IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

CAROLYN GREEN GATES, INDIVIDUALLY, and as personal representative of THE ESTATE OF WILLIAM HOWARD GATES,	§	
Plaintiff,	§	
v.	§	1:15-CV-726-RP
MEDTRONIC, INC.,	§	
Defendant.	§	

ORDER

Before the Court are Defendant Medtronic, Inc.'s Motion to Dismiss, (Dkt. 7), and the responsive pleadings thereto. After reviewing the pleadings, the relevant law, and the factual record, the Court issues the following order.

I. Background

Plaintiff Carolyn Green Gates ("Carolyn Gates") brings this action against Defendant Medtronic, Inc. ("Medtronic") following the death of her husband William Howard Gates ("Mr. Gates"). According to Carolyn Gates, her husband died as a result of Medtronic's negligent acts or omissions following the recall of Medtronic's Sprint Fidelis 6949 lead. (Compl., Dkt. 1, ¶¶ 34–35). Defendant Medtronic moves for dismissal, and argues that Plaintiff's claims are preempted by the Medical Device Amendments to the Federal Food, Drug, and Cosmetics Act. (Mot. to Dismiss, Dkt. 7). Medtronic argues in the alternative that Plaintiff's complaint is deficient under the requirements of Federal Rule of Civil Procedure 8. (Mem. in Supp., Dkt. 8, at 26).

In April of 2006, Mr. Gates had an implantable cardioverter defibrillator ("ICD") surgically implanted into his chest. (Compl., Dkt. 1, ¶ 6). This device monitors the rhythm of the heartbeat. (*Id.* ¶ 8). If the ICD detects an irregular rhythm, it delivers an electric shock to the heart through a wire that is threaded into the heart's right atrium. (*Id.*). The points at which the ICD delivers the shock to the heart are called the leads, and consist of exposed conductive material. (*Id.*). Plaintiff states that "if the lead fractures, the implanted devices fail and the heart is thrown into turmoil." (*Id.*).

Medtronic manufactures a variety of medical devices, including ICDs. Medtronic designed, manufactured, and sold both the ICD and the ICD's Sprint Fidelis 6949 leads that were implanted into Mr. Gates's chest. (*Id.* ¶ 6).

In October of 2007, Medtronic voluntarily recalled all Sprint Fidelis 6949 leads after the leads were discovered to be vulnerable to fracture.[1] (*Id.* ¶ 11, 12). The FDA classified this recall as a Class I Device Recall.[2] (Resp., Dkt. 11, at 5). *See* 21 U.S.C. § 360h(e)(2) (granting FDA authority over device recall orders and timetables); *see also* 21 C.F.R. § 7.41(b) (describing FDA methodology in assessing device recall classification). The recall provided that Sprint Fidelis leads not yet implanted into patients were to be removed from the market. (Compl., Dkt. 1, ¶ 12).

In April of 2011, Medtronic communicated to patients and healthcare providers that removal of the implanted but recalled leads was inadvisable due to the risks associated with surgery. (*Id.* ¶ 14). Four months later, Mr. Gates's Medtronic ICD was replaced with an ICD from a different manufacturer. (*Id.* ¶ 25). Plaintiff alleges that the Sprint Fidelis leads were not removed during this

[1] Voluntary recalls, such as the one Medtronic initiated in this case (called "firm-initiated recalls"), also receive FDA oversight. *See generally* 21 C.F.R. § 7.46.

[2] The FDA classifies device recalls according to a number of factors, including resultant diseases or injuries, potential health hazards, potential risk of harm to specific population segments, the degree of seriousness of the health hazard, the likelihood of the health hazard, and an assessment of the short- and long-term consequences of the occurrence of the hazard. 21 C.F.R. § 7.41(b). This applies to firm-initiated recalls. 21 C.F.R. § 7.46(b).

procedure in reliance on Medtronic's representations regarding the risks associated with removal of the recalled leads. (*Id.* ¶ 6). In September of 2013, Mr. Gates allegedly experienced the type of shocks and discomfort associated with lead fracture. (*Id.*) He was hospitalized and underwent surgery to replace his ICD and to cap the Sprint Fidelis leads. (*Id.*). In October of 2013, a Sprint Fidelis lead attached to Mr. Gates's ICD was discovered to have fractured. Mr. Gates's health deteriorated, and he died on November 30, 2013. (*Id.*).

