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2019 Jul-22 AM 10:27
U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

JONATHAN DAVID GRUBBS,	)	
	)	
Plaintiff,	)	
	)	Civil Action Number
vs.	)	**2:18-cv-01468-AKK**
	)	
MEDTRONIC, INC., et al.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Jonathan David Grubbs brings this products liability action based on alleged defects in a pain pump manufactured by the Medtronic Defendants. According to Grubbs, the pain pump malfunctioned several months after his physician implanted it in Grubbs' body, necessitating a subsequent surgery to replace the pump with one made by another manufacturer. Medtronic moves to dismiss all but one of Grubbs' claims, arguing that the failure-to-warn (Count II) and implied warranty (Count IV) claims are preempted, the warranty claims (Counts III and IV) fail under Alabama law, and the negligent misrepresentation claim (Count V) is insufficiently pleaded. Docs. 6 and 7. Because the failure-to-warn claim is preempted by federal law and Grubbs did not plead the negligent misrepresentation fraud claim with the requisite particularity, the motion to dismiss is due to be granted as to these two claims.

I. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 8(a)(2), a pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." "[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Mere "'labels and conclusions'" or "'a formulaic recitation of the elements of a cause of action'" are insufficient. *Id.* at 678 (quoting *Twombly*, 550 U.S. at 555). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Id*. (quoting *Twombly*, 550 U.S. at 557).

Federal Rule of Civil Procedure 12(b)(6) permits dismissal when a complaint fails to state a claim upon which relief can be granted. When evaluating a motion brought under Rule 12(b)(6), the court accepts "the allegations in the complaint as true and construe[s] them in the light most favorable to the plaintiff." *Hunt v. Aimco Props., L.P.*, 814 F.3d 1213, 1221 (11th Cir. 2016). However, "[t]o survive a motion to dismiss, a complaint must . . . 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). A complaint states a facially plausible claim for relief "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the

defendant is liable for the misconduct alleged." *Id*. In other words, the complaint must establish "more than a sheer possibility that a defendant has acted unlawfully." *Id.*; *see also Twombly*, 550 U.S. at 555 (explaining that "[f]actual allegations [included in the complaint] must be enough to raise a right to relief above the speculative level.").

II. FACTUAL BACKGROUND

Grubbs suffers from chronic back pain, which his physician, Dr. Thomas Kraus, treated by implanting in Grubbs' abdomen a SynchroMed® II Programmable Implantable Infusion Pump System with sutureless catheter (the "Device") manufactured by Medtronic. Doc. 1 at 2, 4, 7. The Device delivered a programmed amount of pain medication into Grubbs' spine. *Id.* at 4. The first Device performed as designed. *Id.* at 4-5. The claims in this lawsuit are related to the second Device Dr. Kraus implanted after the first Device reached the end of its seven-year battery life. *Id.* This second SynchroMed® II Device controlled Grubbs' pain for several months, and then began to stall and fail to deliver the appropriate amount of medication. *Id.* at 5. This resulted in increased pain and medication withdrawal, which led to additional surgery during which Dr. Kraus replaced the Device with a different type of pain pump. *Id.*

III. STATUTORY AND REGULATORY BACKGROUND

Congress enacted the Medical Device Amendments ("MDA") of 1976, 21 U.S.C. § 360k *et seq.*, to the Food, Drug, and Cosmetic Act to give the Food & Drug Administration "regulatory authority over medical devices for human use." *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1325 (11th Cir. 2017) (citation omitted). "Under that authority, the FDA classifies medical devices into three categories, depending on the level of risk presented." *Id.* (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316-17 (2008)). Class III devices, such as the SynchroMed® II Device, present the highest category of risk and must "undergo the FDA's 'premarket approval' process." *Id.* (citing 21 C.F.R. § 814.1).[1]

"Premarket approval is a 'rigorous' process," *Riegel*, 552 U.S. at 317-18 (citations omitted), requiring medical device manufacturers "to demonstrate a 'reasonable assurance' that the device is both 'safe and effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof,'" *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001) (citing 21 U.S.C. §§360e(d)(2)(A)-(B)). During the process, the FDA reviews, among many other things, the manufacturer's proposed labeling for the device, and "must determine that the proposed labeling is neither false nor misleading . . . ." *Riegel*,

[1] Class III medical devices include devices that are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in prevention impairment of human health" or that "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii).

