UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civil No. 18-2124 (DSD/HB)

ASEA/AFSCME Local 52 Health Benefits Trust, individually and on behalf of a class of similarly situated third party payors,

Plaintiff,

v. **ORDER**

St. Jude Medical, LLC, a Delaware corporation, and Abbott Laboratories, an Illinois corporation,

Defendants.

Karl L. Cambronne, Esq., Bryan L. Bleichner, Esq., Jeffrey D. Bores and Chestnut Cambronne, PA, 17 Washington Avenue North, Suite 300, Minneapolis, MN 55401; Robert K. Shelquist, Esq. and Lockridge Grindal Nauen, PLLP, 100 Washington Avenue South, Suite 2200, Minneapolis, MN 55401; Adam J. Levitt, Esq. and Dicello Levitt & Casey LLC, Ten North Dearborn Street, Suite 11th Floor, Chicago, IL 60602; Jason T. Dennett, Esq. and Tousley Brain Stephens PLLC, 1700 Seventh Avenue, Suite 2200, Seattle, WA 98101, counsel for plaintiff.

Barry Fields, Esq. and Kirkland & Ellis, LLP, 300 N. LaSalle, Chicago, IL 60654; Thomas F. Nelson, Esq. and Stinson Leonard Street, LLP, 50 South 6th Street, Suite 2600, Minneapolis, MN 55402, counsel for defendants.

This matter is before the court upon the motion to dismiss by defendants St. Jude Medical, LLC and Abbott Laboratories. Based on a review of the file, record, and proceedings herein, and for the following reasons, the court grants the motion.

BACKGROUND

This putative class action arises out of the Food and Drug Administration's (FDA) October 2016 recall of certain models[1] of St. Jude's cardiac defibrillators due to a battery defect which can cause the device's lithium batteries to deplete suddenly and prematurely.[2] Compl. ¶ 25. The devices are designed to "provide pacing therapy to support slow heart rhythms, and electrical shock or pacing therapy to treat fast heart rhythms." Id. ¶ 23. If the defect occurs, the affected defibrillator could malfunction and cause serious health complications, including death. Id. ¶ 27. St. Jude received FDA approval to market the devices in 2004. See id. ¶ 52.

St. Jude is a medical device manufacturer based in Minnesota. Id. ¶ 2. Abbott Laboratories, an Illinois company, acquired St. Jude on January 4, 2017. Id. St. Jude is now a wholly owned subsidiary of Abbott. Id. ¶ 7.

Plaintiff ASEA/AFSCME Local 52 Health Benefits Trust provides healthcare benefits to employees of the State of Alaska and their

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[1] The devices at issue are the Implantable Cardiac Defibrillator (ICD) and Cardiac Resynchronization Therapy Defibrillator (CRT-D), which are marketed under different trademarked names. Compl. at 1, ¶ 26. St. Jude has sold hundreds of thousands of the devices worldwide. Id. ¶ 26.

[2] The defect is caused by deposits of lithium that "form within the battery and create abnormal electrical connections that cause the battery to short circuit, leading to rapid battery failure." Id. ¶ 25.

eligible family members under a collective bargaining agreement. Id. ¶ 1. Plaintiff is what is referred to as a "third-party payor" (TPP) of medical expenses. Id. ¶ 22. Specifically relevant here, plaintiff, on behalf of its beneficiaries, paid for the cost of implanting the recalled devices and may be required to pay costs incurred in removing and replacing the devices. Id. ¶¶ 1, 33.

