In Re St. Jude Medical Device Litigation
SACV 13-383 JVS (AN)

*This Order Relates to the Lead Case and the Member Cases listed below:

Gene Knoppel, et al. v. St. Jude Medical, Inc., 8:13-CV-383 JVS (AN)
Terry Byerline, et al. v. St. Jude Medical Inc., et al., 2:13-CV-2186 JVS (AN)
Carlos Bueno, et al. v. St. Jude Medical Inc., et al., 2:13-CV-2393 JVS (AN)
Michael V. Thompson v. St. Jude Medical Inc, et al., 2:13-CV-2715 JVS (AN)
Rose Calise et al. v. St. Jude Medical Inc et al., 2:13-CV-06768 JVS (AN)

Tentative Order Denying Motions to Dismiss and
Tentative Order Granting in Part and Denying in Part Motion to Strike

Defendant St. Jude Medical, Inc. ("Defendant") moves this Court to dismiss claims asserted in the operative Complaints in the five member cases referenced above. Defendant also moves to strike language from each of the operative Complaints.[1] As set forth in detail below, the Court denies the Motions to Dismiss and grants in part and denies in part the Motions to Strike.

These consolidated actions arise out of injuries allegedly caused by a medical device manufacturing defect or defects. Familiarity with the Court's Dismissal Orders in the individual cases is presumed.

I. Legal Standards

A. Motion to Dismiss under Rule 12(b)(6) for Failure to State a Claim

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a defendant may move to dismiss for failure to state a claim upon which relief can be granted. A plaintiff must state "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). A claim has "facial

[1] All told, Defendant filed five Motions to Dismiss and five Motions to Strike. Timely Opposition and Reply briefs were filed as to four of the five cases. As to the fifth case, a timely Notice of Non-Opposition was filed, as was an amended pleading that moots the Motion to Dismiss and Motion to Strike in that case. Details regarding the present Motions, including docket references, are set forth in a chart attached hereto.

plausibility" if the plaintiff pleads facts that "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

In resolving a Rule 12(b)(6) motion under Twombly, the Court must follow a two-pronged approach. First, the Court must accept all well-pleaded factual allegations as true, but "[t]hread-bare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Iqbal, 556 U.S. at 678. Most succinctly stated, a pleading must set forth allegations that have "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. Courts "are not bound to accept as true a legal conclusion couched as a factual allegation." Id. (quoting Twombly, 550 U.S. at 555). "In keeping with these principles[,] a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." Iqbal, 556 U.S. at 679.

Second, assuming the veracity of well-pleaded factual allegations, the Court must "determine whether they plausibly give rise to an entitlement to relief." Id. This determination is context-specific, requiring the Court to draw on its experience and common sense, but there is no plausibility "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct." Id.

B. Motion to Strike Pursuant to Rule 12(f)

Pursuant to Rule 12(f) of the Federal Rules of Civil Procedure, a party may move to strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter. Fed. R. Civ. P. 12(f). The grounds for a motion to strike must appear on the face of the pleading under attack, or from matters of which the Court may take judicial notice. SEC v. Sands, 902 F. Supp. 1149, 1165 (C.D. Cal. 1995). The essential "function of a Rule 12(f) motion to strike is to avoid the expenditure of time and money that must arise from litigating spurious issues by dispensing with those issues prior to trial." Fantasy, Inc. v. Fogerty, 984 F.2d 1524, 1527 (9th Cir. 1993) (internal quotation marks and citation omitted). An "[i]mmaterial matter . . . has no essential or important relationship to the claim for relief or defenses being pleaded." Id. (internal quotation marks and citation omitted). An "[i]mpertinent matter consists of

statements that do not pertain, and are not necessary, to the issues in question." Id. (internal quotation marks and citation omitted).

II. Plaintiffs Knoppel and Hansen[2]

A. Background[3]

Knoppel alleges that on February 16, 2005, he was implanted with a defective Riata Lead identified as St. Jude Medical Riata Endocardial Ventricular Lead Model 1580, which is a model included in a Class I Recall issued by the United States Food and Drug Administration ("FDA"). (¶¶ 1, 4–5.)[4] The Riata Lead later had to be surgically extracted on December 22, 2011, after Knoppel suffered more than 60 electrical shocks caused by the defective lead. (Id.) Knoppel experienced approximately 9 electrical shocks from his ICD on May 2011, and experienced more than 50 electrical shocks in July 2011. (¶ 6.) His electrophysiologist referred Knoppel for extraction of the defective lead that was causing the electrical shocks. (Id.)