552 U.S. at 318 (citing §§ 360c(a)(2)(B) and 360e(d)(1)(A)). The FDA "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* (citing § 360e(d)). After a device is approved, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specification, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319 (citing § 360e(d)(6)(A)(i)). In addition, after premarket approval, the MDA imposes a continuing duty on manufacturers to report certain information to the FDA, "including new studies about the device and any adverse events." *Mink*, 860 F.3d at 1325 (citing § 360i). *See also Riegel*, 552 U.S. at 319 (citing 21 C.F.R. § 803.50(a)).

IV. ANALYSIS

The FDA granted premarket approval for the original Class III SynchroMed® II Device in 1988. Docs. 1 at 7; 7-1 at 2.[2] Since then, the FDA has approved multiple supplemental applications for modifications. *See* docs. 1 at 7; 7-1. The specific type of Device implanted in Grubbs received premarket approval in 2003. *See* docs. 1 at 4; 7-2. Based on this premarket approval, Medtronic argues in part that certain claims pleaded by Grubbs are preempted. The court

[2] The court may take judicial notice of Medtronic's exhibits relating to the FDA's premarket approval for the Device because it is a public government record whose authenticity is not disputed. *See* Fed. R. Evid. 201(b)(2).

turns now to the motion to dismiss, and the parties' respective contentions as to each claim at issue.

A. Failure to Warn Claim—Count II

Medtronic argues that Grubbs' failure to warn claim is preempted by the MDA. Section 360(k)(a) of the MDA expressly preempts "any claim based on a state law requirement 'which is different from, or in addition to, any requirement' under the MDA that 'relates to the safety or effectiveness of the device' or any other MDA requirement." *Mink*, 860 F.3d at 1317 (quoting 21 U.S.C. § 360k(a)). In other words, "duties imposed by state law are preempted only to the narrow extent that they add different or extra requirements to the safety and effectiveness of the medical device beyond those required by the federal scheme." *Id.* at 1326. However, "'[p]arallel' state duties survive so long as they claim a violation of state tort law that aligns with a federal requirement." *Id.* (citing *Riegel*, 552 U.S. at 330).

To determine if a claim is expressly preempted, a court must determine (1) whether the Federal Government has established requirements applicable to the device; and (2) if the plaintiff's state law claims are based upon any state law duties or requirements "that are different from, or in addition to, the federal [requirements], and that relate to the safety and effectiveness" of the device. *Id.* (quoting *Wolicki-Gables v. Arrow International, Inc.*, 634 F.3d 1296, 1301 (11th

Cir. 2011)). The first prong is not in contention, and Grubbs concedes that devices that are subject to premarket approval, such as the SynchroMed® II Device, satisfy this inquiry. *See Thomas v. Alcon Labs.*, 116 F. Supp. 3d 1361, 1367 (N.D. Ga. 2013) (citations omitted). *See also Riegel*, 552 U.S. at 322-23. For the second prong, generally, if the state law claim merely parallels federal requirements, without imposing addition or different duties related to the device, then express preemption will not apply. *Riegel*, 552 U.S. at 330.

Even when express preemption does not apply, certain state law claims related to medical devices may be impliedly preempted by the MDA. Section 337(a) provides, for example, that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Thus, section 337(a) impliedly preempts state tort claims that seek to enforce a duty owed by a manufacturer to the FDA. *Mink*, 860 F.3d at 1327 (citing *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001)). But, "traditional state-law tort claims survive implied preemption so long as [the plaintiff does not] seek to privately enforce a duty owed to the FDA." *Id.* Stated differently, sections 360(k)(a) and 337(a) work together to create a "'narrow gap' for pleadings," and "[t]o make it through, a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding

implied preemption)." *Mink*, 860 F.3d at 1237 (citing *In re Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). In other words, Grubbs "may proceed on [his] [failure to warn] claim so long as []he claims the 'breach of a well-recognized duty owed to [him] under state law' and so 'long as []he can show that []he was harmed by a violation of applicable federal law.'" *Id.* (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010)).

