IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

SIRIA GONZALEZ	§	
	§	
Plaintiff,	§	
	§	
VS.	§	CIVIL ACTION H-12-1412
	§	
BAYER HEALTHCARE	§	
PHARMACEUTICALS, INC. and	§	
PLANNED PARENTHOOD OF HOUSTON	§	
AND SOUTHEAST TEXAS,	§	
	§	
Defendants.	§	

OPINION AND ORDER

Pending before the Court in the above referenced products liability case, removed from state court and alleging strict products liability, breach of express warranty, breach of implied warranty, gross negligence, and negligence relating to Defendant Bayer Healthcare Pharmaceuticals, Inc.'s ("Bayer's") contraceptive drug-releasing intrauterine system Mirena® ("Mirena") and intrauterine contraceptive device ("IUD"), is Bayer's motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) (instrument #4).

Bayer removed this case on diversity jurisdiction, arguing that Defendant Planned Parenthood of Houston and Southeast Texas ("Planned Parenthood") was fraudulently joined and never served. Plaintiff Siria Gonzalez did not challenge that contention and filed an amended complaint (#6) omitting Planned Parenthood as a

party defendant,[1] thus mooting portions of the motion to dismiss directed toward Planned Parenthood. The Court therefore addresses the remainder of the motion to dismiss as it pertains to the amended pleading and Plaintiff's claims against Bayer.

Standard of Review

Federal Rule of Civil Procedure 8(a)(2) provides, "A pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." When a district court reviews a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), it must construe the complaint in favor of the plaintiff and take all well-pleaded facts as true. *Randall D. Wolcott, MD, PA v. Sebelius*, 635 F.3d 757, 763 (5th Cir. 2011), *citing Gonzalez v. Kay*, 577 F.3d 600, 603 (5th Cir. 2009).

"While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, . . . a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do . . . ." *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1964-65 (2007)(citations omitted). "Factual

[1] Under the newly amended Federal Rule of Civil Procedure 15(a)(1)(B), a plaintiff may amend its original pleading as a matter of course *inter alia* within 21 days after service of a motion under Rule 12(b).

allegations must be enough to raise a right to relief above the speculative level." *Id.* at 1965, *citing* 5 C. Wright & A. Miller, *Federal Practice and Procedure* § 1216, pp. 235-236 (3d ed. 2004)("[T]he pleading must contain something more . . . than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action"). "*Twombly* jettisoned the minimum notice pleading requirement of *Conley v. Gibson*, 355 U.S. 41 . . . (1957)["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"], and instead required that a complaint allege enough facts to state a claim that is plausible on its face." *St. Germain v. Howard*,556 F.3d 261, 263 n.2 (5th Cir. 2009), *citing In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007)("To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must plead 'enough facts to state a claim to relief that is plausible on its face.'"), *citing Twombly*, 127 S. Ct. at 1974). "'A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Montoya v. FedEx Ground Package System, Inc.*, 614 F.3d 145, 148 (5th Cir. 2010), *quoting Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1940 (2009). Dismissal is appropriate when the plaintiff fails to allege "'enough facts to state a claim to relief that is plausible on its face'" and therefore fails to "'raise a

right to relief above the speculative level.'" *Montoya*, 614 F.3d at 148, *quoting Twombly*, 550 U.S. at 555, 570. The plausibility standard is not akin to a "probability requirement," but asks for more than a "possibility that a defendant has acted unlawfully." *Twombly*, 550 U.S. at 556. "[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice" under Rule 12(b). *Iqbal*, 129 S. Ct. at 1949. The plaintiff must plead specific facts, not merely conclusory allegations, to avoid dismissal. *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000).

On a Rule 12(b)(6) review, although generally the court may not look beyond the pleadings, the Court may examine the complaint, documents attached to the complaint, and documents attached to the motion to dismiss to which the complaint refers and which are central to the plaintiff's claim(s), as well as matters of public record. *Lone Star Fund V (U.S.), L.P. v. Barclays Bank PLC,* 594 F.3d 383, 387 (5th Cir. 2010), *citing Collins*, 224 F.3d at 498-99; *Cinel v. Connick*, 15 F.3d 1338, 1341, 1343 n.6 (5th Cir. 1994). *See also United States ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 379 (5th Cir. 2003)("the court may consider . . . matters of which judicial notice may be taken"). Taking judicial notice of public records directly relevant to the issue in dispute is proper on a Rule 12(b)(6) review and does not transform the motion into one for summary judgment. *Funk v. Stryker Corp.*,

631 F.3d 777, 780 (5th Cir. 2011). "A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Here Bayer has submitted a copy of the United States Food and Drug Administration's ("FDA's") approval letter for the prescription drug Mirena (#4-1, Ex. A), which is a public record of which the Court may take judicial notice. *See, e.g., U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 755-56 & n.9 (S.D. Tex. 2010).

