I. FACTUAL ALLEGATIONS AND PROCEDURAL BACKGROUND

This action arises from a medical device that was surgically implanted in Plaintiff's leg. The FAC alleges that a portion of Plaintiff's left femur was removed due to sarcoma and replaced with femoral endoprothesis (a femoral stem and jointed pieces), in December 1994. Am. Compl., ¶ 11. Plaintiff alleges that the femoral endoprothesis was Defendants' product, and was dangerous and defective when it was inserted into Plaintiff's femur. Compl., \P 12. Plaintiff was 15 at the time of the surgery. The FAC alleges that despite Defendants' Compl., ¶ 11. representations to Plaintiff, Plaintiff's physician and Plaintiff's parents that the product was of superior quality and would last for Plaintiff's lifetime, the product failed and broke in February 2010, causing injury and necessitating surgery to replace portions of the product that broke. Am. Compl., ¶ 13. The FAC contains three claims against Defendants for Strict Liability, Negligence and Breach of Warranty. Plaintiff seeks general damages, medical expenses and lost wages. Defendants move to dismiss the FAC in its entirety. Defendants contend that the FAC does not meet federal pleading standards and pleads claims that are unavailable under California law.

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II. OPINION

A. Legal Standard

A party may move to dismiss an action for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6). In considering a motion to dismiss, the court must accept the allegations in the complaint as true and draw

all reasonable inferences in favor of the plaintiff. Scheuer v. Rhodes, 416 U.S. 232, 236 (1975), overruled on other grounds by Davis v. Scherer, 468 U.S. 183 (1984); Cruz v. Beto, 405 U.S. 319, 322 (1972). Assertions that are mere "legal conclusions," however, are not entitled to the assumption of truth. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1950 (2009), (citing Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007)). To survive a motion to dismiss, a plaintiff needs to plead "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570. Dismissal is appropriate where the plaintiff fails to state a claim supportable by a cognizable legal theory. Balistreri v. Pacifica Police Department, 901 F.2d 696, 699 (9th Cir. 1990).

Upon granting a motion to dismiss for failure to state a claim, the court has discretion to allow leave to amend the complaint pursuant to Federal Rule of Civil Procedure 15(a). "Dismissal with prejudice and without leave to amend is not appropriate unless it is clear . . . that the complaint could not be saved by amendment." <u>Eminence Capital</u>, L.L.C. v. Aspeon, Inc., 316 F.3d 1048, 1052 (9th Cir. 2003).

B. Claims for Relief

1. Strict Liability, First Claim for Relief

The FAC alleges that Defendants designed, researched, formulated, tested, inspected, manufactured, produced, created, assembled, prepared, packaged, labeled, supplied, distributed, marketed, and/or sold the femoral stem product in a defective and dangerous condition. Am. Compl., \P 17. The FAC alleges that the product was defective and dangerous because it did not perform as anticipated and broke into pieces. <u>Id.</u> Plaintiff alleges that he

sustained both physical and emotional injury, incurred medical expenses, and was unable to work in his usual occupation. Am. Compl., ¶¶ 19-21. Defendants argue that these allegations fail to state a claim because they do not differentiate between Stryker, Howmedica and Stryker Sales Corporation (not a party to this motion) and they fail to state how the product is defective. Further, to the extent that Plaintiff is attempting to assert a design defect claim, Defendants contend that such a claim is unavailable against manufacturers of medical implant devices.

California recognizes three theories of product liability: design defect, manufacturing defect, and failure to warn. Yalter v. Endocare, 2004 WL 5237598 at *3 (C.D. Cal. Nov. 8, 2004). The first claim in the FAC is captioned "strict liability" and does not indicate if Plaintiff is attempting to bring a products liability claim for design defect, manufacturing defect, or both.

Accordingly, the Court will discuss both the design defect and manufacturing defect theories. The FAC does not contain any allegations of failure to warn, accordingly it does not appear that the "strict liability" claim is based on a failure to warn theory.

Under the manufacturing defect theory, generally a manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line. <u>Lucas v. City of Visalia</u>, 726 F.Supp.2d 1149, 1154 (E.D. Cal. 2010) (internal citations omitted). The manufacturing defect theory posits that a suitable design is in place, but that the manufacturing process has in some way deviated from that design. <u>Id.</u>

California law prohibits strict liability claims for design defect against manufacturers of prescription implantable medical devices. See e.g. Hufft v. Horowitz, 4 Cal.App.4th 8,19-20(1992) (holding that a manufacturer is not strictly liable for injuries caused by an implanted prescription medical product which has been (1) properly made and (2) distributed with information regarding risks and dangers of which the manufacturer knew or should have known at the time); Rhynes v. Stryker Corp., 2011 WL 2149095 (N.D. Cal. May 31, 2011) (striking medical implant strict liability design defect allegations because the barred by California law), Adams v. I-Flow Corp., 2010 WL 1339948, *8 (C.D. Cal. Mar. 30,2010) (same). Plaintiff argues, without citation to authority, that this rule does not apply to the implanted medical device at issue in this case, because it is not alleged to be inherently dangerous. However, given the bright line rule set forth in Hufft and recognized by California courts and federal courts, Plaintiff's argument is not persuasive.