II. Standard of Review

The Federal Rules of Civil Procedure require a plaintiff to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). However, the initial pleading must contain more than "a formulaic recitation of the elements of a cause of action," or "naked assertion[s]" devoid of "factual enhancement." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–57 (2007). Rather, the complaint must contain sufficient factual allegations, when taken as true in a light favorable to the plaintiff, to "state a claim that is plausible on its face." *Id.* at 470. A claim is plausible when the allegations allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Ashcroft v. Iqbal*, 556 U.S. 662, 663–64 (2009). Under this principle, a court asks whether the "well-pleaded factual allegations" may "plausibly give rise to an entitlement to relief." *Id.* at 64. A pleading that does not meet these requirements cannot survive a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). *Id.*

"Federal preemption is an affirmative defense that a defendant must plead and prove." *Simmons v. Sabine River Auth. Louisiana*, 732 F.3d 469, 473 (5th Cir. 2013) (quoting *Fisher v. Halliburton*, 667 F.3d 602, 609 (5th Cir. 2012)). Dismissal is proper when a sole cause of action is preempted by federal law. *See Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 678 (5th Cir. 2014); *Simmons*, 732 F.3d at 474.

III. Discussion

A. Federal Regulation of Medical Devices

The Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA") expanded the coverage and authority of the Food and Drug Act of 1906, signaling a broad federal stride into the field of public health. 21 U.S.C. §§ 301–363. As complex consumer medical devices grew in popularity, Congress enacted the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c–360m, with the intent to "provide for the safety and effectiveness of medical devices intended for human use." *Medtronic, Inc. v. Lohr*, 518 U.S. 460, 474 (1996). The MDA classify medical devices into three categories: Class I, Class II, and Class III. 21 U.S.C. § 360c(a)(1). Class III devices earn the most FDA oversight due to the role these devices play in "supporting or sustaining human life" and "preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). As such, Class III devices are subject to a premarket approval ("PMA") process before the manufacturer may market and sell the devices. *Id.*

The FDA's PMA process is "a rigorous one." *Lohr*, 518 U.S. at 477. Manufacturers are required to submit records detailing the "safety and efficacy of the devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Id.* Once a device receives approval, the manufacturer may not alter the design of the product in any way without filing a PMA supplement. *See* 21 C.F.R. 814.39(a). The FDA evaluates PMA supplements "under largely the same criteria as an initial [PMA] application." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319 (2008). The FDA also regulates these devices after they are granted PMA, *see* 21 U.S.C. § 360i, by requiring manufacturers to provide reports informing the FDA of new studies, investigations, and incidents resulting in death or serious injury. *Riegel,* 552 U.S. at 319. If a device is found to be "unsafe or ineffective under the conditions in its labeling," the FDA may withdraw its PMA. *Id.*; *see also* 21

U.S.C. § 360e(e)(1) (granting FDA authority to conduct hearings regarding PMA withdrawal); *see also id.* at § 360h(e) (granting FDA recall authority).

B. Federal Preemption of Common-Law Claims under the MDA

Under the Supremacy Clause of the Constitution, Congress has the power to preempt state law. *See Maryland v. Louisiana,* 451 U.S. 725, 746 (1981) (holding a state law claim as preempted because "it interferes with federal regulation[.]"); *McCulloch v. Maryland*, 17 U.S. 316, 427 (1819) (holding federal law to be supreme over state law). A federal law preempts a state law if there is express or implied legislative intent to preempt state law, or actual conflict between state and federal law. *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). A court's consideration of preemption under the supremacy clause begins with the assumption that Congress did not intend to displace state law.[3] *Maryland v. Louisiana*, 451 U.S. at 746.