Plaintiffs allege that as a result of Defendant's defective lead, they suffered significant medical costs. (¶ 7.) Plaintiff Knoppel suffered significant pain and injury from the electric shocks and corrective surgery, and Plaintiff Hansen suffered loss of consortium. (Id.)

In the Second Amended Complaint ("SAC"), Plaintiffs assert several products liability claims against Defendant: (1) strict liability for manufacturing

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[2] Plaintiff Shari Hansen is Knoppel's spouse. (¶ 4.)

[3] The factual background in these cases includes Plaintiffs' factual allegations set forth in the Complaint, and documents of which the Court takes judicial notice. (See Def.'s Requests for Judicial Notice ("RJN") (Docket Nos. 51, 53, 55, 59) and Pltfs.' RJN (Docket No. 66).) Most notably, Plaintiffs rely on an Establishment Inspection Report, which is not attached to the operative Complaints. However, Defendant has proffered the report and has requested the Court judicially notice it. The Court may consider the contents of a document not attached to the complaint where the document's authenticity is not contested, and where the complaint necessarily relies on the document. Parrino v. FHP, Inc., 146 F.3d 699, 706 (9th Cir. 1998).

[4] Otherwise unspecified paragraph references are to the operative Complaint in each individual case.

defect; (2) strict liability failure to warn; (3) negligence for manufacturing defect; and (4) negligence per se. (¶¶ 100–120.)

In the previous Dismissal Order,[5] the Court found that Plaintiffs stated claims for negligence per se and for manufacturing defect under a strict liability and negligence theory, but that Plaintiffs' failure-to-warn claim was deficiently pled. Specifically, the Court observed that Plaintiffs failed to sufficiently allege that Defendant failed to comply with FDA regulations requiring it to report adverse events. (Dismissal Order at 7.) The Court also held that Plaintiffs failed to allege a causal connection between any failed warnings and Plaintiff's injuries. (Id.)

B. Motion to Dismiss

Defendant moves to dismiss Plaintiffs' second claim for strict liability failure to warn. The Court previously dismissed this claim as deficiently pled. (See Dismissal Order at 7 & n.5.) Defendant correctly discerns from the Court's Dismissal Order that to sufficiently plead this claim, Plaintiffs must cure three types of pleading deficiencies. First, Plaintiffs must allege that "Defendant was actually aware of adverse events involving insulation and abrasion events." (See Motion at 1, 4; Dismissal Order at 7.) Second, Plaintiffs must allege facts sufficient to establish that Defendant failed to comply with federal regulations requiring reporting of adverse events. (See Motion at 11; Dismissal Order at 7.) Finally, Plaintiffs must allege facts from which reasonable inferences may be drawn to suggest that if Defendant complied with the reporting requirements, then Plaintiff's doctors would have received that information and extracted the device before Plaintiff experienced the electrical shocks in July and December 2011, or in time to have refrained from implanting the device in the first instance in February 2005. (Motion at 15; Dismissal Order at 7 & n.5.)

As for the first pleading deficiency, most of Plaintiffs' arguments regarding Defendant's awareness are dependent upon the Court's acceptance of Plaintiffs' reliance upon an instance of device perforation of human tissue as "involving [an] insulation and abrasion event[.]" (See Opp'n at 5–7; cf. SAC ¶¶ 41–73.) The Court concludes that it would not be unreasonable to infer that a perforation event

[5] Prior to consolidation of the related cases, the Court issued separate Dismissal Orders. Docket references to the Court's Dismissal Orders are found on the attached chart.

was caused by an abrasion event. It is plausible that wires, implanted in the human body to conduct electrical impulses, when stripped of the insulation to contain and isolate the electrical current, could cause tissue perforation, whether as a result of the escaping electrical current or the escaping wires themselves. Indeed, Plaintiffs make reference in their allegations regarding "externalization," that is, when "the lead wires protrude through the insulation, causing them to be in contact with materials and fluids." (¶ 76.) Thus, Plaintiffs' allegations regarding Defendant's knowledge of complaints regarding perforation sufficiently allege Defendant's awareness of adverse events involving insulation and abrasion events.

