UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN KUBICKI & KAREN KUBICKI ON BEHALF OF CAROLINE KUBICKI,

Plaintiffs,

v.

MEDTRONIC, *ET AL.*,

Defendants.

Civil Action No. 12-00734 **(CKK)**

MEMORANDUM OPINION
(March 21, 2013)

Plaintiffs John Kubicki and Karen Kubicki ("Plaintiffs") bring this products liability action on behalf of Caroline Kubicki, as her parents and legal guardians, against Defendants Medtronic, Inc., Medtronic Diabetes, and Medtronic Minimed, Inc. (collectively "Defendants"). Presently before the Court is Defendants' [4] Motion to Dismiss. Upon careful consideration of the parties' submissions, the applicable authorities, and the record as a whole,[1] the Court shall **GRANT-IN-PART** and **DENY-IN-PART** Defendants' motion. Specifically, the Court shall dismiss, without prejudice, Plaintiffs' misrepresentation, fraud, and unlawful trade practices claims due to Plaintiffs' failure to plead these claims with sufficient particularity as required by Federal Rule of Civil Procedure 9(b). The Court shall also dismiss Plaintiffs' implied warranty claims as duplicative of their strict products liability claims. However, the Court shall deny

[1] While the Court renders its decision on the record as a whole, its consideration has focused on the following documents: Pls' Compl., *See* Original File, ECF No. [9-1]; Defs' Mot. to Dismiss ("Defs' Mot."), ECF No. [4]; Pls' Response in Opp'n to Defs' Mot. to Dismiss ("Pls' Opp'n"), ECF No. [14]; Defs' Reply in Supp. of Mot. to Dismiss ("Defs' Reply"), ECF No. [15]. In an exercise of its discretion, the Court finds that holding oral argument on the instant motion would not be of assistance in rendering a decision. *See* LCvR 7(f).

Defendants' motion insofar as it argues that all of Plaintiffs' claims are expressly and impliedly preempted by federal law. Accordingly, Plaintiffs' remaining claims – specifically, negligence, strict liability, express warranties, and failure to warn – survive dismissal.

I. BACKGROUND

The following facts from Plaintiffs' Complaint are accepted as true for purposes of the Court's resolution of Defendants' motion to dismiss. This case arises out of Caroline Kubicki's use of the Medtronic MiniMed Paradigm REAL-Time Insulin Infusion Pump Model MMT-522 (the "522 Pump"), a prescription medical device indicated for management of diabetes that is manufactured and sold by Defendants. When functioning properly, the 522 Pump administers insulin to the user on a continuous or intermittent basis as needed by the user. Compl. ¶ 12. This process is accomplished through a small syringe in the pump which is connected to the user by way of a small cannula and a serious of electronics and complex algorithms which calculate the insulin dosage necessary for the user throughout the day and night. *Id.* Plaintiffs allege that on September 9, 2007, Ms. Kubicki's 522 Pump malfunctioned, causing her to suffer a hypoglycemic episode – *i.e.*, critically low blood glucose levels – which rendered her unresponsive and unarousable and resulted in a temporary coma and severe and permanent brain injury. *Id*. ¶¶ 16-19. Ms. Kubicki currently resides in a group home due to the constant care that she requires for her activities of daily living. *Id*. ¶ 19.

On March 29, 2012, Plaintiffs, acting on behalf of Ms. Kubicki in their capacity as her parents and legal guardians, filed the instant Complaint in District of Columbia Superior Court, which Defendants subsequently removed to this Court, *see* Notice of Removal, ECF No. [1]. Plaintiffs' Complaint alleges that Defendant Medtronic, Inc., Defendant Medtronic Diabetes (a division of Medtronic, Inc.), and Defendant Medtronic MiniMed, Inc. (a subsidiary of

Medtronic, Inc.) are each engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce the 522 Pump, Compl. ¶¶ 3-8. Plaintiffs' Complaint asserts the following counts against all Defendants: negligence,[2] strict liability,[3] misrepresentation by seller,[4] fraud,[5] express warranties,[6] implied warranties,[7] violation of the District of Columbia Unlawful Trade Practices Act, D.C. Code § 28-3904,[8] and failure to warn.[9] Plaintiffs assert entitlement to compensatory and punitive damages, *see* Compl., Counts XXV-XXVIII, and pray for judgment against Defendants, individually and collectively, in the amount of fifty million dollars, and for additional aggravating circumstances damages, costs, and fees. Compl. at 44.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) provides that a party may move to dismiss on the grounds that the complaint "fail[s] to state a claim upon which relief can be granted." A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief," FED .R. CIV. P. (8)(a), "in order to give the defendant fair notice of what the ... claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555,