According to the complaint, St. Jude became aware of the battery defect as early as 2011, but failed to report or further investigate the problem. Id. ¶¶ 28, 83-89. Plaintiff alleges that in 2014, St. Jude knew that at least one patient had died following premature battery depletion in an ICD. Id. ¶¶ 28, 88. Plaintiff further alleges that St. Jude actively concealed information about the defect from its management boards, the FDA, and the public. Id. ¶¶ 29-31, 89-91. The defect came to light in the spring of 2016 during Abbott's due diligence review as part of the planned merger with St. Jude, which prompted St. Jude to finally investigate the cause of the battery defect. Id. ¶ 32, 97-100. In August 2016, St. Jude decided to recall the defective devices and worked with the FDA to do so. Id. ¶¶ 101-02. On October 10, 2016, the FDA issued a Class I recall of 251,346 St. Jude devices sold in the United States and manufactured before May 2015.[3] Id. ¶ 103.

[3] A Class I recall "is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." Id. ¶ 105 (quoting 21 C.F.R. § 7.3(m)).

St. Jude has offered to reimburse patients for expenses not covered by insurance relating to device removal and replacement. Id. ¶ 113.

In September 2017, plaintiff commenced proposed nationwide and Alaska class actions in the Northern District of Illinois against St. Jude and Abbott alleging breach of express warranty, breach of implied warranty, negligence, failure to warn, product liability - manufacturing defect, strict liability - manufacturing defect, violation of the Minnesota Prevention of Consumer Fraud Act, misrepresentation by omission, unjust enrichment, and violation of the Alaska Consumer Protection Act. The court dismissed the case, concluding that it lacked jurisdiction over St. Jude and that venue was improper because the central events in the case occurred outside of Illinois. ASEA/AFSCME Local 52 Health Benefits Trust v. Abbott Labs., No. 17-6704, 2018 WL 3022670 (N.D. Ill. June 18, 2018).

On July 24, 2018, plaintiff re-filed the case here asserting the same claims raised in the Illinois action except for the strict liability claim. Plaintiff alleges that by not timely disclosing the battery defect, St. Jude caused it and other proposed class members to needlessly pay hundreds of millions of dollars for the defective devices and their replacement costs. Compl. ¶¶ 35-37.

Plaintiff seeks certification of nationwide and Alaska classes,[4] declaratory relief, actual and statutory damages, costs of medical monitoring, pre- and post-judgment interest, and attorneys' fees and costs. Defendants now move to dismiss on various grounds.

DISCUSSION

I. Standing

Defendants first argue that this action should be dismissed because plaintiff, as a TPP, lacks standing to recover for its plan participants' injuries. Article III of the United States Constitution limits the jurisdiction of federal courts to justiciable cases and controversies. U.S. Const. art. III, § 2; Lujan v. Defenders of Wildlife, 504 U.S. 555, 559–60 (1992). Standing is an "essential and unchanging part of the case-or-controversy requirement of Article III." Lujan, 504 U.S. at 560. To satisfy Article III standing requirements, a plaintiff must demonstrate:

> (1) it has suffered an injury in fact that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

[4] Proposed class members include TPPs that paid for the defective devices and/or are responsible for the costs of removing and replacing the defective devices. Compl. ¶¶ 34, 146, 147.

Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 180-81 (2000). Whether the plaintiff has established the three elements of standing is an "inescapable threshold question." Advantage Media, L.L.C. v. City of Eden Prairie, 456 F.3d 793, 799 (8th Cir. 2006). If a plaintiff lacks standing, "the district court has no subject-matter jurisdiction" and must dismiss the case. Faibisch v. Univ. of Minn., 304 F.3d 797, 801 (8th Cir. 2002); Fed. R. Civ. P. 12(h)(3).

A. Causal Connection

Defendants argue that plaintiff lacks standing because plaintiff's alleged injury is not fairly traceable to defendants' conduct. Defendants assert that the causal chain is too attenuated because there is a multi-step "winding" sequence of intervening events. Specifically, defendants argue that plaintiff's causal chain hinges on the following hypothetical events: (1) St. Jude disclosed the defect right away, (2) physicians and the public would have learned about the defect, (3) the FDA would have investigated the defect and issued a recall, (4) physicians would have stopped implanting devices in the proposed class members' plan participants, and (5) plaintiff would not have incurred costs associated with the defective devices.