With this framework in mind, the court turns to the specific contentions in the Complaint. Grubbs pleads that Medtronic breached its alleged duty to disclose risks regarding the SynchroMed® II Device "to users and purchasers, including the FDA," by failing to report adverse events and problems with the Device and by failing to "submit FDA-mandated Medical Device Reports . . . ." Doc. 1 at 29. To the extent that Grubbs bases his claim on Medtronic's failure to directly inform him or his physicians about adverse events related to the Device, "any attempt to predicate [Grubbs'] claim on an alleged state law duty to warn doctors directly would have been expressly preempted under 21 U.S.C. § 360k . . . ." *Stengel v. Medtronic*, 704 F.3d 1224, 1232 (9th Cir. 2013), cert. denied, 134 S. Ct. 2839 (2014)).

Grubbs does not appear to dispute that conclusion. *See* docs. 17 at 7-9; 20 at 3. Rather, Grubbs argues that his claim is not expressly preempted because he "seeks redress under state law for Medtronic's failure to make the necessary and

appropriate disclosures to the FDA for the benefit of Grubbs and others like him." Doc. 17 at 7. But only the FDA can bring a cause of action for a manufacturer's failure to make disclosures to the Agency as required by the MDA. *See Buckman*, 531 U.S. at 347-48; *Mink*, 860 F.3d at 1327, 1330. In that respect, similar to the impliedly preempted claims in *Mink*, Grubbs' failure to warn claims are based on allegations that Medtronic "'failed to adequately investigate adverse events and complaints and failed to properly report these issues to the FDA.'" *Mink*, 860 F.3d at 1330 (quotation omitted). *See also Godelia v. Doe 1*, 881 F.3d 11309, 1320 (11th Cir. 2018) ("[The plaintiff's] claims would have been impliedly preempted if he were asking the court to find [the device manufacturer] liable based solely on a failure to report to the FDA . . . ."). Moreover, Grubbs did not cite to any authority for the proposition that Alabama law imposes a duty on medical device manufacturers to warn a federal agency of dangers associated with a device, and the court has found no such authority. *See* docs. 17 and 20.[3] Consequently, the MDA preempts Grubbs' failure to warn claim.

[3] Alabama has adopted the learned-intermediary doctrine, meaning that a prescription medical device manufacturer's duty to warn extends to physicians. *See Stone v. Smith, Line & French Labs.*, 447 So. 2d 1301, 1304-05) (Ala. 1984). Because the FDA does not automatically make all adverse event reports available to the public or physicians, *see* 21 C.F.R. § 803.9(a), a manufacturer cannot discharge its duty to warn physicians by reporting adverse events to the FDA.

B. Breach of Implied Warranty Claim—Count IV

Medtronic argues next that the breach of implied warranty of merchantability claim is also expressly preempted by the MDA, and alternatively, that Grubbs has failed to allege a plausible claim under Alabama law. Doc. 7 at 11-13. As to the latter contention, the U.C.C., which Alabama has adopted, provides in part that "'a warranty that the goods shall be [fit for the ordinary purposes for which such goods are used] is implied in a contract for their sale . . .'" *Shell v. Union Oil Co.*, 489 So. 2d 569, 571 (Ala. 1986) (quoting Ala. Code § 7-2-314). This implied warranty is not breached if a product performs "the job it was intended to do," and "hazards inherent in the use of the product" caused injury to an individual. *Id.* at 572. Accordingly, "[i]n general, Alabama law does not recognize a cause of action for breach of implied warranty of merchantability for inherently dangerous products." *Barnhill v. Teva Pharma. USA, Inc.*, 819 F. Supp. 2d 1254, 1263 (S.D. Ala. 2011). Indeed, "courts applying Alabama law have seen fit to subsume U.C.C.-based breach of implied warranty claims into tort and product liability claims, where the product is fit for its intended use and there is no evidence of 'non-merchantability' other than a general allegation that the product contains inherent dangers." *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 523 (2007) (citation omitted).

