UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
FORT WAYNE DIVISION

RONALD J. MCAFEE	)	
	)	
Plaintiff	)	
v.	)	CIVIL NO. 1:12-CV-417 RLM
	)	
	)	
MEDTRONIC, INC.	)	
	)	
Defendant	)	

OPINION AND ORDER

Ronald McAfee sued Medtronic, Inc., a medical device manufacturer, under Indiana's Product Liability Act and common law alleging that he was injured by a defective Medtronic Sprint Fidelis Lead (Model 6949). Medtronic has moved to dismiss the amended complaint under Fed. R. Civ. P. 12(b)(6). For the following reasons, the court GRANTS the motion in part, and DENIES it in part.

I. BACKGROUND

The Medtronic Sprint Fidelis Lead is classified as a Class III device–one that "cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii);

Riegel v. Medtronic, Inc., 552 U.S. 312, 317 (2008). As such, it receives the most federal oversight. *Id.*

The Medtronic Sprint Fidelis Lead Model 6949 received Pre-Market Approval, known as a "PMA," from the FDA in June 2004, subject to the conditions in the approval letter (Exh. C to the Amd. Cmplt.) and in the Conditions of Approval for Implantable Defibrillators and Programmers (Exh. B to the Amd. Cmplt.).[1]

The Conditions of Approval for Implantable Defibrillators and Programmers required Medtronic to file "Post-Approval Reports" and adverse event reports. The former were due annually, the latter were to be submitted within 10 days after Medtronic "receive[d] or ha[d] knowledge of information concerning":

> (1) A mixup of the device or its labeling with another article.
> (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and
> (a) has not been addressed by the devices labeling or
> (b) has been addressed by the devices labeling, but is occurring with unexpected severity or frequency.
> (3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specification established in the approved PMA that could not cause or contribute to death or serious injury but are not

[1] The PMA process is governed by the Medical Device Amendments, 21 U.S.C. § 360c *et seq.*, to the Federal Food, Drug and Cosmetic Act (FDCA). 21 U.S.C. § 301 *et seq.* Once a device such as the Sprint Fidelis Lead, a Class III device (one that presents a potentially unreasonable risk of injuring patients, or is used to sustain life), is approved, the manufacturer is not allowed to change the design, manufacturing process, labeling, or other attributes that would affect safety or effectiveness without filing a PMA Supplement. 21 U.S.C. § 360(a)(1)(C); 21 C.F.R. § 814.39(a).

> correctable by adjustments or other maintenance procedures described in the approved labeling…

(Amd. Cmplt. ¶ 13).

On July 10, 2006, Medtronic submitted 15 adverse event reports to the FDA relating to the Sprint Fidelis lead and dating back to March 25, 2006. Eleven days after the reports were submitted, a Sprint Fidelis Lead was implanted in Mr. McAfee.

On March 21, 2007, Medtronic sent a letter to physicians notifying them of the occurrence of adverse events with the Sprint Fidelis Leads involving fracture of the lead wires and inappropriate shocks or loss of therapy; and on October 15, 2007, it initiated a recall of the leads (including the lead implanted in Mr. McAfee).

In November 2010, Mr. McAfee experienced inappropriate shocks in his chest, was hospitalized, and had the pacemaker-defibrillator and lead surgically removed and a new device implanted. He filed this suit two years later.

Mr. McAfee alleges that Medtronic received information about fifteen adverse events related to the Sprint Fidelis Lead causing inappropriate shocks between February 25, 2006 and May 22, 2006, but waited until July 10, 2006 to report those events to the FDA (Amd. Cmplt. at ¶ 21). He thus concludes that Medtronic violated the conditions of approval, thereby invalidating the PMA as of March 8, 2006 (ten days after Medtronic received the first adverse event notice) and rendering the product "adulterated" under 21 U.S.C. 351(f)(B), and "misbranded" under 21 U.S.C. 352(t).

Mr. McAfee alleges that:

> 28. [Medtronic] was or should have been aware no later than March of 2006 that the Medtronic Sprint Fidelis Model 6949 Lead was inordinately prone to develop fractures causing inappropriate shocks or loss of therapy after implementation in patients, yet failed to give effective notice to the physicians who had previoulsy implanted the product…of the danger of the product.
>
> 29. Such a warning, if given, would have caused such physicians, and subsequent patients to consider an alternative product prior to surgical implantation, and to avoid the serious injuries that resulted from implantation of the product.
>
> 30. As a result of [Medtronic's] postmarket failure to properly implement procedures required by the [FDCA] and the FDA regulations, and as a result of [Medtronic's] postmarket negligence, the product became defective and unreasonably dangerous prior to being implanted in Plaintiff Ronald J. McAfee [on July 21, 2006].

