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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 IN PART AND
DENYING IN PART DEFENDANTS'
MOTION TO DISMISS**

Re: Dkt. No. 29

Plaintiff Richard Connelly brings claims against Defendants St. Jude Medical, LLC, Abbott Laboratories, and Pacesetter, Inc. (together, “St. Jude”) arising from injuries he suffered from allegedly defective medical devices. 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 and preempted by federal law. St. Jude’s motion will be granted in part and denied in part.

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1 **I. BACKGROUND**

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

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

15 St. Jude manufactures Class III devices called Riata Leads. Compl. ¶¶ 1, 32, Dkt. No. 1.
16 Riata Leads allow an implantable cardiac defibrillator (“ICD”) to detect a patient’s abnormal
17 heartbeat and deliver an electric shock to restore a normal heartbeat. Id. ¶ 1.

18 In 1996, the FDA approved St. Jude’s PMA application for an ICD lead called the
19 Ventritex VTI Lead. Id. ¶ 34. St. Jude sought and obtained supplemental approval several times in
20 the following years. Id. In 2002, the FDA approved St. Jude’s fourteenth PMA Supplement, which
21 approved design modifications and allowed the leads to be marketed under the Riata name.
22 Id. ¶ 35; Defs.’ Mot. to Dismiss (“MTD”) 5, Dkt. No. 29.

23 Connelly alleges that his doctors surgically installed Riata Leads and connected them to his
24 heart in May 2003 (and again in 2007 and 2015). Compl. ¶¶ 3, 35. St. Jude’s fifteenth and
25 sixteenth PMA Supplements had been approved before then, and the sixteenth supplement was
26 approved in July 2003. Id. ¶ 88; MTD 5.

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1 Starting in October 2005, St. Jude conducted an internal audit to examine “inside-out
2 abrasion” associated with malfunctioning Riata Leads. Compl. ¶¶ 56–57. The “audit concluded
3 that Riata Leads had potentially serious insulation problems.” Id. ¶ 58. In 2009, the FDA
4 conducted an inspection of St. Jude’s facilities and issued a “Form 483 report” that identified
5 possible “violation[s] of the FDCA and related Acts.” Pl.’s Opp’n to Mot. to Dismiss (“Opp’n”) 7,
6 Dkt. No. 35; Compl. ¶¶ 59–63.

7 In 2010, St. Jude published a “Dear Doctor” letter that identified defects in certain Riata
8 Lead models, including the model that was implanted in Connelly. Compl. ¶ 74. St. Jude
9 published an updated letter in November 2011. Id. ¶ 76. In December 2011, the FDA reclassified
10 the letter as a product recall, indicating that “failures associated with lead insulation abrasion on
11 the St. Jude Riata and Riata ST Silicone Endocardial Defibrillation Leads may cause the
12 conductors to become externalized. If this occurs, this product may cause serious adverse health
13 consequences, including death.” Id. ¶¶ 77–78.

14 Plaintiff alleges that, in November 2016, his Riata leads malfunctioned while he slept.
15 Id. ¶ 92. He “was shocked an estimated sixteen to twenty times, causing irreparable harm to his
16 heart, body, and mind.” Id. He underwent surgery in March 2017 to replace the faulty lead.
17 Id. ¶ 95.

18 Connelly brings causes of action for (1) strict liability—manufacturing defect
19 (Compl. ¶¶ 97–103), (2) strict liability—failure to warn (Compl. ¶¶ 104–15), (3) negligence per
20 se (Compl. ¶¶ 116–23), and (4) negligence (Compl. ¶¶ 124–29). St. Jude now moves to dismiss.

21 **II. LEGAL STANDARD**

22 A motion to dismiss under Fed. R. Civ. P. 12(b)(6) tests the legal sufficiency of claims
23 alleged in the complaint. Parks Sch. of Bus., Inc. v. Symington, 51 F.3d 1480, 1484 (9th Cir.
24 1995). Dismissal “is proper only where there is no cognizable legal theory or an absence of
25 sufficient facts alleged to support a cognizable legal theory.” Navarro v. Block, 250 F.3d 729, 732
26 (9th Cir. 2001). The complaint “must contain sufficient factual matter, accepted as true, to ‘state a

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1 claim to relief that is plausible on its face.’ ” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting
2 Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

3 **III. DISCUSSION**

4 St. Jude argues that Connelly’s complaint must be dismissed because (1) three of his
5 claims are expressly preempted, (2) one of his claims is impliedly preempted, and (3) all of his
6 claims are insufficiently pled.

