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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA - WESTERN DIVISION

SAMUEL DENNIS LOWE,

Plaintiff,

vs.

MEDTRONIC, INC. a Minnesota corp., MEDTRONIC MED-REL, INC., MEDTRONIC PUERTO RICO OPERATIONS CO., a corp. existing by virtue of the laws of the Cayman Islands, and "John Doe" 1-5 (said names being fictitious, as the true names are presently unknown), in their individual and official capacities,

Defendants.

CASE NO. CV-11-9551-R (DTBx)

ORDER GRANTING DEFENDANTS MEDTRONIC, INC.'S AND MEDTRONIC PUERTO RICO OPERATIONS CO.'S MOTION TO DISMISS FIRST AMENDED COMPLAINT PURSUANT TO FED. R. CIV. P. 12(b)(6)

Date: May 7, 2012
Time: 10:00 a.m.
Courtroom: 8
Judge: Hon. Manuel L. Real
Date Filed: November 16, 2011
Trial Date: None

On May 7, 2012, Defendants Medtronic, Inc.'s and Medtronic Puerto Rico Operations Co.'s (collectively, "Medtronic") Motion to Dismiss Plaintiff Samuel Dennis Lowe's First Amended Complaint ("FAC") for failure to state a claim upon which relief can be granted, came on for hearing before this Court. Ginger Pigott of Greenberg Traurig, LLP, appeared on behalf of Medtronic and Maurice L. Hudson and Cristopher G. Sabol appeared on behalf of Plaintiff.

After full consideration of all papers, pleadings and matters subject to judicial notice, as well as counsel's oral argument, and good cause appearing therefore,

IT IS ORDERED THAT:

1. Plaintiff's first (failure to warn), second (manufacturing defect), third (negligence), fourth (negligent infliction of emotional distress), fifth (breach of implied warranty) and sixth (breach of express warranty) causes of action in the FAC against Medtronic are expressly preempted by the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act (21 U.S.C. § 360k(a)) as well as impliedly preempted. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Stengel v. Medtronic, Inc.*, 10-17755, 2012 WL 1255040 (9th Cir. 2012). There is no dispute the device at issue in this case, specifically Medtronic's Secura DR Implantable Cardioverter Defibrillator ("ICD"), has Premarket Approval. Each of the causes of action in Plaintiff's FAC seeks to challenge the FDA's Premarket Approval of the Secura DR ICD pursuant to which the FDA approved the design, manufacture and labeling of the Secura DR ICD. The FDA's Premarket Approval process constitutes specific federal requirements that preempt state law tort claims like Plaintiff's, which seek to impose requirements different from, or in addition to, those imposed by the FDA's Premarket Approval process. *Riegel*, 552 U.S. at 323-24. Furthermore, any claims relating to failure to report to FDA are impliedly preempted and barred by statute under 21 U.S.C. Section 337(a). *Buckman*, 531 U.S. at 349 n. 4. There is no private right of action to enforce the FDCA. Therefore, as a matter of law, none of

the causes of action in Plaintiff's FAC against Medtronic can state a claim upon which relief can be granted because they are preempted.

2. Plaintiff has not sufficiently pleaded a purported parallel claim that might survive the impact of express and implied preemption. *Riegel*, 552 U.S. at 321; *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454 (2004); *McMullen v. Medtronic, Inc.*, 421 F. 3d 482, 489 (7th Cir. 2005). Plaintiff must assert a recognized state law claim that would impose duties identical to particular federal requirements imposed through the Premarket Approval process. *Stengel*, 2010 WL 4483970, at *2. "State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law." *McMullen v. Medtronic, Inc.*, 421 F.3d at 489. To properly plead a parallel claim that survive preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or requirements related to the device, and (2) establishing a causal nexus between the alleged injury and the violation. *Cohen v. Guidant Corp.*, 2011 WL 637472, at *1 (C.D. Cal. Feb. 15, 2011). Plaintiff here has not established a parallel claim and has not plead the particular specification allegedly violated and how it links to his claims. *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litigl.*, 592 F.Supp.2d 1147 (D.Minn. 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010). Plaintiff's allegations relating to a warning letter and a subsequent recall are not sufficient to establish a parallel claim. *See Summit Tech., Inc. v. High-Line Med. Instruments, Co.*, 933 F. Supp. 918, 934 n.9 (C.D. Cal. 1996) (FDA warning letters do not constitute final agency action); *and see Blanco v. Baxter Healthcare Corp.*, 158 Cal. App. 4th 1039, 1056, 70 Cal. Rptr. 3d 566 (2008) (a recall does not establish violation of FDA regulations and is insufficient to overcome preemption). Thus, the Court finds Plaintiff's allegations as set forth in the FAC are not sufficient to establish a plausible entitlement to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1940, 173 L. Ed. 2d 868 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007).

3. Medtronic's Motion to Dismiss pursuant to Fed. R. Civ. Proc. 12(b)(6) for failure to state a claim is hereby **GRANTED**. Plaintiff shall have 10 days leave to file a Second Amended Complaint, which shall be filed at the Civil Filing Window in the Clerk's Office.

IT IS SO ORDERED.

Dated: May 9, 2012

Honorable Manuel L. Real
United States District Court Judge