Similarly, we find that the complaint did not allege any violation of the federal misbranding laws or parallel state duties. To the extent Drager makes those claims on appeal they are waived. United States v. Evans, 404 F.3d 227, 236 n.5 (4th Cir. 2005).

B.

Drager also argues that the district court erred by finding Gross's state tort claims to be preempted by the FDCA because of the impossibility of PLIVA's simultaneous compliance with FDCA requirements and relevant Maryland law. Although one of Drager's objections to the district court's reasoning gives us pause, all of Gross's causes of action are indeed preempted by the FDCA. We therefore affirm the district court on all counts.

1.

In Mensing, the Supreme Court reaffirmed the principle that "[p]re-emption analysis requires [courts] to compare federal and state law." 131 S. Ct. at 2573. To make this comparison, courts first "identify[] the state tort duties and federal...requirements applicable" to the parties. Id. If the applicable federal statute does not include a statement that either expressly preempts or expressly preserves otherwise applicable state law duties, the court must determine if there is preemption by conflict. Id. at 2577 n.5.

"[S]tate law is naturally preempted to the extent of any conflict with a federal statute," Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000), because the federal Constitution provides that every federal enactment is superior to any state law or constitutional article, U.S. Const. art. VI, cl. 2. As a result, under the Supremacy Clause, "[w]here state and federal law directly conflict, state law must give way." Mensing, 131 S. Ct. at 2577 (internal quotation marks and citation omitted). The Supreme Court has held that state and federal law conflict when it is impossible for a private party to simultaneously comply with both state and federal requirements. Id. In such circumstances, the state law is preempted and without effect. By definition a party cannot state a claim for which relief may be granted pursuant to a law

that has been "effectively repeal[ed]" as it applies to a particular set of circumstances. Id. at 2579.

Mensing and another recent Supreme Court case, Mutual Pharmaceutical Co., Inc. v. Bartlett, 133 S. Ct. 2471 (2013), address the preemptive effect of the FDCA on state tort laws as they apply to generic drug manufacturers. For a variety of policy reasons, under the Hatch-Waxman amendments, codified at 21 U.S.C. § 355(j), the FDCA imposes substantially different requirements on producers of name brand drugs and producers of non-branded, or generic, counterparts. In greatly simplified terms, manufacturers of generic medications gain authorization to market their products by demonstrating that those products are equivalent to the previously authorized name brand versions in a number of ways, including formulation and labeling. Generics must maintain this equivalence to maintain authorization. See generally 21 U.S.C. § 355(j).

In Mensing, the Supreme Court made clear that under § 355(j) generic drug manufacturers are not entitled to unilaterally change their labeling and therefore any state law tort premised on the failure of a generic to alter its labeling is preempted. Id. at 2578. In Bartlett, the Supreme Court emphasized that generics are also not permitted to change the formulation of their products. 133 S. Ct. at 2471, 2475. Further, the Court rejected the argument that a generic drug

manufacturer is required to leave the marketplace in order to avoid state law liability resulting from its inability to change either its labeling or formulation. Id. at 2477. In other words, courts may not avoid preempting a state law by imposing liability on a generic manufacturer for choosing to continue selling its product.

Together, these cases establish that under the FDCA a generic may not unilaterally change its labeling or change its design or formulation, and cannot be required to exit the market or accept state tort liability. Therefore, if a generic drug manufacturer cannot satisfy a state law duty except by taking one of these four actions, that law is preempted and of no effect.

2.

Drager first argues that we must reverse the district court's order as a whole because it failed to conduct a full preemption analysis. The district court did not undertake to identify and compare all of the relevant duties imposed on PLIVA by Maryland common law and the FDCA. Instead, it held that because of the structure of Maryland products liability law, all of Gross's causes of action, however characterized, must in fact be failure to warn claims, and that they were all therefore preempted under Mensing.

Although we agree that Mensing contemplates a more complete analysis and that such an analysis would have been helpful for our review, the method applied by the district court does not constitute reversible error. Because our review is de novo, we do not defer to the district court and may affirm the dismissal of Gross's complaint on any ground.

3.

Drager also argues that the district court erred by finding each of Gross's individual causes of action to be preempted by the FDCA. Because each alleged cause of action logically requires PLIVA to either change its labeling, change its design or formulation, exit the market, or accept tort liability, the underlying Maryland laws as applicable here are preempted.

a.

Gross's complaint alleges that PLIVA's metoclopramide marketing was negligent because it failed to reasonably and accurately inform the medical community, and by extension patients, of the dangers of the drug. Although Drager concedes on appeal that all failure to warn claims are preempted by the FDCA's labeling requirements under Mensing, he argues that the complaint's allegations of negligent testing, inspection, and post-market surveillance survive because they are actually premised on independent Maryland duties unrelated to labeling.