But the connection between the wrongdoing and the injury is in fact straightforward: St. Jude put a defective product on the market that plaintiff paid for and must pay to replace. Even

acknowledging that certain interim steps occurred before plaintiff paid for the defective devices, the fact is that plaintiff did pay for them and will pay for costs associated with replacing them. In other words, plaintiff has been directly harmed by St. Jude's alleged misconduct.

This conclusion is in accord with Kinetic Co. v. Medtronic, Inc., 672 F. Supp. 2d 933 (D. Minn. 2009), which involved nearly identical allegations regarding battery defects in Medtronic's implantable cardiac defibrillators. In Kinetic, the court rejected the same standing arguments defendants make here. As to causation, the court concluded that the "causative chain is not complicated":

> Medtronic's failure to advise the FDA or the physicians who prescribed the device led doctors to continue to select, and insurers to continue to pay for, potentially defective devices without knowing of the potentially-catastrophic risk. Had Medtronic timely disclosed the risks it knew its product presented, insurers might have refused to pay for the original device or the costs to implant it.

Id. at 943.[5] The same is true here. As a result, the allegations are sufficient to establish causation for purposes of standing.

B. Injury

"To establish injury in fact, a plaintiff must show that he or she suffered an invasion of a legally protected interest that is concrete and particularized and actual or imminent, not conjectural

[5] The court acknowledges the conflicting decision in In re Guidant Corp. Implantable Defibrillators Products Liability Litigation, 484 F. Supp. 2d 973 (D. Minn. 2007), but declines to follow that decision for the reasons set forth in Kinetic. See Kinetic, 672 F. Supp. 2d at 940-41.

or hypothetical." Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1548 (2016)(quoting Lujan, 504 U.S. at 560). An injury is "particularized" when it "affect[s] the plaintiff in a personal and individual way." Id. An injury is "concrete" when it "actually exist[s]." Id. (internal quotation marks omitted).

Defendants argue that plaintiff has not suffered an injury to a legally protected interest because they did not deal directly with plaintiff. The court disagrees. As discussed above, the fact that there were interim steps between defendants' conduct and plaintiff's injury does not sever the connection between the two occurrences. Plaintiff alleges that it has been financially harmed due to defendants' concealment of the battery defect, and that harm reflects the economic reality of our health insurance system. In Kinetic, the court emphatically rejected the same argument:

> But when Medtronic blithely asserts that the third-party payors — which ultimately reimbursed the physicians or hospitals which held the device in inventory — are barred from any recovery, it is wrong. It is wrong, because this cost is simply the last falling domino in a long line started by Medtronic. And when it falls, it injures the third-party payors. Medtronic cannot be protected against its own harm by marketing its products through intermediaries. Each intermediate player has been made whole. It ill-befits Medtronic — and the law will not allow it — to attempt to shield itself from its ultimate and true financial victim.

672 F. Supp. 2d at 941. This court also rejects that argument, and concludes that plaintiff has alleged injury sufficient to confer standing.

II. Ripeness

Defendants next argue that plaintiff's claims should be dismissed as premature because there has been no determination that their conduct harmed any patients or, by extension, plaintiff.

A court lacks subject matter jurisdiction over an action if the action is not ripe for resolution. Dakota, Minn. & E. R.R. Corp. v. S.D., 362 F.3d 512, 520 (8th Cir. 2004). The ripeness doctrine derives from Article III's "cases" and "controversies" requirement and "prudential considerations for refusing to exercise jurisdiction." Paraquad, Inc. v. St. Louis Hous. Auth., 259 F.3d 956, 958 (8th Cir. 2001) (quotation omitted). The doctrine "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements." Abbott Labs. v. Gardner, 387 U.S. 136, 148 (1967). In assessing ripeness, a court evaluates "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." Id. at 149; Neb. Pub. Power Dist. v. MidAm. Energy Co., 234 F.3d 1032, 1038 (8th Cir. 2000) (citing Abbott Labs., 387 U.S. at 149). "The touchstone of a ripeness inquiry is whether the harm asserted has 'matured enough to warrant judicial intervention.'" Vogel v. Foth & Van Dyke Assocs., 266 F.3d 838, 840 (8th Cir. 2001) (quoting Paraquad, 259 F.3d at 958).

