UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

BARBARA COMELLA and
FRANK COMELLA,

Plaintiffs,

v.

SMITH & NEPHEW, INC.,

Defendant.

No. 13 C 1850
Judge James B. Zagel

MEMORANDUM OPINION AND ORDER

Plaintiffs Barbara Comella ("Barbara") and Frank Comella ("Frank") have filed a complaint against Defendant Smith & Nephew, Inc., manufacturer of the Birmingham Hip Resurfacing System ("BHR System"), for strict products liability, negligence, and loss of consortium. Currently before the court is Defendant's motion to dismiss Plaintiffs' complaint. For the following reasons, Defendant's motion is granted in part and denied in part.

I. BACKGROUND

On April 22, 2007, a BHR System, manufactured by Defendant Smith & Nephew and consisting of two components, an acetabular cup and a femoral head, was implanted in Plaintiff Barbara's left hip. The FDA had granted premarket approval ("PMA") for the device on May 9, 2006. Barbara asserts that, at the time of the procedure, her doctor was unaware of adverse effects from the BHR System. Barbara first complained to her doctor, Dr. Sporer, about a squeaking noise in her hip on September 11, 2009, and then, about a severe, sharp pain that radiated throughout her left hip, groin, and buttocks on October 6, 2010. In March 2011, blood serum metal ion tests were performed on Barbara that revealed highly elevated chromium and

cobalt levels. On March 10, 2011, Dr. Sporer performed Barbara's left hip revision surgery and removed the failed BHR System. A post-operative report further revealed corrosion on the device at the modular junction and lab results consistent with metallosis.

As a result of the 2011 revision surgery, Barbara needed to be non-weight bearing for approximately six weeks and required the use of a cane for approximately four additional weeks. Further, Barbara needed multiple medications to manage pain and suffered intestinal problems due to those medications. Despite undergoing two rounds of physical therapy and ongoing treatment with a chiropractor, Barbara continues to suffer daily pain in her hip region and is unable to walk easily for an extended amount of time.

On March 8, 2013, Plaintiffs Barbara and Frank filed a three-count complaint against Defendant Smith & Nephew, and filed additional amended complaints on May 1, May 29, and July 8, 2013. Plaintiffs base their state common-law claims on violations of 21 C.F.R. 820.30 *et seq.*, which describe the "current good manufacturing practices" ("CGMPs") of the U.S. Food and Drug Administration ("FDA"). Defendant filed a motion to dismiss the present case, arguing that Plaintiffs' claims are expressly and impliedly preempted and alternatively, that Plaintiffs' complaint is insufficient under Fed. R. Civ. P. 8. Currently before the court is Defendant's motion to dismiss Plaintiffs' complaint.

II. DISCUSSION

Under the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act ("the Act"), Class III devices, which include hip resurfacing systems, require PMA before they can be made available to consumers. 21 U.S.C. § 360(e). Even after the product undergoes the rigorous PMA review and is granted PMA, the FDA still requires medical device manufacturers to comply with CGMPs "to ensure that finished [medical] devices will be safe and

effective and otherwise in compliance with the [Act]"). 21 C.F.R. § 820.1; see generally 21 C.F.R. § 820 *et seq*.; *Medtronic Inc. v. Lohr*, 518 U.S. 470, 477 (1996). Plaintiffs' strict products liability, negligence, and loss of consortium claims are based on violations of the CGMPs, including Defendant's failure to comply with design controls under 21 C.F.R. § 820.30, failure to comply with reporting requirements under 21 C.F.R. § 820.80, and failure to take appropriate corrective and preventative actions under 21 C.F.R. § 820.100.

A. Express Preemption

The central issue before the court is preemption. Under federal law, a product liability claim may be preempted either expressly or impliedly. For a product liability claim to be expressly preempted, Congress must make "clear and manifest" its purpose to supersede the historic police powers of a state. *Lohr*, 518 U.S. at 485. In the Act, Congress expressly states its intent to preempt any state requirement related to a products liability claim that is, (1) "different from or in addition to" any requirement under the Act; and (2) related to the device's safety or effectiveness, or any other device requirement within the Act. 21 U.S.C. § 360k. A claim, however, based on a state common law duty that is sufficiently parallel to the requirement under the federal regulations, imposes no additional obligation and is not preempted. *Lohr*, 518 U.S. at 495 ("Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.").

