UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

FREDERICK B. NIMTZ, Plaintiff, v. DANIEL CEPIN, M.D., *et al.*, Defendants.	Civil No. 08cv1294 L(AJB) **ORDER GRANTING WITHOUT PREJUDICE DEFENDANT GUIDANT LLC'S MOTION TO DISMISS; DENYING MOTION TO STRIKE FAILURE TO WARN [doc. #18]; GRANTING LEAVE TO AMEND THE COMPLAINT**

Defendant Guidant LLC ("Guidant") moves to dismiss *pro se* plaintiff's complaint or alternatively to strike portions of the complaint. Plaintiff requested and was granted several extensions of time in which to oppose defendant's motion. On February 28, 2011, plaintiff filed his opposition to defendant's motion.[1]

[1] Although plaintiff is appearing without counsel, he is required to comply with the Federal Rules of Civil Procedure and the Civil Local Rules for the Southern District of California. His opposition does not include a certificate of service showing that opposing counsel was sent a copy of the opposition. Civil Local Rule 5.2 provides:

> Proof of service of all papers required or permitted to be served . . . must be filed in the clerk's office promptly and in any event before action is to be taken thereon by the court of the parties. The proof must show the day and manner of service and may be . . . (3) by affidavit of the person who mailed or otherwise served the papers . . . .

The Court will not strike plaintiff's opposition for this noncompliance. But plaintiff is admonished that any future failure to serve all documents submitted for filing on opposing counsel and to provide a certificate of service indicating the day and manner of service will

A. Background

Plaintiff Frederick Nimtz had surgery in 2006, to implant an Insignia I Ultra, Model 1290 pacemaker that was manufactured by Guidant. He alleges that he suffered injury as a result of the implantation of this device. This action against Guidant is based on strict liability, *i.e.*, the pacemaker was defective and unreasonably dangerous in design and manufacture and did not contain adequate instructions as to its use, limitations and/or adequate warnings. (Compl., ¶¶ 17, 18.) Plaintiff alleges a claim of medical malpractice against Daniel Cepin, M.D., who has filed an answer to the complaint. The medical malpractice claim is not addressed in this Order.

B. Legal Standard for a Motion to Dismiss

A plaintiff must "plead a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). This statement must be sufficient to "give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957). Rule 12(b)(6) provides that a complaint may be dismissed for "failure to state a claim upon which relief may be granted." FED. R. CIV. P. 12(b)(6). A complaint may be dismissed as a matter of law if it lacks a cognizable legal theory or states insufficient facts under a cognizable legal theory. *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 534 (9th Cir. 1984).

The factual allegations of a complaint must be "enough to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1965 (2007). A plaintiff must plead more than conclusory allegations to show "plausible liability" and avoid dismissal. *Id.* at 1966 n. 5. The pleading standard of Rule 8 "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation" and a complaint does not suffice "if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Twombly*, 127 S. Ct. at 1966).

In determining the propriety of a Rule 12(b)(6) dismissal, a court may not look beyond

---

result in the documents being stricken from the record.

Further, plaintiff's opposition is presented in all upper case letters which reduces the legibility of his document. All further submissions by plaintiff shall be presented in appropriate upper and lower case letters.

the complaint for additional facts, *e.g.,* facts presented in plaintiff's memorandum in opposition to a defendant's motion to dismiss or other submissions. *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003); *Parrino v. FHP, Inc.*, 146 F.3d 699, 705-06 (9th Cir. 1998); *see also* 2 MOORE'S FEDERAL PRACTICE, § 12.34[2] (Matthew Bender 3d ed.) ("The court may not . . . take into account additional facts asserted in a memorandum opposing the motion to dismiss, because such memoranda do not constitute pleadings under Rule 7(a).").

C. Discussion

1. Inadequate Pleading

In the complaint, plaintiff states that the pacemaker was defective and unreasonably dangerous but fails to offer any facts suggesting what the defective condition was or how the product was unreasonably dangerous. Although courts generally treat *pro se* pleadings under a less stringent standard than pleadings drafted by attorneys, *Haines v. Kerner*, 404 U.S. 519, 520 (1972), courts should not assume that a plaintiff can prove facts that he has not alleged. *Assoc. Gen. Contractors of Cal., Inc. V. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983).

