UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

STEPHEN TILLMAN,	)	
	)	
Plaintiff,	)	
	)	**No. 12 C 4977**
v.	)	
	)	**Judge Joan H. Lefkow**
SMITH & NEPHEW, INC.,	)	
	)	
Defendants.	)	

OPINION AND ORDER

Plaintiff Stephen Tillman filed a two-count amended complaint against defendant Smith & Nephew, Inc. ("Smith & Nephew") alleging negligence and strict products liability. Tillman's amended complaint is based on alleged violations of specific quality control requirements adopted by the U.S. Food and Drug Administration ("FDA") and set forth at 21 C.F.R. § 820 *et seq.* with respect to the Birmingham Hip Resurfacing System (the "BHR System"), which Smith & Nephew manufactures, sells, or distributes. Smith & Nephew has moved to dismiss the amended complaint pursuant to Federal Rule of Civil Procedure 12(b)(6), arguing that Tillman's claims are expressly and impliedly preempted and, alternatively, that Tillman's complaint fails to state a claim. For the reasons set forth herein, Smith & Nephew's motion [#23] is denied.

BACKGROUND[1]

On September 20, 2007, Tillman's orthopedic surgeon performed a left hip resurfacing procedure utilizing the BHR System, a medical device manufactured, sold and/or distributed by Smith & Nephew. Am. Compl. ¶¶ 7, 11-12. The device consisted of two components, a size 58 mm acetabular component and a size 55 mm femoral head. *Id.* ¶ 12. The FDA had

[1] The facts in the background section are taken from the amended complaint and accepted as true for purposes of resolving the pending motion. *Dixon* v. *Page*, 291 F.3d 485, 486 (7th Cir. 2002).

conditionally granted premarket approval ("PMA") for commercial distribution of the BHR System approximately one year before Tillman's surgery. *Id.* ¶¶ 9-10.

On May 27, 2010, Tillman began to experience pain and complications where the BHR System had been implanted. *Id.* ¶ 13. On June 9, 2010, after conducting a physical examination, Tillman's doctor noted clicking in Tillman's left hip and limited range of motion resulting in "a sharp, pinching pain." *Id.* ¶ 14. During an examination in August 2010, Tillman reported experiencing pain with any internal rotation of his left leg. *Id.* ¶ 15. His doctor believed the pain may be caused by an impingement and informed Tillman that revision to a total hip arthroplasty may be required. *Id.* In July 2011, following another physical examination, Tillman's doctor noted he "suffered from a limp favoring his left side, positive impingement signs on the left, and possible femoral component mechanical complications." *Id.* ¶ 16. An x-ray revealed potential problems due to the subsidence of the device's femoral component. *Id.* Tillman's doctor concluded that Tillman would require revision of his left hip resurfacing arthroplasty and counseled him not to continue work. *Id.*

LEGAL STANDARD

In ruling on a Rule 12(b)(6) motion, the court accepts as true all well-pleaded facts in the plaintiff's complaint and draws all reasonable inferences from those facts in the plaintiff's favor. *Dixon* v. *Page*, 291 F.3d 485, 486 (7th Cir. 2002). To survive a Rule 12(b)(6) motion, the complaint must not only provide the defendant with fair notice of a claim's basis but must also establish that the requested relief is plausible on its face. *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009); *see also Bell Atl.* v. *Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). The allegations in the complaint must be "enough to raise a right of relief above the speculative level." *Twombly*, 550 U.S. at 555. At the same time,

the plaintiff need not plead legal theories. *Hatmaker* v. *Mem'l Med. Ctr.*, 619 F.3d 741, 743 (7th Cir. 2010). Rather, it is the facts that count.

ANALYSIS

The court previously dismissed Tillman's complaint without prejudice, finding that his state law claims relied on the existence of a defect in the BHR System. Dkt. 18 at 3. Tillman amended his complaint, including specific regulations he alleges Smith & Nephew violated. Smith & Nephew argues that Tillman has failed to correct the pleading deficiencies identified in the court's prior order and thus his claims remain expressly preempted by 21 U.S.C. § 360k(a). Smith & Nephew also argues that Tillman's claims are impliedly preempted under *Buckman Co.* v. *Plaintiff's Legal Committee*, 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001), because Tillman cannot bring a private action for violations under the Food, Drug, and Cosmetic Act ("FDCA"). Finally, Smith & Nephew argues that, if the claims are not preempted, Tillman has failed to comply with Rule 8's pleading requirements.

