DISTRICT COURT, EL PASO COUNTY, COLORADO 270 S. Tejon Street Colorado Springs, Colorado 80903-2209 Mailing address: P.O. Box 2980 Colorado Springs, CO 80901--2980	DATE FILED: September 24, 2017 5:27 PM CASE NUMBER: 2017CV30568
PLAINTIFFS: GORDON R. GOLDEN, M.D., and VANESSA A. GOLDEN, v. **DEFENDANTS: MICHAEL W. BROWN, M.D.; CATHOLIC HEALTH INITIATIVES COLORADO d/b/a PENROSE HOSPITAL; MEDTRONIC, PLC.; MEDTRONIC, INC.; and MEDTRONIC NEUROMODULATION**	▲ COURT USE ONLY ▲
	District Ct. Case # 17CV30568 Division 21 Courtroom W450 Judge McHenry

RULING ON DEFENDANT MEDTRONIC'S MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT

This matter comes before the court on Medtronic's Motion to Dismiss Plaintiffs' Second Amended Complaint. The court has reviewed the motion, response and reply and all associated exhibits. The court issues the following ruling.

1. This court previously entered a ruling on Defendant Medtronic's Motion to Dismiss Plaintiff's First Amended Complaint. That ruling entered on June 27, 2017. The court ruled that Plaintiff had failed to plead plausible claims for relief under theories of product liability and breach of warranty. The court ruled that Plaintiff's negligence per se claims fail because there was no showing of legislative intent to create a private cause of action in the field of medical device tort claims. The court addressed the issue of federal preemption under *Riegel* and acknowledged that Plaintiff may be able to plead plausible parallel state tort and breach of warranty claims if she could identify the specific model of device at issue and if *Warne's* plausibility standard could be met. The court granted Plaintiff leave to file a second amended complaint. The Medtronic defendants now move to dismiss the second amended complaint by arguing Plaintiff has failed to meet the plausibility standard of *Warne* and that Plaintiff has failed to meet the parallel state claims exception to federal preemption under *Riegel*. The court hereby incorporates by reference the authority and analysis of the court's June 27th ruling for the sake of context.

2. Although Plaintiff has now specified the model of the device implanted into her and shown a connection between that device and various recalls and a consent decree associated with the device, the court concludes that Plaintiff has still failed to meet the plausibility standard of *Warne* because she has not identified a specific defect and has not shown a causal connection between such defect and her injuries.

3. Plaintiff is correct when she underscores that the plausibility standard does not require Plaintiff to make out a *prima facie* case in her complaint. Plaintiff is also correct when she points out that the inspection reports underlying the FDA warning letters and the recalls are not available to the public. Therefore the court understands that Plaintiff is at a severe disadvantage - a disadvantage which the discovery process *might* remedy - because Plaintiff cannot cite more specific violations in her complaint. However, in spite of such disadvantage, it appears to the court that the majority of jurisdictions to address this issue have concluded that the mere existence of federal regulatory action and an alleged device failure is not sufficient to establish a plausible claim, particularly in the absence of facts plausibly suggesting how the purported violations caused a defect or the alleged injuries.

4. The only fact pleaded in support of a defect or causation is that Mrs. Golden's pump was subject to an October 2016 recall related to a "software problem" that "may" cause unintended delivery of medication. Plaintiff admits she does not know the "nature of the defect." Even when recalls concern the device at issue, when a plaintiff fails to link an alleged defect, in any more than a conclusory manner, the claim fails. *Simmons v. Boston Sci. Corp*., 2013 WL1207421, at *4 (C.D. Cal. Mar. 25, 2013); *accord Weaver v. Ethicon, Inc*., 2016 WL 7098781, at *5 (S.D. Cal. Dec. 6, 2016) (dismissing complaint where plaintiffs failed to allege plausible connection between recall and alleged defect).

5. Even if Plaintiff had alleged sufficient facts to plausibly allege a defect that caused her alleged injuries, such would not save her claims from dismissal due to federal preemption. The second amended complaint fails to plausibly allege that any such defect was caused by a federal violation. This court acknowledges that from a lay perspective the history of recalls and the consent decree causes one to become suspicious about whether there exists a nexus between the FDA's concerns and Plaintiff's experience; however such suspicion is insufficient to meet the plausibility standard or to avoid preemption. Multiple courts have held that a recall does not create a presumption that a federal requirement was violated. *Weaver*, 2016 WL 7098781, at *5; *Ellis v. Smith & Nephew, Inc*., 2016 WL 7319397, at *3 n.2 (D.S.C. Feb. 16, 2016); *Leroy v. Medtronic, Inc*., 2015 WL 4600880, at *8 (N.D. Fla. July 29, 2015); *Simmons*, 2013 WL 1207421, at *4; *Gross*, 858 F.Supp. 2d at 474, n. 13.