7 **A. Manufacturing-Defect Claim**

8 St. Jude argues that Connelly’s manufacturing-defect claim is expressly preempted under
9 § 360k(a) of the MDA, which states:

10 Except as provided in subsection (b) of this section, no State or
11 political subdivision of a State may establish or continue in effect
with respect to a device intended for human use any requirement—

12 (1) which is different from, or in addition to, any requirement
13 applicable under this chapter to the device, and

14 (2) which relates to the safety or effectiveness of the device or to
15 any other matter included in a requirement applicable to the device
under this chapter.

16 21 U.S.C. § 360k(a) (emphasis added); see MTD 8–18. Its implementing regulation provides:

17 State or local requirements are preempted only when the Food and
18 Drug Administration has established specific counterpart regulations
or there are other specific requirements applicable to a particular
19 device under the act, thereby making any existing divergent State or
20 local requirements applicable to the device different from, or in
addition to, the specific Food and Drug Administration
21 requirements.... The following are examples of State or local
requirements that are not regarded as preempted by [§ 360k]:

22

23 (2) [Section 360k] does not preempt State or local requirements that
24 are equal to, or substantially identical to, requirements imposed by
or under the act.

25 21 C.F.R. § 808.1(d).

26 Courts apply a two-step test to determine whether state-law claims are expressly preempted

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1 under § 360k(a). Riegel, 552 U.S. at 322–23. First, the court determines whether “the Federal
2 Government has established requirements applicable to” the particular medical device. Id. at 321.
3 If so, the court determines whether the state-law claim would impose “requirements with respect
4 to the device that are ‘different from, or in addition to,’ ” the federal requirements. Id. at 322. The
5 state-law claim is explicitly preempted if both conditions are satisfied. Here, Connelly concedes
6 that St. Jude has satisfied the first prong of the Riegel test (i.e., Connelly agrees that the PMA and
7 PMA Supplements are federal requirements that are applicable to Riata Leads). Opp’n 15.
8 However, Connelly argues that his claims are not preempted because they parallel the federal
9 requirements.

10 Connelly bases his manufacturing-defect claim on five defects that he alleges violated St.
11 Jude’s PMAs:

12 Inconsistent insulation diameters surrounding the electric
13 conductors. Defendants failed to manufacture uniform insulation
14 diameters leading to an increased risk of abrasion at thinner
insulation sites, as well as externalization, which leads to an
increased risk of device failure.

15 Inconsistent application of a lubricious interface between the inner
16 and outer insulation in violation of the design specifications and/or
17 the PMAs. This inconsistent application may have led to increased
friction within the lead body, promoting abrasion and/or
externalization.

18 Failure to comply with the approved methods and/or specifications
19 of curing during the manufacture of the Riata Leads. Defendants
20 failed to follow the approved cure processes, resulting in reduced
tensile strength of the silicone insulation.

21 Failure to comply with the approved methods and/or specifications
22 of sterilization during the manufacture of the Riata Leads.
Defendants failed to follow the approved sterilization processes,
resulting in reduced tensile strength of the silicone insulation.

23 Failure to crimp with a controlled, uniform, degree of force,
24 resulting in insecure crimps over the length of the Riata Leads.

25 Opp’n 15–16 (citing Compl. ¶¶ 66–70).

26 St. Jude argues that Connelly’s claims are preempted because four of these five

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1 requirements do not exist in the PMA and PMA Supplements for the relevant Riata Leads. MTD
2 10–12. Claims based on these nonexistent requirements, St. Jude’s argues, are preempted because
3 they necessarily impose requirements that are “different from, or in addition to,” the federal
4 requirements. Id.

5 Plaintiffs face a dilemma when pleading claims that a manufacturer violated PMA
6 requirements. Because they contain confidential information, PMAs are not publicly available in
7 their entirety. Opp’n 16. The public can view a PMA’s ID number, its date, and a brief description
8 of its contents, but the full contents of the PMA are not publicly disclosed. See Rosen v. St. Jude
9 Med. Inc., 41 F. Supp. 3d 170, 178 (N.D.N.Y. 2014). So, without knowing the specific contents of
10 a PMA, a plaintiff must nonetheless plead a violation of PMA requirement in enough detail to
11 avoid preemption under § 360k and to satisfy federal pleading requirements.