I. Express Preemption

Under the Medical Device Amendments of 1976 ("MDA") to the FDCA, the BHR System is considered a Class III medical device, "the class of devices that are most critical to human health and subject to the most extensive federal regulation." *Bausch* v. *Stryker Corp.*, 630 F.3d 546, 549 (7th Cir. 2010). A Class III medical device manufacturer must obtain PMA for the device before introducing it into the market. *See* 21 U.S.C. § 360e; *Riegel*, 552 U.S. at 317–20. "[T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 323. After obtaining PMA, Class III medical device

manufacturers must also comply with Quality System Regulations, including Current Good Manufacturing Practices ("CGMPs"), adopted by the FDA. *Bausch*, 630 F.3d at 554; *see generally* 21 C.F.R. § 820 *et. seq.* The CGMPs "are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA]." 21 C.F.R. § 820.1(a)(1).

The MDA includes an "express, but limited preemption provision for product liability claims against manufacturers of Class III medical devices." *Bausch*, 630 F.3d at 550. That provision, § 360k(a), 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 or 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). Common law claims for negligence and strict liability against medical device manufacturers that have obtained PMA are preempted by § 360k(a) when liability is premised on state law violations that are "different from, or in addition to" federal requirements for medical devices. *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 330, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008); *McCutcheon* v. *Zimmer Holdings, Inc.*, 586 F. Supp. 2d 917, 923 (N.D. Ill. 2008). "[I]f the referenced defect was in fact intrinsic to the product as approved in the PMA, then it is likely if not certain that any finding of liability based on that defect would place additional and/or different burdens on Defendant's product, necessitating preemption." *Heisner ex rel. Heisner* v. *Genzyme Corp.*, No. 08-C-593, 2008 WL 2940811, at *5 (N.D. Ill. July 25, 2008).

The Supreme Court, however, has also held that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations" where the

state duties "'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330; *see also Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 495, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) (§ 360k does not prevent states from providing a traditional damages remedy for "violations of common-law duties when those duties parallel federal requirements"); *Heisner*, 2008 WL 2940811, at *5 (same). Further, a state law negligent manufacturing claim is not preempted by § 360k(a) where the plaintiff has alleged that the defendant failed to follow FDA requirements or agreed upon procedures. *See Chambers* v. *Osteonics Corp.*, 109 F.3d 1243, 1248 (7th Cir. 1997) (finding "no reason to read the MDA as preempting state negligence law when it seeks only to enforce the standards and procedures set out by the FDA"); *see also Bausch*, 630 F.3d at 553 (concluding that state law "claims for defective manufacture in violation of federal law are not expressly preempted by § 360k").

Tillman's negligence and strict liability claims are based on numerous alleged violations of CGMPs by Smith & Nephew, including failure to comply with design controls under 21 C.F.R. § 820.30, failure to inspect and maintain in-process and final device acceptance activities under 21 C.F.R. § 820.80, failure to implement corrective and preventive actions under 21 C.F.R. § 820.100, and failure to investigate complaints and maintain complaint files under 21 C.F.R. § 820.198. Am. Compl. ¶ 19. These same alleged violations were considered recently by the court in *Elmore* v. *Smith & Nephew, Inc.*, No. 12 C 8347, 2013 WL 1707956 (N.D. Ill. Apr. 19, 2013). There, the court rejected Smith & Nephew's identical argument that the claims are expressly preempted on two grounds: (1) "a medical device manufacturer's required adherence to CGMPs does not end once PMA is granted," and (2) the claims alleged are "sufficiently parallel to the federal requirements." *Id.* at *2. Smith & Nephew sought reconsideration of the court's order, which the court denied. No. 12 C 8347, Dkt. 34 (N.D. Ill.

July 1, 2013). In doing so, the court noted that the plaintiffs had "disclaim[ed] any attempt to plead that the designed [*sic*] approved by the FDA is defective," recognizing that such claims would be preempted. *Id.* at 2.

This court agrees with and adopts *Elmore*'s analysis. Because Tillman's claims are based on alleged violations of CGMPs, they do not impose any additional or different requirements from federal ones and are thus not expressly preempted. To the extent Tillman is pursuing a claim that the BHR System design, as approved by the FDA in the PMA, is defective, such claim is preempted. *Id.* at 2; *see also Bausch*, 630 F.3d at 560 ("If the problem turns out to be a design feature that the FDA approved, section 360k will protect the manufacturer."). But that determination is more appropriately made after discovery reveals the specifications of the PMA. *Bausch*, 630 F.3d at 560.