"Dismissal is proper if the complaint lacks an allegation regarding a required element necessary to obtain relief . . . ." *Rios v. City of Del Rio, Texas*, 444 F.3d 417, 421 (5th Cir. 2006), *cert. denied*, 549 U.S. 825 (2006). Dismissal under Federal Rule of Civil Procedure 12(b)(6) is "appropriate when a defendant attacks the complaint because it fails to state a legally cognizable claim." *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001), *cert. denied sub nom. Cloud v. United States*, 536 U.S. 960 (2002), *cited for that proposition in Baisden v. I'm Ready Productions*, No. Civ. A. H-08-0451, 2008 WL 2118170, *2 (S.D. Tex. May 16, 2008). *See also ASARCO LLC v. Americas Min. Corp.*, 382 B.R. 49, 57 (S.D. Tex. 2007)("Dismissal "'can be based either on a lack of a cognizable legal theory or the absence of sufficient

facts alleged under a cognizable legal theory.'" [citation omitted]), *reconsidered in other part*, 396 B.R. 278 (S.D. Tex. 2008).

When a plaintiff's complaint fails to state a claim, the court should generally give the plaintiff at least one chance to amend the complaint under Rule 15(a) before dismissing the action with prejudice. *Great Plains Trust Co v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 329 (5th Cir. 2002)("District courts often afford plaintiffs at least one opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable or the plaintiffs advise the court that they are unwilling or unable to amend in a manner that will avoid dismissal."). The court should deny leave to amend if it determines that "the proposed change clearly is frivolous or advances a claim or defense that is legally insufficient on its face . . . ." 6 Charles A. Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Proc.* § 1487 (2d ed. 1990).

Relevant Substantive Law

As a general rule under Texas law, the manufacturer of a product must instruct consumers regarding safe use of the product and warn them of dangers or potential harm in its use of which the manufacturer has actual or constructive knowledge at the time the product is sold. *Centocor, Inc. v. Hamilton*, 372 S.W. 3d 140, 153-54 (Tex. 2012), *citing Bristol Myers Co. v. Gonzales*, 561 S.W. 2d

801, 804 (Tex. 1978); *Pavlides v. Galveston Yacht Basin, Inc.*, 727 F.2d 330, 338 (5th Cir. 1984). With certain products however, including prescription drugs, "the manufacturer's or supplier's duty to warn end users of the dangerous propensities of its product is limited to providing an adequate warning to an intermediary, who then assumes the duty to pass the necessary warnings on to end users." *Centocor*, 372 S.W. 3d at 154. "[T]he underlying premise is that prescription drugs are complex and vary in effect, depending on the unique circumstances of an individual user, and for this reason, patients can obtain them only through a prescribing physician." *Id., citing Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974). The Texas Supreme Court further explained,

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between the manufacturer and consumer.

Id. at 159.

Texas courts apply the learned intermediary doctrine in prescription drug products-liability cases. *Id.* at 155, *citing Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W. 3d 87, 91 (Tex. App.--

Texarkana 2000, no pet.)("In prescription drug cases, the courts found that it is reasonable for the manufacturer to rely on the health care provider to pass on its warnings. This is reasonable because the learned intermediary understands the propensities and dangers involved in the use of a given drug, and as the prescriber, he stands between this drug and the ultimate consumer."). In *Centocor*, joining the overwhelming majority of courts that have considered the issue, the Texas Supreme Court adopted the doctrine in the prescription drug context within the physician-patient relationship and "squarely" held "that a prescription drug manufacturer fulfills its duty to warn end users of its product's risks by providing adequate warnings to the intermediaries who prescribe the drug, and, once fulfilled, it had no further duty to warn the end users directly. . . . But, as we have previously indicated, when the warning to the prescribing physician is inadequate or misleading, the prescription drug manufacturer remains liable for the injuries sustained by the patient." *Id.* at 157-58, 159, *citing Humble Sand & Gravel, Inc, v. Gomez*, 146 S.W. 3d 170, 185-96 (Tex. 2004); *Alm v. Aluminum Co. of America*, 717 S.W. 2d 588, 590-92 (Tex. 1986); and *Gravis v. Parke-Davis & Co.*, 502 S.W. 2d 863, 870 (Tex. App.--Corpus Christi 1973, writ ref'd n.r.e.).