In curing the second and third pleading deficiencies, Plaintiffs rely heavily upon the results of an inspection conducted by the FDA in June 2009, which examined complaints regarding the Riata Leads and another similar device. (See ¶¶ 41-55; RJN Ex. A (Docket No. 59-4) (FDA Establishment Inspection Report ("EIR")).) "The . . . inspection focused on Design Control and Corrective and Preventative actions related to perforations with the Riata and Durata family of leads[.]" (Id. at 1, 5.) As part of the inspection, the FDA was provided with a spreadsheet for all complaints received by Defendants from 2002 through the date of the inspection. (Id. at 5.) Comparison with the FDA adverse event database revealed only 3,289 Medical Device Reports ("MDRs") for the same time period. (Id.)

From that spreadsheet, the FDA analyzed perforation reports as compared to total complaints, year-by-year, for 2005 to 2009 (partial year). (Id. at 6 (graph).) Identified perforation events were 2% in 2002, growing to 8% in 2008. (Id.)

As part of the inspection, the FDA made an overall "Observation" that "[a]n MDR report submitted to the FDA did not include all information that was reasonably known to the manufacturer." (Id. at 17 (citing eight specific examples).) Significantly, review of a number of complaint files revealed although the complainants reported adverse events as "perforations," those events were not reported as "perforations" to the FDA. (Id.) Moreover, the FDA identified two instances of known perforation events that, without any explanation, were reported to the FDA a number of years after they were required to be reported. (Id. at 18.)

Thus, the 2009 inspection revealed specific incidents of the failure to report adverse perforation events, that complaints based on perforation events were received by Defendant as early as 2003 and 2004, and that by 2005, 2% of all

complaints were related to identified perforation events. Subsequent inspections revealed that perforation events described in medical literature were not reported to the FDA. (¶ 50.) The FDA also identified problems with accurate reporting of rates of occurrence based on erroneous calculations and/or misclassification of contributing causes. (¶¶ 51-55.)

Taken together, these allegations support inferences regarding Defendant's knowledge of adverse events as well as the reasonable inference that more accurate and timely reporting of adverse events, especially of perforation events, could have led Knoppel's physicians to forego the implantation of a Riata Lead in in Knoppel in 2005.

Additionally, Plaintiffs sufficiently allege Defendant's awareness of adverse events expressly related to abrasion problems. (¶¶ 59–60.) Specifically, Plaintiffs allege that three physicians reported incidents of abrasion to Defendant between 2006 and 2009. (¶ 59.)

Thus, Plaintiffs have cured the first pleading deficiency.

They have likewise cured the second pleading deficiency. Plaintiffs allege numerous reporting deficiencies as noted by the FDA in their inspections. (See generally ¶¶ 41–73.) Specifically, Plaintiffs allege that an FDA inspection resulted in a finding that Defendant failed to submit Medical Device Reporting determinations, and a finding that Defendant failed to comply with review and evaluation requirements. (¶¶ 42–43, 49; see also ¶ 50 (finding no evidence Defendants submitted reports of the perforation events that occurred between 2007 and 2009).) Moreover, Plaintiffs allege that the FDA found that Defendant limited the definition of abrasion to externalized cables, thus excluding events related to exposed cables or other forms of abrasion, thus leading to underestimation of the actual rate of occurrence. (¶ 51.)

Plaintiffs have also cured their third pleading deficiency, related to causation. Plaintiffs have made factual allegations that support an inference that had Defendant fully complied with the regulatory reporting requirements,

Knoppel's physicians would have refrained from implanting the Riata lead in the first instance in February 2005.[6]

Accordingly, the Court finds that Plaintiffs have cured the pleading deficiencies identified by the Dismissal Order, and the Court therefore denies the Motion to Dismiss.

C. Motion to Strike

Defendant moves to strike portions of the SAC falling into two categories. First, Defendant moves to strike all references to Pacesetter, Inc. ("Pacesetter") because Plaintiffs did not seek leave to amend to add Pacesetter as a Defendant. Second, Defendant moves to strike a number of allegations related to design and design defect.

1. Pacesetter

In the Dismissal Order the Court noted that Plaintiffs attempted to assert claims against a new Defendant, Pacesetter, but that Plaintiffs had not sought leave to amend to add Pacesetter. (Dismissal Order at 1 n.1.) The Court further noted that joinder would defeat the Court's diversity jurisdiction. As suggested in the Dismissal Order, Plaintiffs must first seek leave of Court before Pacesetter may be joined.

