NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ESTATE OF SAUNDRA BENN, *et al.*, Plaintiffs, v. MEDTRONIC, INC., *et al.*, Defendants.	No. 22cv6522 (EP) (CLW) **OPINION**

PADIN, **District Judge.**

Plaintiff Samuel Benn, as Administrator of his wife Saundra Benn's estate and individually, alleges that Defendants' Mini Med 600 series insulin pump (the "Pump") had a manufacturing defect that caused Saundra's death. Defendants move to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), arguing that Plaintiff's state law claims are preempted by federal law, and are otherwise inadequately pled. For the reasons below, the Court agrees that the claims are preempted, will **GRANT** the motion, and will **DISMISS** the Complaint without prejudice.[1]

I. BACKGROUND

A. Plaintiff's well-pled factual allegations and procedural history

The Pump was developed, designed, manufactured, and distributed by Defendant Medtronic, Inc. D.E. 1-1 ("Compl.") ¶¶ 1-2. The other Defendants are related entities. Defendants Medtronic MiniMed, Inc. and MiniMed are Delaware corporations with their principal places of business in California. D.E. 1 (notice of removal) ¶¶ 8, 9. Defendants Medtronic, USA, Inc. and

[1] The Court decides the motion without oral argument. L.Civ.R.78(b).

Medtronic, Inc. are Minnesota corporations with their principal places of business in Minnesota. *Id.* ¶¶ 10-11.

Plaintiff's wife Saundra used the Pump to manage Type I diabetes, following the manufacturer's instructions at all times. Compl. ¶ 4. On October 10, 2020, Saundra collapsed at home and was rushed to the hospital for severe hyperglycemia. *Id.* ¶¶ 5-6. Saundra died that day; the hospital listed her cause of death as cardiopulmonary arrest caused by diabetic ketoacidosis, hyperkalemia, and renal failure. *Id.* ¶ 7.

About a year later, on November 24, 2021, Plaintiff received an "urgent medical device recall" letter. *Id.* ¶ 8 (citing D.E. 1-1 at 18, the "Recall Letter"). The Recall Letter referenced a damaged "retainer ring to lock the reservoir in the pump" and announced a recall "due to reported incidents of a loose reservoir that can no longer be locked into the pump." *Id.* ¶ 9. According to the Recall Letter, "[i]f the reservoir is not properly locked into the pump, the improper locking could lead to over or under delivery of insulin, which could then result in hypoglycemia or hyperglycemia." *Id.* ¶ 10.

Plaintiff filed this action in New Jersey Superior Court. The Complaint alleges five causes of action, each one essentially an allegation that the Pump's defect(s) resulted in Saundra's death:

1. Violation of the New Jersey Product Liability Act ("NJPLA"), N.J.S.A. 2A:58C-1, *et seq.*;
2. Negligence, negligent design, negligent manufacture, and breach of warranty;
3. Violation of the New Jersey Consumer Fraud Act ("Consumer Fraud Act");
4. Wrongful death; and
5. Conscious pain and suffering.

Defendants then removed the action to this Court on diversity grounds.[2] 28 U.S.C. § 1332. Defendants now seek to dismiss the Complaint, arguing that Plaintiff's claims are barred by the

[2] Though Plaintiff has not challenged the removal, the Court has independently confirmed diversity jurisdiction. Plaintiff is a New Jersey resident, unlike all named Defendants. Additionally, it is

Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), which preempts state causes of action against manufacturers of medical devices approved through the FDA's premarket approval ("PMA") process. Defendants also argue that the Complaint fails to state a claim under state and federal pleading standards. Plaintiff opposes. D.E. 8 ("Opp'n"). Defendants have replied. D.E. 13 ("Reply").

B. The FDA's PMA process

As complex devices proliferated and some failed in the 1960s and 70s, many states adopted regulatory measures. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-16 (2008) (citing Leflar & Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic,* 64 Tenn. L. Rev. 691, 703 n.66 (1997) (identifying 13 state statutes governing medical devices as of 1976)). Congress then passed the MDA, "which swept back some state obligations and imposed a regime of detailed federal oversight." *Id.* at 316.

The MDA established varying levels of oversight for different types of medical devices, "depending on the risks" associated with a device. *Id.* at 316. Class III devices, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators, receive the most oversight. *Id.* at 317. Class III designation is appropriate "if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness," and the device is "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

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more likely than not that the amount in controversy exceeds $75,000. *Angus v. Shiley, Inc*., 989 F.2d 142, 146 (3d Cir. 1993) (affirming district court's independent appraisal of the value of the claim and finding that a reasonable jury likely could have valued plaintiff's losses over the jurisdictional threshhold).

human health," or "presents a potential unreasonable risk of illness or injury." *Id.* at 317 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).