In a pre-*Centocor* case, *In re Norplant Contraceptive Products Litigation*, 165 F.3d 374 (5th Cir. 1999)("*Norplant II*"), *affirming*,

955 F. Supp. 700 (E.D. Tex. 1997)(*"Norplant I"*), based on an *"Erie* guess"[2] that the Texas Supreme Court would apply the learned intermediary doctrine to the prescriptive contraceptive Norplant, affirmed summary judgment for the drug manufacturer in a case brought by plaintiffs who claimed they were injured by it because "even though physicians may seek to provide greater freedom to their patients in selecting an appropriate form of contraception," it is nevertheless a prescription drug and "physicians play a significant role in prescribing Norplant and in educating their patients about the benefits and disadvantages to using it." *Id.* at 379.

The Texas Supreme Court in *Centocor* also held that "within the prescriptive drug context, the learned intermediary doctrine is more akin to a common-law rule rather than an affirmative defense." *Centocor*, 372 S.W. 3d at 164. It is used to identify "to whom a defendant--usually a prescription drug manufacturer--owes a duty to warn"; it is not used to show that Plaintiff has no valid claim. *Id.* Thus it is not a defense that must be pleaded and proven by the drug manufacturer.

While the learned intermediary doctrine shifts the manufacturer's duty to warn from end user to intermediary, the

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[2] *Erie v. Tompkins*, 304 U.S. 64, 78 (1938)(where the state's highest court has not ruled on an issue under state law, the federal court must make an "Erie guess" and determine as best as it can what that highest court would most likely decide).

plaintiff's burden of proof remains the same, i.e., to prove the product's warning was inadequate. *Centocor*, 372 S.W. 3d at 166.

Even if the plaintiff shows that the warning was inadequate, the plaintiff must also show that the inadequate warning was the producing cause of the plaintiff's injuries. *Id.* at 170. While usually the jury determines the factual issue of the adequacy of a warning,[3] "when the prescribing physician is aware of the product's risks and decides to use it anyway, any inadequacy of the product's warning, as a matter of law, is not the producing cause of the patient's injuries." *Id.*, *citing inter alia Ebel*, 536 F. Supp. 2d at 780 ("[W]here the physicians were unequivocal that new information about the risks would not have changed their decision to prescribe the medication, an inadequate warning was not the proximate cause of plaintiff's injury" and "where a physician testifies that he was aware of the risks of which plaintiff complains, it is then the plaintiff's burden to prove that a different warning would have changed the physician's decision to prescribe the medication."), and *McNeil v. Wyeth*, 462 F.3d 364, 373 (5th Cir. 2006)("Where the physician would have adequately informed

[3] Although adequacy of the warning usually is a jury question in prescription drug cases where the learned intermediary doctrine applies, when "'a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law.'" *McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006), *quoting Rolen v. Burroughs Wellcome Co.*, 856 S.W. 2d 607, 609 (Tex. App.-Waco, 1993, writ denied). Plaintiff's complaint here is that there was no mention of Lupus or autoimmune reactions to the Mirena IUD.

a plaintiff of the risks of a disease, had the label been sufficient, but fails to do so on that account, and where the plaintiff would have rejected the drug if informed, the inadequate labeling could be a 'producing' cause of the injury, because it effectively sabotages the function of the intermediary."). *See also Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 208 (5th Cir. 2008)(where the physician was aware of possible risks in using the prescriptive medication but decided to use it anyway, the plaintiff cannot show the inadequacy of the warning was a producing cause; if the physician was not aware of a risk, plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning the treating physician would not have prescribed the medication).

