IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

MILLARD ANDERSON and JENNIFER ANDERSON, Individually and as Next Friends of CBA, a Minor,	§	
Plaintiffs,	§	
v.	§	Civil Action No. **3:11-CV-1825-L**
ABBOTT LABORATORIES,	§	
Defendant.	§	

MEMORANDUM OPINION AND ORDER

Before the court is Defendant's Motion to Dismiss Complaint for Failure to State a Claim, filed September 27, 2011. After carefully reviewing the motion, briefing, pleadings, and applicable law, the court **grants** Defendant's Motion to Dismiss Complaint for Failure to State a Claim and **dismisses with prejudice** Plaintiffs' claims for strict liability, negligence, and breach of warranty.

I. Background

Plaintiffs Millard Anderson and Jennifer Anderson, individually and as next friends of CBA, a minor, (collectively, "Plaintiffs") brought this products liability action against Abbott Laboratories ("Abbott") on July 29, 2011, alleging claims for strict liability, negligence, and breach of warranty. Jennifer and Millard Anderson are the parents of minor CBA, who is approximately 15 years old. Abbott develops, manufactures, and markets a prescription drug referred to as Humira that is in a class of TNF blockers approved by the Food and Drug Administration ("FDA") to treat rheumatoid arthritis and other autoimmune conditions. Plaintiffs contend that Abbott failed to adequately warn physicians of the risk of pediatric leukemia associated with Humira. Plaintiffs allege that their son

received Humira to treat psoriasis in May 2008, and that he subsequently developed bruising over his body in December 2008, which was diagnosed as pediatric leukemia on January 8, 2009.

It is undisputed that Humira was initially approved by the FDA for the treatment of adult rheumatoid arthritis and other autoimmune conditions before it was prescribed to CBA. Plaintiffs argue, based on a June 4, 2008 FDA "Early Communication," that Humira was no longer approved and changes in its warning label were required as a result. The Early Communication announced that the FDA was investigating a possible association between TNF inhibitors and malignancies in children and young adults. Based on available data, the Early Communication warned that children who used Humira may be at increased risk of developing cancer, including leukemia. After concluding its investigation, the FDA, on August 9, 2009, required that warnings for all TNF blocker drugs include information about the increased risk of lymphoma, adolescent leukemia, and other malignancies in children and adolescents. Because Abbott did not revise the Humira warning after the Early Communication and instead waited until after the FDA mandated that certain information regarding its effect on children be included in the warning, Plaintiffs contend that Abbott failed to act as an ordinarily prudent pharmaceutical company should do under the same or similar circumstances.

On September 27, 2011, Abbott moved to dismiss all of Plaintiffs' claims for failure to state a claim, arguing that section 82.007(a) of the Texas Civil Practice and Remedies Code required dismissal of Plaintiffs' claims because the statute establishes a rebuttable presumption that the warning in the FDA-approved Humira label was adequate as a matter of law. Abbott further argues that Plaintiffs did not plead any facts to establish any of the three exceptions to the statutory presumption. Alternatively, Abbott argues that under Texas's learned intermediary doctrine, a

plaintiff in a failure-to-warn case must show that the allegedly inadequate warning was the proximate cause of his injuries. Because Plaintiffs do not allege facts that the alleged inadequate Humira warning was the proximate cause of CBA's injuries, Abbott contends it is entitled to dismissal of Plaintiffs' claims.

Plaintiffs responds that section 82.007 is inapplicable in cases such as this where the drug label did not contain the most current FDA-approved warnings that included the FDA's concerns as reflected in the Early Communication. Alternatively, Plaintiffs maintains that they have sufficiently pleaded an exception under section 82.007(b)(1).[1] Because no mention of section 82.007 was made by Plaintiffs prior to responding to the motion to dismiss, Abbott disagrees that Plaintiffs have pleaded facts to support a claim under section 82.007(b)(1) and further argues, based on this court's opinion in *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 682 F. Supp. 2d 662 (N.D. Tex. 2010), that any claim based on the exception in section 82.007(b)(1) is preempted under *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