Here, the allegations of the FAC are simply too vague and conclusory to state a claim for strict products liability. To the extent that Plaintiff's claim rests on the manufacturing defect theory, the FAC does not contain allegations of how the femoral stem product deviated from the manufacturer's original design or from other seemingly identical models. See Lucas, supra, at 1155. To the extent that Plaintiff's claim rests on the design defect theory, such a claim is prohibited under California law. See Rhynes, supra. Finally, since no facts are alleged regarding failure to warn, Plaintiff's strict liability claim cannot rest on that theory. Accordingly, the strict liability claim is dismissed,

with leave to amend to state a claim for manufacturing defect.

2. Negligence, Second Claim for Relief

The FAC alleges that Defendants negligently designed, researched, formulated, tested, inspected, manufactured, produced, created, assembled, prepared, packaged, labeled, supplied, distributed, marketed, and/or sold the femoral stem product, so that the product failed. Am. Compl. ¶ 25. The FAC alleges that Defendants' negligence resulted in the product not being fit for its intended use. Id. Plaintiff alleges he suffered injury, incurred medical expenses, and was unable to attend to his usual occupation, due to Defendants' negligence. Am. Compl. ¶¶ 26-28.

As Plaintiff noted in his opposition to the motion to dismiss, Defendants did not address the negligence claim. Though Defendants' Reply brief asserts that "Defendants have moved to dismiss Plaintiff's entire product liability claim, in other words, his entire complaint (which includes the strict liability, negligence and warranty claims), based on the failure to meet the requisite pleading standards," Reply, p. 3, the motion to dismiss does not discuss the negligence claim. The motion to dismiss does not set forth the elements that must be plead to state a claim for negligence, does not argue how the allegations of the FAC fail to plead the necessary elements, and does not set forth any other theory for dismissal of the negligence claim. Accordingly, the motion to dismiss the negligence claim is DENIED.

3. Breach of Warranty, Third Claim for Relief

The FAC alleges that Defendants expressly and impliedly warranted and/or represented to Plaintiff's physician and to Plaintiff, that the femoral stem product was of superior quality

and would last for Plaintiff's lifetime, Am. Compl., ¶ 13, that the product was of good and merchantable quality, and that the product was fit and safe for its ordinary, intended use, Am. Compl., ¶ 31, including the use for which it was used in Plaintiff. Id.

However, the FAC alleges that the product was defective; therefore, it did not conform to Defendants' warranties and/or representations. Am. Compl., ¶ 32. Defendants argue that Plaintiff does not state a claim for breach of warranty because of a lack of privity between Plaintiff and Defendants.

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To plead a cause of action for breach of express warranty, one must allege the exact terms of the warranty, plaintiff's reasonable reliance thereon, and a breach which proximately caused plaintiff injury. Williams v. Beechnut Nutrition Corp., 185 Cal.App.3d 135, 142 (1986). As a general rule, privity of contract is required in an action for breach of either express or implied warranty, and there is no privity between the original seller and a subsequent purchaser who is in no way a party to the original sale. All West Electronics, Inc. v. M-B-W-, Inc., 64 Cal.App.4th 717, 725 (1998) (citing cases). In the implantable medical product context, a patient lacks the privity required to establish a claim for breach of implied warranty. Blanco v. Baxter Healthcare Corp., 158 Cal.App.4th 1039, 1058-59 (2008). See also Adams, 2010 WL 1339948 at *4 (dismissing breach of warranty claim with prejudice, because the complaint was devoid of facts suggesting that plaintiffs relied upon anything other than their physician's skill and judgment in selecting and prescribing the anesthetics and pain pumps); Evraets v. Intermedics Intraocular, Inc., 29 Cal.App.4th 779,788 (1994) (same).

Here, Plaintiff's vague allegations that unidentified "Defendants" made unspecified "representations" to Plaintiff, Plaintiff's parents and Plaintiff's physician are insufficient to state a claim for breach of warranty. Moreover, the FAC is devoid of allegations that Plaintiff relied on the representations that were allegedly made. Because this is a medical implant case, and the FAC alleges that the product was surgically inserted in a hospital, the Court cannot plausibly infer from the FAC that Plaintiff relied on anything other than his physician's skill and judgment in selecting the femoral stem product, nor that any purchase of the product was based on a warranty from the manufacturer to Plaintiff. See Adams, 2010 WL 1339948 at *4. Court cannot plausibly infer that there is a relationship between the Defendants and Plaintiff that would allow Plaintiff to state a breach of warranty claim. See Id. Accordingly, the breach of warranty claim is DISMISSED, WITH PREJUDICE.

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III. ORDER

Defendants' motion to dismiss the FAC is GRANTED in part and DENIED in part, as set forth below:

- 1. The motion to dismiss the first claim for relief for strict liability is GRANTED. The allegations of design defect are dismissed, with prejudice. Plaintiff is given leave to amend the allegations of manufacturing defect.
- 2. The motion to dismiss the second claim for relief for negligence is DENIED.
- 3. The motion to dismiss the third claim for relief for breach of warranty is GRANTED. The breach of warranty claim is

dismissed, with prejudice.

Plaintiff is ordered to file a Second Amended Complaint within twenty-one (21) days of the date of this order.

IT IS SO ORDERED.

Dated: October 12, 2011

JOHN A. MENDEZ, UNITED STATES DISTRICT JUDGE