Finally, the Texas Supreme Court observes that in *Norplant I*, 955 F. Supp. at 709-10, plaintiffs brought claims for strict products liability, negligence, breach of implied warranty of merchantability, misrepresentation, and consumer fraud under the Texas DTPA. The Court dismissed these claims on the grounds that in actuality they were based on the manufacturer's failure to warn or disclose the drug's side effects and therefore the learned intermediary doctrine applies. *Centocor*, 372 S.W. 3d at 168. "'If the doctrine could be avoided by casting what is essentially a failure to warn claim under a different cause of action such a violation of the DTPA or a claim for misrepresentation, then the

doctrine would be rendered meaningless.'" *Id., citing Norplant I* at 709, and *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 773 (5th Cir. 2009)("Where the crux of the suit is based on a failure to adequately warn, the learned intermediary doctrine may apply to strict liability, negligence, misrepresentation, and breach of warranty claims."), *aff'd*, 321 Fed. Appx. 350 (5th Cir. 2009). The Texas Supreme Court agreed and held that "when a patient alleges a fraud-by-omission claim against a prescription drug manufacturer for alleged omissions about a prescription drug's potential side effects, (1) the patient cannot plead around the basic requirements of a failure-to-warn claim, and (2) the learned intermediary doctrine applies." *Centocor*, 372 S.W. 3d at 169. It ruled that the learned intermediary doctrine applies to all of the claims of the plaintiff before it. *Id.*[4]

In the Texas Civil Practice and Remedies Code, "Texas law groups all inadequate warning causes of action together [negligence, strict liability, breach of implied warranty of merchantability] regardless of how they are pleaded" and requires "some form of fraud on the FDA." *Del Valle v. Qualitest Pharms., Inc.*, No. B-11-113, 2012 WL 2899406, *2 (S.D. Tex. June 22, 2012), *appeal dismissed in part*. No. 12-41148 (5th Cir. Feb. 5, 2012).

[4] The Texas Supreme Court stated that it "need not decide whether the learned intermediary doctrine applies against a prescription drug manufacturer in a common-law fraud or misrepresentation claim based on an overt misrepresentation . . . ." *Id.* at 169 n.30.

Texas Civil Practices and Remedies Code § 82.001(2) defines a "products liability action" as "any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product whether the action is based on strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories." Texas Civil Practices and Remedies Code § 82.007(a), which became effective on September 1, 2003, eliminated common law causes of action[5] and established a presumption of nonliability to shield the drug manufacturer:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> > (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended, or
> >
> > (2) the warnings provided were those stated in monographs developed by the United States Food and Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.

[5] *Del Valle v. Qualitest*, 2012 WL 2899406, at *2.

Section 82.007(b) specified the ways in which a claimant could rebut the presumption:

> (b) The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that:
>
> > (1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury;
> >
> > (2) the pharmaceutical product was sold or prescribed in the United States by the defendant after the effective date of an order of the United States Food and Drug Administration to remove the product from the market or to withdraw its approval of the product;
> >
> > (3) (A) the defendant recommended promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration;
> >
> > (B) the product was used as recommended, promoted, or advertised; and
> >
> > (C) the claimant's injury was causally related to the recommended, promoted, or advertised use of the product;
> >
> > (4) (A) the defendant prescribed the pharmaceutical product for an indication not approved by the United States Food and Drug Administration;
> >
> > (B) the product was used as prescribed; and
> >
> > (C) the claimant's injury was causally related to the prescribed use of the product; or
> >
> > (5) the defendant, before or after pre-market approval or licensing of the product, engaged

> in conduct that would constitute a violation of 18 U.S.C. § 201 and that conduct caused the warnings or instructions approved for the product by the United States Food and Drug Administration to be inadequate.

Plaintiff relies on § 82.007(b)(1). Recently in *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372, 374 (5th Cir. 2012), the Fifth Circuit held that unless the FDA itself finds fraud, federal law preempts § 82.007(b)(1) requiring parties in failure-to-warn cases to allege that the manufacturer withheld or misrepresented material information to the FDA in order to rebut the presumption that the drug manufacturer was not liable. "[W]here the FDA has not found fraud, the threat of imposing state liability on [a] drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities. *Id*. at 380. The FDA is responsible for policing fraud and "has the authority to investigate fraud, 21 U.S.C. § 372, consider citizen petitions, 21 C.F.R. § 10.30, and seek criminal and civil penalties particular to fraud-on-the-FDA, 21 U.S.C. § 332-32." 672 F.3d at 376 n.2. Furthermore § 82.007(b)(1)'s term "required information" refers to federal requirements under the [Federal Drug and Cosmetic Act ("FDCA")] and what is "material" and "relevant" must be decided by the FDA, not state court juries. *Id.* at 379. Thus the state law claim would conflict with the FDA's authority to punish fraud on the agency, so it is preempted by the

FDCA. *Id.* at 376.[6]

Therefore if a plaintiff in a failure to warn case fails to allege that the FDA found fraud on the part of Bayer, he cannot rebut the § 82.007 presumption of nonliability and the plaintiff's failure to warn claim must be dismissed. *Lofton*, 672 F.3d at 380.