As an implantable Class III medical device, the SynchroMed® II Device is an inherently dangerous product. *See Emody v. Medtronic, Inc.*, 238 F. Supp. 2d 1291, 1296 (N.D. Ala. 2003) (finding at summary judgment that "an implantable, prescription-only medical device" is an unavoidably unsafe product) (citing *Stone v. Smith, Kline & French Laboratories*, 447 So. 2d 1301 (Ala. 1984) and *Purvis v. PPG Indus., Inc.*, 502 So. 2d 714, 718 (Ala. 1987)). This fact does not automatically warrant dismissal because Grubbs does not base his breach of implied warranty of merchantability claim on "a general allegation that the product contains inherent dangers." *See Bodie*, 236 F. App'x at 523. Instead, Grubbs cites Medtronic's alleged failures to manufacture the Device in accordance with the FDA's requirements. Doc. 1 at 26, 34. In that respect, this case is distinguishable from the Alabama cases involving inherently dangerous products due to Grubbs' contention that the Device implanted in him was not fit for its intended use in light of Medtronic's alleged failures to comply with FDA regulations. Doc. 1 at 33-34. Consequently, Medtronic has not shown at this juncture that Grubbs failed to plead a plausible breach of implied warranty claim under Alabama law.

As for Medtronic's primary contention that this claim is expressly preempted by the MDA, as noted above, the SynchroMed® II Device satisfies the first prong of the test for express preemption. *See* pp. 6-7, *supra*. As for the second prong, Grubbs' implied warranty claim relates to the safety and

effectiveness of the Device. *See* doc. 1 at 33-34. As such, under the relevant law, express preemption requires a finding that that the implied warranty claim is based on requirements that are "different from, or in addition to" any federal requirements imposed by the MDA. *See* 12 U.S.C. § 360k(a). Here, however, Grubbs alleges that the SynchroMed® II Device was not fit for its intended purpose due to Medtronic purportedly failing to manufacture and label the Device in accordance with FDA's regulations. Allegedly, Medtronic failed "to control production processes to ensure that a device conforms to its specification," and failed "to review, evaluate, and investigate complaints involving the possible failure of a device . . . ." Doc. 1 at 12-19, 34. These alleged breaches describe failures to comply with requirements imposed on Medtronic by the FDA and parallel the federal requirements for the device, rather than imposing different or additional requirements. Therefore, based on the pleadings, Medtronic has not shown that the implied warranty claim is preempted by the MDA.

C. <u>Breach of Express Warranty Claim--Count III</u>

Medtronic also argues that Grubbs failed to allege the existence of an express warranty. Doc. 7 at 13-14. Under Alabama law, an express warranty is created by "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain . . . [and] [a]ny description of the goods which is made part of the basis of the bargain . . . ."

Ala. Code. § 7-2-313(1). "[B]ut an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." *Id.* at § 7-2-313(2).

The Complaint pleads that Medtronic represented the SynchroMed® II Device as a (1) "safe effective, reliable medical device[]; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, including the controlled release of Morphine for the treatment of patients suffering from chronic and severe pain;" (2) "a safer way to receive pain medication" that would "reduce [a patient's] need for oral pain medication;" and (3) as "conform[ing] to FDA regulations and specifications." Doc. 1 at 8, 31. These alleged statements exceed mere affirmation of the value of the Device or Medtronic's opinion or commendation regarding the Device, and are sufficient to plead an express warranty claim under Alabama law. Whether Grubbs will ultimately succeed on the claim is a matter for another day. At this juncture of the case, because Grubbs expressly alleges that he relied on Medtronic's representations in deciding to have the SynchroMed® II Device implanted, doc. 1 at 31, Grubbs has sufficiently alleged the existence of an express warranty for this claim to survive a motion to dismiss.