[2] *See* Compl., Counts I, II, and III (each asserted, without variation, against Medtronic, Inc., Medtronic Diabetes, and Medtronic MiniMed Inc., respectively).
[3] *See* Compl., Counts Counts IV, V, and VI (each asserted, without variation, against Medtronic, Inc., Medtronic Diabetes, and Medtronic MiniMed Inc., respectively).
[4] *See* Compl., Counts VII, VIII, and IX (each asserted, without variation, against Medtronic, Inc., Medtronic Diabetes, and Medtronic MiniMed Inc., respectively).
[5] *See* Compl., Counts X, XI, and XII (each asserted, without variation, against Medtronic, Inc., Medtronic Diabetes, and Medtronic MiniMed Inc., respectively).
[6] *See* Compl., Counts XIII, XIV, and XV (each asserted, without variation, against Medtronic, Inc., Medtronic Diabetes, and Medtronic MiniMed Inc., respectively).
[7] *See* Compl., Counts XVI, XVII, and XVIII (each asserted, without variation, against Medtronic, Inc., Medtronic Diabetes, and Medtronic MiniMed Inc., respectively).
[8] *See* Compl., Counts XIX, XX, XXI (each asserted, without variation, against Medtronic, Inc., Medtronic Diabetes, and Medtronic MiniMed Inc., respectively).
[9] *See* Compl., Counts XXII, XXIII, XXIV (each asserted, without variation, against Medtronic, Inc., Medtronic Diabetes, and Medtronic MiniMed Inc., respectively).

127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (citation omitted). Although "detailed factual allegations" are not necessary to withstand a Rule 12(b)(6) motion to dismiss for failure to state a claim, a plaintiff must furnish "more than labels and conclusions" or "a formulaic recitation of the elements of a cause of action." *Id.* "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009). "Nor does a complaint suffice if it tenders naked assertion[s] devoid of further factual enhancement." *Id*. (citation omitted). Rather, a complaint must contain sufficient factual allegations that, if accepted as true, "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 663.

In evaluating a Rule 12(b)(6) motion to dismiss, a court may consider "the facts alleged in the complaint, documents attached as exhibits or incorporated by reference in the complaint," or "documents upon which the plaintiff's complaint necessarily relies even if the document is produced not by [the parties]." *Ward v. D.C. Dep't of Youth Rehab. Servs.*, 768 F. Supp. 2d 117, 119 (D.D.C. 2011) (citations omitted). The court must construe the complaint in a light most favorable to the plaintiff and must accept as true all reasonable factual inferences drawn from well-pleaded factual allegations. *In re United Mine Workers of Am. Employee Benefit Plans Litig.*, 854 F. Supp. 914, 915 (D.D.C. 1994); *see also Schuler v. United States*, 617 F.2d 605, 608 (D.C. Cir. 1979) ("The complaint must be 'liberally construed in favor of the plaintiff,' who must be granted the benefit of all inferences that can be derived from the facts alleged."). While the court must construe the complaint in the plaintiff's favor, it "need not accept inferences drawn by the plaintiff if such inferences are unsupported by the facts set out in the complaint."

Kowal v. MCI Comm'ns Corp., 16 F.3d 1271, 1276 (D.C. Cir. 1994). Moreover, the court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555 (citation omitted)*; accord Taylor v. FDIC*, 132 F.3d 753, 762 (D.C. Cir. 1997).

III. DISCUSSION

Defendants assert several arguments as to why Plaintiffs' Complaint should be dismissed. First, Defendants argue that the Complaint must be dismissed in its entirety because Plaintiffs' claims are expressly preempted by the Medical Device Amendment ("MDA"), 21 U.S.C. § 360k, to the Federal Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq*. Second, Defendants argue that, to the extent Plaintiffs' claims seek to enforce the provisions of the FDCA and the implementing regulations of the Food and Drug Administration ("FDA"), they are impliedly preempted as explained by the Supreme Court in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and precluded by the "no private right of action" provision of the FDCA, 21 U.S.C. § 337(a), which prohibits private plaintiffs from directly enforcing federal law. Third, Defendants argue that, in addition to being preempted, Plaintiffs' claims for misrepresentation, fraud, and violation of the District of Columbia Unlawful Trade Practices Act are barred for the separate and independent reason that Plaintiffs have not sufficiently pled these claims because they fail to articulate any misrepresentations made to them by Defendants. Fourth, Defendants argue that Plaintiffs' breach of implied warranty claims must be dismissed because they are pled in conjunction with strict products liability claims, but Plaintiffs fail to allege any contractual privity with Defendants. Finally, Defendants argue that because no amendment would cure the foregoing defects in Plaintiffs' complaint, the Court should dismiss Plaintiffs' case in its entirety, without leave to amend.

The Court shall address each of Defendants' arguments in turn.

A. Express Preemption

Congress enacted the MDA to extend the coverage of the FDCA to medical devices. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996). The MDA divides medical devices into three categories, based upon the risks that the devices pose to the public. *Id*. at 477. Class III devices are subject to the greatest level of oversight because they "present[ ] a potential unreasonable risk of illness or injury" or 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 preventing impairment of human health." *Id*. at 478 (citing § 360c(a)(1)(C)). Before a manufacturer may introduce a new Class III device to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is safe and effective through a "rigorous" process known as "premarket approval" – widely referred to as "PMA." *Id*. at 478 (citing 21 U.S.C. § 360e(d)(2)). After the FDA grants premarket approval to a device, its regulatory efforts do not end, as the manufacturer continues to have various reporting and other post-approval obligations to the agency. Most notably for this case, once the FDA approves a device, the manufacturer is required to report to the FDA any information that reasonably suggests that the device (1) "[m]ay have caused or contributed to a death or serious injury" or (2) "[h]as malfunctioned" and that any recurring malfunction "would be likely to cause or contribute to a death or serious injury." 21 C.F.R. § 803.50(a); *see* 21 U.S.C. § 360i(a).

In addition to separating medical devices into three categories, the MDA contains an express preemption provision, which provides, in pertinent part:

> [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).

