

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

KATHRYN KIKER, *et al.*,

Plaintiffs,

v.

Case No. 2:14-cv-2164

CHIEF JUDGE EDMUND A. SARGUS, JR.

Magistrate Judge Terence P. Kemp

SMITHKLINE BEECHAM CORPORATION,
d/b/a GLAXOSMITHKLINE LLC,

Defendant.

OPINION AND ORDER

This matter is before the Court on the Defendant's Motion for Judgment on the Pleadings (ECF No. 51) and Plaintiffs' Response to Defendant's Motion for Judgment on the Pleadings, which consists of a request for leave to amend their Complaint (ECF No. 55). For the reasons that follow, the Court **DENIES** without Defendant's Motion for Judgment on the Pleadings (ECF No. 51), and **GRANTS** Plaintiffs' request to file an Amended Complaint.

I. BACKGROUND

Plaintiffs are a mother and her child, C.S., a minor. C.S. was born with a heart defect which the mother asserts resulted from her use of the drug Paxil® ("Paxil"), during her pregnancy. C.S. was born on March 14, 2001.

Plaintiffs' original complaint was filed in the United States District Court for the Eastern District of Pennsylvania, and the claims were made in accordance with Pennsylvania law. (ECF No. 55.) The case was subsequently transferred to this Court.

On December 18, 2014, Defendant filed a motion for judgment on the pleadings moving for dismissal of all counts because the version of the Ohio Products Liability Act ("OPLA"),

Ohio Rev. Code § 2307.71 *et seq.*, abrogates those claims.¹ (ECF No. 51.) Defendant moved for judgment as a matter of law as to Count One (Negligence and Negligence *per se*), Count Two (Negligent Pharmaco-Vigilance), Count Three (Strict Liability), Count Four (Failure to Warn), Count Five (Breach of Express Warranty), Count Six (Breach of Implied Warranty), Count Seven (Fraud), Count Eight (Negligent Infliction of Emotional Distress), Count Nine (Negligent Design), and Count Eleven (Negligent Misrepresentation) on the ground that those claims have been abrogated by the OPLA.² Defendant also moved for dismissal of Count Seven (Fraud), on the ground that Count Seven is allegedly insufficiently pled. Finally, Defendant moved for the dismissal of Count Twelve (Violation of Pennsylvania Unfair Trade Practices and Consumer Protection Law) as failing to state a claim under Ohio law.

On January 15, 2015, Plaintiff filed a response in opposition to Defendant's Motion for Judgment on the Pleadings. (ECF No. 55.) In this response, Plaintiffs requested to amend their Complaint. Plaintiffs additionally agreed with Defendant's choice-of-law analysis, concluding that Ohio law applies to Plaintiffs' claims in this action.

On January 22, 2015, Defendant filed a reply brief in support of its Motion for Judgment on the Pleadings. (ECF No. 57.) In the reply brief, Defendant also opposed Plaintiffs' request to amend her Complaint based on its contention that it would be futile to do so.

On July 10, 2015, the Court directed Plaintiffs to submit a proposed amended complaint, and a brief explaining why amendment would not be futile. (ECF No. 61.)

On July 24, 2015, Plaintiffs filed a proposed amended complaint consisting of five claims. (ECF No. 62.) Plaintiffs alleged the following: Count One (Common Law Negligence),

¹ The Ohio Product Liability Act was enacted in 1988, and amended effective April 7, 2005. *See* Ohio Rev. Code § 2307.71 *et seq.*

² The original complaint did not contain a Count Ten. (ECF No. 1.)

Count Two (Negligent Pharmaco-Vigilance), Count Three (Common Law Strict Liability), Count Five (Common Law Breach of Express Warranty), and Count Seven (Common Law Fraud). Plaintiffs withdrew the claims for Count Four (Failure to Warn), Count Six (Breach of Implied Warranty), Count Eight (Negligent Infliction of Emotional Distress), Count Nine (Negligent Design), Count Eleven (Negligent Misrepresentation), and Count Twelve (Violation of Pennsylvania Unfair Trade Practices and Consumer Protection Law).

