[Dkt. Ent. 14]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

JACK MILLMAN, et al., Plaintiffs, v. MEDTRONIC, Defendant.	Civil Action No. 14-cv-1465 **OPINION**

Appearances:

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Bumb, United States District Judge:

Defendant Medtronic, Inc. ("Medtronic" or "Defendant") moves to dismiss the Amended Complaint filed by Plaintiffs Jack and Janet Millman ("Plaintiffs") pursuant to Federal Rules of Civil Procedure 12(b)(6), 9(b) and 8(a)(2). For the reasons that follow, the motion is granted. Plaintiffs, however, will

be given 30 days to file a motion for leave to file an amended complaint consistent with this Opinion.

A. Amended Complaint

Plaintiffs' Amended Complaint alleges Jack Millman has Parkinson's Disease, for which "a medical device (a DBS Patient Programmer) [is] inserted into his body to regulate his brain activity." Compl. ¶ 9. He alleges that he has had four Medtronic devices implanted during surgeries on April 12, 2005, April 9, 2009, May 10, 2011 and September 17, 2013. Compl. ¶¶ 1, 24-25, 32, 34, and 37. Plaintiffs aver that the first three devices had to be replaced due to "defective product and/or battery." Compl. ¶¶ 4-6, 111.

Plaintiffs further allege that after each of Mr. Millman's four surgeries he met with "Mike," a Medtronic representative, who allegedly "advised Plaintiffs each time that the devices were malfunctioning, and that they needed to be replaced with a different type of device." Compl. ¶¶ 35-36. According to Plaintiffs, "Mike" made unspecified misrepresentations to them, and he omitted unspecified information. Compl. ¶¶ 39-40. Through "Mike" and the Medtronic brochures and operating manuals, Plaintiffs allege they were "assured" Mr. Millman was a candidate for the Medtronic device and would receive properly manufactured and functioning devices. As a result, they decided

that Mr. Millman would undergo the four surgeries. Compl. ¶ 68, 72.

Plaintiffs claim Mr. Millman's health has deteriorated since the surgeries and his life activities are impaired. Compl. ¶¶ 47-66, 82. Plaintiffs also allege that their insurance company was billed more than $32,000 for the April 2009 surgery, of which Plaintiffs had to pay $125. Compl. ¶ 77. Also, Plaintiffs assert they are being billed more than $5,000 for the surgery on September 13, 2013. See Compl. ¶ 78. Plaintiffs allege Mr. Millman was and continues to be billed for a defective medical device. Compl. ¶ 87. Plaintiffs have attached bills and a collection demand from Pennsylvania Hospital as exhibits to their Amended Complaint.

Plaintiffs have pled twelve counts against Medtronic for: 1) violation of the New Jersey Consumer Fraud Act; 2) consumer fraud in billing Plaintiffs for a defective device; 3) consumer fraud because Medtronic intentionally misrepresented and/or omitted the integrity of the device; 4) common law fraud for misrepresentations and omissions; 5) strict liability for product defect; 6) failure to warn of defect; 7) breach of warranty; 8) negligent design and/or manufacture; 9) negligence for product defect; 10) negligence/carelessness; 11) negligence for not maintaining the integrity of products design and manufacturing; and 12) breach of contract.

Defendant advances several arguments in support of its motion to dismiss, to which the Court now turns.

B. Motion to Dismiss

A Rule 12(b)(6) motion to dismiss for failure to state a claim upon which relief may be granted must be denied if the plaintiff's factual allegations are "enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true, (even if doubtful in fact)." Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955, 1965 (2007) (internal citations omitted). Moreover, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, . . . a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. at 1965 (internal citations omitted).

A district court must accept any and all reasonable inferences derived from those facts. Unger v. Nat'l Residents Matching Program, 928 F.2d 1392 (3d Cir. 1991); Glenside West Corp. v. Exxon Co., U.S.A., 761 F. Supp. 1100, 1107 (D.N.J. 1991); Gutman v. Howard Sav. Bank, 748 F. Supp. 254, 260 (D.N.J. 1990). Further, the court must view all allegations in the Complaint in the light most favorable to the plaintiff. See Scheuer v. Rhodes, 416 U.S. 232, 236 (1974); Jordan v. Fox,

Rothschild, O'Brien & Frankel, 20 F.3d 1250, 1261 (3d Cir. 1994).