[Doc. No. 19 at pp. 10-11].

The amended complaint contains four theories of liability:

(1) Strict Liability – Mr. McAfee alleges that the lead was defective and unreasonably dangerous as a result of inadequate warnings, in violation of 21 U.S.C. §§ 331(a), 351(f)(1)(b), 352(t), 360i, and 360(f), 21 C.F.R. §§ 803.50, 814.82(a)(9), 814.84, 820.198(a)(1), and 820.198(a)(3), and IND. CODE §§ 34-20-2-2 and 34-20-4-2;

(2) Breach of Express Warranty – Medtronic allegedly misrepresented that the lead was safe for implantation and for its use with a pacemaker-defibrillator, when it knew of should have known that it was subject to

fracture and causing inappropriate shocks, in violation of 21 U.S.C. §§ 331(a), 351(f)(1)(b), 21 CFR § 814.82(a)(9), and IND. CODE §§ 26-1-2-313;

(3) Breach of Implied Warranty of fitness for a particular purpose, in violation of 21 U.S.C. §§ 331(a), 351(f)(1)(b), 21 CFR § 814.82(a)(9), and IND. CODE §§ 26-1-2-315, 26-1-2-314, and 34-20-4-1; and

(4) Negligence – Mr. McAfee alleges that Medtronic was negligent in: designing, manufacturing, and marketing the lead; failing to warn, monitor, and report adverse events as required by Medical Devices Amendments, PMA, conditions of approval, and FDA regulations; and representing that the lead was suitable for its intended purpose, when it was not.

Medtronic moved to dismiss all four claims with prejudice, contending that the claims are:

(1) expressly and/or impliedly preempted under the Medical Device Amendments to the Federal Drug and Cosmetic Act, *see* Riegel v. Medtronic, Inc., 552 U.S. 312; 21 U.S.C. § 360k(a)(expressly preempted); Buchman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001); 21 U.S.C. § 337(a) (impliedly preempted);

(2) inadequately pleaded; and/or

(3) barred by IND. CODE § 34-20-4-4 (codifying Comment k to § 402A of the Restatement (Second) of Torts).

In response, Mr. McAfee argues that:

(1) the claims based on failure to warn (Counts I and IV) aren't expressly or impliedly preempted by the MDA because he alleges violations of federal laws and parallel state laws, *citing* Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996); Stengel v. Medtronic, Inc., 704 F.3d 1224 (9th Cir. 2013), *cert. denied*, 134 S.Ct. 2839 (2014); Bausch v. Stryker Corp., 630 F.3d 546, 549 (7th Cir. 2010), *cert. denied*, 132 S.Ct. 498 (2011).

(2) Comment k to § 402A of Restatement (Second) (IND. CODE § 34-20-4-4) "parallels the requirements of the MDA and other federal statutes and regulations which call for proper warning" and doesn't bar any of the claims asserted.

(3) All claims have been sufficiently pleaded given the limited information available to the plaintiff, but should the court disagree, Mr. McAfee asserts that he should be allowed to conduct discovery related to the design and manufacture of the Sprint Fidelis Lead (Model No. 6949) and to amend his complaint "upon complete disclosure of the design and manufacturing process."

II. STANDARD OF REVIEW

When considering a Rule 12(b)(6) motion to dismiss, the court must construe the complaint in the light most favorable to the plaintiff, accept all well-pleaded facts as true, and draw all inferences in her favor. Reynolds v. CB

Sports Bar, Inc., 623 F.3d 1143, 1146 (7th Cir. 2010). But Fed. R. Civ. P. 8(a)(2) "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007)). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. at 678 (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. at 570); *see also* Morrison v. YTB Int'l, Inc., 649 F.3d 533, 538 (7th Cir. 2011); Brooks v. Ross, 578 F.3d 574, 581 (7th Cir. 2009). A claim is plausible if "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. at 678; Bell Atlantic Corp. v. Twombly, 550 U.S. at 555 (the allegations "must be enough to raise a right to relief above the speculative level" and give the defendant fair notice of the claims being asserted and the grounds upon which they rest). *See also* Swanson v. Citibank, N.A., 614 F.3d 400, 404 (7th Cir. 2010)("the plaintiff must give enough details about the subject-matter of the case to present a story that holds together.").

