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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

RICHARD CONNELLY,
Plaintiff,
v.
ST. JUDE MEDICAL, INC., et al.,
Defendants.

Case No. [5:17-cv-02006-EJD](#)

**ORDER GRANTING DEFENDANTS'
RENEWED MOTION TO DISMISS
PLAINTIFF'S FAILURE-TO-WARN
CLAIM**

Re: Dkt. No. 45

Plaintiff Richard Connelly (“Connelly” or “Plaintiff”) brings claims against Defendants St. Jude Medical, LLC, Abbott Laboratories, and Pacesetter, Inc. (collectively, “St. Jude” or “Defendants”) arising from injuries he suffered from allegedly defective medical devices. In a First Amended Complaint (“FAC”), Connelly re-pleads, among other things, a cause of action for strict liability—failure to warn. FAC ¶¶ 103-16, Dkt. No. 41. St. Jude moves to dismiss under Fed. R. Civ. P. 8(a) and 12(b)(6) on the grounds that Connelly’s claims are insufficiently pled. Mot. to Dismiss (“MTD”), Dkt. No. 45. The Court finds this matter suitable for decision without oral argument. Civ. L.R. 7-1(b). For the reasons discussed below, St. Jude’s motion will be GRANTED.

I. BACKGROUND

A. Factual Background

The factual background of this case is set forth in the Court’s order regarding St. Jude’s motion to dismiss Connelly’s original Complaint. Dkt. No. 38. For clarity, the Court reviews facts as alleged in the FAC below:

1 In 1976, Congress enacted the Medical Device Amendments (“MDA”) to the Food, Drug,
2 and Cosmetic Act (“FDCA”). The MDA gave the Food and Drug Administration (“FDA”)
3 authority to regulate medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008).

4 Medical devices that support human life, or pose a high risk of illness or injury, are known
5 as Class III devices. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 344 (2001).
6 Manufacturers must apply for and receive premarket approval (“PMA”) from the FDA before they
7 can sell Class III devices. *Id.* The FDA grants approval after a rigorous review process. *Riegel*,
8 552 U.S. at 317. After a device has received approval, the manufacturer may not make changes
9 that would affect the device’s safety or effectiveness without applying for and receiving
10 supplemental approval (a “PMA Supplement”) from the FDA. *Id.* at 319. The manufacturer is
11 required “to report incidents [to the FDA] in which the device may have caused or contributed to
12 death or serious injury, or malfunctioned in a manner that would likely cause or contribute to
13 death or serious injury if it recurred.” *Id.*

14 St. Jude manufactures Class III devices called Riata Leads. FAC ¶¶ 1, 32. Riata Leads
15 allow an implantable cardiac defibrillator (“ICD”) to detect a patient’s abnormal heartbeat and
16 deliver an electric shock to restore a normal heartbeat. *Id.* ¶ 1.

17 In 1996, the FDA approved St. Jude’s PMA application for an ICD lead called the
18 Ventritex VTI Lead. *Id.* ¶ 34. St. Jude sought and obtained supplemental approval several times
19 in the following years. *Id.* ¶¶ 34-35. In 2002, the FDA approved St. Jude’s fourteenth PMA
20 Supplement, which approved design modifications and allowed the leads to be marketed under the
21 Riata name. *Id.* ¶ 35.

22 Connelly alleges that his doctors surgically installed Riata Leads and connected them to his
23 heart in May 2003 (and again in 2007 and 2015). *Id.* ¶¶ 3, 87-90. Connelly underwent this
24 surgery based on the advice of two cardiologists who he saw starting in 2002. *Id.* ¶ 86. Connelly
25 alleges that one of these cardiologists was a “specialist in pacemaker and ICD implants” who
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1 “would have tracked the [FDA’s Manufacturer and User Facility Device Experience (“MAUDE”)¹
2 database] for problems with the Ventritex TVI and Riata Leads and all competitors before
3 recommending any implant to Mr. Connelly.” *Id.*