12 The Ninth Circuit has not directly addressed this issue, although a number of other district
13 and appellate courts have considered the level of detail a plaintiff must provide when pleading
14 PMA violations. See id. at 178–81 (collecting and synthesizing relevant cases). This Court finds
15 the Rosen court’s reasoning persuasive, and agrees that “where a plaintiff has limited access to the
16 PMAs at the time she files her complaint, allegations that the defendant violated [PMAs], so long
17 as they are supported by sufficient factual evidence and demonstrate a causal connection to the
18 alleged injuries, are all that is required to satisfy Twombly and avoid preemption under § 360k and
19 Riegel.” Id. at 181 (emphasis in original); accord Hofts v. Howmedica Osteonics Corp., 597 F.
20 Supp. 2d 830, 838 (S.D. Ind. 2009).

21 St. Jude argues that Connelly’s complaint is “devoid of any facts that would plausibly
22 suggest that St. Jude ever violated any of the purported requirements.” MTD 13. However,
23 Connelly’s complaint identifies specific facts from an internal St. Jude audit, three FDA
24 enforcement actions, two Dear Doctor Letters, and the 2011 Class I recall of the Riata Leads.¹

25
26 ¹ St. Jude asks the Court to adopt factual findings from Pinsonneault v. St. Jude Medical, Inc., No
27 12-cv-1717, 2014 WL 2879754 (D. Minn. June 24, 2014). The Court declines to do so because
28 Pinsonneault involved a motion for summary judgment, not a motion to dismiss. Unlike here, the
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1 Opp'n 16 (citing Compl. ¶¶ 56–83). Together, this evidence suggests that St. Jude violated the
2 requirements contained in the applicable PMAs. Connelly has also demonstrated a plausible
3 connection between the alleged manufacturing defects and his injuries. Accordingly, the Court
4 finds that Connelly has sufficiently alleged a parallel state claim that survives preemption under
5 Riegel and § 360k(a).

6 **B. Negligence Claim**

7 St. Jude argues that Connelly's negligence claim is expressly preempted and inadequately
8 pleaded "for the same reasons as Plaintiff's strict-liability manufacturing defect claim." MTD 18,
9 24; Defs.' Reply in Support of Mot. to Dismiss ("Reply") 11, 15. Connelly states that his
10 arguments regarding his manufacturing-defect claims "apply with equal force" to his negligence
11 claims.

12 Having found that Connelly has adequately stated non-preempted claims for
13 manufacturing defects, the Court also finds that Connelly's negligence claim is sufficient to
14 survive St. Jude's motion to dismiss.

15 **C. Failure-to-Warn Claim**

16 Manufacturers of Class III devices have a duty to "report incidents [to the FDA] in which
17 the device may have caused or contributed to death or serious injury, or malfunctioned in a
18 manner that would likely cause or contribute to death or serious injury if it recurred." Riegel, 552
19 U.S. at 319. Here, Connelly alleges that "from 1997 through at least November 2016, Defendants
20 failed to comply with their duty to file adverse-event reports with the FDA and, at the same time,
21 breached their state law duty to warn of dangerous product defects." Opp'n 17–18.

22 St. Jude acknowledges that the Ninth Circuit has found that similar failure-to-warn claims
23 are not expressly preempted. MTD 14–15 (citing Stengel v. Medtronic, 704 F.3d 1224 (9th Cir.
24 2013)). However, St. Jude argues Connelly's failure-to-warn claim nevertheless fails because
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26 parties in Pinsonneault had conducted discovery, and the court was not required to accept the
27 plaintiff's allegations as true.

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1 Connelly has not identified specific adverse events that St. Jude knew of but failed to report, and
2 Connelly has not established a causal link between St. Jude’s alleged failure to warn and
3 Connelly’s injuries. MTD 15–18; Reply 8–11.

4 Connelly correctly notes that the PMA for the Riata Leads’ predecessor was first approved
5 in 1996. Opp’n 20. In 2002, the fourteenth PMA Supplement approved the type of Riata Leads
6 that were implanted in Connelly. Id. Connelly’s leads were surgically implanted in 2003. Id. On
7 this basis, Connelly argues:

8 As alleged in the Complaint, notwithstanding multiple reports of
9 inside-out abrasion from doctors and internal audits regarding the
10 same, St. Jude failed to make the required disclosures to the FDA.
11 See, e.g., Complaint, ¶¶ 8, 56-58, 60-62, 73.

12 Id. Connelly argues that, if St. Jude had reported these events to the FDA, Connelly’s “physicians
13 would never have installed the devices and [he] would never have been damaged.” Id.

