IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

Frederick Arters, et al.,

Plaintiffs,

v.

Sandoz Inc., et al.,

Defendants.

Case No. 2:10-cv-142

Judge Graham

Magistrate Judge Deavers

OPINION AND ORDER

This matter is before the court on a motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), filed by defendants Sandoz, Inc. (Sandoz) and Eon Labs, Inc. (Eon). Plaintiffs Frederick and Barbara Arters bring this five-count complaint alleging negligence, violation of the Ohio Products Liability Act, breach of implied warranty, and fraud.[1] Doc. 4 at 36-48. Defendants seek dismissal of plaintiffs' four remaining counts. Doc. 67.

I. Factual Background

This action arises from plaintiff Frederick Arters's ingestion of the drug amiodarone between November 2003 and February 2004. Doc. 4 ¶¶ 1, 4. According to plaintiffs, as a result of ingesting amiodarone manufactured and distributed by defendant Eon, Mr. Arters suffered eye damage and vision loss. He was diagnosed as permanently blind in 2004. Doc. 4 ¶¶ 1, 2, 5. Plaintiffs allege, *inter alia*, that defendants failed to warn consumers of the significant risks of amiodarone; that amiodarone is unreasonably dangerous; and that defendants improperly promoted "off-label" use of

[1] The Court has previously dismissed Count V brought by Barbara Arters for loss of consortium. See doc. 65.

amiodarone. Doc. 4 ¶¶ 11, 16-17, 150-55.

II. Legal Standard

A motion for judgment on the pleadings pursuant to Rule 12(c) should not be granted "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Conley v. Gibson, 355 U.S. 41, 45-46 (1957). See also Grindstaff v. Green, 133 F.3d 416, 421 (6th Cir. 1998) ("The standard of review applicable to motions for 'judgment on the pleadings' under Fed. R. Civ. Pro. 12(c) is the same *de novo* standard applicable to motions to dismiss under Rule 12(b)(6)."). All well-pleaded allegations must be taken as true and must be construed most favorably toward the non-movant. Scheuer v. Rhodes, 416 U.S. 232, 236 (1974). A motion for judgment on the pleadings is directed solely to the complaint and any exhibits attached to it. Roth Steel Prods. v. Sharon Steel Corp., 705 F.2d 134, 155 (6th Cir. 1983). The merits of the claims set forth in the complaint are not at issue on a motion for judgment on the pleadings. Consequently, a complaint will be dismissed pursuant to Fed. R. Civ. P. 12(c) if there is no law to support the claims made, or if the facts alleged are insufficient to state a claim, or if on the face of the complaint there is an insurmountable bar to relief. See Rauch v. Day & Night Mfg. Corp., 576 F.2d 697, 702 (6th Cir. 1978); Westlake v. Lucas, 537 F.2d 857, 858 (6th Cir. 1976). The court "need not accept as true legal conclusions or unwarranted factual inferences." Morgan v. Church's Fried Chicken, 829 F.2d 10, 12 (6th Cir. 1987) (citations omitted).

III. Analysis

Defendants' motion rests on a single argument–that plaintiffs' claims are preempted by the

"Hatch-Waxman Act"–formally the Drug Price Competition and Patent Term Restoration Act, which, in 1984, amended the Federal Food, Drug, and Cosmetic Act (FDCA). Pub. L. No. 89-417, 98 Stat. 1585; *see* 21 U.S.C. § 355(j) (setting forth procedures for approval of generic drugs). The Hatch-Waxman Act sought to expand the availability of generic drugs by, *inter alia*, changing the approval requirements for generic drugs. Under the Hatch-Waxman Act, a manufacturer wishing to market a generic drug must submit an Abbreviated New Drug Application (ANDA), showing that the drug has the same active ingredients and is otherwise the "bioequivalent" of an existing approved drug. 21 U.S.C. § 355(j). Plaintiff alleges that defendant Eon manufactured and sold the drug amiodarone and that amiodarone is the generic bioequivalent of the name-brand drug Cordarone, distributed by non-party Wyeth Pharmaceuticals. Doc. 4 ¶¶ 2, 3; see also doc. 67 at 7 ("Eon's amiodarone ANDA was approved by the FDA . . . .".)

The Federal Food, Drug, and Cosmetic Act extensively regulates the testing, manufacture, labeling and marketing of pharmaceuticals. Most basically, "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." Pliva, Inc. v. Mensing, 131 S.Ct. 2567, 2574 (2011) (citing 21 U.S.C. § 355(b)(1), (d); Wyeth v. Levine, 555 U.S. 555, 567 (2009)). The extent to which these requirements of federal law preempt state-law causes of action has been the subject of much litigation. Defendants assert that all of plaintiffs' remaining claims are preempted by the FDCA.