In *Riegel v. Medtronic, Inc.*, the Supreme Court established a two-step analysis for determining whether state law claims are preempted by the MDA. 552 U.S. 312, 321-23, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008). First, the court must decide that the federal government has established "specific requirements" applicable to the particular medical device in question. *Id*. If so, the court must then find that the plaintiff's claims are based on "state requirements" related to safety and effectiveness that are "different from, or in addition to" the federal requirements. *Id*. If both prongs are met, the state law claim is preempted by § 360k(a). As the *Riegel* Court made clear, included in the meaning of "state requirements" subject to federal preemption are negligence, strict liability, and other common law causes of action. *Id*. at 324-25, 327-28.

As Defendants correctly contend, state law claims for alleged injuries relating to medical devices approved pursuant to the PMA process automatically satisfy the first condition because, as the Supreme Court explained in *Riegel*, "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application[.]" 552 U.S. at 322-32. Defendants aver that the 522 Pump is a Class III medical device that was approved by the FDA through the rigorous PMA process on April 7, 2006, which approval remains in place to this day, and they request the Court to take judicial notice of this fact. *See* Defs' Mot. at 3-5 & Defs' Request for Judicial Notice in Supp. of Mot. to Dismiss (with Exhibits). *See also, e.g.*, *Koutny v. Martin*, 530 F. Supp. 2d 84, 89 (D.D.C. 2007) (noting that a court "may take judicial notice of matters of a general public nature" without converting a motion to dismiss into motion for summary judgment).

Plaintiffs counter that the FDA's PMA approval is a limited approval, which extends only to the ability of the larger 522 system (which combines the insulin delivery method of the 522 Pump with the glucose monitoring capability of Medtronic's Guardian RT sensor) to read data gathered by its sensor and for the sensor to communicate directly to the pump. *See* Pls' Opp'n at 6-9. The broader system itself (including its component 522 Pump), Plaintiffs argue, was never subject to the PMA process but was instead cleared for market through the FDA's less intensive § 510(k) process, which does not impose device specific requirements within the meaning of *Riegel's* first prong. *Id*.

Defendants retort that Plaintiffs' argument has been twice considered, and rejected, in other federal cases involving this same 522 Pump which expressly found, based upon publicly available records from the FDA, that the FDA granted premarket approval to the *entire* device – cases which Plaintiffs' opposition tellingly neglectes to address. *See* Defs' Reply at 1, 3-6 (citing *Duggan v. Medtronic, Inc.*, 840 F. Supp. 2d 466 (D. Mass. 2012); *Bentzley v. Medtronic*, 827 F. Supp. 2d 443 (E.D. Pa. 2011)). *See also Duggan*, 840 F. Supp. at 472 (considering the FDA's Premarket Approval forms and an FDA response to a citizen petition filed by the *Duggan* plaintiffs and concluding that the FDA had "ma[de] clear that it intended to grant PMA to the entire system, including the 522 Pump.").

In view of *Duggan* and *Bentzley*, the Court harbors serious doubt about the validity of Plaintiffs' argument regarding the 522 Pump's lack of PMA approved, Class III status. Nevertheless, the Court need not, and on the incomplete factual record before it, shall not resolve the question at this early, pre-discovery stage of the litigation. This is because, as explained below, even assuming *arguendo* that the FDA had approved the entire 522 Pump, each of

Plaintiffs' state law claims would nevertheless be excepted from MDA preemption under step two of the *Riegel* analysis.

As the Supreme Court has made clear, the preemption provision of the MDA is limited, as it "simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." *Lohr*, 518 U.S. at 486-87, 491 (reasoning that under a broader reading of the statute, "Congress would have barred most, if not all, relief for persons injured by defective medical devices," with the "perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation."). Rather, under the second prong of *Riegel*'s inquiry, "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. Thus, § 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." *Riegel*, 552 U.S. at 330 (citing § 360k(a)(1); *Lohr*, 518 U.S. at 495). *Accord Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) ("To escape preemption by § 360k(a), then, a state-law claim must be premised on the breach of a state-law duty that is the same as a duty imposed under the FDCA (or one of its implementing regulations).") (citing *Riegel*, 552 U.S. at 330).

Notably, where the preemption issue is decided on the pleadings, and "the precise contours of [the plaintiff's] theory of recovery have not yet been defined" but it is nonetheless "clear that the [plaintiff's] allegations may include claims that [the defendant] has, to the extent that they exist, violated FDA regulations," such claims "can be maintained without being preempted by § 360k." *Lohr*, 518 U.S. at 495.

Here, Defendants argue that although styled differently, the crux of each of Plaintiffs' claims is that the FDA-approved design, manufacturing process, and labeling for the 522 Pump were somehow deficient – or, put differently, that the device should have been designed, labeled, and manufactured in accordance with a state-law standard different from, or in addition to, what the FDA required. Defs' Mem. at 5-6, 9, 12. Defendants contend that because these are exactly the types of claims that § 360k was intended to preclude, Plaintiffs' claims are expressly preempted by the MDA and must be dismissed with prejudice for this reason alone. *See id*. at 8-15.

