IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ELMER HEISNER, Individually and on Behalf of JAYNE HEISNER, *Plaintiff*,	)	
v.	)	No. 08-C-593
GENZYME CORPORATION, a Massachusetts Corp. *Defendant*.	)	Honorable David H. Coar

MEMORANDUM OPINION AND ORDER

Before this Court is Defendant Genyzme's ("Defendant") Motion to Dismiss Plaintiff Elmer Heisner's ("Plaintiff") Second Amended Complaint. On September 3, 2008, Plaintiff filed his Second Amended Complaint containing four counts: strict liability (Count I), negligence (count II), negligence per se (Count III), and breach of express warranty (Count IV). For the reasons stated below, Defendant's Motion to Dismiss on all counts is GRANTED.

I. Alleged Facts

On January 19, 2006, Jayne Heisner, wife of Elmer Heisner, underwent surgery to remove an ovarian cyst. To prevent potential post-surgical adhesions, a Seprafilm barrier, made and marketed by Defendant, was placed into her body. Seprafilm is a Class III medical device approved by the United States Food and Drug Administration ("FDA") pursuant to its premarket approval (PMA) process. Seprafilm is composed of chemically modified hyaluronic acid and

carboxymethylcellulose. Individuals who have an allergy to the source animal or microorganism that synthesized the hyaluronic acid may have an increased risk of side effects and the potential to develop an allergic response. Mrs. Heisner developed an intense fibrous reaction of the small intestines with collections of foreign body cells [concrete intestines], and died on February 22, 2006.

On January 28, 2009, Plaintiff filed a seven-count complaint against Defendant seeking damages in connection with the death of his wife. After Defendant filed a motion to dismiss the original complaint, Plaintiff filed a five-count amended complaint. Defendant argued that Plaintiff's claims were preempted by the Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetics Act (FDCA). 21 U.S.C. § 360c *et seq.* On July 25, 2008, this Court granted Defendant's motion to dismiss, but allowed Plaintiff to replead. *See Heisner v. Genzyme,* No. 08-CV-593, Mem. Op. and Order (July 25, 2008) (hereinafter "July 2008 Memorandum Opinion"). Plaintiff filed his Second Amended Complaint, the subject of the instant motion to dismiss, on September 3, 2008.

II. Standard of Review

In ruling on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the Court will assume that all facts alleged in the Complaint are true and construe the allegations in the Plaintiff's favor. *Tamayo v. Blagojevich,* 526 F.3d 1074, 1081 (7th Cir. 2008). A party's claim should only be dismissed if it is clear that no set of facts in support of the claim would entitle the party to relief. *Ledford v. Sullivan*, 105 F.3d 354, 356 (7th Cir. 1997) (quoting *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)). "In ruling on a 12(b)(6) motion, a district court

may take judicial notice of matters of public record." *Anderson v. Simon,* 217 F.3d 472, 474-75 (7th Cir. 2000).

III. Analysis

Defendant's motion to dismiss is premised in part on the MDA's preemption clause. That clause provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement ---
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The MDA therefore preempts any claim that is different from, or in addition to, federal requirements. *See Riegel v. Medtronic,* 128 S. Ct. 999, 1011 (2008); *Mitchell v. Collagen Corp.,* 126 F.3d 902 (7th Cir. 1997). The Supreme Court has clarified that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements." *Riegel,* 128 S. Ct. at 1011. The question here is whether Plaintiff's claims parallel the MDA, as he contends.

A. Strict Liability, Negligence, and Negligence Per Se Claims (Counts I, II, and III)

This Court dismissed earlier iterations of Plaintiff's tort claims in the Memorandum Opinion and Order of July 25, 2008, on the ground that they lacked the specificity required for the Court to evaluate whether they were preempted by § 360k of the MDA. In his Second

Amended Complaint, Plaintiff supplements his earlier tort claims with two specific allegations: 1) Genzyme failed to report the death of the Plaintiff, and 2) Genzyme excluded clinical trial participants exhibiting known allergies to hyaluronic acid in its November 2007 post-market Cesarean Delivery study conducted by Winthrop University Hospital, but has not yet reported to the FDA and made post-market label changes to the Warning section of the package insert to reflect this warning. Plaintiff argues that, as amended, his tort claims parallel the Defendant's duties under the MDA and as such, are not subject to preemption. *See Riegel*, 128 S. Ct. at 1011