The new regulatory regime under the MDA "swept back some state obligations," *Riegel*, 552 U.S. at 316, by including an express preemption provision, which provides:

> Except as provided in subsection (b) of this section, 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 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.

[3] *But see Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218, 230 (1947) ("Such a purpose [to displace state law] may be evidenced in several ways. The scheme of federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it. Or the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject. Likewise, the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose. Or the state policy may produce a result inconsistent with the objective of the federal statute.") (internal citations omitted).

21 U.S.C. § 360k(a). The broad strokes with which Congress drafted this provision generated some division among courts,[4] until the Supreme Court approved the majority approach in *Riegel* and set forth a two-prong test for determining whether a state- or common-law cause of action could be subject to MDA preemption. *See Riegel*, 552 U.S. at 321–25. Under the *Riegel* test, a court first asks whether the Federal Government has established requirements applicable to the device. *Id.* at 323. If so, the court then looks to whether the state law cause of action imposes "requirements with respect to the device that are 'different from, or in addition to'" the federal requirements, and "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." *Id.* (quoting 21 U.S.C. § 360k(a)).

Courts have generally found that common-law causes of action involving medical devices are preempted by the MDA. The Supreme Court held in *Lohr* that common-law negligence causes of action impose "requirements" and are thus pre-empted by federal requirements under the MDA. *Lohr,* 518 U.S. at 512. The Court again clarified this issue in *Riegel*, and found that the MDA's express preemption provision barred state law tort causes of action. *Riegel*, 552 U.S. at 344. The Court assigned to all federal cases involving the Sprint Fidelis lead held that all twenty-one claims in that multidistrict litigation were preempted by the MDA. (Mem. in Supp., Dkt. 8, at 2) (citing *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1149–1155 (D. Minn. 2009), *aff'd sub nom. In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.,* 623 F.3d 1200 (8th Cir. 2010)).

C. Defendant's Preemption Defense

Medtronic contends that Gates's claims are preempted by federal law. (Mem. in Supp., Dkt. 8, at 16). Gates responds that the FDA does not govern Medtronic's behavior post-recall, and that even if her claims "touch on federal regulation," they "neither add to nor conflict with any

[4] Compare *Goodlin v. Medtronic, Inc.,* 167 F.3d 1367, 1382 with *Kemp v. Medtronic, Inc.,* 231 F.3d 216, 237 (6th Cir. 2000) for early differences in approach to the MDA's express preemption of common-law tort causes of action after *Lohr*, but before *Riegel*. *See also In re Medtronic, Inc.,* 592 F. Supp. 2d 1147, 1151 (D. Minn. 2009) (early comparison and discussion of post-*Riegel* cases in a multi-district litigation specific to the Sprint Fidelis leads).

applicable federal law." (Compl., Dkt. 1, ¶ 30). Rather, she believes her claims operate in "parallel" to federal law. (*Id.*). Medtronic disagrees. It asserts that the FDA does in fact govern the regulation of post-recall conduct and that Carolyn Gates's state-law claims add to existing FDA regulation of such conduct, and thus are preempted. (Mem. in Supp., Dkt. 8, at 23).

1. *Riegel*: Prong One

Applying the two-prong test created in *Riegel,* the Court looks first to whether the Federal Government has established requirements applicable to the relevant medical device. The MDA classify the Sprint Fidelis 6949 lead as a Class III device—subject to PMA. (Mem. in Supp., Dkt. 8, at 9). The Supreme Court has made clear that the PMA process and subsequent PMA status create "requirements" for the purposes of the first prong of the test. *Riegel*, 552 U.S. at 322.

