UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
SOUTHERN DIVISION
PIKEVILLE

TERESA COOLEY, as Executrix for Estate of GEORGE COOLEY, et al.,	)	
Plaintiffs,	)	Civil No. 09-30-ART
v.	)	
MEDTRONIC, INC., et al.,	)	**MEMORANDUM OPINION & ORDER**
Defendants.	)	

*** *** *** ***

T. S. Eliot wrote that the world would end "not with a bang, but a whimper." T. S. Eliot, *The Hollow Men*, in Poems 1909-1925, at 123, 128 (Goldberg Press 2007) (1925). The plaintiffs' claims have been in litigation for years, traveling through several courts and mingling with hundreds of other claims in a mass tort case. After all that time, they are now before this Court on a motion to dismiss—and the plaintiffs did not even respond. Despite the hullabaloo, the case now ends with a whimper. The Court must grant the motion to dismiss because the plaintiff's claims are preempted by federal law.

BACKGROUND

In July 2005, George Cooley underwent an operation to place an implantable cardiac defibrillator ("ICD") in his heart. R. 1-2 at 5. Three years later, Mr. Cooley went into cardiac arrest and died. *Id.* In February 2009, Mr. Cooley's widow, Teresa Cooley, filed suit in Kentucky state court against the ICD's manufacturer, Medtronic, Inc.—as well as its affiliates Medtronic International Technology, Inc. and Medtronic Puerto Rico Operations

Co.—and an unnamed employee of Medtronic, Inc., John Doe. *Id.* at 3. Cooley alleged fourteen causes of action against the defendants.[1]

Soon after Cooley filed her lawsuit, the defendants, (collectively, "Medtronic") removed the case to federal court. R. 1. The United States Judicial Panel on Multidistrict Litigation then transferred the case to the United States District Court for the District of Minnesota ("MDL court") to consolidate Cooley's claims with hundreds of other cases alleging defects in Medtronic's ICDs. R. 12-1 at 1–2.

Once before the MDL court, all plaintiffs' claims were presented for dispositive motion practice in a Master Consolidated Complaint. *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009). The MDL court concluded that federal law preempted all claims. *Id.* at 1156. After rejecting motions for reconsideration and for leave to amend the Master Consolidated Complaint, the MDL court entered judgment in 225 cases so that the Plaintiffs' Steering Committee could appeal these dismissals. *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 2009 WL 294353, at *4 (D. Minn. Feb. 5, 2009). The Eighth Circuit affirmed. *Bryant v. Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2010).

During the course of the appeal, most of the parties entered into settlement agreements. These agreements resolved all but six cases, including Cooley's. R. 12-1 at 4. Rather than enter judgment on these few remaining cases, the MDL court believed that "continued centralization" would not "serve the convenience of the parties" or promote

[1] Cooley's causes of action are: negligence, failure to warn, manufacturing defect, breach of implied warranty, breach of express warranty, negligent misrepresentation, intentional misrepresentation, fraud, constructive fraud, negligent infliction of emotional distress, intentional infliction of emotional distress, unjust enrichment, violation of state consumer protection statutes, and loss of consortium. R. 1-2.

efficient litigation. *Id.* at 2–3. Accordingly, the MDL court remanded the remaining cases to their respective transferor courts. *Id.* at 3.

Once remanded to this Court, Medtronic filed a motion to dismiss Cooley's complaint. In accord with the MDL court's holding, Medtronic asserts that the preemption clause of the Medical Device Amendments ("MDA"), 21 U.S.C. § 360k(a), preempts all of Cooley's claims. R. 22.

DISCUSSION

Cooley begins at a disadvantage for two reasons. First, she has not responded to the motion to dismiss. Under the Court's local rules, failure to respond to a motion "may be grounds for granting the motion." LR 7.1(c); *see also Scott v. Tennessee*, 878 F.2d 382, at *2 (6th Cir. 1989) (unpublished table case) ("[I]f a plaintiff fails to respond or to otherwise oppose a defendant's motion, then the district court may deem the plaintiff to have waived opposition to the motion."). Second, and maybe telling of why Cooley did not respond, the MDL court has already held that the MDA preempts Cooley's claims. Still, out of an abundance of caution, the Court will rule on the merits of Medtronic's motion to dismiss.

