IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA SOUTHERN DIVISION

SHENIKA HOUSTON,	}	
	}	
Plaintiff,	}	
	}	CIVIL ACTION NO.
V.	}	2:14-cv-00035-WMA
	}	
BAYER HEALTHCARE	}	
PHARMACEUTICALS, I	INC., }	
	}	
Defendant.	}	

MEMORANDUM OPINION

Before the court is the motion of defendant Bayer Healthcare Pharmaceuticals, Inc, to dismiss this action pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons that follow, the motion will be granted as to plaintiff's implied warranty claim, but denied as to all other claims.

Background

For purposes of this opinion, all facts alleged in the complaint are taken as true. Plaintiff is a 26-year-old woman seeking to recover damages for injuries she alleges were caused by Mirena, a birth control device manufactured by defendant. Mirena is a physical device placed in the uterus for up to five years. Compl. \P 19. It regularly releases "levonorgestral," a prescription medication, directly into the uterus. *Id.* \P 13, 17. It is used for birth control, *id.* \P 17, and "for treatment of heavy menstrual bleeding in women who choose to use intrauterine

contraception as their method of contraception," id. \P 15.

According to plaintiff, the levonorgestral released by Mirena has been linked to development of a condition called "pseudotumor cerebri," also known as "idiopathic intracranial hypertension," (hereinafter, "PTC/IIH"). *Id.* ¶ 26. PTC/IIH occurs when fluid builds up in the skull. *Id.* ¶ 27. It causes "severe migraines or migraine-like headaches with blurred vision, diplopia (double vision), temporary blindness, blind spots, or other visual deficiencies," *id.* ¶ 28, and "'whooshing' or ringing in the ear, clinically called tinnitus," *id.* ¶ 29. If not corrected diagnosed and treated, it "may lead to permanent vision loss and even blindness." *Id.* ¶ 34. PTC/IIH is treatable, but positive outcomes are not assured. *Id.* ¶ 35-44.

Plaintiff used the Mirena device, *id.* ¶ 70, and was subsequently diagnosed with PTC/IIH, *id.* ¶ 72. She brings this action seeking recovery for her injuries under nine state law causes of action. The court has diversity jurisdiction under 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000, and because defendant is a citizen of New Jersey and plaintiff is a citizen of Alabama.

Defendant now moves the court, pursuant to Federal Rule of Civil Procedure 12(b)(6), for dismissal of this case for failure to state a claim.

Analysis

Under the standard provided by Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007), and Ashcroft v. Iqbal, 556 U.S. 662 (2009), a motion to dismiss under Rule 12(b)(6) is analyzed using a "two-pronged approach." Id. at 679. First, the court sifts out and discards all of the legal conclusions from the complaint. See id. at 678. Second, the court determines whether what is left states a "plausible" claim for relief. See id. at 679. Defendant argues that under this standard, the complaint in this case is so glaringly deficient that it must be dismissed in its entirety. In the alternative, defendant argues that each of plaintiff's claims suffers some individual defect that requires its dismissal.

A. "Global Deficiency"

Defendant first argues that the complaint contains so few facts as to deprive defendant of fair notice of what it is being sued for. See Def.'s Mem. at 3-4; Def.'s Reply at 2-4 (arguing complaint is "so globally deficient" that it must be dismissed in its entirety, without analysis of any individual cause of action). As an initial matter, the court disagrees that there exists an abstract sufficiency hurdle, contained in the Federal Rule, that is entirely separate from any substantive law. So long as a plaintiff lists some cause of action in his complaint, the question is whether he has alleged facts to support that cause of action, not simply whether he has alleged facts. Indeed, the second prong of

the *Iqbal* test, in which the court determines whether the complaint states a plausible claim for relief, requires by logical necessity some discussion of the elements of the causes of actions alleged. *See* 556 U.S. at 675 ("In *Twombly*, the Court found it necessary first to discuss the antitrust principles implicated by the complaint. Here too we begin by taking note of the elements a plaintiff must plead to state a claim"); *Resnick v. AvMed*, *Inc.*, 693 F.3d 1317, 1325 (11th Cir. 2012) ("First, we determine what must be pled for each cause of action.") (collecting state court cases to establish the elements of the causes of action at issue).