Therefore, in deciding a motion to dismiss, a court should look to the face of the complaint and decide whether, taking all of the allegations of fact as true and construing them in a light most favorable to the nonmovant, plaintiff has alleged "enough facts to state a claim for relief that is plausible on its face." Twombly, 127 S. Ct. at 1974. Only the allegations in the complaint, matters of public record, orders, and exhibits attached to the complaint, are taken into consideration. Chester County Intermediate Unit v. Pennsylvania Blue Shield, 896 F.2d 808, 812 (3d Cir. 1990).

Defendant has moved to dismiss the Amended Complaint, first, on the ground that federal law expressly preempts the claims asserted by Plaintiffs. Specifically, Defendant contends that Plaintiffs' claims based on product defect, failure to warn, consumer fraud, breach of warranty, and negligence are all squarely preempted by Amendments of the Food Drug and Cosmetic Act ("FDCA").

1. Preemption Under the Medical Device Amendments

The Medical Devices Amendments ("MDA"), 21 U.S.C. § 360c et seq. to the FDCA, 21 U.S.C. § 301 et seq., authorize the FDA to regulate the safety and effectiveness of medical devices. Under the MDA, medical devices are divided into three categories

according to the risks that the devices present. The parties do not dispute that the device in this case was a Class III device. 21 U.S.C. § 360(c)(a)(1)(C). The MDA usually requires Class III devices to receive premarket approval before the FDA will allow them to be sold. The FDA will approve the devices for distribution only if it is satisfied that the device is reasonably safe and effective for its intended purpose. 21 U.S.C. § 360(e)(d)(2).

At the outset, the Court notes that Medtronic avers that Plaintiffs mistakenly identify the devices implanted into Mr. Millman as "DBS Patient Programmers," see Compl. ¶ 9, but that the DBS Patient Programmer is actually a handheld device that is not implanted and is used to program and adjust the settings of implanted devices that are part of the Activa Deep Brain Stimulation System ("Activa System"). According to Medtronic, the exhibits attached to and incorporated by reference into the Amended Complaint make clear that what was actually implanted into Mr. Millman are implantable pulse generators and leads that are part of the Activa System. Because Plaintiffs do not dispute this fact, the Court will assume it as true. Medtronic contends that the Activa System's design, construction, manufacturing, warning labeling and testing were all reviewed and approved by the FDA. Dismissal of Plaintiffs' claims is therefore required because they are all preempted by the MDA, as

interpreted by the Supreme Court in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), and many other courts since.

Enacted in 1976, the MDA granted the FDA exclusive authority to regulate medical devices and created a comprehensive "regime of detailed federal oversight." Riegel, 552 U.S. at 316. Recognizing the "und[e] burden[]" imposed by differing state regulations, Congress adopted a "general prohibition on non-Federal regulation" of medical devices. H.R. Rep. No. 94-853, at 45 (1976). Codified at 21 U.S.C. § 360k(a), the MDA's express-preemption provision specified that no state may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable . . . to the device" under federal law. 21 U.S.C. § 360k(a).

A Class III device such as the Activa System[1] must receive FDA's Premarket Approval ("PMA") before it may be brought to market, and "incur[s] the FDA's strictest regulation." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 343 (2001). The PMA process is the most exacting form of FDA review for devices. Obtaining "[p]remarket approval is a 'rigorous' process." Riegel, 552 U.S. at 317 (internal citations omitted). FDA "grants premarket approval only if it finds there is a

[1] As mentioned, Plaintiffs do not dispute this fact.

'reasonable assurance' of the device's 'safety and effectiveness.'" Id. (quoting 21 U.S.C. § 360e(d)).

> To obtain FDA's PMA approval, a manufacturer: Must submit a detailed PMA application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information.

Riegel v. Medtronic, Inc., 451 F.3d 104, 109 (2d Cir. 2006), aff'd 552 U.S. 312 (2008).

FDA closely and rigorously scrutinizes PMA applications, "'weigh[ing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" Riegel, 552 U.S. at 318 (quoting 21 U.S.C. § 360(a)(2)(C). As part of the PMA process, FDA must review a device's proposed labeling to "evaluate safety and effectiveness under the conditions of use set forth on the label," and "determine that the proposed labeling is neither false nor misleading." Id. (quoting § 360e(d)(1)(A)). If FDA decides a device's design, manufacturing methods, or labeling should be revised, it can require revisions before approval. See id. at 319 (citing 21 C.F.R. § 814.44e).

"Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission,

changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. (citing 21 U.S.C. § 360e(d)(6)(A)(i)). A manufacturer wishing to make such changes must submit a PMA Supplement and may not implement the proposed changes without FDA approval. See id. The PMA Supplement is subject to the same rigorous standards of review as an initial PMA application. Id. The MDA also imposes post-approval reporting obligations on manufacturers. FDA regulations require manufacturers "to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of . . . and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." Id. (citing 21 C.F.R. §§ 803.50(a), 814.84(b)(2)).

Medtronic contends that through 21 U.S.C. § 360k(a) Congress has expressly preempted state-law claims like Plaintiffs' claims that challenge the safety or effectiveness of a medical device approved by the FDA via the PMA process. Defendants rely upon the Supreme Court's decision in Riegel as well as many subsequent decisions addressing this issue.

In Riegel, the plaintiffs brought a personal injury suit against Medtronic, the manufacturer of a Class III, PMA-

approved, balloon catheter that ruptured during the plaintiffs' angioplasty procedure. The plaintiffs asserted state-law product liability claims, including strict liability, breach of implied warranty, and negligence. See Riegel, 552 U.S. at 312. The Supreme Court, however, held that each of the plaintiffs' state law claims was preempted. Id. at 322-23, 330. The Court explained that the MDA preemption clause establishes a two-step procedure for determining if state law claims are preempted. First, a court must determine whether "the Federal Government has established requirements applicable to" the particular medical device. Id. at 321. If it has, the court then must determine whether the state law claims raised by the plaintiffs would impose "requirements with respect to the device that are 'different from, or in addition to'" the federal requirements and that relate to either (i) "safety or effectiveness" or (ii) "any other matter included in a requirement applicable to the device [under the MDA, 21 U.S.C.] § 360k(a)." Id. at 321-23. If both conditions are satisfied, then the claim is preempted.[2]

[2] There is a narrow exception to express preemption for claims that "'parallel,' rather than add to, federal requirements." Riegel, 552 U.S. at 330 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996)). To be "parallel," a claim must rest on the violation of a state-law requirement that is "identical" to the alleged violation of a federal requirement. Lohr, 518 U.S. at 495. To state a "parallel" claim, a plaintiff must allege (1) the violation of a specific federal requirement applicable to the device; (2) the violation of an identical state-law duty; and (3) that the predicate federal violation

The FDA has set forth specific requirements for the device at issue in this case, the Activa System. Thus, the first step of the Riegel analysis is met. As for the second step, the Court must decide whether Plaintiffs' claims are based on state requirements that "are different from or in addition to" the federal PMA requirements and whether those requirements relate to safety and effectiveness. Because the FDA determined, by granting PMA, that the Activa System was safe and effective as manufactured and designed in the PMA application, this Court finds that Plaintiffs' claims based on a manufacturing defect, design defect, failure to warn, negligence and a breach of contract/warranty theory are preempted because they impose requirements that are different from the federal requirements set forth in the PMA process. Each claim, as currently alleged, seeks to impose requirements that are either different from or in addition to those required by federal law.

Since Riegel, "courts across the country [including the Third Circuit] have applied Section 360k(a) broadly, preempting claims from strict products liability and negligence, to breach of warranty, to failure to warn and manufacturing-and-design-

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caused his or her injuries. See, e.g., Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1300-01 (11th Cir. 2011). Here, Plaintiffs' Complaint does not plead a parallel claim.

