UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

JENNIFER LACOGNATA et al,

Plaintiffs,

v. **Case No. 8:12-cv-822-T-30TGW**

HOSPIRA, INC.,

Defendant.
_____/

ORDER

THIS CAUSE comes before the Court upon Defendant's Motion to Dismiss Plaintiffs' Complaint for Failure to State a Claim (Dkt. 12) and Plaintiffs' Response in opposition (Dkt. 16). The Court, having considered the motion, response, and being otherwise advised of the premises, concludes that the motion should be granted and this action dismissed with prejudice.

BACKGROUND

Plaintiff Jennifer Lacognata brings this action individually and on behalf of all others similarly situated based on Defendant Hospira, Inc.'s failure to provide Plaintiff injectable vitamin A. Hospira is the seller of Aquasol A, a prescription form of injectable Vitamin A. Plaintiff alleges that Hospira is the sole supplier of Aquasol A.[1] Plaintiff alleges that she suffers from a vitamin A deficiency that was diagnosed in April 2011. Because she is unable to absorb vitamin A through her diet, she requires injections of vitamin A to prevent the

[1] Plaintiff and Hospira do not have a contractual relationship; Hospira is simply the manufacturer/seller of Aquasol A, which is used by those in medical need of injectable Vitamin A.

symptoms of vitamin A deficiency, which can cause permanent blindness, susceptibility to infections, and other catastrophic injuries.

Plaintiff alleges that prior to November 2010, Hospira was able to manufacture enough Aquasol A to meet market demand. But subsequently, Hospira ceased shipping Aquasol A to the market. Plaintiff alleges that in December 2010, Hospira promised patients that it would resume shipping Aquasol A in 2011. Plaintiff alleges that Hospira now predicts that it will begin shipping the product at the end of 2012. Plaintiff alleges that "[b]y withdrawing access to Aquasol A, Hospira through its own negligence and reckless disregard for human life and health created a global shortage which led directly to patients' otherwise preventable injuries." (Dkt. 1).

Plaintiff alleges claims against Hospira for: negligence (Count I); negligence *per se* (Count II); tortious interference with a business relationship and a physician/patient relationship (Count III); breach of implied contract (Count IV); and loss of consortium (brought by her husband) (Count V).

Hospira moves to dismiss the entirety of Plaintiffs' claims for their failure to state a plausible claim under Fed. R. Civ. P. 12(b)(6).

MOTION TO DISMISS STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(6) allows a complaint to be dismissed for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When reviewing a motion to dismiss, a court must accept all factual allegations contained in the complaint as true, and view the facts in a light most favorable to the plaintiff. *See Erickson*

v. Pardus, 551 U.S. 89, 93-94 (2007). However, unlike factual allegations, conclusions in a pleading "are not entitled to the assumption of truth." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1950 (2009). On the contrary, legal conclusions "must be supported by factual allegations." *Id.* Indeed, "conclusory allegations, unwarranted factual deductions or legal conclusions masquerading as facts will not prevent dismissal." *Davila v. Delta Air Lines, Inc.*, 326 F.3d 1183, 1185 (11th Cir. 2003).

DISCUSSION

I. Plaintiff's Negligence Claim

Under Florida law, the first element of a negligence claim is "[a] duty, or obligation, recognized by the law, requiring the [defendant] to conform to a certain standard of conduct, for the protection of others." *Clay Elec. Co-op., Inc. v. Johnson*, 873 So. 2d 1182, 1185 (Fla. 2003) (internal quotation marks and citation omitted). Whether a defendant owes a legal duty to a plaintiff is a question of law for the court. *See McCain v. Fla. Power Corp.*, 593 So. 2d 500, 503 (Fla. 1992).

In Count I, Plaintiff contends that Hospira "owed a duty" to provide her with "sufficient quantities of Aquasol A" to protect her from the adverse effects of vitamin A deficiency. Defendant argues that there is simply no authority for that proposition. And that, to the contrary, it is bedrock law that "[t]he fact that the actor realizes or should realize that action on his part is necessary for another's aid or protection does not of itself impose upon him a duty to take such action." *Thompson v. Baniqued*, 741 So. 2d 629, 631 (Fla. 1st DCA 1999).

The Court agrees that Plaintiff's negligence claim fails as a matter of law. There is no authority that supports Plaintiff's argument that a drug manufacturer, like Hospira, has a duty to continue supplying a patient with a drug that it knows the patient relies upon for his or her medical health. It is not this Court's role to dramatically expand Florida law as Plaintiff seeks. *See generally Sobkowski v. Wyeth, Inc.*, 2004 WL 3569704, at *6 (May 17, 2004). Accordingly, this claim is dismissed with prejudice.

II. Plaintiff's Negligence *Per Se* Claim

In Count II, Plaintiff seeks to recover under a negligence *per se* theory, asserting that Hospira should be presumed negligent because it purportedly violated an FDA regulation - 21 C.F.R. § 314.161 - by withdrawing access to Aquasol A without obtaining FDA approval to do so.

