IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

RAYEANN BOROFF etc.,

Plaintiff,

Case No. 3:09 CV 1595

-vs-

MEMORANDUM OPINION

ALZA CORPORATION, et al.,

Defendant.

KATZ, J.

The Plaintiff in this action, Rayeann Boroff, brings claims arising from the death of her husband, Michael Boroff, whose death is alleged to have resulted from his use of the prescription drug Duragesic. Defendants Alza Corporation, Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Sandoz, Inc. ("Defendants") now move to dismiss the complaint pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim on which relief can be granted (Doc. 8). In her response (Doc. 12), Plaintiff, while maintaining that the complaint is not deficient, moves in the alternative for leave to amend the complaint if any part is found deficient.

For the reasons that follow, the Defendants' motion to dismiss will be granted in part and denied in part, and Plaintiff will be given 45 days to file an amended complaint in this Court.

I. Background

As is relevant to the present motion, the complaint sets forth the following factual allegations, which are to be taken as true at this stage of the proceedings. Michael Boroff was prescribed and used the pharmaceutical drug Duragesic, a transdermal fentanyl patch. The Defendants are manufacturers and distributors of transdermal fenatyl patches. Boroff's death was caused by leakage of a fatal dose of fentanyl into his system from the patch he was using. At the time of his death, Boroff did not know, and had no reason to know, of the risk of harm posed by

his use of Duragesic. The Defendants expressly represented to Boroff and/or his doctors that Duragesic was "safe and fit for use for the purposes intended," was "of merchantable quality," was "adequately tested and fit for [its] intended use", "did not produce any dangerous side effects," and that any side effects it did produce "were accurately reflected in the warnings". The patches prescribed to Boroff, however, "did not conform to these express representations because they were not safe and caused serious side effects and death."

II. Discussion

A. Standard of Review

At the outset, the parties disagree as to the proper standard for analyzing the Defendants' motion to dismiss. Specifically, Plaintiff argues that the pleading standards set forth in the Supreme Court's recent decisions in *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009), and *Bell Atlantic Corp v. Twombly*, 550 U.S. 544 (2007), do not apply to her claims.

The Federal Rules of Civil Procedure require notice pleading. Under Fed. R. Civ. P. 8(a)(2), the plaintiff's complaint generally need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief." For 50 years, it was axiomatic that, under Rule 8, "a complaint should not be dismissed for failure to state a claim 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).

But the Supreme Court's decision in *Twombly* "retired" the familiar "no set of facts" language of *Conley*. *Id*., 550 U.S. at 563. Instead, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Id*. at 570. Thus, under *Twombly*, the fact that the complaint provides the defendant with "fair notice" of the nature of the claim may not be

sufficient to survive dismissal. Instead, the plaintiff must "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S.Ct. at 1949.

Questions as to the scope of the *Iqbal* and *Twombly* pleading standards have generated much discussion among lawyers and judges of late. In a recent opinion, Judge Posner offered his own characteristically insightful take on the question:

> In our initial thinking about the case, however, we were reluctant to endorse the district court's citation of the Supreme Court's decision in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), fast becoming the citation du jour in Rule 12(b)(6) cases, as authority for the dismissal of this suit. The Court held that in complex litigation (the case itself was an antitrust suit) the defendant is not to be put to the cost of pretrial discovery-a cost that in complex litigation can be so steep as to coerce a settlement on terms favorable to the plaintiff even when his claim is very weak-unless the complaint says enough about the case to permit an inference that it may well have real merit. The present case, however, is not complex. Were this suit to survive dismissal and proceed to the summary judgment stage, it would be unlikely to place on the defendants a heavy burden of compliance with demands for pretrial discovery . . . .
> But *Bell Atlantic* was extended, a week after we heard oral argument in the present case, in *Ashcroft v. Iqbal*, --- U.S. ----, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)-over the dissent of Justice Souter, the author of the majority opinion in *Bell Atlantic*-to all cases, even a case (*Iqbal* itself) in which the court of appeals had "promise[d] petitioners minimally intrusive discovery." *Id*. at 1954. Yet *Iqbal* is special in its own way, because the defendants had pleaded a defense of official immunity and the Court said that the promise of minimally intrusive discovery "provides especially cold comfort in *this* pleading context, where we are impelled to give real content to the concept of qualified immunity for high-level officials who must be neither deterred nor detracted from the vigorous performance of their duties." *Id*. (emphasis added). So maybe neither *Bell Atlantic* nor *Iqbal* governs here.

