UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN KUBICKI & KAREN KUBICKI, on behalf of CAROLINE KUBICKI, Plaintiffs, v. MEDTRONIC, INC., *et al.*, Defendants.	Civil No. 12-cv-734 (KBJ)

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MEMORANDUM OPINION

I. INTRODUCTION

This complex products-liability action arises out of a tragic event in the life of Caroline Kubicki, a Type-I diabetic who began using a mechanical pump and an associated infusion set to administer the insulin necessary to manage her diabetes when she was 12 years old. Caroline was 19 and a sophomore at George Washington University ("GW") in early September of 2007, when she experienced severe hypoglycemia in her dormitory room and suffered a traumatic brain injury as a result of the low blood sugar levels. Caroline currently resides in a group home in a persistent vegetative state, and her parents, John and Karen Kubicki ("Plaintiffs" or "the Kubickis"), have filed the instant lawsuit against the company that designed and manufactured the insulin pump and a component of the associated infusion set that Caroline was using at the time of the incident—Medtronic, Inc.—along with certain of its subsidiaries, Medtronic Diabetes and Medtronic MiniMed, Inc. (collectively, "Medtronic"). The Kubickis have also sued Unomedical Devices SA de CV, the manufacturer and assembler of the infusion set, and one of that company's affiliates, Unomedical A/S (collectively, "Unomedical").

The Kubickis' amended complaint contains 25 state law claims that concern two medical devices: the Medtronic MiniMed Paradigm® Insulin Pump Model MMT-522 ("the MMT-522 Pump") and the Medtronic MiniMed Paradigm® Quick-set Infusion Set, Model MMT-396 ("the MMT-396 Infusion Set"). (*See* Second Am. Compl. ("2nd Am. Compl."), ECF No. 124, ¶¶ 6, 20.) The complaint's myriad claims can generally be grouped into five categories. The first five counts (hereinafter referred to as "the

negligence claims") generally allege that the defendants committed common law negligence with respect to the design and manufacturing of both the MMT-522 Pump and the MMT-396 Infusion Set, and that defendants breached both the duty to provide adequate consumer instructions, labels, and warnings with respect to these devices, and the duty to take "reasonable care in documenting, logging, investigating, and reporting to the FDA" public complaints about these devices. (*Id.* ¶ 91; *see id.* ¶¶ 88–117 (Counts I–V).) Counts VI through X cast similar allegations as common law "strict liability" claims (*see, e.g.*, *id.* ¶ 149 (contending that defendants "sold the [insulin-delivery devices] to Ms. Kubicki in a defective condition what was unreasonably dangerous to consumers"); *see also id.* ¶¶ 118–152 (Counts VI–X)), while Counts XI through XV (hereinafter the "express warranty claims") assert that each defendant breached an express warranty upon which Caroline, her parents, and her physicians relied (*see id.* ¶¶ 153–203). The final two groups of claims in the complaint (the "failure to warn" claims) allege that the defendants failed to warn users and the FDA "of the foreseeable harm associated with the use" of the insulin-delivery devices (*id.* ¶ 205; *see id.* ¶¶ 204–253 (Counts XVI–XX)), and that the Kubickis are entitled to "punitive damages" because each defendant company "acted maliciously, willfully, wantonly, and recklessly without regard to the safety of others" (*id.* ¶ 262; *see id.* ¶¶ 254–263 (Counts XXI–XXV)). To date, the parties have completed fact discovery—but not expert discovery—in this matter, and Plaintiffs have pared down the charges against Unomedical, such that the only claims remaining against the Unomedical defendants are the failure to warn claims that appear in the complaint both as separate

claims and as part of the negligence and strict liability theories. (*See* Mot. Hr'g Tr., ECF No. 152, at 5:5–6:1 (Nov. 3, 2016).)

Before this Court at present are two motions for summary judgment that Medtronic and Unomedical have filed. (*See* Medtronic Mot. for Summ. J. or, in the Alternative, for Partial Summ. J. ("Medtronic's MSJ"), ECF No. 133; Unomedical Mot. for Summ. J. ("Unomedical's MSJ"), ECF No. 134.)[1] Plaintiffs oppose these motions, but have not cross-moved for summary judgment. (*See* Pls.' Opp'n to Defs.' Mots. for Summ. J. ("Pls.' Opp'n"), ECF No. 141.) Medtronic first argues that Plaintiffs cannot establish the requisite causation because, among other things, the existing record evidence definitively establishes that Caroline was not wearing her insulin pump at the time of the hypoglycemic incident.[2] In addition, Medtronic also maintains that the Kubickis' common law tort and express warranty claims are entirely preempted and/or barred by the applicable statutes of limitations (*see* Mem. in Support of Medtronic's Mot. for Summ. J. or, in the alternative, for Partial Summ. J. ("Medtronic's Mem."), ECF No. 133-1, at 31–62), and Medtronic further contends that, because the record contains no evidence of intentional wrongdoing, it is entitled to summary judgment on the punitive damages counts (*id.* at 63–70). Unomedical's motion for summary judgment argues that the failure to warn claims it faces are untimely and impliedly

[1] Page numbers cited herein, except for transcript and deposition citations, refer to those that the Court's electronic case-filing system automatically assigns.

[2] Medtronic's motion for summary judgment references an expert declaration from Helena W. Rodbard, M.D., FACP, MACE, which sets forth Dr. Rodbard's expert opinion regarding various other potential causes of Caroline Kubicki's injuries. (*See* Decl. of Helena W. Rodbard ("Rodbard Decl."), ECF No. 133-6.) Because the parties have yet to engage in expert discovery, this Court previously granted Plaintiffs' motion to strike the portions of this declaration (and related briefing) that suggest possible alternative causes of Caroline's hypoglycemic event. (*See* Min. Order of Apr. 8, 2016.)

preempted, and it also presses the same causation and punitive damages arguments that Medtronic makes. (*See* Mem. in Support of Unomedical's Mot. for Summ. J. ("Unomedical's Mem."), ECF No. 134-1, at 25–34, 37–47.)

This Court has carefully parsed the defendants' myriad summary judgment arguments regarding causation, timeliness, preemption, and other issues, along with the prior written ruling of the Court that resolved the Medtronic defendants' initial motion to dismiss. *See Kubicki v. Medtronic*, No. 12cv0734, 2013 WL 1739580 (D.D.C. Mar. 21, 2013). As explained fully below, this Court now concludes that Medtronic's Motion for Summary Judgment must be **GRANTED IN PART AND DENIED IN PART**, and that Unomedical's Motion for Summary Judgment must be **GRANTED** in full. In sum, this Court has determined that neither defendant is entitled to summary judgment on causation grounds at this point in the litigation (prior to expert discovery), but that summary judgment can and will be entered in Unomedical's favor on the basis of the statute of limitations. The Court will also grant summary judgment to Medtronic with respect to certain claims in the complaint—*i.e.*, all claims that pertain to the MMT-522 Pump (with the exception of Plaintiffs' manufacturing defect claim) and the failure to report claims that relate to the MMT-396 Infusion Set—because federal law either expressly or impliedly preempts such claims. In addition, the Court will grant Medtronic's motion for summary judgment on Plaintiffs' breach of warranty claim because the statements on which Plaintiffs predicate their claim do not create an actionable warranty. The Court will also grant Medtronic's motion for summary judgment with respect to Plaintiffs' stand-alone claim for punitive damages, because D.C. law does not recognize such a claim, but the Court finds that any ruling on the

availability of punitive damages as a remedy is premature prior to the completion of expert discovery. This Court sees no other basis for granting summary judgment in Medtronic's favor with respect to the remaining infusion set claims (negligent design, manufacture, and labeling, and failure to warn) at this time. However, Medtronic can seek summary judgment on causation grounds upon the parties' completion of expert discovery.

A separate Order consistent with this Memorandum Opinion will follow.

II. FACTS RELATED TO CAROLINE AND HER INJURIES

A. The Hypoglycemic Event

Caroline was diagnosed with Type I diabetes at the age of six, and was first prescribed an insulin pump in March of 2001, at age 12, after she had experienced difficulty controlling her blood glucose levels with self-administered insulin shots. (*See* Medtronic's Stmt. of Undisputed Material Facts ("Medtronic's Stmt. of Facts"), ECF No. 133-2, ¶¶ 13–14, 17; *see also* Pls.' Stmt. of Genuine Issues of Material Fact ("Pls.' Stmt. of Facts"), ECF No. 138-70, ¶¶ 8–9) (noting that Caroline had experienced three hypoglycemic events prior to receiving a prescription for the insulin pump in 2001).) [3] In October of 2006, Caroline's physician, Dr. Paresh Dandona, prescribed Caroline the MMT-522 Pump and the MMT-396 Infusion Set that are at issue in this case. (*See* Dep. of John Kubicki ("J. Kubicki Dep."), Ex. E to Decl. of Michael K. Brown ("Brown Decl."), ECF No. 133-5 at 67–92, at 114:6–14.) Nearly one year

[3] The pancreas of an individual with Type I diabetes is unable to produce insulin, which is a hormone that allows the body to process glucose. (*See* Medtronic's Stmt. of Facts, ¶ 1.) Type I diabetics rely on daily doses of insulin to control their levels of blood glucose and to prevent hypoglycemia (blood glucose levels that are too low) and hyperglycemia (blood glucose levels that are too high). (*See id.* ¶¶ 1, 3.)

later—sometime between the late evening of September 8, 2007, and the early morning of September 9, 2007—Caroline experienced the hypoglycemic event that gives rise to the claims at issue here. (*See* Unomedical's Stmt. of Material Facts as to Which There Is No Genuine Issue ("Unomedical's Stmt. of Facts"), ECF No. 132-10, ¶ 34.)

Although there are gaps in the timeline, the following basic facts are undisputed. Caroline and her roommate, Magdelena Posthumus, were together in their shared dorm room on GW's campus from approximately 7:00 p.m. to 10:30 p.m. on the evening of September 8, 2007. (*See* Dep. of Magdelena E. Posthumus ("Posthumus Dep."), Ex. G to Brown Decl., ECF No. 139-1 at 68–82, at 58:4–59:2.) During that time, Posthumus observed Caroline napping, waking and eating a bowl of cereal, and then returning to bed. (*See id.*) The various data points that Caroline's parents were able to retrieve from Caroline's pump and glucometer indicate that Caroline's blood sugar level was 77 mg/dL at approximately 7:02 p.m., and that Caroline gave herself six units of insulin at approximately 8:30 p.m. (*See* Dep. of Karen Kubicki ("K. Kubicki Dep."), Ex. F to Brown Decl., ECF No. 133-5 at 94–106, at 129:20–130:8; J. Kubicki Dep. at 212:3–24; *see also* Handwritten Glucometer Readings, Ex. 21 to K. Kubicki Dep., ECF 133-5, at 117.) Posthumus left the dorm for a couple of hours beginning at around 11:00 p.m., and Caroline was sleeping both when Posthumus left and when she returned around 12:30 a.m. (*See* Posthumus Dep. at 60:3–61:20.) At 8:00 a.m. the following morning, Posthumus discovered Caroline in distress in her bed; Caroline was foaming at the mouth and was otherwise unresponsive. (*See* Medtronic's Stmt. of Facts ¶ 28.)

Posthumus immediately notified a resident advisor, Siobhan Chapman, who in turn notified another resident advisor, Rebecca Barloon. (*See* Dep. of Rebecca Barloon

("Barloon Dep."), Ex. 1 to Pls.' Opp'n, ECF No. 138-3, at 42:21–23.) Posthumus also called 911 and reported that Caroline was unconscious and vomiting. (*See* GW Police Dep't Incident Report, Ex. 11 to Pls.' Opp'n, ECF No. 138-13, at 2.) Emergency personnel responded, and when they checked Caroline's blood sugar, it registered at 20 mg/dL—an extraordinarily low level. (*See* DCFEMS Incident Report, Ex. 13 to Pls.' Opp'n, ECF No. 138-15, at 3.) The paramedics gave Caroline an emergency injection of glucose, and then transported her to GW Hospital, where doctors administered further glucose; however, none of these efforts changed Caroline's condition. (*See id.*; GW Hosp. Recs., Ex. 2 to Pls.' Opp'n, ECF No. 138-4, at 6.) At GW Hospital, a CT head scan revealed that Caroline was suffering from "diffuse cerebral edema." (GW Hosp. Recs. at 2.)[4] Caroline now resides in a nursing facility in a persistent vegetative state, with no realistic possibility of recovery. (*See* Mot. Hr'g Tr. at 9:23–10:8.)

The readings that Plaintiffs were able to recover from Caroline's glucometer showed that Caroline's insulin levels had fluctuated in the days leading up to her injury—from a low of 43 mg/dL to a high of 568 mg/dL. (*See* Handwritten Glucometer Readings.) The full set of data could not be recovered from the MMT-522 Pump's memory because Mr. Kubicki removed the battery from the pump after a Medtronic customer service representative told him that doing so would not impact the data saved on the device. (*See* Tr. of Tele. Call, Ex. 17 to Pls.' Opp'n, ECF No. 138-19, at 9.) The parties conducted joint non-destructive testing of Caroline's pump, which did not

[4] "A CT scan is a computed tomography scan, also referred to as a CAT scan or computed axial tomography scan. The CT scan generates a three dimensional image of the inside of an object from a large series of two-dimensional X-ray images taken around a single axis of rotation." *McCarty v. Astrue*, Civ. No. 08–432, 2008 WL 4922323, at *6 n.11 (M.D. Pa. Nov. 13, 2008).

reveal any defects. (*See* Pls.' Opp'n at 67–68.)[5] The MMT-396 Infusion Set that Caroline was using was discarded at an unknown time shortly after Caroline's injury, and therefore the parties were not able to conduct any testing on that device. (*See* K. Kubicki Dep. at 322:14–325:16.)

In the days after the hypoglycemic event, the Kubickis began gathering information in an attempt to determine what had caused Caroline's blood sugar to drop so low. Their efforts included speaking to Caroline's treating physicians at GW Hospital, one of whom suggested to the Kubickis that they preserve and test the MMT-522 Pump because it appeared that Caroline had suffered an insulin overdose. (*See* J. Kubicki Dep. at 23:25–25:13.) The Kubickis collected and retained Caroline's medical supplies, including the packaging materials for the discarded infusion set, and they consulted with an attorney approximately five weeks after the incident. (*See id.* at 22:22–23:18.)

B. The Medtronic Paradigm Insulin Pump Model MMT-522 And The Medtronic MiniMed Paradigm Quick-set Infusion Set, Model MMT-396

1. The Design And Operation Of These Medical Devices

The MMT-522 Pump is an FDA-regulated, insulin-pumping medical device that a patient wears outside her body. The device both monitors the patient's blood glucose levels and delivers insulin at rates that the patient programs. (*See* Decl. of Donna Twisdom ("Twisdom Decl."), ECF No. 35-4, ¶ 3.) The MMT-522 Pump and the MMT-

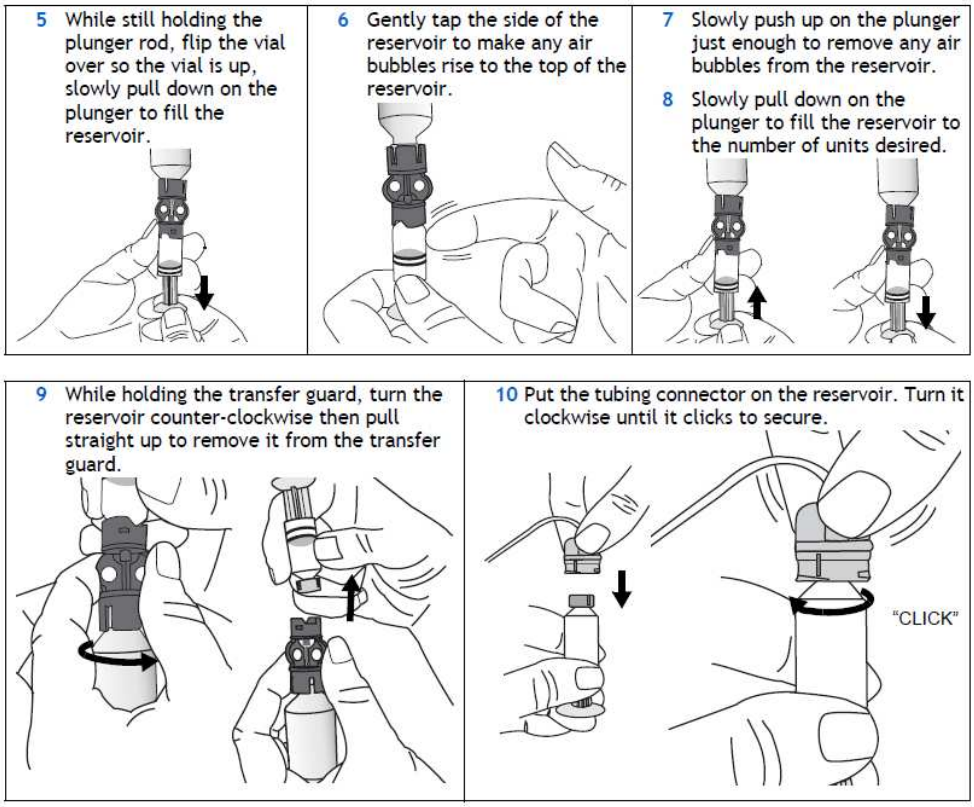
[5] The only reported abnormality was the pump's registering of an alarm code for "A45 Alarm after Prime/A33 Test." (Pls.' Opp'n at 19.) The record does not reveal what this alarm code means, but Plaintiffs represent that they "have reason to believe that it is triggered based on the amount of insulin delivered by the Insulin Pump." (*Id.* at 19 n.7.)

396 Infusion Set work together as a system, and appear as follows when attached to a patient:

Generally speaking, the insulin pump works by delivering background insulin throughout the day according to the "basal rate" that the user sets, and the user can also give herself a dose of insulin (called a "bolus") on demand when she eats. (*See* Mot. Hr'g Tr. at 59:21–60:21.) A cylindrical reservoir housed in the pump contains the insulin itself, and the insulin is delivered to the body through the infusion set. The infusion set, which is a separate medical device, consists of a thin plastic tube that has a tubing connector—called a "p-cap"—at one end; the p-cap connects the tube to the insulin reservoir. (*See* Decl. of Rabi Gharabli ("Gharabli Decl."), ECF 132-1, ¶ 10.) On the other end of the tube, there is a small needle that the user inserts into her body. (*See id.*)

Notably, when the pump's insulin reservoir needs to be refilled, the user must follow a number of steps carefully to accomplish this goal successfully. Specifically, the user must disconnect the infusion set from her body; remove the empty reservoir

from the pump; fill a new reservoir with insulin from an insulin vial; rewind the pump; insert the new reservoir into the pump; and push insulin through to the infusion set—all before reattaching the infusion set to her body. (*See* User Guide, Ex. B to Twisdom Decl., ECF No. 35-4, at 66–72.) The portion of the manual instructing users on how to fill the reservoir, disconnect the vial, and attach the infusion set in 2007 (when Caroline was injured) is reproduced below:



(*Id.* at 67.) Significantly for present purposes, when removing the vial from the reservoir, the user is required to keep the reservoir upright, and she must ensure that the inside of the p-cap connector and the top of the reservoir are not wet when they are reconnected. (*See infra* Part II.C.3.)

The design and operation of the infusion set's p-cap connecter is at the center of the products-liability claims in this case. As Medtronic describes it, this particular connector is a marvel of biomedical mechanical engineering:

> [it] contains four small one-way vent openings which provide airflow to equalize the pressure in the reservoir compartment with the surrounding atmospheric pressure. The p-cap vent openings are covered by a polytetrafluoroethylene ("PTFE") membrane that allows air to flow in and out of the compartment thus eliminating any pressure differential between the insulin reservoir and the end of the infusion set (such as may be created when completing a manual prime of the pump or during a rapid and dramatic change in altitude).

(Medtronic's Mem. at 17 (citations omitted).) Notably, the p-cap's vent covering is comprised of two different materials: the PFTE membrane is only on the topside, while the underside (the part of the p-cap that touches the reservoir) is comprised of polyester. (*See* Dep. of Mark Curtis ("Curtis Dep."), Ex. 22 to Pls.' Opp'n, ECF No. 138-24, at 211:7–19.)

Medtronic purportedly adopted this vented p-cap design for its insulin pumps so that the pump can be watertight. (*See* Dep. of Susan McConnell Montalvo ("McConnell Dep."), Ex. 20 to Pls.' Opp'n, ECF No. 138-22, at 43:17–44:14, 49:15–20, 53:5–9.) The proper functioning of the vents is key to ensuring that the reservoir maintains appropriate internal pressure and that the pump delivers insulin at the appropriate rates. (*See id.* at 49:17–20; 94:22–95:19.) If the pressure inside the reservoir is too high (which can occur if the vents are blocked), the stopper in the pump will push insulin into the infusion set in order to achieve pressure equilibrium, even if the pump is not programmed to deliver that insulin, resulting in an unscheduled delivery of insulin. (*See id.* at 94:2–4; 96:6–19.)

2. The Approval, Manufacturing, And Marketing Of These Medical Devices

The MMT-522 Pump and MMT-396 Infusion Set are two of a number of medical devices that Medtronic markets for the management of diabetes. In June of 1999, the FDA approved a PMA Application that Medtronic submitted for a precursor device—the Guardian Continuous Glucose Monitoring System, which consisted of a Guardian RT sensor and an external machine that measured and recorded an individual's glucose levels. *See* PMA Application No. P980022, Summary of Safety & Effectiveness Data[6]; *see also infra* Part VII.A.1 (discussing the FDA's "premarket approval" ("PMA") process). This system did not include an insulin pump as a component.

