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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION

ASHLYE M. BARCAL,	}	
	}	
Plaintiff,	}	
	}	
v.	}	**Case No.: 5:14-cv-01709-MHH**
	}	
EMD SERONO, INC.,	}	
	}	
Defendant.	}	

MEMORANDUM OPINION

Plaintiff Ashlye M. Barcal brings this products liability action against defendant EMD Serono, Inc. EMD Serono manufactures the fertility drug Serophene. Ms. Barcal alleges that she suffered severe cardiac birth defects as a result of her mother's ingestion of Serophene, and Ms. Barcal asserts thirteen causes of action against the company.

EMD Serono moved to dismiss the action pursuant to Fed. R. Civ. P. 12(b)(6). EMD Serono attached to its motion the Serophene label in effect when Ms. Barcal's mother used the fertility drug and several journal articles that Ms. Barcal mentioned in her complaint. Because of EMD Serono's reliance on the label and the articles, the Court converted EMD Serono's motion to dismiss into a motion for summary judgment pursuant to Fed. R. Civ. P. 12(d) and 56 and provided the parties an opportunity to file supplemental materials pertaining to the

summary judgment motion. After consideration of the parties' submissions, the Court will grant EMD Serono's converted motion for summary judgment in part, defer consideration of it in part, and grant Ms. Barcal's request for discovery pursuant to Fed. R. Civ. P. 56(d).

I. STANDARD OF REVIEW

"If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion." Fed. R. Civ. P. 12(d).

The Court must grant summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The Court must "examine the evidence in the light most favorable to the non-moving party," drawing all inferences in favor of that party. *Earl v. Mervyns, Inc.*, 207 F.3d 1361, 1365 (11th Cir. 2000).

"If a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may defer considering the motion or deny it; allow time to obtain affidavits or declarations or to take discovery; or issue any other appropriate order." Fed. R. Civ. P. 56(d). "The party opposing a motion for summary judgment has a right to challenge the

affidavits and other factual materials submitted in support of the motion by conducting sufficient discovery so as to enable him to determine whether he can furnish opposing affidavits," so "summary judgment should not be granted until the party opposing the motion has had an adequate opportunity for discovery." *Snook v. Trust Co. of Ga. Bank of Savannah*, 859 F.2d 865, 870 (11th Cir. 1988).

II. RELEVANT FACTS AND PROCEDURAL HISTORY

In 1982, EMD Serono received approval from the FDA to market and sell under the name Serophene a fertility medication known as clomiphene citrate.[1] (Doc. 1, ¶ 13). From August 1993 through January 1994, Mary Durham, Ms. Barcal's mother, was prescribed and took Serophene to help her conceive. (Doc. 1, ¶ 14). Ms. Durham became pregnant in February 1994, and Serophene was still present in her system. (Doc. 1, ¶¶ 16-17). Ms. Barcal was born prematurely on September 8, 1994, at approximately 34 and 3/7ths weeks. (Doc. 1, ¶ 18).

On September 23, 1994, doctors diagnosed Ms. Barcal with a heart murmur and a large ventricular septal defect (VSD). This defect is characterized as a hole in the septum—the wall of the heart—causing blood to flow between the lower chambers of the heart instead of properly entering the aorta for distribution throughout the body. (Doc. 1, ¶ 19). Shortly after she was born, Ms. Barcal was

[1] Clomiphene citrate was initially approved by the FDA in 1967 under the brand name Clomid, manufactured by Aventis, Inc. (Doc. 1, ¶¶ 3-4, 12). Ms. Barcal initially named Aventis as a defendant in this action, asserting the first thirteen causes of action only against Aventis. The Court previously dismissed all claims against Aventis without prejudice, consistent with the parties' joint stipulation of dismissal. (*See* Docs. 32, 33).

diagnosed with Tetralogy of Fallot, a form of congenital heart disease that consists of high pulmonic stenosis, VSD, dextroposition of the aorta, and right ventricular hypertrophy. (Doc. 1, ¶ 20). Ms. Barcal had to undergo surgery in 1995 to address her cardiac issues. She has dealt with cardiac complications her entire life, dramatically affecting her quality of life. (Doc. 1, ¶¶ 21-26).

EMD Serono provided a label that the company asserts it attached to all Serophene containers during the period in which Ms. Durham took the drug. (Doc. 19-2). The label mentions that congenital heart defects were observed in children whose mothers' pregnancies had been induced by clomiphene citrate, but "[t]he cumulative rate of congenital abnormalities does not exceed that reported in the general population." (Doc. 19-2 at 4). The label also states: "Although no direct effect of clomiphene citrate therapy on the human fetus has been established, clomiphene citrate should not be administered in cases of suspected pregnancy as such effects have been reported in animals." (Doc. 19-2 at 3).