This much is clear: Federal law preempts some but not all state-law claims precipitated by injury from use of pharmaceuticals. In Wyeth v. Levine the Supreme Court considered a jury award to a plaintiff who had lost her forearm after having an anti-nausea medication administered using an "IV push" method. 555 U.S. at 559. Plaintiff's negligence and strict-liability claims against the

brand-name manufacturer of the drug were based on the argument that the drug label, though sufficient under federal law, was insufficient under state law to warn her of the risks of using the IV push method to administer the drug. Id. at 559-61. The Court held that the plaintiff's failure-to-warn claims were not preempted under either conflict or implied preemption analysis. Id. at 563-64.

In considering whether allowing plaintiff to proceed with her failure-to-warn claim would be an obstacle to the purposes of the FDCA, the Court broadly held that state law causes of action do not frustrate the federal law, but are consistent with its purpose "to bolster consumer protection against harmful products." Id. at 574.

> Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers. . . . If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70-year history."

Id.

Regarding conflict preemption, the Court conducted a narrower analysis. Federal and state laws are in conflict and the state law must yield when "it is impossible for a . . . party to comply with both state and federal requirements . . . ." English v. General Elec. Co., 496 U.S. 72, 79 (1990). In Levine, the Court held that it was not impossible for the defendant drug manufacturer to comply with both federal law and state product warning requirements. The drug manufacturer argued that it could not change its label without FDA approval, and thus it was impossible to comply with any state law that required it to have any label other than the one approved by the FDA. The Court held otherwise, finding that FDA regulations allow a manufacturer to "add or strengthen a contraindication, warning, precaution, or adverse reaction" without FDA approval. 555 U.S. at 562. Thus, the manufacturer could have unilaterally strengthened the drug's warning label in order to comply with the state law.

Id. at 573. Because it was possible for the defendant to comply with both state and federal law, the state law was not preempted. Id.

The United States Supreme Court recently revisited this conflict preemption analysis in Pliva, Inc. v. Mensing, 131 S.Ct. 2567 (2011). In Mensing, the plaintiffs had taken metoclopramide, a generic bioequivalent of the brand-name drug Reglan, a treatment for digestive tract problems. Id. at 2572. Since Reglan's initial approval, "[e]vidence ha[d] accumulated that long-term metoclopramide use can cause tardive dyskinesia, a severe neurological disorder." Id. "Accordingly, warning labels for the drug have been strengthened and clarified several times." Id. Both plaintiffs received generic versions of the drug for several years and both developed tardive dyskinesia. Id. at 2573. The plaintiffs claimed that the labels were inadequate under their respective state laws. Id. Defendants argued, as had the defendant in Levine, that they were not subject to liability under state law which was preempted by federal law. Id. at 2574-75.

Unlike the Court in Levine, the Mensing Court held that the plaintiffs' state-law failure to warn claims were preempted by the FDCA. The key difference between the cases was that in Levine the defendant was a brand-name manufacturer and in Mensing the defendants were generic drug manufacturers. Id. at 2475. Under the FDA's interpretation of its regulations, "generic drug manufactures have an ongoing federal duty of 'sameness.'" Id. Generic drug labels must be the same as the label for the brand-name drug of which the generic is the bioequivalent. Id. Because of this duty of sameness, the Court found that generic drug manufacturers may not unilaterally strengthen their own warning labels, but must instead "propose . . . stronger warning labels to the agency if they believe[] such warnings [are] needed." Id. at 2576. The agency could then decide to accept or reject the proposed label. Id. The Court held that because the generic manufacturer could

not alone change the warning label, it was impossible and "not lawful under federal law for the Manufacturers to do what state law required of them." Id. at 2577. Thus, plaintiffs' failure to warn claims were preempted. Importantly, the Mensing Court construed its holding as consistent with, rather than overruling Levine. Id. at 2581 (distinguishing the cases because "the federal regulations applicable to Wyeth allowed the company, of its own volition, to strengthen its label in compliance with its state tort duty.").

In the case at hand, plaintiffs concede that to the extent their state-law failure-to-warn claims rest on a requirement that defendants change the generic drug labels, they are preempted by Mensing. See doc. 70 at 13. Nonetheless, plaintiffs argue that their complaint contains theories of liability that are not preempted by the FDCA. Plaintiffs argue that a) amiodarone is unreasonably dangerous and has a design defect under the Ohio Product Liability Act, Ohio Rev. Code §§ 2307.71, *et seq*.,; b) defendants failed to warn physicians and consumers directly, (rather than through labels,) of known dangers of the drug; and c) defendants negligently promoted amiodarone for off-label routine use, rather than as a drug of last resort.