Here, plaintiff's bald assertion that the pacemaker was defective is not sufficient to state a cause of action. *Papasan v. Allain*, 478 U.S. 265, 286 (1986). Paragraphs 17, 20 and 21 of the operative complaint provide:

> 17. The aforementioned pacemaker manufactured by the Defendant GUIDANT was defective and unreasonably dangerous in design and manufacture.
> 20. The Defendant GUIDANT knew or should [h]ave known of the defective condition, characteristics and risks associated with said product as outlined herein.
> 21. The Plaintiff did not know, nor had reason to know, prior to the use and application of the aforementioned product for some period of time, of the defective condition of said product.

(Compl. at 8.)

Plaintiff fails to even suggest how the pacemaker was allegedly defectively designed or manufactured. In his opposition to defendant's motion to dismiss, plaintiff states he intends to file an amended complaint that will allege that he does not "claim strict liability based on manufacturing defects. It is based on a failure to warn." (Opp. at 2.) As noted above, the Court cannot look to plaintiff's opposition for changing legal theories or facts. Nor can the Court look to intended future pleadings. Plaintiff has failed to meet the pleading standard with respect to

alleging strict liability based on manufacturing or design defect.

In the second cause of action for strict liability, plaintiff also alleges strict liability based on a failure to warn:

> 18. The aforementioned pacemaker failed to be accompanied by or contain adequate instructions as to it's [sic] use and limitations and/or adequate warnings concerning the defective condition, characteristics and the risks associated with said product.

(Compl. at 8.)

A "manufacturer owes a foreseeable user of its product a duty to warn of risks of using the product." *Huynh v. Ingersoll-Rand*, 16 Cal. App.4th 825, 833 (1993). Manufacturers are strictly liable for injuries caused by their failure to warn of known or reasonably scientifically knowable dangers at the time they manufactured and distributed their product. *Johnson v. American Standard, Inc.*, 43 Cal.4th 56, 64 (2008); *Carlin v. Superior Court*, 13 Cal.4th 1104, 1108-09 (1996).

Plaintiff's defective warning claim suffers from the same inadequacy as his defective manufacturing or design claim. The Complaint does not identify what warning was given, or how the warning given was inadequate. In other words, plaintiff does not identify which specific danger Guidant should have been warning against. *See Johnson*, 43 Cal.4th at 64. To state a plausible claim for failure to warn, a complaint should at least identify which danger was not warned against, that the danger was substantial, that the danger was not readily recognizable to an ordinary consumer, that the manufacturer knew or should have reasonably known of the danger, and causation. *See Johnson*, 43 Cal.4th at 64-67. Here, the allegation that the "pacemaker failed to be accompanied by or contain adequate instructions as to it's [sic] use and limitations and/or adequate warnings concerning the defective condition, characteristics and the risks associated with said product" is a legal conclusion that does not allege a plausible cause of action. *See Iqbal*, 123 S. Ct. at 1249-50.

Because the design, manufacturing defects and failure to warn allegations are not adequately identified in the Complaint, no plausible strict products liability claims are stated and plaintiff's complaint must be dismissed. The question becomes whether the complaint should be

dismissed with leave to amend. Rule 15 advises the court that leave to amend shall be freely given when justice so requires. FED. R. CIV. P. 15(a). "This policy is to be applied with extreme liberality." *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1051 (9th Cir. 2003) (internal quotation marks and citation omitted).

> In the absence of any apparent or declared reason – such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc. – the leave sought should, as the rules require, be "freely given."

Foman v. Davis, 371 U.S. 178, 182 (1962).

Thus, dismissal with prejudice and without leave to amend is not appropriate unless it is clear that the complaint could not be saved by amendment. *Id*. But Courts may dismiss a case without leave to amend if the plaintiff is unable to cure the defect by amendment. *Lopez v. Smith*, 203 F.3d 1122, 1129 (9th Cir. 2000).