Allegations in

Plaintiff's Amended Pleadings/Original Complaint (#6)

Plaintiff alleges that Bayer is in the business of designing and manufacturing its IUD and designing, manufacturing, selling, and distributing the drug Mirena to clinics throughout the United States, including Texas.

Plaintiff was a patient at the Planned Parenthood clinic of Houston and Southeast Texas on May 19, 2009, where she was prescribed the Mirena IUD system, which was implanted in her. During the next several months Plaintiff suffered from rashes, hair loss, rapid weight loss, weakness, muscle deterioration, and chronic pain. The Mirena IUD was removed on December 3, 2009. Later that month Plaintiff was hospitalized and subsequently diagnosed with Systematic Lupus Erythematosus ("Lupus"), which she contends was caused by the Mirena IUD device.

Plaintiff's first cause of action is for defective design of the IUD by Bayer that caused it to be unreasonably dangerous to

[6] The Fifth Circuit recognized there is a split in the Circuits addressing similar provisions in other states. *Id.* at 377. This Court is bound by the Fifth Circuit's ruling in *Lofton.*

Plaintiff and other persons similarly situated. She claims that Bayer failed to adequately test the drug for causing the onset of autoimmune disorders, including Lupus, before submitting it to the FDA for approval and before selling and distributing it to the general public. She asserts that Bayer failed to conduct a sufficiently large clinical trial test for this rare disorder and/or to adequately and completely report the clinical trial data regarding the drug's risks. Alternatively, she argues that Bayer suppressed and diluted evidence in clinical trials of serious autoimmune reactions, including Lupus.

Second, in a cause of action titled "marketing defect," Plaintiff asserts that the IUD was defective and unreasonably dangerous because it was marketed without a warning or no adequate warning of the risk of side effects, including autoimmune disorders. There was also inadequate instruction about what to do in the event of serious side effects, including whether removal of the IUD would alleviate or improve the side effects. These marketing defects were the producing cause of Plaintiff's injuries and of the delay of treatment for them.

Plaintiff's third cause of action is for breach of express warranty. Bayer made express warranties about the IUD's utility in preventing pregnancy without making clear the extreme dangers associated with a toxic reaction to the drug, which was not of the quality or condition expressly warranted by Bayer, but inherently

dangerous. She insists that the drug cannot be used in the manner intended without serious risk of physical injury to the user. Plaintiff claims there was no warning about Lupus or other allergic reactions linked with any other autoimmune disorder even though Bayer knew, or should have known, about the substantial number of Lupus cases linked to the use of the Mirena IUD. The lack of warning was allegedly a producing cause of Plaintiff's permanent injuries.

In addition Plaintiff asserts that Bayer breached an implied warranty that the IUD was of merchantable quality and was safe and fit for its intended purpose when used under ordinary circumstances and in an ordinary and/or foreseeable manner. She claims that Bayer knew or had reason to know of the purposes and use for which Plaintiff sought the IUD and that Plaintiff was relying on Defendant's skill and judgment to select and furnish a suitable IUD. Plaintiff maintains that the Mirena IUD was not fit for its intended purpose and use.

Plaintiff's claim for negligence and/or gross negligence asserts that Bayer had a duty to use reasonable care in labeling, packaging, selling, advertising, warning, and otherwise distributing Mirena. She charges that "even though (1) the defendant knew there was a causal relationship between the IUD and Lupus, and that it could result in a serious or life threatening and debilitation reaction; (2) defendant knew that medical

literature had shown a connection between autoimmune disorders and Mirena defendants deliberately placed the drug on the market without warning the user or consumer that the insertion of the Mirena IUD would result in Lupus, or the onset of other severe autoimmune disorders." Bayer also "failed to warn plaintiff and plaintiff's physician to remove the IUD immediately and seek medical attention if the symptoms of Lupus developed." These actions or omissions, individually or together, constituted negligence or gross negligence and were a proximate cause of Plaintiff's injuries. Bayer also failed to report or file with the FDA literature showing the risks of Lupus associated with the allergic reactions to Mirena.

