UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

KIRK VINCENT,

Plaintiff,

v.

MEDTRONIC, INC. and MEDTRONIC USA, INC.,

Defendants.

No. 16 CV 02990

Judge Manish S. Shah

MEMORANDUM OPINION AND ORDER

Plaintiff Kirk Vincent underwent a procedure to implant in his chest a pacemaker and a pacemaker lead, which was designed, manufactured, and sold by defendants Medtronic, Inc. and Medtronic USA, Inc. Ten years later, the pacemaker lead had broken down, and Vincent had it removed. He claims the lead was defective and had not been approved by the United States Food and Drug Administration. Vincent filed this lawsuit seeking relief based on the Illinois Consumer Fraud and Deceptive Business Practices Act and theories of strict liability, negligence, and breach of express warranty. Defendants move to dismiss Vincent's claims. For the following reasons, the motion is granted.

I. Legal Standards

To survive a motion to dismiss under Rule 12(b)(6), a complaint must contain factual allegations that plausibly suggest a right to relief. *Virnich v. Vorwald*, 664 F.3d 206, 212 (7th Cir. 2011) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 558 (2009)). "The purpose of a motion to dismiss is to test the sufficiency of the

complaint, not to decide the merits." *Triad Assocs., Inc. v. Chicago Hous. Auth.*, 892 F.2d 583, 586 (7th Cir. 1989). On a 12(b)(6) motion, a court may only consider allegations in the complaint, documents attached to the complaint, documents that are both referred to in the complaint and central to its claims, and information that is subject to proper judicial notice. *Geinosky v. City of Chicago*, 675 F.3d 743, 745 n.1 (7th Cir. 2012). Executive and agency determinations are subject to judicial notice and may be considered even if not mentioned in the complaint. *Houston v. United States*, 638 F.App'x 508, 514 (7th Cir. 2016) (citing *Fornalik v. Perryman*, 223 F.3d 523, 529 (7th Cir. 2000)). A court must construe all factual allegations as true and draw all reasonable inferences in the plaintiff's favor, but a court need not accept legal conclusions or conclusory allegations. *Virnich*, 664 F.3d at 212 (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 680–82 (2009)).

II. Background

On February 12, 2004, plaintiff Kirk Vincent, diagnosed with intermittent complete heart block, underwent surgery to install a pacemaker. [18] ¶ 9.[1] The pacemaker was connected to his heart with a screw-in pacemaker lead, a device designed, manufactured, marketed, and sold by defendants Medtronic, Inc. and Medtronic USA, Inc.[2] [18] ¶¶ 9, 11. Medtronic represented in its marketing and labeling that the lead, identified by model number 5076, had been approved by the FDA as a "Class III" device through its premarket approval procedure. [18] ¶¶ 13,

[1] Bracketed numbers refer to entries on the district court docket. The operative complaint is [18].

[2] Any distinction between the Medtronic entities is immaterial to the present motion, so they will be referred to collectively as "Medtronic."

14. But Medtronic did not tell Vincent or his treating physicians that it had submitted the lead for supplemental approval just two days before the surgery, and did not receive that approval until March 10. [18] ¶¶ 12, 14. The procedure was a success, and Vincent experienced no complications. [18] ¶ 17.

Ten years later, however, Vincent discovered that the lead had fractured and needed to be removed. [18] ¶ 18. He underwent two more surgeries to remove the lead fragments and repair some of the damage they caused, but Vincent now has permanent heart damage. [18] ¶¶ 19, 26–27. Vincent alleges that the lead's fragmentation resulted from defects in its design and manufacture. [18] ¶¶ 21–23. Vincent also alleges that, before the surgery, Medtronic knew the lead carried a risk of malfunctioning and fracturing, but failed to provide sufficient warnings of that risk. [18] ¶ 15.

Vincent originally filed a complaint alleging a claim for "Product Liability," *see* [1], and Medtronic filed a motion to dismiss arguing that Vincent's claims were inadequately plead and preempted by federal law. *See* [13]. In response to that motion, Vincent amended the complaint to include allegations that the lead had not received FDA approval at the time of the initial procedure, and that Medtronic failed to tell Vincent or his doctors of that fact. *See* [18]. The amended complaint also alleges a claim for "Strict liability" rather than the original "Product Liability," and adds claims for "Negligence," "Breach of Express Warranty," and "Illinois [Consumer] Fraud and Deceptive Business Practices." *See* [18].[3] In response to

[3] Jurisdiction arises under 28 U.S.C. § 1332, because there is complete diversity between the parties—Vincent is a citizen of Indiana, and the two Medtronic entities are citizens of

Medtronic's arguments that Vincent failed to plausibly allege the breach of express warranty and consumer fraud claims, Vincent agrees to the dismissal of those claims without prejudice. *See* [31] at 3 n.5. Those claims are therefore dismissed without further discussion.