In considering whether these claims are preempted by the FDCA, some deference to state law is appropriate: "[I]n all preemption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Levine, 555 U.S. at 565 (internal quotations omitted).

a. Design Defect

The Court in Mensing limited its preemption analysis to failure to warm claims and did not address other types of product liability claims, including design defect claims. See Mensing, 131

S.Ct. at 2578-79. Since Mensing, a handful of district courts and two courts of appeals have touched upon the issue of whether design defect claims are preempted by the FDCA. In Bartlett v. Mutual Pharmaceutical Company, the First Circuit held that design defect claims are not preempted. 678 F.3d 30, 38 (3d Cir. 2012), cert. granted, 133 S.Ct. 694 (Nov. 30, 2012) (No. 12-142). The court found that the failure to warn claim in Mensing was distinguishable from a design defect claim. In Mensing, the plaintiffs sought a stronger label, something that the defendants could not provide consistent with federal law. 678 F.3d at 37. In the design defect claim at issue in Bartlett, the plaintiffs' argument was that the drug should not have been marketed at all. The defendants could have achieved this result consistent with federal law which allows and regulates–but does not require–the marketing of pharmaceuticals. Id. The First Circuit in Bartlett reasoned that "the FDCA might permit states to tell Mutual it ought not [market a given drug] if the risk-benefit analysis weights against the drug, despite what the Supreme Court made of similar arguments in the labeling context." Id. The First Circuit interpreted Levine as creating "a general no-preemption rule" and Mensing as a limited exception to that rule. Id. at 38. "[I]t is up to the Supreme Court to decide whether [that] exception is to be enlarged to include design defect claims." Id. To date, neither the Supreme Court nor the Sixth Circuit Court of Appeals have directly addressed this question.

Other courts have reached the opposite conclusion, that design defect claims are preempted by the FDCA after Mensing. In Demahy v. Schwarz Pharma, Inc., the Fifth Circuit stated in dicta that it was persuaded that plaintiff's design defect claim was preempted by the FDCA because "[p]ost-Mensing, . . . a seeming majority of federal district courts to consider other state-law tort claims have found them to be preempted based on the fact that the plaintiffs' claims are failure-to-warn claims under different names. . . . Thus, although unnecessary for the disposition of this case,

we are persuaded that [Plaintiff's] design defect claim would be preempted." No. 11-31073, 2012 WL 6698692, at *6 (5th Cir. Oct. 25, 2012). District courts considering the issue have further developed this logic. For example, in In re Darvocet, Darvon and Propoxyphene Products Liability Litigation, the Eastern District of Kentucky followed the Mensing Court's logic to find that a design defect claim was preempted by the FDCA. MDL No. 2226, 2012 WL 718618 at *3 (E.D. Kent. Mar.5, 2012). The court held that the design defect claim was preempted because generic drug manufacturers have a duty of sameness not only for the labeling of their product, but also for its composition. Id. Thus, according to the court, just as the Mensing defendants could not change their labels to comply with state labeling laws, the generic drug defendants in Darvocet could not unilaterally change the composition of the drug in order to comply with state design defect laws. Id.; see also, e.g., Strayhorn v. Wyeth Pharmaceuticals, Inc., No. 11-2058, et al., 2012 WL 3261377 at *16 (W.D. Tenn. Aug. 8, 2012) (following the logic of Mensing to hold that design defect claims are preempted by the FDCA).

None of the cases cited by either party bind this Court on the issue of whether design defect claims are preempted by the FDCA. The two most relevant binding cases, Mensing and Smith v. Wyeth, 657 F.3d 420 (6th Cir. 2011), are distinguishable from the case at hand. In these cases, the Supreme Court and the Sixth Circuit consider only failure to warn claims, not design defect. Mensing, 131 S.Ct. at 2578-79; Smith, 657 F.3d at 423. Defendants argue that Smith reaches all of plaintiffs claims, and that all are preempted. Doc. 71 at 1-2. But in Smith, the Sixth Circuit ruled narrowly and only addressed claims that would require a generic drug manufacturer to change the label on its product. 657 F.3d at 423 (clearly limiting the preemption analysis to failure to warn).

The Court recognizes that other district courts within the Sixth Circuit have reached the

opposite conclusion, holding that after Mensing, not just failure to warn claims, but design defect and other tort claims against generic drug manufacturers are preempted by the FDCA. These Courts have considered different state laws and different factual situations. Here, plaintiffs' design-defect claim rests on the alleged violation of an entirely different duty than their failure to warn claim. Like the plaintiffs in Mensing, the Arters' failure to warn claim alleges that the defendant generic drug manufacturer violated its duty to provide an adequate warning. Doc. 4 ¶ 154. The relevant state laws related to failure to warn do not simply prohibit the sale of the drug at issue, they condition that sale on the provision of adequate warnings. It is this duty to warn that defendants can not unilaterally satisfy in compliance with the FDCA. Plaintiffs' design defect claim, on the other hand, rests on an alleged violation of an entirely different duty–not the duty to give a specific warning, but the duty to refrain from selling a product that is, according to state law, unreasonably dangerous. See Doc 4 ¶¶ 164-165; Ohio Rev. Code § 2307.76. This duty may be satisfied in accordance with federal law. The FDCA *limits* the production and sale of pharmaceuticals, requiring drugs to comply with the federal regulatory system. The federal law neither compels nor grants generic drug manufacturers a substantive right to sell their product in contravention of Ohio Law.