Ms. Barcal initiated this suit against EMD Serono on September 4, 2014, asserting thirteen causes of action. The claims are primarily based on two distinct theories: (1) Serophene is a defective product because it unreasonably increases the risk of cardiac birth defects,[2] and (2) Serophene's warning label is inadequate

[2] The Court considers the following claims to fall under the first theory: Count XIV (AEMLD Design Defect); Count XVI (Implied Warranty of Fitness for a Particular Purpose), because the warranty turns on the suitability of the product, *see* Ala. Code § 7-2-315; and Count XX (Implied

because it does not sufficiently warn physicians and consumers of the increased risk of cardiac birth defects caused by the drug.[3] In support of her causation theory, Ms. Barcal cites several journal articles in her complaint which, in her mind, demonstrate the increased risk and put EMD Serono on notice of the risk, either actually or constructively.

EMD Serono moved to dismiss the action on various grounds. Most notably, it attached to its motion the articles that Ms. Barcal referenced in her complaint and argued that the articles do not provide factual support for her causation theory and did not put EMD Serono on notice of any increased risk of cardiac birth defects. (Docs. 18-19). The parties submitted briefing, and Ms. Barcal attached to her submission an affidavit under Fed. R. Civ. P. 56(d), in which her attorney contends that summary judgment in this action would be premature because the parties have not conducted discovery. (Doc. 39-1). She asks the Court to deny EMD Serono's motion without prejudice to the company's right to file another summary judgment motion after the parties engage in discovery.

Warranty of Merchantability), because the warranty turns on the fitness of the product, *see* Ala. Code § 7-2-314. Counts XVIII (Negligence) and XXV (Unjust Enrichment) fall under both theories.

[3] The Court considers the following claims to fall under the second theory: Count XV (AEMLD Warning); Count XVII (Express Warranty); Count XIX (Failure to Warn); Count XXII (Fraud), to the extent the alleged fraud is based on misrepresentations in the warning label; Count XXIII (Negligent Misrepresentation); and Counts XXIV (Negligence per se) and XXVI (ADTPA Violation), because both are premised on the label's false representations. Counts XVIII (Negligence) and XXV (Unjust Enrichment) fall under both theories.

III. ANALYSIS

Ms. Barcal's Rule 56(d) request is well-taken. The Court will grant the motion. The Court will not require Ms. Barcal to present evidence in support of her claims when she has not had the opportunity to discover relevant evidence. *See Snook*, 859 F.2d at 870. Pursuant to Rule 56(d), the Court will therefore review Ms. Barcal's claims for legal sufficiency, dismissing only those claims with defects that cannot be cured by discovery. The Court will defer consideration of EMD Serono's motion for summary judgment until after the parties conduct discovery.

A. Design Defect Claims

EMD Serono presents two legal challenges to Ms. Barcal's claims that Serophene is defectively designed. Because the Court finds both grounds to be meritorious, the Court will dismiss all of Ms. Barcal's claims premised upon her design defect theory.

1. Unavoidably Unsafe Products

In defining the contours of the Alabama Extended Manufacturer's Liability Doctrine in *Stone v. Smith, Kline & French Labs.*, the Alabama Supreme Court recognized a category of products that are "unavoidably unsafe," that is, products that "are quite incapable of being made safe for their intended and ordinary use." 447 So. 2d 1301, 1303 n.1 (Ala. 1984); *see also* Restatement (Second) of Torts § 402A cmt. k (Am. Law Inst. 1965). The Alabama Supreme Court found that

prescription drugs fall within this category and held: "in the case of an 'unavoidably unsafe' yet properly prepared prescription drug, the adequacy of the accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous." *Id.*at 1304. Therefore, no AEMLD design defect claim for prescription drugs exists apart from a challenge to the adequacy of the warning, a claim that Ms. Barcal has separately stated.

EMD Serono argues that this principle operates as a bar to all of Ms. Barcal's design defect claims, whether premised on the strict liability of the AEMLD or on a negligence theory. The Court agrees. All of the design defect claims, no matter the cause of action under which they are presented, hinge on the safety of the product.[4] The Alabama Supreme Court has found the safety element common to both strict liability and negligence claims. *See McMahon v. Yamaha Motor Corp.*, 95 So. 3d 769, 772 (Ala. 2012). Indeed, in *Stone*, the Alabama Supreme Court specifically linked the exception to negligence principles. *Stone*, 447 So. 2d at 1303 ("The requirement that the product be unreasonably dangerous, as amplified by comments j and k, produces essentially the same result as traditional negligence theory.") (quoting R. Merrill, *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1, 31 (1973)). Because the rationale of the exception

[4] As stated above, the implied warranty claims turn on the suitability or fitness of the drug. Ms. Barcal's negligence claim, as related to design defects, centers on the drug not being "reasonably safe." (Doc. 1, ¶ 198). Her unjust enrichment claim focuses on the quality and fitness of the drug. (Doc. 1, ¶ 255).

turns on the notion that prescription drugs are desirable even though they may never be made fully safe, the Court finds the exception equally applicable to design defect claims outside of the AEMLD. All of Ms. Barcal's design defect claims will accordingly be dismissed.

