UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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TAMMI BRANDT, Plaintiff, v. MEDTRONIC, INC., et al., Defendants.	Case No. 2:14-cv-01112-MMD-NJK ORDER (Def.'s Motion to Dismiss – dkt. no. 26.)

I. SUMMARY

Plaintiff asserts claims for injuries resulting from implantation of a medical device. Before the Court is Defendant Medtronic, Inc.'s Motion to Dismiss ("Motion") (dkt. no. 26). The Court has reviewed Plaintiff Tammi Brandt's response (dkt. no. 28) and Medtronic's reply brief (dkt. no. 29). For the reasons discussed below, the Motion is granted; and Plaintiff is granted leave to amend.

II. BACKGROUND

In 2000, Medtronic developed the Enterra Therapy System ("the Device" or "the Enterra Device"), a medical device designed to treat gastroparesis, a stomach condition that leads to chronic nausea and vomiting. (Dkt. no. 1 at 7.) Plaintiff, who suffers from gastroparesis, had the Device implanted in May 2009. (*Id.* at 8.) Plaintiff has since suffered pain, nervous system damage, and additional problems with her digestive system because, she claims, the implanted Device has "broken, malfunctioned or otherwise failed." (*Id.*) Plaintiff alleges that her problems with the Device are the result of the Device's "defective design, warnings, construction and unreasonably dangerous

character." (*Id.*) She claims that Defendant concealed these defects; had she been aware of them, she would not have consented to having the Device implanted. (*Id.*)

Plaintiff initiated this lawsuit in Nevada state court in June 2014, asserting claims for negligence, strict products liability, inadequate warning, breach of express warranty and the implied warranty of merchantability, and negligent and intentional misrepresentation. (*Id.* at 9-17.) Medtronic learned of the filing before being served with the Complaint; it removed the action to this Court on July 8, 2014, on the basis of diversity jurisdiction. (*Id.* at 2-3.) Medtronic moved to dismiss the Complaint in April 2015. (Dkt. no. 26.)

III. LEGAL STANDARD

A court may dismiss a plaintiff's complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). A properly pleaded complaint must provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). While Rule 8 does not require detailed factual allegations, it demands more than "labels and conclusions" or a "formulaic recitation of the elements of a cause of action." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555). "Factual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. Thus, "[t]o 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.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570).

In *Iqbal*, the Supreme Court clarified the two-step approach district courts are to apply when considering motions to dismiss. First, a district court must accept as true all well-pleaded factual allegations in the complaint; however, legal conclusions are not entitled to the assumption of truth. *Id.* at 678. Mere recitals of the elements of a cause of action, supported only by conclusory statements, do not suffice. *Id.* Second, a district court must consider whether the factual allegations in the complaint allege a plausible claim for relief. *Id.* at 679. A claim is facially plausible when the plaintiff's complaint

alleges facts that allow a court to draw a reasonable inference that the defendant is liable for the alleged misconduct. *Id*. at 678. Where the complaint does not "permit the court to infer more than the mere possibility of misconduct, the complaint has alleged — but it has not 'shown' — 'that the pleader is entitled to relief.'" *Id*. at 679 (alteration omitted) (quoting Fed. R. Civ. P. 8(a)(2)). When the claims in a complaint have not crossed the line from conceivable to plausible, the complaint must be dismissed. *Twombly*, 550 U.S. at 570. A complaint must contain either direct or inferential allegations concerning "all the material elements necessary to sustain recovery under *some* viable legal theory." *Id.* at 562 (quoting *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1106 (7th Cir. 1984)).

IV. ANALYSIS

The Motion raises two theories for dismissal: first, Plaintiff's claims are entirely preempted by federal law, and second, the Complaint is inadequately pleaded. (Dkt. no. 26 at 2.) The gist of the preemption argument is that the Device is heavily regulated under the premarket approval ("PMA") process of the Food and Drug Administration ("FDA"), such that state law claims that exceed or differ from the governing federal laws must yield to the federal regulatory scheme.[1] Because the Court finds that the preemption arguments are dispositive of the Motion, the Court will not reach the sufficiency of the pleadings.