Bayer's Motion to Dismiss (#4)

Bayer contends that Plaintiff's petition is merely a formulaic recitation of the elements of her causes of action, bare labels, and conclusions devoid of factual support, and it must therefore be dismissed under Rules 8 and 12(b)(6).

Plaintiff acknowledges that Mirena is an FDA approved prescription contraceptive, a prescription drug and not a medical device. Ex. A, FDA Approval Letter dated December 6, 2000.

Bayer contends that Plaintiff fails to state a strict liability claim. Texas has adopted Section 402A of the *Restatement (Second) of Torts*, which requires a plaintiff claiming strict liability to allege (1) a product defect; (2) that existed at the

time the product left the manufacturer's hands; (3) that the product was unreasonably dangerous; and (4) that it was a producing cause of the plaintiff's injuries. *Parsons v. Ford Motor Co.*, 85 S.W. 3d 323, 329 (Tex. App.--Austin 2002)(citation omitted). A prescription drug product that is "properly prepared[] and accompanied by proper directions and warnings[] is not defective, nor is it unreasonably dangerous." *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002)(quoting *Restatement (Second) Torts* § 402A cmt. K (1965). Plaintiff's formulaic recitation of the elements of strict liability claim (that Bayer placed "into the stream of commerce an unreasonably dangerous product," which "was unsafe by reason of the defects in the design, manufacture, testing, labeling, packaging and marketing," and which "directly and proximately caused harm") is insufficient to state a claim under Rule 12(b)(6). She does not identify the nature of the defect, indicate how it made Mirena unreasonably dangerous, nor explain how Mirena caused her alleged injuries. Thus the claim should be dismissed.

Furthermore, contends Bayer, Plaintiff fails to state a claim under the learned intermediary doctrine. Plaintiff alleges that she obtained the prescription drug Mirena through her healthcare provider. Therefore the learned intermediary doctrine applies to all her claims, including any possible failure-to-warn claims asserted under the doctrine of strict liability. Any duty of Bayer

to warn ran to Plaintiff's healthcare provider, Planned Parenthood, not to Plaintiff. *See Ebel v. Eli Lilly and Co.*, 536 F. Supp. 2d 767, 772-73 (S.D. Tex. 2008)("Where the crux of the suit is based on a failure to adequately warn, the learned intermediary doctrine may apply to strict liability, negligence, misrepresentation and breach of warranty claims."), *aff'd*, 321 Fed. Appx. 350 (5th Cir. Mar. 30, 2009)(applying learned intermediary doctrine to strict liability and breach of warranty claims); *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 709 (E.D. Tex. 1997)("If the doctrine could be avoided by casting what is essentially a failure to warn claim under a different cause of action . . . then the doctrine would be rendered meaningless."), *aff'd*, 165 F.3d 374 (5th Cir. 1999). Because Plaintiff does not allege that the warning to her healthcare provider was inadequate nor identify the warnings or materials which her doctor received or reviewed, much less demonstrate that the doctor would not have prescribed Mirena if the warning had been different, and does not allege facts necessary to show causation, she fails to satisfy *Twombley* and *Iqbal* as a matter of law. *See Pustejovsky v. Pliva*, 623 F.3d 271, 276 (5th Cir. 2010)("The learned intermediary doctrine . . . requires that the inadequate warning was a 'producing cause' of the plaintiff's injuries. . . . [P]laintiff . . . must also show that the alleged inadequacy caused her doctor to prescribe the drug for her.")(citation and internal quotation marks omitted); *Ebel*,

536 F. Supp. 2d at 777 (holding that a plaintiff claiming failure to warn through improper marketing practices must show that the marketing "reached and [a]ffected the prescribing physician").

Plaintiff's breach of warranty claims are also subject to the learned intermediary doctrine claims. She fails to state a plausible claim because she does not allege what warranties were made to her prescribing physician nor state how they were breached, leaving only "an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 129 S. Ct. at 1949.