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[6] The Court previously noted that Plaintiffs' pleading burden could also be met if the allegations supported the inference that had Defendant fully complied with its regulatory reporting requirements, Plaintiff Knoppel's physicians would have extracted the device before Plaintiff experienced the electrical shocks in July and December 2011. (Dismissal Order at 7 & n.5.) Since that time, further briefing by Defendant has convinced the Court that a strict liability failure-to-warn claim has a temporal limitation, and such a claim must be based on a failure to warn at the time of the device's sale. See, e.g., Carlin v. Superior Court, 13 Cal. 4th 1104, 1111–12 (1996) (rejecting a strict liability failure-to-warn claim where the defect was "unknown or unknowable" at the time of manufacture or distribution); Rosa v. Taser Int'l, Inc., 684 F.3d 941, 949 (9th Cir. 2012) (applying California law and distinguishing a strict liability failure-to-warn claim, which is limited to the "time a product [is] distributed," from a negligent failure-to-warn claim, which may include liability "for failure to warn of a risk that [is] subsequently discovered.").

Generally, at an early stage of an action, the burden in obtaining leave is not great, but in this instance leave must be sought by filing a Motion for Leave to Amend the Complaint. See Fed. R. Civ. P. 15(a)(2). However, the inquiry of whether to grant leave in this instance would be complicated by the fact that Pacesetter's citizenship could divest the Court of its diversity jurisdiction.[7] See 28 U.S.C. § 1447(e) (identifying two options for district courts when non-diverse defendants are joined in a diversity case); Morris v. Princess Cruises, Inc., 236 F.3d 1061, 1068–69 (9th Cir. 2001) (noting that § 1447(e) authorizes district courts to deny joinder or to permit joinder and order remand); Bonner v. Fuji Photo Film, 461 F. Supp. 2d 1112, 1119–20 (N.D. Cal. 2006) (identifying six discretionary factors district courts should consider in deciding whether to permit joinder); Boon v. Allstate Ins. Co., 229 F. Supp. 2d 1016, 1119–20 (C.D. Cal. 2002) (same); Hardin v. Wal-Mart Stores, Inc., 813 F. Supp. 2d 1167, 1173–74 (E.D. Cal. 2011) (identifying nine factors).

Because Pacesetter is not a Defendant to this action, the Court strikes all references to Pacesetter.

2. Design Defects

The parties understand that claims may not be premised on design defects as any such state law claims are preempted. (See Motion at 2; Opp'n at 2.) Instead, Plaintiffs may assert claims only for manufacturing defects. Therefore, Defendant moves to strike from the SAC multiple allegations related to its design changes and processes. Specifically, Defendant moves to strike all or portions of paragraphs 56, 62, 64(c), (e)–(h), 66, 68–69, 71–73, and 117.

Plaintiffs respond that manufacturing defect claims implicate design issues because manufacturing defects occur when products are manufactured in a manner that is inconsistent with the product design. (Opp'n at 2–3.) See also Barker v. Lull Eng'g Co., 20 Cal.3d 413, 429, 143 Cal.Rptr. 225, 573 P.2d 443 (1978) (defining a product with a manufacturing defect as "one that differs from the

[7] The Court's observation that joinder of Pacesetter to this action would destroy diversity jurisdiction was not and is not intended to suggest that such joinder is foreclosed without further consideration. (Dismissal Order at 1 n.1.) Instead, whether Pacesetter should be joined to this action, and what effect such joinder would have, are inquiries that are best undertaken after full briefing by the parties.

manufacturer's intended result or from other ostensibly identical units of the same product line").

Defendant argues that many regulations cited by Plaintiffs in the SAC are irrelevant.[8] A discussion of those regulations, found in four parts of Title 21, Chapter I, Subchapter H of the Code of Federal Regulations,[9] is therefore in order before the Court rules on Defendant's specific requests for relief.

First, Defendant challenges references to part 814. "This part implements [a section of the Federal Food, Drug, and Cosmetic Act] by providing procedures for the premarket approval of medical devices intended for human use." 21 C.F.R. § 814.1. With the exception of Subpart E, related to post-approval requirements, the pre-market approval of medical devices relates to their design rather than their manufacturer. Thus, part 814 is largely irrelevant. However, Subpart E, comprised of §§ 814.80 through .84, imposes certain postapproval requirements that can implicate manufacturing issues. See, e.g., § 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.") Therefore, references to Subpart E are not irrelevant to Plaintiffs' claims.