defect, to negligence per se." In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009), aff'd 623 F.3d 1200 (8th Cir. 2010); see also Williams v. Cyberonics, Inc., 388 F. App'x 169, 171 (3d Cir. 2010) ("Appellants' allegations of strict products liability based on manufacturing defect and breach of warranty are pre-empted by the MDA."); Desai v. Sorin CRM USA, Inc., No. 12-2995, 2013 WL 163298, at *4-6 (D.N.J. Jan. 15, 2013) (finding that the plaintiffs' claims under the N.J. Products Liability Act were preempted); Hayes v. Howmedica Osteonics Corp., No. 08-6104, 2009 WL 6841859, at *6 (D.N.J. Dec. 15, 2009) (finding that a failure to warn claim is preempted); Delaney v. Stryker Orthopaedics, No. 08-03210, 2009 WL 564243, at *3 (D.N.J. Mar. 5, 2009) (holding that "the MDA preempts products liability claims, including" failure to warn, defective design, negligence and breach of implied warranty); Gross v. Stryker, 858 F. Supp. 2d 466, 490 (W.D. Pa. 2012) (stating that breach of implied warranty is a state claim "that imposes requirements that are different [from], or in addition to, specific federal requirements"); Betzley v. Medtronic, Inc., 827 F. Supp. 2d 443, 453 (E.D. Pa. 2011) (deciding that design defect claims are preempted); Mayen v. Tigges, No. 7411/11, 2012 WL 3553378, at *1 (N.Y. Sup. Ct. Aug. 17, 2012) (holding that the plaintiff's state law claims for design and manufacturing defect, negligent

design, failure to warn and breach of warranties were preempted by the FDA through the PMA process for Class III medical devices).

As stated by one court, "Riegel is loud and clear: if a manufacturer complies with the premarket approval, it gets a free pass on [products liability and implied breach of warranty] claims." Williams v. Cyberonics, 654 F. Supp. 2d 301, 306 (E.D. Pa. 2009), aff'd 388 F. App'x 169 (2010). Plaintiffs lament that preemption would effectively leave them without any recourse. As such, they aver, this could not possibly be what Congress intended. The dissent in Riegel, in fact, voiced the same lamentation. The Riegel majority, however, explained it this way:

> [T]his is exactly what a pre-emption clause for medical devices does by its terms. The operation of a law enacted by Congress need not be seconded by a committee report on pain of judicial nullification. See, e.g., Connecticut Nat. Bank v. Germain, 503 U.S. 249, 253-54 (1992). It is not our job to speculate upon congressional motives. If we were to do so, however, the only indication available -- the text of the statute -- suggests that the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 . . . to all innovations.

Riegel, 552 U.S. at 326.

Thus, for the foregoing reasons, Plaintiffs' consumer fraud claims (Counts 1, 2 and 3), common law fraud (Count 4), strict

liability (Count 5), failure to warn (Count 6),[3] breach of warranty (Count 7),[4] negligent design/manufacture (Count 8),[5] negligence (Count 9 and 10), failure to maintain integrity (Count 11) and breach of contract (Count 12) are all preempted because they are all theories of liability relating to the safety or effectiveness of the device and seek to impose additional requirements upon Defendant.

2. Other Grounds for Dismissal

Medtronic argues for dismissal of the Complaint on the independent ground that Plaintiffs have failed to allege any facts supporting their bare legal claims. As such, these claims

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[3] Plaintiffs do not allege that Medtronic failed to provide any warnings required by FDA through the PMA process. To the extent Plaintiffs assert that, to comply with state law, Medtronic was required to give additional or different warnings than those required by FDA, this claim is preempted.

[4] See, e.g., Fidelis Leads, 592 F. Supp. 2d at 1164 (warranty claims preempted because "the safety and effectiveness of [PMA-approved devices] are matters solely for the FDA"); see also, e.g., Timberlake v. Synthes Spine, Inc., No. V-08-4, 2011 WL 711075, at *7 (S.D. Tex. Feb. 18, 2011) (finding express warranty claim preempted where "a jury would . . . have to decide that the [device] was unsafe and ineffective in order to find that Defendants breached these warranties").

[5] It is important to note that Plaintiffs do not allege the design or manufacture of the Activa System devices deviated in any way from the design, manufacture or warning approved by the FDA through the PMA process. Thus, to prevail on their state-law design, manufacturing and failure to warn claims, Plaintiffs necessarily would have to prove that the Activa System devices should have employed a design, manufacture or label different from that approved by the FDA. Riegel squarely forecloses any such claim. Cf. 552 U.S. at 320 (MDA preempts "claims of strict liability . . . and negligence in the design" of a device.)

fail under Ashcroft v. Igbal, 129 S. Ct. 1937 (2009) and Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). Although this Court finds that Plaintiffs' claims are preempted (with the caveat discussed below), the Court does agree that Plaintiffs failed to allege facts in support of their non-fraud-based claims and, thus, the claims must be dismissed for this reason as well.