2. Preemption

Alternatively, EMD Serono correctly argues that federal law preempts Ms. Barcal's design defect claims. "Under the Supremacy Clause, state laws that require a private party to violate federal law are pre-empted and, thus, are 'without effect.'" *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). "[S]tate law [is] impliedly preempted where it is 'impossible for a private party to comply with both state and federal requirements.'" *Id*. at 2473 (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2579 (2011). "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id*. at 2581. Neither is impossibility preemption avoided if the party may comply with both federal and state law by ceasing to act altogether. *Bartlett*, 133 S. Ct. at 2477.

The FDA approved Serophene's composition in 1982. (Doc. 1, ¶ 13). "Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" *Bartlett*, 133 S. Ct. at 2471 (quoting 21 C.F.R. § 314.70(b)(2)(i)). Alabama tort design defect claims, however, would essentially require EMD Serono to redesign Serophene. *See id.* at 2479 (rejecting the dissent's characterization of state tort law as "merely creat[ing] an incentive" to change the drug rather than imposing an actual "legal obligation"). This is precisely the kind of impossibility in which the Supreme Court has found preemption. *Id*. ("[W]e hold that state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling."). The fact that the FDA may approve an alteration does not negate the present impossibility. *See PLIVA*, 131 S. Ct. at 2581. Ms. Barcal's design defect claims are preempted.

Ms. Barcal argues that the cases cited above do not apply to her claims because all of those cases regard failure-to-warn claims against manufacturers of generic drugs approved under the FDA's Abbreviated New Drug Application,

while Serophene was approved under the standard New Drug Application process, and EMD Serono is asserting preemption of design defect claims, not failure-to-warn claims. These assertions do not negate the fact that any approved drug, whether through the NDA or ANDA process, cannot be altered without the FDA's prior permission, rendering compliance with both state and federal law impossible. *Wyeth v. Levine*, 555 U.S. 555 (2009), is not to the contrary. In that case, the Court found no preemption of failure-to-warn claims against an NDA drug manufacturer because a process existed by which the manufacturer could strengthen the label warnings unilaterally and seek subsequent FDA approval. No such process exists for changes to a drug's chemical composition, however, so the *Levine* holding is inapplicable.

B. Adequacy of Warning Label Claims

In contrast to its challenge to the design defect claims, EMD Serono asserts no legal challenges to Ms. Barcal's claims regarding the adequacy of the Serophene label (apart from the fraud and statutory claims discussed below). Instead, it contends that the warning claims fail because the journal articles cited by Ms. Barcal do not establish an increased risk of cardiac birth defects and thus could not have put the company on notice of those risks. This is essentially a factual challenge to the sufficiency of the evidence submitted by Ms. Barcal because EMD Serono seeks to use the studies to contradict Ms. Barcal's assertions

that the label did not adequately warn of the increased risk. Ms. Barcal, however, has not had the opportunity to conduct discovery and therefore cannot be expected to submit evidence in support of her claims. Consequently, the Court will defer consideration of EMD Serono's converted motion for summary judgment as to the warning label claims until the parties have conducted discovery.

Lest EMD Serono feel slighted by the Court's conversion of its motion to dismiss into a motion for summary judgment and subsequent use of that conversion to defer the motion, the Court also finds that Ms. Barcal's failure-to-warn claims would survive EMD Serono's Rule 12(b)(6) motion. Ms. Barcal alleged that the articles she cites in her complaint placed EMD Serono on notice that Serophene increased the risk of the occurrence of cardiac birth defects. (*See, e.g.*, Doc. 1, ¶¶ 86, 115). This notice was either actual (prompting the misrepresentation theories) or constructive (prompting the negligence/strict liability theories). Thus, Ms. Barcal plausibly alleges her failure-to-warn claims.