Here, plaintiff alleges that it paid for defective devices and

will pay for removal and replacement of those devices. The claim is unquestionably ripe. See Kinetic, 672 F. Supp. 2d at 944 (finding nearly identical claim to be ripe because "[a]ll events giving rise to Kinetic's causes of action have occurred .... Kinetic ... paid cash, out of pocket, to buy a particular device with flaws known to, but concealed by, Medtronic, and then paid again to replace the device when Medtronic finally publicly acknowledged the problem").

III. Preemption

Defendants argue that all of plaintiff's claims are preempted under the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (MDA), because plaintiff is challenging the safety and effectiveness of pre-market approved (PMA) devices. The Eighth Circuit Court of Appeals has explained the preemption of state-law claims relating to Class III medical devices:

> The MDA contains an express preemption provision: no State "may establish or continue in effect with respect to a device ... 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." 21 U.S.C. § 360k(a). In [Riegel v. Medtronic, Inc., 552 U.S. 312, 128 S. Ct. 999, 169 L. Ed.3d 892 (2008)], the Court held that, for § 360k(a) preemption purposes, (i) FDA pre-market approval is "federal safety review" that results in federal "requirements" specific to the approved device, and (ii) common law product liability claims result in "state requirements" that are preempted to the extent they relate to the safety and effectiveness of the device and are "different from, or in addition to," the federal requirements established by PMA approval. 552 U.S. at 322–24, 128 S. Ct. 999.

> However, the Court noted, § 360k "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Id. at 330, 128 S. Ct. 999.
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> The MDA also provides that all actions to enforce FDA requirements "shall be by and in the name of the United States," 21 U.S.C. § 337(a). In Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4, 121 S. Ct. 1012, 148 L. Ed.2d 854 (2001), the Court construed § 337(a) as barring suits by private litigants "for noncompliance with the medical device provisions." Read together—
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> > Riegel and Buckman create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The 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).

In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1204 (quoting Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

Plaintiff's state-law claims are all based on the premise that St. Jude - and later Abbott - knew the devices did not conform to the PMA and federal requirements, concealed that fact from the FDA and the public, and sold the defective devices anyway. According to plaintiff, the complaint fits through the "narrow gap" identified in Riley and upheld in Sprint Fidelis. The court disagrees.

The Eighth Circuit and this court have rejected the same

arguments in strikingly similar cases. In Sprint Fidelis, the plaintiffs alleged that Medtronic manufactured and sold defective cardiac leads.[6] 623 F.3d at 1203. The court held that the plaintiffs' state-law claims - including failure to warn, negligence, defective design and manufacturing, breach of express warranty, and fraud - were expressly preempted under § 360k(a). Id.

With respect to the failure-to-warn claim, the court held that because the plaintiffs sought to impose disclosure requirements beyond FDA-approved warnings, the claim was not parallel and therefore preempted. Id. at 1205. As to negligence - based in part on the allegation that Medtronic continued to sell the defective lead after it received approval to sell a modified lead - the court held that the claim was preempted because the FDA allowed Medtronic to sell the unmodified lead and, thus, any obligation to discontinue those sales would impose a state requirement that "would be 'different from or in addition to' the federal requirement." Id. Further, to the extent the negligence claim was based on Medtronic's failure to timely file adverse events reports with the FDA, the court determined that the claim was impliedly preempted under § 337(a) as a private party's attempt to enforce the MDA. Id. at 1205-06. The court held that the plaintiffs'

[6] A cardiac lead is "a wire that delivers signals that allow an implantable cardiac defibrillator to detect an abnormal heart rhythm and deliver a shock to help the heart return to the appropriate rhythm." Id.