III. DISCUSSION

A. *Failure to Warn*

Mr. McAfee devoted most of his response to the failure to warn claims asserted in Counts I and IV of his complaint, contending that those claims aren't subject to preemption by the Medical Devices Amendments and should not be dismissed because they're plausible under Medtronic v. Lohr, 518 U.S. 470 (1996) and Stengel v. Medtronic, Inc., 704 F.3d 1224, 1232-33 (9th Cir. 2013), *cert. denied*, 134 S.Ct. 2839 (2014). He concludes that the express and implied warranty claims are also premised on a failure to warn (as evidenced by ¶¶ 47, 55, and 62 which incorporate by reference the allegations in Count I), and therefore not subject to preemption.

The Medical Devices Amendments provide that:

> [N]o 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).[2] It also has a preemption provision that provides that all actions to enforce the FDA requirements must be "by and in the name of the

[2] An exception in subsection (b) permits the FDA to exempt some state and local requirements from preemption. Riegel v. Medtronic, Inc., 552 U.S. at 316.

United States," 21 U.S.C. § 337(a), and bars suits by private litigants "for noncompliance with the medical device provisions." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001).

Mr. McAfee's failure to warn claims are based on state tort law, not fraud-on-the-agency, and aren't impliedly preempted under Buckman. *See* Bausch v. Stryker Corp., 630 F.3d at 557; Stengel v. Medtronic, Inc., 704 F.3d at 1233; Hughes v. Boston Scientific Corp., 631 F.3d 762, 771 (5th Cir. 2011). But they might be expressly preempted if they're not premised on a violation of a state-law duty that parallels a federal-law duty under the Medical Devices Amendments. Riegel v. Medtronic, Inc., 552 U.S. at 330; Buckman v. Plaintiffs, 531 U.S. 341; Medtronic, Inc. v. Lohr, 518 U.S. 470; Stengel v. Medtronic, Inc., 704 F.3d 1224; Hughes v. Boston Scientific Corp., 631 F.3d at 765; Bausch v. Stryker Corp., 630 F.3d at 549, 558; In re Medtronic,Inc., Sprint Fidelis Leads Products Liability Litigation, 623 F.3d 1200 (8th Cir. 2010) ("The plaintiff must be suing for conduct that violates the [FDCA] (or else his claim is expressly preempted by 360k(a)), but the plaintiff must not be suing because the conduct violates the [FDCA] (such a claim would be impliedly preempted under *Buckman*).")

> In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are "*genuinely equivalent*." Bates [v. Dow Agrosciences LLC, 544 U.S. 431, 454 (2005)] (emphasis in original). State and federal requirements are not genuinely equivalent if the manufacturer could be held liable under state law without having vioalted the federal law.

McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005); *see also* Stengel v. Medtronic Inc., 704 F.3d at 1231; Bausch v. Stryker Corp., 630 F.3d at 552; 21 C.F.R. 808.1(d)(2) (state requirements not preempted if they "are equal to, or substantially identical to, requirements imposed by or under the act").

To the extent Mr. McAfee's claims are premised on Medtronic's alleged failure to provide an additional warning to physicians about the risks of fracturing and shock associated with the Sprint Fidelis Model Lead, as alleged in ¶¶ 28-30 of the amended complaint, those claims impose a requirement that differs from, or adds to, the federal requirements at issue here (which only required Medtronic to report adverse events to the FDA, not physicians or the ultimate consumer), are expressly preempted by the Medical Devices Amendments, and must be dismissed. *See* 21 U.S.C. § 360k(a); Riegel v. Medtronic, Inc., 552 U.S. at 321-322; McMullen v. Medtronic, Inc., 421 F.3d at 488; Mitchell v. Collogen Corp., 126 F.3d 902, 913-914 (7th Cir. 1997).

If, however, the state-law failure to warn claims are premised on Medtronic's failure to file adverse event reports with the FDA and the duty to warn extends to third parties like the FDA under Indiana law, the state regulation/requirement would parallel, rather than add to, the federal requirement, and wouldn't be preempted under the Medical Devices Amendments. *See* Stengel v. Medtronic, Inc., 704 F.3d at 1232-1233 (claims arose under Arizona law); Hughes v. Boston Scientific Corp., 631 F.3d at 771 (claims arose under Mississippi law); Bausch v.

Stryker Corp., 630 F.3d at 552 (claims arose under Illinois law). *But compare* In re Medtronic, Inc., Sprint Fidelis Leads Product Liability Litigation, 623 F.3d 1200, 1205-1206 (8th Cir. 2010) (claims based on failure to file adverse event reports "are simply an attempt by private parties to enforce the MD" foreclosed by implied preemption). Neither party addresses the breadth of Indiana's Product Liability Act, but the amended complaint alleges that Medtronic violated the PMA and conditions of approval by failing to file timely adverse event reports, and contains allegations of a general failure to warn, as well as the specific allegations about failing to warn physicians. When, as here, "the hypotheses are consistent with the complaint," the court gives Mr. McAfee "the benefit of imagination." Bausch v. Stryker Corp., 630 F.3d at 559. Mr. McAfee has stated plausible claims for relief under state law based on an alleged failure to warn the FDA and so denies Medtronic's motion to dismiss those claims.