Also on July 24, 2015, Plaintiffs filed a brief addressing why amendment of the IR Complaint was not futile. (ECF No. 63.) Specifically, Plaintiffs argue that OPLA does not apply to this case because the claims arose before the revised statute was enacted.

On August 8, 2015, Defendant filed its reply to Plaintiff's request to amend their Complaint, and addressed Plaintiffs' contention that such amendment would not be futile. (ECF No. 66.) Defendant asserted that amendment of the Complaint is futile because the claims arose after the April 7, 2005 effective date of the tort reform statute. Defendant also reiterated its contention that it is entitled to judgment on Count Seven (Fraud) because the proposed amended complaint still fails to plead the claim with particularity as required by the Federal Rules of Civil Procedure.

A. Federal Rule of Civil Procedure 12(c)

The same analysis is applied to motions for judgment on the pleadings pursuant to Rule 12(c) as to motions to dismiss pursuant to Rule 12(b)(6). *McGath v. Hamilton Local Sch. Dist.*, 848 F.Supp.2d 831, 836 (S.D. Ohio 2012), citing *Warrior Sports, Inc. v. Nat'l Collegiate Athletic Ass'n*, 623 F.3d 281, 284 (6th Cir. 2010).

Courts apply the same analysis to motions for judgment on the pleadings under Rule 12(c) as they apply to motions to dismiss under Fed. R. Civ. P. 12(b)(6). *See Warrior Sports, Inc. v. Nat'l Collegiate Athletic Ass'n*, 623 F.3d 281, 284 (6th Cir. 2010). "For purposes of a motion for judgment on the

pleadings, all well-pleaded material allegations of the pleadings of the opposing party must be taken as true, and the motion may be granted only if the moving party is nevertheless clearly entitled to judgment.” *JPMorgan Chase Bank, N.A., v. Winget*, 510 F.3d 577, 582 (6th Cir. 2007) (internal citation and quotation marks omitted). However, the court need not accept as true legal conclusions or unwarranted factual inferences. *Id.* (citing *Mixon v. Ohio*, 193 F.3d 389, 400 (6th Cir. 1999)).

In considering a motion for judgment on the pleadings, the court considers the pleadings, which consist of the complaint, the answer, and any written instruments attached as exhibits. Fed. R. Civ. P. 12(c), Fed. R. Civ. P. 7(a) (defining “pleadings” to include both the complaint and the answer); *Housing Authority Risk Retention Group, Inc. v. Chicago Housing Auth.*, 378 F.3d 596, 600 (7th Cir. 2004). While the allegations in the complaint are the primary focus in assessing a Rule 12 (c) motion, “matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint[] also may be taken into account.” *Barany-Snyder v. Weiner*, 539 F.3d 327, 332 (6th Cir. 2008) (quoting *Amini v. Oberlin Coll.*, 259 F.3d 493, 502 (6th Cir. 2001)).

Id. at 836-37.

B. Federal Rule of Civil Procedure 15(a)

Although leave to amend should be given “freely . . . when justice so requires,” Fed. R. Civ. P. 15(a)(2), a court “need not grant a motion for leave to amend where amendment would be futile,” including when “the proposed amendment would not permit the complaint to survive a motion to dismiss.” *Tretola v. Tretola*, No. 2:14-CV-576, 2014 U.S. Dist. LEXIS 160312, at *7 (S.D. Ohio Nov. 14, 2014) (quotations omitted).

III. ANALYSIS

The parties agree that Plaintiffs have alleged product liability claims as defined by the

OPLA:

“Product liability claim” means a claim or cause of action that is asserted in a civil action and that seeks to recover compensatory damages from a manufacturer or supplier . . . that allegedly arose from . . . (a) [t]he design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of [a] product, . . . (b) [a]ny warning or instruction, or lack of warning or instruction,

associated with th[e] product, . . . [or] (c) [a]ny failure of that product to conform to any relevant representation or warranty.