In addition because Plaintiff failed to plead negligence, as a matter of law she cannot bring a claim for gross negligence against Bayer. *Trevino v. Lightning Laydown, Inc.*, 782 S.W. 2d 946, 949 (Tex. App.--Austin 1990, writ denied)(although gross negligence refers to a different character of conduct than negligence, "one's conduct cannot be grossly negligent without being negligent.").

Bayer is also immune from liability because the FDA approved the Mirena warnings. Texas Civil Practice and Remedies Code section 82.007(a) creates a rebuttable presumption that pharmaceutical manufacturers are not liable as a matter of law for an alleged failure to warn if the FDA has approved the warnings. The Mirena label was approved by the FDA. Ex. A; 21 U.S.C. A. § 355(b)(1)(F) (West 2012); 21 U.S.C. A. § 355(d). Thus Bayer is entitled to this presumption of no liability. Plaintiffs have not

alleged any facts that would rebut that presumption.

In sum, because Plaintiff fails to state a cognizable legal theory against Bayer, Plaintiff's claims should be dismissed.

Plaintiff's Response (#10)

Plaintiff claims that Defendant bears the burden of showing that it properly informed any physicians prescribing its medication of the risks associated with it. Here Bayer claims it did not know of any risks associated with Mirena that were related to Plaintiff's injuries and tries to improperly shift the burden to the Plaintiff to plead a failure to warn case. Furthermore, Plaintiff has alleged defective design, manufacture, and marketing of an inherently dangerous product and argues that the learned intermediary doctrine should not apply because it would allow Defendant to avoid liability that does not involve a failure to warn.

As for the rebuttable presumption created by FDA's approval of Mirena's label, Plaintiff claims she has rebutted it by alleging that Bayer failed to report or file literature with the FDA about the risks of Lupus associated with the allergic reactions caused by Mirena.

Bayer's Reply (#11)

Because, according to Bayer, pleadings are now closed and because Plaintiff's amended complaint still fails to satisfy Rules 8 and 12, Bayer requests the Court to convert its motion to one

under Rule 12(c)[7] and dismiss it with prejudice. Plaintiff did not respond to this request.

Bayer asserts that it is clear from the amended complaint that Plaintiff's claims for design defect,[8] express warranty, negligence, and gross negligence[9] are premised on Bayer's failure to warn that the use of Mirena could result in the development of Lupus. *Centecor, Inc. v. Hamilton*, 372 S.W. 3d 140, 169 (Tex. 2012)(holding that Plaintiff's claims "collapse" into a single failure-to-warn theory).

Under Texas law all causes of action based on a claim of inadequate warnings or information, regardless of how they are characterized, are grouped together as inadequate warning cases and

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[7] A motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c) is "designed to dispose of cases where the material facts are not in dispute and a judgment on the merits can be rendered by looking to the substance of the pleadings and any judicially noticed facts." *Herbert Abstract Co. v. Touchstone Props., Ltd.*, 914 F.2d 74, 76 (5th Cir. 1990), *citing* 5A Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1367, at 509-10 (1990).

[8] Bayer claims Plaintiff's defective design claim is based on Bayer's alleged failure to "adequately test the drug for causing the onset of autoimmune disorders . . . and/or [its] fail[ure] to adequately and completely report clinical trails data regarding the drug's risk." Amended Complaint ¶ 11. *See Am. Tobacco Co. v. Grinnell*, 951 S.W. 2d 420, 437 (Tex. 1997)(rejecting a negligent testing claim that was predicated on a duty to discover a product's inherent dangers because that claim was "inextricably intertwined" with the plaintiff's unsuccessful failure-to-warn claim).

[9] Bayer points out Plaintiff erroneously styled her negligence and gross negligence claim as a breach of an implied warranty claim, but that the body of the claim shows she is alleging negligence and gross negligence. Amended Complaint ¶¶ 18-21.

are governed by § 82.007 of the Texas Civil Practice and Remedies Code. *Del Valle v. Qualitest Pharms., Inc.*, No. B-11-113, 2012 WL 2899406, *2 (S.D. Tex. June 22, 2012), *appeal dismissed in part*. No. 12-41148 (5th Cir. Feb. 5, 2012). Section 82.007(a) of the Texas Civil Practices and Remedies Code Annotated entitles a pharmaceutical manufacturer to a rebuttable presumption that it is not liable for failure to warn if the FDA approved the "warnings and information" that accompanied the product. That presumption can only be overcome if the plaintiff pleads and proves one of the following: (1) Defendant committed fraud on the FDA; (2) Defendant sold the product after the FDA ordered it removed from the market; (3) Defendant promoted the product for an unapproved use and the injury was caused by that use; or (4) Defendant bribed an FDA official, causing the FDA approved warnings to be inadequate. Bayer reiterates Plaintiff has failed to allege any facts to overcome the presumption of non-liability.