Defendant argues that Plaintiff has failed to properly state a claim for strict liability, negligence, and negligence per se because the two incidents he cites took place after Jayne Heisner's death and could not have proximately caused her injury. Illinois strict liability claims based on a defect in product require the Plaintiff to show that the defect in the product proximately caused Plaintiff's injury. *See Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 345 (Ill. 2008). Because the incidents cited by Plaintiff do not satisfy the causation requirement, they cannot form the basis of his strict liability claim. Plaintiff's negligence and negligence per se claims present the same causation issue. *See McDonnell v. McPartlin*, 736 N.E.2d 1074, 1084 (Ill. 2000) (plaintiff must show that defendant's conduct was the proximate cause of his injury in order to prevail on a negligence claim); *Kalata v. Anheuser-Busch Cos.*, 581 N.E.2d 656, 661 (Ill. 1991) (plaintiff must show that defendant's statutory violation was the proximate cause of his injury in order to prevail on a negligence per se claim). Therefore, Claims I, II, and III cannot be premised on the incidents described by Plaintiff.

Plaintiff's remaining allegations consist of the same, overly vague statements contained in the earlier versions of his complaints. As this Court discussed at length in the July 2008 Memorandum Opinion, those allegations cannot form the basis of his claims because their lack

of specificity prevents the Court from evaluating them for the purpose of determining whether his claims are preempted under § 360k. Therefore, Counts I, II, and III are DISMISSED without prejudice.

B. Breach of Contract Claim (Count IV)

Plaintiff's final claim is express breach of warranty. Plaintiff's original claim for express breach of warranty was dismissed in the July 2008 Memorandum Opinion on the ground that Plaintiff insufficiently pled the factual basis for the claim, failing to give the Defendant notice as its substance. Plaintiff's amended breach of warranty claim is premised on three statements, two of which were contained in the package insert approved by the FDA, and the third in the PMA Protocol approved by the FDA. Plaintiff argues that his breach of warranty claim is proper because it is "parallel" to the MDA. *Riegel,* 128 S. Ct. at 1011. Although Defendant concedes that a breach of express warranty claim does not necessarily run afoul of MDA preemption, it argues that Plaintiff's particular claim is preempted because it is predicated on the package inserts and PMA protocol, both of which are FDA-approved materials.

Although the Seventh Circuit has not directly addressed this issue, other courts have ruled that breach of warranty claims premised on FDA-approved materials are subject to preemption under the MDA. *See, e.g., Gomez v. St. Jude Medical Diag. Div., Inc.*, 442 F.3d 919 (5th Cir. 2006); *In re Sulzer Hip Prosthesis and Knee Prosthesis Liability Lit.,* 455 F.Supp.2d 709 (N.D. Ohio 2006). In *Gomez,* the Fifth Circuit ruled that a patient's breach of express warranty claim was preempted because "[a] jury hearing [plaintiff's] state-law breach of express warranty claim would have to decide whether [defendant's] representations about [the device] were true. Because those representations—including the label, warnings, and IFU—were approved by the

FDA through the PMA process, the duties arising under the … breach of warranty statute relate to, and are potentially inconsistent with, the federal regulatory scheme." *Gomez*, 442 F.3d at 932. Similarly, Plaintiff's breach of warranty claim would require the trier of fact to consider whether Defendant's FDA-approved materials meet the additional standard set by state law. The Supreme Court, discussing tortuous mislabeling claims, has also held that "the MDA would pre-empt a jury determination that the FDA-approved labeling for a [medical device] violated a state common-law requirement for additional warnings" because it would "have the effect of establishing a substantive requirement for a specific device… that is different from, or in addition to a federal requirement." *Riegel*, 128 S. Ct. at 1011 (internal citations and quotation marks omitted). Plaintiff's express breach of warranty claim would have the same effect, and is therefore preempted under § 360k. Therefore, Count IV is DISMISSED with prejudice.

IV. Conclusion

For the foregoing reasons, Defendant's Motion to Dismiss Plaintiff's Second Amended Complaint is GRANTED in full. Count IV of Plaintiff's Second Amended Complaint is DISMISSED WITH PREJUDICE. Counts I, II, and III of Plaintiff's Second Amended Complaint are DISMISSED with leave to amend within 21 days.

Enter:

/s/ David H. Coar

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David H. Coar
United States District Judge

Dated: **April 30, 2009**