Ohio Rev. Code § 2307.71(A)(13).

The parties also agree that the OPLA applies to “ethical drugs” like Paxil® (“Paxil”), which are “prescription drugs that are prescribed or dispensed by a physician or any other person who is legally authorized to prescribe or dispense a prescription drug.” *Id.* § 2307.71(A)(4); *see also Stratford v. SmithKline Beecham Corp.*, No. 2:07-CV-639, 2008 U.S. Dist. LEXIS 84826, at *9-10 (S.D. Ohio June 17, 2008) (applying the OPLA to claims for negligence, negligent pharmaco-vigilance, reach of express warranty, and fraud based on injuries allegedly caused by Paxil). The OPLA abrogates common law products liability claims such as those alleged by Plaintiffs in the instant action. Ohio Rev. Code § 2307.71(B).

The parties, however, dispute whether the 2005 amendments to the OPLA apply to Plaintiffs’ claims in this case. The 2005 amendments do not apply retroactively. Ohio Rev. Code § 1.48) (“A statute is presumed to be prospective in its operation unless expressly made retrospective.”; *Heffelfinger v. Connolly*, No. 3:06-CV-2823, 2009 WL 112792, at *2 (N.D. Ohio Jan. 15, 2009) (finding no retroactive application of the Act); *Doty v. Fellhauer Elec., Inc.*, No. OT-07-023, 175 Ohio App. 3d 681 (Ohio Ct. App. Mar. 21, 2008) (amended OPLA did not apply retroactively). “Although R.C. 2307.71 clearly states the intent to abrogate all common law product liability claims, it does not provide that causes of action accruing prior to the effective date would be subject to the amendment.” *Doty*, 175 Ohio App. 3d at 686.

Thus, the issue for resolution by the Court is when C.S.’s injury arose for purposes of application of the 2005 amendments to the Ohio Tort Reform Act. The parties also dispute whether Plaintiffs’ sufficiently plead their claim for fraud in their amended complaint.

A. OPLA

Defendant argues that Plaintiffs' common law product liability claims accrued after the 2005 amendments to Ohio's Tort Reform Act and are therefore abrogated by the OPLA.

Defendant relies upon Ohio Revised Code § 2305.10, which states that "an action based on a product liability claim," for "bodily injury or injuring personal property" that is "caused by exposure to hazardous or toxic chemicals, ethical drugs, or ethical medical devices," accrues

upon the date on which the plaintiff is informed by competent medical authority that the plaintiff has an injury that is related to the exposure, or upon the date on which by the exercise of reasonable diligence the plaintiff should have known that the plaintiff has an injury that is related to the exposure, whichever date occurs first.

Ohio Rev. Code § 2305.10(B)(1).

Thus, Defendant concludes that, for purposes of application of the 2005 amendments to the Tort Reform Act, C.S.'s claims accrued in September 2005 when Defendant informed the medical community of the serious risk of birth defects and when third party research was released which showed the association between Paxil® and cardiac birth defects. Plaintiffs disagree, asserting that their claims arose when the injury occurred, which is March 14, 2001, the date C.S. was born. This Court agrees.

The provision of the Tort Reform Act Defendant relies upon *supra* is a provision that provides the limitations period. Ohio Revised Code § 2305.10. That provision incorporates a discovery rule so that a claim based on bodily injury may be extended to a date when it was reasonable for the injured party to have discovered that her injury was related to a defendant's product. However, as this Court recently explained in *In Re: E.I. Du Pont de Nemours and Company C-8 Personal Injury Litigation*, No. 13-md-2433, slip op. (S.D. Ohio September 8, 2015), the date an injury arose or accrued for purposes of determining application of the 2005

amendments to Ohio's Tort Reform Act does not incorporate a discovery rule. The Court explained:

As to the determination of the triggering date for application of the Tort Reform Act, many courts have appropriately considered it a distinct concept from the date triggering a statute of limitations, particularly one that incorporates a discovery rule. For example, a sister district court explained that “[t]he point at which a cause of action ‘arises’ can be different from the point at which it ‘accrues.’ A cause of action ‘accrues,’ or ‘come[s] into existence as an enforceable claim,’ when the injured party becomes aware, or reasonably should become aware, of the injury and the cause. . . . a cause of action ‘arises’ when the act or omission complained of occurs.” *Abramson v. P.J. Currier Lumber Co.*, No. 00-315-M, 2001 WL 274772, *1, 2001 U.S. Dist. LEXIS 1039, at *2-3 (D.N.H. Jan. 17, 2001). Other courts agree with this reasoning and recognize a distinction. See e.g., *Kaplan v. Shure Bros.*, 153 F.3d 413, 422 (7th Cir. 1998) (“[A] cause of action can ‘arise’ before it ‘accrues.’”); *Van Den Hul v. Baltic Farmers Elevator Co.*, 716 F.2d 504, 510 n.4 (8th Cir. 1983) (noting that “in certain contexts, the words ‘accrue’ and ‘arise’ have significantly different meanings”); *Vine v. Republic of Iraq*, 459 F. Supp.2d 10, 21 (D. D.C. 2006) *reversed in nonrelevant part at 529 F.3d 1187* (D.C. Cir. 2008) (a claim “arises” on the date that the action in question occurred, yet does not “accrue” until a prior disability to suit is removed); *Heinrich v. Sweet*, 118 F.Supp.2d 73, 79-80 (D. Mass. 2000) (explaining the “subtle, yet important, difference between the two words”); *Adobe Lumber, Inc. v. Hellman*, CIV 05-1510-WBS-PAN, 2008 WL 4615285, *4 (E.D. Cal., Oct. 17, 2008) (“The discovery rule allows claims based on distinct types of wrongdoing to accrue at different times, even though the claims arise out the same injury to a plaintiff.”). Consequently, the Court finds that the discovery rule does not apply to the determination of when a claim arose for purposes of determining whether the Tort Reform Act applies to a cause of action.

Id. at 9-10.

The Court finds the same here. That is, the statute of limitations provision that includes the discovery rule relied upon by Defendant does not dictate the date that Plaintiffs' claims arose for purposes of determining whether the 2005 amendments to the OPLA apply to their claims. As to that determination, “[c]ourts have routinely held that the relevant date for determining whether the [2005 amendment to the OPLA] applies is the date the conduct giving rise to the plaintiff's cause of action occurred.” *Heffelfinger*, 2009 WL 112792 at *3; see also *Blair v.*

McDonagh, 177 Ohio App.3d 262, 282 (Ohio Ct. App. 2008) (“[A] court cannot apply statute to causes of action that arose before the statute’s effective date even if some of the conduct giving rise to the cause of action occurred after the [statute’s] effective date.”). Indeed, three cases from this Court have made clear that determining when a claim arises or accrues for purposes of determining application of the Ohio Tort Reform Act depends on “whether the initial injury took place before . . . April 7, 2005,” regardless of when the plaintiff may have actually discovered or “should have” discovered the injury. *Liming v. Stryker Corp.*, No. 1:11-CV-00788, 2012 WL 1957287, at *3 (S.D. Ohio May 31, 2012) (accrual of claim occurred before effective date of the Act when injuries occurred in 2001, even though plaintiff did not become aware of his cause of action until 2009); *Troyer v. I-Flow Corp.*, No. 1:11-CV-00045, 2011 WL 2517031, at *4 (S.D. Ohio June 23, 2011) (same); *Edwards v. Warner-Lambert*, No. 2:05-cv-657, 2011 WL 5914008, at *4-5 (S.D. Ohio Nov. 28, 2011) (evidence existed supporting plaintiff’s argument that his cause of action accrued within meaning of the Act in 2004, because his injuries occurred between 2002 and 2004, even though he did not become aware of his causes of action until after April 7, 2005)). In the case *sub judice*, C.S.’s injury occurred at the latest on the date of his birth in 2001. Therefore, the 2005 amendments to the OPLA do not abrogate Plaintiffs’ claims.