II. Implied Preemption

Smith & Nephew also argues that Tillman's amended complaint is impliedly preempted under *Buckman* because his claims depend exclusively on alleged FDCA violations that only the government is empowered to enforce. In *Buckman*, the Court found a state law fraud claim related to allegedly fraudulent representations to the FDA in the market approval process preempted. 531 U.S. at 348. Because the fraud claim conflicted with the FDA's statutory authority to punish and deter fraud, that claim was preempted. *Id.* The Court also recognized a presumption against preemption in situations "implicating federalism concerns and the historic primacy of state regulation of health and safety matters." *Id.* at 341, 347. Thus, claims involving FDCA violations are not impliedly preempted where liability is independent of the FDCA, *i.e.*, where plaintiffs claim "breach of a recognized state-law duty" for their benefit and harm arising from violation of applicable federal law. *Bausch*, 630 F.3d at 558.

Elmore persuasively addressed Smith & Nephew's implied preemption argument. 2013 WL 1707956, at *3–4. As there and in *Bausch*, Tillman's claims "do not conflict with the primary objective of the FDA's regulatory scheme—ensuring the safety and effectiveness of medical devices." *Id.* at *4. Instead, Tillman alleges a breach of a well-recognized duty owed to him under state law: "the duty of a manufacturer to use due care in manufacturing a medical device." *Bausch*, 630 F.3d at 558; *Elmore*, 2013 WL 1707956, at *4. This duty imposes liability independent of the FDCA; it is not a state claim that "would not exist if the FDCA did not exist," as Smith & Nephew argues. *Riley* v. *Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (setting forth as an example of a claim preempted under *Buckman* a "state-law claim that the defendant made misrepresentations to the FDA"). "Although [plaintiff's] claims are premised on alleged violations of federal regulations, they are also capable of existing independent of those regulations." *Elmore*, 2013 WL 1707956, at *4. Tillman will have to establish that he "was harmed by a violation of applicable federal law," *Bausch*, 630 F.3d at 558, but at this stage, his claims survive the implied preemption analysis.

III. Sufficiency of Tillman's Amended Complaint

Lastly, Smith & Nephew argues that Tillman's amended complaint should be dismissed because Tillman has failed to plead any "plausible" factual matter to support Smith & Nephew's alleged liability. Tillman's complaint must provide Smith & Nephew with fair notice of the nature of the claim against it but need be no more than "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2); *see also Bausch*, 630 F.3d at 559.

Smith & Nephew argues essentially for a heightened pleading standard, wanting specific facts to support each allegation. But no heightened pleading requirement attaches to the claims

at issue here. *Bausch*, 630 F.3d at 558 ("There are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular."). "[M]uch of the product-specific information" Smith & Nephew claims is required "is kept confidential by federal law." *Id.* "Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim." *Id.* Thus, "[w]hile a complaint must still satisfy Rule 8, a plaintiff's pleading burden corresponds to the amount of information available." *Elmore*, 2013 WL 1707956, at *5.

Smith & Nephew argues that Tillman's amended complaint is "nothing more than an 'unadorned, the-defendant-unlawfully-harmed-me accusation'" that, unlike the complaint examined in *Bausch*, does not provide a sufficient factual basis for liability. Def.'s Mot. to Dismiss at 18–19 (citing *Iqbal*, 556 U.S. at 678). In *Bausch*, the plaintiff had alleged that a batch of hip replacement systems had been recalled and that the FDA had informed and in fact issued a letter to the manufacturer warning of quality control violations. 630 F.3d at 558–59. Here, no such facts relating to the BHR System are alleged, although Tillman does complain that Smith & Nephew did not properly respond to adverse incident reports, Am. Compl. Ct. I ¶ 19(I), Ct. II ¶ 18(I), allowing the inference that such reports were made. Although to a lesser extent than the plaintiffs in *Elmore*, Tillman does allege facts as to the medical complications that occurred after the implantation. These complications plausibly suggest a link between his injuries and the alleged BHR System defects. Additional allegations would strengthen Tillman's claims, but Tillman's pleading "is commensurate with the amount of information [he] can access prior to discovery." *Elmore*, 2013 WL 1707956, at *6. Thus, Tillman's claims will be allowed to proceed as pleaded.

CONCLUSION

Defendant Smith & Nephew's motion to dismiss [#23] is denied. Smith & Nephew is directed to answer the complaint by August 1, 2013. The parties are directed to appear for a scheduling conference on September 12, 2013 at 8:30 a.m.

Dated: July 18, 2013

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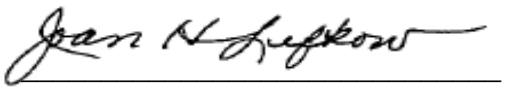

JOAN HUMPHREY LEFKOW
United States District Judge