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6 UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
7 AT SEATTLE

8 K. SEAN O'NEIL, *et al.*,

9 Plaintiffs,

10 v.

11 ST. JUDE MEDICAL, INC., *et al.*,

12 Defendants.

No. C13-0661RSL

ORDER DENYING DEFENDANTS'
MOTION TO DISMISS

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14 This matter comes before the Court on "Defendants' Amended Motion to
15 Dismiss." Dkt. # 10. Plaintiff K. Sean O'Neil alleges that defendants failed to manufacturer its
16 implantable cardiac defibrillator ("ICD") device in a manner that was consistent with the
17 manufacturing and process changes approved by the Food and Drug Administration ("FDA")
18 between 2005-2010. Complaint (Dkt. # 1) at ¶ 51. In particular, plaintiff alleges that the Riata
19 leads on his ICD were subject to premature abrasion and protrusion through the insulation
20 because defendants failed to (a) manufacture uniform insulation diameters, (b) consistently apply
21 lubricious interface between insulation, (c) comply with the approved methods and
22 specifications for curing and sterilization of the leads, and (d) properly crimp the leads, all as
23 required by FDA regulations and the FDA-approved design criteria. *Id.* at ¶¶ 52-57. Plaintiff
24 alleges facts from which one could reasonably infer that defendants were aware of the defects in
25 the insulation of the Riata leads but failed to take timely and adequate measures to analyze
26 problems and alert the FDA, medical providers, and/or customers. *Id.* at ¶¶ 46-50, 59-64, and

ORDER DENYING MOTION TO DISMISS

1 76. The FDA ultimately recalled the Riata leads because the abrasion of the insulation could
2 lead to externalization of the leads. Id. at ¶ 67. Plaintiff further alleges that externalization of
3 the leads exposes them to materials and fluids that cause them to malfunction, sending
4 unnecessary and painful shocks of electricity to the heart or preventing the ICD from working
5 altogether. Id. at ¶¶ 53-54. Finally, plaintiff alleges that he suffered electrical shocks from his
6 ICD, he had to have it surgically removed and replaced in October 2012, and his surgeon
7 confirmed that his Riata lead was defective. Id. at ¶ 1 and ¶ 6. Based on these allegations,
8 plaintiffs have asserted three strict liability claims under the Washington Products Liability Act,
9 RCW 7.72 *et seq.*, namely manufacturing defect resulting from the failure to comply with the
10 specifications approved by the FDA (Count 1), failure to comply with a list of federal standards
11 that were incorporated into the Conditions of Approval for the ICD (Count 2), and breach of the
12 on-going duty to evaluate the risks posed by the product and provide necessary warnings (Count
13 3). Plaintiffs allege that the product defect engendered by the failures set forth in the complaint
14 caused physical injuries, emotional and mental distress, economic loss, and other damages.
15 Defendants seek dismissal of all of plaintiffs' claims on the ground that they were not adequately
16 alleged under Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007). Defendants also seek dismissal
17 of Count 2 on the ground that it is preempted by the Medical Devices Amendments of 1976.

18 Having reviewed the Class Action Complaint and the memoranda submitted by the
19 parties,¹ the Court finds as follows:

20 **A. Adequacy of the Pleadings**

21 Pursuant to Fed. R. Civ. P. 8(a)(2), a complaint must include "a short and plain
22 statement of the claim showing that the pleader is entitled to relief." Where defendant

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24 ¹ Plaintiffs allege that defendant obtained the FDA's pre-market approval for the original Riata
25 lead application. Complaint (Dkt. # 1) at ¶ 24. The Court need not take judicial notice of that or any
26 other matter outside the pleading in order to determine the adequacy of the existing allegations.

26 This matter can be decided on the papers submitted. Defendants' request for oral argument is,
therefore, DENIED.

1 challenges the adequacy of a complaint under Fed. R. Civ. P. 12(b)(6), the Court assumes the
2 truth of the plaintiffs’ allegations and draws all reasonable inferences in the plaintiffs’ favor.
3 Usher v. City of Los Angeles, 828 F.2d 556, 561 (9th Cir. 1987). In order to survive a motion to
4 dismiss, plaintiffs’ allegations must give rise to something more than mere speculation that
5 plaintiffs have a right to relief. Twombly, 550 U.S. at 555. The complaint must offer “more
6 than labels and conclusions” or a “formulaic recitation of the elements of a cause of action.” Id.
7 Detailed factual allegations are not required, however: the question for the Court is whether the
8 facts set forth in the complaint state a “plausible” ground for relief. Id. at 570.