In Maryland, to state a cause of action for negligence in the products liability context, the plaintiff "must allege and prove (1) that the defendant was under a duty to protect the plaintiff from injury, (2) that the defendant breached that duty, (3) that the plaintiff suffered actual injury or loss, and (4) that the loss or injury proximately resulted from the defendant's breach of the duty." Ga. Pac., LLC v. Farrar, 69 A.3d 1028, 1031-32 (Md. 2013). Contrary to Drager's assertions, it is not clear that Maryland law recognizes specific causes of action for negligent testing, inspection, and surveillance.[1]

More importantly, it is apparent from the nature of Gross's claim that any alleged failure by PLIVA to conduct adequate pre-market testing or post-market observation of its drug is in actuality merely a particular act or omission in an overall negligent sale. Divorced from the context of an eventual sale to the consumer, PLIVA could not owe any duty to that consumer to perform any testing or inspection on its product, and there could therefore be no cause of action for negligence. If we

[1] Drager cites no support for his argument that it does. His citation to Worm v. Am. Cyanamide Co. actually undermines his contention; in that case we interpreted the plaintiff's negligent testing claim to allege a failure to warn cause of action. 970 F.2d 1301, 1304 (4th Cir. 1992). Drager's citations to Restatement (Second) of Torts § 324A and Lucarelli v. Renal Advantage, Inc., No. AW-08-2219, 2009 U.S. Dist. LEXIS 75506 (D. Md. Aug. 25, 2009), concern the Good Samaritan Rule and are simply inapposite.

assume that under Maryland law there is a general duty to protect consumers from injury based on the negligent marketing and sale of a product, it is clear that a generic drug manufacturer whose product is unreasonably dangerous as sold could not satisfy that duty without changing its warnings, changing its formulation, exiting the market, or accepting tort liability. Therefore, Gross's negligence claims are preempted by impossibility.

b.

Gross's complaint alleges that PLIVA's metoclopramide was defective in design as marketed due to an unreasonably dangerous formulation, inadequate warnings and instructions, or both. Drager maintains on appeal that PLIVA is strictly liable for introducing its product into the stream of commerce in its defective condition and that this claim is not preempted by the requirements of the FDCA.

In Maryland, to state a claim for strict products liability, a plaintiff must allege that:

> (1) the product was in defective condition at the time that it left the possession or control of the seller, (2) that it was unreasonably dangerous to the user or consumer, (3) that the defect was a cause of the injuries, and (4) that the product was expected to and did reach the consumer without substantial change in its condition.

Gourdine v. Crews, 955 A.2d 769, 780 (Md. 2008) (quoting Phipps v. Gen. Motors Corp., 363 A.2d 955, 958 (Md. 1976)). Gross's

complaint alleges all of these facts and we must accept them as true for purposes of this analysis.

However, Drager also concedes that PLIVA was authorized to market metoclopramide with the labeling and formulation specified by the FDA, that it was not permitted to change the labeling, and that it was not permitted to change the formulation. It is clear then, from Drager's arguments, that he is attempting to rely on a "stop selling" rationale. In effect, he contends that although PLIVA was prohibited from altering its metoclopramide to make it safer, it was only permitted, not obligated, to sell the drug, and is therefore liable for voluntarily introducing a defective product into the stream of commerce. In other words, if PLIVA wanted to avoid liability, it should have exercised its option to not sell unreasonably dangerous metoclopramide. As discussed above, the stop selling rationale is an impermissible means of avoiding preemption under Bartlett.

Drager contends that Bartlett is not controlling because Maryland assesses the unreasonableness of the danger of a product using a consumer-expectations test while New Hampshire, the state whose tort laws Bartlett interprets, uses a risk-utility approach. To the extent that there is a difference in

approach between the two states, it is immaterial.[2] The Court in Bartlett did not determine that the New Hampshire law was preempted because it applied the risk-utility approach. Instead, it concluded that there was no action that the defendant could take under that approach to increase the safety of its product without violating the restrictions of the FDCA. We have no trouble concluding that the same is true under either the risk-utility or the consumer-expectations approach in Maryland. PLIVA cannot be required to stop selling its product, but at the same time it is prohibited from making any changes to the product itself or the accompanying warnings. Regardless of the way in which Maryland assesses the unreasonableness of a product's risks, if PLIVA's metoclopramide is unreasonably unsafe, there is no apparent action that PLIVA can take in compliance with FDCA restrictions to avoid strict liability.[3]

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[2] It is not clear that there is any difference. Maryland uses both approaches in different situations, and applies risk-utility when a product has malfunctioned, which is arguably the case here. Halliday v. Sturm, Ruger & Co., 792 A.2d 1145, 1153 (Md. 2002).