The only case from this district cited by defendandant in support of its "global deficiency" theory, Weldon v. Washington Nat. Ins. Co., 2:13-CV-02209-RDP, 2014 WL 130486 (N.D. Ala. Jan. 14, 2014), is not to the contrary of this principle. There the court specifically couched its dismissal of the action in terms of the elements of the causes of action alleged by the plaintiff. See id. at *2 ("Plaintiff not only neglects to outline the elements of the claims he asserts (i.e., negligence and wantonness), but he also fails to articulate any factual allegations that relate to those elements, such as facts regarding Defendant's alleged negligence or Defendant's allegedly wrongful denial of Plaintiff's insurance claim."). Equally unpersuasive is Bosch v. Bayer Healthcare Pharm., Inc., 3:13-CV-00656-JHM, 2013 WL 5656111 (W.D.

Ky. Oct. 16, 2013), the case on which defendant primarily relies. Bosch, an unpublished decision from a different district, has no holding that this court can discern, as the court there declined to analyze the complaint before it on the grounds that doing so would provide the plaintiffs an advisory opinion. See id. at *4 ("The Court notes that it is neither necessary nor desirable for it to detail the deficiencies in Plaintiffs' complaint."). The reason for this curious coyness must be derived from the court's final disposition on the motion to dismiss. The court reserved ruling on the motion, and ordered the plaintiffs to file an amended complaint, even without plaintiffs' having moved to do so. Because "[t]he case [was] still in its earliest stages," and because the court for whatever reason found the complaint hopeless, the court thought it most fair and efficent to simply re-start the case with a more detailed complaint before providing any meaningful analysis of the merits of the case. Id. at *3. It does not follow from this unique disposition, as defendant seems to believe, that a case can be dismissed outright, with prejudice, without any analysis of the elements of a plaintiff's claims.

Even were such a "global deficiency" principle to exist, the court takes with healthy skepticism defendant's claim that it has no notice here as to why it is being sued. The opening sentence of the complaint spells out that plaintiff seeks redress for "personal injuries suffered as a proximate result of [p]laintiff being

prescribed and properly using the defective and unreasonably dangerous product Mirena . . . " Compl. at 1. Later, plaintiff explains simply that she "had the Mirena IUS inserted into her body," Compl. ¶ 70; that she subsequently became ill and "was ultimately diagnosed with [PTC/IIH]," *id.* ¶ 73; and that there exists some evidence that the disease was caused by the Mirena, *id.* ¶ 74; *see id.* ¶¶ 46-60 (evidence of possible link between levonorgestrel and PTC/IIH). Finally, the complaint names and spells out eight causes of action, Compl. ¶¶ 76-189, so that defendant knows exactly where it needs to focus its attention as the case moves to the discovery phase. The complaint thus contains the "short and plain statement of the claim," Fed. R. Civ. P. 8(a)(2), and the "demand for the relief sought," 8(a)(3), required by the Federal Rules.

B. Missing Elements

While the complaint has not earned any general dismissal for "global deficiency," it must still contain factual allegations sufficient to satisfy the elements of each individual claim. The court finds that plaintiff has failed to state a claim for breach of implied warranty, but that her other claims all survive defendant's motion to dismiss.

1. Breach of Implied Warranty

Defendant's sole winning argument is that plaintiff fails to state a claim for Breach of Implied Warranty (plaintiff's Count

Implied warranties are covered by the Alabama Commercial IV). Code. Under § 7-2-314(1), "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Under § 7-2-314(2)(c), "goods to be merchantable must be at least such as . . . [a]re fit for the ordinary purposes for which such goods are used." Defendant argues that "[p]laintiff does not state facts to explain how Mirena was not of merchantable quality and unfit for the ordinary purposes for which it is used, e.g., preventing pregnancy." Def.'s Mem. at 7. The key to defendant's argument is the "e.g., preventing pregnancy" at the end of it. Defendant implicitly argues that the Commercial Code implied warranty applies only when a product fails to accomplish its primary purpose, and not when the product accomplishes this purpose but has dangerous side effects.