manufacturing defect claim - based on the allegation that Medtronic failed to comply with FDA Current Good Manufacturing Practices (CGMPs) - was preempted because the plaintiffs "failed to identify any specific federal requirement in the PMA approval for the Sprint Fidelis Leads that forms the basis for an unpreempted parallel claim." Id. at 1206. Finally, with respect to the breach of express warranty claims, which were premised on representations that the leads "were safe, effective, fit and proper for their intended use," the court concluded that to prevail, the plaintiffs were required to "persuade a jury that Sprint Fidelis Leads were not safe and effective, a finding that would be contrary to the FDA's approval of the PMA Supplement." Id. at 1207-08.

Likewise, in Kinetic Co., Inc. v. Medtronic, Inc., No. 08-6062, 2011 WL 1485601 (D. Minn. Apr. 19, 2011), the court dismissed Kinetic's state-law claims (relevant here, violation of Minnesota's consumer fraud act, unjust enrichment, breach of express warranty, breach of implied warranty, and misrepresentation by omission) as preempted. Kinetic alleged, as plaintiff does here, that Medtronic manufactured and sold ICDs with defective batteries. Id. at *1. Relying heavily on Sprint Fidelis, the court concluded that all but one of the claims,[7] which were based on "allegations that Medtronic

[7] The court allowed Kinetic's claim that Medtronic breached its contractual warranty to pay certain costs associated with removing and replacing devices to proceed because "it has nothing to do with the safety and effectiveness of the devices." Id. at *5. Plaintiff does not raise a similar claim here.

failed to disclose the defects in the devices and that Medtronic affirmatively misrepresented the safety and effectiveness of the devices," were preempted. Id. at *3. In holding that the claims were expressly preempted under § 360k, the court reasoned that:

> Kinetic seeks to hold Medtronic liable for failing to include additional warnings — specifically, a warning about the devices' battery problems and resulting high risk of failure. But Kinetic admits that there is no federal requirement that Medtronic disclose this information to doctors or patients. Because there is no such requirement under the FDCA, Kinetic is seeking to use state law to impose requirements on Medtronic that are "different from, or in addition to," the requirements imposed by the FDCA .... Kinetic cannot do this under § 360k.

Id. The court further held that Kinetic's claim that Medtronic violated federal regulations by failing to timely disclose the battery problems to the FDA was impliedly preempted as "'an attempt by private parties to enforce the MDA.'" Id. (quoting Sprint Fidelis, 623 F.3d at 1205-06). As in Sprint Fidelis, the court also concluded that Kinetic's claim that Medtronic falsely represented and warranted the safety of the devices was preempted because to prevail Kinetic would have to establish that the devices were unsafe, which would contradict FDA approval of the device. Id. at *4.

And in Pinsonneault v. St. Jude Medical, Inc., 953 F. Supp. 1006 (D. Minn. 2013), which involved allegedly defective cardiac leads, the court denied the plaintiff's motion to amend the complaint to include proposed claims for negligence, failure to warn, and breach of express warranty as futile. The court

specifically held that the proposed claims would be expressly and impliedly preempted for the reasons set forth in Sprint Fidelis and Kinetic. Id. at 1015-19.

The court is unpersuaded that this case is factually or legally distinct from the above cases so as to require a different result. Indeed, the allegations here are nearly identical to those raised in the above cases, particularly Kinetic. Thus, under Sprint Fidelis, Kinetic, and Pinsonneault, the court is constrained to conclude that plaintiff's claims are preempted. As a result, the court must dismiss the case.

Because the claims are preempted, the court will not address whether the complaint is adequately pleaded. Nor will the court consider the jurisdictional arguments raised by Abbott.

CONCLUSION

Accordingly, based on the above, **IT IS HEREBY ORDERED** that:

1. The motion to dismiss [ECF No. 32] is granted; and

2. The case is dismissed with prejudice.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: January 24, 2019

s/David S. Doty
David S. Doty, Judge
United States District Court