The second and third parts, Parts 803 and 806, are best discussed together. Part 803 "establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors." 21 C.F.R. § 803.1(a). One requirement is for manufacturers to submit reports (described in §§ 803.50–.56) "of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction." 21 C.F.R. § 803.10(c). These reports are not limited to instances in which the reportable

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[8] Defendant does so in the context of limiting the bases for its negligence per se claim. (Motion at 6–7.) Negligence per se is based on "the rule that a presumption of negligence arises from the violation of a statute which was enacted to protect a class of persons of which the plaintiff is a member against the type of harm that the plaintiff suffered as a result of the violation." Quiroz v. Seventh Ave. Center, 140 Cal.App.4th 1256, 1285 (2006).

[9] Title 21 relates to "Food and Drugs," Chapter I relates to the "Food and Drug Administration," and Subchapter H regulates "Medical Devices."

incident is due to a design defect; thus, it is possible that such reports would relate to manufacturing defects.

Similarly, Part 806 also "establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors." 21 C.F.R. § 806.1(a). One requirement is that manufacturers report "correction[s] or removal[s] of . . . device[s] initiated by such manufacturer . . . if the correction or removal [is] initiated . . . [t]o reduce a risk to health posed by the device." 21 C.F.R. § 806.10(a)(1); see also 806.2 (defining "correction" and "removal"). Like the reports mandated by Part 803, these reports are not limited to instances in which the reportable incident is due to a design defect; thus, it is possible that such reports would relate to manufacturing defects.

The role of the failure to report is discussed at length *supra* II.B. Therefore, the Court concludes that references to Parts 803 and 806 are relevant to Plaintiffs' claims.

As for the fourth part, Part 820, its relevance to Plaintiffs' claims is clear. Part 820 is a "quality system regulation" that sets forth "[c]urrent good manufacturing practice (CGMP) requirements [that] govern the methods used in, and the facilities and controls used for, the design, *manufacture*, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a) (emphasis added). Moreover, one requirement of Part 820 is that manufacturers "establish and maintain procedures for implementing corrective and preventive action" in order to "identify existing and potential causes of nonconforming product[s.]" 21 C.F.R. § 820.100(a)(1). Those procedures require, *inter alia*, "[a]nalyzing processes, work operations, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data." Id. In the Court's view, this provision makes relevant to manufacturing defect claims broad categories of a manufacturer's operations and processes.

In accordance with these more general principles, the Court rules as follows: The Court denies the Motion to Strike as to 56, 62, 64(c) and (e)–(h), 66, 68–69, and 71–73. The conclusions drawn by the FDA regarding Defendant's reporting and processes, although not conclusive, are also not completely irrelevant to

Plaintiffs' claims.[10] The Court grants in part and denies in part the Motion to Strike paragraph 117. The Court strikes references to the following sections of Part 814: .1, .3, .9, .20, .37, and .39. The Motion to Strike the remainder of paragraph 117 is denied.

III. Plaintiffs Terry and Sherry Byerline[11]

A. Background

Plaintiff Terry Byerline alleges that he was implanted with a Riata Lead Model 1580/65 on December 22, 2005. (¶ 67.) On April 12, 2012, Terry Byerline first learned from his physician that his Riata Lead was failing, and underwent invasive surgery to remove and replace the defective Riata Lead four days later on April 16. (¶¶ 68–69.) He claims that he was injured as a result of the defective lead. (Id. ¶ 70.)

In the FAC, Plaintiffs assert several products liability claims against Defendants: (1) strict liability for manufacturing defect; (2) negligence in manufacturing; (3) negligence per se; (4) failure to warn; and (5) loss of consortium. (Id. ¶¶ 71–95.)

In the previous Dismissal Order, the Court found that Plaintiffs stated claims for negligence per se and for manufacturing defect under a strict liability and negligence theory, but that Plaintiffs' failure-to-warn claim was deficiently pled. Specifically, the Court observed that Plaintiffs' allegations were deficient on the same bases as were the allegations made by Plaintiff Knoppel. (Dismissal Order at 11.)

[10] Paragraph 71 does not fit within this rationale, but paragraph 71 provides background to paragraphs 72–73.