Plaintiffs' Complaint is far-reaching and contains sweeping allegations that the 522 Pump was defectively "manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised, warned, and otherwise distributed." Compl. ¶ 45. As such, Defendants are not unreasonable in perceiving the Complaint as a direct challenge to the FDA's assessment and approval of the design, method of manufacture, testing, marketing, and labeling of the pump. *See* Defs' Mot. at 10-17. To the extent Defendants' understanding of the Complaint is correct in that Plaintiffs are alleging that Defendants' FDA-approved processes and labels were inadequate under District of Columbia law (and assuming, without holding, that the 522 Pump is indeed a Class III device such that *Riegel's* first prong is automatically met), such claims would be preempted by the MDA. *See, e.g.*, *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010) ("The FDA's PMA approval includes specific language for Class III device labels and warnings. Plaintiffs did not allege that Medtronic modified or failed to include FDA-approved warnings. Rather, they alleged that, by reason of state law, Medtronic was required to give additional warnings, precisely the type of state requirement that is 'different from or in addition to' the federal requirement and therefore

preempted.") (citing *Riegel*, 552 U.S. at 333). *See also Riegel*, 552 U.S. at 329 (Section 360k(a) "[s]urely … would pre-empt a jury determination that the FDA-approved labeling for a [device] violated a state common-law requirement for additional warnings.").

However, upon a careful review of the Complaint, the Court notes that Plaintiffs claims are also abounding with allegations that Defendants harmed Plaintiffs, in violation of state common law, by failing to comply with federal requirements. Defendants concede as much. *See* Defs' Mot. at 6 (stating that the Complaint is "replete" with allegations that Defendants "violated certain federal statutes and regulations"). Specifically, the Complaint alleges that Defendants knew, or should have known that technical problems were occurring in the 522 Pump *subsequent* to PMA approval, but never notified the FDA, Plaintiff's physicians, or Plaintiffs of these failures, despite their obligations under the federal regulations to do so. *See, e.g.*, Compl. ¶¶ 14, 20, 26, 33, 46; *see also* 21 C.F.R. §§ 803, 822. Relatedly, the Complaint alleges failure to conduct *post*-approval market surveillance, including reporting all serious adverse events, in violation of 21 C.F.R. §§ 803, 814, 821, and 822. *See, e.g.*, *id*. ¶¶ 27, 30, 33, 45. Finally, the Complaint also contains allegations that Defendants deviated from several enumerated FDA requirements regarding the manufacturing of the device, resulting in an "adulterated" product. *See, e.g., id.* ¶¶ 21-23, 28, 33, 45.

Further (and perhaps in recognition of the broad-sweeping nature of their allegations), Plaintiffs' opposition brief makes an apparent effort to clarify the scope of the Complaint. Plaintiffs' representations are unequivocal:

> Defendants' argument against each count is that because the FDA approved their product, any state law claims Plaintiffs could bring for injuries the product caused would be "different from, or in addition to" FDA regulations. That is simply not the case and not what Plaintiffs have alleged. First, the basis of Plaintiffs' Complaint is that Defendants failed to change their post-approval representations to consumers once they were aware that their product was defective, as is required by 21 C.F.R. § 801. Second, Plaintiffs'

> claims cannot be dismissed as sufficient discovery has not been performed to determine whether the FDA-approved form of the device was actually followed once the device was released to consumers. Analyzing each of Plaintiffs' claims demonstrates that they all attempt to enforce requirements parallel to the MDA and are not pre-emtped by federal law.

Pls' Opp'n at 12. Indeed, upon the Court's review of the Complaint – according Plaintiffs the benefit of all inferences that can be derived from the facts alleged as is required on a Rule 12(b)(6) analysis – each count asserted may be fairly read as asserting a claim premised upon Defendants' alleged violation of one or more federal laws. Plaintiffs' general factual allegations, negligence, and strict liability counts expressly cite to, and rely on, specific provisions of the MDA and its implementing regulations, *see e.g.*, ¶¶ 21-30, 31, 43, and all remaining counts incorporate by reference these allegations and, in substance, are plainly premised upon Defendants' alleged failure to comply with federal laws applicable to post-approval surveillance, reporting, and manufacturing.

If there remains any doubt, in separately discussing all but one category of claims (the warranty claims, which shall be addressed *infra*), Plaintiffs' opposition brief expressly and unambiguously confirms that each claim is premised exclusively upon post-approval violations of federal law – a representation on which this Court today relies, and to which Plaintiff shall, in the future course of this litigation, be bound. *See* Pl.'s Opp'n at 14 ("Plaintiffs' negligence claims are premised entirely upon actions taken post-approval."); *id*. at 15 (arguing that because Plaintiffs' strict liability claims are premised upon "post-approval" violations of FDA regulations, Defendants cannot "shield itself with PMA approval under this count"); *id*. at 16 (explaining that the alleged misrepresentation and fraud occurred subsequent to PMA approval and in violation of FDA regulations regarding post-market surveillance and proper labeling); *id.* at 17 ("Plaintiffs' claims under the [Unlawful Trade Practices Act] are not pre-empted because

they pertain to misrepresentations made post-approval … [in violation] of FDA regulations requir[ing] product manufacturers to report post-approval adverse events and to update their labeling when they find post-approval defects."); *id*. at 18-19 (failure to warn claims "pertain only [to] statements Defendants made post-marketing and post-approval" in violation of federal law mandating reporting of post-approval defects).

