IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

Kathleen Spies and Alan Spies,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	20 L 8663
	)	
Abdul Amine, M.D., individually, and	)	
Abdul Amine, M.D., a service corporation,	)	
Ebby Jido, M.D., Margarita Kos, N.P.,	)	
Midwest Anesthesiologists, Ltd.,	)	
Brandon Gaynor, M.D., Jeffrey Curtin, D.O.,	)	
Joseph Kowalczyk, M.D., Vinson Uytana, M.D.,	)	
Advocate Health & Hospitals Corporation, and	)	
Medtronic, Inc.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

The Medical Device Amendments to the Food, Drug and Cosmetics Act expressly or impliedly preempt nearly all negligence claims based on alleged defects in class III medical devices. This court has given the plaintiffs three opportunities to cure its defective complaint and plead a cognizable cause of action against a device manufacturer. The complaint's latest iteration still fails to establish an actionable claim; therefore, the defendant's motion to dismiss count 26 must be granted, this time with prejudice.

Forward

In a December 28, 2020 memorandum opinion and order, this court presented the relevant facts underlying Kathleen and Alan Spies' causes of action. This court also explained the federal law that serves as the framework severely limiting the types of

claims that may be brought against manufacturers of allegedly defective class III medical devices. The facts and the law need not be repeated here. Rather, this court will adopt its prior ruling and focus on the new factual allegations the Spies present in count 26 of their current complaint directed against Medtronic, Inc.

Facts

The Spies' latest complaint presents new allegations directed at Medtronic's alleged failures in manufacturing its intrathecal pump. In support of these allegations, the Spies attach as exhibits to their complaint four warning letters issued by the Department of Health and Human Services dated August 29, 2006, July 3, 2007, June 1, 2009, and July 12, 2012. These letters detail the findings of HHS Food and Drug Administration inspectors who concluded that various Medtronic products were adulterated. The FDA inspection reports—so-called, form 483s—are included with each warning letter. Several of the form 483s also contain handwritten notes at various places stating, "Promised to correct" and, "Reported corrected, not verified."

The Spies also attach as an exhibit to the complaint an April 27, 2015 consent decree and an undated permanent injunction between the Department of Justice and Medtronic entered in the federal district court of Minnesota. The inunction required Medtronic, among other things, to cease manufacturing and delivering adulterated products, permit the FDA to make subsequent comprehensive inspections of Medtronic facilities, and require Medtronic to provide practitioners with a copy of the consent decree, disclosure letter, and acknowledgement forms. The Spies now allege that Medtronic failed to provide Kathleen's physicians with the required forms related to the intrathecal pump in violation of the consent decree and injunction.

Analysis

The Spies' new allegations compound previous factual and legal defects in their cause of action against Medtronic. As a

factual matter, it is entirely conjecture that Kathleen's treaters implanted in her an adulterated intrathecal pump. Indeed, the April 2015 consent decree explicitly prohibited Medtronic from thereafter manufacturing or delivering adulterated products. Although the Spies have pleaded the intrathecal pump malfunctioned, they have failed to allege either that the pump Kathleen received four months later, in August 2015, was adulterated or how it malfunctioned.

These fundamental factual shortcomings are echoed in various legal shortcomings. First, the Spies' amended complaint and exhibits ineffectively attempt to bridge a causation gap. The Spies infer that the FDA's prior findings that Medtronic had manufactured and delivered adulterated products necessarily mean that Kathleen's physicians implanted in her an adulterated or malfunctioning pump. Those are two independent sets of facts with nothing to link them. If the pump was adulterated as alleged, the Spies have failed to identify the adulteration or how it caused the pump to fail.

Second, the Spies' allegations that Medtronic failed to deliver the required warnings to Kathleen's treaters present another causation gap. Even if it is assumed Medtronic breached the requirements of the consent decree and injunction by failing to provide the required notices, the Spies fail to allege that the lack of notice caused Kathleen's intrathecal pump to fail. Going further back in time, the Spies have also failed to allege the failure to provide the required notices caused Medtronic to create an adulterated product in the first place. Once again, the Spies allege independent sets of facts, but no causation.

Third, the Spies' amended complaint faces a temporal hurdle. The amended complaint fails to identify specific federal requirements in the intrathecal pump's pre-market approval process that are the basis for a non-preempted parallel state law claim. *See In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1206 (8th Cir. 2010). Medtronic's alleged failures to provide warnings to medical practitioners after the

intrathecal pump had been manufactured and delivered certainly cannot serve as the basis for a claim based on a violation of the pre-market approval process. Further, if Medtronic violated the subsequent consent decree or injunction, that alleged transgression is a matter for the Justice Department, not this court.

Fourth, the Spies have still failed to identify an Illinois statute imposing requirements equivalent to the federal pre-market approval requirements that authorizes their cause of action against Medtronic. It bears repeating that, absent a well-founded violation of a federal requirement applicable to the allegedly injurious product, the Spies cannot present a parallel state law claim. *See Bausch v. Stryker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010) (parallel state law claims require violation of federal regulations as well as causation); *Bass v. Stryker Corp.* 669 F.3d 501, 510 (5th Cir. 2012). Further, the Spies' latest complaint shows they are still attempting to enforce exclusively federal duties. As this court previously noted, state law tort claims are expressly and impliedly preempted if they seek to enforce privately a duty owed under federal law. *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017). The Spies have still failed to identify the Illinois statute that imposes a requirement equivalent to the federal one. Lastly, the Spies' reliance on *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), is not well taken as that case did not address the pre-market approval process that is at issue in this case. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322-23 (2008).

In sum, the Spies' newest, and last, complaint still fails to plead a recognized cause of action against Medtronic.

Conclusion

For the reasons presented above and in its December 28, 2020 memorandum opinion and order, it is ordered that:

1. Medtronic's motion to dismiss count 26 is granted;
2. Medtronic is dismissed from this case with prejudice; and
3. Pursuant to Illinois Supreme Court Rule 304(a), there is no just reason to delay the enforcement or appeal, or both, of this court's order.

John H. Ehrlich, Circuit Court Judge

Judge John H. Ehrlich

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Circuit Court 2075