II. Standard for Rule 12(b)(6) - Failure to State a Claim

To defeat a motion to dismiss filed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Reliable Consultants, Inc. v. Earle*, 517 F.3d 738, 742 (5th Cir. 2008); *Guidry v. American Pub. Life Ins. Co.*, 512 F.3d 177, 180 (5th Cir. 2007). A claim meets the plausibility test "when the plaintiff pleads factual content that allows the

[1] Section 82.007(b)(1) provides: "The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that . . . 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." Tex. Civ. Prac. & Rem. Code Ann. § 82.007(b)(1).

court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citations omitted). While a complaint need not contain detailed factual allegations, it must set forth "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly,* 550 U.S. at 555 (citation omitted). The "[f]actual allegations of [a complaint] must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* (quotation marks, citations, and footnote omitted). When the allegations of the pleading do not allow the court to infer more than the mere possibility of wrongdoing, they fall short of showing that the pleader is entitled to relief. *Iqbal*, 556 U.S. at 679.

In reviewing a Rule 12(b)(6) motion, the court must accept all well-pleaded facts in the complaint as true and view them in the light most favorable to the plaintiff. *Sonnier v. State Farm Mutual Auto. Ins. Co.,* 509 F.3d 673, 675 (5th Cir. 2007); *Martin K. Eby Constr. Co. v. Dallas Area Rapid Transit*, 369 F.3d 464, 467 (5th Cir. 2004); *Baker v. Putnal*, 75 F.3d 190, 196 (5th Cir. 1996). In ruling on such a motion, the court cannot look beyond the pleadings. *Id.*; *Spivey v. Robertson*, 197 F.3d 772, 774 (5th Cir. 1999), *cert. denied*, 530 U.S. 1229 (2000). The pleadings include the complaint and any documents attached to it. *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498-99 (5th Cir. 2000). Likewise, "'[d]ocuments that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to [the plaintiff's] claims.'" *Id.* (quoting *Venture Assocs. Corp. v. Zenith Data Sys. Corp*., 987 F.2d 429, 431 (7th Cir. 1993)).

The ultimate question in a Rule 12(b)(6) motion is whether the complaint states a valid claim when it is viewed in the light most favorable to the plaintiff. *Great Plains Trust Co. v. Morgan Stanley Dean Witter*, 313 F.3d 305, 312 (5th Cir. 2002). While well-pleaded facts of a complaint are to be accepted as true, legal conclusions are not "entitled to the assumption of truth." *Iqbal*, 556 U.S. at 679 (citation omitted). Further, a court is not to strain to find inferences favorable to the plaintiff and is not to accept conclusory allegations, unwarranted deductions, or legal conclusions. *R2 Invs. LDC v. Phillips*, 401 F.3d 638, 642 (5th Cir. 2005) (citations omitted). The court does not evaluate the plaintiff's likelihood of success; instead, it only determines whether the plaintiff has pleaded a legally cognizable claim. *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004). Stated another way, when a court deals with a Rule 12(b)(6) motion, its task is to test the sufficiency of the allegations contained in the pleadings to determine whether they are adequate enough to state a claim upon which relief can be granted. *Mann v. Adams Realty Co.*, 556 F.2d 288, 293 (5th Cir. 1977); *Doe v. Hillsboro Indep. Sch. Dist*., 81 F.3d 1395, 1401 (5th Cir. 1996), *rev'd on other grounds*, 113 F.3d 1412 (5th Cir. 1997) (en banc). Accordingly, denial of a 12(b)(6) motion has no bearing on whether a plaintiff ultimately establishes the necessary proof to prevail on a claim that withstands a 12(b)(6) challenge. *Adams*, 556 F.2d at 293.