As for Plaintiffs' fraud-based claims, a plaintiff must satisfy the even more rigorous pleading requirements of Fed. R. Civ. P. 9(b) "requiring that facts be pleaded with particularity," including "the 'who, what, when, where, and how of the events at issue.'" Kanter v. Barella, 489 F.3d 170, 175 (3d Cir. 2007) (quoting In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d Cir. 1997)). Plaintiffs' consumer fraud and common law fraud claims fall short of satisfying the heightened pleading requirements under Rule 9(b).

While Plaintiffs claim to have relied on Medtronic's representations, they do not identify any specific representations or omissions they purportedly considered in deciding to have the devices implanted. Although Plaintiffs assert a Medtronic representative named "Mike" made representations to Mr. Millman around the time of each of his surgeries, Plaintiffs do not describe the substance of these representations that "Mike" purportedly made, identify the

"malfunctions" that "Mike" allegedly pointed out, describe which representations were purportedly false or state what allegedly omitted information would have changed Mr. Millman's decisions to have the Medtronic devices implanted. See Compl. ¶ 35-36, 39-40. To the extent Plaintiffs allege Medtronic failed to disclose a product defect (see Compl. ¶ 116), Plaintiffs have failed to plead Medtronic knew of the purported defect. See Gotthelf v. Toyota Motor Sales, U.S.A., Inc., 525 F. App'x 94, 104 (3d Cir. 2013) (under failure to disclose defect theory, plaintiff must show defendant "knowingly, with the intent of inducing reliance, conceal[ed], suppress[ed], or omit[ed] a material fact").

Moreover, Plaintiffs do not identify any representations or advertisements about the devices upon which they purportedly relied prior to Mr. Millman's decision to consent to implantation of the Medtronic devices in the first instance. Plaintiffs state critical information was omitted but do not explain what that information was, how it would have changed Mr. Millman's decision or why they believe there was a duty to disclose it. Compl. ¶¶ 13, 40, and 90. Plaintiffs include as an exhibit to the Amended Complaint a manual related to Mr. Millman's devices, but allege Mr. Millman received this manual only after he underwent his second surgery. Compl. ¶ 29. He has also failed to specify what if anything about the manual's

content that he believes is deceptive. Accordingly, Plaintiffs' claims sounding in fraud fail to state a claim under Rule 9(b) as well.[6]

C. Conclusion

Although the Court has dismissed all counts of the Complaint for the reasons set forth above, the Court does so with the following caveat. The Court assumes that Plaintiffs have not alleged any "parallel claims." In other words, the Court does not interpret any of Plaintiffs' claims as alleging that the Activa System did not conform to federal requirements. See, e.g., Perez v. Nidek Co., Ltd., 711 F.3d 1109, 1117 (9th Cir. 2013) ("MDA does not preempt a state-law claim for violating state-law duty that parallels a federal-law under the MDA"). To the extent Plaintiffs intend to assert such claim(s), they must be alleged in accordance with the Twombly and Iqbal standards set forth above. Moreover, if the claim is that Medtronic (through its agent "Mike") intentionally made false and misleading claims about the device to induce Mr. Millman to undergo the surgeries, such claims would not be barred under Riegel as a fraud-in-the-inducement claim does not impose a requirement different from, or in addition to, the PMA requirements. However, Plaintiffs must satisfy Rule 9(b)'s

[6] Because the Court finds that Plaintiffs' claims as currently pled are preempted and insufficiently pled, the Court does not address Defendant's arguments.

requirements. To allege that Defendant knew that its product was defective and dangerous but nevertheless marketed it (Pl. Br. at 12) is conclusory and does not state a claim under Rule 12(b)(6). Finally, if the claim Plaintiffs allege relates to Defendant's improper billing for a product Plaintiffs never received or received but should not have to pay for because of its defect [their defects], this claim would not be preempted.[7]

Renée Marie Bumb
RENÉE MARIE BUMB
United States District Judge

Dated: February 24, 2015

[7] Even if these foregoing claims, once amended, did survive a motion to dismiss, it is not clear this Court would have subject matter jurisdiction, given that damages appear to be under $75,000. As such, in the event Plaintiffs choose to amend the Complaint, this Court's subject matter jurisdiction will need to be addressed.