Medtronic first released its "Paradigm" insulin pump system into the market in 2001, and it received 510(k) approval for its Paradigm MMT-515 Insulin Pump in May of 2004. *See* 510(k) Premarket Notification.[7] Thereafter, in October of 2005, Medtronic sought "approval for modifications to the MMT 515/715 external insulin pump and to the Guardian RT sensor to enable the pump to accept data from the sensor, and to enable the sensor to communicate directly to the pump." (Ex. A. to Decl. of Mark Faillance ("PMA Approval"), ECF No. 35-5, at 9.) The FDA approved this new, combined system, known as the Paradigm Real Time System, through a PMA Supplement on April 7, 2006. (*See* Decl. of Mark Faillance ("Faillance Decl."), ECF

[6] Available at https://www.accessdata.fda.gov/cdrh_docs/pdf/P980022B.pdf.

[7] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K040676

No. 35-5, ¶ 8.) The pump component of this approved device is the Paradigm MMT-522.[8]

The FDA cleared the MMT-396 Infusion Set, including the vented p-cap connector that is at the center of this case, on June 7, 2001, through the 510(k) clearance process. (*See* Decl. of Mark O'Donnell ("O'Donnell Decl."), ECF No. 133-3, ¶ 8.) Medtronic designed and manufactured the p-cap connector, while Unomedical, which owns the 510(k) for the MMT-396 Infusion Set, designed and manufactured all the other components of the MMT-396 Infusion Set. (*See id.* ¶¶ 8–9.) Printed on the exterior of the MMT-396 Infusion Set packaging is the notation, "Assembled for Unomedical AS in Mexico," (Packaging Photos, Ex. 61 to Pls.' Opp'n, ECF No. 138-63, at 2), and Unomedical's name also appears on the instruction sheet for the MMT-396 Infusion Set (Infusion Set Instructions, Ex. F to Gharabli Decl., ECF No. 134-3, at 22), as well as on the individual MMT-396 Infusion Sets themselves (Mot. Hr'g Tr. 73:19–74:6).

Unomedical's role with respect to the p-cap was limited to the assembling of its MMT-396 Infusion Set tubing with the p-cap that Medtronic provided. (*See* Unomedical's Stmt. of Facts ¶ 29.) Unomedical then provided the assembled MMT-396 Infusion Set to Medtronic, which Medtronic in turn sold to users in connection with its line of Paradigm insulin pumps, including the MMT-522 Pump. (*See id.* ¶ 30; O'Donnell Decl. ¶ 9.) The MMT-522 Pump and MMT-396 Infusion Set are

[8] Medtronic claims that the FDA advised it to proceed through the PMA Supplement process rather than the 510(k) process because "creation of a new pump that incorporated a continuous glucose monitoring system software was a significant change, and the new pump would not be substantially equivalent to any existing or pre-amendment device." (Faillance Decl. ¶ 7.)

prescription-only devices (*see* Medtronic's Stmt. of Fact, ECF No. 131-2, ¶¶ 7, 9), which means that the devices are "available to the public only through a physician and are to be [used] only under a physician's supervision[.]" *MacPherson v. Searle & Co.*, 775 F. Supp. 417 , 422 (D.D.C. 1991).

C. Infusion Set Recalls In 2009 And 2013

1. 2009 Return And Replace Recall Of The "Lot 8" Batch

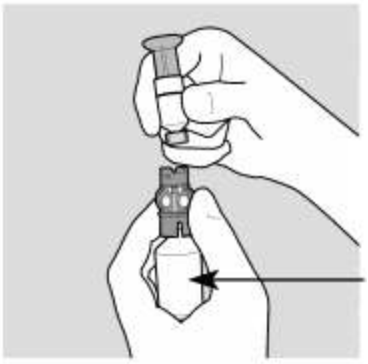
On June 29, 2009, approximately 22 months after Caroline's injury, Medtronic issued a recall for the "Lot 8" batch of its Paradigm infusion sets because of a possible manufacturing defect. Specifically, Medtronic determined that a silicone lubricant used during manufacturing could clog the vents in the p-cap of the infusion sets in the impacted lot, and thus could cause the pump to deliver too much or too little insulin. (*See* Lot 8 Recall Notice, Ex. 26 to Pls.' Opp'n, ECF No. 138-28.) Patients with impacted infusion sets were instructed not to use them and to return the sets to Medtronic for replacements. (*See id.*) The MMT-396 Infusion Set that Caroline had at the time of her injury did *not* come from Lot 8 and therefore would not have been part of this recall. (*See* Medtronic's Resp. to Pls.' Fourth Set of Reqs. for Produc., Ex. 28 to Pls.' Opp'n, ECF No. 138-30 at 4.)

In connection with the Lot 8 recall, Medtronic issued a "Questions & Answers" sheet in which it stated that all other Medtronic infusion sets were safe to use. (*See* Questions & Answers Regarding the "Lot 8" Quick-set Induction Set Recall, Ex. 27 to Pls.' Opp'n, ECF No. 138-29, at 2–3.) Medtronic made no mention of Unomedical—which had manufactured the parts of the infusion set other than the p-cap and had assembled the infusion sets, as explained above—in the documents associated with this recall.

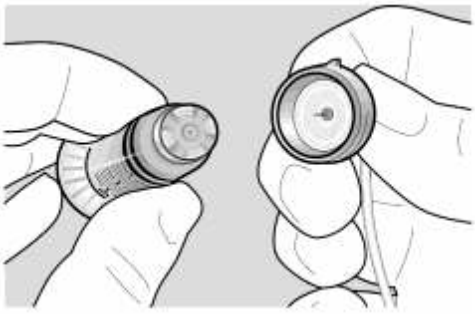
2. 2013 Paradigm Infusion Set Recall

Four years after the Lot 8 recall, on June 7, 2013, Medtronic issued a broad "Class I recall" of its Paradigm infusion sets, including the MMT-396 Infusion Set that Caroline had owned at the time of her injury. (*See* Infusion Sets Recall Notice ("2013 Recall Notice"), Ex. 18 to Pls.' Opp'n, ECF No. 138-20, at 2.) Unlike the Lot 8 recall, this recall did not involve replacement of the recalled device; rather, Medtronic provided more information to users, explaining in the recall announcement that there was a risk of under- or over-delivery of insulin if the top of the insulin reservoir or the inside of the p-cap becomes wet while the user is refilling the reservoir with insulin. (*See id.*) The impetus for this recall was Medtronic's discovery (first through viewing videos uploaded on YouTube) that some users were holding the insulin reservoir horizontally when refilling it, which can result in fluid touching the inside of the p-cap and blocking the vents. (*See* E-Mail from S. Schriever (June 11, 2013), Ex. 57 to Pls.' Opp'n, ECF No. 138-59, at 2.) In the notification sent to pump users in connection with the recall, Medtronic specifically instructed users to ensure that the insulin vial is upright when removing it from the reservoir in order to prevent liquid transfer to the p-cap, and it also declared that users should ensure that the reservoir tip and p-cap are dry before connecting them. (*See* Letter from Shirajul Karim (June 10, 2013) ("Dear User Letter"), Ex. 29 to Pls.' Opp'n, ECF No. 138-31, at 2-3.) The recall notice identified Unomedical A/S as one of the manufacturers of the recalled infusion sets. (*See* 2013 Recall Notice at 2.)

The pictures from the safety notification, which were issued to remind users about the correct way to refill the reservoir, are reproduced below.



Hold insulin vial upright when removing reservoir.



Make sure these are dry when connecting.

(Dear User Letter at 2–3.)

In the context of the instant litigation, Medtronic characterizes the issue that led to the 2013 infusion set recall as a "temporary blocked vent," and it asserts that "[t]he precise sequence of events required for the temporary blocked vent to occur (spilled fluid on the interior of the p-cap connector, saturation of all four vents, and excess pressure building) make it a rare occurrence." (Medtronic's Mem. at 29.) Medtronic further maintains that it is even more unlikely that a temporary blocked vent will injure an infusion set user, because the user should have detached the pump and infusion set from herself while the reservoir was being refilled. (*See id.* at 29–30.) Medtronic claims that it has received fewer than 100 complaints per year from users regarding temporary blocked vents (out of approximately 425,000 pump users), and that it "implemented [the 2013 recall as a] voluntary field corrective action" after "becoming

aware of the sequence of events that could le[a]d to a temporary blocked vent[.]" (*Id.* at 29–30.)

3. 2013 FDA Warning Letter

On September 19, 2013, the FDA issued a formal "warning" letter to Medtronic following an inspection of Medtronic's Northridge, California office. (*See* Ex. 55 to Pls.' Opp'n ("2013 Warning Letter"), ECF No. 131-3.) This warning was purportedly based on the agency's finding that Medtronic had violated certain rules known as the "current good manufacturing process regulations" ("CGMPs") with respect to its Paradigm insulin pumps (including the MMT-522 model pumps) in a number of ways. (*Id.* at 2.)[9] The FDA cited various deficiencies, including Medtronic's "[f]ailure to establish and maintain procedures for implementing corrective and preventative action, as required by 21 C.F.R. 820.100(a)[,]" (*id.* at 3); "failure to identify actions needed to correct and prevent recurrence of the Paradigm Insulin Infusion Pumps (MMT-5XX, 7XX) device failure" (*id.*); and "failure to review and evaluate all complaints to determine whether an investigation is necessary and to maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate when no investigation is made" (*id.* at 5). The FDA also announced the agency's conclusion that, due to the 13 different CGMP violations the that agency had found, Paradigm insulin pumps dating back to 2002 qualify as "adulterated" under 21 U.S.C. § 351(h), and also "misbranded under section 502(t)(2)

[9] CGMPs are general regulations that the FDA has promulgated which govern "the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a)(1).

of the Act." (*Id*. at 2, 15.) None of the 13 CGMP violations that are discussed in the warning letter pertain to the temporary-block-vent condition of the MMT-396 Infusion Set that the Kubickis allege in their complaint.[10]

Notably, in the text of its 2013 letter to Medtronic, the FDA expressly admonished Medtronic for its reporting failures. (*See id.* at 25–26 (asserting that Medtronic's "Paradigm Insulin Infusion Pumps are misbranded . . . in that your firm failed or refused to furnish material or information respecting the device that is required by or under the [MDA]" regarding incidents where users reportedly received an overdose of insulin from the pump).)[11] The FDA further faulted Medtronic for not "establish[ing] internal systems that provide for timely and effective indication, communication, and evaluation of events that may be subject to [medical device reporting] requirements[,]" and for not "establish[ing] internal systems that provide for a standardized review process to determine when an event meets the criteria for reporting under this part." (*Id.* at 26.)

[10] One potentially similar defect identified in the FDA warning letter is a failure to take corrective action regarding "overlay leaks . . . which could cause moisture ingress into the pump and pump failure." (2013 Warning Letter at 3.) However, the root cause of these leaks is identified as the "ultrasonic window welding process [which] causes initiation of stress-cracks, thus causing adverse effects to the finished device." (*Id.* at 4.) And Plaintiffs do not contend that Caroline's injury was caused by any such "overlay leak." Similarly, the 2013 Warning Letter faults Medtronic for failing to review and investigate pump-related complaints properly, citing as examples a pump where "the keypad overlay had weak adhesive bond at locations[;]" two pumps with "loose motor support disk[s;]" and one pump with "faulty FSR (gold)." (*Id.* at 7.) None of the cited examples involved the failure to investigate temporary blocked vent problems.

[11] The FDCA bars both the misbranding of any medical device in interstate commerce, and the introduction of any misbranded device into interstate commerce. 21 U.S.C. § 331(a), (b). The statute delineates a number of ways in which a medical device can be deemed misbranded, including where the product labeling is defective, *see id.* § 352 (b), (c), where the device was manufactured in an unregistered facility, *see id.* § 352 (o), or where a manufacturer or importer has failed to comply with adverse event reporting requirements, *see id.* § 352(t).

III. PROCEDURAL HISTORY

A. The Initial Pump-Related Legal Action The Plaintiffs Brought Against Medtronic Alone

On September 2, 2010, the Kubickis filed a lawsuit against Medtronic on Caroline's behalf in the Superior Court of the District of Columbia. (*See* Brown Decl. ¶ 3.) That complaint was dismissed without prejudice after the parties entered into a tolling agreement, and when the agreement expired, the Kubickis initiated the instant lawsuit by refiling their complaint against Medtronic in Superior Court. (*See id.*) Their initial complaint asserted claims for negligence, strict liability, misrepresentation, fraud, breach of express and implied warranties, violation of the District of Columbia Deceptive Trade Practices Act, and failure to warn under Restatement of Torts § 388, based on Caroline's use of the "Medtronic MiniMed Paradigm® Insulin Pump Model MMT-522." (*See* Compl., Ex. A to Notice of Removal, ECF No. 1, ¶ 4.) This initial complaint did not contain any specific allegations pertaining to the MMT-396 Infusion Set. (*See generally id.*)

Medtronic removed the complaint to federal court on May 8, 2012. (*See* Notice of Removal, ECF No. 1-2.)[12] Shortly after removal, Medtronic filed a motion to dismiss the Kubickis' complaint, asserting that Plaintiffs had failed to plead their claims sounding in fraud with particularity; that their implied warranty claims were duplicative of their strict liability claims; and that the doctrines of express and implied preemption barred all of the claims. (*See* Medtronic Mot. to Dismiss, ECF No. 4.) The Court granted this motion in part, dismissing without prejudice the Kubickis' fraud-

[12] U.S. District Judge Colleen Kollar-Kotelly presided over this case until it was transferred to the undersigned in July of 2013.

based claims, as well as their implied warranty claims. *See Kubicki v. Medtronic*, No. 12cv0734, 2013 WL 1739580, at *1 (D.D.C. Mar. 21, 2013). However, the Court rejected Medtronic's contention that the remaining claims in the complaint should be dismissed on either express or implied preemption grounds. *Id.* at *9–11.[13]

With respect to express preemption, the Court found that the Kubickis had "assert[ed] violations of the requirements set forth by the FDA as the cause of the alleged defects and ensuing violation of District of Columbia law[,]" such that the state law claims survived a challenge under Rule 12(b)(6). *Id.* at *8. However, in so holding, the Court kept the door open for Medtronic to renew its express preemption challenge following discovery, noting that "[w]hile 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." *Id.* at *9.

As for implied preemption, the Court rejected Medtronic's preemption argument on the grounds that Plaintiffs were not seeking to assert claims based on violation of FDA regulations (which the Supreme Court has found improper), but instead were pleading claims under "'traditional state tort law.'" *Id.* at *11 (quoting *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341, 352 (2001)).

[13] *See infra* Part VI.A.2 and VI.A.3 for a discussion of the doctrines of express and implied preemption.

B. Plaintiffs' Amended Complaint, Which Adds Unomedical And Claims That Relate Specifically To The Infusion Set

The Kubickis filed an amended complaint on January 10, 2014. (*See* Am. Compl., ECF No. 51.) With leave of Court and over Medtronic's objection (*see* Pls.' Mot. for Leave to Amend the Compl., ECF No. 38; Medtronic Opp'n to Pls.' Mot. for Leave to Amend the Compl., ECF No. 41), the Kubickis' amended complaint included Unomedical as a defendant, and also, for the first time in the course of the litigation, made specific allegations regarding defects in the MMT-396 Infusion Set. (*See* Am. Compl. ¶ 27.)[14] Medtronic and Unomedical then filed pre-discovery dispositive motions related to the amended complaint, which this Court denied on January 14, 2015; the Court instructed the parties instead to proceed to engage in fact discovery, and it provided both defendants with the opportunity to file either an answer or an omnibus motion addressing all issues regarding the legal sufficiency of the complaint in response to a second amended complaint that the plaintiffs proposed to file after discovery. (*See* Order Revising Schedule for Pretrial Proceedings, ECF No. 111.)

On July 31, 2015, after the scheduled period of fact discovery ended, the Kubickis filed a second amended complaint, which is the operative complaint for the purpose of the instant motions. (*See* 2d Am. Compl.). As noted above, this complaint asserts causes of action for negligence (Counts I–V), strict liability (Counts VI–X), breach of express warranties (Counts XI–XV), failure to warn (Counts XVI–XX), and punitive damages (Counts XXI-XXV). (*See generally id.*) There are multiple counts

[14] Plaintiffs also added Flextronics International USA, Inc, as a defendant in their amended complaint, alleging that the company was involved in the manufacture and/or sale of the Infusion Set (*see* Am. Compl. ¶ 11), but later voluntarily dismissed the claims against Flextronics (*see* Stip. of Dismissal as to Flextronics Int'l USA, Inc., ECF No. 69).

pertaining to each theory of liability because each theory is asserted separately against each of the five entities named as defendants in the complaint (Medtronic, Inc., Medtronic Diabetes, Medtronic MiniMed Inc., Unomedical Devices SA de CV, and Unomedical Devices A/S, respectively). (*See generally id.*) The claims against Medtronic pertain to both the MMT-522 Pump and the MMT-396 Infusion Set (*see id.* Counts I–III, VI–VIII, XI–XIII, XVI–XVIII, XXI–XXVIII, while the claims against Unomedical pertain only to the MMT-396 Infusion Set (*see id.* Counts IV–V, IX–X, XIV–XV, XIX–XX, XXIV–XXV).

Notably, the Kubickis' negligence claims against Medtronic allege that Medtronic violated various duties in connection with the company's design and marketing of the MMT-522 Pump and MMT-396 Infusion Set, including:

- "[the D]uty to act with reasonable care in designing the MiniMed Insulin Pump and Paradigm Infusion Sets [which] parallels the federal requirements set forth in 21 C.F.R. § 820.30 *et seq*. related to design controls[]" (*id.* ¶ 89);

- "[the D]uty to act with reasonable care in providing adequate instructions for use, labeling and warnings for the MiniMed Insulin Pump and Paradigm Infusion Sets [which] parallels the federal requirements set forth in 21 C.F.R. § 801, *et seq*. and 21 U.S.C. § 352[]" (*id.* ¶ 90);

- "[the D]uty to act with reasonable care in documenting, logging, investigating, and reporting to the FDA and the public any complaints it received from users concerning instances of unintended overdelivery of insulin in the MiniMed Insulin Pump and Paradigm Infusion Sets [which] parallels the requirements set forth in 21 C.F.R. § 820, *et seq*. and 21 C.F.R. 803, *et seq*[]" (*id*. ¶ 91); and

- "[the D]uty to act with reasonable care in manufacturing the MiniMed Insulin Pump and Paradigm Infusion Sets

> [which] parallels the requirements set forth in 21 C.F.R. § 820, *et seq*" (*id.* ¶ 92).

(*See also id.* at ¶¶ 95–98, 101–04.) The Kubickis assert these same alleged negligent breaches of duty with respect to Unomedical regarding the MMT-396 Infusion Set. (*See id.* ¶¶ 107–10, 113–16.)

As for their strict liability claims against Medtronic, which are asserted under the Restatement of Torts § 402A, the Kubickis allege that Medtronic sold "MiniMed Insulin Pumps and Paradigm Infusion Sets to Ms. Kubicki in a defective condition that was unreasonably dangerous to consumers such as Ms. Kubicki[]" due to the inadequate labeling, inadequate instructions for priming and filling, inadequate warnings concerning the devices' potential to cause an unintended overdelivery of insulin, improper design in violation of FDA design control regulations, improper manufacture in violation of FDA CGMPs, and failure to provide notice of complaints and adverse events. (*Id.* ¶¶ 121, 128, 135.) The Kubickis make identical allegations against Unomedical with respect to the MMT-396 Infusion Set. (*See id.* ¶¶ 142–49.)

The Kubickis' breach of warranty claims assert that Medtronic breached an express warranty allegedly set forth in the product packaging that the MMT-522 Pump would be free from "defects in materials and workmanship for a period of four years from the date of purchase[,]" (*id.* ¶ 158), as well as the express guarantee that the MMT-396 Infusion Set would be free from "defects in materials and workmanship for a period of up to three days from the date the packaging of the individual infusion set was opened" (*id.* ¶ 160). Plaintiffs further allege that Medtronic had "warranted in advertising and promotional materials" that the MMT-522 Pump and MMT-396 Infusion Set were "safe for use because the company had modified the design from

previous models to move the pressure-venting component from the insulin pump to the infusion set . . . [and] that this [design modification] would make the updated models of the devices safer than the previous versions and other models on the market by preventing vent blockage[,]" and that Medtronic had breached this warranty. (*Id.* ¶ 162; *see also id.* at ¶¶ 164–85.) Plaintiffs likewise assert that Unomedical breached the three-day warranty that it offered on the MMT-396 Infusion Set, in addition to the promotional warranty that the design changes made the device safer. (*See id.* ¶¶ 191–93, 200–02.)

C. Medtronic's And Unomedical's Motions For Summary Judgment

Medtronic and Unomedical have each moved for summary judgment with respect to Plaintiffs' Second Amended Complaint. (*See* Medtronic's MSJ; Unomedical's MSJ.) Medtronic makes three overarching arguments, each of which would dispose of this case in its entirety: (1) there is no evidence of causation (Medtronic's Mem. at 21–31), (2) Plaintiffs' claims are expressly and impliedly preempted (*see id.* at 31–45), and (3) the statute of limitations bars Plaintiffs' claims (*see id.* at 45–53). Medtronic further argues that Medtronic is entitled to summary judgment on the punitive damages claim because the record contains no evidence of intentional wrongdoing. (*See id.* at 58–60.) Unomedical asserts that it is entitled to summary judgment on the basis of the statute of limitations and implied preemption (Unomedical's Mem. at 25–26; 44–47), and it also seeks summary judgment on Plaintiffs' punitive damages claims, arguing that its alleged misconduct is not sufficiently outrageous or egregious to state a claim for punitive damages (*see id.* at 49–50).