For all of the foregoing reasons, the Court finds that each of the claims in Plaintiffs' Complaint – with the possible exception of Plaintiffs' express warranty claims, which shall be addressed *infra* – may be reasonably understood to assert violations of the requirements set forth by the FDA as the cause of the alleged defects and ensuing violation of District of Columbia laws (and *not* that the device violated District of Columbia products liability laws despite compliance with federal regulations and requirements). Accordingly, Plaintiffs have sufficiently pled parallel claims that are not subject to express preemption under *Riegel*. *See, e.g. Stengel v. Medtronic Inc*., 704 F.3d 1224, 1232-33 (9th Cir. 2013) (en banc) (reversing the district court's order denying, on preemption grounds, plaintiffs leave to file a proposed amended complaint to assert a claim that the defendant had violated a state-law duty of care by failing to report known risks associated with use of its medical device to the FDA); *Hughes v. Boston Scientific*, 631 F.3d 762, 769 (5th Cir. 2011) (affirming district court's grant of summary judgment dismissing as preempted a failure to warn claim to the extent such claim would question the sufficiency of FDA-approved labeling but reversing and remanding dismissal of claim that manufacturer failed to provide adequate warning or sufficiently communicate information about risks associated with the device to the extent that the claim was predicated on the manufacturer's failure to report serious injuries and malfunctions of the device as required by the applicable FDA regulations); *Bausch v. Stryker Corp.*, 630 F.3d 546, 550-56 (7th Cir. 2010) (finding that the district court

erred in dismissing as preempted the plaintiff's common law claims for defective manufacture of Class III medical devices in violation of federal requirements).

The Court pauses to note, however, that this finding should in no way be viewed as discounting Defendants' argument that in order to avoid preemption, a plaintiff must specifically identify a federal requirement applicable to the device which the defendant allegedly violated and a valid, pre-existing state law duty that is *genuinely* parallel to that federal requirement, and also explain how the alleged federal violation cause the alleged injury. *See* Defs' Mot. at 15-17; Defs' Reply at 13, n.5. The Court agrees with Defendants that Plaintiffs' pleading is admittedly skimpy in this regard. Nevertheless, as several courts have observed, "[t]here are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular." *Bausch*, 630 F.3d at 558. Indeed, these courts have recognized "how difficult it is to plead such a claim sufficiently to survive a motion to dismiss for failure to state a claim," and that because "much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law[,] [f]ormal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for [his or] her claim." *Bausch*, 630 F.3d at 558.

This given, while Plaintiffs' Complaint has not defined "the precise contours of [their] theory of recovery," *Lohr*, 518 U.S. at 495, it is nevertheless clear from the allegations, and further corroborated by the representations in Plaintiffs' briefing in connection with the instant motion, that Plaintiffs' claims are in fact premised on the theory that Defendants have violated FDA regulations and that these violations were the primary cause of Ms. Kubicki's injuries. At this preliminary stage of the litigation, such claims "can be maintained without being preempted by § 360k." *Lohr*, 518 U.S. at 495. *See, e.g.*, *Bausch*, 630 F.3d at 560 ("Defendants object that

the original complaint does not specify the precise defect or the specific federal regulatory requirements that were allegedly violated. Although the complaint would be stronger with such detail, we do not believe the absence of those details shows a failure to comply with Rule 8 of the Federal Rules of Civil Procedure or can support a dismissal under Rule 12(b)(6).")

While the Court finds Plaintiffs' pleading sufficient to pass muster at this motion to dismiss stage, the Court does expect that as this action proceeds, Plaintiffs will refine their claims to more specifically articulate the parallel relationship between the alleged common law duties and the federal requirements. Should Plaintiffs fail to do so, Defendants may renew their express preemption objections at a later, appropriate time.

Finally, the Court must separately address Plaintiffs' express warranty claims. In contrast to their other claims, Plaintiffs do not appear to limit their express warranty claims exclusively to post-approval conduct violative of one or more specific federal regulations, *see* Compl. ¶¶ 109-123; Pl.'s Opp'n at 16-17. Rather, the crux of Plaintiffs' express warranty claims is that Defendants, at an unspecified time, expressly warranted the safety of the 522 Pump through its "advertising and promotional materials." *See id.* Defendants argue that the Court should find this claim preempted because it contradicts the FDA's conclusive determination, via the PMA process, that the device was safe and effective as labeled. Defs' Mot. at 13. Plaintiffs counter that because the alleged warranties were made by way of Defendants' advertising and promotional materials – materials that, unlike the device's labeling, did not require or obtain FDA approval – and because Defendants voluntarily undertook to make those warranties, there is no imposition by the "state" of any additional or different requirement that would conflict with federal law. Pls' Mot. at 16-17.

