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12
13 UNITED STATES DISTRICT COURT
14 CENTRAL DISTRICT OF CALIFORNIA

15
16 THEODORE COHEN, individually and)
on behalf of all others similarly situated)
17)
18 Plaintiffs,)
19 vs.)
20 GUIDANT CORPORATION, and)
DOES 1-50, inclusive. ,)
21 Defendants.)
22)

Case No. CV-05-8070-R
Judge: Hon. Manuel L. Real
Ctm: 8

**[ORDER GRANTING DEFENDANTS
GUIDANT LLC, GUIDANT SALES
LLC, CARDIAC PACEMAKERS,
INC., AND BOSTON SCIENTIFIC
CORPORATION'S MOTION TO
DISMISS**

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[PROPOSED] ORDER GRANTING DEFENDANTS GUIDANT LLC, GUIDANT SALES LLC, CARDIAC
PACEMAKERS, INC. AND BOSTON SCIENTIFIC CORPORATION'S MOTION TO DISMISS

1 On November 19, 2010, the Court issued an Order granting Defendants Guidant
2 LLC, Guidant Sales LLC, Cardiac Pacemakers, Inc., and Boston Scientific
3 Corporation’s Motion to Dismiss Plaintiff’s First Amended Complaint pursuant to
4 Rules 8(a), 9(b), and 12(b)(6) of the Federal Rules of Civil Procedure. In the same
5 Order, the Court granted Plaintiff leave to amend his Complaint. Plaintiff filed his
6 Second Amended Complaint on December 1, 2010. Defendants filed a Motion to
7 Dismiss the Second Amended Complaint on December 13, 2010. The motion of
8 Defendants for dismissal of Plaintiff’s Second Amended Complaint pursuant to Rules
9 8(a), 9(b), and 12(b)(6) of the Federal Rules of Civil Procedure came on regularly for
10 hearing by the Court on February 7, 2011.

11 The Court, having reviewed all of the pleadings in this matter, and having
12 heard oral argument of the parties, and good cause appearing therefor, hereby orders
13 that the motion is GRANTED based on the following grounds:

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15 **A. PREEMPTION**

16 1. All Plaintiff’s state law claims are preempted by federal law because the
17 pacemaker at issue in this action, an Insignia Plus DR Model 1298 (“Insignia 1298”),
18 is a Class III Medical Device that was evaluated under the equivalent of the FDA’s
19 premarket approval (PMA) process. *Riegel v. Medtronic, Inc.* 552 U.S. 312, 128 S.
20 Ct. 999, 169 L. Ed. 2d 892 (2008).

21 2. *Riegel* underscored that the FDA has exclusive authority to regulate and
22 assess the safety and effectiveness of medical devices through the PMA or an
23 equivalent process. *Riegel*, 552 U.S. at 316-320. State law claims are preempted
24 under *Riegel* to the extent that they impose requirements “different from or in addition
25 to” those imposed by federal law. *Id.* at 330. *Riegel* left open the possibility that there
26 is a narrow, so-called “parallel” claim exception to express preemption for state
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1 damages remedies premised on a violation of FDA regulations so long as the state
2 duties “‘parallel,’ rather than add to, federal requirements.” *Id.*

3 3. In order for Plaintiff to plead properly parallel claims that survive
4 preemption under *Riegel*, he must demonstrate facts (1) showing an alleged violation
5 of FDA regulations or requirements related to his pacemaker, and (2) establishing a
6 causal nexus between the alleged injury and the violation. *See, e.g., Parker v. Stryker*
7 *Corp.*, 584 F. Supp. 2d 1298, 1301-1302 (D. Colo. 2008) (rejecting plaintiff’s claim
8 that manufacturer violated the FDA’s PMA approval standards because “nowhere
9 does plaintiff’s complaint provide any factual detail to substantiate the crucial
10 allegation”); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 282 (E.D.N.Y. 2009)
11 (“[A] plaintiff must demonstrate a cognizable link between the defendant’s federal
12 violations and plaintiff’s injury.”). Absent factual support and details, general
13 allegations that Defendants failed to comply with federal requirements are inadequate
14 to plead parallel claims under *Riegel*. *Bagumyan v. Medtronic, Inc.*, No. B219506,
15 2010 WL 4009891 (Cal. Ct. App. Oct. 14, 2010).