This Court held a hearing on these motions on November 3, 2016, during which Plaintiffs represented to the Court that they were abandoning all of the claims against Unomedical except for the failure to warn claims that are brought under both the negligence and strict liability theories. (*See* Mot. Hr'g Tran. at 5:5–6:1.)

IV. LEGAL STANDARD FOR MOTIONS FOR SUMMARY JUDGMENT

The standard that applies to motions for summary judgment brought under Federal Rule of Civil Procedure 56 is clear beyond cavil. A court must grant summary judgment to the movant if the moving party "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A fact is material if it 'might affect the outcome of the suit under the governing law,' and a dispute about a material fact is genuine 'if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" *Steele v. Schafer*, 535 F.3d 689, 692 (D.C. Cir. 2008) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

The moving party has the burden of demonstrating the absence of a genuine dispute as to any material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the moving party has met this burden, the non-moving party must "designate 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 324 (quoting Fed. R. Civ. P. 56(e)). Although the Court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inference in that party's favor, *see, e.g.*, *Grosdidier v. Broad. Bd. of Governors, Chairman*, 709 F.3d 19, 23 (D.C. Cir. 2013) (citation omitted), the non-moving party must show more than "[t]he mere existence of a scintilla of evidence in support of" his or her position, *Anderson*,

477 U.S. at 252. That is, in order to advance to trial, "there must be evidence on which the jury could reasonably find" for the non-moving party. *Id.* Thus, the non-moving party "may not rest upon mere allegation or denials of his pleading but must present affirmative evidence showing a genuine issue for trial." *Laningham v. U.S. Navy*, 813 F.2d 1236, 1241 (D.C. Cir. 1987) (internal quotation marks and citation omitted).

V. RULING ON CAUSATION

As explained, Medtronic's summary judgment brief opens with an argument that it maintains disposes of this entire case: that the record contains insufficient evidence to support a jury finding that either the MMT-522 Pump or the MMT-396 Infusion Set actually *caused* Caroline's injuries, and thus there is no genuine dispute of fact regarding the causation element, which pertains to all of Plaintiffs' claims. (*See* Medtronic's Mem. at 31–32.)[15] To be specific, Medtronic insists that the record evidence indisputably demonstrates that Caroline *was not connected to her insulin pump at the time of her hypoglycemic incident*, which means that the pump and infusion set could not possibly have caused her injury. (*See id.* at 35.) And Medtronic offers various alternative causes for the precipitous drop in Caroline's blood sugar level—such as "inadequate monitoring of blood sugar levels, hypoglycemia unawareness, inadequate food intake, excessive exercise, dosing error by the patient, or some combination of these things[,]" (*id.*)—to bolster its causation argument, as laid out in an affidavit from Helena W. Rodbard, M.D., FACP, MACE, one of Medtronic's retrained expert witnesses (*see* Rodbard Decl.).

[15] As noted above, Unomedical has adopted Medtronic's arguments regarding causation (*see* Unomedical's Mem. at 10 n.1), and therefore the analysis in this section of the Memorandum Opinion applies to Unomedical's request for summary judgment on causation grounds as well.

This Court has already found that, by offering Dr. Rodbard's assessment of potential alternative causes for Caroline's injuries prior to the parties' formal entry into the expert-discovery phase of this litigation, Medtronic has jumped the gun. (*See* Min. Order of Apr. 8, 2016 (holding that "Medtronic's submission of an expert declaration (and related argument) regarding causation is premature").) As a result, the Court previously granted Plaintiffs' motion to strike the causation-hypothesis-related portions of Dr. Rodbard's declaration, as well as the parts of Medtronic's summary judgment brief that rely on the stricken parts of the declaration. (*See id.*) Thus, today, this Court considers only whether Defendants are entitled to summary judgment on causation grounds based on what the (admittedly incomplete) record that is now before this Court reveals.

As explained below, this Court finds that the record is such that a genuine dispute currently exists regarding the material question of whether Caroline was, in fact, connected to her insulin pump at the time of the hypoglycemic incident, which means that summary judgment is inappropriate at this time. However, the Court will permit Defendants to renew their causation arguments following the close of the forthcoming period of expert discovery.[16]

[16] Thus, today's causation ruling pertains only to what the *current* record demonstrates regarding the issue of whether Caroline was connected to the pump when the hypoglycemic incident occurred. The statements that Medtronic makes to suggest that (a) Caroline did not experience a temporary blocked vent even if she was connected to the pump, and (b) such a blockage could not have caused her injury in any event (*see* Medtronic's Mem. at 37–39), have not been squarely presented as a basis for the instant request for summary judgment, nor could they be, given that expert discovery is still pending. Therefore, the instant Memorandum Opinion addresses only one aspect of Defendants' causation-related contentions—i.e., that Caroline was not in fact connected to the insulin pump at the time of her injury—and should not be construed more broadly. (*See* Min. Order of Apr. 8, 2016 (preserving for current consideration only "the portions of Medtronic's brief [relating to causation] that argue that there is no evidence that Caroline Kubicki was wearing her insulin pump at the time of her underlying injury").)

A. The Record Evidence Thus Far Submitted Is Not Sufficient To Warrant Granting Summary Judgment To Defendants On Causation Grounds

As Medtronic itself acknowledges, "[b]ecause [Caroline] was alone for a significant portion" of the evening of September 8, 2007, "we are left with an incomplete picture of exactly what happened to [her]." (Medtronic's Mem. at 21–22.) Nevertheless, Medtronic maintains that it is entitled to summary judgment at this juncture, because, in its view, what we *do* know from the facts that the parties have gathered thus far indicates that Caroline was not actually using her insulin pump and the associated infusion set at the time of her hypoglycemic event. (*Id.* at 35.) The centerpiece of Medtronic's causation claim is the deposition testimony of Caroline's roommate (Magdelena Posthumus) that the MMT-522 Pump was "not attached to [Caroline]" when Posthumus discovered Caroline in distress on the morning of September 9, 2007, but instead was laying on Caroline's desk. (*See* Medtronic's Mem. at 22 ("According to Ms. Posthumus, when she discovered Ms. Kubicki at 8:00 a.m., the MMT-522 Pump was not attached to Ms. Kubicki." (citing Posthumus Dep. at 20:5–12, 20:20–23, 67:24–68:22, 70:5–13)) (emphasis omitted); *see also* Medtronic's Stmt. of Facts ¶ 29.) In addition, Medtronic points to Posthumus's statement to the 911 dispatcher, made shortly after she discovered her roommate, that Caroline, "'ha[d] something that's supposed to attach to her body but it's not attached[,]'" and that Posthumus did not know whether Caroline "'took it out herself[.]'" (Medtronic's Mem. at 22 (quoting 911 Call Transcript, Ex. W to Brown Decl., ECF No. 133-5, at 221) (first alteration in original).)

Medtronic further maintains that the police officers who responded to the scene reported that Posthumus had told them that Caroline "'carried around a device that

periodically dosed medication into her body'" and that "'there was no indication that the device was attached'" to Caroline's body when Posthumus discovered her. (*Id.* (quoting Police Report, Ex. V to Brown Decl., ECF No. 133-5, at 214).) Caroline's medical records also appear to indicate that the responding paramedics "'found [the] insulin pump disconnected'" on Caroline's desk, but that, in the paramedics' view, it was "'unclear'" whether Posthumus "'did this when [Caroline was] found unresponsive[.]'" (*Id.* (quoting GWU Medical Records, Ex. U to Brown Decl., ECF No. 133-5, at 209) (first alteration in original).)

Plaintiffs vociferously dispute Medtronic's contention that the pump was detached from Caroline's body (*see* Pls.' Stmt. of Fact ¶ 1), characterizing Posthumus's testimony as "equivocal and unreliable" (Pls.' Opp'n at 55), and noting that not only had Posthumus failed to recall certain details about the insulin pump (*id.* at 59 (citing Posthumus Dep. at 133:3–25)), she did not even remember the fact that she had called 911 on the morning in question (*id.* (citing Posthumus Dep. at 131:10–16)). Plaintiffs further argue that Posthumus had been out late with her friends on the evening of September 8, 2017, "and it is unclear whether she was consuming alcohol, affecting her memory and cognition the following morning." (*Id.*) Plaintiffs also point out that Posthumus testified that Caroline was wearing pajamas and that Posthumus could not rule out the pump being underneath Caroline's sleep clothes; that Posthumus did not notice the location of the pump on the desk until several minutes had passed, during which time numerous people had entered and left the dorm room; and that she did not know when the pump was placed on the desk. (*See id.* at 59–60 (citing Posthumus Dep. at 134:5–13, 160:19–21, 163:12–14).)

The Kubickis further maintain that, far from establishing that Caroline was not using the pump on the night in question, Caroline's medical records actually support the contention that Caroline was, in fact, connected to her pump. For instance, Plaintiffs read Caroline's hospital records to state that Caroline's pump was covered in vomit, and they argue that the pump "could not feasibly have been covered with pink vomit unless it was with Caroline at the time she suffered her acute hypoglycemic injury." (*Id.* at 61 (citing GWU Hosp. Records, ECF No. 138-4, at 4).) Plaintiffs also point to other statements in Caroline's medical records that suggest that it was Posthumus who removed the pump from Caroline's body (*id.* at 61 (citing GWU Hosp. Records at 4)), or that Caroline had removed the pump herself on the morning of September 9 (*id.* at 61 (citing GWU Hops. Records at 6)). Plaintiffs also note that a resident advisor had recalled seeing an small plastic box on Caroline's body while Caroline was unconscious in her bed (*id.* at 61–62 (citing Barloon Dep. at 59, 96:18–25, 89:25–93:23, 97:8–15)), and that a paramedic has removed a "sticker" attached to Caroline's abdomen, which they surmise was the "the adhesive attached to her infusion set" (*id.* at 62 (citing Humphrey Dep. at 46:21–47:10, 59:8–15)). Additionally, when deposed, both of the Kubickis testified that it simply was not Caroline's practice to take her pump off at night. (*See id.* (citing J. Kubicki Dep. at 418:2–4; K. Kubicki Dep. at 395:15–21).)

In response, Medtronic insists that the Kubickis "mischaracteriz[e]" the evidence (Reply in Support of Medtronic's Mot. ("Medtronic's Reply"), ECF No. 145, at 11), and it provides detailed, alternative characterizations of the deposition testimony and medical records at issue (*id.* at 10–14). Moreover, Medtronic reiterates that "[t]he only testimony concerning what Ms. Kubicki was doing on the evening in question came

from Posthumus, who testified Ms. Kubicki was asleep when Posthumus left for the evening and remained in that state from the time Posthumus returned to her dorm and read a book for an hour to when she awoke and discovered Ms. Kubicki in distress the following morning." (Medtronic's Reply at 15 (citing Medtronic Mem at 22).)

This Court has no doubt that the instant record is not sufficient to establish indisputably that Caroline was not connected to her insulin pump on the night in question, because there is evidence the points in both directions, and because the issue primarily turns on Ms. Postumus's recollection of events, as Medtronic appears to have acknowledged. It is well established that "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge at summary judgment." *Barnett v. PA Consulting Grp., Inc.*, 715 F.3d 354, 358 (D.C. Cir. 2013) (citation omitted). And, indeed, this Court's role in deciding a motion for summary judgment is not to "determine the truth of the matter, but instead [to] decide only whether there is a genuine issue for trial." *Id.*

As this Court views the current record, there is evidence from which a reasonable jury could conclude *either* that the insulin pump was involved in Caroline's injury because it was attached to her on the night in question (*see, e.g.*, GWU Hosp. Records at 4, 6; Barloon Dep. at 59, 96:18–25, 89:25–93:23, 97:8–15) *or* that the insulin pump had nothing to do with Caroline's injury because it was laying on her desk unused at the time that Postumous discovered Caroline (*see, e.g.*, Posthumus Dep. at 20:5–12, 20:20–23, 67:24–68:22, 70:5–13; 911 Call Transcript). Drilling down even farther, it appears that, even if the jury were to conclude that the pump was on Caroline's desk, the causation question would not be entirely resolved, because the current record does not

explain *when* or *how* Caroline's insulin pump ended up there. Based on the existing record evidence, then, a jury could only reasonably infer that the pump was placed on the desk sometime between 8:30 p.m. on the evening of September 8th—when Caroline gave herself six units of insulin (*see* K. Kubicki Dep. at 129:20–130:8)—and the morning of September 9th—when emergency personnel took Caroline to the hospital. Within this key block of time is a substantial period for which no competent individual can provide eyewitnesses testimony, because Posthumus was out with friends from 10:30 p.m. the evening of September 8th until 12:30 a.m. the following morning, and was asleep thereafter. Thus, Posthumus's testimony does not go far enough in answering the question of whether the pump did or did not contribute to Caroline's injury, even if it is deemed credible, which means that expert opinion regarding whether the factual circumstances reflected in the record indicate that Caroline was actually using the allegedly defective pump within the pertinent timeframe on the night of September 8th and the morning of September 9th is likely to be necessary.

Consequently, the current testimony and documentary evidence are simply not sufficient to establish that there is no issue of fact for trial with respect to the material issue of whether Caroline was using her insulin pump at the time of her injury. If nothing else, it is patently obvious that the parties' volley of competing evidentiary interpretations and witness-credibility assessments raise more causation questions than the record presently answers, and these lingering questions are plainly ones that a jury—and not this Court—must resolve. *See In re Fort Totten Metrorail Cases Arising Out of Events of June 22, 2009*, 895 F. Supp. 2d 48, 70 (D.D.C. 2012) (noting that "proximate causation is ordinarily a question of fact for the jury. . . . [and] that it is

only the exceptional case in which questions of proximate cause pass from the realm of fact to one of law" (internal quotation marks and citations omitted)); *see also Boodoo v. Cary*, 21 F.3d 1157, 1161 (D.C. Cir. 1994) ("The court may not substitute its judgment for that of the jury: it neither assesses witness credibility nor weighs evidence." (citation omitted)); *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1536 (D.C. Cir. 1984) (finding that, where there was conflicting evidence regarding causation, court properly submitted the question to jury).

B. The Parties Will Be Permitted To Revisit The Causation Question After Expert Discovery Is Completed

To be clear: this Court's ruling on causation is a relatively narrow one, in that it pertains only to the pending motions for summary judgment. (*See supra* n.16.) The Court anticipates that the parties will undertake expert discovery in this matter (*see* Order Revising Schedule for Pretrial Proceedings, ECF No. 11, at 1–3 (setting schedule for fact discovery and initial motions, and providing that "[i]f any claims remain after this Court rules on the dispositive motions, the Court will schedule an additional period of expert discovery in preparation for trial")), and in complex medical product liability cases such as this one, expert testimony regarding causation is ordinarily indispensable under District of Columbia law. *See, e.g.*, *Otis Elevator Co. v. Tuerr*, 616 A.2d 1254, 1260 (D.C. 1992) (noting the necessity of expert testimony "when recovery is sought for permanent injuries or where there are complicated medical questions related to causation of such injuries") (citations omitted); *see also Baltimore v. B.F. Goodrich Co.*, 545 A.2d 1228, 1231 (D.C. 1988) (explaining that expert testimony is necessary to establish causation in cases involving "medically complicated" claims with "multiple and/or preexisting causes") (citations omitted).

As detailed below, the Court is permitting certain claims against Medtronic to proceed (*see infra* Part VII.B, VII.C)), and therefore, the Court will issue a separate order that requires the parties to submit a joint proposed schedule for a period of expert discovery to commence forthwith. Once this expert discovery period has concluded, the Court will permit Medtronic to renew and supplement its request for summary judgment on the issue of causation.

VI. RULING ON TIMELINESS

Turning to another major argument that Medtronic and Unomedical raise in the context of their motions for summary judgment—timeliness—the Court notes that the parties do not dispute that Plaintiffs' product-liability claims for negligence, strict liability, and failure to warn are subject to the three-year statute of limitations laid out in D.C. Code § 12-301. (*See* Medtronic's Mem. at 55; Unomedical's Mem. at 25; Pls.' Opp'n at 63.) *See also* D.C. Code § 12-301(8) (actions "for which a limitation is not otherwise specially prescribed" must be brought within three years "from the time the right to maintain the action accrues"). And the parties also appear to agree that the Kubickis' claims *as they relate to the MMT-522 Pump* are timely. (*See* Medtronic's Mem. at 55.) The statute of limitations dispute is over whether the tort claims that pertain to the MMT-396 Infusion Set—which were first introduced into this litigation on November 19, 2013, six years after Caroline's injury—are time-barred. (*See id.* at 55–62; Unomedical's Mem. at 25–34; Pls.' Opp'n. at 63–76; Pls.' Mot. for Leave to File the First Am. Compl., ECF No. 38.) For the reasons explained below, this Court finds that the infusion set-related tort claims that the Kubickis have brought against Unomedical are not timely, because such claims could have (and should have) been

discovered shortly after Caroline's injury in 2007, and Unomedical had no notice of the infusion set claims against it until the Kubickis filed an amended complaint, six years after the injury occurred. However, the infusion set-related tort claims against Medtronic are not time-barred, because these otherwise untimely claims concerning the MMT-396 Infusion Set relate back to the timely claims that the Kubickis had filed against Medtronic concerning the MMT-522 Pump.

A. The Law Pertaining To Timeliness: Statutes Of Limitations, The Discovery Rule, And The Relation Back Doctrine

A statute of limitations is the legislatively prescribed time period (usually a period of years) within which an authorized legal claim must be filed. *See* Statute of Limitations, Black's Law Dictionary (10th ed. 2014) (defining statute of limitations); *see also Rudder v. Williams*, 47 F. Supp. 3d 47, 52 (D.D.C. 2014) ("'Statutes of limitations . . . represent a pervasive legislative judgment that it is unjust to fail to put the adversary on notice to defend within a specified period of time and that the right to be free of stale claims in time comes to prevail over the right to prosecute them.'" (quoting *United States v. Kubrick*, 444 U.S. 111, 117 (1979) (alteration in original))). Claims that are brought beyond the statutory time period are ordinarily barred. *See Untalasco v. Lockheed Martin Corp.*, 249 F. Supp. 3d 318, 323 (D.D.C. 2017) ("[T]he general rule that one can glean from [precedent] is that courts should apply the [District of Columbia] statute of limitations strictly, even though barring actions often seems arbitrary and inequitable." (internal quotation marks, citation, and emphasis omitted)). However, when a plaintiff files a timely legal action regarding an injury, and then later seeks to assert a potentially out-of-time claim in the context of an amended complaint, two independent and alternative concepts can apply to permit such an amendment: "the

discovery rule" (which considers when the *plaintiff* knew or should have known of the potential claim), *see Bussineau v. President & Directors of Georgetown Coll.*, 518 A.2d 423, 425 (D.C. 1986), and "the relation back doctrine" (which considers the connection between the old claim and the new one to determine whether the *defendant* knew or should have known of the claim), *see Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 866 (D.C. Cir. 2008). The contours of each of these doctrines is laid out below.

1. The Discovery Rule

The discovery rule alters the typical understanding of when the statute of limitations starts to run, (i.e., when it "accrues.") It is well established that, "[w]here the fact of an injury can be readily determined, a claim accrues for purposes of the statute of limitations at the time the injury actually occurs." *Colbert v. Georgetown Univ.*, 641 A.2d 469, 472 (D.C. 1994) (citations omitted). But, if the injury is not apparent, and/or if the causal link between tortious conduct and injury is not immediately clear, District of Columbia courts apply the "discovery rule[,]" which holds that the statute of limitations begins to run not on the date that the injury happened, but "'when the plaintiff has knowledge of (or by the exercise of reasonable diligence should have knowledge of) (1) the existence of the injury, (2) its cause in fact, and (3) some evidence of wrongdoing.'" *Lee v. Wolfson*, 265 F. Supp. 2d 14, 17 (D.D.C. 2003) (quoting *Bussineau*, 518 A.2d at 425); *see also Colbert*, 641 A.2d at 473 (holding that plaintiff's claim for medical malpractice did not accrue until she "discovered or reasonably should have discovered all of the essential elements of her possible cause of actions") (quotation marks and citation omitted).

The District of Columbia Court of Appeals has made clear that, per the discovery rule, "the statute of limitation[s] for negligence begins to run at such time a prospective

plaintiff gains inquiry notice that wrongdoing may be involved." *Bussineau*, 518 A.2d at 427–28. This means that what a plaintiff knows, or should have known, about the defendant's potential fault is key. *Id.* Nevertheless, the statute of limitations will be deemed to run even if the plaintiff does not fully comprehend the extent to which a potential defendant may have caused the injury. *See Baker v. A.H. Robins Co.*, 613 F. Supp. 994, 996 (D.D.C. 1985). Furthermore, a plaintiff who has suffered an injury must act reasonably and diligently to investigate the possibility of a claim, and a litigant is deemed to have inquiry notice of a claim that he should have discovered by exercising this reasonable diligence. *See id*. at 996; *see also Reeves v. Eli Lilly & Co.*, 368 F. Supp. 2d 11, 21 (D.D.C. 2005) (emphasizing that the reasonableness of an investigation is evaluated under an objective standard). Put another way:

> In every case, the plaintiff has a duty to investigate matters affecting her affairs with reasonable diligence under all of the circumstances. Once the plaintiff actually knows, or with the exercise of reasonable diligence would have known, of some injury, its cause-in-fact, and some evidence of wrongdoing, then she is bound to file her cause of action within the applicable limitations period, measured from the date of her acquisition of the actual or imputed knowledge.