III. Analysis

Medtronic argues that Vincent's state-law claims are preempted by the Medical Device Amendments Act of 1976, 21 U.S.C. § 360c *et seq.*, which amended the Food, Drug and Cosmetic Act and established FDA oversight for medical devices. "Class III" devices are those "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," or "presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii). Class III devices must undergo a "rigorous" premarket approval process, in which a manufacturer typically submits a multivolume application that the FDA spends an average of 1,200 hours reviewing. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–18 (2008). Once a device has received premarket approval, the Act forbids the manufacturer to make any changes to the device that would affect safety or effectiveness without FDA permission; such changes are subject to a supplemental premarket approval application. *Riegel*, 552 U.S. at 319; 21 U.S.C. § 360e(d)(6). That supplemental application is "evaluated under largely the same criteria as an initial application."

Minnesota—and the amount in controversy exceeds $75,000. [18] ¶¶ 1–3, 6. The events giving rise to this suit occurred in this district, and no objection has been raised as to venue. [18] ¶ 4.

Riegel, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6); 21 CFR § 814.39(c)). "[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." *Riegel*, 552 U.S. at 323.

The Act also contains a preemption provision. No 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). Under this provision, common-law claims for negligence and strict liability against medical device manufacturers are expressly preempted if: (1) there are federal requirements applicable to the device in question (which may take the form of the specifications approved by the FDA during the premarket approval process), and (2) the common-law claims are based on state requirements that are different from, or in addition to, those requirements and relate to safety and effectiveness. *Riegel*, 552 U.S. at 321–22. But § 360k does not bar state-law claims that are based on violations of federal regulations, since the state-imposed duties in those claims "parallel" the federal requirements. *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010); *see also Riegel*, 552 U.S. at 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

In addition to the express preemption provision, state-law claims are also subject to implied preemption under the Act. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001). "Fraud-on-the-agency" claims rooted in violations of federal administrative and reporting requirements, but not traditional state tort law, are impliedly preempted. *Id.* at 353. To escape both express and implied preemption, state-law claims must fit within a "narrow gap." *Bausch*, 630 F.3d at 557–58 (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). "The plaintiff must be suing for conduct that violates the [Food, Drug, and Cosmetic Act] (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the [Food, Drug, and Cosmetic Act] (such a claim would be impliedly preempted under *Buckman*)." *Id.* (emphasis and alterations in original). In other words, a state-law claim survives preemption if it alleges a violation of the Act in the context of a pre-existing, "well-recognized duty owed to [the plaintiff] under state law." *Bausch*, 630 F.3d at 558.

Medtronic argues that Vincent's claims are expressly preempted because the lead received approval from the FDA under its premarket approval process, and Vincent does not explicitly allege that the lead failed to meet its FDA-approved specifications. Medtronic requests that judicial notice be taken of the facts that the FDA granted premarket approval to an earlier version of the lead and multiple supplemental premarket approvals as Medtronic modified the lead throughout the years, including the August 31, 2000 supplemental premarket approval of the model

5076 lead.[4] Vincent does not object and, as publicly-available government agency determinations that appear on an agency website, these approvals by the FDA are subject to judicial notice. *See Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011). According to Medtronic, if the lead satisfied the requirements established by the FDA in its premarket approval of the device (in either its original or modified form), then Vincent could prevail on his claims only if a jury found that state law imposed requirements that are different from, or in addition to, those federal requirements. Such claims are expressly preempted.

Vincent responds that preemption does not apply to the lead at issue because the FDA did not issue its approval of the device until after his surgery. He argues that preemption does not apply because Medtronic waived its preemption defense by failing to comply with 21 C.F.R. § 814.39, which provides the procedure of obtaining supplemental premarket approval of a device when making changes that affect the safety or effectiveness of that device. Vincent cites to a number of cases for the proposition that parties are not entitled to statutory rights unless they comply with the applicable statutory prerequisites, but this principle is not about waiver of federal preemption. Medtronic's compliance with regulations may bear on whether the claim is preempted, but that conduct does not waive the congressional determination to preempt state law.

[4] The FDA's March 1996 premarket approval of an earlier model of the lead can be found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P930039, and the August 31, 2000 supplemental premarket approval of the model 5076 lead can be found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P930039S009.