16 4. Here, Plaintiff’s Second Amended Complaint is just as flawed as his First
17 Amended Complaint because it lists boilerplate FDA regulations without linking any
18 of those regulations to a defect in his specific pacemaker that was caused by
19 Defendants violating FDA regulations.

20 5. Plaintiff’s reliance on *Phillips v. Stryker*, No. 03:09-cv-488, 2010 WL
21 2270683 (E.D. Tenn. June 3, 2010) to demonstrate that his Complaint survives
22 dismissal is misplaced. The plaintiff in *Phillips* clearly linked the FDA regulations to
23 compliance failures in his hip prosthesis, and more importantly, how those compliance
24 failures resulted in the ultimate failure of his specific device, which in turn caused
25 injury to the plaintiff – notably, pain in plaintiff’s hip where the device was implanted.
26 *Phillips*, 2010 WL 2270683, at *7.

1 6. Here, Plaintiff has not provided any factual support in his Complaint that
2 there is a defect in his pacemaker, much less that a defect occurred as a result of
3 Defendant’s violation of FDA regulations related to his device. Plaintiff’s pacemaker
4 was implanted in 2004 and has not failed. Even if Plaintiff were able to plead
5 adequately a defect in his device that resulted from Defendants’ violation of FDA
6 requirements, Plaintiff has suffered no harm. Thus, unlike the plaintiff in *Phillips*,
7 Plaintiff here cannot demonstrate any causation between purported violations of FDA
8 requirements and the alleged harm. Moreover, “with any tort claim, the plaintiff must
9 prove the alleged defect caused [the] injury.” *Carson v. Depuy Spine, Inc.*, 365 Fed.
10 Appx. 812, 814 (9th Cir. 2010). Plaintiff cannot allege any defect in his pacemaker
11 and thus has failed to demonstrate how any defect resulted from a violation of FDA
12 regulations.

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14 **B. FEAR OF FUTURE INJURY IS NOT A LEGALLY COGNIZABLE**
15 **CLAIM UNDER CALIFORNIA LAW.**

16 7. A plaintiff’s claims are actionable under California law only if the
17 plaintiff alleges that an actual manifestation of a defect results in an injury. Plaintiff’s
18 claim of fear of future injury, premised on the risk that his pacemaker may
19 malfunction in the future, is not a legally cognizable injury under California law.
20 *Khan v. Shiley, Inc.*, 217 Cal. App. 3d 848, 857, 266 Cal. Rptr. 106, 112 (1990).
21 Plaintiff’s reliance on *Potter v. Firestone Tire & Rubber Co.*, 6 Cal. 4th 965, 25 Cal.
22 Rptr. 2d 550 (1993), where fear of contracting cancer after being exposed to asbestos
23 was found to be a legally cognizable claim, is distinguishable and not persuasive to
24 extend fear of future injury to the instant case.

C. PLAINTIFF DID NOT PLEAD HIS FRAUD CLAIMS WITH THE REQUISITE SPECIFICITY UNDER RULE 9(b).

8. Plaintiff’s argument that his fraud claims survive under *Khan* is unavailing. Although the court in *Khan* did not grant summary judgment on the fraud claims, the court specifically noted it did not dismiss the plaintiff’s fraud claims because defendants’ summary judgment motion failed to dispute those claims. *Khan*, 217 Cal. App. 3d at 858. Regardless, all Plaintiff’s fraud claims in the instant case fail because they are improperly pled under federal pleading standards.

9. First, Plaintiff’s fraud claims fail under Rule 9(b) because Plaintiff relies on alleged conduct related to other devices, and not linked to his own, which is not sufficient to state a claim for fraud.


10. Second, Plaintiff’s First and Second Amended Complaints recite general statements contained in websites about his pacemaker and Guidant Corporation, but there is no evidence that Plaintiff read or relied on this information prior to accessing it for purposes of initially asserting the statements in the First Amended Complaint.

D. PLAINTIFF FAILS TO PLEAD ADEQUATELY HIS CAUSES OF ACTION UNDER FEDERAL PLEADING STANDARDS.

11. Plaintiff’s causes of action are merely a formulaic recitation of their elements and therefore are not adequately pled under the Rule 8(a) standards announced in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) and *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009).

IT IS FURTHER ORDERED that Plaintiff’s Second Amended Complaint is dismissed with prejudice.

Dated: February 15, 2011



Hon. Manuel L. Real
United States District Court Judge