9 Plaintiffs have provided a short and plain statement of the facts giving rise to a
10 plausible claim for relief under each cause of action asserted in the complaint. They have
11 alleged the standards that governed defendants’ conduct, specific breaches of those standards,
12 and resulting damages. Defendants utilize a number of techniques to overcome the allegations
13 of the complaint, but none is availing in the context of a motion to dismiss. Defendants may not,
14 for example, simply ignore the facts alleged in the complaint. See Motion (Dkt. # 10) at 9
15 (asserting that plaintiffs “do not allege any facts that plausibly suggest that the FDA ever
16 imposed” requirements regarding insulation diameters when in fact plaintiffs alleged at ¶ 52 that
17 “insulation diameters are required by the design specifications, PMA, and/or federal
18 requirements to be consistent”). Nor may defendants refuse to draw perfectly reasonable
19 inferences in plaintiffs’ favor in order to argue that a claim fails as a matter of law. See Motion
20 (Dkt. # 10) at 10 (asserting that there are no factual allegations that plausibly suggest that
21 plaintiff was injured as a result of the defect despite the fact that the type of harm plaintiff
22 suffered was exactly the type of harm one would expect from the externalization of the lead and
23 his surgeon confirmed the existence of a defect).

24 Defendants do not argue that plaintiffs’ complaint contains nothing more than a
25 formulaic recitation of the elements of the claim, but rather suggest that the complaint is
26 defective because the factual allegations are not supported by additional, underlying factual

1 allegations. Layers of detailed factual allegations are not required by Fed. R. Civ. P. 8(a) or
2 Twombly, however. In order to allege causation, for example, plaintiffs need not definitively
3 allege what his surgeon would have done had defendants accurately evaluated the risks
4 associated with the Riata leads and timely notified the FDA. While plaintiffs will ultimately
5 have to prove that if defendants had properly reported the adverse events, Mr. O’Neil could have
6 avoided the discomfort of unnecessary electrical shocks and the uncertainty of having his
7 defibrillator turned off until he was awaiting surgery, that is not their burden at this point in the
8 litigation. For purposes of the causes of action alleged, the allegations regarding the
9 manufacturing and reporting standards imposed by federal regulation and the approval process,
10 the specific manufacturing defects arising from noncompliance with those standards, the FDA
11 investigation and recall, defendants’ knowledge of product defects and subsequent reporting
12 failures, the impact the alleged defects would have on the functioning of an ICD, the nature of
13 plaintiff’s injuries, and the condition of his Riata lead upon removal, considered together, are
14 sufficient to state plausible claims for relief.²

16 ² The Court acknowledges that a number of products liability claims related to the Riata leads
17 have been dismissed for failure to satisfy Twombly. In each of those cases, however, the factual
18 allegations were more conclusory than those present here and failed to raise a plausible inference that
19 defendant could be liable. See Scianneaux v. St. Jude Med. S.C., Inc., 2013 WL 4417455, at * 4 (E.D.
20 La. Aug. 19, 2013) (plaintiff alleged only that defendant “deviated from FDA requirements” and the
21 product specifications without identifying the requirements that were violated or explaining how the
22 design or manufacture of the product deviated from those requirements); Knoppel v. St. Jude Med., Inc.,
23 2013 WL 3803612, at *2 (C.D. Cal. May 7, 2013) (allegation that product defect increased risk of injury
to patients did not give rise to a plausible inference that the Riata lead in plaintiff’s ICD was defective or
that plaintiff’s unspecified injury was causally-related to the alleged defect); Viserta v. St. Jude Med.,
24 Inc., 2012 WL 667814, at *4 (D.S.C. Feb. 29, 2012) (plaintiff failed to allege facts from which one
could plausibly infer a causal connection between the alleged manufacturing defect and her injury).