Waiver aside, the parties dispute whether Medtronic's failure to obtain FDA approval for the lead before the surgery means that all state-law claims related to that lead necessarily escape preemption. At least one court has found that strict liability and negligence claims were not preempted when the medical device at issue was not approved by the FDA at the time the device was used. *See Mears v. Marshall*, 944 P.2d 984 (Or.Ct.App. 1997). In *Mears*, the court reasoned that, before premarket approval or supplemental premarket approval, no federal requirements applied to the device, so state-law claims were not preempted. *Id*. at 992. Medtronic notes that *Mears* predates *Buckman*, and argues that a claim about a device used during an interim period between premarket and supplemental premarket approval is better thought of as a claim based on a failure to adhere to 21 C.F.R. § 814.39. Such a claim is about distributing a modified device without complying with the procedure for obtaining FDA-approval for that modification, and would amount to enforcement of an FDA requirement without implicating a common-law duty. That kind of action may be brought by the FDA alone. *See* 21 U.S.C. § 337(a); *Buckman*, 531 U.S. at 349 n.4.

Medtronic is correct that the lead was subject to FDA regulations, which satisfies the first part of the *Riegel* test. Even though the surgery took place before Medtronic obtained supplemental premarket approval for the specific iteration of the lead at issue, Vincent's contention that no federal requirements applied to the lead is incorrect. The original premarket approval process, along with any supplemental premarket approvals obtained prior to the surgery, established

federal requirements in the form of FDA-approved specifications and procedures. *Riegel*, 552 U.S. at 322–23. Obtaining supplemental premarket approval for a change in the lead's specifications might change those requirements, but failing to obtain that approval would not cause previously established requirements to simply evaporate. *See McMullen v. Medtronic*, 421 F.3d 482, 487–88 (7th Cir. 2005) (holding that federal requirements applied to a Class III medical device even though defendant failed to comply with post-premarket approval requirements imposed by the FDA). *Mears* is not persuasive. At the time of the surgery, federal requirements applied to the lead, even though supplemental premarket approval was pending at the time, and the preemptive effect of those requirements must be considered.

Vincent's strict liability and negligence claims are both expressly and impliedly preempted. Vincent alleges that the lead was unreasonably dangerous due to its defective design and defective manufacture, and that Medtronic failed to provide adequate warnings of the lead's defective condition, risk of failure, and FDA-approval status. But Vincent does not allege that Medtronic violated any federal regulations in designing, manufacturing, or labeling the lead, or that such a violation caused him injury. The only violation of federal regulations that Vincent alleges is the failure to comply with procedures governing supplemental premarket approval of a device. *See* 21 C.F.R. § 814.39. And Vincent does not allege that Medtronic's premature distribution of the lead breached any recognized state-law duties or injured him in any way. As a result, Vincent's claims do not fit into the narrow gap between express and implied preemption. Because Vincent's state-law

claims are not based on violations of federal law, but instead assert violations of state tort law "notwithstanding compliance with the relevant federal requirements," *Riegel*, 552 U.S. at 330, they are expressly preempted by 21 U.S.C. § 360k. To the extent that Vincent brings claims based solely on Medtronic's noncompliance with the FDA's supplemental premarket approval procedures, those claims are impliedly preempted.

Medtronic emphasizes the fact that the lead received supplemental premarket approval shortly after the surgery, suggesting that, because the modification was eventually approved, state-law claims based upon that modification are preempted. But that is not necessarily true. If the modification made to the lead required FDA approval for the lead to conform to the FDA's standards of safety and effectiveness, then until that approval is given, that modification is not incorporated into the applicable federal requirements. A jury could be presented with a negligence claim based on that modification (and no other, approved aspect of the device) and impose liability. If Vincent alleged that he were harmed by a deviation from the FDA-approved specifications in place at the time of the surgery, even if that deviation were the modification itself, he would be alleging harm based on a violation of applicable federal law, and his claim would escape preemption. But the complaint cannot be read to make such an allegation, so Vincent's claims are preempted.

While "[p]reemption is an affirmative defense, and pleadings need not anticipate or attempt to circumvent affirmative defenses," *Bausch*, 630 F.3d at 561

(citations omitted), Vincent does not object to Medtronic's raising of the issue on its Rule 12(b)(6) motion and instead requests an opportunity to amend his complaint. Medtronic requests dismissal of the complaint with prejudice, because Vincent already had one opportunity to amend his complaint in response to Medtronic's first motion to dismiss. Medtronic's request is denied. Vincent's complaint is dismissed without prejudice, and he has leave to amend his complaint to articulate a claim that is not preempted.

IV. Conclusion

Medtronic's motion to dismiss, [26], is granted. Vincent's complaint is dismissed without prejudice.

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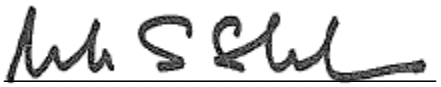

Manish S. Shah
United States District Judge

Date: 12/20/16