Defendant argues that this claim fails as a matter of law because, under Florida law, negligence *per se* involves the violation of a statute that establishes a duty to take precautions to protect a particular class of persons from a particular injury or type of injury. Defendant also points out that Florida law does not recognize a claim for negligence *per se* based on an alleged violation of the Food, Drug and Cosmetic Act ("FDCA"), or the FDA's implementing regulations.

The Court concludes that this claim fails as a matter of law. First, the FDA regulation Plaintiff relies on does not require a manufacturer to obtain FDA approval to stop supplying a prescription product to the market; it merely states that after a manufacturer has voluntarily withdrawn a product from the market, the FDA may investigate the reasons for the

withdrawal. More importantly, however, Florida law does not recognize a claim based upon a theory of negligence *per se* for an alleged violation of this particular federal regulation. *See Pantages v. Cardinal Health 200, Inc.*, 2009 WL 2244539, at *2-*3 (M.D. Fla. July 27, 2009); *Blinn v. Smith & Nephew Richards, Inc.*, 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999); *see also Metz v. Wyeth LLC*, 2012 WL 1058870, at *6 (M.D. Fla. Mar. 28, 2012).

Accordingly, because there is no set of facts which Plaintiff could offer that could establish a claim for negligence *per se* based upon this federal regulation, Count II is dismissed with prejudice.

III. Plaintiff's Tortious Interference Claim

In Count III, Plaintiff claims that Hospira's alleged failure to supply Aquasol A amounts to a tortious interference with her business and physician/patient relationship with her physician. The elements of a tortious interference claim are "(1) the existence of a business relationship; (2) knowledge of the relationship on the part of the defendant; (3) an intentional and unjustified interference with the relationship by the defendant; and (4) damage to the plaintiff as a result of the breach of the relationship." *Tardif v. People for the Ethical Treatment of Animals*, 829 F. Supp. 2d 1219, 1231 (M.D. Fla. Nov. 4, 2011) (internal quotation marks and citation omitted).

Here, as Hospira points out, there is no authority for the proposition that a manufacturer commits an "intentional and unjustified" interference with the physician/patient relationship by failing to supply sufficient quantities of a medication prescribed during the course of that relationship. In sum, there is no set of facts Plaintiff could allege that would

establish even a plausible claim of tortious interference. And Plaintiff's arguments to the contrary are without merit.

Accordingly, Count III is dismissed with prejudice.

IV. Plaintiff's Implied Contract Claim

In Count IV, Plaintiff alleges that, in June 2011, Hospira told her that Aquasol A would be backordered until September 2011, that she detrimentally relied on this promise, and Hospira did not provide her with Aquasol A in accordance with its promise. As Defendant points out, although Plaintiff labeled this claim as a "breach of implied contract," it is really a promissory estoppel claim, which requires proof that: (1) the promisor made a representation as to a material fact that is contrary to a later-asserted position; (2) the promisee reasonably relied on the representation; and (3) the promisee changed his or her position to his or her detriment based on the representation. *See Erickson's Drying Sys., Inc. v. QBE Ins. Corp.*, 2012 WL 469746, at *2 (M.D. Fla. Feb. 13, 2012).

Defendant argues, among other things, that this claim fails as a matter of law because Plaintiff has not alleged, nor could she, that Hospira made her a promise with definite terms. The Court agrees. Under Florida law, "promissory estoppel does not apply if the terms of the promise are indefinite." *Vencor Hosps v. Blue Cross Blue Shield of R.I.*, 284 F.3d 1174, 1185 (11th Cir. 2002). Plaintiff alleges that Hospira told her that Aquasol A would be backordered until September 2011. This hardly amounts to a promise with definite terms.

Also, Plaintiff does not allege that she changed her position to her detriment based on the representation. For example, Plaintiff does not allege that she gave up the opportunity to utilize other treatment options in reliance on Hospira's alleged promise.

In sum, taking the factual allegations as true, Plaintiff does not establish a plausible claim of promissory estoppel. And, under these circumstances, no set of facts could establish such a claim; it simply does not apply as a matter of law. Accordingly, Count IV is dismissed with prejudice.

V. Plaintiff's Husband's Loss of Consortium Claim

Plaintiff's husband's loss of consortium claim is derivative of Plaintiff's claims and is therefore dismissed.

CONCLUSION

Plaintiff's claims for personal injury damages as a result of Hospira's drug shortage have no basis under Florida law. It is simply unprecedented to hold Hospira responsible for the alleged worsening of her condition; Hospira did not have a duty to supply Plaintiff with the drug and it did not have a duty to supply the market generally.

It is therefore **ORDERED AND ADJUDGED** that:

1. Defendant's Motion to Dismiss Plaintiffs' Complaint for Failure to State a Claim (Dkt. 12) is GRANTED.
2. Plaintiffs' complaint is dismissed with prejudice.
3. The Clerk of Court is directed to close this case and terminate any pending motions as moot.

DONE and **ORDERED** in Tampa, Florida on July 2, 2012.

JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel/Parties of Record

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