Class III devices require PMA, which is a "rigorous process" requiring

> full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling.

Id. at 317-318 (quoting 21 U.S.C. § 360e(c)(1)); *see also* 21 U.S.C. § 360e(g) (permitting request for additional data from manufacturer); 21 CFR § 814.44(a) (2007) (authorizing reference to panel of outside experts).

The Pump is a Class III device. Beginning in 2006, the FDA has granted PMA to Medtronic 600-series insulin pumps and modifications to those pumps, including the Pump used by Saundra and listed in the Recall Letter.[3] *See* U.S. Food and Drug Administration, *Premarket Approval*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P980022S013 [last visited June 8, 2023]; D.E. 6-1-6-4 (Minimed 630G device supplements).

II. LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 12(b)(6), a court accepts all well-pled facts as true, construes the complaint in the plaintiff's favor, and determines "whether, under any

[3] The Court may take judicial notice of published government records such as the FDA's PMA documents like Exhibits A and B, as well as FDA database entries like Exhibits C and D. *See, e.g.*, *U.S. ex rel. Bennett v. Bayer Corp.*, 2022 U.S. Dist. LEXIS 59793, at *28 (D.N.J. Mar. 31, 2022) (taking judicial notice of transcript of FDA meeting); *Desai v. Sorin CRM USA, Inc.*, No. 12-2995, 2013 U.S. Dist. LEXIS 5795, at *10 (D.N.J. Jan. 15, 2013). Importantly, Plaintiff does not dispute the validity of any of Defendants' FDA history, or the Court's discretion to consider it.

reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. Cnty. Of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (cleaned up). "In deciding a Rule 12(b)(6) motion, a court must consider only the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010).

To survive a Rule 12(b)(6) challenge, the plaintiff's claims must be facially plausible, meaning that the well-pled facts "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). The allegations must be "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. "[A] court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Ashcroft*, 556 U.S. at 679. Finally, "[w]hile legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Id*.

III. ANALYSIS

The Court agrees with Defendants that Plaintiff's state law claims are preempted by the MDA, which provides, as relevant here, that:

> no 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 Act 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 Act.

FDCA § 360k(a).

In *Riegel v. Medtronic, Inc.*, the Supreme Court held that the MDA preempts state tort claims to the extent that they depart from federal law. 552 U.S. 312 (2008). Courts within the Third Circuit have consistently held that tort claims based on negligence, manufacturing and design defects, strict liability, breach of warranty, failure to warn, and state consumer fraud statutes are therefore preempted by the MDA. *See, e.g.*, *Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010) (strict product liability allegations based on manufacturing defect and breach of warranty are preempted by the MDA); *Morton v. Allegran, Inc.*, No. 14-cv-1312, 2015 U.S. Dist. LEXIS 188871, at *7 (D.N.J. Apr. 2, 2015) (collecting cases). That encompasses all five of the Complaint's counts: NJPLA, negligence/negligent design and manufacture, Consumer Fraud Act, wrongful death, and pain and suffering. *See id.* ("state tort-based requirements of safety and effectiveness implicate the core concerns of the federal PMA process").

The crux of Plaintiff's opposition is that "federal manufacturing and labeling requirements are not pre-empted under state law." Opp'n at 5 (citing *Wyeth v. Levine*, 129 S.Ct. 1187, 1204 (1996)). But *Wyeth* and similar cases[4] cited by Plaintiff relate to drugs (for which Congress did not enact preemption), not medical devices (for which they did). *Hart v. Medtronic, Inc.*, No. 1:16-cv-05403, 2017 U.S. Dist. LEXIS 196837, at *11 n.4 (D.N.J. Nov. 30, 2017); *see also Germain v. Teva Pharms., USA, Inc. (In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.)*, 756 F.3d 917, 924-25 (6th Cir. 2014) (distinguishing between implied preemption under *Wyeth* and express preemption under the MDA and *Riegel*).