This question came before the Supreme Court of Alabama, on certification from the Eleventh Circuit, in *Spain v. Brown & Williamson Tobacco Corp.*, 872 So. 2d 101 (Ala. 2003). There, the administrator of a deceased cigarette smoker's estate brought suit against a cigarette manufacturer, including an implied warranty claim with its wrongful death and design defect tort claims. *Id.* at 103. The Alabama Supreme Court was called on by the Eleventh Circuit to answer a number of questions, including whether the Circuit was correct "that that the sale of cigarettes does not

violate the implied warranty of merchantability under Code of Alabama 1975, § 7-2-314." Id. at 103-04.

The Supreme Court's answer was lengthy and not totally clear. The Court began by citing its decision in *Shell v. Union Oil Co.*, 489 So. 2d 569 (Ala. 1986), an implied warranty case against the manufacturer of a "naptha product" that "contained benzene, a cancer-causing agent." *Spain*, 872 So. 2d at 106. In *Shell*, the court concluded that "[w]hether this product was unreasonably dangerous . . . could properly be raised in an action brought under Alabama's Extended Manufacturer's Liability Doctrine (A.E.M.L.D.), but not in this U.C.C. action for breach of warranty." 489 So. 2d at 571. The Court reasoned:

The implied warranty mandated by this section of the U.C.C. is one of *commercial* fitness and suitability, and a private right of action is afforded only where the user or consumer is injured by the breach of *that* warranty. That is to say, the U.C.C. does not impose upon the seller the broader obligation to warrant against health hazards inherent in the use of the product when the warranty of commercial fitness has been complied with. Those injured by the use of or contact with such a product, under these circumstances, must find their remedy outside the warranty remedies afforded by the U.C.C.

Id. at 572 (emphases in original).

This reasoning would seem to answer the question decisively: the commercial code creates only commercial warranties, not safety warranties. However, the *Spain* court next described a subsequent case, *Allen v. Delchamps, Inc.*, 624 So. 2d 1065 (Ala. 1993), in

which the court reached an apparently opposite result. Spain, 872 So. 2d at 109. In Allen, the plaintiff brought an implied warranty claim, along with AMELD and other tort claims, after having a reaction to chemicals present on celery purchased from the defendant grocery store. 624 So. 2d at 1066-67. The Allen court held, without acknowledging Shell, that AMELD and implied warranty claims were not mutually exclusive; indeed, "[t]hese two standards 'go hand-in-hand,' at least as applied to food products, 'for it is apparent that a food product is defective or unreasonably dangerous if it is unmerchantable or unfit for human consumption.'" Id. at 1068 (citations omitted).

Without clear explanation, the Spain court concluded from these cases that "a claim alleging breach of an implied warranty of merchantability is separate and distinct from an AEMLD claim and is viable to redress an injury caused by an unreasonably dangerous product," and permitted its plaintiff to move forward on the implied warranty claim. 872 So. 2d at 111. The best way to explain the Spain holding is that there is no hard and fast rule governing the relationship between implied warranty and AEMLD claims. The implied warranty analysis "requires a fact-intensive analysis" separate from any tort claims. Id. at 108. The crucial fact in this "fact-intensive analysis" is what the purpose of the product at issue is. When the entire purpose of the product is simply to be consumed, as was the case with the cigarettes in Spain

and the food in *Allen*, the fact that consumption is dangerous makes the product unmerchantable. But when the product has some other purpose, as did the industrial product in *Shell*, the implied warranty applies only to that purpose, and any unreasonable danger of the product must be addressed by the AMELD or some other theory of recovery.

The product at issue in this case, the Mirena device, has a clear function other than consumption. It is used "for treatment of heavy menstrual bleeding in women who choose to use intrauterine contraception as their method of contraception," Compl. \P 15, and "for birth control," id. ¶ 17. The Commercial Code implied warranty is therefore not breached unless the Mirena fails to achieve these functions, regardless of what other harms it causes. That does not mean, of course, that a birth control device manufacturer can produce a device with unlimited danger so long as the device actually prevents pregnancy. It simply means that these dangers must be addressed by claims under tort theories such as the AEMLD, rather than under the Commercial Code. Because the only Mirena defect that plaintiff alleges in this case is that it increases the risk of PTC/IIH, plaintiff has not stated a claim for breach of implied warranty, and the implied warranty count will be dismissed.