EMD Serono argues that the journal articles do not actually support the liability theory that Ms. Barcal advances. That may be true, but this is not a proper juncture for the Court to make such a determination. EMD Serono would have the Court reject Ms. Barcal's view and find her causation and notice theories implausible because none of the articles explicitly link Serophene to an increased risk of cardiac birth defects. In Ms. Barcal's view, however, the articles function

as building blocks to that ultimate conclusion.[5] Disagreeing with this view is not, as EMD Serono suggests, simply an exercise in resolving a contradiction between pleadings and exhibits in favor of the exhibits. *See Griffin Indus., Inc. v. Irvin*, 496 F.3d 1189, 1206 (11th Cir. 2007). Rather, it requires a factual determination regarding the import of the articles that the Court cannot make at this stage. These are arguments better suited to summary judgment, so the Court will defer consideration of them until that time.

Neither is EMD Serono absolved from liability simply because of the presence of a warning on the label regarding cardiac birth defects and ingestion during pregnancy. Ms. Barcal contends that the warning is inadequate because it fails to properly convey the full extent of the risks of cardiac birth defects allegedly caused by the drug. That a warning regarding these issues was present does not conclusively establish that it was adequate.

C. Fraud Claim

"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "Particularity means that a plaintiff must plead facts as to time, place, and substance of the defendant's alleged fraud, specifically the details of the defendant['s] allegedly

[5] Contrary to EMD Serono's assertions, even the articles that post-date Ms. Durham's ingestion of Serophene are not wholly irrelevant. While they cannot have served to put the company on notice of an increased risk of cardiac defects, the articles could support Ms. Barcal's theory that an increased risk is present and could potentially show that EMD Serono may have discovered the risk by conducting additional testing.

fraudulent acts, when they occurred, and who engaged in them." *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1357 (11th Cir. 2006) (internal quotations omitted). Ms. Barcal has alleged fraud based on EMD Serono's statements made on the Serophene label, in advertisements, and in other acts of concealment and suppression. Her claims concerning the warning label have been set forth with particularity, but the others have not. Ms. Barcal has not alleged any specific fraudulent advertisements or acts apart from the label. Instead, she seeks discovery to uncover the statements made in the relevant advertisements, but this is not permitted by Rule 9(b). *See id*. at 1359 ("The particularity requirement of Rule 9 is a nullity if Plaintiff gets a ticket to the discovery process without identifying a single claim.") (quoting *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1307 (11th Cir. 2002)). Therefore, Ms. Barcal's fraud claim (Count XXII), except as regarding the Serophene label, will be dismissed.

D. Statutory Claims

In Count XXVI, Ms. Barcal asserts a claim under the Alabama Deceptive Trade Practices Act. *See* Ala. Code § 8-19-1 *et seq*. She also asserts a statutory negligence claim in Count XXIV, which she later clarified is only brought under the ADTPA. (*See* Doc. 34 at 20). As discussed above, Ms. Barcal asserts common law fraud and negligence claims. The ADPTA's savings clause provides:

> An election to pursue any civil remedies available at common law, by statute or otherwise, for fraud, misrepresentation, deceit, suppression

> of material facts or fraudulent concealment arising out of any act, occurrence or transaction actionable under this chapter shall exclude and be a surrender of all rights and remedies available under this chapter.

Ala. Code § 8-19-15(b). Although the ADPTA's savings clause would preclude Ms. Barcal from ultimately obtaining relief under both the ADPTA and her common law claims, Federal Rule of Civil Procedure 8 allows parties to plead alternative, even inconsistent, theories. *See* Fed. R. Civ. P. 8(d)(3) ("A party may state as many separate claims or defenses as it has, regardless of consistency."). Therefore, at this stage, the Court will allow Counts XXIV and XXVI to move forward as alternatively pled claims.

E. Punitive Damages Claim

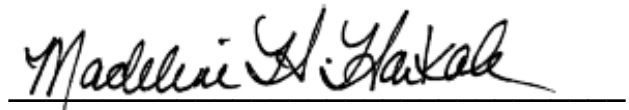
In Count XXI, Ms. Barcal asserts a claim for punitive damages. Under Alabama law, however, punitive damages are merely a remedy, not a cause of action, so she may not assert a claim solely for punitive damages. *See* Ala. Code § 6-11-28 ("Nothing contained in this article shall be construed to grant or create a cause of action or right to recover punitive damages."). Count XXI will accordingly be dismissed.

IV. CONCLUSION

For the reasons discussed above, the Court will dismiss Ms. Barcal's design defect and punitive damages claims, and will partially dismiss her fraud claim. The action will proceed on the balance of Ms. Barcal's claims. The Court will

enter a separate order consistent with this memorandum opinion.

DONE and **ORDERED** this March 21, 2016.



MADELINE HUGHES HAIKALA
UNITED STATES DISTRICT JUDGE