Defendants further argue that plaintiffs' design defect claim is preempted because it is simply a failure to warn claim artfully plead to avoid preemption. This argument is impossible to square with Ohio Law which allows recovery under distinct theories of failure to warn and design defect. The Ohio Product Liability Act establishes liability for defective design and failure to warn claims separately. Section 2307.75 establishes that "a product is defective in design or formulation if . . . the foreseeable risks associated with its design or formulation . . . exceed[] the benefits associated with that design or formulation . . . ." Ohio Rev. Code § 2307.75. Section 2307.76 establishes

circumstances in which "a product is defective due to inadequate warning or instruction . . . ." Ohio Rev. Code § 2307.76. Plaintiffs' complaint states claims that defendants have violated both sections, only the latter is preempted by the FDCA.

b. Failure to Warn

Though plaintiffs acknowledge that after *Mensing* the FDCA preempts failure to warn claims that would require a generic drug manufacturer to change the drug's label, they claim that under Ohio Law, defendants have a duty to warn consumers and physicians of known dangers of amiodarone in other ways. Plaintiffs argue that defendants should have taken steps other than changing the drug's label, which they could not do, to "adequately warn healthcare providers or the FDA of all adverse event reports and all warnings mandated by the FDA." Doc. 70 at 2. The plaintiffs in *Mensing* made a similar argument, that the generic manufacturers "could have used 'Dear Doctor' letters to send additional warnings to prescribing physicians and other healthcare professionals." 131 S.Ct. at 2576. The Court, however, deferred to the FDA's interpretation that such letters would constitute "labeling" of the drug. Id. The Court held that while the defendants could have made additional warnings if they were consistent with the approved label, they could not do so if they "contained substantial new warning information . . . ." Id. A generic drug manufacturer who warns of risks not present in the approved label or strengthens the warning through "dear doctor" letters or other means creates labeling that is not consistent with the approved label, and is thus inconsistent with the FDCA. See id.

c. Off-Label Promotion

Plaintiffs allege that defendants promoted the off-label use of amiodarone as a routine treatment, rather than a drug of last resort. Doc. 4 ¶¶ 181-82. Plaintiffs argue that marketing the

drug for this use encouraged a dangerous use of amiodarone that caused the loss of the Mr. Arters vision and was in violation of defendants' duty of care. Doc. 70 at 9. Plaintiffs frame this theory of liability alternatively as negligence, doc. 4 ¶¶ 154(q), (r), (s), breach of implied warranty, doc. 4 ¶¶ 175-77, and fraud, doc. 4 ¶¶ 181-82. Under each theory, plaintiffs argue, defendants had a duty not to promote a dangerous use of amiodarone that is inconsistent with the FDA-approved label. Plaintiffs do not argue simply that in promoting the drug for off-label use, defendants failed to adequately warn consumers fo the risks of off-label use. Instead, each of plaintiffs' legal theories is based on the idea that defendants promoted the drug in a fraudulent or unreasonably dangerous way. Nothing in the FDCA requires defendants to promote their drug for an off-label use, nor is the federal law otherwise at odds with the negligence, breach of implied warranty, and fraud claims brought by plaintiffs.

Defendants argue that plaintiffs may not seek to privately enforce FDA regulations that prevent defendants from promoting the off-label use of amiodarone. Just so. See 21 U.S.C. § 337. However, this argument misunderstands plaintiffs' claims. They do not seek to enforce FDA regulations regarding the promotion of off-label use. Plaintiffs assert that defendants violated their duty not because the use they promoted was off-label, but because they promoted a use of amiodarone that was in violation of Ohio law.

IV. Conclusion

To the extent plaintiffs' claims rely on defendants' failure to warn consumers of the risks of amiodarone, they are preempted by the FDCA. However, as discussed above, each of plaintiffs' four remaining counts rests, in part, on alternate theories of liability that are not preempted. For the

foregoing reasons, defendants' motion for judgment on the pleadings (Doc. 67) is DENIED.

IT IS SO ORDERED.

S/ James L Graham
James L. Graham
UNITED STATES DISTRICT JUDGE

Date: January 25, 2013