Diamond v. Davis, 680 A.2d 364, 381 (D.C. 1996). In the context of the discovery rule, it is the defendant's burden to show that the plaintiff has not acted with reasonable diligence. *See Smith v. Brown & Williamson Tobacco Corp.*, 108 F. Supp. 2d 12, 17 (D.D.C. 2000).

2. The Relation Back Doctrine

Federal Rule of Civil Procedure 15(c) "governs when an amended pleading 'relates back' to the date of a timely filed original pleading and is thus itself timely even though it was filed outside an applicable statute of limitations." *Krupski v. Costa*

Crociere S. p. A., 560 U.S. 538, 541 (2010). Rule 15(c) addresses three instances where relation back is appropriate; Plaintiffs here rely on the second of the three: where "the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading." Fed. R. Civ. P. 15(c)(1)(B). (*See* Pls.' Opp'n at 74 ("The allegations concerning the Infusion Set 'arise out of the same conduct' alleged in the original complaint and Plaintiffs have not introduced any new legal theories since their original complaint." (quoting Fed. R. Civ. P. 15(c)(1)(B))).)

Significantly for present purposes, the relation-back doctrine and the discovery rule both generally pertain to knowledge of the claim; however, these doctrines address different parties. The discovery rule focuses on the knowledge *of the plaintiff*, while the relation back doctrine focuses on whether *a defendant has had fair notice* of the plaintiff's claim. *Compare Lee*, 265 F. Supp. 2d at 17 (holding that the statute of limitations begins to run under the discovery rule when a plaintiff knows, or should know, of an injury, its causation, and some wrongdoing on the part of the defendant) *with Meijer, Inc.*, 533 F.3d at 866 ("The underlying question is whether the original complaint adequately notified the defendants of the basis for liability the plaintiffs would later advance in the amended complaint."); *Hartley v. Wilfert*, 931 F. Supp. 2d 230, 233 (D.D.C. 2013) (explaining that, for purposes of the relation back doctrine, "notice to the defendant is relevant to the inquiry"); *see also, e.g.*, *Dover v. Medstar Wash. Hosp. Ctr.*, 989 F. Supp. 2d 57, 59, 61–62 (D.D.C. 2013) (holding that claims for violations of D.C.'s overtime statute did not relate back to timely claims for intentional interference with prospective advantage and economic expectancy, intentional

misrepresentation, and defamation because of defendants' lack of notice of the alleged wage payment violations). Ultimately, "[s]o long as the original and amended [complaints] state claims that are tied to a common core of operative facts, relation back will be in order." *Mayle v. Felix*, 545 U.S. 644, 664 (2005).

B. Plaintiffs Could Have Discovered Their Claims Against Unomedical Regarding The MMT-396 Infusion Set Near The Time Of Caroline's Injury; Therefore, The Infusion Set Claims That Plaintiffs Belatedly Asserted Against Unomedical Are Untimely

Plaintiffs first named Unomedical as a defendant, and made associated claims arising from Unomedical's manufacture of the MMT-396 Infusion Set, on January 10, 2014—more than six years after Caroline's hypoglycemic event. (*See* Am. Compl.) In response to the timeliness objection that both Medtronic and Unomedical raise in their summary judgment motions, Plaintiffs insist that their newly-asserted infusion set claims are not time-barred, because Plaintiffs "could not have conceivably connected Caroline Kubicki's severe hypoglycemic injury" to a defect or malfunction in the MMT-396 Infusion Set prior to June 2013 Paradigm Infusion Set recall. (Pls.' Opp'n at 65; *see also id.* at 66 ("[T]he public was not made aware of the role of the Infusion Set in the over-delivery of insulin until June 7, 2013, when the Class I recall concerning the temporary vent block condition was issued." (citation omitted)).) This Court rejects the Kubickis' contention that their product-liability claims arising from the MMT-396 Infusion Set accrued only as of June 2013, and that prior to that date they could not possibly have discovered that the infusion set—and its manufacturer, Unomedical—might have been the cause of Caroline's injuries, for the following reasons.

1. Caroline's Insulin-Delivery Device Is A Multifaceted Medical Product, And The Manufacturers Of The Various Components Are Clearly Identified

First of all, as explained in Part II.B, *supra*, a mechanical insulin-delivery pump is a complex medical device that has many intricate parts, even to the lay observer. In the wake of Caroline's injury, basic due diligence in evaluating the suspected source of the alleged insulin overdose would have led a reasonable plaintiff to discover relatively quickly that Caroline's insulin-delivery device has various components; moreover, a reasonable plaintiff certainly would have surmised that any one of the device's various components could have been responsible for Caroline's injury. Indeed, the record establishes that the Kubickis understood at the time of Caroline's injury that the MMT-522 Pump and the MMT-396 Infusion Set *worked together* to provide insulin to Caroline (*see* J. Kubicki Dep. at 85:3-9; K. Kubicki Dep. at 324:3-16), which makes it all the more unreasonable for Plaintiffs to have filed an initial complaint that only contained claims related to an alleged defect in *one* component of Caroline's insulin-delivery device (the MMT-522 Pump).

The fact that Karen Kubicki may have subjectively believed that the potentially defective insulin-delivery product was a unitary object (*see* K. Kubicki Dep. at 324:3–16 (asserting that she considered the pump and infusion set as "one [and] the same")) is of no moment. As explained, the applicable standard of knowledge for the purposes of the discovery rule is an *objective one*, *see Baker*, 613 F. Supp. at 996, and given the totality of the facts and circumstances here, (including those that would have been uncovered by a diligent investigation), it is clear to this Court that an objectively reasonable plaintiff would have readily discovered that the pump and the infusion set were distinct components of the Caroline's insulin-delivery device, especially after one

of Caroline's physicians specifically expressed to the Kubickis a concern about the fact that Caroline's MMT-396 Infusion Set had been discarded after the injury. (*See* K. Kubicki Dep. at 322:6-7 (acknowledging that the doctor had told them "you would want everything that [Caroline] was using" in trying to figure out what happened); *see also id.* at 322:14–23, 324:3–16.) And even without such pointed statements from persons with knowledge of the device in question, a reasonable plaintiff would have at least consulted the packaging materials that accompanied the seemingly defective medical device, and thereby would have discovered that the infusion set tubing that delivers insulin to the body *was packaged separately* from the potentially defective mechanical pump—another indisputable marker of a separate piece of medical equipment.

Plaintiffs' contention that, as laypeople, they could not possibly have known that a defect in the p-cap valve of the MMT-396 Infusion Set caused Caroline's injury before the recall in June of 2013 (*see* Pls.' Opp'n at 66) misses the mark entirely, insofar as it suggests that the statute of limitations does not accrue on a products-liability claim until the plaintiff has sufficient information to make specific allegations with respect to causation. Quite to the contrary, it is well established that, while a plaintiff must have "knowledge of wrongdoing to commence the statute of limitation[s,]" *Bussineau,* 518 A.2d at 432 n.11, he need not "have certain knowledge of causation[,]" *Dawson*, 543 F. Supp. at 1334. Thus, it was sufficient that the Kubickis suspected wrongdoing related to the mechanism by which insulin went from the MMT-522 Pump's reservoir, through the infusion set, and into Caroline's body—even if they did not understand the precise failure mode—and they had developed this suspicion by at least the year 2010. This Court has no doubt that, under such circumstances, a

reasonable plaintiff would have discovered, and presumably raised, tort claims that pertain to *all* of the components of that allegedly faulty insulin-delivery system.

In this case, there is an additional wrinkle: the Kubickis' unreasonable failure to assert timely product-liability tort claims relating to a key component of Caroline's insulin-delivery device also means they *failed to identify Unomedical*, and to include that company as a defendant in this action in a timely fashion. Again, while Karen Kubicki may not have *actually* known that there was another company involved in the manufacture of the medical device that she suspected caused Caroline's injury (*see* Pls.' Opp'n at 68 (referencing Karen Kubicki's statement that she "did not know who made the Infusion Set and only thought that Medtronic was involved")), and in this Court's view, an objectively reasonable plaintiff would easily have discovered at the time of Caroline's injury that a potential tort claim arising from the MMT-396 Infusion Set existed and was assertable against that product's manufacturer. What is more, the product packaging and instructions related to the MMT-396 Infusion Set clearly state that the MMT-396 Infusion Set was "Assembled in Mexico for Unomedical A/S" (Packaging Photos; Infusion Set Instructions), and *Unomedical's name also appears on the MMT-396 Infusion Set itself* (Mot. Hr'g Tr. 73:19–74:6.), which makes the Kubickis' failure to conduct even the most minimal investigation all the more obvious here.

In any event, there is no question that the Kubickis had an obligation to conduct an investigation into all of the potential sources of the product that they suspected was the cause of Caroline's injury. They were certainly aware that *someone* had manufactured all of the components of the device in question; thus, they were on

"inquiry" notice that medical-device manufacturers had a role in making Caroline's infusion set, and should have looked into whether any companies other than Medtronic were involved. *See Berkow v. Lucy Webb Hayes Nat'l Training Sch. for Deaconesses & Missionaries Conducting Sibley Mem'l Hosp.*, 841 A.2d 776, 781 (D.C. 2004) (noting that "a plaintiff's knowledge of one defendant's misconduct will 'create inquiry notice of claims against a potential co-defendant . . . if (1) a reasonable plaintiff would have conducted an investigation as to the co-defendant, and (2) such an investigation would have revealed some evidence of wrongdoing[,]'" and holding that plaintiff's knowledge of one doctor's misdiagnosis of him placed him on inquiry notice of claims against other doctors who allegedly contributed to the misdiagnosis (quoting *Cevenini v. Archbishop of Wash.*, 707 A.2d 768, 773 (D.C. 1998) (alteration in original))).

This all means that nothing about the circumstances here persuades this Court that it was reasonable for the Kubickis to forego an investigation of all of the potential producers of the various parts of Caroline's insulin-delivery device when they undertook to bring a timely products-liability lawsuit in 2010. It is undisputed that the MMT-396 Infusion Set works together with the MMT-522 Pump, and even setting aside the obvious indications on the packaging materials and the device itself that a company other than Medtronic was involved with the manufacture of that component, a reasonable plaintiff would have investigated the origins of the device in question, and such investigation would have revealed that Unomedical had a sufficient connection to the manufacturing of the MMT-396 Infusion Set to warrant naming Unomedical as a co-defendant in the 2010 complaint. *See also* 21 C.F.R. § 803.3(1) (FDA regulations defining manufacturer as "any person who manufactures, prepares, propagates,

compounds, assembles, or processes a [medical] device"). In other words, although the Kubickis were intent upon suing Medtronic based on their concerns about the operation of the insulin pump, the company that the manufactured the infusion set—a component of Medtronic's insulin-delivery device—was readily ascertainable by the public at the time of Caroline's injury, and should have been known to Plaintiffs as well, long before to the 2013 Recall.

2. Plaintiffs Rely On Dissimilar Cases To Support Their Contention That Their Infusion Set Claims Accrued In 2013

The functional connection between the MMT-522 Pump and the MMT-396 Infusion Set, and the fact that the Kubickis suspected a defect in Caroline's insulin-delivery system immediately but chose to file a timely action against only one of the companies involved in the manufacture of the components of that system, differentiates this case from *Lee v. Wolfson*, 265 F. Supp. 2d 14 (D.D.C. 2003), on which Plaintiffs rely. The plaintiff in *Lee* sued for damages as a result of injuries that she suffered when an unattended vehicle in a parking garage struck her. Notably, after testing showed no issues with the parking break mechanism, Lee's complaint alleged that the cause of her injury was human error in either failing to set the parking brake or inadvertently releasing it, *id.* at 16, and consistent with this theory, Lee initially named the owner of the rolling car and the parking garage as defendants, *id.* The National Highway Traffic Safety Administration subsequently issued a recall to correct a defect in the parking brake design, which prompted Lee to seek to amend her complaint to add the car's manufacturer, *id.* at 16–17, and the Court authorized the amendment as timely. In finding that Lee's claims against the manufacturer did not accrue until the recall notice issued, the *Lee* court held that "plaintiff here cannot automatically be expected to know

that wrongful conduct on the part of [the manufacturer] might have caused the release of the [rolling car's] parking brake at the time of her injury, particularly when no defect in the parking brake was revealed during the investigation of the accident by the police or plaintiff's expert." *Id.* at 18.

Here, by contrast, the Kubickis' initial claim of wrongdoing concerned an alleged product-related defect pertaining to the insulin-infusion system that Caroline used (otherwise they could not have in good faith sued Medtronic). And having suspected a problem with that system, it was incumbent upon the Kubickis to conduct a reasonable inquiry into *all* of the possible components of that system in a timely fashion. *See Diamond*, 680 A.2d at 381; *see also Colbert*, 641 A.2d at 472–73 (holding that "[w]here the fact of an injury can be readily determined, a claim accrues for purposes of the statute of limitations at the time the injury actually occurs[,]" but "[w]here the relationship between the fact of injury and the alleged tortious conduct may be obscure," the claim accrues when the plaintiff "knew or should have known that she had suffered injury as a result of the defendants' negligence"). In other words, the instant case is substantially different from *Lee*, because while the plaintiff in *Lee* lacked fair notice of any wrongdoing with respect to the parking brake system of the car that had injured her and was instead proceeding on a human-error tort theory, the Kubickis suspected a product defect from the outset, and therefore, had the obligation to examine timely all of the aspects of the allegedly defective product for statute of limitations purposes.

A more analogous case is *Colarossi v. Schmid Laboratories, Inc.*, 830 F. Supp. 230 (D.N.J. 1993), in which the court found that a claim against a manufacturer of

intrauterine devices ("IUDs") was untimely under District of Columbia law. The plaintiff in *Colarossi* learned from her doctor in 1978 that her IUD might have caused an infection that led to permanent injuries. *Id.* at 237. The court found that her claim accrued at that point in time, noting that "[f]aced with permanent injury and [a] statement by her doctor that her IUD may have been the cause, wrongdoing by someone was more than a hypothetical possibility and the wrongdoing element was met." *Id.* (alterations, internal quotation marks, and citation omitted); *see also id.* at 236 ("The wrongdoing element does not, however, require that the plaintiff know the identity of the party responsible for the injury."). In the alternative, the court found that the claim accrued no later than 1986, which was when the plaintiff learned of, and participated in, litigation related to Dalkon Shield IUDs. *Id.* at 237. Notably, the *Colarossi* plaintiff made a critical mistake in connection with that litigation: she failed to review her own medical records to determine the specific manufacturer of the IUD that she had used, and as a result, she only sued the manufacturer of Dalkon Shield IUDs, *not* the manufacturer of the brand of IUD that was identified in her medical records. *Id.* When the plaintiff later learned of her error and tried to sue the correct manufacturer, the court pegged 1986 as the latest possible accrual date because, at that point, "not only was [the plaintiff] aware of the possibility of wrongdoing, she took affirmative action to obtain legal redress." *Id.*; *see also id.* (faulting plaintiff for failing to exercise due diligence because she failed to examine her medical records before initiating suit).

So it is here. The Kubickis knew of potential wrongdoing on the part of the manufacturers of Caroline's insulin-deilvery system in 2007, when Caroline suffered her injury and when her treating physician advised them that Caroline's insulin-delivery

system (consisting of the MMT-522 pump and MMT-396 Infusion Set) could be the cause. (*See* J. Kubicki Dep. at 23:25–25:13.) And even if it was reasonable for the Kubickis to fail to make a connection between the insulin-deilvery system and potential wrongdoing in 2007, they undeniably had made that connection by the time they filed a lawsuit against Medtronic in 2010, which means that, at the very latest, their product-liability claims accrued in 2010 (*see* Brown Decl. ¶ 3), four years before they undertook to litigate tort claims specifically pertaining to the MMT-396 Infusion Set.

The 2009 Lot 8 recall—through which Medtronic recalled certain MMT-396 Infusion Sets from a particular manufacturing lot but provided public assurances that all other lots were safe and effective (*see* 2009 Recall Notice, Ex. 18 to Pls.' Opp'n, ECF No. 138-28, at 1)—has no bearing on the aforementioned analysis of the accrual of the Kubickis' claims. Plaintiffs assert that Medtronic's safety assurances with respect to non-Lot 8 infusion sets "led Plaintiffs to not consider the MMT-396 Infusion Set as a potential cause in fact." (Pls.' Opp'n at 70.) But, if anything, the 2009 recall notice would have spurred a reasonable plaintiff to inquire *further* regarding this component of the Caroline's insulin-deilvery system, because in the context of the Lot 8 recall, Medtronic expressly identified a particular fault mechanism in the MMT-396 Infusion Set that could result in the over-delivery of insulin, i.e., the blocking of air vents in the tubing connector. (*See* Questions & Answers Regarding the "Lot 8" Quick-set Infusion Set Recall, Ex. 27 to Pls.' Opp'n, ECF No. 138-29, at 3; *see also* 2009 Recall Notice at 1 (explaining, specifically, that Lot 8 MMT-396 Infusion Sets potentially had a manufacturing defect that "may not allow the insulin pump to vent air pressure properly

[which] could potentially result in the device delivering too much or too little insulin and may cause serious injury or death.")

Thus, armed with the general knowledge that blockage of the infusion set air vents could lead to an over-delivery of insulin, and believing that Caroline was injured as the result of an over-delivery of insulin, an objectively reasonable plaintiff would by no means have felt "reassured" by Medtronic's assertions; instead, she would have even more vigorously investigated, and pursued, tort claims against any entity that had played a role in the manufacture of Caroline's MMT-396 Infusion Set, including Unomedical.[17]

3. The Relation Back Doctrine Does Not Save The Infusion Set-Related Claims Against Unomedical

Plaintiffs have invoked the "relation back" doctrine to maintain that, even if this Court concludes that the amended complaint's claims related to the MMT-396 Infusion Set are untimely because those claims could have been discovered long before Plaintiffs filed the amended complaint, the infusion set claims should nevertheless be deemed timely. (*See* Pls.' Opp'n at 74.) To support this argument, Plaintiffs cite to Federal Rule of Civil Procedure 15(c)(1)(B), which provides that an amended pleading relates back to the date of the original pleading when "the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out—or attempted

[17] The holdings of the cases that Plaintiffs cite to support their contention that they "justifiably relied on Defendants to provide information about the safety risks of their products[,]" (Pls.' Opp'n at 70), are inapposite. The court in *Diamond*, for example, noted that it could take into account the existence of a "confidential or fiducial relationship between the plaintiff and defendant" in determining whether the plaintiff rightfully relied on representations the defendant made. 680 A.2d at 381. No such fiduciary or confidential relationship exists in this case. Nor is this a circumstance where there is a latent product defect that only becomes evident after the limitations period had run. *See, e.g.*, *Ehrenhaft v. Malcolm Price, Inc.*, 483 A.2d 1192, 1202 (D.C. 1984). Here, the injury itself was immediately evident, and Plaintiffs unquestionably had knowledge of the insulin-deilvery system's potential role in Caroline's injury by at least 2010.

to be set out—in the original pleading[.]" Fed. R. Civ. P. 15(c)(1)(B). In this regard, Plaintiffs argue that "the Second Amended Complaint does not introduce any *new* legal theories into this litigation, but instead only amplifies the original factual allegations to include the Infusion Set" (Pls.' Opp'n at 75 (emphasis added) (internal citations and quotation marks omitted)). Be that as it may, this Court concludes that the infusion set-related claims against Unomedical cannot be considered to relate back to the original complaint for statute of limitations purposes, for the following reasons.

It is clear beyond cavil that relation back under Rule 15(c)(1)(B) is permissible only if the defendant had "sufficient notice of the facts and claims giving rise to the proposed amendment" prior to the expiration of the statute of limitations. *United States v. Hicks*, 283 F.3d 380, 388 (D.C. Cir. 2002). Thus, the general rule is that "new parties, either plaintiffs or defendants, cannot be added to an action by amendment after the applicable limitations period has expired[,]" 6A Charles A. Wright, et al., Federal Practice & Procedure § 1498 (3d ed. 2017), because a new defendant typically would not be aware of the claims, having not been named in the original suit. Rule 15(c)(1)(C) alters this general rule, but it allows the addition of a new party if Fed. R. Civ. P. 15(c)(1)(B) is satisfied *and* if the party to be added "(i) received such notice of the action [within the time allotted for service of the original complaint] that it would not be prejudiced in defending on the merits; and (ii) knew or should have known that the action would have been brought against it, but for a mistake concerning the proper party's identity." Fed. R. Civ. P. 15(c)(1)(C); *see also Bayatfshar v. Aeronautical Radio, Inc.*, 934 F. Supp. 2d 138, 144 (D.D.C. 2013) (an amendment adding a new party relates back to the prior complaint "'when the requisite notice and identity of interests

showings'" that Rule 15(c)(1)(C) requires are made (quoting *Stoppelman v. Owens*, 580 F. Supp. 944, 946 (D.D.C. 1983))).