2. Negligent Design

The remainder of defendant's criticisms are less successful.

Defendant first argues that plaintiff fails to state a claim for negligent design (plaintiff's Count I). Def.'s Mem. at 5-6. As the parties agree, negligence has four elements: plaintiff must provide evidence "that defendant (1) breached (2) a duty, which (3) proximately caused (4) plaintiff's injury." *E.R. Squibb & Sons*, *Inc. v. Cox*, 477 So. 2d 963, 969 (Ala. 1985). Defendant argues that these elements are not met because the complaint contains only legal conclusions which, under the first prong of the *Iqbal* test, must be discarded by the court. *See* Def.'s Mem. at 6. For example, defendant points out, \P 80 of the complaint conclusorily states that "[Mirena] is more dangerous than a reasonably prudent consumer would expect," and \P 82 states that "[Mirena] was the proximate cause of the injuries sustained by the Plaintiff."

Defendant is correct that these statements are legal conclusions, and the court will not consider them for purposes of the motion to dismiss. But defendant fails to take into account the many other statements in the complaint that do allege factual details. With respect to the duty and breach elements, the complaint alleges, among other things, that Mirena had "forseeable risks associated with [its] design or formulation [including] the development of PTC/IIH, and rapid or sudden weight gain," Compl. ¶ 80; and that "[d]espite an increasing number of [reported health issues], Defendant has made no effort to warn physicians, the healthcare community, or patients of the risk of developing

[PTC/IIH] with Mirena," Compl. \P 90. With respect to the causation and injury elements, plaintiff recites a medical history of the levonorgestrel hormone, stretching back to 1991, that arguably links the hormone to PTC/IIH. *Id.* $\P\P$ 46-60. She combines this history with the simple statements that she used a Mirena device, *id.* \P 70, and was subsequently diagnosed with PTC/IIH, *id.* \P 73. At this early stage of litigation, these allegations are sufficient to avoid dismissal under Rule 12(b)(6).

Plaintiff meets the test of plausibility. It is, of couse, true that one man's "plausibility" is another man's "implausibility." It is as slippery a word as the word "reasonable." Frankly, a jury is as qualified to determine what is or is not "plausible."

3. Strict Liability/AEMLD Design Defect

Defendant next argues that plaintiff fails to state a claim for strict liability under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD") (plaintiff's Count III). Under the AEMLD, a plaintiff can recover under strict liability if he can show that "he suffered injury or damages to himself or his property by one who sells a product in a defective condition unreasonably dangerous to the plaintiff as the ultimate user or consumer, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold."

Yamaha Motor Co., Ltd. v. Thornton, 579 So. 2d 619, 621 (Ala. 1991). It is undisputed here that defendant is engaged in the business of selling the Mirena device, and that the device was expected to and did reach plaintiff in the condition that it was sold. The only question is whether plaintiff has alleged facts that "plausibly" show that Mirena is a product "in a defective condition unreasonably dangerous to the plaintiff."

Defendant originally argued in its Rule 12(b)(6) motion that plaintiff "does not identify what aspect of the Mirena design is allegedly defective." Def.'s Mem. at 6. This argument is easily disposed of. Plaintiff alleged that the crucial defect of the Mirena device is that it "releases levonorgestral, a synthetic progestogen, directly into the uterus," Compl. ¶ 17, and that this increases the risk of developing PTC/IIH, Compl. ¶ 26. This must have occurred to defendant shortly after it filed its motion, because defendant's argument had changed considerably by the time it filed its reply brief. There, it argues that plaintiff has not alleged a design defect because a Mirena without levonorgestrel would be an entirely different product. Def.'s Reply at 4-6. According to defendant, "[a]n allegation that a defendant should have manufactured a different product does not state a plausible design-defect claim." Id. at 5.