[3] Drager argues that we should follow the Eighth Circuit and remand the strict liability question to the district court because of the alleged difference in approach between Maryland and New Hampshire. In Fullington v. Pfizer, Inc., the Eighth Circuit speculated that Arkansas law, which applies the consumer expectations test, might provide "an opportunity, consistent with federal obligations, to somehow alter an otherwise unreasonably dangerous drug." 720 F.3d 739, 746-47 (8th Cir. 2013). There is no such opportunity for PLIVA to simultaneously (Continued)

c.

Gross's complaint next alleges that PLIVA created and breached express and implied warranties regarding the safety of its metoclopramide by marketing it without sufficient warnings in an unreasonably unsafe condition. This argument similarly lacks merit.

First, although the Maryland Court of Appeals has not explicitly ruled on this question, it appears that Maryland law does not recognize causes of action for breach of implied warranties of merchantability or fitness for a particular purpose when the goods at issue are pharmaceuticals. See Rite Aid Corp. v. Levy-Gray, 894 A.2d 563, 570-71 (Md. 2006). However, even if such claims are cognizable, they are preempted in the case of generic drug manufacturers.

When a seller is a merchant with respect to the kind of good being sold, an implied warranty of merchantability, a promise that a good is fit for its ordinary purpose, arises automatically at the time of the sale. Id. at 570 n.5 (citing Md. Code Ann., Com. Law § 2-314 (2002)). When a seller has reason to know that a buyer is relying on his skill and judgment

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comply with the restrictions of the FDCA and Maryland strict products liability law. Because the existence of such an option is a question of law, there is no reason to remand to make this determination.

to select a good suitable for a particular purpose, an implied warranty of fitness for that purpose arises automatically at the time of sale. Id. at 570 n.4 (citing Md. Code Ann., Com. Law § 2-315 (2002)). We accept as true for purposes of this analysis that PLIVA is a merchant of pharmaceuticals, that it had reason to know of Gross's particular purpose in purchasing metoclopramide, and that as marketed its metoclopramide was unreasonably dangerous when used as intended. On these facts, PLIVA unavoidably created and breached these implied warranties by selling metoclopramide. Because PLIVA was not permitted to change its warnings or formulation, it could not have avoided liability for breach of these implied warranties except by exiting the market. Therefore, to the extent that implied warranties of merchantability or fitness for a particular purpose can arise in this context under Maryland law, they are preempted by the requirements of the FDCA.

Drager argues that state law liability for breach of an express warranty is not preempted by the requirements of the FDCA because it is a violation of contract law and not tort. He contends that manufacturers voluntarily elect to make certain assertions about their products in warnings and promotional materials and that as a result the manufacturers themselves, not the law, impose the obligation to conform to those assertions. Whatever the merits of this argument might be in general, it is

indisputable that the content of generic drug manufacturers' product descriptions and other assertions is mandated by federal law. Because PLIVA cannot change its written materials or the formulation of its product to ensure that its metoclopramide functions as expressly warranted, it cannot avoid liability for breach of express warranty except by leaving the market. Gross's cause of action for breach of express warranties is therefore preempted by the FDCA.

d.

Finally, Gross's complaint alleges that, through its promotional and warning materials, PLIVA made negligent misrepresentations and fraudulently concealed information about the safety of its product from consumers and medical professionals. Drager's contention that these claims survive preemption is frivolous. Both causes of action are premised on the content of statements made by the defendant to the plaintiff. See Lloyd v. Gen. Motors Corp., 916 A.2d 257, 273 (Md. 2007) (reciting the elements of Maryland negligent misrepresentation); id. at 274 (reciting the elements of Maryland fraudulent concealment). Drager's conclusory statement that the duties imposed by these legal principles are unlike state law obligations concerning warnings is unavailing. Assuming that PLIVA's representations are false or misleading because its metoclopramide is unreasonably unsafe as marketed,

it has no authority to add or remove information from its materials or to change the formulation of the product to make its representations complete or truthful. Therefore, PLIVA's only remaining options are to leave the market or accept tort liability. As a result, Gross's misrepresentation and fraudulent concealment claims are preempted by the FDCA.

IV.

For the foregoing reasons the district court's denial of Gross's request to amend her complaint and its dismissal of her state law tort causes of action are

AFFIRMED.