In their complaint, Plaintiffs allege that Defendant breached a common law duty by failing to advise the FDA about dangers that became manifest after the product was put on the market. In its motion to dismiss, Defendant contends that this state common-law duty to warn imposes a requirement that is "in addition" to federal requirements and thus, expressly preempted. Plaintiffs argue that their claim, based on the common law duty to warn, is

sufficiently parallel to the requirement to make disclosures under the federal regulations so as not to be preempted. I agree. Defendant was required under the Act and CGMPs to make certain reports and disclosures to the FDA, and the state common law duty to warn creates no requirement "different from, or in addition to" the requirements of the federal regulations. *Lohr*, 518 U.S. at 495; see *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

On the other hand, to the extent that the complaint alleges a breach of a duty to advise or warn the public and medical community, it creates an additional requirement and is preempted. While the federal requirement permits Defendants to provide interim supplemental warnings pending approval by the FDA, it does not require it. Consequently, a common law duty to provide a warning to the public and medical community imposes a requirement additional to the federal regulations and is preempted. *See McMullen v. Medtronic, Inc.*, 421 F.3d 482 (2005) ("Because § 814.39 permits, but does not require, a manufacturer to provide interim supplemental warnings pending approval by the FDA, a common-law duty to provide such a warning imposes an additional obligation.").

For the foregoing reasons, Defendant's motion to dismiss under the express preemption doctrine is granted in part, denied in part.

B. Implied Preemption

A state law claim that conflicts with a federal agency's regulatory regime may also be found to be impliedly preempted. The entire relationship between the FDA and the entities it regulates "originates from, is governed by, and terminates according to federal law." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). Consequently, a private right of action under the FDA could skew the "delicate balance of statutory objectives" addressed by the federal regulations. *Id*. As such, a plaintiff generally has no private right of action under the Act

to sue a manufacturer for "fraud-on-the-agency" or noncompliance with the FDA. Id. Tort claims, however, are based on a state common law duty to warn and fall within the state's traditional role of protecting the health and safety of its citizens. *Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (2010). For this reason, tort claims are distinguishable from fraud claims and are not impliedly preempted. *Id*.

Defendant argues that Plaintiffs' claims are impliedly preempted because Plaintiffs do not have a private right of action under the Act to sue a manufacturer for what are fundamentally fraud allegations or noncompliance with the Act. Plaintiffs do not disagree that a fraud claim would be impliedly preempted. Rather, Plaintiffs contend that their claim is not based on fraud, but a breach of a state common law duty to warn based on failure to comply with disclosure and reporting requirements. I agree. Although Plaintiffs' claims are premised on alleged violations of federal regulations, they are also capable of existing independent of these regulations as failure of the duty to warn.

As in the Seventh Circuit's holding in *Bausch*, Plaintiffs' claims are tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law. *Bausch*, 630 F.3d at 557 (violating a federal law "goes a long way toward showing that the manufacturer breached a duty under state law"). As such, Plaintiffs' claims are only preempted to the extent intended by Congress—in this case, as directly stated under the express preemption provision of the Act. *Lohr*, 518 U.S. at 485. Plaintiffs' claims, then, are preempted only to the extent that the duty to warn imposes an obligation on Defendant that is additional to the federal requirements. *Bausch*, at 557 (finding "no indication that Congress intended preemption of state claims based on violations of federal law, beyond the limitations set forth in the express preemption clause").

For these reasons, Plaintiffs' negligence and strict liability claims, based on the breach of the duty to warn, are not impliedly preempted. *See Bausch*, 630 F.3d at 557-58; *Lohr*, 518 U.S. at 495. Because Plaintiffs' loss of consortium claim is contingent on the underlying negligence and strict liability claims, it also is neither expressly nor impliedly preempted.

C. Sufficiency of Plaintiff's complaint

Defendant argues that Plaintiffs' complaint is inadequate under Fed. R. Civ. P. 8 because it fails to include relevant facts to support a failure to warn claim and deprives Defendant of requisite notice. This argument, however, was not raised or developed until Defendant's reply brief and so, is waived. *Coker v. Trans World Airlines, Inc.*, 165 F.3d 579, 586 (7th Cir. 1999) (finding that failure to develop an argument until the reply, even if it is preserved, "is a day late and a dollar short."); *see also Dobrzeniecki v. Salisbury*, 2013 WL 500847, at *2 (N.D. Ill. Feb. 11, 2013) ("arguments developed for the first time in a reply brief are considered waived."). Nonetheless, even considering Defendant's argument, I find Plaintiffs' complaint sufficiently pled.

Rule 8 requires that a complaint contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8. Rule 8(a)(2). Notice pleading remains the standard under Rule 8, and heightened fact pleading is not required to state a claim. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Notice pleading requires that a complaint contain more than bare legal conclusions. While there must be a reasonable expectation that discovery will reveal evidence to support the plaintiff's allegations, a plaintiff's pleading burden corresponds to the amount of information available. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *see also Brooks v. Ross*, 578 F.3d 574, 581 (7th Cir. 2009). In the case of Class III medical devices, potentially valuable information related to PMA is kept confidential as a matter of

federal law and formal discovery may be required before a plaintiff can fairly be expected to identify specific defects. *Bausch*, 630 F.3d at 560.

