IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Richard Stengel, et al., Plaintiffs, vs. Medtronic, Inc. Defendant.	No. CV 10-318-TUC-RCC **ORDER**

Pending before this court is (1) Defendant's Motion to Dismiss (Doc. 4); (2) Plaintiff's Motion for rule 56(f) Relief (Doc. 8); and (3) Plaintiff's Motions to Amend Complaint (Docs. 10, 21, 22). For the reasons set forth below, the court will grant Defendant's motion and deny Plaintiff's motions.

Medtronic's Motion to Dismiss

Medtronic has filed a motion to dismiss pursuant to FED.R.CIV.P. 12(b)(6), claiming federal preemption bars Plaintiff's claims. Specifically, Medtronic asserts that the Supreme Court in *Riegel v. Medtronic, Inc*, 451 F.3d 104, 109 (2d Cir. 2006), *aff'd* 552 U.S. 312 (2008), held that Congress precluded plaintiffs from bringing state-law claims challenging the design, manufacturing process, or labeling of a medical device that has been approved by the FDA via the Premarket Approval process because such claims would involve a jury second guessing the FDA's determination that the

device could be marketed as approved. Medtronic argues that Plaintiff's claims should be precluded on the same grounds.

1. FDA Premarket Approval Process

The SychroMed EL Pump and Intrathecal Catheter at issue in this case are newer generation models in a family of pain pump systems that are Class III medical devices regulated by the Food and Drug Administration (FDA) pursuant to the 1976 Medical Device Amendments (MDA), 21 U.S.C. § 360c. Class III devices are devices that are "for a use in supporting or sustaining human life," that are "for a use which is of substantial importance in preventing impairment of human health," or that "present[] a potential unreasonable risk of illness or injury . . ." 21 U.S.C. § 360c(a)(1)(C).

Class III devices receive more extensive federal oversight than other classes of medical devices and are subject to a comprehensive and rigorous process known as "premarket approval" (PMA). *See Riegel*, 128 S.Ct. at 1004-05. The PMA process "requires the applicant to demonstrate a 'reasonable assurance' that the device is both 'safe . . . [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.'" *Buckman v. Plaintiff's Legal Committee*, 531 U.S. 341, 344 (2001) (quoting 21 U.S.C. § 360e(d)(2)(A)-(B)). During the PMA process, manufacturers must provide the FDA with full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information. *Riegel*, 415 F.3d at 109. On March 14, 1988, Medtronic received PMA for their original pain pump system. Def. RFJN, Exh. A.

Once a device has received PMA, a manufacturer must submit a PMA Supplement and obtain FDA approval prior to making any changes to the device. Medtronic filed PMA supplements for the SynchroMed EL Pump and Intrathecal Catheter at issue in this case and obtained FDA approval for both on February 26, 1999 (pump) and October 29, 1999 (catheter). Def. RFJN, Exhs. B & C. Even once a device has received PMA status, FDA oversight continues as they retain the

authority to prohibit sale of a device or withdraw PMA status. Currently, the FDA has not withdrawn PMA status for either the SynchroMed EL Pump or Intrathecal Catheter. Def. RFJN, Exhs. A-C.

2. Federal Preemption

Under the Federal Food Drug and Cosmetic Act (FDCA), there is an express preemption clause that provides, in relevant part:

> "[N]o 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." 21 U.S.C. § 360k(a).

The Supreme Court in *Riegel* addressed the meaning of this provision and held that to the extent a state common-law duty imposes requirements "different from, or in addition to" the requirements imposed by the FDCA, those state common law duties are expressly preempted by § 360k(a). *Riegel*, 128 S.Ct at 1007.

In order to avoid express preemption, a state law claim must be arise from a state law duty that is the same duty imposed under the FDCA. *Id.* at 1011. In other words, "the conduct that is alleged to give the plaintiff a right to recover under state law must be conduct that is forbidden by the FDCA." *Riley v. Cordis Corporation*, 625 F.Supp.2d 769, 776 (D. Minn. 2009). In those situations, the state law claim would become a "parallel" claim not expressly preempted by § 360k(a).