[11] Plaintiff Sherry Byerline is Terry Byerline's spouse. (¶ 94.)

B. Motion to Dismiss

Although Plaintiff Byerline is a resident of Kentucky, after considering arguments from the parties and application of choice of law principles, the Court previously determined that the law of California applies. (Dismissal Order at 6–7.)

Defendant moves to dismiss Plaintiffs' fourth claim for failure to warn. The Court previously dismissed this claim as deficiently pled. (See Dismissal Order at 10–12.) Consideration of Plaintiff Byerline's claims parallels consideration of Plaintiff Knoppel's claims. They are governed by California law, they are based on almost identical factual allegations, and their Riata Leads were both implanted in 2005 and removed in 2012.

As did Knoppel, Byerline relies on Defendant's awareness of events of device perforation of human tissue as being sufficiently related to insulation and abrasion events. (See Opp'n at 3–6.) As noted above, the Court concludes that it would not be unreasonable to infer that a perforation event was caused by an abrasion event. Notably, Byerline alleges the same danger caused by "externalization" as does Knoppel. (¶ 46.) Thus, Byerline's allegations regarding Defendant's knowledge of complaints regarding perforation sufficiently allege Defendant's awareness of adverse events involving insulation and abrasion events.

Like Knoppel, Byerline has also alleged numerous reporting deficiencies as noted by the FDA in their inspections; thus, he sufficiently alleges a failure to report. (See generally ¶¶ 44–73.) Finally, Byerline makes the same allegations as does Knoppel regarding causation, which the Court finds to be sufficiently pled.

Thus, the Court denies the Motion to Dismiss.

C. Motion to Strike

In accordance with the discussion set forth above regarding the Motion to Strike portions of Knoppel's SAC, the Court rules as follows on the Motion to Strike portions of Byerline's FAC: The Court denies the Motion to Strike as to paragraphs 64, 66(c) and (e)–(g), 68, 70, 71, and 73. The conclusions drawn by the FDA regarding Defendant's reporting and processes, although not conclusive, are

also not completely irrelevant to Plaintiffs' claims.[12] The Court grants in part and denies in part the Motion to Strike paragraph 82. The Court strikes references to the following sections of Part 814: .1, .3, .9, .20, .37, and .39. The Motion to Strike the remainder of paragraph 82 is denied.

IV. Plaintiff Michael V. Thompson

A. Background

Plaintiff Michael Thompson alleges that he was implanted with a Riata Lead Model 1580 in 2004, and that on April 19, 2012, his physician advised him that his Riata Lead was failing and that his lead needed to be replaced. (¶ 8.) On June 18, 2012, Plaintiff's defective Riata Lead was removed via laser abstraction. (¶ 9.) Plaintiff alleges that he has suffered injury as a result of the lead's defects, including damages relating to multiple fluoroscopy procedures, extrusion of the conductor, compromised lead insulation, increased lead impedance, and electrical abnormalities in his Riata Lead resulting in invasive and dangerous laser extraction surgery. (¶¶ 1, 10.)

In the FAC, Plaintiffs assert several products liability claims against Defendants: (1) strict liability for the manufacturing defect; (2) negligence in manufacturing; (3) negligence per se; (4) negligence *res ipsa loquitur*; and (5) negligent failure-to-warn. (Compl. ¶¶ 88–115.)

In the previous Dismissal Order, the Court found that Plaintiff stated claims for negligence per se and for manufacturing defect under a strict liability and negligence theories, but that Plaintiff's failure-to-warn claim was deficiently pled. Specifically, the Court observed that Plaintiffs' allegations were deficient on the same bases as were the allegations made by Plaintiff Knoppel.

B. Motion to Dismiss

Defendant moves to dismiss Plaintiff's claim for negligent failure to warn.

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[12] Paragraph 73 does not fit within this rationale, but it provides background to other allegations.

As do Knoppel and Byerline, Thompson relies on Defendant's awareness of events of device perforation of human tissue as being sufficiently related to insulation and abrasion events. (See Opp'n at 3–5.) As noted, the Court concludes that it would not be unreasonable to infer that a perforation event was caused by an abrasion event. Notably, Thompson alleges the same danger caused by "externalization" as do Knoppel and Byerline. (¶ 80.) Thus, Thompson's allegations regarding Defendant's knowledge of complaints regarding perforation sufficiently allege Defendant's awareness of adverse events involving insulation and abrasion events.