Smith v. Duffey, 576 F.3d 336, 339-340 (7th Cir. 2009).

Judge Posner's proposed (narrow) reading of *Iqbal* and *Twombly* holds obvious appeal to lawyers and judges familiar with the venerable *Conley* pleading standard. But it cannot be reconciled with the clear statement in *Iqbal* that the *Twombly* standard applies to "all civil

actions." *Iqbal*, 129 S.Ct. 1937, 1953. While there were persuasive arguments against the Court's decision to overrule *Conley* as an original matter, see *Twombly*, 550 U.S. at 579 (Stevens, J., dissenting) ("I would not rewrite the Nation's civil procedure textbooks and call into doubt the pleading rules of most of the states without far more informed deliberation as to the costs of doing so."), it is nonetheless clear that the Supreme Court has consigned the *Conley* standard to the dustbin of history. Therefore, the sufficiency of the complaint in the instant case must be evaluated under the standards set forth in *Iqbal* and *Twombly*.

Under those cases, a complaint must contain sufficient factual material to state a claim that is "plausible on its face" to survive dismissal. *Iqbal*, 129 S.Ct. at 1949. Conclusory allegations or legal conclusions masquerading as factual allegations will not suffice. See *Twombly*, 550 U.S. at 555. Nor is it enough for the complaint to state facts that are "merely consistent with a defendant's liability." Rather, the complaint's "factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true.'" *Ass'n of Cleveland Fire Fighters v. City of Cleveland, Ohio*, 502 F.3d 545, 548 (6th Cir. 2007) (quoting *Bell Atlantic*, 550 U.S. 544, 555 (2007)).

It should be noted, however, that the term "plausible" is to be understood in a peculiarly narrow sense, and does not refer to the likelihood that the plaintiff will be able to prove a particular allegation. See *Iqbal*, 129 S.Ct. at 1951 ("To be clear, we do not reject these bald allegations on the ground that they are unrealistic or nonsensical."); *Twombly*, 550 U.S. at 556 ("[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable."). Rather, the Court meant the term to refer to the plausibility of the

plaintiff's legal theories, when considered in light of the factual allegations in the complaint. With this standard in mind, the Court turns to an evaluation of the complaint in the instant case.

B. Inconsistencies and Ambiguities in the Complaint

Defendants point to several seeming inconsistencies and ambiguities in the complaint. First, they repeatedly argue that the complaint fails "to 'identify' the product at issue." Doc. 8 at 4. But the complaint specifically identifies "the pharmaceutical drug Duragesic (fentanyl transdermal system CII) patch" as the relevant product (Doc. 1 ["Complaint"] at ¶4), and it is not clear how much more specific the complaint could be on this point. Thus, this argument is not well taken.

Next, Defendants point out, correctly, that the complaint fails to consistently allege the date of Michael Boroff's death. Compare Complaint at ¶22 (identifying the date of Boroff's death as "July 13, 2009") with *id.* at ¶24 (giving the date of death as "July 2007"). But this appears to be an inadvertent error that may be easily corrected through amendment.

Defendants also take issue with the complaint for bringing claims against the Defendants generally, instead of identifying specifically the role of each Defendant in the design and manufacture of the patch at issue. But in considering a motion to dismiss, the Court is required to accept all of the allegations in the complaint as true, and the complaint does allege that Defendants "are manufacturers, as defined at [Ohio] Revised Code §2307.71, and distributors, which designed, produced, created, made, constructed and/or assembled the drug . . .". There is nothing properly in the record at present to indicate that this allegation is untrue, and thus the Court cannot accept Defendants' assertion in its brief that "each Defendant had a different (and largely distinct) role in the design, manufacturing, and distribution of fentanyl patches".

C. Claims Under the Ohio Product Liability Act

1. Manufacturing Defect

Plaintiff brings four claims under the Ohio Product Liability Act (OPLA). Her first claim is that the Duragesic used by her late husband was "defective in manufacture". Ohio Rev.Code § 2307.74 provides that:

> A product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction.