However, even a parallel state law claim that is not expressly preempted may still be subject to implied preemption under *Buckman*. 531 U.S. 341. There, the Supreme Court held there is no private right of action under the FDCA, therefore, a private litigant cannot sue a defendant for violating the FDCA. *See Buckman*, 531 U.S. at 349 n.4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.' 21 U.S.C. § 337(a)."). Private litigants are only permitted to bring state law claims that predate the federal enactment in question. *Id.* at 353; see also *Riley*, 625 F.Supp.2d at 777 ("[T]he conduct on which the [state]

claim is premised must be the type of conduct that would traditionally give rise to liability under state law-and that would give rise to liability under state law even if te FDCA had never been enacted.").

Here, Mr. Stengel is alleging state law tort claims of strict liability, negligence, and breaches of express and implied warranties. All four of these state tort law claims would impose a higher duty upon Defendant than what was required of them during the PMA process. In order for a state law claim to survive preemption, it must impose the *same* duty imposed under the FDCA. Defendants necessarily fulfilled their duty under the FDCA as evidenced by the fact that they received PMA for the medical devices at issue in this case. Any state law claims that go beyond the FDA's findings that a devices is safe and effective is subject to express preemption. *See Williams v. Allergan*, 2009 WL 3294873 (D. Ariz. 2009).

Plaintiff's Motions to Amend Complaint

In the alternative, Plaintiff has moved to amend his complaint to correct any deficiencies contained in the original complaint. In his amended complaint, Plaintiff alleges the same four causes of action—(1) strict liability; (2) breach of express warranties; (3) breach of implied warranties; (4) negligence—but now includes allegations that Defendant failed to warn/inform the FDA and medical physicians that their medical devices could cause granulomas, in violation of their duties under the FDCA.

As previously stated, Plaintiff's state law claims are expressly preempted. Furthermore, although Plaintiff does not articulate a separate cause of action, the new allegations in the proposed amended complaint suggest Plaintiff is now raising a fraud/failure to warn claim against Defendant. Under *Buckman*, Plaintiff's new claim is impliedly preempted. There is no private right of action for violations of the FDCA as 21 U.S.C. § 337(a) makes clear that the United States is the only party that has standing to bring such a claim. Here, Plaintiff is now alleging that Defendants violated their duties under the FDCA by failing to warn/inform the FDA of the potential dangers of their medical devices. This is impliedly preempted.

Furthermore, any state law claims not subject to express preemption must rest on conduct that is actionable even if the federal law did not exist. *See Buckman*, 531 U.S. at 353. Here,

Plaintiff's new allegations rests on violations of the FDCA. As such, his new claim of fraud/failure to warn would not exist had the FDCA not been enacted. Plaintiff's proposed amended complaint does nothing to remedy the fact that his claims are preempted.

Plaintiff's Motion for Rule 56(f) Relief

Plaintiff has also moved for FED.R.CIV.P. 56(f) relief on the grounds that Defendant—by including documents they would like this Court to take judicial notice of—has transferred their motion to dismiss into a motion for summary judgment. As such, Plaintiff argues, he is entitled to Rule 56(f) relief because a motion for summary judgment is premature until Plaintiff has an opportunity to conduct additional discovery.

Plaintiff is not entitled to Rule 56(f) relief because this Court may take judicial notice of matters of public record without converting Defendant's motion to dismiss to a motion for summary judgment. *See U.S. v. 14.02 Acres of Land More or Less*, 547 F.3d 943, 955 (9th Cir. 2008). Here, the only items Defendant have requested the Court take judicial notice of are the FDA documents showing the pump and catheter received premarket approval. These are matters of public record and they do not transform Defendant's motion to dismiss into a motion for summary judgment. Moreover, additional discovery is futile because Plaintiff's claims are preempted and additional discovery will not remedy that.

Accordingly, **IT IS SO ORDERED:**

1. Defendant's Motion to Dismiss (Doc. 4) is **granted**.

3. Plaintiff's Motion for Rule 56(f) Relief (Doc. 8)is **denied**.

2. Plaintiff's Motions to Amend Complaint (Docs. 10, 21, 22) are **denied**.

4. The Clerk of the Court must enter judgment accordingly and close this case.

DATED this 8th day of November, 2010.

Raner C. Collins
United States District Judge