Like Knoppel and Byerline, Thompson has also alleged numerous reporting deficiencies as noted by the FDA in their inspections; thus, he sufficiently alleges a failure to report. (See generally ¶¶ 41–71.) Finally, Thompson makes the same allegations as do Knoppel and Byerline regarding causation, which the Court finds to be sufficiently pled.

Thus, the Court denies the Motion to Dismiss as to Thompson's negligent failure-to-warn claim.

C. Motion to Strike

In accordance with the discussion set forth above regarding the Motion to Strike portions of Knoppel's SAC, the Court rules as follows on the Motion to Strike portions of Thompson's FAC: The Court denies the Motion to Strike as to paragraphs 61, 63(c) and (e)–(g), 65, 67–68, 70–71, and 73. The conclusions drawn by the FDA regarding Defendant's reporting and processes, although not conclusive, are also not completely irrelevant to Plaintiffs' claims.[13] The Court grants in part and denies in part the Motion to Strike paragraph 112. The Court strikes references to the following sections of Part 814: .1, .3, .9, .20, .37, and .39. The Motion to Strike the remainder of paragraph 112 is denied.

[13] Paragraph 70 does not fit within this rationale, but it provides background to other allegations.

V. Plaintiffs Bueno and Craft

A. Background

Plaintiff Bueno was implanted with a Riata Lead identified as "7000/65" in July 2006; it was removed on September 3, 2013. (¶ 8.) Plaintiff Craft was implanted with a Riata Lead identified as "1580" in June 2005; it was removed on December 12, 2012. (Id.) Plaintiffs allege that they have suffered injury and damages as a result of the defects in the Riata Leads. (¶ 11.)

Specifically, Plaintiff Bueno alleges he has suffered physical pain, mental anguish, and loss of income as a result of the implantation of the device, including surgical opening of his body, suturing, scarring, shortness of breath, pain, and discomfort. (¶ 12.) He was required to take medications as a result of the device's implantation, which has led to insomnia and the inability to work. (¶¶ 11–14.) The recall of the device led to mental anguish and fear, and the removal procedure caused pain and suffering similar to those associated with the implantation procedure. (¶¶ 15–18.) Plaintiff Craft suffered similar injuries. (¶¶ 19–25.)

Plaintiffs assert several product liability claims against Defendants: (1) strict liability for manufacturing defect; (2) negligence in manufacturing; (3) negligent failure to warn; and (4) strict product liability failure to warn. (Id. ¶¶ 155–81.)

In the previous Dismissal Order, the Court found that Plaintiffs claims were deficiently pled because they failed to make non-conclusory allegations regarding the nature of their injuries, and because they failed to allege a sufficient causal nexus between the alleged defects and their injuries.

B. Motion to Dismiss

1. Previous Pleading Deficiencies

Defendant moves to dismiss Plaintiffs' claims for negligent and strict liability failure to warn.

As discussed, the Court finds relevant Defendant's awareness of events of device perforation of human tissue because it is sufficiently related to insulation and abrasion events. As noted, the Court concludes that it would not be unreasonable to infer that a perforation event was caused by an abrasion event. Bueno and Craft make the same allegations regarding the danger caused by "externalization" as do the other Plaintiffs. (¶ 64.) Thus, Bueno and Craft have sufficiently pled Defendant's awareness of adverse events.

Additionally, Bueno and Craft have alleged numerous reporting deficiencies as noted by the FDA in their inspections. (See generally ¶¶ 101–154.)

Bueno and Craft have also sufficiently alleged causation as their failure-to-warn claim. (See, e.g., 106–07 109–110, 114, 117–118.)

Thus, the Court denies the Motion to Dismiss.

2. Preemption

Defendant contends that a number of Plaintiffs' claims are preempted. Specifically, Defendant contends that Plaintiffs attempt to assert fraud-on-the-FDA claims (Motion at 20–22), claims based on inadequate manuals, labeling, and user instructions (id. at 22–23), and a claim based on the failure to disclose alternative designs (id. at 23–24), all of which are preempted. For their part, Plaintiffs disavow any intention of asserting such claims. (Opp'n at 6 n.3, 17–18, 23–25.)

The Court has elsewhere in these consolidated cases discussed the California state-law claims that escape preemption. (See, e.g., Knoppel Dismissal Order at 9–11.) As noted, "a plaintiff may avoid preemption by stating claims that parallel federal requirements or that are premised on a violation of FDA regulations." (Id. at 10.)