The Court notes that *Stratford v. SmithKline Beecham Corp.*, No. 2:07-CV-639, 2008 U.S. Dist. LEXIS 84826, at *9-10 (S.D. Ohio June 17, 2008), the main case relied upon by Defendant, is not contradictory. In that case, the parties had briefed the issue that is currently before this Court. However, the *Stratford* court did not address the argument, which had not yet been fleshed out in the case law as it has been since then, and instead chose to allow amendment to the complaint to permit the plaintiff to recast its claims as statutory ones.

Consequently, because the Court finds that Plaintiffs' common law products liability claims have not been abrogated by the OPLA, it is not futile to allow amendment to her complaint. The Court therefore **DENIES** Defendant's Motion for Judgment on the Pleadings with regard to those claims and **GRANTS** Plaintiffs' request to file the proposed amended complaint.

B. Fraud

In response to Plaintiffs' proposed amended complaint, Defendant filed an additional reply brief in support of its motion for judgment on the pleadings, and asserted that, even if not abrogated by the OPLA, Plaintiffs' fraud claim fails because it is not pled with the particularity required by Fed. R. Civ. P. 9(b). (ECF No. 66). Rule 9(b) provides that "in alleging a fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."

Fed.R.Civ.P. 9(b) requires that averments of fraud must be stated with particularity. The Sixth Circuit reads this rule liberally, however, requiring a 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 the defendants; and the injury resulting from the fraud." Ballan v. Upjohn Co., 814 F.Supp. 1375, 1385 (W.D. Mich.1992) (citing Michaels Bldg. Co. v. Ameritrust Co. N.A., 848 F.2d 674, 679 (6th Cir.1988)). However, "allegations of fraudulent misrepresentation must be made with sufficient particularity and with a sufficient factual basis to support an inference that they were knowingly made." *Id.* The threshold test is whether the complaint places the defendant on "sufficient notice of the misrepresentation," allowing the defendants to "answer, addressing in an informed way plaintiffs [sic] claim of fraud." Brewer, 644 F.Supp. at 1273.

Coffey v. Foamex L.P., 2 F.3d 157, 161-62 (6th Cir. 1993)). The elements of common law fraud in Ohio consist of:

- (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, 570 N.E.2d 1076, 1083-84 (Ohio 1991). A duty to disclose and corresponding liability for failure to disclose arises when

the party fails to exercise reasonable care to disclose a material fact which may justifiably induce another party to act or refrain from acting, and the non-disclosing party knows that the failure to disclose such information to the other party will render a prior statement or representation untrue or misleading.

Glassner v. R.J. Reynolds Tobacco Co., 223 F.3d 343, 353 (6th Cir. 2000).

Thus, the Court must examine the proposed amended complaint to determine whether the averments sufficiently plead the time, place, and content of the alleged misrepresentation upon which Plaintiffs' allegedly relied; the fraudulent scheme and intent of the defendant; and any injury resulting from the misrepresentation. The allegations must be stated with enough particularity to put defendants on "sufficient notice of the misrepresentation." *Coffey*, 2 F.3d, at 162.

Plaintiffs' fraud claim incorporates by reference paragraphs 1 through 73 of the amended complaint, which includes a general statement of facts and allegations. These allegations describe the drug Paxil, and allege that it was first approved for use in the United States by the Food and Drug Administration in 1992 for the treatment of depression in adults. (ECF No. 62, ¶ 10.) The general allegations further assert that Plaintiff took Paxil "as prescribed by her treating physician while pregnant with C.S in the City of Hilliard, Ohio," and that she gave birth to C.S. on March 14, 2001. At birth, C.S. suffered from infant respiratory distress syndrome and ventricular septal defect, "a serious heart defect." (ECF No. 62, ¶¶ 10, 11, 12.) Thus, Plaintiffs allege the time, place and context of the reliance on the misrepresentations as occurring during the pregnancy, and preceding the birth in March 2001. Taken as true, these averments set the

time frame, place, and context for the reliance on the misrepresentations as occurring in Ohio, from some time during 2000 until the birth in March, 2001.