Riegel did not address the preemption issue with regard to a claim for breach of warranty, as the district court had found that the MDA did not preempt a breach of express warranty allegation and subsequently granted summary judgment to the defendant on that claim. 522 U.S. at 320-21 & n.2. Nor have the parties pointed to any Circuit authority on this issue, and this Court has found none. Post-*Riegel* federal cases outside of this Circuit have divided on the issue of whether or not the MDA preempts express warranty claims. *Compare, e.g.*, *Bentzley*, 827 F. Supp. 2d at 454 (Because the "parties, not the state, define the substantive obligations of the contract and hence any express warranties," claims for breach of express warranty do not involve a state "requirement" and are not preempted by the MDA); *Riley*, 625 F. Supp. 2d at 769 ("[A] breach-of-express-warranty claim based on voluntary statements is not preempted by § 360k(a) because, in order to avoid state-law liability, the manufacturer need do nothing more than refrain from making voluntary warranties."), *with Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 285 (E.D.N.Y. 2009) ("Plaintiff's breach of express warranty claim is preempted to the extent that it is premised on FDA approved representations made by the manufacturer."). Even those courts that have found express warranty claims subject to MDA's preemption provision, however, have acknowledge that preemption may be avoided where the representations at issue "exceed the scope of the FDA approved statements, thereby establishing a contractual obligation voluntarily entered into by the manufacturer." *Horrowitz*, 613 F. Supp. at 285 (citation omitted).

Here, Plaintiffs' Complaint on the express warranty counts is far from a model of clarity. Beyond vague assertions of a warranty of the "safety" of the device, the Complaint does not identify what express promise or promises Defendants made, and on which Ms. Kubicki relied, in the advertising and promotional materials. *See* Compl. ¶¶ 109-123. Accordingly, even if the Court aligned with those federal courts holding that breach of express warranty claims may be

subject to MDA preemption, it would nevertheless be unable to determine whether the representations alleged here were premised on FDA approved representations (thus requiring preemption) or exceeded the scope thereof (thus escaping preemption). Absent additional information about the content of the alleged representations, and how such representations may or may not implicate the federal regulatory scheme, the Court declines to dismiss Plaintiffs' express warranty claims on preemption grounds.[10]

For all of the above reasons, the Court shall deny Defendants' motion insofar as it argues that all of Plaintiffs' claims are expressly preempted by federal law.

B. Implied Preemption

Defendants next argue that, even if Plaintiffs' claims are not expressly preempted, they nevertheless require dismissal because they are impliedly preempted as explained by the Supreme Court in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and prohibited by 21 U.S.C. § 337(a), which prohibits private plaintiffs from directly enforcing federal law. *See* 21 U.S.C. § 337(a) ("Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States."). Essentially, Defendants argue that, to the extent that Plaintiffs' claims seek to impose liability for alleged violations of the FDCA and the FDA's implementing regulations, such claims are impliedly precluded as conflicting with the MDA's statutory scheme, in that they are impermissible incursions upon the FDA's ability to police its own regulations in accordance

[10] Because Defendants' motion argued for dismissal of Plaintiffs' breach of express warranty claims exclusively on the basis of preemption, the Court does not here opine on whether Plaintiffs have adequately pled the elements of a breach of express warranty claim under District of Columbia law. Defendants argument that Plaintiffs have not adequately pled any voluntary statements beyond what premarket approval required, raised for the first time in a footnote in their reply brief, shall not be considered. *See, e.g., Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1001 (D.C.Cir.2008) ("We need not consider this argument because plaintiffs ... raised it for the first time in their reply brief.").

with its expertise, discretion, judgment, and objectives. Defs' Mot. at 18-20. For the below reasons, the Court finds Defendants' argument unavailing.

The plaintiffs in *Buckman* brought state law negligence claims for personal injuries resulting from the use of orthopedic bone screws. *Id*. at 343-44. Specifically, the plaintiffs alleged that the defendant, a consulting company, had made fraudulent representations to the FDA about the use of the screws in patients' spines in the course of obtaining premarket approval for its client, the manufacturer. *Id*. The plaintiffs argued that but for this fraud, the FDA would not have approved the screws, thus sparing the plaintiffs from injury. *Id*. at 347. The Court held that permitting what the Court described as the plaintiffs' "fraud-on-the-FDA claims" would conflict with the MDA's regulatory scheme – which empowers only the FDA to punish and deter fraud against the Administration. *Id*. at 348. The Court held that the plaintiffs' suit was therefore impliedly preempted under 21 U.S.C. § 337(a). *Id*. at 348 & n.4.

Importantly, the *Buckman* Court distinguished the plaintiffs' "fraud-on-the-agency" claims from "traditional state tort law" claims that were not preempted. *See id*. at 352 (distinguishing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 241, 258 (1984), in which it had held that a negligence claim was not preempted by the Atomic Energy Act by explaining: "Silkwood's claim was not based on any sort of fraud-on-the-agency theory, but on traditional state tort law principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant."). The Court also emphasized that some parallel state claims survive preemption by the MDA, stating: "[I]t is clear that the [*Lohr*] claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements," whereas "[i]n the present case, however, the fraud

claims exist solely by virtue of the FDCA disclosure requirements." *Id*. at 352-53 (citing *Lohr*, 518 U.S. at 481).

As evident from the face of the Complaint, Plaintiffs' claims, like those in *Lohr*, and unlike those in *Buckman*, are state claims based upon Defendants' alleged violation of common law and statutory duties to Plaintiffs – not fraud on the FDA. Because Plaintiffs are asserting breach of recognized state law duties which are *parallel* to federal regulations (as opposed to an independent implied right action under the MDA to directly *enforce* those regulation), their claims are not impliedly preempted under *Buckman*. *See, e.g.*, *Stengel*, 704 F.3d at 1233 ("[W]e do hold, under *Lohr*, *Buckman*, and *Riegel*, that [the plaintiffs' failure-to-warn] claim is not preempted, either expressly or impliedly, by the MDA. It is a state-law claim that is independent of the FDA's pre-market approval process that was at issue in *Buckman*. The claim rests on a state-law duty that parallels a federal-law duty under the MDA, as in *Lohr*."); *Hughes*, 631 F.3d at 775 (finding the plaintiffs' failure to warn claim was not impliedly preempted under *Buckman*, explaining: "The plaintiffs in *Buckman* were attempting to assert a freestanding federal cause of action based on violation of the FDA's regulations; the plaintiffs did not assert violation of a state tort duty. In contrast, Hughes is asserting a Mississippi tort claim based on the underlying state duty to warn about the dangers or risks of product.").