Plaintiff first argues that the Sprint Fidelis leads did not undergo "a full PMA," (Compl., Dkt. 1, ¶ 8), contending that federal requirements did not exist because the PMA process did not occur. (*Id.* ¶ 8). However, the leads did go through the process of obtaining a PMA supplement, which is virtually identical to the ordinary PMA process and, by extension, status. *See Riegel*, 552 U.S. at 319 ("All procedures and actions that apply to [a PMA] application also apply to PMA supplements."). Accordingly, to the extent that the PMA process constitutes the imposition of federal requirements under the first prong of *Riegel*, so too does the process for obtaining a PMA supplement.

Next, Plaintiff argues that, even if the lead was subject to the FDA's PMA process, that process does not regulate communications related to recalled-but-implanted devices. (Compl., Dkt. 1, ¶ 6). Accordingly, Plaintiff contends that Medtronic's post-recall conduct was not subject to FDA regulation—thus avoiding preemption under the first prong of the *Riegel* test. (*Id.* ¶ 6, 14, 18). In fact, the FDA does regulate post-recall communications.

The FDA may formally designate a firm-initiated recall "only if the [FDA] regards the product as involving a violation that is subject to legal action, e.g., seizure." 21 C.F.R. § 7.46(a). When this occurs, the manufacturer must provide the FDA with the reasons for the device recall, the level of risk associated with the defect, the degree to which the defect has pervaded the marketplace, and most notably here, a copy of the firm's recall communication and proposed strategy for conducting the recall. *Id.* When a medical device is found to be harmful[5] and the potential for that harm may be alleviated through notification, FDCA language grants to the FDA the power to regulate communications from "all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification." 21 U.S.C. § 360h(a)(2). This includes firm-initiated recalls. 21 C.F.R. § 7.46(c). The FDA did not merely regulate post-recall communication—they actively took part in it by publishing it on their website.[6] The law is clear in that the FDA regulates in this area; a manufacturer's recall and post-recall communications do fall under the authority of the FDA.

The Court adheres to the view that devices approved by a PMA supplement are subject to federal requirements, and that post-recall communications, including those related to implanted devices, are federally regulated. Accordingly, the Court concludes that the first prong of the *Riegel* test reveals that the Federal Government has established requirements applicable to Medtronic's Sprint Fidelis leads in this case.

[5] For example, during or after a device recall.

[6] Following Medtronic's recall of the Sprint Fidelis leads, the FDA published notice of the recall on their website, stating that the "FDA [and] Medtronic . . . [do not] recommend the routine surgical removal of a fractured lead because removal carries risks," and noting that the "FDA agrees with Medtronic's recommendation" that ICD settings can be adjusted to lessen the risk of harm. (Mem. in Supp., Dkt. 8-7, at 3). The FDA also published on its website information advising patients to consult Medtronic's recommendations, noting that "it is generally recommended to leave functioning leads in place," and that patients should consult their doctor as well. (Mem. in Supp., Dkt. 8-6, at 3).

2. *Riegel*: Prong Two

The second prong of the *Riegel* test asks whether the state-law cause of action imposes requirements which add to or differ from the federal requirements, and relate to the safety and effectiveness of the device. *Riegel*, 552 U.S. at 323 (citing 21 U.S.C. § 360k(a)). Plaintiff asserts common-law negligence and gross negligence causes of action. (Compl., Dkt. 1, ¶ 32, 35). The *Riegel* Court adhered to the finding in *Lohr* that "common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." *Riegel*, 552 U.S. at 323 (quoting *Lohr*, 518 U.S. at 512). The Court in *Riegel* asserted that, in at least a medical device context, the tort duties associated with negligence and strict liability would also be duties related to device safety and efficacy, and that "excluding common-law duties from the scope of pre-emption would make little sense. State tort law that requires a [medical device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." *Riegel*, 552 U.S. at 325.