Thus, "relation back under Rule 15(c)(1)(C) depends on what the *party to be added* knew or should have known, not on the amending party's knowledge or its timeliness in seeking to amend the pleading." *Krupski*, 560 U.S. at 541 (emphasis added); *see also Philogene v. Dist. of Columbia*, 864 F. Supp. 2d 127, 133 (D.D.C. 2012) ("This Circuit has explained that the purpose of [Rule 15(c)(1)(C)] is to 'avoid the harsh consequences of a mistake that is neither prejudicial nor a surprise to the misnamed party.'" (quoting *Rendall-Speranza v. Nassim*, 107 F.3d 913, 918 (D.C. Cir. 1997))); *see, e.g.*, *Placide Ayissi-Etoh v. Mae*, 49 F. Supp. 3d 9, 13–14 (D.D.C. 2014) (holding that amendment adding individual capacity claims to employment discrimination suit did not relate back under Rule 15(c)(1)(C) to original complaint alleging corporate capacity claims where record "strongly support[ed] an inference that the individual [d]efendants did not have notice" of potential for individual capacity claims, such that the amendment "would be highly prejudicial"). Consequently, "[a] potential defendant who has not been named in a lawsuit by the time the statute of limitations has run is entitled to repose—unless it is or should be apparent to that person that he is the beneficiary of a mere slip of the pen, as it were." *Rendall-Speranza*, 107 F.3d at 918.

The Kubickis here have presented no evidence that contradicts Unomedical's contention that it was not aware of this litigation until 2014. (*See* Decl. of Rabi Gharabit, Ex. D to Unomedical's Reply, ECF No. 142-5, ¶ 4.) Nor is this a circumstance where the omission of Unomedical was due to clerical error or confusion

about closely-related corporate entities. *Cf. Krupski*, 560 U.S. at 554–55 (concluding that the district court erred in denying relation back where the corporate defendant that plaintiff sought to add under Rule 15(c)(1)(C) was related to named defendant, had "constructive notice" of the original complaint within the Rule 4(m) period, and should have known that it would have been named in the original complaint but for plaintiff's mistake about which corporate entity was the proper defendant); *Miller v. Holzmann*, Civil Action No. 95-1231, 2007 WL 778599, at *2–3 (D.D.C. Mar. 6, 2007) (holding that an amended complaint adding a new defendant related back to prior complaint where all defendants were closely-related members of the same corporate family and represented by the same counsel and the newly-named defendant should have known that it was the intended defendant all along). Indeed, the Kubickis did not make any specific product-defect allegations regarding the MMT-396 Infusion Set—the only portion of the insulin-delivery system to which Unomedical had any connection—until 2014, and Unomedical therefore would have no reason to suspect before that time that it could be subject to liability for Caroline's injuries. This lack of notice undoubtedly forecloses the Kubicki's reliance on the relation back doctrine to render timely their tort claims against Unomedical. *See, e.g., Meijer, Inc.*, 533 F.3d at 866.

C. Plaintiffs' Infusion Set Claims Against Medtronic Relate Back To Their Preexisting MMT-522 Pump Claims Against That Defendant, And Thus Are Deemed Timely

As a party to the original action, Medtronic stands in markedly different shoes than Unomedical does, as far as the Kubicki's infusion set claims are concerned. As explained above, Federal Rule of Civil Procedure 15(c)(1)(B) specifically contemplates the circumstances under which an amendment to a pleading "relates back to the date of the original pleading" for the purpose of the statute of limitations, and unlike the

infusion set claims against Unomedical (which had nothing to relate back to because Unomedical was not named in the original complaint), the relation-back question with respect to the MMT-396 Infusion Set claims that Plaintiffs have belatedly brought against Medtronic is whether these claims "arose out of the conduct, transaction, or occurrence" laid out in Plaintiffs' initial pleading, Fed. R. Civ. P. 15(c)(1)(B), such that Medtronic had "been put on notice regarding the claim . . . raised by the amended pleading[,]" 6A Charles A. Wright, et al., Federal Practice & Procedure § 1497 (3d ed. 2017).

Not surprisingly, Medtronic says 'no': it argues that the initial complaint provided no notice of the potential infusion set claims, and that "[t]he addition of an entirely new device as a potential cause of Ms. Kubicki's injuries is a 'substantial' alteration to this case and provides Plaintiffs with an entirely new legal theory for why Ms. Kubicki was injured." (Medtronic's Mem. at 62.) Elsewhere in its brief, however, Medtronic acknowledges that "the MMT-522-Pump and MMT-396 Infusion Set worked together to deliver insulin[,]" such that one component of the system would be useless for insulin-delivery without the other. (*Id.* at 61.) In addition, Medtronic does not dispute the fact that both medical devices are sold under Medtronic's name, and are components of the same system that Medtronic markets for use to deliver insulin to consumers. (*See* Product Photos, Ex. 61 to Pls.' Opp'n, ECF 138-63, at 2; Infusion Set User Guide, Ex F. to Decl. of Michael Wallace, ECF No. 133-4, at 12 ("The Quick-set is indicated for the subcutaneous infusion of medicine, including insulin, from a Paradigm infusion pump and reservoir."); Pump User Guide, Ex. 24 to Pl.'s Opp'n, ECF

No. 138-26, at 4 (instructing user to "insert the infusion set into your body as described in the next section.").)

Thus, Medtronic's insistence that it had no notice of any potential claims arising from the design or operation of Caroline's infusion set is unpersuasive. The initial complaint clearly alleges that Caroline was injured when she received an overdose of insulin as a result of being connected to the MMT-522 Pump. (*See* Compl. ¶¶ 14 ("A number of technical problems have been reported with the use of insulin pumps including, but not limited to, the pumps' delivery of too much insulin resulting in hypoglycemia."); 16 ("On or about September 9, 2007, Caroline Kubicki. . . was found to be unresponsive and unarousable by her roommate as a result of her malfunctioning MiniMed Insulin Pump."); 72 ("If Caroline had known the true facts concerning the risks of the use of the MiniMed Insulin Pump, in particular, the risk of significant hypoglycemic event with anoxic brain injury, she would not have used the product.").) Consequently, Medtronic knew from the outset that the company was facing timely allegations of product-related deficiencies that had allegedly caused a serious injury, and the subsequent addition of even more specific allegations regarding another component of the insulin-delivery device in question—the MMT-396 Infusion Set—does not give rise to "an entirely new legal theory[,]" as Medtronic argues. (Medtronic's Mem. at 62.) Instead, it is reasonably clear that Plaintiffs' amendment merely refines the theory of liability that Plaintiffs had already pled in their timely complaint. *See Hicks*, 283 F.3d at 388 (concluding that, where an amended complaint "amplif[ies] the facts already alleged," the amended complaint relates back to the initial complaint); *Jones v. Ottenberg's Bakers, Inc.*, No. 13-814, 2013 WL 6119322, *3

(D.D.C. Nov. 21, 2013) (holding that an amended complaint relates back to the original complaint if the "amended complaint is logically related to, and seeks recovery for, the same acts alleged in the initial complaint").

In short, as explained above, the relation back doctrine deems timely an otherwise untimely amendment to a complaint when the defendant had adequate notice of the claims that are subsequently added, and this Court is confident that such is the case with respect to the Kubicki's infusion set claims against Medtronic. Given the allegations of the original complaint and the interrelation between the pump and the infusion set in delivering insulin to users, Medtronic knew or should have known from Plaintiffs' initial allegations that infusion set claims existed and may yet be asserted, and Medtronic can hardly be heard to complain that it was not sufficiently alerted to a potential problem with MMT-396 Infusion Set and the p-cap valve in particular, when these components play a crucial role in ensuring that the pump delivers insulin at the correct rate and when the Kubickis' core allegation was over-delivery of insulin to a pump-user. Therefore, although the claims in Plaintiffs' complaint concerning the MMT-396 Infusion Set were not asserted timely in the first instance, this Court concludes that these otherwise time-barred claims relate back to the timely claims regarding the MMT-522 Pump that Plaintiffs brought against Medtronic in the initial complaint, and as a result, these claims against Medtronic are deemed timely for statute of limitations purposes.

VII. RULING ON PREEMPTION

The thorniest legal issue that Medtronic raises as grounds for dismissal of the Kubickis' claims is preemption—a doctrine that has its roots in the Supremacy Clause

of the U.S. Constitution. *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992) ("[U]nder the Supremacy Clause, from which our pre-emption doctrine is derived, any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." (internal quotation marks and citation omitted)). As relevant here, Congress has vested the Food and Drug Administration ("FDA") with the authority to regulate medical devices; consequently, state law legal claims that pertain to such devices implicate questions of both express preemption and implied preemption. As a general matter, express preemption occurs when a federal statute explicitly sets forth the particular circumstances in which state law claims cannot be maintained. *See Waterview Mgmt. Co. v. FDIC*, 105 F.3d 696, 700 (D.C. Cir. 1997). By contrast, as relevant here, "[i]mplied preemption occurs . . . where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress left no room for supplementary state regulation[,]" *Armstrong v. Accrediting Council for Continuing Edu. & Training*, 168 F.3d 1362, 1369 (D.C. Cir. 1999) (internal quotation marks and citation omitted), which renders state law claims that seek merely to enforce federal duties effectively barred. *See Buckman*, 531 U.S. at 352.

Medtronic argues that Section 360k(a) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act ("FDCA") expressly preempts the Kubickis' MMT-522 Pump claims, and furthermore, that the claims in the Kubickis' complaint pertaining to both components of Medtronic's insulin-deilvery system (the pump and the MMT-396 Infusion Set) are impliedly preempted because the Kubickis are seeking to enforce FDA regulations rather than attempting to vindicate independent state law duties. (*See*

Medtronic's Mem. at 44–55.) The Kubickis have myriad responses to Medtronic's preemption contentions (*see* Pls.' Opp'n at 36–53), including the argument that there is no express preemption of their MMT-522 Pump claims because the state laws on which the claims are based track the federal requirements (*see id.* at 38–40), and the implied preemption doctrine is inapplicable because the complaint asserts stand-alone state law claims that do not usurp the FDA's enforcement authority (*see id.* at 51–53).

The parties' arguments are largely based on established law concerning the express and implied preemption of state law claims involving medical devices—law that is "charitably speaking, utterly conflicted[,]" *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1150 (D. Minn. 2009)—and as explained below, the parties' various contentions yield mixed results. In sum, this Court concludes that *all* of the claims pertaining to the MMT-522 Pump are expressly preempted, with the exception of one narrow aspect of the claim alleging a pump-related manufacturing defect, and that *none* of the claims pertaining to the MMT-396 Infusion Set are impliedly preempted, except for one claim that pertains to Medtronic's allegedly tortious failure to report adverse events to the FDA. What remains, then, is a single manufacturing defect claim concerning the MMT-522 Pump, as well as almost all of the claims against Medtronic that pertain to the MMT-396 Infusion Set; these will be the claims at issue during the forthcoming period of expert discovery.

A. The Law Pertaining To Classification Of Medical Devices And The Express And Implied Preemption Of State Law Claims Under The Medical Device Amendments To The Food, Drug And Cosmetics Act

1. The MDA's Device-Classification Scheme

In 1976, Congress responded to "a bevy of state laws regulating medical devices largely enacted due to the failure of the Dalkon Shield contraceptive in the 1970s," *id.* at 1150, by enacting the Medical Device Amendment ("MDA") to the Federal Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301–399h. In essence, the MDA expanded the regulatory scope of the FDCA to include medical devices. *See In re Medtronic*, 592 F. Supp. 2d at 1150–51 (citing 21 U.S.C. § 360k). As amended, the FDCA "classifies medical devices in three categories based on the risk that they pose to the public[,]" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996), with Class III being reserved for those devices that pose the most significant risk of illness or injury to users.[18] "The [MDA] makes Class III the default category for new (that is, post–1976) medical devices," *Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 83 (D.C. Cir. 2014), and it requires that such devices be subjected to a rigorous and time-consuming premarket approval ("PMA") process, during which a manufacturer must prove to the FDA that the device is both safe and effective, *see Lohr*, 518 U.S. at 477; *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008) (noting that the PMA process

[18] Class I devices "present no unreasonable risk of illness or injury . . . and are subject only to minimal regulation by 'general controls.'" *Lohr*, 518 U.S. at 477 (quoting 21 U.S.C. § 360c(a)(1)(A)). Class II devices are "potentially more harmful[,]" and are subject to federal performance regulations known as "'special controls[,]'" though the FDA need not approve the marketing of Class II devices in advance. *Id.* (quoting 21 U.S.C. § 360c(a)(1)(B)). Class III devices are those that either "presen[t] 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 477 (quoting 21 U.S.C. § 360c(a)(1)(C)) (quotation marks omitted).

typically requires a manufacturer to submit a multi-volume application). When it analyzes the device-related application that manufacturers submit, "the FDA must weigh the 'probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *In re Medtronic*, 592 F. Supp. 2d at 1150 (quoting 21 U.S.C. § 360c(a)(2)(C)). And pursuant to this calculus, the FDA "may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Riegel*, 552 U.S. at 318.

Notably, once the FDA has granted premarket approval to a device, the manufacturer generally may not make changes to the design, labeling, manufacturing process, or any other aspect of the device without further FDA approval. *See id.* at 319; *see also id.* at 323 ("[T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness."). "If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application." *Id.* (citing § 360e(d)(6), 21 C.F.R. § 814.39(c)). Furthermore, a PMA device manufacturer also has certain post-approval reporting duties, including the obligation to report to the FDA all known incidents in which the device "(1) [m]ay have caused or contributed to death or serious injury, or (2) [may have] malfunctioned and . . . would be likely to cause or contribute to death or serious injury, if the malfunction were to recur[.]" 21 CFR § 803.50(a). Such reporting must take place within 30 days of

when the manufacturer "receive[s] or otherwise become[s] aware of [the] information." *Id*.

In recognition of the fact that the lengthy PMA process can substantially delay the introduction of improvements to existing medical devices, "the [MDA] . . . permits devices that are 'substantially equivalent' to pre-existing devices to avoid the PMA process." *Lohr*, 518 U.S. at 478 (quoting 21 U.S.C. § 360e(b)(1)(B)). To be substantially equivalent to a pre-existing Class I, II, or III medical device, "the new device must have the same intended use as the predicate device, and either (i) have the same technological characteristics as the predicate device or (ii) be shown to be as safe and effective as the predicate devices." *Ivy Sports*, 767 F.3d at 83 (quoting 21 U.S.C. § 360c(i)(1)(A) (internal quotation marks omitted). The FDA has a process for conducting a substantial equivalence review—known as the "§ 510(k) process"—which is triggered when a manufacturer who intends to introduce a new medical device into the market submits to the FDA a "premarket notification" that "states the new device's intended use, identifies the predicate devices to which the new device is substantially equivalent, and offers a proposed classification." *Id.* at 83 (citing 21 C.F.R. § 807.87).

It is important to recognize that "[t]he § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." *Lohr*, 518 U.S. at 478–79 (citation omitted). This is in large part because, while the PMA process focuses on the safety and efficacy of a device, the § 510(k) process focuses only on whether the new device is equivalent to an existing device. *Id.* at 493. Thus, "'[t]he attraction of substantial equivalence to manufacturers is clear.

[Section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.'" *Id.* at 479 (quoting Robert Adler, The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction, 43 Food Drug Cosm. L.J. 511, 516 (1988)) (second alteration in original). Consequently, the abbreviated § 510(k) process has become the route by which the vast majority of new medical devices—including Class III devices, which by definition pose the highest level of risk to the patient—enter the marketplace. *See id.*; *see also Riegel*, 552 U.S. at 1004 ("In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices.").

2. Express Preemption Of State Law Claims Under the MDA

Manufacturers who opt to engage in the expensive and time-consuming PMA process with respect to new medical devices get the benefit of express statutory protection from certain state law claims relating to the device. *See* 21 U.S.C. § 360k(a); *Lohr*, 518 U.S. at 492–94. In this regard, section 360k(a) of Title 21 of the U.S. Code states (in relevant part) that

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The reach of this express exemption clause has been extensively litigated over the past three decades, and as a result, the Supreme Court has established

a two-part test that courts must use when evaluating whether state law claims fall within the scope of 21 U.S.C. § 360k(a). *See Riegel*, 552 U.S. at 321–22. Pursuant to the prescribed analysis, courts must consider, first, "whether the Federal Government has established requirements applicable to" the device, and second, "whether the [plaintiff's] common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Id.* (quoting 21 U.S.C. § 360k(a)).

It is by now well established that the FDA's affirmative grant of premarket approval to a medical device through the PMA review process satisfies the first prong of this two-part inquiry. *Id.* at 322–23 (noting that premarket approval "imposes requirements under the MDA" because "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application" (internal quotation marks omitted)). By contrast, if a device has been approved through the less-arduous Section 510(k) substantial equivalence process, the first part of the Supreme Court's express preemption test does not apply. *See Lohr*, 518 U.S. at 493–94; *see also Duggan v. Medtronic, Inc.*, 840 F. Supp. 2d 466, 469 (D. Mass. 2012) (explaining that "medical devices entering the market pursuant to the § 510(k) process are not subject to specific federal requirements under the MDA, because those devices receive less scrutiny from the FDA").[19]

[19] Per the Supreme Court's reasoning, the FDA's Section 510(k) substantial equivalence process "is focused on *equivalence*, not safety[,]"*Lohr*, 518 U.S. at 493 (emphasis in original; internal quotation marks and citation omitted); therefore, when the FDA grants marketing approval through the substantial equivalence review process, it does not actually "require" that the device at issue "take any particular form for any particular reason" as is necessary to trigger express preemption, *id*. at 493 (internal quotation marks omitted). The *Lohr* Court further concluded that permitting state law claims to proceed with respect to devices that have only undergone substantial equivalence review as opposed to PMA review is consistent with congressional intent. *See id.* at 494 (explaining that "[t]here is no

With respect to the second prong of the express preemption inquiry, the Supreme Court has held that state common law claims for negligence, strict liability, and breach of warranty, among other things, qualify as "requirements. . . with respect to devices" for the purpose of the MDA's express preemption clause. *Riegel*, 552 U.S. at 324, 327. Thus, current express preemption disputes in the medical-device context often involve the issue of whether the asserted state common law claims effectively impose obligations on manufacturers that are "different from, or in addition to" the federal requirements. *Id.* at 321 (quoting § 360k(a)(1)); *see, e.g.*, *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424–25 (6th Cir. 2005); *In re Medtronic, Inc.*, 592 F. Supp. 2d at 1156–65; *see also Duggan*, 840 F. Supp. 2d at 469 (commenting that "[m]any state common law claims impose duties with respect to devices that are "different from, or in addition to" federal requirements, satisfying the preemption test's second prong" (citations omitted)).

It is important to underscore the fact that, as the MDA has been interpreted, the express preemption clause does *not* afford the manufacturer of a PMA-approved medical device *absolute* immunity from all device-related lawsuits arising under state law, but only those that are based on requirements that differ from, or augment, the federal requirements. *See Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 767 (5th Cir. 2011) ("[A] manufacturer is not protected from state tort liability when the claim is based on the manufacturer's violation of applicable federal requirements."). This

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suggestion in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents[,]" and "[t]hat status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design").

means that "[Section] 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 (citations omitted). However, "[p]laintiffs cannot simply incant the magic words '[the manufacturer] violated FDA regulations' in order to avoid preemption." *In re Medtronic*, 592 F. Supp. 2d at 1158. Rather, for such a "parallel" claim to survive, a plaintiff must (1) point to *specific* federal requirements that the manufacturer violated; (2) *specifically* identify a state law claim that is parallel to the federal requirements, and (3) causally connect the simultaneous violations of federal and state law and to the alleged injury. *See Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1214 (W.D. Okla. 2013), *aff'd*, 784 F.3d 1335 (10th Cir. 2015).

Thus, while it is the device manufacturer's burden to invoke the MDA's express preemption clause based on the FDA's premarket approval of the device at issue, *see Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 251 n.2 (2011) (noting that federal preemption is an affirmative defense which a defendant must invoke and establish in the first instance), once the defendant does so, the burden shifts to the plaintiff to establish that the state law claims it seeks to maintain are truly parallel to the federal requirements at issue, and that the alleged breach of these parallel duties caused the plaintiff's injury, *cf. Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1287–88 (C.D. Cal. 2008) (applying burden shifting framework to an FDCA express preemption clause relating to prescription drugs). And it is in the context of demonstrating that the state law claims are not expressly preempted because the state law duty is "genuinely equivalent" to the applicable federal law requirements for a device, *Wolicki–Gables v.*

Arrow Int'l, Inc., 634 F.3d 1296, 1300 (11th Cir. 2011) (internal quotation marks and citation omitted), that the plaintiff must specify the particular federal requirement at issue, identify the truly parallel state law claim, and establish the requisite causation. *See McAfee v. Medtronic, Inc.*, No. 12-cv-417, 2016 WL 2588807, at *1 (N.D. Ind. May 5, 2016); *see also Wolicki–Gables*, 634 F.3d at 1300 (explaining that "[s]tate and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law" (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)).

3. Implied Preemption Of State Law Claims Under the MDA

Unlike express preemption, the doctrine of implied preemption does not rest on the provisions of a statute; instead, it necessarily follows from the legislature's intent to confer all regulatory authority to a federal body. For example, the FDCA vests the FDA with *exclusive* authority to investigate potential violations of medical device requirements, regardless of whether the FDA has approved the device through the rigorous PMA process or the less onerous § 510(k) substantial equivalence process. *See, e.g.*, *Martin v. Medtronic, Inc.*, No. 15-cv-0994, 2017 WL 825410, at *9 (E.D. Ca. Feb. 24, 2017) (finding that doctrine of implied preemption barred warranty claim relating to PMA-approved device); *Jones v. Medtronic, Inc.*, 89 F. Supp. 3d 1035, 1046 (D. Ariz. 2015) (noting that implied preemption is available where device is approved through the 510(k) process)). Thus, a plaintiff's attempt to enforce federal requirements in the context of private litigation (even a suit that ostensibly involves only state law claims) may run afoul of this delegation.