C. Misrepresentation, Fraud, and Unlawful Trade Practice Claims

Defendants also argue that even if the Court finds that Plaintiffs' claims for misrepresentation, fraud, and violation of the District of Columbia Unlawful Trade Practices Act are neither expressly nor impliedly preempted, these claims nevertheless require dismissal because Plaintiffs have failed to plead these claims with sufficient particularity. For the below reasons, the Court agrees.

"Under District of Columbia law, an allegation of fraud must include the following essential elements: "(1) a false representation, (2) concerning a material fact, (3) made with knowledge of its falsity, (4) with the intent to deceive, and (5) upon which reliance is placed." *Acosta Orellana v. CropLife Intern*, 711 F. Supp. 2d 81, 96 (D.D.C. 2010) (citing *In re Estate of McKenney*, 953 A.2d 336, 341 (D.C. 2008)). *See also* D.C. Unlawful Trade Practices Act, D.C. Code § 28-3904 (providing, in pertinent part that "[i]t shall be a violation of this chapter, whether or not any consumer is in fact misled, deceived or damaged thereby, for any person to … misrepresent as to a material fact which has a tendency to mislead."). "Fraud is never presumed and must be particularly pleaded … [The pleader] must allege such facts as will reveal the existence of all the requisite elements of fraud." *Bennett v. Kiggins*, 377 A.2d 57, 59-60 (D.C. 1977).

Furthermore, "[a] complaint alleging fraud must also 'meet the requirements of Rule 9(b) of the Federal Rules of Civil Procedure.'" *Acosta Orellana*, 711 F. Supp. 2d at 96. Rule 9(b) requires that a party alleging fraud "must state with particularity the circumstances constituting [the] fraud." FED. R. CIV. P. 9(b). In this Circuit, the circumstances that the claimant must plead with particularity include matters such as the "time, place, and content of the false misrepresentations, the fact misrepresented and what was retained or given up as a consequence of the fraud," as well as the "identi[ty] [of the] individuals allegedly involved in the fraud." *United States ex rel. Williams v. Martin-Baker Aircraft Co.*, 389 F.3d 1251, 1256 (D.C. Cir. 2004) (citations omitted). "Unless a complaint pleads with particularity a defendant's alleged fraudulent representations, the plaintiff will not be permitted to maintain the claim. This requirement is imposed because to permit a fraud claim to go forth on less specific allegations

would permit 'the discovery of unknown wrongs,' which Rule 9(b) seeks to prevent." *Acosta Orellana*, 711 F. Supp. 2d at 96 (internal editing and citations omitted).

Upon review of Plaintiffs' Complaint, the court finds that Plaintiffs' allegations of misrepresentation, fraud, and unlawful trade practices fail to satisfy the heightened pleading requirements of Rule 9(b). First, Plaintiffs at no point describe the content of any specific representations made, or material facts concealed, by Defendants. Plaintiffs broad reference to Defendants' alleged misrepresentations and/or concealments "concerning the character, safety and effectiveness of the MiniMed Insulin Pump," Compl. ¶ 68, and the "results of post market studies," Compl. ¶ 69, are simply too imprecise.

Plaintiffs likewise fail to plead the circumstances in which the alleged misrepresentations were made and/or material facts concealed. Plaintiffs argue that they have satisfactorily pled the requisite circumstances by broadly alleging that Defendants' fraud occurred by way of their "actions and omissions in advertising, promoting, reporting to the FDA, labeling, or otherwise," *see* Pls' Opp'n. at 24 (citing Compl. ¶ 68), and at some time "subsequent to FDA approval" and "during post-market surveillance of their product," *see id*. (citing Compl. ¶ 20). However, these open-ended allegations simply fail to provide the particular time, place, and manner of the alleged misrepresentations (or when and how the omitted material information should or could have been revealed), or the identity of the individuals allegedly involved, as required under Rule 9(b). *See* FED. R. CIV. P. 9(b); *Williams*, 389 F.3d 1251 (D.C. Cir. 2004).

While Plaintiffs argue that their fraud allegations are "as specific as possible without the benefit of discovery," *see* Pls' Opp'n at 24, "as courts in this and other jurisdictions have noted, the heightened pleading standards of Rule 9(b) serve in part to prevent the filing of a complaint as a means of discovering an unknown wrong." *United States ex rel. Folliard v. Hewlett-*

Packard Co., 272 F.R.D. 31, 35 n.5 (citing cases). Permitting Plaintiffs to proceed on their misrepresentation, fraud, and unlawful trade practice claims would contravene this purpose.