The complaint in this case, however, is bereft of any allegation that the Duragesic used by the decedent deviated from any design specifications, formula, or performance standards, or any factual allegations that would support such a claim. Plaintiff thus fails to state a claim for violation of Ohio Rev.Code § 2307.74. *Stratford v. SmithKline Beecham Corp.*, 2008 WL 2491965 at *7 (S.D. Ohio June 17, 2008). Because Plaintiff has not yet been permitted an opportunity to amend her complaint, see *United States ex rel. Bledsoe v. Cmty. Health Sys.*, 342 F.3d 634, 644 (6th Cir.2003), however, her claim for violation of Ohio Rev.Code § 2307.74 will be dismissed without prejudice. Thus, she will be permitted to assert it in her amended complaint if she so chooses, provided that she is able to provide a more substantial basis for this claim.

2. Design Defect

Plaintiff's next claim alleges that the Duragesic used by the decedent was defective in design or formulation, in violation of Ohio Rev.Code § 2307.75. Ohio Rev.Code § 2307.75(A) provides that:

> Subject to divisions (D), (E), and (F) of this section, a product is defective in design or formulation if, at the time it left the control of its manufacturer, the

> foreseeable risks associated with its design or formulation as determined pursuant to division (B) of this section exceeded the benefits associated with that design or formulation as determined pursuant to division (C) of this section.

Subsection (D) provides that:

> An ethical drug or ethical medical device is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug or ethical medical device provides adequate warning and instruction under section 2307.76 of the Revised Code concerning that unavoidably unsafe aspect.

It is true that the complaint in the present case does not specifically allege that the foreseeable risks associated with Duragesic's design or formulation exceeded the benefits of that design or formulation. But there would appear to be little benefit to forcing a plaintiff, as a matter of pleading, to assert legal conclusions corresponding to the elements of the complicated multi-factor balancing test set forth in R.C. § 2307.75. It is enough that the well-pled factual material in the complaint gives rise to a fair inference that the foreseeably unsafe aspects of the drug's design or formulation outweigh the benefits, and that the drug does not fall within the exception in Subsection (D).

In the present case, the complaint alleges that Duragesic "has been recalled for causing death to users due to an excessive leak of fentanyl, a dangerous narcotic medication, into the skin," and that this sort of leakage caused the death at issue in this case. Complaint at ¶¶ 20-21. That is enough to give rise to a plausible inference that the foreseeable risks associated with Duragesic's design or formulation outweighed its benefits.

The complaint also contains allegations that Duragesic was "not safe", and that the Defendants knew of the risk but did not provide an accurate warning. See, *e.g.*, Complaint at ¶¶43-44. These allegations, however, are pled in connection with Plaintiff's common law breach of express warranty claim, and not her OPLA claims. "Claims that are authorized by the OPLA

should be pled with reference to the applicable provision of the OPLA." *Stratford*, 2008 WL 2491965 at *5. Because the lack of an adequate warning is an element of a OPLA design defect claim involving prescription drugs, Plaintiff will be permitted to amend her complaint in order to assert the lack of an accurate warning with respect to her OPLA claim. The motion to dismiss this portion of the complaint is therefore overruled.

3. Inadequate Warning

Next, Plaintiff claims that the patch used by the decedent was "defective due to inadequate warning or instruction, pursuant to the provisions of Ohio Rev.Code § 2307.76." Ohio Rev.Code § 2307.76 provides, in pertinent part, that:

> (A) Subject to divisions (B) and (C) of this section, a product is defective due to inadequate warning or instruction if either of the following applies:
> (1) It is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:
>
> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.
>
> (2) It is defective due to inadequate post-marketing warning or instruction if, at a relevant time after it left the control of its manufacturer, both of the following applied:
>
> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for

> which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.
>
> (B) A product is not defective due to lack of warning or instruction or inadequate warning or instruction as a result of the failure of its manufacturer to warn or instruct about an open and obvious risk or a risk that is a matter of common knowledge.
>
> (C) An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

As noted above, the complaint contains allegations that Duragesic was "not safe", and that the Defendants knew of the risk but did not provide an accurate warning. See, *e.g.*, Complaint at ¶¶43-44. Because these allegations are pled in connection with Plaintiff's common law breach of express warranty claims, and not her OPLA claims, Plaintiff will be permitted to amend her complaint in order to make these allegations under the aegis of the OPLA. The motion to dismiss this portion of the complaint is therefore overruled.