III. Analysis

A. Whether Plaintiffs' Failure to Warn Claims are Preempted

Abbott contends that all of Plaintiffs' claims are barred by section 82.007(b)(1) in light of the holdings in *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372 (5th Cir. 2012), and *Murthy v. Abbott Laboratories*, 847 F. Supp. 2d 958 (S.D. Tex. 2012), that came out after briefing on Abbott's motion to dismiss was complete. The Fifth Circuit in *Lofton* affirmed this

court's opinion in *Lofton*, 682 F. Supp. 2d 662, and held that section "82.007(b)(1) is a fraud-on-the-FDA provision analogous to the claim considered in *Buckman*, . . . that it is preempted by the FDCA unless the FDA itself finds fraud." *Lofton*, 672 F.3d at 381. *Murthy* similarly concluded that the plaintiff's failure to warn claims under section 82.007(b)(1) were preempted based on the Fifth Circuit's holding in *Lofton*. *Murthy v.* 847 F. Supp. 2d at 976.

By order dated March 2, 2012, the court permitted the parties to submit supplemental briefing and authority to address the effect of *Lofton* on Plaintiffs' claims under section 82.007(b)(1). As previously noted, Plaintiffs initially maintained in response to Abbott's motion to dismiss that their claims under 82.007(b)(1) are not preempted. In their supplemental brief, Plaintiffs do not address whether their claims under section 82.007(b)(1) are preempted in light of *Lofton* but instead argue that their claims, as pled, also state a claim under the exception in section 82.007(b)(3), and that section 82.007(b)(3) was not at issue and thus not affected by the courts' decisions in *Lofton* and *Murthy*.

The court addresses Plaintiffs' argument regarding section 82.007(b)(3) later in this opinion. With regard to Plaintiffs' claims for strict liability, negligence, and breach of warranty under section 82.007(b)(1), the court concludes that these claims are preempted based on the court's reasoning in *Lofton*. *Lofton*, 672 F.3d at 381. Accordingly, Plaintiffs have failed to state claims upon which relief can be granted under section 82.007(b)(1), and Abbott is entitled to dismissal of all of Plaintiff's claims under this section. The court further rejects Plaintiffs' alternative argument that section 82.007(b)(1) is inapplicable because Abbott's Humira warning did not include the most current FDA warning information. Plaintiffs have cited no authority, and the court is aware of none, to support their argument that the Early Communication affected the FDA's prior approval of

Humira warnings or that Abbott was required to revise its Humira label warning prior to August 9, 2009, the date the FDA required warnings for all TNF blocker drugs to include information about the increased risk of lymphoma, adolescent leukemia, and other malignancies in children and adolescents. Moreover, if as Plaintiffs contend, that Abbott was required as a result of the FDA's Early Communication to warn of the potential effects of TNF blockers to children and adolescents, there would have been no reason for the FDA to subsequently mandate such warnings in August 2009. Accordingly, this argument does not save Plaintiffs' claims from the applicability of section 82.007(a) and presumption that the warning in the FDA-approved Humira label was adequate as a matter of law. *See* Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a).

B. Whether Plaintiffs Have Stated a Claim Under Section 82.007(b)(3)

For the first time in their supplemental briefing, Plaintiffs contend that *Lofton* and *Murthy* focused on the availability of section 82.007(b)(1) as a means to rebut the presumption in section 82.007(a) and concluded that failure to warn claims under section 82.007(b)(1) were preempted but did not address the exception in section 82.007(b)(3). Plaintiffs argue that even if their claims are preempted under section 82.007(b)(1), they have stated a claim under section 82.007(b)(3) because they have alleged that Abbott promoted the use of Humira for an "off-label" use not approved by the FDA, that is, Abbott promoted Humira for the treatment of pediatric psoriasis. Plaintiffs therefore contend that *Lofton's* and *Murthy's* holdings that the section 82.007(b)(1) failure-to-warn claims are preempted is not dispositive of Plaintiffs' claims.