Because common-law causes of action impose the types of requirements that may be preempted, the remaining question under the second prong of *Riegel* is whether the specific claims asserted by Plaintiff add to or differ from federal requirements. Plaintiff does not allege that Medtronic violated federal law. Medtronic, then, correctly points out that Plaintiff's claims "necessarily rest on the proposition that state law required Medtronic to have done something other than that which it was required to do by federal law." (Mem. in Supp., Dkt. 8, at 24). Nonetheless, Plaintiff suggests she is able to utilize an exception to federal preemption for state requirements that parallel federal requirements. (Compl., Dkt. 1, ¶ 30).

Both *Riegel* and *Lohr* describe this narrow exception to federal preemption.[7] According to those decisions, when a claim is "parallel," that is, when a claim rests on a violation of a state law identical to the applicable federal law, the claim is not preempted. The MDA's express preemption provision, however, 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. Plaintiff's claims do not on their face mirror any federal requirements. In fact, Plaintiff repeatedly argues that her claims are not regulated by the FDA—but if they "touch on federal regulation," she argues they are "parallel to federal regulation." (*Id.* ¶ 7, 18, 30). However, Plaintiff provides no support for the contention that her claims parallel a federal requirement.

Plaintiff's allegations of negligence and gross negligence focus on an alleged breach of duties owed "resulting from [Medtronic's] post-recall misconduct." (Compl., Dkt. 1, ¶ 32). Plaintiff argues that Medtronic failed to exercise reasonable care in procedures and communications associated with the period of time after the recall of the Sprint Fidelis leads. (*Id.* ¶ 33). Her pleadings are general statements of duty and allegations of a breach of that duty, which amount to common-law tort claims for negligence and gross negligence. (*Id.* ¶¶ 30, 32–33). Plaintiff does not point to any specific federal regulation that mirrors duties imposed by her common-law causes of action. As stated, common-law tort claims for negligence do not parallel any requirements set forth by the FDA, and are held to be "requirements" within the meaning of the *Riegel* test. *Riegel*, 552 U.S. at 323; *Lohr*, 518 U.S. at 512. In the absence of a federal requirement that closely parallels the requirements imposed

[7] This parallel claims exception has yet to be fully clarified. 'In *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341[ ] (2001), the Court construed 21 U.S.C. § 337(a) as barring suits by private litigants 'for noncompliance with the [MDA].' Read together—

> *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 [ ], but the plaintiff must not be suing because the conduct violates the FDCA [ ].

In re Medtronic, Inc., Sprint Fidelis Leads., 623 F.3d at 1204 (8th Cir. 2010) (quoting *Riley v. Cordis Corp.*, 625 F.Supp.2d 769, 777 (D.Minn.2009)) (internal quotes and citations omitted).

by Plaintiff's claims, those claims remain preempted by the MDA's express preemption provision. *See Riegel* 522 U.S. at 330; *Lohr*, 518 U.S. at 495.

The Court concludes that the common-law tort duties imposed by Plaintiff's negligence and gross negligence causes of action add to or differ from those federal requirements imposed by the FDA. Having applied both prongs of *Riegel* test to the facts at hand, the Court finds that Plaintiff's claims are expressly preempted by federal law.

D. Adequacy of Plaintiff's Pleadings

Finally, Medtronic argues that Plaintiff's pleadings are deficient under the Federal Rules of Civil Procedure. (Mem. in Supp., Dkt. 8, at 26). The Court need not address this argument, as Plaintiff's claims are preempted by the MDA's express preemption provision.

IV. Conclusion

Defendant's Motion to Dismiss (Dkt. 7) is hereby **GRANTED**. The Court hereby **DISMISSES WITH PREJUDICE** Plaintiff's claims of negligence and gross negligence. Defendant's Motion to Stay Deadlines and Discovery (Dkt. 15) is hereby **DISMISSED AS MOOT**.

SIGNED on June 29, 2016.

ROBERT PITMAN
UNITED STATES DISTRICT JUDGE