Under Federal Rule of Civil Procedure 12(b)(6), the Court reviews whether Cooley's complaint alleges "sufficient factual matter" to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). To meet this standard, Cooley must plead "factual content that allows the court to draw the reasonable inference that [Medtronic] is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). At this stage, the Court construes factual allegations "in the light most favorable to the plaintiff" and draws "all reasonable inferences

in favor of the plaintiff." *Watson Carpet & Floor Covering, Inc. v. Mohawk Indus., Inc.*, 648 F.3d 452, 456 (6th Cir. 2011) (quoting *In re Travel Agent Comm'n Antitrust Litig*., 583 F.3d 896, 903 (6th Cir. 2009)).

I. The MDA Preempts Most State Law Causes of Action

Congress passed the MDA in 1976 to amend the Federal Food, Drug, and Cosmetic Act ("FDCA"). *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). The FDCA had "long required" that the Food and Drug Administration ("FDA") approve new pharmaceutical drugs before they could enter the market. *Id.* But prior to the MDA, new medical devices were "left largely for the States to supervise as they saw fit." *Id.* After a number of notable medical device failures, Congress passed the MDA to "impose[] a regime of detailed federal oversight" over complex medical devices. *Id.*

The MDA expressly preempts states from imposing requirements "different from, or in addition to" federal requirements. 21 U.S.C. § 360k(a)(1)-(2). In *Riegel*, the Supreme Court determined that once a medical device receives premarket approval from the FDA, the MDA's preemption clause bars common law claims challenging the safety and effectiveness of that medical device. 552 U.S. at 321–24. The Court used a two-step analysis that tracks the language of § 360k(a). First, the Court determined that the FDA's premarket approval process imposes federal "requirements" as understood by the MDA. *Id.* at 322. Second, the Court determined that permitting the plaintiffs' state claims to proceed would impose state requirements "different from, or in addition to" premarket approval requirements. *Id.* at 324.

But the MDA does not prevent state claims "premised on a violation of FDA regulations" because such state duties would be "parallel" to federal requirements rather than

additional to them. *Id.* at 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)). In other words, the MDA does not preempt claims that allege a manufacturer failed to adhere to the specifications imposed by the FDA's premarket approval.

II. The MDA Preempts All of Cooley's Claims

Based on the Supreme Court's holding in *Riegel*, there are two inquiries for the Court's MDA preemption determination: (1) Are Medtronic's ICDs subject to federal requirements? (2) If so, would Cooley's state law claims impose requirements that are different from or in addition to federal requirements? *See Degelman v. Advanced Med. Optics Inc.*, 659 F.3d 835, 841 (9th Cir. 2011) (applying the two-step analysis); *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300–01 (11th Cir. 2011) (same). In this case, the answer to both inquiries is yes. Cooley's claims are therefore preempted.

A. Federal Requirements

Medtronic's ICDs are clearly subject to federal requirements because they received premarket approval from the FDA.[2] *Riegel*, 552 U.S. at 322–23 ("Premarket approval, in contrast [to general labeling duties], imposes 'requirements' under the MDA . . . ."). Medical devices that receive FDA premarket approval must be manufactured with "almost

