UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
OCALA DIVISION

JOHN ANDREW PANTAGES, JR.,

Plaintiff,

v. Case No. 5:08-cv-116-Oc-10GRJ

CARDINAL HEALTH 200, INC., a foreign for-profit corporation, and ALLEGIANCE HEALTHCARE CORPORATION, a foreign for-profit corporation,

Defendant.
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ORDER

Pending before the Court are: (1) Defendant, Cardinal Health 200, Inc.'s Motion to Dismiss Count VI of Third Amended Complaint and Incorporated Memorandum of Law (Doc. 46); and (2) Plaintiff's Third Motion for Partial Summary Judgment. (Doc. 80.) The parties have filed their respective responses in opposition (Docs. 49 & 105) and therefore the motions are ripe for review. For the reasons set discussed below, Defendant, Cardinal Health 200, Inc.'s Motion to Dismiss Count VI of Third Amended Complaint (Doc. 46) is due to be **GRANTED**, and Plaintiff's Third Motion for Partial Summary Judgment (Doc. 80) is due to be **DENIED**.

I. BACKGROUND AND FACTS

This is a products liability action arising from personal injuries purportedly resulting from the surgical placement of a defective catheter in Plaintiff. At some point prior to Plaintiff's surgery, Defendant manufactured and distributed a 4341B Thoracentesis Catheter, Lot #L3N243 ("Catheter") to Munroe Regional Medical Center

("MRMC"). Thereafter, MRMC allegedly stored the Catheter in such a manner that it was exposed to ultraviolet ("UV") light. On February 10, 2006, Plaintiff's surgeon inserted the Catheter into Plaintiff during an elective thoracentesis procedure. During the procedure, the Catheter broke inside of Plaintiff necessitating additional subsequent surgical procedures to remove the pieces of the broken catheter that had lodged into Plaintiff's chest cavity.

Defendant, Cardinal Health 200, Inc. ("Cardinal 200"), is in the business of manufacturing, designing, packaging, distributing, supplying and selling medical devices including but not limited to the 4341B Thoracentesis Catheter, Lot #L3N243 ("Catheter") at issue here.

On November 3, 2008, Plaintiff filed his six-count complaint, purporting to allege in Count VI a claim for negligence *per se* based upon Defendant's alleged violation of 21 C.F.R. § 820.130. (Doc. 43.) On November 18, 2008, Defendant filed a motion to dismiss Count VI. (Doc. 46.) Thereafter, while the Motion to Dismiss was still pending before the Court, Plaintiff filed a motion seeking partial summary judgment on his claim in Count VI for negligence *per se* based upon Defendant's alleged violation of 21 C.F.R. § 820.130.

II. STANDARD OF REVIEW

In ruling on a motion to dismiss under Rule 12(b)(6), the Court is charged with the task of testing the facial sufficiency of the complaint.[1] The Court must accept factual

[1] Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007).

allegations in the complaint as true[2] and must limit its consideration to the pleadings and written instruments attached as exhibits.[3] Although the allegations in the complaint need not be detailed, they "must be enough to raise a right to relief above the speculative level."[4]

III. DISCUSSION

Count VI of Plaintiff's Third Amended Complaint purports to allege a claim for negligence *per se* based upon Defendant's violation of a federal regulation promulgated by the Federal Drug Administration ("FDA"). Specifically, Plaintiff bases the claim on section 820.130 of Title 21 of the Code of Federal Regulation entitled "Device Packaging." This regulation provides: "Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution."

Plaintiff requests that the Court grant summary judgment in his favor as to Count VI because there is no genuine issue of material fact that Defendant's packaging of the Catheter was deficient in violation of § 820.130. According to Plaintiff, the packaging was deficient because it failed to protect the catheters from ultraviolet ("UV") light and prolonged exposure to UV light causes the plastic component of the catheters to

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[2] Jackson v. Okaloosa County, Fla., 21 F.3d 1532, 1534 (11th Cir. 1994).

[3] FED. R. CIV. P. 10(c) ("A copy of a written instrument that is an exhibit to a pleading is a part of the pleading for all purposes."); GSW, Inc. v. Long County, Ga., 999 F.2d 1508, 1510 (11th Cir.1993).

[4] Bell Atlantic Corp., 550 U.S. at 555; *see also* Davila v. Delta Air Lines, Inc., 326 F.3d 1183, 1185 (11th Cir. 2003) ("[C]onclusory allegations, unwarranted factual deductions or legal conclusions masquerading as facts will not prevent dismissal.")

become brittle and lose their flexibility rendering them more likely to break or fracture during use. Such failure, according to Plaintiff, constitutes negligence *per se*.

Defendant, on the other hand, urges the Court to dismiss Count VI because it fails to state a cause of action for which relief can be granted. Defendant contends that it could not have violated § 820.130 because the Catheter at issue is not a medical device subject to the regulatory controls set forth in Part 820.

Part 820 of Title 21 of the Code of Federal Regulations sets forth a regulatory scheme designed "to ensure that finished [medical] devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FDCA)."[5] Its provisions establish a minimum standard that manufacturers of certain medical devices are required to meet.[6] The provisions of the part, however, do not apply to manufacturers of "class I devices"[7] not listed in § 820.30(a)(2). Thus, Defendant's argument depends on the classification of the Catheter at issue as a "class I device."