4. Misrepresentation

Plaintiff also claims that the Duragesic used by decedent was "defective" because it did not "conform to representations made, pursuant to the provisions of Ohio Revised Code § 2307.77." Ohio Revised Code § 2307.77 provides that:

> A product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation.

Again, the factual material that would support this claim is pled in connection with Plaintiff's claim for common-law breach of express warranty, and not her claim for violation of

the OPLA. For example, Plaintiff alleges that the Defendants "expressly represented to decedent and/or his physicians and healthcare providers that the Patches were safe and fit for use for the purposes intended . . . .", but that "[t]he Patches did not conform to these representations because they were not safe and caused serious side effects and death . . . ." Complaint at ¶¶ 42, 44. Plaintiff will thus be permitted to amend her complaint to make these factual allegations with respect to Ohio Revised Code § 2307.77.

D. Fraudulent Misrepresentation Claim

Plaintiff's third claim for relief is for "fraudulent misrepresentation." The elements of common law fraud are: (1) a representation or, where there is a duty to disclose, concealment of a fact, (2) which is material to the transaction at hand, (3) made falsely, with knowledge of its falsity, or with such utter disregard and recklessness as to whether it is true or false that knowledge may be inferred, (4) with the intent of misleading another into relying upon it, (5) justifiable reliance upon the representation or concealment, and (6) a resulting injury proximately caused by the reliance. *Russ v. TRW, Inc.*, 59 Ohio St.3d 42, 49 (Ohio 1991).

Fed.R.Civ.P. 9(b) dictates that, "in alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Rule 9(b) requires the plaintiff, at a minimum, to "allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of defendant; and the injury resulting from the fraud." *Yuhasz v. Brush Wellman, Inc.*, 181 F.Supp.2d 785, 788 (N.D.Ohio 2001).

In the present case, the complaint alleges, in general terms, that the Defendants actively and intentionally misrepresented the safety of Duragesic. Claims of active misrepresentation (as opposed to failure to warn) in connection with a product are not abrogated by the OPLA. See

Hollar v. Phillip Morris, Inc., 43 F.Supp.2d 794, 809 (N.D. Ohio 1998) (holding that claims of active misrepresentation implicate a broader "duty not to deceive" and are thus not product liability claims barred by the OPLA). But the claims of active misrepresentation in the complaint are not sufficiently pled under Rule 9(b) because the complaint does not state the time, place and context of the alleged misrepresentations. Instead, the allegations of fraud are vague and conclusory.

The failure to properly plead fraud is not grounds for dismissal with prejudice. See *United States ex rel. Bledsoe v. Cmty. Health Sys.*, 342 F.3d 634, 644 (6th Cir.2003). Thus, Plaintiff's fraudulent misrepresentation claim is dismissed without prejudice, and Plaintiff will be permitted to reassert this claim in her amended complaint, if she so chooses, provided that she is able to plead the circumstances surrounding the fraud with sufficient particularity.

E. Remaining Common Law Claims

Plaintiff also brings claims for common-law breach of express warranty, negligence, and negligence *per se*. These claims have all been abrogated by the OPLA. See *White v. DePuy, Inc.*, 129 Ohio App.3d 472, (Ohio Ct.App.1998) (OPLA codified claims for breach of express warranty); *Tompkin v. American Brands*, 219 F.3d 566, 575 (6th Cir. 2000) ("common law negligence claims have been preempted by OPLA"). Therefore, these claims are dismissed without prejudice so that they might be pled in the amended complaint under the OPLA. See *Stratford*, 2008 WL 2491965 at *5 (dismissing count of complaint without prejudice to be replead pursuant to OPLA); *Delahunt v. Cytodyne Techs*, 241 F.Supp.2d 827, 844 (S.D. Ohio 2003) (same).

III. Conclusion

Defendant's motion to dismiss (Doc. 8) is granted in part. Plaintiff's claims for a manufacturing defect under Ohio Rev.Code § 2307.74, breach of express warranty, fraudulent misrepresentation, negligence and negligence *per se* are dismissed without prejudice. The motion to dismiss is denied as to the remaining claims, and Plaintiff will be given 45 days to file an amended complaint with this Court.

IT IS SO ORDERED.

s/ *David A. Katz*
DAVID A. KATZ
U. S. DISTRICT JUDGE