In *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Supreme Court held that if establishing the defendant's liability for the plaintiff's state

law claim requires demonstrating that the FDCA has been violated, then prosecution of the state law action intrudes upon the FDA's exclusive province to enforce the FDCA, rendering the suit impliedly preempted. *Id.* at 349–53. The Supreme Court was also clear in *Buckman* that implied preemption is by no means absolute; that is, a plaintiff may rely on a violation of an FDCA requirement as a predicate for a state tort claim where the plaintiff brings a claim for a "traditional state tort law which [] predated the federal enactments in question[.]" *Id.* at 353. By contrast, if the state law claim would not exist in the absence of the FDCA, "then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman*." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (citation omitted).

All this means that the doctrines of express and implied preemption, though related, are analytically distinct. The MDA's express preemption provision prohibits a plaintiff from imposing additional requirements on a PMA-approved device, but allows enforcement of genuinely parallel state law requirements with respect to that device. Implied preemption in the medical-device context prohibits a plaintiff from enforcing FDCA requirements in the absence of a preexisting state law claim that addresses those same duties, irrespective of whether the device was approved through the PMA process (as was the case with Medtronic's MMT-522 Pump) or the § 510(k) substantial equivalence process (as was the case with the MMT-396 Infusion Set). With respect to PMA-approved medical devices, then, the interrelation between express preemption and implied preemption produces a "narrow gap" in which plaintiffs can proceed to vindicate established state law duties that exist entirely independent of federal law, but

only to the extent that such common law tort claims are truly parallel to the requirements of federal law. *See Cupek*, 405 F.3d at 423. But where applicable, either doctrine suffices to prevent a plaintiff from advancing state common law claims regarding alleged injuries from the use of FDA-approved medical devices.

B. With One Exception, The MDA Expressly Preempts All Of The Kubickis' MMT-522 Pump Claims

As a threshold matter, the instant parties dispute whether the insulin pump that was prescribed to Caroline Kubicki at the time of her injury—Medtronic's MMT-522 Pump—is a PMA-approved medical device such that express preemption applies at all. (*See* Medtronic's Mem. at 15–16; Pls.' Opp'n at 40–42.) They also disagree regarding (a) whether Plaintiffs have identified specific federal requirements that can form the basis for a parallel state claim under *Riegel* (*see* Medtronic's Mem. at 47–52; Pls.' Opp'n at 44–51); (b) whether Plaintiffs have, in fact, asserted state law claims that are genuinely parallel to any such federal requirement (*see* Pls.' Opp'n at 50–51; Medtronic's Reply at 19); and (c) whether the alleged violation of state and federal law caused Caroline's injury (*see* Medtronic's Mem. at 49–52, 52 n.12; Pls.' Opp'n at 53–55; Medtronic's Reply at 19–20). For the reasons explained below, this Court concludes that Medtronic is entitled to summary judgment based on express preemption for all of the tort claims that pertain to the MMT-522 Pump, with the exception of Plaintiffs' pump-related manufacturing defect claim, which cannot be adequately assessed prior to expert discovery.[20] The Court's conclusions regarding express

[20] With respect to this carve-out, the Court rejects Medtronic's argument that it is entitled to summary judgment "because there is absolutely no evidence of any manufacturing defect with the MMT-522 Pump . . . Caroline was allegedly using at the time of the incident." (Medtronic's Mem. at 33; *see also id*. at 33–34 (arguing that manufacturing records show that Caroline's pump using at the time

preemption are based on its finding that (1) the FDA approved the MMT-522 Pump through the PMA process, and thus the MDA's express preemption provision is applicable to that device, and (2) with respect to the non-manufacturing pump-related claims, Plaintiffs have either failed to identify a specific FDA requirement upon which their allegedly parallel state law claims can be based, or failed to establish that any genuinely equivalent parallel state law claim exists.

1. State Law Claims Pertaining To The MMT-522 Pump Are Subject To The MDA's Express Preemption Provision Because That Device Was Approved Pursuant To The FDA's Premarket Approval Process

In support of its argument that the Kubickis' pump-related claims are expressly preempted under the MDA, Medtronic points to evidence that it says "conclusively demonstrates [that] the MMT-522 Pump has Premarket Approval." (Medtronic's Mem. at 44 (citing a declaration that it says establishes that "the FDA approved the MMT-522 Pump as a PMA supplement—PMA No. P980022/S013").) Plaintiffs appear to accept the representation that the insulin-delivery *system* of which the MMT-522 Pump is a part received the FDA's stamp of premarket approval, but they argue that the FDA's approval was not all-encompassing for the purpose of the MDA's express preemption clause, because "the FDA did not approve the use of the MMT-522 Insulin Pump *in isolation*, but instead approved the Real Time System [consisting of the pump and a

conformed with all applicable specifications and were free from manufacturing defects).) While Plaintiffs concede that they "do not have evidence at this point that there were any deviations from any . . . manufacturing specifications that the FDA approved[,]" (Mot. Hr'g Tr. at 28:21–24), *their experts have yet to conduct any destructive testing of the pump*, (*see id.* at 29:2–30:6). Thus, this Court finds that it would be premature to dismiss the claims that are based on the assertion that Medtronic deviated from the manufacturing specifications for the MMT-522 pump, and that such a deviation caused Caroline's injury, prior to expert discovery. (*See id.* at 28:11–30:6.) *See also Riegel*, 552 U.S. at 321–22. If the proposed destructive testing of the pump is conducted during the expert discovery process, and if it does not reveal any evidence of a manufacturing defect, Medtronic may renew its preemption contention with respect to the manufacturing defect claim.

blood glucose sensor] 'as a whole' and on the basis that it would purportedly be marketed, sold, and ultimately used as a system[.]" (Pls.' Opp'n at 41 (emphasis added).) As a result, Plaintiffs say, Medtronic cannot rely on the express preemption doctrine with respect to the MMT-522 Pump standing alone.

At least two federal district courts have rejected this same argument in the context of litigation pertaining to this same pump model. *See Duggan*, 840 F. Supp. 2d at 471-73; *Bentzley v. Medtronic*, 827 F. Supp. 2d 443, 450–51 (E.D. Pa. 2011). The plaintiffs in both *Duggan* and *Bentzley* argued—as Plaintiffs do here—that although Medtronic's Paradigm Real Time System (which consists of both the MMT-522 Pump and a continuous glucose monitor) was approved through the PMA process, the MMT-522 Pump should be considered to be substantially equivalent to Medtronic's earlier model MMT-515 pump, which had only "entered the market through the § 510k process and not the premarket approval process." *Duggan*, 840 F. Supp. 2d at 471 ("The Duggans argue that while certain aspects of the Paradigm Real Time System may have received premarket approval, the [MMT-522] pump itself did not; instead, they contend, only the capacity of the pump and the sensor to communicate with each other was granted premarket approval."); *see Bentzley*, 827 F. Supp. 2d at 451 ("Plaintiff attempts to raise an issue of material fact by arguing that the MMT–522 pump is separate and apart from the insulin infusion system and did not gain approval through the PMA process." (internal quotation marks and citation omitted)). Both courts rejected this contention, noting that it is well-established that "once premarket approval is granted, all claims relating to all components of the device are preempted." *Duggan*, 840 F. Supp. 2d at 471 (citations omitted); *Bentzley*, 827 F. Supp. 2d at 452 ("Plaintiff's

contention that, in considering a preemption issue, the Court must break a medical device into its component parts, is without legal support. In fact, courts that have dealt with this issue have done just the opposite." (citations omitted)); *see also, e.g.*, *Aaron. v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1003 (S.D. Ohio 2016) ("Premarket approval extends to all components of an approved device, even when a physician uses the components separately."); *Hawkins v. Medtronic*, No. 13cv0499, 2014 WL 346622, at *5 (E.D. Cal. Jan. 30, 2014) ("The requirements set forth in the premarket approval for the entire device are just as applicable to the components that together form the FDA-approved device as the device itself."). This Court agrees with the persuasive views expressed in these prior cases for several reasons.

To begin with, it is clear that breaking down a PMA-approved medical device into its components for the purpose of evaluating the reach of the MDA's express preemption clause, as Plaintiffs suggest, runs afoul of the statutory definition of "device" under the MDA. That is, per the statute, a medical "device" includes "any component, part, or accessory[,]" 21 U.S.C. § 321(h), and in the context of the Paradigm Infusion System, there is no question that the MMT-522 Pump is precisely such a component part. Thus, the MMT-522 Pump falls within the scope of the device-related PMA approval that Medtronic received.

Nor can this Court accept the Kubickis' related argument that the FDA has *conceded* that only the Paradigm Infusion System as a whole—and not the MMT-522 Pump standing alone—was approved through the PMA process. (*See* Pls.' Opp'n at 41 (citing FDA Response to Citizen Petition, Sept. 23, 2011, Ex. C to Decl. of Michael Brown, ECF No. 133-5, at 56–58)). In this regard, Plaintiffs point to a Citizen Petition

that was submitted to the FDA in 2010, requesting that the FDA modify the PMA letter the agency had issued for the Paradigm Infusion System to include the following language: "This approval is limited solely to the ability of the pump to accept data from the sensor and the ability for the sensor to communicate directly to the pump, and this approval does not extend to the pump itself." (*Id.* at 57 (internal quotation marks omitted).) The FDA rejected this request, stating that it had "approved the PMA supplement for the Paradigm System, including both the 522 pump and the Guardian RT sensor, on April 7, 2006[,]" and that the amendment request was being denied "[b]ecause the approval letter, as issued, applies to the Paradigm System as a whole[.]" (*Id.* at 58.) Like the *Duggan* and *Bentzley* courts (which considered and rejected the same Citizen Petition argument Plaintiffs make here, *see Duggan*, 840 F. Supp. 2d at 472; *Bentzley*, 827 F. Supp. 2d at 451), this Court sees no ambiguity in the agency's statements regarding the scope of the PMA approval: the letter states unequivocally that "*both* the 522 pump *and* the Guardian RT sensor" had received premarket approval. (FDA Response to Citizen Petition at 58 (emphasis added).) And the fact that the agency expressly *declined* to amend its materials to exclude the pump from its PMA approval further underscores that it was not the agency's intention for any such exclusion to be made. *See Duggan*, 840 F. Supp. 2d at 472 ("To the extent there was any ambiguity about the scope of the approval letter, this rejection of the Citizen Petition is the cherry on the icing.").

In arguing that the MMT-522 Pump was not PMA approved and is therefore ineligible for express-preemption treatment, the Kubickis actually make no mention of *Duggan* or *Bentzley* (*see* Pls.' Opp'n at 40–42), and this Court sees no obvious reason to

reach a different conclusion than its sister courts did when those courts carefully considered whether Medtronic's MMT-522 Pump should have received premarket approval for the purpose of the expression-preemption analysis. Therefore, this Court likewise holds that the FDA granted the MMT-522 pump premarket approval, and that the first prong of the *Riegel* test for express preemption (i.e., whether the medical device at issue is subject to federal requirements) is satisfied. *See Duggan*, 840 F. Supp. 2d at 469 (explaining that "[t]he FDA's premarket approval ('PMA') process imposes federal requirements on a medical device under the MDA").[21]

2. Plaintiffs Have Not Established That Their Pump-Related State Law Claims Are Genuinely Equivalent To Specific Federal Law Requirements

Turning to the next step in the *Riegel* analysis, as explained above, plaintiffs who seek to counter a defendant's authorized invocation of the MDA's express preemption provision with respect to a medical device that received premarket approval must identify specific federal requirements with respect to which genuinely parallel state law claims exist, and must plausibly allege that the defendants' violation of state (and federal) law in the claimed manner caused the plaintiffs' injury. The Kubickis' early

[21] The recent authority that Plaintiffs have brought to this Court's attention, *see Brackin v. Medtroni*c, No. 12-cv-00734-KGB (W.D. Tenn. September 14, 2017), does not alter this Court's conclusion. (*See* Ex. 1 to Pls.' Notice of Supp. Auth., ECF No. 156-1.) *Brackin* involved a motion to dismiss, and that court merely concluded that it could not "conclusively determine whether [the pump at issue has] received premarket approval" at that early stage of the litigation. *Brackin*, slip op. at 10; *see also id.* at 6 (considering the express preemption defense but "emphasiz[ing] that this issue arises at the motion to dismiss stage"). The *Brackin* court also noted that the pump at issue therein was the MMT-523 Pump, and that defendants' assertion that the MMT-522 Pump was a predecessor to the MMT-523 Pump was "insufficient to establish that the 523 pump was subject to premarket approval within the meaning of *Riegel*." *Brackin*, slip. op. at 9. By contrast, this case concerns the MMT-522 Pump, and the record here contains unrefuted evidence that the MMT-522 Pump received premarket approval as a component of the Real Time System. (*See* FDA Response to Citizen's Petition.) Moreover, *Brackin*'s reasoning is not binding on this Court, and to the extent that the *Brackin* court's holding could be read to allow a court to break a PMA-approved system into component parts for purposes of the express preemption analysis, this Court finds that the decision runs counter to the prevailing weight of authority cited above and is unpersuasive.

attempts to accomplish this difficult task were "admittedly skimpy[,]" *Kubicki*, 2013 WL 1739580, at *8, but the Court deemed them passable for the purpose of Medtronic's motion to dismiss, *id*. Notably, however, in its opinion regarding the motion to dismiss, the Court expressly announced its expectation 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." *Id.* at *9. And it further warned that "[s]hould Plaintiffs fail to do so, Defendants may renew their express preemption objections at a later, appropriate time." *Id.*

This means that the express preemption arguments that Medtronic makes in the instant motion for summary judgment are both anticipated and well-founded.[22] Yet, Plaintiffs are correct to note that the mere fact that the FDA has granted premarket approval to a device does not render all state law claims relating to the product preempted carte blanche. (*See* Pls.' Opp'n at 38 ("A PMA-approved medical device manufacturer 'is protected by law from civil liability so long as they *comply* with federal law[.]'" (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 550 (7th Cir. 2010) (emphasis in original))).) *See also Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1205 (8th Cir. 2010) (explaining that a state law claim that "parallel[s]" federal requirements and is "premised on a violation of FDA regulations" can survive express preemption).

[22] Plaintiffs make the odd suggestion that the Court's ruling on Medtronic's motion to dismiss disposed of the preemption question in their favor such that Medtronic cannot raise a preemption argument now. (*See* Pls.' Opp'n at 38–39 ("Medtronic. . . has re-couched its failed motion to dismiss as a motion for summary judgment, asserting the precise arguments this Court has already rejected.")). Given the language of the Court's ruling on the motion to dismiss, however, any such contention is misguided; indeed, the Court's opinion sought to stave off this very argument by expressly stating that the preemption findings therein "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 [must] also explain how the alleged federal violation caused the alleged injury." *Kubicki*, 2013 WL 1739580, at *8 (emphasis omitted).

Therefore, for present purposes, the key question is which violations of state law are the Kubickis claiming in regard to the MMT-522 Pump in the context of this action, and are those state law claims truly parallel to identified federal law requirements applicable to that device?

The Kubickis have brought five categories of state law claims in the instant action, including negligence, breach of warranty, and failure to warn (*see supra* Part III.B), and importantly, they maintain that these state law claims do not impose any requirements that are "different from, or in addition to" the FDA's requirements, 21 U.S.C. § 360(k)(a)(1), because these claims are predicated on the MMT-522 Pump having been "manufactured, designed, and labeled *in violation of federal law*[.]" (Pls.' Opp'n at 44(emphasis added).)[23] The federal requirements that Plaintiffs say Medtronic has violated with respect to the design, manufacturing, and labeling of the MMT-522 Pump are certain of the FDA's "current good manufacturing practice" (CGMP) requirements—i.e., the generic FDA regulations that "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use[,]" 21 C.F.R. § 820.1(a)(1)—and also the FDA regulations that require medical device manufacturers to monitor and report adverse events involving their products (*see* 21 C.F.R. § 803, and to adhere to certain standards with respect to the product's labeling and use instructions, *see* 21 C.F.R. §§ 801.5, 801.15. Furthermore, as *proof* that the

[23] Plaintiffs have forcefully disclaimed any contention that their complaint alleges "that the Insulin Pump should have been designed, labeled, or manufactured differently from its FDA-approved standards." (Pls.' Opp'n at 44.) *See Kubicki*, 2013 WL 1739580, at *7 ("Plaintiffs[] expressly and unambiguously confirm[] 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.") This is to be expected, as any such claims would clearly be preempted. *See Riegel*, 552 U.S. at 321–22.

MMT-522 Pump violates these particular federal standards, Plaintiffs cite the 2013 Warning Letter that memorialized the FDA's determination that Medtronic's manufacture and distribution of the MMT-522 Pump had transgressed certain CGMPs (*see supra* Part II.C.3), and they also point to the fact that Medtronic indisputably failed to report to the FDA certain post-approval adverse incidents regarding the pump. (*See* Pls.'s Opp'n at 44–51.)

Plaintiffs are correct that the FDA once determined that Medtronic violated various CGMPs with respect to its production and marketing of the MMT-522 Pump, and it is undisputed that Medtronic failed to notify the FDA of certain adverse events that were allegedly pump-related (including Caroline's injury) in a timely manner. (*See* 2013 Warning Letter at 25–26). But for the reasons that follow, this Court finds that the CGMPs that Plaintiffs cite are generally insufficient to be the basis for an allegedly parallel state law claim regarding the MMT-522 Pump, and that there is no truly parallel state common law claim that pertains to the one sufficiently-specific federal law requirement that Plaintiffs rely upon (the requirement that manufacturers report adverse incidents).

a. *The CGMPs and general labeling and instruction regulations that Plaintiffs cite are insufficient to support a parallel state law claim asserting a design, manufacturing, or labeling defect, or a breach of warranty*

The Kubickis say that their negligent design, manufacturing, labeling, and breach of warranty common law claims parallel the following CGMPs and other regulations that pertain to product labeling and use instructions:

- 21 C.F.R. § 820.25 (requiring manufacturers to hire "sufficient" personnel and ensure that they have the "necessary" education, training and experience);

- 21 CFR § 820.30 (requiring manufacturers, in general, to establish maintain "procedures to control the design of the device" in order to ensure that specified design requirements are met);

- 21 CFR § 820.50 (requiring manufacturers, in general, to establish procedures to ensure products and services conform to specified requirements);

- 21 CFR § 820.70 (requiring manufacturers, in general, to "establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications");

- 21 CFR § 820.72 (requiring manufacturers to ensure that all inspection, measuring, and test equipment is "suitable");

- 21 CFR § 820.75 (requiring manufacturers to establish, maintain, and update process parameters and conduct revalidations when processes or designs change, and to ensure that "qualified individuals" perform the validated processes);

- 21 CFR § 820.80 (requiring manufacturers, in general, to "establish and maintain procedures for acceptance activities");

- 21 C.F.R. § 820.90 (requiring manufacturers, in general, to "establish and maintain procedures to control product that does not conform to specified requirements");

- 21 C.F.R. § 820.100 (requiring manufacturers, in general, to "establish and maintain procedures for implementing corrective and preventive action");

- 21 C.F.R. § 820.198 (requiring manufacturers to "establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit[,]" including ensuring "timely" and "uniform" review of complaints);

- 21 CFR § 820.250 (requiring manufacturers, "[w]here appropriate," to "establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics");

- 21 C.F.R. § 801.5 (requiring device manufacturers to provide "adequate directions for use"); and

- 21 C.F.R. § 801.15 (requiring medical device labeling to be "prominen[t] and "conspicuous[]").

(*See* 2d Am. Compl. ¶¶ 43–53.)

Medtronic insists that because these CGMPs and regulations pertaining to product labels and use instructions "are not device-specific regulations[,]" they cannot qualify as "device specific federal requirements" that can be the basis for any purportedly parallel state law claim "within the meaning of [the MDA's express preemption clause]." (Medtronic's Mem. at 48; *see also id.* at 49.) Thus, Medtronic appears to have invoked one side of an existing circuit split over whether the CGMPs "can[] support any viable parallel claim surviving express preemption[.]" (*Id*. at 48.) The Eighth and Eleventh Circuits have held that a plaintiff cannot rely on the CGMPs to escape the MDA's express preemption mandate, because the CGMPs are too general to create specific federal requirements that can be enforced under state law. *See Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1206–07 (8th Cir. 2010). By contrast, the Fifth, Sixth, and Seventh Circuits have found that certain CGMPs *are* sufficiently specific to create federal requirements that a plaintiff can enforce through a parallel state law tort action. *See, e.g., Bass v. Stryker Corp.*, 669 F.3d 501, 511–13 (5th Cir. 2012); *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440 (6th Cir. 2010); *Bausch v. Stryker Corp.*, 630 F.3d 546, 554–56 & 554 n.1 (7th Cir. 2010).