There is, however, a narrow category of exceptions to MDA preemption for state law claims that "parallel," rather than add to, federal requirements. *Riegel*, 552 U.S. at 330. For

[4] *See, e.g.*, *McDarby v. Merck & Co.,* 401 N.J. Super. 10 (App. Div. 2008); *Feldman v. Lederle Labs.*, 97 N.J. 429 (1984).

example, the MDA would "not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Id.* "This 'parallel claim' exception to preemption, however, requires more than just a change of terminology; a plaintiff 'cannot simply incant the magic words '[Defendant] violated FDA regulations' in order to avoid preemption." *Morton*, 2015 U.S. Dist. LEXIS 188871, at *8-9 (quoting *In re Medtronic*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009)). "Rather, the plaintiff must plead facts that, if proven, would show a link between a specific federal violation and the plaintiff's injury." *Id.* (citing *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 282 (E.D.N.Y. 2009)).

Plaintiff attempts to fit the Complaint's allegations within the preemption exception:

> The Complaint explains that the insulin pump was designed with a retainer ring to lock in the pump, and that the pumps were recalled due to issues with a "damaged clear retainer ring … due to reported incidents of a loose reservoir that can no longer be locked into the pump." The Complaint continues to reference the recall notice, explaining that "If the reservoir is not properly locked into the pump, the improper locking could lead to over or under delivery of insulin, which could then result in hypoglycemia or hyperglycemia. Severe hypoglycemia and hyperglycemia can be life threatening or may result in death."

Opp'n at 7 (quoting Recall Letter).

But an argument that the retainer ring failed does not allege a deviation from pre-market, FDA-approved specifications; it simply recasts a preempted defect as an actionable deviation. *See Banner v. Cyberonics, Inc.*, 2010 U.S. Dist. LEXIS 9393, at *9-10 (D.N.J. Feb. 4, 2010) ("[I]f the FDA approves a manufacturing process and the defendant-manufacturer conforms with it, a device thereby produced that nevertheless does not function as intended does not give rise to liability."); *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1114 (9th Cir. 2019) (citations omitted) (explaining that as part of the PMA process, "the FDA performs a cost-benefit analysis and may approve devices knowing that they sometimes will fail" and that evidence that a device was defective and

malfunctioned "is not evidence that [the manufacturer] deviated from the FDA's pre-market approved procedures"), *cert. denied*, 140 S. Ct. 2555 (2020).

Nor does a product recall create an inference that PMA specifications were violated. Courts have consistently held that a product recall alone, without more, does not suggest a PMA specification violation. *See, e.g.*, *Shuker v. Smith & Nephew PLC*, 2015 U.S. Dist. LEXIS 43141, at *63-64 (E.D. Pa. Mar. 31, 2015) (refusing to draw an inference of a manufacturing defect from the allegation that the device was recalled); *see also Weber v. Allergan, Inc.*, 940 F.3d 1106, 1114 (9th Cir. 2019) ("[P]roduct recalls do not create a presumption that FDA requirements have been violated."), *cert. denied*, 140 S. Ct. 2555 (2020); *Erickson v. Boston Sci. Corp.*, 846 F. Supp. 2d 1085, 1093 (C.D. Cal. 2011) (cleaned up) ("Many courts have recognized that product recalls do not create a presumption that FDA requirements have been violated."); *Wheeler v. Frank*, 2012 Colo. Dist. LEXIS 2832, at *4 (2012) ("[T]he FDA's recall of a PMA Class-III medical device does not give rise to a claim capable of surviving federal preemption."). Accordingly, Plaintiff's state law claims are preempted and, because they make up the entirety of the Complaint, dismissal is warranted. Having dismissed the claims on this basis, the Court need not address Defendants' other argument that Plaintiff's Complaint fails to adequately plead the asserted causes of action.

To the extent, however, that Plaintiff requests leave to amend, Plaintiff is correct that courts "should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). Rule 15 "codifies a liberal approach to the amendment of pleadings to promote the policy of deciding cases on the merits, instead of on technicalities." *Phillips v. Borough of Keyport*, 179 F.R.D. 140, 143 (D.N.J. 1998). Thus, while the preemption issue is a straightforward legal question, the Court cannot say with absolute certainty that amendment—for example, to plead a valid preemption exception—

would be futile. Because Plaintiff has not previously amended the Complaint, the Court will permit an opportunity to do so.

IV. CONCLUSION

For the reasons above, Defendant's motion to dismiss (D.E. 6) will be **GRANTED**, and the Complaint will be **DISMISSED WITHOUT PREJUDICE**. Plaintiff may file an Amended Complaint within 30 days. An appropriate Order accompanies this Opinion.

June 12, 2023

Evelyn Padin, U.S.D.J.