B. *Negligent Design and Manufacture*

Mr. McAfee alleges that the Medtronic was negligent in the marketing of its leads in one or more of the following ways:

a. designing the lead;

b. manufacturing the lead;

c. failing to properly market the lead;

d. failing to provide adequate warnings…as required by the [FDCA], FDA regulations and [state law];

> e. in representing that the lead was suitable for its intended purpose;
>
> f. failing to monitor the lead as required by the [FDCA] and FDA regulations;
>
> g. failing to report adverse events…to the FDA…as required by the [FDCA], FDA regulations, the product's premarket approval order, and the CONDITIONS OF APPROVAL….

(Amd. Cmplt. at ¶ 66). He alleges that each of these acts, alone or in combination, proximately caused his injuries and damages; that the doctrine of *res ipsa loquitar* applies; and that "[he] cannot more specifically allege the acts of negligence on the part of Defendant, for the reason that the facts in that regard are peculiarly within the knowledge of the Defendant." (Amd. Cmplt. at ¶¶ 67 and 68).

For the reasons already stated, Mr. McAfee's negligence claims aren't preempted to the extent they are premised on a failure to comply with the FDCA, FDA regulations, or FDA-approved specifications and protocols set forth in premarket approval standards. *See* Stengel v. Medtronic, Inc., 704 F.3d 1224; Bausch v. Stryker Corp., 630 F.3d 546; Waltenburg v. St. Jude Medical, Inc., 33 F.Supp.3d 818 (W.D. Ky. 2014); Hawkins v. Medtronic, Inc., 909 F.Supp.2d 901 (S.D. Ohio 2012).

But Class III devices, by their very nature, pose a potential risk of injury to patients, and so are subject to heightened scrutiny by the FDA. *See* Riegel v. Medtronic, Inc., 552 U.S. at 317; 21 U.S.C. 360(a)(1)(C)(ii). "[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." Id. at 323. "It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." Id. at 318.

Mr. McAfee doesn't allege that Medtronic violated any federal law, regulation, or requirement when it designed or manufactured the leads at issue or that the leads he received deviated from specifications and protocols set forth in premarket approval standards. While he isn't required to allege a violation of a "concrete, devise-specific" federal regulation to avoid preemption at this stage of the proceedings, Bausch v. Stryker Corp., 630 F.3d at 554-556, Federal Rule of Civil Procedure 8(a)(2) "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Ashcroft v. Iqbal, 556 U.S. at 678. The conclusory allegations in paragraphs 66(a), (b), (c), and (e) and paragraph 68 of the amended complaint offer nothing more.

To the extent Mr. McAfee alleges that Medtronic is liable under a theory of *res ipsa loquitur* even if it adhered to the design, manufacturing, and marketing standards required by the FDA in the pre-market approval of the leads, his claims are preempted by the Medical Devices Amendments, 21 U.S.C. § 360k(a), and must be dismissed. *See* Riegel v. Medtronic, Inc., 552 U.S. 312; Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296 (11th Cir. 2011); Gomez v. St. Jude Medical Daig Division, Inc., 442 F.3d 919 (5th Cir. 2006); Waltenburg v. St. Jude, 33 F.Supp.3d

818; Martin v. Medtronic, Inc., 32 F.Supp.3d 1026 (D. Ariz. 2014); Caplinger v. Medtronic, Inc. 921 F.Supp.2d 1206, 1222 (W.D. Okl. 2013); Sons v. Medtronic, Inc., 915 F.Supp.2d 776 (W.D. La. 2013); Duggan v. Medtronic, Inc., 840 F.Supp.2d 446 (D. Mass. 2012). The dismissal, however, is without prejudice, and Mr. McAfee will be given a reasonable opportunity to amend his complaint, if appropriate, as the case proceeds. *See* Bausch v. Stryker Corp., 630 F.3d at 549.

IV. CONCLUSIONS

For these reasons, Medtronic's motion to dismiss [Doc. No. 22] is GRANTED in part, and DENIED in part. The motion is DENIED as to all claims premised on an alleged failure to warn the FDA, and GRANTED in all other respects. The remaining claims (those based on any theory other than a failure to warn the FDA) are DISMISSED without prejudice.

SO ORDERED.

ENTERED: June 4, 2015

/s/ Robert L. Miller, Jr.
Judge, United States District Court