Notably, the courts that refuse to find that the FDA's CGMPs can give rise to parallel state law claims for express preemption purposes note that the CGMPs are *general* prescriptions that "govern 'the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage installation and

servicing of *all* finished devices intended for human use.'" *In re Medtronic*, 592 F. Supp. 2d at 1157 (emphasis added) (quoting 21 C.F. R. § 820.1(a)(1)). Accordingly, these courts reason, the CGMPs "are simply too generic, standing alone, to serve as the basis for [a] manufacturing-defect claim[]" because "the CGMPs[] provide specific methods to be used for only a small number of medical devices" and "[i]n most cases, it is left to the manufacturer to determine the best methods to obtain quality objectives." *Id.* (emphasis, internal quotation marks, and citation omitted); *see also id.* at 1162 (finding that design-defect claims which are derivative of a CGMP-based manufacturing claim are preempted); *Ilarraza v. Medtronic, Inc.*, 677 F.Supp.2d 582, 588 (E.D.N.Y. 2009) (holding that claims based on an alleged violation of the CGMPs are preempted because the CGMPs are "intentionally vague and open-ended"); *cf. Horn v. Boston Sci. Neuromodulation Corp.*, No. CV409-074, 2011 WL 3893812, at *9 (S.D. Ga. Aug. 26, 2011) (concluding that a claim based on the alleged breach of FDA regulations was preempted where the regulations at issue "fail to provide any tangible or concrete standard" because "to allow a violation of such a flexible standard to result in liability would, in itself, be imposing a standard 'different from, or in addition to' those imposed by the MDA" (quoting 21 U.S.C. § 360k(a)(1))). In the absence of any guidance from the D.C. Circuit on this issue, this Court finds such reasoning compelling, and thus it, too, concludes that the CGMPs that Plaintiffs have cited are insufficient to qualify as a federal requirement upon which the Kubickis' purportedly parallel state law claims can be based.

As previously explained, in order to have a viable—i.e., not expressly preempted—state law claim for an injury allegedly caused by a medical device that

received premarket approval, the plaintiff must identify specific, concrete federal requirements that are applicable to the device in question and that the manufacturer has allegedly violated in a manner that also gives rise to liability under state law. *See Caplinger*, 921 F. Supp. 2d at 1214. There is no question that if a state law claim is to be identified as truly "parallel" (i.e., not demanding anything more of the manufacturer than the federal law requires), the federal-requirement baseline must be specifically established; yet, by their nature, the CGMPs merely prescribe overarching guidelines for manufacturers to follow when developing their own procedures, rather than specifically enforceable duties. Indeed, the FDA itself has noted the flexibility that the CGMPs afford to manufacturers:

> Because this regulation must apply to so many different types of devices, *the regulation does not prescribe in detail how a manufacturer must produce a specific device*. Rather, the regulation provides *the framework* that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device.

Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, 61 Fed. Reg. 52,602, 52,603 (Oct. 7, 1996) (emphasis added). This Court is persuaded that federal regulations that admittedly "do[] not prescribe in detail how a manufacturer must produce a specific device[,]" *id.*, are incapable of serving as the benchmark for a reasoned determination of whether state law claims that impose liability for a manufacturer's failure to produce the device in a certain way establish duties that are truly parallel to the federal law.

The Sixth Circuit's decision in *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440 (6th Cir. 2010), which Plaintiffs cite (*see* Pls.' Opp'n at 45), is not to the

contrary. The plaintiff in *Howard* brought a claim for negligence per se, seeking relief for injuries that he suffered when his implanted artificial knee failed due to oily residue left behind on the implant as the result of the manufacturing processes. The *Howard* court concluded that these claims were not expressly preempted because the plaintiff had "identif[ied] a specific GMP that he thought had been violated" and "*the particular GMP that he cites is not so vague as to be incapable of enforcement*." 382 F. App'x at 440 (emphasis added). The court in *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), another case on which Plaintiffs rely (*see* Pls.' Opp'n at 44), likewise recognized that the court must evaluate whether particular CGMPs prescribe duties specifically enough to permit evaluation of the parallel character of a state law claim. *Cf. Bausch*, 630 F.3d at 556 ("First, the meaning of the FDA's requirements will present questions of law for the court to decide, not questions of fact for a jury to decide. Second, those questions of law will be questions of federal law, subject to the usual processes for reconciling conflicting views.").

Here, this Court finds that, for the most part, the CGMPs that Plaintiffs cite are simply too vague and generic to form the foundation for a reasoned assessment of a parallel state claim for a design, manufacturing, or labeling defect, or for breach of warranty. In their amended complaint, for example, Plaintiffs cite to 21 C.F.R. § 820.25(a), which requires every manufacturer to "have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed." 21 C.F.R. § 820.25(a). (*See also* 2d Am. Compl. ¶ 48.) The federal regulations do not specify any ratio of employees to products, nor does it say whether "necessary education" means a GED, high school

diploma, bachelor's degree, or otherwise. How, then, can a court reasonably determine that common law negligence liability based on an allegedly insufficient number of qualified employees extends no farther than the federal regulation that it purportedly parallels? Similarly, elsewhere in their amended complaint, Plaintiffs cite to the CGMP regulation that requires manufacturers to "establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient." 21 C.F.R. § 820.30(c). (*See also* 2d Am. Compl. ¶ 62.) Here, again, this regulation provides no guidance on what is *specifically* required to achieve compliance, and thus cannot serve as a genuine comparator for any considered evaluation of the scope of similar state law duties.

With respect to product labeling and use instructions, the non-CGMP regulations that Plaintiffs cite similarly only require that information on a label be "conspicuous[]" and "prominen[t]," *see* 21 C.F. R. § 801.15, and that the manufacturer provide "adequate directions . . . under which the layman can use a device safely and for the purposes for which it is intended[,]" 21 C.F.R. § 801.5. Again, the lack of specificity with respect to the demands of federal law means that there is no meaningful baseline against which to compare the requirements of the state common law, and thus no reasonable way to determine whether Plaintiffs' state common law claims are truly parallel. And none of the other CGMPs and regulations that Plaintiffs reference—save the adverse event reporting requirements, discussed below—are any more specific.[24]

[24] *See, e.g.*, 21 C.F.R. § 820.30(c) ("Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient."); *id* § 820.30(e) ("Each manufacturer shall

Consequently, the FDA's 2013 Warning Letter that put Medtronic on notice of its violation of certain generalized CGMP provisions is really of no moment,. To be sure, the FDA did find that Medtronic had violated certain CGMPs in the exercise of its expertise and discretion, but none of the delineated violations specifically pertained to the blocking of the vents on the p-cap (*see infra* Part III.C.3; 2013 Warning Letter at 2–25), and the FDA did not flesh out any of the general CGMPs in a manner that is sufficient to establish that the exact requirements of federal law such that Plaintiffs can credibly claim that truly parallel state law requirements exist. The 2013 Warning Letter also says nothing about the non-CGMP labeling and use instruction regulations on which Plaintiffs rely, and to this Court's knowledge, the FDA has no otherwise illuminated the specific contours of those general federal standards.

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establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed."); *id.* § 820.30(f) ("Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF."); *id.* § 820.70(g) ("Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use."); *id.* § 820.72(a) ("Each manufacturer shall ensure that all inspection, measuring, and test equipment . . . is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained."); *id.* § 820.90(a) ("Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented."); *id.* § 820.100(a) ("Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action."); *id.* § 820.198(a) ("Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit."); *id.* § 820.198(b) ("Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.").

b. *Plaintiffs have not identified a genuinely equivalent parallel state law claim pertaining to Medtronic's failure to report events to the FDA*

With respect to Plaintiffs' reliance on 21 C.F.R. § 803 to support the state common law claims that arise from Medtronic's alleged failure to track incidents and make required reports to the FDA (*see, e.g.*, 2d Am. Compl. ¶ 49), a slightly different preemption analysis is required. This particular regulation stands in stark contrast to the general CGMPs and the product labeling and use instruction regulations described above, because the reporting mandates laid out in this regulation are fairly specific about what types of events must be reported to the agency and when. For example, section 803.50(a) requires device manufacturers to make certain reports within 30 days of the manufacturer's receipt of certain information, as follows:

> (a) If you are a manufacturer, you must report to us the information required by § 803.52 in accordance with the requirements of § 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:
>
> > (1) May have caused or contributed to a death or serious injury or
> >
> > (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

Id. Another provision of this federal regulation requires Medtronic to report certain information within five days of becoming aware of an "event [that] necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health[,]" *id.* § 803.53(a), and the precise information that such reports must contain is also specified in the regulation, *see id.* § 803.52(a)–(c) (requiring the reporting of

"[p]atient information[,]" including name, age, gender, and weight; the "[a]dverse event or product problem[,]" including the nature of the event, the date of the event, the date of the report, and any test results; and "[d]evice information[,]" including brand, manufacture location, model number, and date the device was implanted). Thus, unlike the general, flexible guidelines that the various CGMPs to which Plaintiffs point establish, *see supra* Part VII.B.2, these particular reporting requirements are plainly "not so vague as to be incapable of enforcement." *Howard*, 382 F. App'x at 440.

Where Plaintiffs' preemption arguments fall short is with respect to Plaintiffs' obligation to assert state common law claims that are "genuinely equivalent" to these FDA regulations, *Wolicki–Gables*, 634 F.3d at 1300, such that the lawsuit does not impose any requirements that are "different from, or in addition to, the federal ones," *Riegel*, 552 U.S. at 321–22 (internal quotation marks and citation omitted). The Kubickis' counsel all but admitted during this Court's motions hearing that no equivalent adverse event reporting claims exist under state law. (*See* Mot. Hr'g Tr. at 17:9–14 ("So if you're asking whether or not the District of Columbia has an identical requirement, either codified in a state statute or that exists in common law, regarding the tracking of complaints to take an example, the answer is no.").) And that admission is, in effect, a concession that the Kubickis' state law failure to warn claims that are based on Medtronic's alleged failure to report adverse events to the FDA are expressly preempted. *See Riley*, 625 F. Supp. 2d at 777.[25]

[25] The cases on which Plaintiffs rely in this context—*Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), and *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013)—are inapposite. In *Hughes*, the plaintiffs were able to point to a specific Mississippi statute that contained reporting requirements, *see* 631 F.3d at 769, and in *Stengel*, the court found that a failure to warn claim survived a motion to dismiss where the state law "contemplates a warning to a third party such as the FDA[,]" 704 F.3d at 1233.

In their papers, Plaintiffs struggle mightily to avoid the implications of the undisputed fact that there is no D.C. common law claim that imposes liability for a manufacturer's failure to report to the FDA adverse incidents concerning an approved medical device. For example, they point to the established D.C. common law claim for failure to warn consumers of foreseeable harm associated with use of the product (*see, e.g.*, 2d Am. Compl. Counts XVI–XVIII), and construct the following argument: because Medtronic failed to track adverse events adequately and to notify the FDA in a timely manner of adverse events involving the over-delivery of insulin to patients, Medtronic deprived the FDA of important information regarding the pump that the agency could have then used to require Medtronic to change its label in order to provide the adequate warnings to Caroline and her physicians regarding risks associated with the pump that D.C. law requires. (*See, e.g.*, 2d Am. Compl. ¶ 49 ("Medtronic's failure to track and report adverse events kept important safety information from the FDA and, therefore, device users such as Caroline Kubicki.").) Thus, Plaintiffs insist that Medtronic's violation of the federal reporting requirements effectively amounted to a failure to warn consumers for the purpose of D.C.'s common law tort. (*See, e.g.*, *id.* ¶ 212.)

This creative effort to craft a D.C. common law claim that is substantially equivalent to the federal law's adverse-event reporting requirements fails for at least two reasons. First of all, it ignores the overarching mandate that the state claim and the federal claim must be *genuinely*—as opposed to effectively—equivalent. That is, if Plaintiffs' core contention is that the state common law was violated because Medtronic failed to warn consumers of device-related risks upon learning new adverse

information, then the federal requirement that such a claim actually parallels is a duty to warn *consumers* of device-related risks in light of new adverse events (i.e., the duty to update product labels post-approval), *not* the C.F.R.'s requirement that manufacturers report such events *to the FDA*. Put another way, the common law failure to warn claim is not, in fact, the functional equivalent of a manufacturer's failure to report adverse incidents to the FDA in violation of federal law, and Plaintiffs have not identified a federal regulation that imposes upon manufacturers the specific obligation to warn consumers of adverse post-approval events.

Second, Plaintiffs' parallel state law claim argument ultimately relies on sheer speculation: Plaintiffs contend that, *if* Medtronic had complied with the federal requirement to report adverse events to the FDA, and *if* the FDA had directed Medtronic to update the label of the MMT-522 Pump based on these reported events, then Medtronic would have had the duty to provide adequate warnings to consumers, as D.C. common law requires. But it is by no means certain that the FDA would have directed Medtronic to give consumers different or additional information about the MMT-522 Pump if the agency had been made aware of other incidents that predated Caroline's hypoglycemic injury. And unless such label changes would *necessarily* have occurred as a result of Medtronic's failure to notify the FDA, Plaintiffs' contention that Medtronic's failure to notify the agency is the functional equivalent of failing to warn consumers in violation of state law cannot be sustained. *Cf. Webster*, 259 F. Supp. 2d at 36 ("Nor can plaintiffs create an issue of fact regarding their defective warning claim by speculating that if the FDA had known of the delayed perforation and tamponade incidents during the clinical trials and if defendant had investigated all the adverse

incidents, the FDA would have either recalled the lead or placed it on alert, and therefore, Dr. Lewis would not have implanted it in plaintiff's heart." (emphasis omitted)). Thus, this Court does not accept Plaintiffs' argument that Medtronic's established reporting failures are truly parallel to the complaint's claims that Medtronic is liable for failing to provide adequate warnings to Caroline and her physicians regarding risks associated with the pump under District of Columbia law.

The court in *In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation*, 592 F. Supp. 2d 1147 (D. Minn. 2009), reached a similar conclusion about the plaintiffs' purportedly parallel state law claims in the context of a multi-district litigation relating to another Medtronic product, when it characterized the state law claims as actually and plainly imposing additional requirements on Medtronic under these circumstances. It reasoned that a defective-labeling state law claim that is tied to the manufacturer's alleged failure to disclose new information it discovered after the FDA's premarket approval of its medical device falls squarely within the preemptive scope of *Riegel*:

> Plaintiffs cannot escape that under their theory of liability, Medtronic would have been required to provide warnings above and beyond those on the [] product label—a label that was specifically approved by the FDA as part of the PMA process. Mandating that a manufacturer provide warnings beyond those on the device label would impose requirements different from, or in addition to those approved by the FDA, and are thus preempted. Simply put, Section 360k(a) preempts claims that are, as here, premised on a post-sale duty to warn, where the plaintiff alleges the defendant was required to provide additional warnings in light of later-received reports of injury to others caused by the same medical device.

Id. at 1159 (internal quotation marks and citations omitted).

The instant case involves this same dynamic, because the Kubickis' pump-related failure to warn claim are fundamentally based on the contention that Medtronic breached a duty to provide additional warnings, and to recall the pump for label changes, in light of the deficiencies in the device that the post-approval events revealed. But the MDA's express preemption clause prohibits the Court (or a jury) from making any such liability determination. *See id.*; *see also Cupek*, 405 F.3d at 424 ("Any claim, under state law . . . that Defendant failed to warn patients beyond warnings required by the FDA, or that Defendant failed to recall a product without first going through the PMA supplement process[,] would constitute state requirements 'different from' or 'in addition to' the requirements of the federal PMA application and supplement process." (quoting 21 U.S.C. § 360k(a))); *Horn v. Thoratec Corp.*, 376 F.3d 163, 176–77 (3d Cir. 2004) (holding that failure to warn claims are preempted if they would require the manufacturer "to provide different warnings and instructions from those approved by the FDA[,]" since the manufacturer was "prohibited . . . by the FDA's PMA approval order from making any such changes" (citations omitted)).

All things considered, then, this Court is confident that the one claimed violation of federal law that is sufficiently specific to support a parallel state law claim concerning the MMT-522 Pump—i.e., Medtronic's established failure to report subsequent adverse events to the FDA in a timely manner, as the adverse reporting regulations require (*see* 2013 Warning Letter at 25–26)—does not actually equate with the D.C. common law failure to warn claims that the Kubickis allege (*see* 2d Am. Compl. ¶¶ 495, & Counts I–III (failure to warn as element of negligence); XVI–XVIII

(failure to warn under Restatement of Torts)), and as a result, the MDA's express preemption provision bar these state law claims.

C. The Implied Preemption Doctrine Does Not Bar Plaintiffs' Claims Against Medtronic For The Allegedly Negligent Design, Manufacture, And Labeling Of The MMT-396 Infusion Set, And The Claims Based On Medtronic's Alleged Failure To Warn Consumers About That Product Also Survive

At this point, it is crucial to recall that the FDA authorized Medtronic to market the allegedly defective components of the insulin-delivery system that Caroline was using at the time of her injury through two different processes: the MMT-522 Pump was subjected to the PMA process, while the agency cleared the MMT-396 Infusion Set through the § 510(k) "substantial equivalence" route. (*See* Medtronic's Stmt. of Facts ¶¶ 7–9.) Thus, the doctrine of *express* preemption is inapplicable to claims pertaining to the MMT-396 Infusion Set, *see Lohr*, 518 U.S. at 492–94, and the Kubickis can proceed with their infusion set-related state law tort claims so long as those claims do not implicate the FDA's exclusive authority to enforce the FDCA and its implementing regulations. *See* 21 U.S.C. § 337(a); *see also Buckman*, 531 U.S. at 349 n.4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions.").

In its prior opinion denying Medtronic's motion to dismiss, the Court addressed the issue of whether Plaintiffs' claims relating to the MMT-522 Pump (the only claims asserted in the complaint at that time) were impliedly preempted, and determined that they were not. *See Kubicki*, 2013 WL 1739580, at *11 ("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*." (citations

and emphasis omitted)). This Court need not revisit the pump-related implied preemption evaluation now, because it has already decided that the Kubickis' pump-related claims are expressly preempted in any event. (*See supra* Part VI.B.)[26] Thus, the only preemption question that remains at this time is whether implied preemption bars the Kubickis' state law claims against Medtronic concerning the MMT-396 Infusion Set.

It is well established that state law tort claims with respect to a § 510(k) device can persist unabated if they "rely[] on traditional state tort law [that] had predated the federal enactments" that purportedly preempt them, *Buckman*, 531 U.S. at 353; and alternatively, state law claims are deemed impliedly preempted if "the existence of the federal enactments is a critical element in their case[,]" *id.* The seminal Supreme Court case on implied preemption—*Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001)—involved an allegation that a medical device manufacturer had made fraudulent representations to the FDA regarding the intended use of a medical device, which had led the FDA to grant § 510(k) approval to the device that injured the plaintiff. *See id.* at 343. The Supreme Court ruled that such a "fraud-on-the-FDA" claim could not be established apart from the federal approval process, and would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. Therefore, the Court held that the fraud claim was impliedly preempted. *See id.* at 348; *see also id.* at 347–48 (noting

[26] As suggested above, when it comes to PMA-approved devices, the overly of express and implied preemption analyses results in a particularly complex, nuanced inquiry. *See In re Medtronic, Inc.*, 623 F.3d at 1204 (citing *Riley*, 625 F. Supp. 2d at 777) (explaining that "[t]he plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).").

that "petitioner's dealings with the FDA were prompted by the MDA, and the very subject matter of petitioner's statements were dictated by that statute's provisions"). Accordingly, courts have held that "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist." *Riley*, 625 F. Supp. 2d at 777 (citing *Buckman*, 531 U.S. at 352–53); *see also Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 705 (S.D. Tex. 2014) ("Because these claims would apply to a seller of a product not subject to any federal regulations who engaged in similar alleged misconduct, they are not impliedly preempted.").

Applying these standards, and keeping in mind the Supreme Court's admonition in *Lohr* that, a medical device manufacturer that elects to proceed through § 510(k) faces the possibility of having "to defend itself against state-law claims" that would have been expressly preempted if it had instead opted for the more arduous PMA process, *see Lohr*, 518 U.S. at 494, this Court concludes that the Kubickis' claims against Medtronic that allege the negligent design, manufacture, and labeling of the MMT-396 Infusion Set exist independently of the FDCA, and in fact, are precisely the type of claims that the *Lohr* Court anticipated would be allowed to proceed. *See, e.g.*, *Schouest*, 13 F. Supp. 3d at 704 (finding that state law fraud, negligence, and breach of warranty claims relating to medical device were not impliedly preempted where they "would exist in a world without the FDCA"); *In re Medtronic, Inc. Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 899–900 (D. Minn. 2006) (holding that negligence and strict liability claims were not impliedly preempted because plaintiffs

relied on traditional state causes of action and did not seek to recover for fraud on the FDA).

In addition, although Plaintiffs have conceded that no common law claim for failure to report adverse events to the FDA exists under District of Columbia law, to the extent that the Kubickis' failure to warn claim alleges that Medtronic breached "a duty of reasonable care" *owed to Caroline Kubicki, her parents, and her physicians* "to adequately warn of the foreseeable harm associated with the use" of the MMT-396 Infusion Sets (2d Am. Compl. ¶ 205)—including "a duty to provide *specific* directions for the safe use" of the product (*id.* ¶ 206 (emphasis in original)) and "sufficient warnings and instructions for use" (*id.* ¶ 210)—this claim, too, survives Defendant's implied preemption argument.[27] Under D.C. law, there has long been a recognized tort claim that can be brought against manufacturers that fail to warn consumers of known product defects. *See, e.g.*, *Payne v. Soft Sheen Prods.*, 486 A.2d 712, 721–22 (D.C.