In the alternative, Defendant argues that even if the Court were to find that the Catheter is not exempt from the requirements in § 820.130, the issue as to whether Defendant's packaging was "deficient" presents numerous genuine issues of material fact which precludes the entry of summary judgment as to Count VI.

Although the parties focus on the narrow issue of whether the packaging Defendant used for the Catheter was compliant with the packaging and storage requirements of § 820.130, there is a more fundamental problem with Plaintiff's claim

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[5] 21 C.F.R. § 820.1(a)(1)

[6] 21 C.F.R. § 820.1(a)(1)

[7] See 21 U.S.C. § 360c for the statutory definition of a "class I device."

for negligence *per se.* That problem is whether Florida law recognizes a cause of action for negligence *per se* based upon an alleged violation of a regulation promulgated by the FDA. As explained below, because Florida law does not recognize such a claim, Count VI of the Complaint is due to be dismissed and Plaintiff is not entitled to partial summary judgment in his favor.

Under Florida law the violation of a federal regulation does not create civil liability based upon a theory of negligence *per se* in the absence of evidence "of a legislative intent to create a private cause of action."[8] Where a statute or regulation does not expressly provide for a civil cause of action, the Court must look to the legislative intent of the statute to determine whether the legislative body enacting the law "intended to create the private remedy asserted."[9] "In general, a statute that does not purport to establish civil liability but merely makes provision to secure the safety or welfare of the public . . . will not be construed as establishing a civil liability."[10]

The FDA promulgated Part 820 of Title 21 of the Code of Federal Regulations pursuant to authority granted to it by Congress under the Federal Drug and Cosmetics Act ("FDCA"). The stated purpose of the regulation is to ensure that medical devices are safe, effective, and compliant with the FDCA by requiring manufacturers of certain types of medical devices to meet a minimum quality standard in the design, manufacture, packaging, labeling, and storage of their products. Neither the regulation nor the FDCA

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[8] Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999)

[9] Murthy v. N. Sinha Corp., 644 So. 2d 983, 985 (Fla. 1994) (quoting Transamerica Mortgage Advisors, Inc. v. Lewis, 444 U.S. 11, 15-16 (1979)).

[10] Moyant v. Beattie, 561 So. 2d 1319, 1320 (Fla. 4th DCA 1990).

expressly create civil liability for the noncompliance with the part. Indeed, the federal regulation only provides for regulatory action in the event of noncompliance and is completely silent with regard to the availability of private remedies.[11] This strongly suggests a legislative intent *not* to create a private cause of action.[12]

Accordingly, regardless of whether the Catheter is in fact exempt from the requirements set forth in § 820.130, Plaintiff's claim fails to state a cause of action for which relief can be granted because Florida law does not recognize a claim based upon a theory of negligence *per se* claim for an alleged violation of this particular federal regulation. 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 VI is due to be dismissed.

Because the Court concludes that Count VI fails to state a cause of action based upon a theory of negligence *per se*, the Court does not need to discuss Plaintiff's Motion for Summary Judgment in any significant detail. However, even if Florida law recognized a claim for negligence *per se* based upon a violation of § 820.130, Plaintiff would not be entitled to partial summary judgment because there are genuine issues of material fact with regard to whether the packaging was compliant with federal regulation. The federal regulation does not require that the manufacturer ship the Catheter in a foil package but only that a device must be packaged to protect it from damage during storage. The issue of whether foil packaging is necessary to protect UV damage is disputed because the issue of whether exposure to UV light caused the

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[11] 21 C.F.R. § 820.1(c).

[12] *See, e.g.*, Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999) (language of FDCA strongly suggests legislative intent not to create private remedy for statutory violation).

breakage of the catheter in this case is itself a pivotal factual dispute to be decided by a jury.

Thus, because the packaging issue is dependent upon whether UV light caused the failure of the catheter, it remains to be determined whether the Catheter in this case complies with § 820.130. Lastly, based upon the evidence presented in support of the motions before the Court,[13] it is unresolved whether the Catheter at issue is even among those class I devices specifically exempt from the federal regulation.[14]

IV. CONCLUSION

In view of the foregoing, Defendant, Cardinal Health 200, Inc.'s Motion to Dismiss Count VI of Third Amended Complaint (Doc. 46) is **GRANTED**, and Count VI of Plaintiff's Third Amended Complaint is hereby **DISMISSED with prejudice**. Plaintiff's Third Motion for Partial Summary Judgment (Doc. 80) is, therefore, due to be **DENIED**.

IT IS SO ORDERED.

DONE AND ORDERED in Ocala, Florida, on July 27, 2009.

GARY R. JONES
United States Magistrate Judge

Copies to:
All Counsel

[13] Defendant filed a document entitled "FDA Product Classification Database: Needle, Catheter" in support of its Motion to Dismiss. (Doc. 47.) This same document was also filed as "Exhibit F" to Defendant's Response to Plaintiff's Third Motion for Partial Summary Judgment. (Doc. 105-2, p.26.) However, the document sheds little light with regard to the appropriate classification of the specific catheter at issue.

[14] While the issue of whether the Catheter at issue is exempt from the federal regulation as a class I device is not determinative of whether Florida law recognizes a claim for negligence *per se* for violation of this federal regulation, the issue may become relevant to the extent the Plaintiff attempts to refer to § 820.130 as evidence that Defendant was negligent. To that extent the Court may have to address at trial (or later in the case) the applicability of the federal regulation to the Catheter at issue in this case.