4 Starting in October 2005, St. Jude conducted an internal audit to examine “inside-out
5 abrasion” associated with malfunctioning Riata Leads. *Id.* ¶¶ 56-57. The “audit concluded that
6 Riata Leads had potentially serious insulation problems.” *Id.* ¶ 58. In 2009, the FDA conducted
7 an inspection of St. Jude’s facilities. *Id.* ¶ 59. As a part of this audit, the FDA requested a list of
8 all Corrective and Preventative Action (“CAPA”) and Product Improvement Requests (“PIR”)
9 opened since 2002. *Id.* Connelly alleges that the FDA inspection “revealed that Defendants had
10 deficiencies in the handling of complaints, making Medical Device Reporting (‘MDR’)
11 determinations, Corrective and Preventative Action (‘CAPA’) procedures, and receiving
12 protocols.” *Id.* ¶¶ 35, 56, 60. As a result of the investigation, the FDA issued a “Form 483 report”
13 that identified possible “violation[s] of the FDCA and related Acts.” *Id.* ¶ 63.

14 In 2010, St. Jude published a “Dear Doctor” letter that identified defects in certain Riata
15 Lead models, including the model that was implanted in Connelly. *Id.* ¶ 72. St. Jude published an
16 updated letter in November 2011. *Id.* ¶ 76. In December 2011, the FDA reclassified the letter as a
17 product recall, indicating that “failures associated with lead insulation abrasion on the St. Jude
18 Riata and Riata ST Silicone Endocardial Defibrillation Leads may cause the conductors to become
19 externalized. If this occurs, this product may cause serious adverse health consequences, including
20 death.” *Id.* ¶¶ 77.

21 Connelly alleges that, in November 2016, his Riata leads malfunctioned while he slept.
22 *Id.* ¶ 91. He “was shocked an estimated sixteen to twenty times, causing irreparable harm to his
23 heart, body, and mind.” *Id.* He underwent surgery in March 2017 to replace the faulty lead.

24
25 ¹ The MAUDE is a voluntary reporting system in which the FDA lists adverse-event reports
26 received from device manufacturers. *Id.* ¶ 78; MTD 5. Manufacturers are required by law to
27 report device-related adverse events. *Id.*; see 21 U.S.C. § 360i(a)(1). The FDA also “may
28 disclose” adverse-event reports on the MAUDE, but it is not required to do so. 21 C.F.R.
§ 803.9(a).

1 *Id.* ¶ 95.

2 **B. Procedural Background**

3 Connelly initiated this suit on April 11, 2017. Compl., Dkt. No. 1. In his original
4 complaint, Connelly brought causes of action for (1) strict liability—manufacturing defect
5 (Compl. ¶¶ 97-103), (2) strict liability—failure to warn (Compl. ¶¶ 104-15), (3) negligence per se
6 (Compl. ¶¶ 116-23), and (4) negligence (Compl. ¶¶ 124-29). St. Jude moved to dismiss, Dkt. No.
7 29, which the Court granted in part and denied in part with leave to amend, Dkt. No. 38 (“MTD
8 Order”). Among the claims dismissed was Connelly’s claim for strict liability—failure to warn,
9 which the Court dismissed because Connelly had not sufficiently alleged a causal link between St.
10 Jude’s alleged failure to warn and Connelly’s injuries. MTD Order 8.

11 Connelly filed his FAC on September 8, 2017. Dkt. No. 41. In his FAC, Connelly alleges
12 causes of action for (1) strict liability—manufacturing defect (FAC ¶¶ 96-102), (2) strict
13 liability—failure to warn (FAC ¶¶ 103-16), and (3) negligence (FAC ¶¶ 117-23). St. Jude now
14 moves to dismiss Connelly’s second claim for strict liability—failure to warn. Dkt. No. 45.

15 **II. LEGAL STANDARD**

16 A motion to dismiss under Fed. R. Civ. P. 12(b)(6) tests the legal sufficiency of claims
17 alleged in the complaint. *Parks Sch. of Bus., Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir.
18 1995). Dismissal “is proper only where there is no cognizable legal theory or an absence of
19 sufficient facts alleged to support a cognizable legal theory.” *Navarro v. Block*, 250 F.3d 729, 732
20 (9th Cir. 2001). The complaint “must contain sufficient factual matter, accepted as true, to ‘state a
21 claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting
22 *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

23 **III. DISCUSSION**

24 The Ninth Circuit has recognized a “narrow gap” through which a state law claim—such as
25 Connelly’s strict liability claim here—will not be impliedly preempted by the FDCA. *Perez v.*
26 *Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013). “To properly plead parallel [state law] claims
27 that survive preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA

28 Case No.: [5:17-cv-02006-EJD](#)

1 regulations or requirements related to [the device], and (2) establishing a causal nexus between the
2 alleged injury and the violation.” *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1174 (C.D.
3 Cal. 2013) (quoting *Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal.
4 2011)) (internal quotation marks omitted).