[27] Once again, the distinction between the alleged negligent failure to report adverse events to the FDA, on the one hand, and the failure to warn the public about foreseeable risks associated with a device, on the other, matters. The courts of appeals have split over whether a state law failure to report claim (when one is recognized) is impliedly preempted: the Sixth and Eighth Circuits have refused to allow state law tort claims based on alleged violations of FDA reporting requirements to proceed, finding that such claims encroach on the FDA's exclusive province to enforce the FDCA, *see, e.g.*, *Marsh v. Genentech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012) (holding that "failure to submit reports to the FDA that the FDA requires is arguably a species of fraud on the agency under the state Act" that directly implicates that Supreme Court's holding in *Buckman*); *In re Medtronic, Inc.*, 623 F.3d at 1204, while the Fifth, Seventh, and Ninth Circuits have held that state law failure to report claims based on allegations that a manufacturer failed to report adverse events to the FDA are not impliedly preempted under *Buckman*, because such claims are based on an alleged "breach of a 'recognized state-law duty' rather than 'an implied right of action under federal law[,]'" *Hughes*, 631 F.3d at 775 (quoting *Bausch*, 630 F.3d at 557–58); *see also, e.g.*, *Stengel*, 704 F.3d at 1233 ("The Stengels' proposed new claim under Arizona law, insofar as the state-law duty parallels a federal-law duty under the MDA, is not preempted."). The D.C. Circuit has not waded into this dispute, and this Court finds no reason to do so here, given Plaintiffs' admission that there is no common law claim for failing to report adverse events to the FDA in this jurisdiction. The resulting inevitable conclusion is that the only potentially viable failure to warn claim in Plaintiffs' complaint is the contention that Medtronic breached its duty to warn consumers directly. (*See, e.g.*, 2d Am. Compl. ¶ 212 (alleging that Medtronic "breached its duty to warn Caroline Kubicki, her parents, her physicians and the FDA of the foreseeable harm associated with the use" of its product).)

1985); *Russell v. G. A. F. Corp.*, 422 A.2d 989, 991 (D.C. 1980). Therefore, this Court is persuaded that the Kubickis' failure to warn consumers claim (i.e., their contention that Medtronic negligently failed to warn consumers about the dangers of the MMT-396 Infusion Set and to provide sufficient instructions for its safe use) exists independently of federal law in a manner that withstands Defendants' implied preemption argument.

In sum, with respect to Medtronic's preemption contentions, this Court concludes that (1) Medtronic is entitled to summary judgment, on the basis of express preemption, with respect to the all of the claims that pertain to the MMT-522 Pump (with the exception of Plaintiffs' manufacturing defect claim), and (2) the Kubickis cannot maintain a (non-existent) state law claim for Medtronic's alleged failure to report to the FDA adverse events involving the MMT-396 Infusion Set, and thus Medtronic is entitled to summary judgment on any such claim on the basis of implied preemption, but (3) the doctrine of implied preemption presents no bar to the Kubickis' claims relating to design, manufacture, and labeling of the MMT-396 Infusion Set, or to their claims that Medtronic violated established state common law by failing to warn consumers about risks associated with the MMT-396 Infusion Set.

VIII. RULING ON THE LEARNED INTERMEDIARY DOCTRINE, THE KUBICKIS' INFUSION SET WARRANTY CLAIM, AND PUNITIVE DAMAGES

Finally, this Court turns to a series of alternative and miscellaneous arguments that Medtronic makes in support of its contention that it is entitled to an award of summary judgment in this case.

A. Medtronic Is Not Entitled To Summary Judgment With Respect To The Failure To Warn Claims On The Basis Of The Learned Intermediary Doctrine

To further assail the Kubickis' unpreempted infusion set-related failure to warn consumers claims, Medtronic points to "the learned intermediary doctrine" (Medtronic Mem. at 63–66), which "holds that, because prescription [devices] are available to the public only through a physician and are to be administered only under a physician's supervision, the [device] manufacturer's duty is to adequately inform the physician, who is expected to function as a 'learned intermediary' between the company and the patient in protecting the patient and providing direct information about the [device] to the patient.'" *MacPherson*, 775 F. Supp. at 422-23; *see also Patteson v. AstraZeneca, LP*, 876 F. Supp. 2d 27, 34 (D.D.C. 2012) ("As long as the [prescription] manufacturer properly warns a prescribing physician of the dangerous propensities of its product, the manufacturer is excused from warning each patient who receives the [product]."). In this regard, Medtronic argues that, because "Medtronic's duty to warn of any dangers associated with these products ran [only] to the licensed medical professional who prescribed them[,]" and because Dr. Dandona (Caroline's physician) testified that "he did not read or rely upon the warnings and would not have altered his decision to prescribe the MMT-522 Pump and MMT-396 Infusion Set" to Caroline even if the warnings had been sufficient (Medtronic's Mem. at 64), the Kubickis cannot establish that Medtronic's alleged failure to warn caused Caroline's injury. In other words, through the learned intermediary doctrine, Medtronic maintains that the allegedly inadequate warnings—which Dr. Dandona admittedly did not see or read—could not have caused Caroline's injury, and thus the company cannot be held liable for its alleged failure to warn. (*See id.* (arguing that when the physician would have

prescribed the medical device regardless of what he "may have read or not read," or "when the prescribing physician did not read, or rely upon, the warnings that were actually provided, there can . . . be no liability").)

This Court rejects Medtronic's conclusion that there is no genuine issue of material fact related to its potential liability for the allegedly faulty labels and instructions that purportedly failed to warn Caroline, her parents, and Dr. Dandona of the risks pertaining to improper use of the MMT-396 Infusion Set for at least two reasons. First of all, the case law makes clear that, for the learned intermediate doctrine to absolve a manufacturer, the warning that is given to the professional *must be adequate*. *See McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006 ("[E]ven in the context of a learned intermediary, if the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for injuries sustained by the ultimate user." (internal quotation marks omitted)); *see also Patteson*, 876 F. Supp. 2d at 34 (holding that if the manufacturer "*properly* warns a prescribing physician of the dangerous propensities of its product, the manufacturer is excused from warning each patient" (emphasis added)). The adequacy of the label and insert that Medtronic provided with the MMT-396 Infusion Set is indisputably still at issue in this case, which plainly precludes summary judgment in Medtronic's favor on learned intermediary grounds. *See Payne*, 486 A.2d at 723 ("[I]n cases in which there is a potential for serious injury, the adequacy of even a relatively clear warning should not be determined as a matter of law but is a question of fact for the jury[.]").

Second, and possibly even more significant, while Medtronic is correct to observe that the professional's actual reliance on the allegedly inadequate information

that a manufacturer provides is key to assessing causation, *see Patteson*, 876 F. Supp. 2d at 34 ("An inadequate warning alone, however, is not enough; the learned-intermediary doctrine also requires that the inadequate warning be a 'producing cause' of the plaintiff's injury."), Medtronic has not successfully established that there is no genuine issue of fact regarding causation in the instant case. This is primarily because, although Dr. Dandona did testify that he did not review or rely upon the instructions for the infusion set (*see* Dep. of Paresh Dandona ("Dandona Dep."). Ex. 5 to Pls.' Opp'n, ECF No. 138-7, at 7:16–20), his sworn testimony reveals that Dr. Dandona was *not* the medical professional who was responsible for reviewing Medtronic's materials and explaining to patients how to use the device. In response to a direct deposition question about whether or not he had "ever reviewed [] the instructions for use for . . . the infusion set?" Dr. Dandona stated:

> No. I'm – I'm not into the technology of each individual pump. It's too much. *And that function is given to the CDEs, who are the pump trainers, and they have all the details of that*.
>
> So I sort of decide on the policy of installing a pump, the kind of infusion rates that should be appropriate for a patient, *but the rest of the functions are carried out by the educators*.

(*Id.* at 7:19–8:2.) Thus, the record makes crystal clear that Dr. Dandona viewed his role as determining the overall "policy of installing a pump" and setting "the kind of infusion rates that should be appropriate for a patient," and that he *delegated* the technical responsibility of providing patients with instructions for using the prescribed insulin-delivery device properly to agents he calls "pump trainers." Yet, to this Court's knowledge, the pump trainers have not testified in the context of this matter, so nothing in the record establishes that the pump trainers who instructed Caroline on how to use the infusion set eschewed reading or relying upon the allegedly inadequate instructions

and warnings that Medtronic included in the infusion set packaging. Furthermore, under District of Columbia law, there is a presumption that the functional user of a device (here, the trainers) would have read the manufacturers' instructions and would have known how to use the device based on those instructions, in the absence of any evidence about what the trainers actually knew and said. *See Payne*, 486 A.2d at 725 (explaining that the law presumes that "the user would have read an adequate warning, and that in the absence of evidence rebutting the presumption, a jury may find that the defendant's product was the producing cause of the plaintiff's injury").

Consequently, on the record the parties have provided, a reasonable jury might well conclude that Medtronic's infusion set instructions (imparted to Caroline by the pump trainers) were inadequate and ultimately caused Caroline's injury, despite Dr. Dandona's testimony regarding his own personal lack of review and reliance on any such instructions when he prescribed the device to Caroline. Put another way, contrary to Medtronic's contentions, it was Caroline's pump trainer, *not* Dr. Dandona, who was the pertinent 'learned intermediary' for the purpose of Plaintiffs' failure to warn claim, and thus, Dr. Dandona's testimony about his own personal lack of reliance on Medtronic's materials (without regard to what the agents who served as the relevant instructing professionals for present purposes relied upon) is manifestly insufficient to break the chain of causation between the allegedly inadequate instructions and Caroline's injury as a matter of law.

B. Medtronic Is Entitled To Summary Judgment On Plaintiffs' Breach Of Express Warranty Claim Because The Statements On Which Plaintiffs Rely Do Not Create An Actionable Warranty

Medtronic also insists that summary judgment is warranted with respect to the the MMT-396 Infusion Set breach of warranty claims that Plaintiffs have brought. (*See* Medtronic's Mem. at 67–68; Medtronic's Reply at 30–31.)[28] As clarified in Plaintiffs' opposition brief, the Kubickis allege that Medtronic warrantied that the MMT-396 Infusion Set was safe and functional through advertising and promotional statements about that product, and Medtronic also represented that design modifications to the venting system made the insulin-deilvery system safer, but that turned out not to be so. (*See* Pls.' Opp'n at 81–82 (pointing to statements that Medtronic made in advertising materials, including that Medtronic infusion sets "ensure success"; that the vents in the p-cap would reduce "clogging and malfunction"; and that Medtronic infusion sets "are made with patented tubing, which is clog and kink resistant, assuring that the insulin is being safely delivered" (quoting Medtronic Infusion Set Brochure, Ex. 65 to Pls.' Opp'n, ECF No. 138-68, at 3).)[29] As explained below, this Court finds that Medtronic is entitled to summary judgment on these express warranty claims, because the statements to which Plaintiffs point do not amount to an enforceable warranty.

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[28] This Court has already held that any warranty claims relating to the MMT-522 Pump are expressly preempted. *See supra* Part VII.B.

[29] Notably, the Kubickis' express warranty contentions, which reference Medtronic's advertising and promotional materials, differ from the complaint's related claim that Medtronic included an express warranty *in the product packaging* for the MMT-396 Infusion Set. (*See* 2d Am. Compl. ¶ 160.) Plaintiffs appear to have abandoned their product-packaging express warranty claim, as they have not countered Medtronic's representation that the infusion set lots at issue in this case "were not accompanied by any warranty." (Medtronic's Stmt. of Facts ¶ 27; *see also* Pls.' Opp'n at 81–82 (arguing that, with respect to the infusion set, a warranty existed as a result of statements made in advertisements).)

In order to succeed on a breach of warranty claim under District of Columbia law, a plaintiff must prove "that the defendant breached an express promise made about the product sold." *Witherspoon v. Philip Morris Inc.*, 964 F. Supp. 455, 464 (D.D.C. 1997). The D.C. Code explains that an enforceable express warranty arises when the seller makes to the buyer "(a) [a]ny affirmation of fact or promise . . . which relates to the goods and becomes part of the basis of the bargain" or "(b) [a]ny description of the goods which is made part of the basis of the bargain[.]" D.C. Code § 28:2-313(1). In either case, such an expression "creates an express warranty that the goods shall conform to the [description], affirmation or promise." *Id*. An express warranty can exist even if the seller does not use the words "warrant" or "guarantee," but it is well established that "an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." D.C. Code. § 28:2-313(2). Furthermore, when the plaintiff alleges only that a manufacturer's "advertisements and promotionals statements contained *broad* claims amounting to a warranty[,]" the alleged breach of warranty claim cannot survive. *Witherspoon*, 964 F. Supp. at 465 (emphasis added; internal quotation marks and citation omitted); *see also, e.g., Forouzesh v. Starbucks Co.*, No. CV 16-3830, 2016 WL 4443203, at * 4 (C.D. Cal. Aug. 19, 2016) (dismissing breach of warranty claim predicated on the defendant's representations that its beverages were sold "in cups of various sizes[,]" because a reasonable consumer would not have interpreted the defendant's representation to be an affirmation of fact or description regarding the "specific amount of liquid" in the cups); *Hubbard v. Gen. Motors Corp.*, No. 95Civ.4362, 1996 WL 274018, at *7 (S.D.N.Y. May 22, 1996) (holding that statements

made in advertisements that vehicles are "the most dependable, long-lasting trucks on the planet" constituted "puffery" rather than an actionable warranty regarding vehicle's braking system, particularly where the statements made "no reference whatsoever to the type or quality of the vehicles' braking system").

Here, it is clear to this Court that any warranty claim that is based on the statements in Medtronic's advertising materials to which Plaintiffs point to fails as a matter of law, due to the nature of the statements at issue. For example, Plaintiffs contend that Medtronic warrantied the MMT-396 Infusion Set's p-cap vent design by asserting that the vents in the p-cap would reduce "clogging and malfunction" and that Medtronic infusion sets "are made with patented tubing, which is clog and kink resistant, assuring that the insulin is being safely delivered" (*see* Pls.' Opp'n at 81–82 (quoting Medtronic Infusion Set Brochure in the advertising materials)), but such a generalized endorsement of the product's purportedly superior structure is not a fact-based promise that the product will perform in a certain way. *See Witherspoon*, 964 F. Supp. at 464; *Hoffman v. A.B. Chance Co.*, 339 F. Supp. 1385, 1387 (M.D. Pa. 1972) (holding that advertisements representing that a brake lock device "offered unprecedented safety" did not create an actionable warranty). Indeed, to qualify as an express promise of the type that is enforceable as a warranty, the manufacturer must do more than make generalized statements commending the product; instead, it must articulate verifiable facts about product performance, such that lack of conformity with those representations can plausibly be established. *See, e.g., City of Wyoming v. Procter & Gamble Co.*, No. 15-2101, 2016 WL 5496321, at *9–10 (D. Minn. Sept. 28, 2016) (holding that packaging and advertising statements describing wet wipes as

"flushable" were "affirmations of fact" sufficient to create an express warranty). By contrast, Medtronic's statements about the MMT-396 Infusion Set appear to this Court's eye to be more in the nature of advertising "puffery," *see Pearson v. Chung*, 961 A.2d 1067, 1076 (D.C. 2008), rather than specific affirmations of fact upon which a reasonable consumer could reasonably rely and ultimately seek to enforce.

In this regard, *In re General Motors Corp. Anti–Lock Brake Products Liability Litigation*, 966 F. Supp. 1525 (E.D. Mo. 1997), is instructive. In that case, plaintiffs sought to assert a breach of warranty claim against General Motors, arguing that General Motors's advertising statements that a vehicles' crash avoidance system was "99 percent more effective" than a crash protection system, and that "[a] driver is 100 times more likely to benefit from a vehicle's crash-avoidance capabilities (such as anti-lock brakes) than from its crash-survival capabilities (such as air bags)[,]" created a warranty that the vehicles' systems were free of safety defects, and that General Motors had breached this warranty because the systems were defective and not, in fact, safe. *Id.* at 1531. The court dismissed this warranty claim, finding that "comparative claims [such as these], often involving large numbers, are puffing because a consumer cannot reasonably believe that there is a test behind the claims." *Id.*; *cf. In re XM Satellite Radio Holdings Sec. Litig.*, 479 F. Supp. 2d 165, 180 (D.D.C. 2007) (dismissing securities fraud claim that was predicated on adverting statements because "generalized positive statements about 'cost effective,' 'smart,' 'sound' and 'efficient' growth are vague and incapable of objective verification, they are not the type of statement upon which a reasonable investor would rely" and instead constitute mere "puffery"); *Hoyte v. Yum! Brands, Inc.*, 489 F. Supp. 2d 24, 30 (D.D.C. 2007) (granting motion to

dismiss negligent misrepresentation claim based on "KFC's claims that its restaurants serve the 'best food'" because such a statement "is a non-measurable, 'bald statement of superiority' that is non-actionable puffery").

The bottom line is this: in this Court's considered judgment, much of the advertising language that Plaintiffs say gives rise to their breach of warranty claims actually dooms these allegations, because instead of essentially guaranteeing that the MMT-396 Infusion Set will operate a certain specified way, Medtronic's statements appear to be merely the type of general commendation that courts have long held does not create an enforceable warranty. *See Witherspoon*, 964 F. Supp. at 464.

C. While Medtronic Is Entitled To Summary Judgment On Plaintiffs' Stand-Alone Punitive Damages Claim, It Is Premature To Foreclose Punitive Damages As A Remedy

Finally, Medtronic argues that summary judgment should be entered in its favor with respect to Plaintiffs' punitive damages claims. (*See* Medtronic Mem. at 68–70.) Plaintiffs' complaint alleges that all of Medtronic's failures and deficiencies with respect to the medical devices at issue in this case were malicious, willful, and wanton, and that the company has acted without regard for the safety of others—facts that, Plaintiffs say, entitle them to an award of punitive damages. (*See* 2d Am. Compl. ¶¶ 254–259.) *See also Rogers v. Ingersoll-Rand Co.*, 971 F. Supp. 4, 12 (D.D.C. 1997) ("Punitive damages are properly awarded where the act of the defendant is accompanied by fraud, ill will, recklessness, wantonness, oppressiveness, willful disregard of the plaintiff's rights, or other circumstances tending to aggravate the injury."). To the extent that Plaintiffs seek punitive damages *as a separate cause of action*, Medtronic's motion is well-founded, and this Court can easily dispose of such claims, as it is clear beyond cavil that the District of Columbia only recognizes punitive damages as a

remedy and not an independent cause of action. *See, e.g.*, *Mitchell v. E. Sav. Bank, FSB*, 890 F. Supp. 2d 104, 110 (D.D.C. 2012); *Gharib v. Wolf*, 518 F. Supp. 2d 50, 56 (D.D.C. 2007) (citing *Int'l Kitchen Exhaust Cleaning Ass'n v. Power Washers of N. Am.*, 81 F. Supp. 2d 70, 74 (D.D.C. 2000)). Therefore, and on this basis alone, Medtronic is entitled to summary judgment on Counts XXI, XXII, and XXIII of Plaintiffs' Second Amended Complaint.

However, notably, nothing in this Court's decision should be construed as precluding Plaintiffs from seeking punitive damages as a remedy at the appropriate time. That is, insofar as Medtronic argues that no such remedy is available on the current record (*see* Medtronic's Mem. at 69–70), the parties are reminded that the record is subject to further development in this case, because they have yet to engage in expert discovery. (*See supra* Part V.) This Court will not accept Medtronic's suggestion that it evaluate—and foreclose completely—any punitive damages remedy now; instead, the Court will await future discussion of the appropriateness of Plaintiffs' request for punitive damages in the context of the parties' preparations for trial. *Cf.* D.C. Std. Civ. Jury Instr. Nos. 13-12, 16-2, 16-3.

IX. CONCLUSION

The facts of this matter are relatively straightforward—a tragic, devastating injury purportedly caused by Defendants' allegedly tortious conduct with respect to a widely marketed insulin-delivery device—but the intersection of law and life can be quite complicated. Even prior to engaging in expert discovery, Medtronic and Unomedical have vigorously maintained that the Kubickis cannot persist with the various state law claims they have filed pertaining to the MMT-522 Pump and MMT-

396 Infusion Set for several nuanced reasons, and having carefully reviewed the parties' summary judgment filings and the exhibits thereto, as well as their statements of fact, this Court agrees with Defendants with respect to certain claims, and disagrees with respect to others. For the reasons explained at length above, the Court finds that Unomedical is entitled to summary judgment with respect to all of the claims Plaintiffs have brought against it on timeliness grounds, and Medtronic is entitled to summary judgment with respect to certain claims, as follows: (1) all of Plaintiffs' claims that pertain to the MMT-522 Pump, except Plaintiffs' manufacturing defect claim, (2) Plaintiffs' claims that Medtronic failed to report to the FDA adverse events regarding the MMT-396 Infusion Set in violation of state law, (3) Plaintiffs' breach of warranty claims, and (4) Plaintiffs' stand-alone claim for punitive damages. However, the Court concludes that genuine issues of material fact remain with respect to Plaintiffs' negligent design, manufacture, labeling, and failure to warn consumers claims relating to the MMT-396 Infusion Set, and that there are also triable issues of fact with respect to causation—at least for now. Thus, as set forth in the accompanying order, Unomedical's Motion for Summary Judgment is **GRANTED**, Medtronic's Motion for Summary Judgment is **GRANTED** in part and **DENIED** in part, and the parties are ordered to submit a joint proposed schedule for expert discovery.

DATE: February 5, 2018

Ketanji Brown Jackson

KETANJI BROWN JACKSON
United States District Judge