Strict Liability

To state a claim for strict product liability, a plaintiff must show that the product was "unreasonably dangerous" at the time it left the defendant's control. *Apperson v. E.I. du Pont de Nemours & Co.*, 41 F.3d 1103, 1106 (7th Cir. 1994). Design or manufacturing defects, as well as the failure to warn of a non-obvious risk, may cause a product to become unreasonably dangerous. Id. Additionally, under both federal and Illinois law, a product that does not comply with applicable federal standards may be considered unreasonably dangerous. *Ross v. Black & Decker, Inc.*, 977 F.2d 1178 (7th Cir. 1992).

Plaintiffs allege that the particular BHR System implanted in Barbara was defective and unreasonably dangerous because Defendant failed to adhere to the approved design. Plaintiffs point to high levels of chromium and cobalt found in Barbara's blood as an indicator that the BHR System was in an "unreasonably dangerous" condition at the time it left Defendant's control. Plaintiffs also offer Barbara's eventual need for revision surgery and complete removal of the BHR System as further evidence that the BHR System was defective. *Bausch*, at 558-59; *Elmore v. Smith & Nephew*, 2013 WL 1707956, at 10 (N.D. Ill. Apr. 19, 2013) ("two revision surgeries, coupled with increased chromium and cobalt levels in [plaintiff's] blood, provide sufficient factual grounding on which to base negligence and strict liability claims").

Plaintiffs further allege that Defendant failed to advise the FDA about dangers that became manifest after the product was put on the market, in violation of federal law. Plaintiffs contend that this failure to comply with federal requirements set by government regulations indicates that the BHR System was unreasonably dangerous.

Plaintiffs' complaint is plausible on its face. Accordingly, Plaintiffs have sufficiently pled that the BHR System implanted in Barbara was "unreasonably dangerous" at the time it left Defendant's control to state a claim for strict product liability.

Negligence

To state a claim for negligence in Illinois that is based on a violation of a statute designed to protect human life, a plaintiff must show that (1) the violation proximately caused his or her injury; and (2) the statute was designed to protect a class of persons from injury to which the plaintiff belongs. *Kalata v. Anheuser-Busch Co., Inc.*, 581 N.E.2d 656, 661 (1991).

As a threshold matter, Defendant characterizes Plaintiffs' allegations as failing to identify a single breach of any federal regulation. Even assuming, *arguendo*, that Defendant is correct, the Seventh Circuit held that the failure to specify which federal regulatory requirements were allegedly violated did not amount to a failure to comply with Fed. R. Civ. P. 8 and could not support a dismissal under Rule 12(b)(6). *Bausch*, 630 F.3d at 560.

Plaintiffs allege that Defendant violated the Act and CGMPs under various provisions of 21 C.F.R. § 820. Specifically, Plaintiffs claim that Defendant's handling of over six hundred Adverse Events Reports was significantly delayed and that Defendant failed to make complete and accurate post-market reports. Plaintiffs also allege that Defendant did not adequately conduct metal ion testing as expressly required under the PMA. Given the amount of information to which they had access, Plaintiffs made plausible allegations and have sufficiently pled a violation of a federal regulation by Defendant.

We now proceed to the question of whether the Act and CGMPs were designed to protect a class of persons to which Plaintiffs belong from injury. Plaintiffs allege that the Act and CGMPs were designed to protect consumers by continuing monitoring of medical devices.

Plaintiffs also contend that Defendant's failure to report and disclose dangers of the BHR System to the FDA was the proximate cause of Plaintiffs' injuries. Plaintiffs assert that, had Defendant complied with the federal regulations, the dangers of the product would have been disseminated, Plaintiff Barbara Comella's doctor would not have recommended the BHR System to Plaintiff, and Plaintiff would not have suffered the injuries caused by the BHR System.

As pled, Plaintiffs' complaint is plausible on its face. Plaintiffs' allegations provide sufficient factual grounding on which to base negligence and strict liability claims. As the Seventh Circuit has recognized, Plaintiffs' alleging specific defects relating to Class III medical devices face particular difficulty in pleading, and their burden is commensurate with the amount of information they can access prior to discovery. *Bausch*, 630 F.3d at 561. Here, Plaintiffs have assembled the minimum factual grounding necessary to meet the plausibility standard required under *Twombly* and *Iqbal*. Consequently, the complaint complies with Fed. R. Civ. P. 8.

III. CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss is granted in part, denied in part. Plaintiffs are ordered to strike the portion of their complaint seeking additional state remedies. Defendant is directed to answer the complaint within 21 days.

DATE: December 11, 2013

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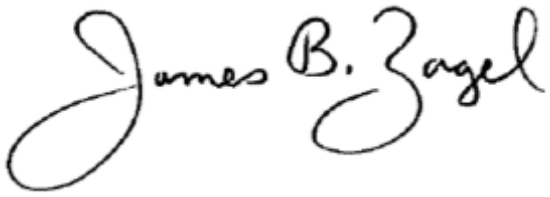

James B. Zagel

United States District Judge