Plaintiff has had no opportunity to respond to this new argument, and the motion to dismiss should be denied as to the

AEMLD claim for that reason alone. See United States v. Krasnow, 484 F. App'x 427, 429 (11th Cir. 2012) ("Parties cannot raise new issues in reply briefs.") (citing Timson v. Sampson, 518 F.3d 870, 874 (11th Cir.2008)). However, because the result is the same, and to spare defendant the trouble of advancing the same argument at the summary judgment stage, the court will consider this argument in this opinion.

Despite the fact that plaintiff's claim is based specifically on a doctrine called the "Alabama Extended Manufacturer's Liability Doctrine," defendant relies exclusively for its argument on cases applying the design defect laws of New York, Texas, and Louisiana. See Def.'s Reply at 5. Regardless of the definitions provided by those cases, "[f]or purposes of the AEMLD, 'a 'defect' is that which renders a product 'unreasonably dangerous,' i.e., not fit for its intended purpose.'" Rudd v. Gen. Motors Corp., 127 F. Supp. 2d 1330, 1333 (M.D. Ala. 2001) (quoting Casrell v. Altec Indus., Inc., 335 So. 2d 128, 133 (Ala. 1976)). "[I]t makes no difference whether [a product] is dangerous by design or defect. The important factor is whether it is safe or dangerous when the product is used as it was intended to be used." Rudd, 127 F. Supp. 2d at 1333 (quoting Casrell, 335 So. 2d at 133) (alterations in Rudd). In this case, plaintiff has alleged that the Mirena device is dangerous when used as it was intended to be used because it increases the risk of developing PTD/IIH. This allegation is all

that is required for the AEMLD claim to survive defendant's motion to dismiss.

4. Breach of Express Warranty

Defendant next argues the plaintiff has failed to state a claim for breach of express warranty (plaintiff's Count V). The Alabama Commerical Code provides that an express warranty is created by "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain," § 7-2-313(1)(a), or by "[a]ny description of the goods which is made part of the basis of the bargain," § 7-2-313(1)(b). Defendant argues that plaintiff has failed to allege that any such affirmation of fact, promise, or description was made about the Mirena device.

Plaintiff has alleged facts to support her express warranty claim, albeit by the skin of her teeth. As to the "affirmation of fact or promise" element, she has alleged that the "designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, and distributing of Mirena were expressly warranted to be safe . . . for [p]laintiff and members of the public generally." Compl. ¶ 153. As to the "part of the basis of the bargain" element, she has alleged that she "relied on [d]efendant's representations regarding Mirena in its package insert . . . in deciding to use . . . Mirena." Id. ¶ 71. As to the breach element, she has alleged that

"Mirena does not conform to these express warranties and representations because Mirena is not safe or effective and may produce serious side effects, including the development of [PTC/IIH] . . . " Id. ¶ 154. Taken as true, these allegations "plausibly," in the eyes of this court, state a claim for breach of express warranty.

5. Fraud-Based Claims

Finally, defendant argues that plaintiff has failed to state claims based on fraud under the heightened pleading requirement of Federal Rule of Civil Procedure 9(b). These include plaintiff's claims for negligent misrepresentation (plaintiff's Count VI), fraudulent misrepresenation (plaintiff's Count VII), and fraud by suppression and concealment (plaintiff's Count VIII). Rule 9(b) requires that, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." In the Eleventh Circuit, this means that "a plaintiff must allege: '(1) the precise statements, documents, or misrepresentations made; (2) the time, place, and person responsible for the statement; (3) the content and manner in which these statements misled the Plaintiffs; and (4) what the defendants gained by the alleged fraud.'" Am. Dental Ass'n v. Cigna Corp., 605 F.3d 1283, 1291 (11th Cir. 2010) (citation omitted). Like the Iqbal standard, this is not a hard-and-fast test, but can vary based on the nature of the claim asserted. See Pirelli Armstrong

Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co., 631 F.3d 436, 442 (7th Cir. 2011) ("[B]ecause courts and litigants often erroneously take an overly rigid view of the formulation, we have also observed that the requisite information . . . may vary on the facts of a given case."). "Fraud" is a general word that has many different definitions in many different legal contexts. Thus, whether a plaintiff has "state[d] with particularity the circumstances constituting fraud," Fed. R. Civ. Pro. 9(b), depends on the nature of the "fraud" at issue.