Plaintiff further avers that at the time Paxil was prescribed to her, Defendant knew through pre-market studies and post-marketing studies and reports that the drug “was associated with a significant increased risk of cardiac birth defects in babies whose mothers ingested Paxil during pregnancy,” and that, notwithstanding this knowledge, Defendant “aggressively and actively promoted Paxil for use with pregnant women.” Specifically, Defendant avers that, at the time Paxil was marketed to healthcare professionals and prescribed to Ms. Kiker, Defendant was engaged in marketing misrepresentations “to give a false impression of both the safety and efficacy of the drug to the medical community, prescribing doctors and patients.” (ECF No. 62, ¶¶ 13, 14.) Additionally, Defendant avers that it did not begin to inform doctors of the serious risk to pregnant women “until September 2005, when third party research was released which showed the association between Paxil and cardiac birth defects.” In September 2005, Defendant revised its label for Paxil to warn of the “increased risk for cardiovascular malformations” for infants whose mothers used Paxil during pregnancy. (ECF No. 62, ¶ 15.)

As part of its second claim, for negligent pharmaco-vigilance, incorporated by reference into the fraud claim, Plaintiff avers that “[b]y 1998, [Defendant’s] internal pregnancy adverse event reports showed the company had received hundreds of adverse events related to Paxil exposure during pregnancy” and this represented a “significant finding.” However, Defendant “refused to conduct additional animal testing to determine the safety of Paxil use during pregnancy and failed to inform the medical community, including Ms. Kiker’s prescribing physician, of this ‘significant finding.’” Rather, by 1999, Defendant “still refused to study

Paxil's in utero effects in animals, saying 'don't touch this with a barge pole.'" (ECF No. 62, ¶¶ 42, 43, 44.)

Plaintiffs' fraud claim incorporates those averments, and further specifically alleges that Defendant, "having voluntarily undertaken the manufacturing, marketing, dispensing, distribution, and promotion of Paxil as described herein, owed a duty to provide accurate and complete information regarding the drug." (ECF No. 62, ¶ 76). Specifically, the claim states that Defendant "[f]raudulently misrepresented in the Paxil label at the time of Ms. Kiker's use of the drug in 2000 that 'the cause of these [rat] deaths is not known,' thereby deceiving Ms. Kiker and her prescribing physician about the safety of using Paxil during pregnancy" and withheld from Ms. Kiker's prescribing physician and the medical community the fact that, during clinical trials, [Defendant], as early as October 1995, knew that the administration of Paxil *caused* in embryo-fetal rat deaths and pup deaths, and instead misrepresented in the Paxil label at the time of Plaintiff's use of the drug in 2000 that "these [clinical] studies have revealed no evidence of tetragenic effects," "thereby deceiving [Plaintiff] and her prescribing physician about the safety of using Paxil during pregnancy." (ECF No. 62, ¶ 78).

The Court concludes that the proposed amended complaint places Defendant on "sufficient notice of the misrepresentation" to allow the it to "answer, addressing in an informed way plaintiffs [sic] claim of fraud." *Coffey*, at 162. Because the Court finds that Plaintiffs' proposed amended complaint pleads fraud with sufficient particularity, Defendant's Motion for Judgment on the Pleadings on the Plaintiffs' common law fraud count is **DENIED**.

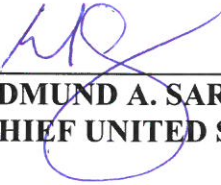
IV.

Based on the foregoing, the Court **DENIES** Defendant's Motion for Judgment on the Pleadings (ECF No. 51), and **GRANTS** Plaintiffs' request to file an Amended Complaint.

IT IS SO ORDERED.

9-30-2015

DATE



EDMUND A. SARGUS, JR.
CHIEF UNITED STATES DISTRICT JUDGE