For the foregoing reasons, the Court concludes that Plaintiffs' causes of action for misrepresentation, fraud, and violation of the District of Columbia Unlawful Trade Practice Act are not supported by sufficient pleading of the particular content and circumstances of the alleged misrepresentations or omissions to satisfy Rule 9(b). Accordingly, the Court shall grant Defendants' motion to dismiss these counts for insufficient pleading. Such dismissal shall be without prejudice. *See United States ex rel. Joseph v. Cannon*, 642 F.2d 1373, 1386 (D.C. Cir. 1981) ("The usual method for dealing with a nebulous complaint … is either to grant leave to amend or to dismiss the complaint without prejudice.").

D. Implied Warranty Claims

Finally, Defendants argue that Plaintiffs' breach of implied warranty claims require dismissal because these claims are pled in conjunction with strict products liability claims, yet Plaintiffs do not allege any contractual privity with Defendants. Defendants are correct that Plaintiffs' implied warranty claims are based upon the same underlying conduct as their (broader) strict liability claims. *Compare, e.g.*, Compl. ¶ 48(a)-(e) (citing Defendants' deceptive marketing representations and inadequate warnings as a basis for Plaintiffs' strict liability claim), *with* Compl. ¶125 ("Defendant, through its advertising and promotional materials, impliedly warranted that the MiniMed Insulin Pump was safe for the use for which it was intended."), *see also* Pl.'s Opp'n at 16 ("Plaintiffs' claims in this [implied warranty] category are essentially that Defendant made … implied warranties through its advertising and promotional materials that the Insulin Pump was safe for its intended use when it actually was not.").

Defendants are also correct that "claims of strict products liability and breach of implied warranty are considered a single tort in the District of Columbia." *In re Fort Totten Metrorail Cases Arising Out of Events of June 22, 2009*, 793 F. Supp. 2d 133, 151-52 (D.D.C. 2011) (citing *Wainwright v. Washington Metro Area Transit Auth.*, 903 F. Supp. 133, 140 (D.D.C. 1995) ("Breach of implied warranty and strict liability in tort are expressions of a single basic public policy as to liability for defective products."); *Bowler v. Stewart-Warner Corp.*, 563 A.2d 344 (D.C. 1989) (granting new trial where the trial judge instructed the jury in both strict liability and implied warranty of merchantability because the two claims represent one tort); *Payne v. Soft Sheen Prods., Inc.*, 486 A.2d 712, 720 (D.C. 1985) ("[W]here [there are] no issues unique to warranty, ... a claim of strict liability in tort [is] effectively made out [in a] complaint for breach of warranty.")).

"Furthermore, this rule applies only in cases, such as this case, where a third party is bringing an action against a manufacturer of a product, and thus, privity of contract is absent." *Id*. at 152 (citing *Liberty Mut. Ins. Co. v. Equip. Corp. of Am.*, 646 F. Supp. 2d 51, 66 (D.D.C. 2009)). Accordingly, "where a plaintiff alleges claims for both strict products liability and breach of implied warranties based on allegedly defective products against a party not in privity with the plaintiff, the implied warranty claims must be dismissed because the actions are the same." *Id*. (granting motion to dismiss and dismissing breach of implied warranty claim as duplicative of strict products liability claim).

As Defendants accurately observe, Plaintiffs' Complaint nowhere alleges that Plaintiffs purchased the 522 Pump from Defendants or otherwise allege any privity of contract with Defendants. In their opposition, Plaintiffs do not dispute that they have failed to allege contractual privity with Defendants. Accordingly, Plaintiffs' breach of implied warranty claim

should be dismissed pursuant to District of Columbia law as duplicative of their strict products liability claim. *See Hopkins v. Women's Div., Gen. Bd. of Global Ministries*, 284 F. Supp. 2d 15, 25 (D.D.C. 2003) ("It is well understood in this Circuit that when a plaintiff files an opposition to a dispositive motion and addresses only certain arguments raised by the defendant, a court may treat those arguments that the plaintiff failed to address as conceded.") (citing *FDIC v. Bender*, 127 F.3d 58, 67–68 (D.C. Cir. 1997); *Stephenson v. Cox.*, 233 F. Supp. 2d 119, 121 (D.D.C. 2002)), *aff'd*, 98 Fed. Appx. 8 (D.C. Cir. 2004).

IV. CONCLUSION

For the reasons stated in this Memorandum Opinion, the Court shall **GRANT-IN-PART** and **DENY-IN-PART** Defendants' Motion to Dismiss. Specifically, Plaintiffs' misrepresentation claims (Counts VII, VIII, and IX), fraud claims (Counts X, XI, and XII), and unlawful trade practices claims (Counts XIX, XX, XXI) shall be dismissed, without prejudice, due to Plaintiffs' failure to plead these claims with sufficient particularity as required by Federal Rule of Civil Procedure 9(b). Plaintiffs' implied warranty claims (Counts XVI, XVII, and XVIII) shall also be dismissed as duplicative of their strict products liability claims. The Court shall deny Defendants' motion insofar as it argues that all of Plaintiffs' claims are expressly and impliedly preempted by federal law. Accordingly, Plaintiffs' remaining claims – specifically, negligence (Counts I, II, and III), strict liability (Counts IV, V, and VI), express warranties (Counts XIII, XIV, and XV), and failure to warn (Counts XXII, XXIII, and XXIV) – survive dismissal.

An appropriate Order accompanies this Memorandum Opinion.

Date: March 21, 2013

_____/s/_____

COLLEEN KOLLAR-KOTELLY
United States District Judge