The allegations in this particular complaint meet the 9(b) standard when viewed in the context of the state law under which they are brought. In Alabama, a drug manufacturer "may be held liable for fraud or misrepresentation (by misstatement or omission)" based on "information and warning deficiencies" on a drug's labelling. *Wyeth, Inc. v. Weeks,* No. 1101397, 2013 WL 135753, at *19 (Ala. Jan. 11, 2013).¹ The *Wyeth* court reached this

¹The Alabama Supreme Court has granted reargument in *Wyeth*, but the disposition of the issues under debate in that reargument will not effect the outcome of this case. In *Wyeth*, the plaintiff named as defendant the brand-name manufacturer of the drug at issue, though he had in fact been injured by a generic version of the drug produced by a third-party manufacturer. The Court agreed with plaintiff that liability for the brand-name manufacturer was appropriate because, under FDA rules, the generic manufacturer was required to reproduce verbatim the warning labels of the the brand-name manufacturer. Whether or not the Supreme Court revisits that holding will not affect the underlying premise that a failure to provide proper warnings on drug labeling creates liability for fraud/misprepresentation by omission.

holding even despite defendant's argument that "the [plaintiff's] claims [were], in essence, 'product-liability' claims." *Id.* at *3. The Mirena device is not a drug itself, but it works by releasing a prescription drug into the user's body. Compl. ¶ 13. It also carries with it the same FDA approval requirements as did the drug in *Wyeth*. Compl. ¶ 14. Thus, like the *Wyeth* plaintiffs, plaintiff here can base her fraud and misrepresentation claims on the defendant manufacturer's breach of its "duty to warn . . . about the risks associated with the long-term use of the drug" in its labeling. *Wyeth*, 2013 WL 135753, at *2.

Plaintiff has stated a claim of this kind with the "particularity" required by Rule 9. As to the "precise statements" requirement and the "time, place, person" requirement, she has alleged that Mirena comes with a package label that warns about certain dangers. Compl. $\P\P$ 20-22. As to the "content and manner in which the statements misled" requirement, she has alleged that defendant "owed a duty to provide accurate and complete information regarding Mirena" on this labeling, *id.* \P 158, and that it breached this duty by failing to warn about "the increased risk of developing PTC/IIH, and the increased risk of suffering severe consequences due to not removing Mirena once a patient experiences symptoms of papilledema and/or [PTC/IIH]," *id.* \P 160. As to the "what defendants gained" requirement, she has alleged that this

162, 164. Defendant's motion to dismiss will therefore be denied as to plaintiff's fraud-based claims.

6. Failure to Warn

Defendant does not argue that plaintiff's final claim, the failure to warn claim, (plaintiff's Count II), is deficient. The motion to dismiss will therefore be denied as to this claim.

C. Amendment

In a short, single paragraph at the end of her brief, plaintiff concludes with the request that, "should this [c]ourt find any of [p]laintiff's claims insufficient, [p]laintiff respectfully requests leave to amend her complaint." Pl.'s Mem. at 27. As defendant points out, "[w]here a request for leave to file an amended complaint simply is imbedded within an opposition memorandum, the issue has not been raised properly." Rosenberg v. Gould, 554 F.3d 962, 967 (11th Cir. 2009) (quoting Posner v. Essex Ins. Co., 178 F.3d 1209, 1222 (11th Cir. 1999)). This is especially true when, as here, the plaintiff does not bother to submit or even describe its proposed amendment. See id. The court will therefore deny plaintiff's non-motion request to amend her insufficient breach of implied warranty claim. She has no need to amend any other claims.

CONCLUSION

For all the foregoing reasons, defendant's motion to dismiss will be granted as to plaintiff's breach of implied and express

warranty claims, but denied as to all other claims. The court will contemporaenously issue an order consistent with this opinion.

DONE this 28th day of March, 2014.

Witho M. Achury WILLIAM M. ACKER, JR.

UNITED STATES DISTRICT JUDGE