5 Manufacturers of Class III devices have a duty to “report incidents [to the FDA] in which
6 the device may have caused or contributed to death or serious injury, or malfunctioned in a
7 manner that would likely cause or contribute to death or serious injury if it recurred.” *Riegel*, 552
8 U.S. at 319. Here, Connelly alleges that “from 1997 through at least November 2016, Defendants
9 failed to comply with their duty to file adverse-event reports with the FDA and, at the same time,
10 breached their state law duty to warn of dangerous product defects.” Opp’n 8, Dkt. No. 48; FAC
11 ¶¶ 106-07, 110-12. Connelly alleges that these failures caused his injury in two ways: (1) if St.
12 Jude had not failed to submit adverse-event reports to the FDA prior to the implantation of Riata
13 Leads (in May 2003), Connelly’s surgeon never would have implanted them; and (2) if St. Jude
14 had not failed to submit adverse-events reports to the FDA after implantation, Connelly’s surgeon
15 would have removed them prior to the November 2016 malfunction. Opp’n 11-13; FAC ¶¶ 107,
16 113.

17 In its order dismissing Connelly’s failure to warn claim, the Court found that Connelly had
18 failed to allege a causal connection between his injuries and St. Jude’s failure to warn. MTD
19 Order 8. Connelly’s allegations in the FAC suffer from this same deficiency.

20 First, as to Connelly’s first theory of injury—that Connelly’s surgeon never would have
21 implanted the Riata Leads but for St. Jude’s alleged failure—Connelly again fails to allege any
22 facts that plausibly establish a causal nexus. As was the case with all of Connelly’s allegations in
23 his original Complaint, most of Connelly’s allegations in the FAC refer to adverse events that
24 occurred after the Riata Leads were implanted in him (in 2003). *See* FAC ¶¶ 8 (“No later than
25 2005 and likely sooner, St. Jude realized the Riata Leads were defective.”), 56-58 (primarily
26 referring to incidents that occurred in 2005 and 2008), 60-62 (referring to results of FDA
27 inspections that were made available in 2009 and cover a period running from 2002), 74 (referring

1 to a 2010 Dear Doctor letter). The only specific allegation that Connelly makes regarding adverse
2 events that occurred prior to the 2003 implantation is that the 2009 FDA inspection, which
3 covered a period starting from 2002, “revealed that Defendants had deficiencies in the handling of
4 complaints, making [MDR] determinations, [CAPA] procedures, and receiving protocols.” FAC
5 ¶¶ 35, 56, 60. However, Connelly alleges no facts regarding whether any of these “deficiencies in
6 the handling of complaints . . .” occurred in 2002-03, related to the Riata Leads (and, specifically,
7 the abrasion malfunction that allegedly caused his injuries), or actually amounted to failures in
8 reporting. In short, Connelly fails to allege anything more than a speculative connection between
9 the 2009 FDA inspection and potentially unreported adverse events.

10 Moreover, judicially noticeable materials² relating to the 2009 FDA inspection confirm the
11 speculative nature of Connelly’s allegation. According to the Establishment Inspection Report
12 (“EIR”) issued by the FDA upon completion of the 2009 inspection, the primary focus of the
13 inspection was on malfunctions relating to perforation—not abrasion. *See* Taubert Decl., Ex 1.,
14 Dkt. No. 45-2 (“EIR”), at 5-8. At least for perforation events, the FDA concluded that it “did not
15 identify any adverse events that failed to be reported.” *Id.* at 13. It identified two adverse events
16 that were reported significantly past the mandatory reporting timeframes, but neither of these were
17 reported prior to May 2013. *Id.* at 18. Given this, the possibility that there were relevant pre-
18 implantation adverse events seems even more attenuated. Accordingly, Connelly’s allegation
19 regarding the 2009 FDA inspection cannot form a plausible basis for his pre-implantation theory.