[2] Cooley did not allege the make or model of Medtronic's pacemaker in the complaint; she simply alleged that a "Medtronic Cardiac Defibrillator" was implanted into Mr. Cooley's chest. R. 1-2 at 5. For its part, Medtronic asserts that their records reflect the precise model implanted in Mr. Cooley. R. 22-1 at 15. However, considering this information would require the Court to convert Medtronic's 12(b)(6) motion to dismiss into a Rule 56 motion for summary judgment. *See* Fed. R. Civ. P. 12(d) ("If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56."); *Wysocki v. Int'l Bus. Machine Corp.*, 607 F.3d 1102, 1104 (6th Cir. 2010). But the Court does not need to consider the specific model implanted into Mr. Cooley. All of Medtronic's available pacemakers have received premarket approval. This information is a matter of public record, *see* RR. 22-2–22-7, which the Court may consider "without converting a Rule 12(b)(6) motion into a Rule 56 motion," *Jones v. City of Cincinnati*, 521 F.3d 555, 562 (6th Cir. 2008) (citing *Jackson v. City of Columbus*, 194 F.3d 737, 745 (6th Cir. 1999)). Thus, the Court does not need to go outside of the pleadings to determine that Cooley's complaint implicates a device that received FDA premarket approval.

no deviations from the specifications" in the approval application. *Id.* at 323. Because the FDA's approval process "provides a reasonable assurance of safety and effectiveness," *id*., any changes to a device's design specifications, manufacturing process, labeling, or other attribute that would affect safety require FDA approval, 21 U.S.C. § 360e(d)(6)(A)(i). As a result, premarket approval "imposes [federal] 'requirements'" as understood by the MDA. *Riegel*, 552 U.S.. at 322.

B. State Law Claims

As an initial matter, Cooley's state law claims are not parallel claims. Cooley does not allege that Medtronic's ICD devices deviated from FDA requirements. Rather, each of Cooley's claims asserts that Medtronic failed duties owed to Cooley. R. 1-2. These claims are wholly dependent on state common law. In other words, Cooley asserts that Medtronic's ICDs violated state law notwithstanding their compliance with the FDA premarket approval requirements. Thus, the question is whether Cooley's state law claims impose additional requirements. They do.

Failure to warn: Cooley contends that Medtronic negligently failed to "warn and/or instruct the Plaintiffs . . . of known defects in" Medtronic's ICDs. R. 1-2 at 12. The MDA preempts this claim because success on the claim would require Medtronic to have provided different or additional warnings from those approved by the FDA. *See Riegel,* 552 U.S. at 329 (holding that the MDA preempts "a jury determination that the FDA-approved labeling for [an approved medical device] violated a state common-law requirement for additional warnings").

Manufacturing Defect: Cooley alleges that Medtronic is liable on a negligence and strict liability basis because its ICD devices were "manufactur[ed] and assembl[ed]" in a way that made them prone to "fail to operate and/or malfunction." R. 1-2 at 11. Manufacturing defect claims may avoid MDA preemption when the plaintiff alleges that a medical device did not satisfy the FDA's premarket approval standards. *See Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 933 (5th Cir. 2006) ("The district judge properly limited Gomez's negligence claims to a claim that the Angio-Seal used in her surgery was defectively manufactured because it did not comply with the FDA-approved specifications."). But the plaintiff must also allege a non-speculative factual basis to support the claim. *See Twombly*, 550 U.S. at 555 (holding that a complaint's factual allegations "must be enough to raise a right to relief above the speculative level"); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1302 (D. Colo. 2008) ("Although [the plaintiff's manufacturing defect] claim appears to constitute the type of parallel claim the *Riegel* Court found to be outside the preemptive reach of section 360k, nowhere does plaintiff's complaint provide any factual detail to substantiate that crucial allegation."). Here, Cooley did not even allege a specific defect in Medtronic's ICDs, let alone provide any basis to believe Medtronic violated FDA standards. Without this factual support, the manufacturing defect claim simply alleges that Medtronic's manufacturing process or the ICD specifications themselves are deficient. The MDA preempts this cause of action because Cooley would have to prove that the devices should have been manufactured differently from the manner approved by the FDA. *See Kemp v. Medtronic, Inc.*, 231 F.3d 216, 220 (6th Cir. 2000) ("To permit a jury to find Medtronic negligent for failing to manufacture [an approved medical device] with [a component

different than what the FDA approved] would be to impose a requirement different from and in addition to those established by the FDA.").