14 However, Connelly’s allegations refer exclusively to adverse events that occurred after the
15 Riata Leads were implanted in him (in 2003). See Compl. ¶¶ 8 (“No later than 2005 and likely
16 sooner, Defendants realized the Riata Leads were defective”), 56–58 (referring to incidents that
17 occurred in 2005 and 2008), 60–62 (referring to the results of FDA inspections that were made
18 available in 2009), 73 (referring to a 2010 Dear Doctor letter).

19 None of these allegations suggest that St. Jude failed to report known adverse events
20 before Connelly’s Riata leads were implanted in 2003. Connelly’s allegation that St. Jude knew of
21 defects “[n]o later than 2005 and likely sooner” (Compl. ¶ 8) is insufficient because Connelly
22 provides no factual basis for his claim that St. Jude knew of defects in Riata Leads, but failed to
23 report them to the FDA, before 2005.

24 As such, the Court finds that Connelly has failed to establish a causal connection between
25 Connelly’s injuries and St. Jude’s failure to warn. Connelly’s failure-to-warn claim will be
26 dismissed with leave to amend.

27 **D. Negligence-Per-Se Claim**

28 Connelly’s negligence-per-se claim is based entirely on violations of the FDCA and its

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1 implementing regulations. Compl. ¶ 118. St. Jude argues that claims that exist solely by virtue of
2 FDCA requirements are impliedly preempted under § 337(a) because the federal government has
3 exclusive authority to enforce FDCA requirements. Reply 12; see also Buckman, 531 U.S. at 353
4 (holding that claims were impliedly preempted because they “exist solely by virtue of the FDCA
5 disclosure requirements”). Connelly attempts to limit Buckman to fraud-on-the-FDA claims.
6 Opp’n 22–23. But St. Jude argues that courts routinely interpret Buckman to preempt a variety of
7 other types of claims. See Reply 12 (collecting cases); see also, e.g., Martin v. Medtronic, Inc., 32
8 F. Supp. 3d 1026, 1034 n.22 (D. Ariz. 2014) (“Plaintiffs suggest that Buckman only applies to
9 fraud-on-the-FDA claims because that was the claim at issue in that case, but Buckman cannot be
10 read that narrowly.”)

11 The Court agrees with St. Jude that there is “no material distinction between [Connelly’s]
12 claims and those held impliedly preempted in Buckman.” Reply 12. As such, Connelly’s
13 negligence-per-se claim will be dismissed with leave to amend.

14 **E. Abbott as a Defendant**

15 Connelly alleges that Abbott Laboratories is liable as the successor in interest to St. Jude
16 Medical, Inc. Compl. ¶ 2. St. Jude states that, according to publicly available Form 8-K records,
17 St. Jude Medical, Inc. merged with a subsidiary of Abbott to create a new, separate entity: St. Jude
18 Medical, LLC. MTD 24–25. St. Jude argues that St. Jude Medical, LLC—not Abbott
19 Laboratories—is the successor in interest of St. Jude Medical, LLC. Id. On that basis, St. Jude
20 argues that Abbott Laboratories is not a proper defendant in this action and must be dismissed. Id.

21 Connelly responds that Abbott is a proper defendant because the Abbott–St. Jude merger
22 occurred on April 27, 2016, but Connelly was not injured until six months later. Opp’n 25.
23 Connelly argues that “each Defendant”—including Abbott—“had an ongoing duty of care to
24 [Connelly] under the negligence claim.” Id.

25 St. Jude points out that Connelly has apparently abandoned his successor-liability theory in
26 favor of a negligence theory. Reply 15. Even under a negligence theory, however, St. Jude argues

1 that Abbott is not a proper defendant because the merger was announced on April 27, 2016,² but it
2 was not closed until January 5, 2017—nearly two months after Connelly’s injuries occurred. Id.

3 The Court finds that Abbott Laboratories must be dismissed as a defendant. However,
4 Connelly may amend his complaint to clarify the basis on which he believes Abbott may be held
5 liable.

6 **IV. CONCLUSION**

7 St. Jude’s motion to dismiss is DENIED as to Connelly’s claims for manufacturing defects
8 and negligence. St. Jude’s motion to dismiss is GRANTED with leave to amend as to Connelly’s
9 claims for failure to warn and negligence per se. Abbott Laboratories is dismissed as a defendant
10 with leave to amend to explain why Abbott is a proper defendant. Connelly shall file an amended
11 complaint by September 8, 2017.

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13 **IT IS SO ORDERED.**

14 Dated: August 23, 2017



EDWARD J. DAVILA
United States District Judge

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27 ² St. Jude’s reply brief states that the merger was announced on April 27, 2017. This appears to be
a typo. The context makes clear that the merger was announced on April 27, 2016.

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