20 Connelly’s remaining allegations regarding adverse effects fare no better. For example,
21 Connelly alleges that “St. Jude was informed by physicians of several incidents where, as a result
22 of abrasion from the inside-out of the lead wires, St. Jude defibrillators sent unnecessary jolts to
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24 ² The Court takes judicial notice of the FDA’s Establishment Inspection Report (“EIR”) because it
25 is a “matter of public record” whose content is “not subject to reasonable dispute” and “can be
26 accurately and readily determined from sources whose accuracy cannot reasonably be questioned.”
27 *Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001) (quoting *Mack v. S. Bay Beer*
Distrib., 798 F.2d 1279, 1282 (9th Cir. 1986)); Fed. R. Evid. 201(b). In addition, it appears that
28 Connelly’s complaint “necessarily relies on it,” as the allegation of FAC ¶ 59 mirrors language in
the EIR. *Compare* FAC ¶ 59, with EIR 9.

1 the heart or failed to deliver lifesaving shocks to return chaotic heart rhythms back to normal.”
2 FAC ¶ 56. However, these are simply “‘naked assertions’ devoid of ‘further factual
3 enhancement.’” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555, 557). As such, they
4 also do not plausibly establish any pre-implantation adverse events that could form the basis for
5 Connelly’s claim.

6 Second, as to Connelly’s second theory of injury—that Connelly’s surgeon would have
7 removed the Riata Leads but for St. Jude’s alleged failure—, this too lacks a causal nexus.
8 Although Connelly’s allegations reference adverse events that occur within the relevant timeframe
9 (2003-16), Connelly alleges no facts that would establish any causal nexus between alleged
10 failures to report these events and his injury. The only allegation he makes with respect to this
11 second theory is that “[h]ad Defendants not breached their duty to warn, relevant information
12 relating to the safety and efficacy of the Riata Leads would have reached Plaintiff’s doctors, and
13 would have caused Plaintiff to extract the device, prior to Plaintiff suffering the repeated, violent
14 electrical shocks, as alleged above.” FAC ¶ 113. However, this is conclusory and insufficient as a
15 matter of law. Moreover, if anything, the factual allegations in the FAC—even construed in the
16 light most favorable to Connelly—suggest the opposite. Despite St. Jude’s 2010 and 2011 Dear
17 Doctor letters and the FDA’s 2011 Class I Recall reclassification, FAC ¶¶ 74-77, Connelly’s
18 doctor decided to not replace the Riata Leads when Connelly underwent surgery in 2015, FAC
19 ¶ 90. This suggests that, even if St. Jude had not allegedly failed to report adverse events, it would
20 not have caused Connelly’s surgeon to remove the Riata Leads. As such, Connelly has not
21 plausibly alleged a causal nexus.

22 Moreover, to the extent Connelly’s claim is premised on a theory that St. Jude had a post-
23 distribution (i.e., post-implantation) duty to warn, this fails as a matter of law. Under California
24 law, a defendant may be held strictly liable for a failure to warn only if “the defendant did not
25 adequately warn of a particular risk that was known or knowable . . . at the time of manufacture
26 and distribution.” *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 558 (Cal. 1991)
27 (emphasis added). Accordingly, Connelly’s second theory is problematic for this reason as well.

1 In sum, Connelly has not plausibly alleged a causal connection between his injuries and St.
2 Jude’s failure to warn. Accordingly, his claim will be DISMISSED. Further, since this was
3 Connelly’s second opportunity to plead this claim and Connelly’s second attempt fails for the
4 same reasons as before, *see* MTD Order 8, this claim will be dismissed without leave to amend as
5 allowing for further amendment would be futile. *Miller v. Rykoff-Sexton*, 845 F.2d 209, 214 (9th
6 Cir. 1988) (“A motion for leave to amend may be denied if it appears to be futile or legally
7 insufficient.”).

8 **IV. ORDER**

9 St. Jude’s motion to dismiss is GRANTED. Connelly’s claim for failure to warn will be
10 DISMISSED without leave to amend.

11 **IT IS SO ORDERED.**

12 Dated: February 6, 2018



EDWARD J. DAVILA
United States District Judge