A. Background on Federal Regulation of Medical Devices

The 1976 Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA") created an express preemption clause to facilitate better federal

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[1]Medtronic asks the Court to take judicial notice of several documents relating to the Device's regulation by the FDA. (Dkt. no. 27.) Courts may "'take judicial notice of matters of public record outside the pleadings' and consider them for purposes of [a] motion to dismiss.'" *Mir v. Little Co. of Mary Hosp.*, 844 F.2d 646, 649 (9th Cir. 1988) (quoting *MGIC Indem. Corp. v. Weisman*, 803 F.2d 500, 504 (9th Cir. 1986)). Medtronic's documents are online public records of the Device's PMA process. (*See* dkt. no. 27.) The Court will consider them in analyzing the Motion.

regulation of complex medical devices. *Riegel v. Medtronic*, 552 U.S. 312, 315-16 (2008). The clause prohibits any state (and any political subdivision of a state) from:

> establish[ing] or continu[ing] 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). The MDA additionally created a multi-level regulatory scheme that classifies medical devices into three categories: Class I, Class II, and Class III. *Riegel*, 552 U.S. at 316-17; *see* 21 U.S.C. § 360c. The Enterra Device falls into Class III, the most stringently regulated category. (*See* dkt. no. 27-5 at 2-4 (approving the Device for commercial distribution after a premarket analysis).) "If a device cannot be determined to provide a reasonable assurance of safety and effectiveness under Class I or II controls and is either marketed as a life-supporting device or may cause an unreasonable risk of illness or injury, it is a Class III device." *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1226 (9th Cir. 2013) (en banc).

Class III devices are subjected to a "rigorous" PMA process, during which the FDA reviews, among other documents, reports about the device's safety, a full documentation of the device's components, a description of the device's manufacturing and processing methods and facilities, and samples of the device and its labeling. *Riegel*, 552 U.S. at 318. "The FDA spends an average of 1,200 hours reviewing each [premarket] application." *Id.* After receiving 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.* at 319. PMA recipients also retain an ongoing obligation to update and inform the FDA of certain incidents involving a device's safety. *Id.* at 319-20.

The FDA's PMA review of the Enterra Device proceeded through a humanitarian device exemption ("HDE"), which applies to devices designed to treat or diagnose conditions that affect "fewer than 4,000 individuals in the United States per year." (Dkt.

no. 27-4 at 2.) The HDE review process is similar to the PMA process, but HDE alleviates the need to demonstrate scientifically "that the device is effective for its intended purpose." (*Id.*) Before approving a device through an HDE review, the FDA must find that "the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use." 21 U.S.C. § 360j(m)(2)(C). The Enterra Device received HDE approval in March 2000. (Dkt. no. 27-5 at 2-4.)

B. Express Preemption

In *Riegel*, the Supreme Court held that the MDA's express preemption provision, 21 U.S.C. § 360k(a), applied to common-law tort claims directed toward a Class III device. 552 U.S. at 322-25. Because § 360k(a) applies only to "requirement[s] applicable" to a regulated device, the Court first assessed whether federal regulations constitute "requirements" that could be displaced by state laws. *See id.* at 321-22. The PMA process, the Court reasoned, imposes "federal safety review" requirements that are specific to covered devices; the PMA process therefore "imposes 'requirements' under the MDA." *Id.* at 322. Next, the Court examined whether common-law tort claims would qualify as state-level requirements, which are "different from, or in addition to," the PMA process, and which "relate[] to the safety or effectiveness of the device." 21 U.S.C. § 360k(a); *see Riegel*, 552 U.S. at 323-24. Looking at other statutes' use of the phrase "requirement," the Court concluded that, for § 360k(a) purposes, "a State's 'requirements' includes its common-law duties." *Riegel*, 552 U.S. at 324. The Court therefore affirmed the lower courts' dismissal of the plaintiffs' strict liability, implied warranty, and negligence claims. *Id.* at 320, 330. The Court clarified, however, that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330.

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Here, there is no dispute that the Enterra Device was subjected to a PMA process, albeit through an HDE.[2] (Dkt. no. 26 at 8; dkt. no. 28 at 3.) In light of the Device's premarket review, Medtronic insists that § 360k(a) bars Plaintiff's common-law claims for negligence, strict liability, breach of warranty, and fraudulent misrepresentation. (Dkt. no. 26 at 8-10.) In each claim, Plaintiff generally asserts that Medtronic designed, manufactured, produced, and distributed a fundamentally flawed product, and failed to disclose or accurately represent those flaws to the public. (*See* dkt. no. 1 at 9-17.) Plaintiff's negligence claim, for example, alleges that Defendant breached a duty to exercise reasonable care "in the designing, researching, manufacturing, marketing, supplying, promoting, sale, quality assurance, quality control, instruction, warning, distribution and/or recall of the Enterra Device." (*Id.* at 9.) Defendant's failure to exercise due care began, Plaintiff alleges, "at the earliest date that it became known to Defendants that the device was, in fact, dangerous and defective." (*Id.*) Plaintiff's strict products liability claims similarly allege that "[a]t all times relevant herein, the Enterra Device was designed, manufactured, advertised, promoted, marketed, sold, and/or distributed by Defendants in an unsafe, defective, and inherently dangerous condition." (*Id.* at 10; *see id.* at 12 (alleging that despite Defendants' knowledge of the Device's failure rate, they "failed to give consumers adequate warning of such risks").) Her warranty claims further suggest that the Device fails to conform to Defendant's promises of its effectiveness and safety. (*Id.* at 13-14.) Finally, the misrepresentation claims aver that Defendant misled the public, Plaintiff, and her physicians "regarding the quality, safety and effectiveness of the Enterra Device." (*Id.* at 15; *see id.* at 16 (alleging that Defendant intentionally made false statements and concealed knowledge about the Device's safety).)