Here, the Court notes that the allegations to which Defendant points in support of its assertion that Plaintiffs attempt to assert preempted claims provide general support to Plaintiffs' (non-preempted) state-law negligent failure-to-warn claim. (See ¶¶ 140–153.) Generally speaking, factual allegations of regarding "who knew what when" are highly relevant to a failure-to-warn claim. More specifically, what Defendant knew about the Riata Leads, and more particularly, what

Defendant knew about the performance of Riata Leads' insulation, as well as when Defendant knew those facts, is directly relevant to Plaintiffs' claims. Also relevant to a failure-to-warn claim are allegations regarding what was disclosed by Defendant about the leads, and to whom those disclosures were made. Allegations regarding Defendant's improvements to the design of the leads may be relevant to their knowledge of the leads' performance as well.[14]

As set forth, the Court does not find that Plaintiffs' claims are preempted. Therefore, the Court denies the Motion to Dismiss to the extent it is premised on this argument.

C. Motion to Strike

In accordance with the discussion set forth above regarding the Motion to Strike portions of Knoppel's SAC, the Court rules as follows on the Motion to Strike portions of Bueno and Craft's FAC: The Court denies the Motion to Strike as to paragraphs 70, 83, 120, 125, 127–30, 132, 134–35, and 137–38.[15] The Court grants in part and denies in part the Motion to Strike paragraph 166. The Court strikes references to the following sections of Part 814: .1, .3, .9, .20, .37, and .39. The Motion to Strike the remainder of paragraph 166 is denied.

VI. Plaintiffs Paul and Rose Calise

Plaintiffs Paul Calise and Rose Calise individually, and Rose Calise as the Representative of the Estate of Daniel Calise, allege that Daniel Calise was implanted with a Riata Lead Model 1580-65 on December 13, 2005. (¶ 6.) On September 6, 2011, Daniel Calise suffered cardiopulmonary arrest and died, allegedly as a result of the failure of his Riata Lead. (¶ 6.) After Daniel Calise's death, the Riata Lead was found to be abraded and Plaintiffs allege that it

[14] As noted, and as understood by the parties, claims predicated on design defects are preempted. Nevertheless, design issues are not wholly irrelevant regarding the existence of a manufacturing defect, and design issues are not wholly irrelevant to a manufacturer's knowledge of adverse performance that could be attributable to manufacturing defects.

[15] Paragraph 137 does not fit within the rationale previously noted by the Court, but it provides background to other allegations.

malfunctioned as a result of the abrasion. (¶ 100.)

As noted previously, the Motion to Dismiss and Motion to Strike are denied as moot in light of the filing of the First Amended Complaint. (See Docket No. 27.)

VII. Conclusion

As set forth herein, the Court denies the Motions to Dismiss and grants in part and denies in part the Motions to Strike.

IT IS SO ORDERED.

ATTACHMENT A

Docket References In Re: St. Jude Medical Devices Litigation					
Plaintiff(s) and Case Number	**Previous Dismissal Order[1]**	**Operative Complaint**	**Motion**	**Opposition**	**Reply**
Knoppel, SACV 13-00383 JVS (AN)	39	SAC 46	Dismiss 59 Strike 60	Dismiss 73 Strike 74	Dismiss 81 Strike 82
Byerline, CV13-02186 JVS (AN)	42	FAC 47	Dismiss 53 Strike 54	Dismiss 67 Strike 68	Dismiss 77 Strike 78
Bueno, CV13-02393 JVS (AN)	39	FAC 46	Dismiss 55 Strike 56	Dismiss 66 Strike 65	Dismiss 75 Strike 76
Thompson, CV13-02715 JVS (AN)	43	FAC 48	Dismiss 51 Strike 52	Dismiss 72 Strike 71	Dismiss 79 Strike 80
Calise, CV13-06768 JVS (AN)	N/A	FAC 27	Dismiss 57 Strike 58	Dismiss 70 Strike 69	N/A
Dobner, CV 13-07958 JVS (AN)	N/A	Complaint 1	N/A	N/A	N/A

[1] All docket numbers for the dismissal Orders and the operative Complaints refer to the docket of each individual case number. All other docket numbers refer to the docket of the lead case, although the present Motions are filed on each individual docket as well.