Breach of Implied Warranty & *Breach of Express Warranty*: Cooley asserts that Medtronic "impliedly warranted" that its ICD devices "were merchantable and fit and safe for ordinary use" and "were fit for the particular purpose for which they were sold." R. 1-2 at 29–30. Additionally, Cooley contends that Medtronic "expressly warranted to Plaintiff" that its ICD devices were "safe, effective, fit and proper for their intended use." *Id.* at 34. The MDA preempts these causes of action because a jury would have to find that the devices were "not safe and effective, a finding that would be contrary to the FDA's approval." *Bryant*, 623 F.3d at 1208; *see also Riegel*, 552 U.S. at 318 ("The FDA . . . grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness." (internal citations omitted)).

Negligent Misrepresentation, *Intentional Misrepresentation*, *Fraud*, *Constructive Fraud*: In each of these counts, Cooley alleges that Medtronic "misrepresent[ed] and/or fail[ed] to adequately warn" Cooley about the risks of Medtronic's ICD devices, R. 1-2 at 51, or "concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of the" ICD devices, *id.* at 45, 58. The MDA preempts these claims because they would each require a finding that Medtronic's statements about the safety and effectiveness of the ICD devices were false or misleading. This contention challenges the FDA's determination that the device's "labeling is neither false nor misleading," *Riegel*, 552 U.S. at 318 (citing 21 U.S.C. § 360e(d)(1)(A)), and would therefore impose labeling requirements different from the FDA's requirements.

Remaining Claims—Negligent Infliction of Emotional Distress, Intentional Infliction of Emotional Distress, Unjust Enrichment, Violation of State Consumer Protection Statutes, and *Loss of Consortium*: All of Cooley's remaining claims are derivative of the above tort claims. Since the MDA preempts all of the tort claims, the MDA preempts all of the derivative claims as well. *See Kemp*, 231 F.3d at 237 ("In light of the foregoing analysis that Elizabeth Kemp's claims are preempted by § 360k of the MDA, Clifford Kemp's derivative spousal claim is similarly preempted.").

Cooley's claims for negligent and intentional infliction of emotional distress are based on Cooley's assertion that Medtronic either "carelessly" or "knowingly and/or recklessly" "manufactured, marketed and sold" its ICD devices. R. 1-2 at 63, 67. In essence, these claims assert that Medtronic caused Cooley emotional distress because of manufacturing defects. But since the MDA preempts the manufacturing defect claim, Cooley's emotional distress claims are also preempted.

Cooley's unjust enrichment claim alleges that Medtronic "voluntarily accepted" profits for a product that Medtronic knew was not of the "quality, nature or fitness" that Medtronic had represented to the Cooleys. *Id.* at 74. This claim relies on assertions of misrepresentation and fraud. But the MDA preempts those assertions because a jury would have to find that the FDA approved labeling was false or misleading.

Cooley's consumer protection statute claim alleges that Medtronic's "deceptive, unconscionable or fraudulent representations and material omissions" constituted "unfair and deceptive acts and practices." *Id.* at 79. This claim also relies on assertions of

misrepresentation and fraud as well as failure to warn. The claim is preempted because it would ultimately require changes to the FDA's approved labeling on the devices.

Cooley's loss of consortium claim is dependent on her assertion that Mr. Cooley's death was the result of Medtronic's negligence. *Id.* at 93. Because the MDA preempts Cooley's negligence claim, it also preempts the loss of consortium claim.

CONCLUSION

The Court must dismiss Cooley's complaint because all of her claims are preempted by federal law. *See Hutchison v. Fifth Third Bancorp.*, 469 F.3d 583, 584, 587 (6th Cir. 2006). Accordingly, it is **ORDERED** that Medtronic's motion to dismiss, R. 22, is **GRANTED**. The claims asserted against all of the defendants are **DISMISSED WITH PREJUDICE**. This case is **STRICKEN** from the Court's active docket and all other pending motions are **DENIED** as moot.

This the 20th day of April, 2012.

Signed By:
Amul R. Thapar AT
United States District Judge