24 At page 14 of their opening memorandum, defendants challenged the legal viability of plaintiff’s
25 claim that they had violated two of the specified regulations (rather than simply challenging the
26 adequacy of the factual allegations). In particular, defendants argued that they could not, as a matter of
law, violate 21 C.F.R. § 814.3 and § 814.9 because it is logically and legally impossible for defendants
to have violated the definitions section of the regulations or duties imposed on the FDA. These
arguments appear to have merit, but instead of seeking dismissal of the relevant portion of Count 2,
defendants sought dismissal of all of Count 2 without addressing the many other regulations that appear

1 **B. Preemption**

2 Defendants argue that Count 2, which is based on an alleged failure to comply
3 with federal regulations regarding the manufacture, marketing, and sale of the Riata leads, is
4 preempted by the Medical Device Amendment of 1976 (“MDA”). The Ninth Circuit recently
5 addressed MDA preemption in Stengel v. Medtronic Inc., 704 F.3d 1224 (2013). Faced with
6 three hard-to-reconcile Supreme Court decisions,³ the Ninth Circuit concluded that a state
7 failure-to-warn claim based on a manufacturer’s failure to report adverse events to the FDA as
8 required by federal law was not predicated wholly on federal law (and therefore impliedly
9 preempted by 21 U.S.C. § 337(a)) and would not impose a state requirement that was “different
10 from, or in addition to” the federal requirements (and therefore expressly preempted by 21
11 U.S.C. § 360k). The court noted that Arizona tort law includes a cause of action for failure-to-
12 warn, and that such claims may be predicated on an alleged failure to notify a third party, such as
13 the FDA, if the information would likely reach those whose safety depends on the warning.
14 Stengel, 704 F.3d at 1233.⁴ Because the Stengels’ claim paralleled and did not add to a federal
15 requirement under the MDA, the failure-to-warn claim could proceed. The fact that the
16 underlying obligation to report adverse events to the FDA arose solely out of the Food, Drug,
17 and Cosmetic Act was not fatal to the Stengels’ claim.

18 The same result applies here. States have traditionally exercised their police
19 powers to protect the health and safety of their citizens, and Congress has not “clearly signaled

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21 to be directly applicable.

22 ³ The three cases are Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), Buckman Co. v. Plaintiffs’
23 Legal Comm., 531 U.S. 341 (2001), and Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

24 ⁴ The concurrence pointed out that, because the Stengels had to plead between the Scylla of
25 § 337(a) preemption and the Charybdis of § 360k preemption, they “face[d] a causation hurdle that
26 would not otherwise exist. To prevail, they will ultimately have to prove that if Medtronic had properly
reported the adverse events to the FDA as required under federal law, that information would have
reached Mr. Stengel’s doctors in time to prevent his injuries. . . . But at this juncture . . . the Stengels’
allegations of causation are adequate.” Stengel, 704 F.3d at 1234-35 (Watford, J., concurring).

1 its intent to deprive States of any role in protecting consumers from the dangers inherent in many
2 medical devices.” Stengel, 704 F.3d at 1231 (quoting Lohr, 518 U.S. at 486-87). Plaintiffs
3 allege that defendants breached their duty of care under the Washington Product Liability Act
4 and that the scope and nature of the duty owed is established by the listed federal regulations
5 (which were also incorporated into the Conditions of Approval for the product). Under
6 Washington tort law, a claim may, in appropriate circumstances, be based on a duty of care
7 established by an applicable statute or regulation. See Barrett v. Lucky Seven Saloon, Inc., 152
8 Wn.2d 259, 269 (2004) (applying Restatement (Second) of Torts § 286 (1965) when determining
9 whether a legislative enactment or administrative regulation provides the standard of conduct of
10 a reasonable man); Schooley v. Pinch’s Deli Market, Inc., 134 Wn.2d 468, 474-75 (1998)
11 (same).⁵ As was the case in Stengel, plaintiffs’ second cause of action specifically alleges a
12 violation of Washington law based on a failure to comply with federal regulations. Such a claim
13 parallels the underlying federal requirements and imposes no different or additional state
14 requirements: defendants’ preemption argument therefore fails.

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19 ⁵ Restatement (Second) of Torts § 286 (1965) provides:


20 The court may adopt as the standard of conduct of a reasonable man the requirements of
21 a legislative enactment or an administrative regulation whose purpose is found to be
22 exclusively or in part

- 23 (a) to protect a class of persons which includes the one whose interest is invaded, and
24 (b) to protect the particular interest which is invaded, and
25 (c) to protect that interest against the kind of harm which has resulted, and
26 (d) to protect that interest against the particular hazard for which the harm results.

It is at least arguable that many, if not all, of the regulatory requirements on which Count 2 is based were intended to protect the health and well-being of plaintiff and other consumers of medical devices against the type of hazards and harms plaintiff actually experienced.

1 For all of the foregoing reasons, defendants' motion to dismiss (Dkt. # 10) is
2 DENIED.

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4 DATED this 22nd day of November, 2013.

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7 Robert S. Lasnik
8 United States District Judge
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