Recently the Fifth Circuit held that the fraud-on-the-FDA provision of the Texas statute is preempted by the Federal Food, Drug, and Cosmetic Act unless the plaintiff can show that "the FDA itself has found fraud." *Lofton v. McNeill Consumer & Specialty Pharms.*, 672 F.3d 372, 380 (5th Cir. 2012)(where "the FDA has not found fraud, the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrudes on the competency of the FDA . . . [and is] a violation of the Supremacy Clause").

Plaintiff has not alleged that the FDA has found fraud, nor can she, and thus her fraud-on-the-FDA claim is preempted and cannot be used to rebut § 82.007's presumption of non-liability for failure to warn. *Id.* Thus all of her claims fail as a matter of law.

Court's Decision

As a threshold matter, the Court agrees with Bayer that Plaintiff's petition is a conclusory, bare-bones, formulaic recitation of the elements of her proposed causes of action that fail to meet the plausibility standard of *Twombly* and *Iqbal* under Rule 12(b)(6) review. Hers are not "well pleaded" statements entitled to an assumption of truth,

Second, the Court agrees with Bayer that a review of Plaintiff's claims for defective design, marketing defect, breach of express[10] and implied warranties, negligence and gross negligence demonstrates that they are in actuality disguised failure-to-warn, fraud-by-omission claims subject to Section 82.007 of the Texas Civil Practices and Remedies Code. Plaintiff cannot employ such characterizations to plead around the learned intermediary doctrine, which is clearly applicable here. *Centocor*, 372 S.W. 3d at 168; *Ebel*, 536 F. Supp. 2d at 772-73; *Norplant I*, 955 F. Supp.

[10] Even Plaintiff's breach of express warranty alleges omission–-while Bayer informed the physician of the IUD's utility in preventing pregnancy, it failed to make clear the extreme dangers of a toxic reaction, its inherent dangers, the risk of Lupus and allergic reactions linked with other autoimmune disorders.

at 709. The Court accordingly dismisses the causes of action for defective design, marketing defect, breach of warranties, negligence and gross negligence. Her failure-to-warn claim, to be viable, must fall under and satisfy Section 82.007 of the Texas Civil Practice and Remedies Code and rebut the presumption of nonliability.

Even though Bayer is not liable under the learned intermediary doctrine to Plaintiff for failure to warn her as end user about the risks of its Mirena IUD, it may still be liable if its warning to the physician intermediary at Planned Parenthood was not adequate and she sustained injuries as a result of using it. Plaintiff has not alleged facts specifically showing that the warnings on the Mirena IUD were inadequate, nor even more so, that the allegedly inadequate warning was the producing cause of Plaintiff's injuries. She claims Bayer knew or should have know abut the connection of the Mirena IUD with autoimmune disorders from the substantial number of Lupus cases linked to the Mirena IUD, but does not identify any or cite any medical literature on the subject nor allege any other facts showing how or why Bayer knew or should have known of the risks of the contraceptive causing autoimmune reactions. There are no facts supporting her claim that the Mirena IUD was the producing cause of her injury nor relating to Planned Parenthood doctors' role in deciding to prescribe it for her.

As for the presumption under § 82.007 that Bayer is not liable

because the FDA approved the warning on its prescription drug, Plaintiff has failed to show that the FDA found fraud in order to rebut it under § 82.007(b)(1), nor identified any other exception that might apply to her case.

For the reasons stated above, the Court

ORDERS that Bayer's motion to dismiss is GRANTED as to Plaintiff's causes of action for defective design, marketing defect, breach of express and implied warranties, negligence and gross negligence, but DENIED as to § 82.007 because the Court can not say for certain that she cannot state a claim under it. Therefore the Court

ORDERS that Plaintiff is granted leave to file an amended complaint within twenty days that meets the requirements of that statute and Rule 12(b)(6). Failure to comply will result in dismissal of this action.

SIGNED at Houston, Texas, this 12th day of March, 2013.

MELINDA HARMON
UNITED STATES DISTRICT JUDGE