D. Negligent Misrepresentation Claim—Count V

Finally, Medtronic argues that Grubbs did not state his negligent misrepresentation claim with sufficient particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure. Doc. 7 at 14-16. Under Alabama law, a "negligent misrepresentation constitutes legal fraud." *Bank v. Talmage Kirkland & Co.*, 155 So. 3d 231, 238 (Ala. 2014) (citing Ala. Code. § 6-5-101 ("Misrepresentations of a material fact made willfully to deceive, or recklessly without knowledge, and acted on by the opposite party, or if made by mistake and innocently and acted on by the opposite party, constitute legal fraud.")). To state a valid claim, Grubbs must plead "(1) a false representation (2) concerning a material existing fact (3) relied upon by the plaintiff (4) who was damaged as a proximate result." *Fisher v. Comer Plantation, Inc.*, 772 So. 2d 455, 463 (Ala. 2000). In addition, Grubbs "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). This requires Grubbs to allege:

> (1) precisely what statements or omissions were made in which documents or oral representations; (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) them; (3) the content of such statements and the manner in which they misled the plaintiff; and (4) what the defendant obtained as a consequence of the fraud.

Findwhat Investor Grp. v. FindWhat.com, 658 F.3d 1282, 1296 (11th Cir. 2011) (citations omitted).

Here, Grubbs alleges that Medtronic made certain statements "[i]n their marketing," and "marketed the SynchroMed® II Device directly to patients through conversations with Medtronic employees, patient testimonials, and colorful brochures with images of individuals smiling and pain medication patients riding motorcycles." Doc. 1 at 8. These contentions fall short of alleging which documents, if any, contain the alleged statements. And, relatedly, Grubbs' allegation that, prior to the implantation of the Device, Medtronic "negligently misrepresented to [] Grubbs and his medical providers that the SynchroMed® II Device implanted in [] Grubbs was safe and effective," *id.* at 34-35, falls short of stating the precise statements made, or the time and place of the alleged misrepresentations. In light of Grubbs' failure to allege fraud with particularity as required by Rule 9(b), his negligent misrepresentation claim is due to be dismissed without prejudice to replead.[4]

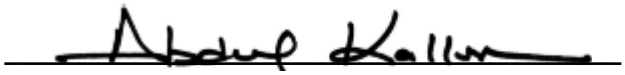
[4] Medtronic also argues that Alabama law does not recognize negligent misrepresentation claims in this context. Doc. 7 at 15-16. While the Supreme Court of Alabama "adopted the Restatement (Second) of Torts § 552 (1977) as the law of [Alabama] in cases involving negligent misrepresentations relied upon by third parties, or parties who were not in privity of contract with the person making the misrepresentation," the Court has not limited negligent misrepresentation claims to professionals such as accountants or real estate appraisers. *Fisher v. Comer Plantation, Inc.*, 772 So. 2d 455, 462 (Ala. 2000). And, the Eleventh Circuit indicated that a plaintiff may have a basis for a negligent misrepresentation claim against a drug manufacturer if the manufacturer "knew or should have known of [the drug's] harmful effects and did not tell [the plaintiff] . . . ." *Legg v. Wyeth*, 428 F.3d 1317, 1324 (11th Cir. 2005). Thus, Medtronic's contention is unavailing.

V. CONCLUSION AND ORDER

Medtronic's motion to dismiss, doc. 6, is **GRANTED** as to the failure to warn (Count II) and negligent misrepresentation (Count V) claims. These claims are **DISMISSED WITHOUT PREJUDICE**. In all other respects, the motion, doc. 6, is **DENIED**.

The parties are **ORDERED** to submit a Rule 26(f) report to this court by September 3, 2019 that has this case ready for trial in March 2021.

DONE the 22nd day of July, 2019.



ABDUL K. KALLON
UNITED STATES DISTRICT JUDGE