[2]Plaintiff asserts, without citing any legal authority, that the HDE process does not trigger the preemptive effects of § 360k(a). (Dkt. no. 28 at 3.) But, as Medtronic points out, the *Riegel* Court explicitly referenced an HDE device as an example of a device subject to FDA's premarket approval process. 552 U.S. at 318; (*see* dkt. no. 29 at 8 n.2). Plaintiff's unsupported argument is not persuasive.

These common-law allegations fit within the broad preemptive reach of § 360k(a). *See Riegel*, 552 U.S. at 324. Plaintiff's general assertions stretch from the Device's inception and design through its manufacturing and distribution — processes that would be covered and controlled by the HDE approval process. Furthermore, Plaintiff's allegations that Medtronic misled and failed to warn the public about the Device's safety issues expand on the FDA's existing PMA protocols for device labeling. *See id.* at 318 ("The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label . . . and must determine that the proposed labeling is neither false nor misleading.") To the extent these claims could be read as alleging that Medtronic misled the FDA while seeking HDE approval, they still warrant dismissal — the Supreme Court has rejected such "fraud-on-the-FDA" claims as impliedly preempted by the MDA. *Stengel*, 704 F.3d at 1229 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001)). As alleged, Plaintiff's common law claims add to, and differ from, the HDE premarket approval process that applied to the Enterra Device. Federal law therefore preempts Plaintiff's claims, and dismissal is proper.

C. Parallel State-Law Claims

In opposing the Motion, however, Plaintiff argues that her claims qualify for an exception to preemption under § 360k(a). Under this logic, Plaintiff's claims suggest that Medtronic violated Nevada law by withholding information from the FDA after obtaining PMA of the Enterra Device, or by failing to monitor the product for defects once it was on the market. (Dkt. no. 28 at 3-4.) Rather than differing from, or adding to, the FDA's PMA process, these claims run parallel to federal requirements and are not preempted by § 360k(a). *See Riegel*, 552 U.S. at 330.

The Ninth Circuit has determined that a similar failure-to-warn claim brought under Arizona's negligence laws was not preempted by § 360k(a). *Stengel*, 704 F.3d at 1232-34. There, the claim alleged that the defendant had a continuing duty under federal law to monitor, discover, and report any problems with an approved medical device to

the FDA. *Id.* at 1232. The plaintiffs alleged that the defendant's failure to carry out its federal duty constituted a breach of "its 'duty to use reasonable care' under Arizona negligence law." *Id.* Rather than expand or modify an existing federal duty, the Arizona negligence claim simply sought to hold the defendant accountable under state law for failing to carry out a federal-law duty — that is, to notify the FDA of "information 'reasonably suggesting' that one of its devices 'may have caused or contributed to a death or serious injury.'" *Id.* at 1234 (Watford, J., concurring) (alteration omitted) (quoting 21 C.F.R. § 803.50(a)). The Ninth Circuit accordingly held that § 360k(a) did not preempt the Arizona negligence claim. *Id.* at 1233.

As they currently stand, Plaintiff's claims fall short of alleging a state-law claim that runs parallel to federal requirements. She does allege, however, that Medtronic "failed to exercise reasonable care" in overseeing "quality assurance [and] quality control" of the Device. (Dkt. no. 1 at 9.) She further claims that Medtronic withheld known safety risks from the public. (*Id.* at 15-16.) Plaintiff does not specify when Medtronic learned of those safety risks — if they arose after the Device's PMA, then Plaintiff may be able to make out a claim to hold Medtronic accountable under state law for breaching a parallel duty under federal law. *See Stengel*, 704 F.3d at 1232-34. Because the Court cannot conclude that Plaintiff would be unable to cure the preemption issues that currently plague the Complaint, the Court will grant Plaintiff leave to amend.

V. CONCLUSION

The Court notes that the parties made several arguments and cited to several cases not discussed above. The Court has reviewed these arguments and cases and determines that they do not warrant discussion or reconsideration as they do not affect the outcome of Medtronic's Motion.

It is therefore ordered that Medtronic's Motion to Dismiss (dkt. no. 26) is granted. If Plaintiff wishes to attempt to cure the preemption issues noted above, she has leave to file an amended complaint within fourteen (14) days of the date of this Order. Failure to

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file an amended complaint within this deadline will result in dismissal of this action with prejudice.

DATED THIS 31st day of March 2016

MIRANDA M. DU
UNITED STATES DISTRICT JUDGE