Abbott counters that Plaintiffs waived this argument by not initially raising it in response to the motion to dismiss and that Plaintiffs cannot salvage their case by relying on section 82.007(b)(3). Even if the belated argument is not waived, Abbott contends that Plaintiffs cannot meet the off-label

exception in section 82.007(b)(3) because they have not alleged facts sufficient to survive dismissal under *Iqbal*. Abbott asserts that Plaintiffs "have not alleged that Abbott salespersons encouraged Dr. Townsend a rheumatologist with an adult practice to prescribe Humira for psoriasis, a dermatological condition, to children, nor have they alleged that Dr. Townsend relied on such off-label promotion to prescribe Humira to CBA." Def.'s Supp. Resp. 1. Abbott maintains that Plaintiffs, at a minimum must allege facts that: "(1) Abbott salespersons specifically promoted Humira to Dr. Townsend, a **rheumatologist** with an **adult** practice, (2) for an off-label indication for psoriasis, a **dermatological** condition to **pediatric** patients, and (3) that such promotions **caused** Dr. Townsend to prescribe Humira to CBA." *Id.* 5-6 (emphasis added). The court agrees.

Section 82.007(b)(3) provides:

> The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that . . . (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.

§ 82.007(b)(3)(A)-(C). Plaintiffs point to paragraphs 8, 10, and 16 of their Complaint to support their argument that they have pleaded facts sufficient to withstand dismissal under Rule 12(b)(6). In paragraph 8, Plaintiffs allege, "Abbott . . . promoted Humira for 'off-label' use, like the prescription for psoriasis that young [CBA] received from his grandmother's rheumatologist." Compl. ¶ 8. Paragraph 10 does not contain any factual allegations to support a claim under section 82.007(b)(3). In paragraph 16, Plaintiffs allege:

> [CBA's] grandmother, Mary Anderson, mentioned her grandson's psoriasis to her rheumatologist, Dr. Henry Townsend. Though Dr. Townsend does not generally treat children in his practice, he decided to see [CBA]. Dr. Townsend prescribed Humira in May 2008. On information and belief it is alleged that Abbott's sales

> representatives "detailed" Dr. Townsend and that Abbott encouraged him, in this and other ways, to prescribe Humira to treat psoriasis. On information and belief it is further alleged that, between the FDA "Early Communication" on June 3, 2008, and December of 2008, Abbott's salesmen called on Dr. Townsend or others in his practice on numerous occasions and failed to do anything to alert them to this risk.

Id. ¶ 16. The court concludes that Plaintiffs' allegations in this regard are insufficient to withstand dismissal under Rule 12(b)(6). As previously noted, "[w]hile a complaint need not contain detailed factual allegations, it must set forth "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly,* 550 U.S. at 555 (citation omitted). Plaintiffs' allegations are nothing more than a formulaic recitation of the first two elements under section 82.007(b)(3), and Plaintiffs allege no facts whatsoever in support of the third causation element. Accordingly, the court determines that Plaintiffs have failed to state a claim under section 82.007(b)(3), and Abbott is entitled to dismissal of Plaintiffs' claims under this section.

C. Whether Section 82.007(b)(1) is Severable from Section 82.007(a)

Plaintiffs contend that if section 82.007(b)(1) is preempted, then section 82.007(a)(1) is also preempted because section 82.007(b)(1) is not severable from section 82.007(a)(1). Based on general rules of statutory construction and legislative history, Abbott contends that Plaintiffs' argument is without merit.

In *Lofton*, the plaintiffs made a similar argument; however, because the argument was raised for the first time on appeal, the court declined to consider it. *Lofton*, 672 F.3d at 380. The only court that appears to have addressed this specific issue is *Murthy*, which disagreed with the plaintiff's argument that if section 82.007(b)(1) is unconstitutional, section 82.007(a) must also be

unconstitutional. The *Murthy* court concluded that "§ 82.007(a) and § 82.007(b)(1) are clearly independent of one another," reasoning that:

> The unconstitutionality of one part of a statute does not require us to invalidate the entire statute unless the unconstitutional provision is not separable from the remainder." *Commission for Lawyer Discipline v. Benton*, 980 S.W.2d 425, 441 (Tex. 1998) (citing *Harris County Water Control & Improvement Dist. No. 39 v. Albright*, 153 Tex. 94, 263 S.W.2d 944, 947 (1954); *Black v. Dallas Cnty. Bail Bond Bd.*, 882 S.W.2d 434, 437 (Tex. App. Dallas 1994, no writ)). "'[W]here a statute contains an unconstitutional provision, and another which, if standing by itself, would be valid, the latter will be given effect, provided they are so clearly independent of each other that the court can say the Legislature would have passed it if the former had been omitted.'" *Association of Texas Prof'l Educators v. Kirby*, 788 S.W.2d 827, 830 31 (Tex. 1990) (quoting *Texas & Pac. Ry. Co. v. Mahaffey*, 98 Tex. 392, 395 (1905)). "'If, when the unconstitutional portion is stricken out, that which remains is complete in itself, and capable of being executed in accordance with the apparent legislative intent, wholly independent of that which was rejected, it must stand.'" *Rose v. Doctors Hosp*., 801 S.W.2d 841, 844 (Tex. 1990) (quoting *Western Union Tel. Co. v. State*, 62 Tex. 630, 634 (1884)). The Court concludes that § 82.007(a) and § 82.007(b)(1) are clearly independent of one another, such that the former would have been passed even if the latter had been omitted. Indeed, once § 82.007(b)(1) is stricken, § 82.007(a) remains complete in itself, and capable of being executed in accordance with the apparent legislative intent-specifically, of limiting the liability of health care providers, manufacturers, distributors, and prescribers in pharmaceutical failure to warn cases. *See also* Tex. Gov. Code Ann. § 311.032(c) ("In a statute that does not contain a provision for severability or nonseverability, if any provision of the statute or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the statute that can be given effect without the invalid provision or application, and to this end the provisions of the statute are severable.").

Murthy, 847 F. Supp. 2d at 976 n.8. The court agrees with the *Murthy* court's reasoning and similarly concludes that sections 82.007(a)(1) and 82.007(b)(1) are independent of and severable from one another, and the preemption of 82.007(b)(1) does not affect section 82.007(a)(1).

IV. Amendment of Pleadings

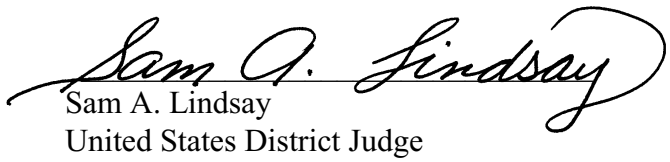
Despite Plaintiffs being put on notice of Abbott's contention in its motion to dismiss and supplemental briefing that Plaintiffs have failed to allege sufficient facts under *Twombly* and *Iqbal*, Plaintiffs have not requested to amend their pleadings. Plaintiffs have steadfastly maintained that their "Complaint alleges enough facts to overcome even the most strained construct of plausibility" under *Twombly* and *Iqbal*. Pls.' Resp. 1-3. In light of Plaintiffs' steadfast position on the sufficiency of their allegations, and because they have not requested to amend, the court assumes that Plaintiffs have stated their "best case" and that they cannot improve upon or supplement the allegations as pleaded. The court therefore concludes that Plaintiffs cannot set forth additional allegations that exist to state a claim upon which relief can be granted and that further attempts to amend would be futile. Accordingly, the court will not allow Plaintiffs to amend their pleadings.

V. Conclusion

For the reasons herein set forth, Plaintiffs have failed to state claims upon which relief can be granted against Abbott for strict liability, negligence, and breach of warranty.[2] Accordingly, the court **grants** Defendant's Motion to Dismiss Complaint for Failure to State a Claim and **dismisses with prejudice** Plaintiffs' claims for strict liability, negligence, and breach of warranty. The court will issue a judgment by separate document pursuant to Rule 58 of the Federal Rules of Civil Procedure.

[2] Having concluded that Abbott is entitled to dismissal of Plaintiffs' claims on other grounds, the court need not address the parties' arguments regarding the applicability of the Texas learned intermediary doctrine.

It is so ordered this 30th day of September, 2012.



Sam A. Lindsay
United States District Judge