6. It is important to note that all of the regulatory actions cited by Plaintiff concern alleged violations of manufacturing guidelines (CGMPs). As most courts have recognized, the CGMP violations mentioned in the Form 483s and warning letters "cannot serve as the basis for a parallel claim" that avoid express preemption CGMPs are "intentionally vague and open-ended," and are "open to a particular manufacturer's interpretation." *Ilarraza v. Medtronic, Inc*., 677 F.Supp. 2d 582, 588 (E.D.N.Y. 2009); *see also Pearsall v. Medtronic, Inc*., 2015 WL 8160888, at *7 (E.D.N.Y. 2015) ("The CGMPs are guidelines that do not create a federal requirement, and a claim based on alleged failure to comply with the guidelines fails to plea a violation of a federal requirement."); *Burkett v. Smith & Nephew GmbH*, 2014 WL 1315315, at *5 (E.D.N.Y.

2014) ("Because [plaintiff's] manufacturing defect claim is based on violation of generally applicable CGMPs, as opposed to federal requirements specific to the [device at issue], preemption bars the claim."); *Hernandez v. Stryker Corp*., 2014 WL 7044171, at *5-7 (W.D. Wash. 2014) (CGMPs cannot support a parallel claim); *Horn v. Boston Scientific*, 2011 WL 3893812, at *9 (S.D. Ga. 2011) ("Because [CGMPs] fail to provide any tangible or concrete standard, this court agrees that to allow a violation of such a flexible standard to result in liability would, in itself, be imposing a standard "different from, or in addition to" those imposed by the [Medical Device Amendments].") quoting 21 U.S.C. § 360k(a)(1)).

7. In addition, even if the alleged CGMP violations could theoretically support a parallel claim, Plaintiff's allegations would still fall short of stating a parallel claim because they fail to allege facts plausibly suggesting the alleged CGMP violations proximately caused Plaintiffs injuries.

8. Regarding Plaintiff's Failure to Warn claim, Defendant asks the court to reconsider the viability of the case law cited by the court, specifically *Stengel* and *Hughes*. The court has reconsidered and agrees that these cases cannot be reconciled with 21 U.S.C. § 360k(a) as interpreted in *Riegel* or 21 U.S.C. § 337(a) as interpreted in *Buckman*. There is no state law duty identical to the federal requirement that a device manufacturer report adverse events to the FDA, as required to state a parallel claim. *Otis-Wisher v. Medtronic, Inc*. 616 F. App 433, 434 (2d Cir. 2015); *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996) Thus, allegations that Defendant failed to report adverse events to the FDA do not state a parallel claim. Further, Plaintiff has pleaded no facts here supporting such claim.

9. Regarding Plaintiff's Implied Warranty of Merchantability claim, the court also finds it to be expressly preempted. To the extent Plaintiff argues the devices were not safe and effective as designed, manufactured and marketed pursuant to their premarket approval, such a claim is expressly preempted as such a finding would directly contradict the FDA's determination in granting premarket approval that "there is a reasonable assurance of a device's safety and effectiveness." *Reigel*, 552 U.S. at 317. Further, Plaintiff's failure to identify a specific federal violation and causally link it to Plaintiff's injuries results in failing to state a parallel claim.

10. Further, this court concludes that Plaintiff's specific claims are impliedly preempted. Although Plaintiff argues the claims are premised on Colorado common law principles, this is true merely in title, not substance. To survive implied preemption, Plaintiff's claims must allege *conduct* that gives rise to liability under state law even if the FDCA had never been enacted. However, here Plaintiff's claims arise merely *because* the conduct violates the FDCA. Having failed to explain how Defendant's conduct violated state law duties absent the FDCA, Plaintiff's claims are impliedly preempted.

11. Finally, Plaintiff's Consumer Protection Act claim fails as a matter of law because the statute does not apply to medical device claims. Colorado recognizes the unique nature of claims involving pharmaceuticals and medical devices that can only be obtained with a physician's prescription. See *O'Connell v. Biomet*, Inc. 250 P.3d 1278, 1281-82 (Colo. App. 2010) (applying learned intermediary doctrine in the context of failure to warn claim involving a medical device "available only to physicians and obtained by prescription"). A number of courts have held that such prescription-only products are not subject to consumer fraud acts precisely

because they are not freely available and are already the subject of significant regulation designed to protect the consumer. See, e.g. *White v. Wyeth*, 705 S.E. 2d 828 (W. Va. 2010). The same rationale applies here.

WHEREFORE, Medtronic's Motion to Dismiss Plaintiff's Second Amended Complaint is hereby GRANTED.

Done this 24th day of September, 2017.

Michael P. McHenry
District Court Judge