Defendants contend that the complaint must be dismissed with prejudice because plaintiff's strict liability claim is preempted by federal law, and therefore amendment would be futile.

2. Federal Preemption

In enacting the Medical Device Amendments of 1976 (MDA) (21 U.S.C. §360c et seq.) to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), Congress sought to " 'to provide for the safety and effectiveness of medical devices intended for human use.'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996). The MDA divides medical devices into three classifications: Class I, Class II, and Class III. 21 U.S.C. §360c(a)(1). A Class III device, such as the Insignia I Ultra, Model 1290 pacemaker, receives the most federal oversight, and requires premarket approval by the FDA. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-319 (2008). This "rigorous" process requires an applicant to submit "full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a 'full statement' of the device's 'components, ingredients, and properties and of the principle or principles of operation'; 'a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device'; samples or device components required by the FDA; and a

specimen of proposed labeling." 21 U.S.C. §360e(c)(1). The pacemaker at issue in this action was approved by the FDA through the Product Development Protocol process. 64 Fed. Reg. 68696 (Dec. 8, 1999). Pre-Market Approval (PMA) or equivalent process and the PDP process is euqivalent to the PMA process. *See Betterton v. Evans,*351 F. Supp.2d 529, 535 (N.D. Miss. 2004).

The MDA contains an express preemption provision: no State "may establish or continue in effect with respect to a device ... any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." 21 U.S.C. § 360k(a). As the Supreme Court made clear in *Riegel*, states are not permitted to indirectly regulate the safety and effectiveness of an FDA approved medical device through the tort system. *See Riegel*, 552 U.S. at 324. Since the Supreme Court decided *Riegel*, courts have routinely held that state law claims for strict products liability, failure to warn and manufacturing-and-design-defect are preempted. *See In re Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig.*, 592 F. Supp.2d 1147, 1152 (D. Minn. 2009) (collecting cases). And so it is in the present case. Plaintiff's strict liability claim, whether based on design or manufacturing defect or failure to warn, are preempted by federal law.

But *Riegel* "left open a back door for plaintiffs: claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's PMA are not preempted." *In re Medtronic*, 592 F. Supp.2d at 1152 (citing *Riegel*). In other words, claims that allege a failure to comply with the federal standards which were established through the PMA process are not preempted because they merely "parallel" federal requirements, *i.e.*, they do not add to or differ from federal requirements, which is the cornerstone of FDCA preemption. *Riegel*, 128 S. Ct. at 1011 (citing 21 U.S.C. § 360k(a)(1)).

As discussed above, plaintiff's basic allegations concerning strict liability do not state a claim against Guidant because they are nothing more than conclusory statements with no factual basis for the claim provided and therefore do not state a plausible claim under Rule 8(a) and *Twombly and Iqbal*. But even more importantly, plaintiff's strict liability claims are preempted

under 21 U.S.C. § 360k(a)(1) and *Riegel*. And because plaintiff has not set forth that Guidant failed to comply with the PMA process with respect to warnings and/or failing to manufacture or design the pacemaker in the manner required by the FDA's regulations, he has not alleged that his strict liability claims are outside of preemption.

Plaintiff will be given an opportunity to file an amended complaint to allege design defect, manufacturing defect and/or failure to warn claims against Guidant that are not preempted under FDCA, *i.e.*, the claim does not impose additional or different requirements to the federal regulations, but is parallel to the federal requirements. The amended complaint must meet the pleading standard found in *Twombly* and *Iqbal*.

D. Motion to Strike Failure to Warn Allegations

Defendants seek to strike allegations that Guidant failed to warn plaintiff about the alleged defects in the pacemaker because a manufacturer's duty to warn runs to the physician and not to the patient or general public. *See Carlin v. Superior Court*, 13 Cal.4th 1104, 1116 (1996)(In personal injury cases involving prescription medications and devices, a manufacturer's duty to warn runs only to the physician or other "learned intermediary" and not to the patient or the general public.).

Rule 12(f) provides that the court "may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." "'Immaterial' matter is that which has no essential or important relationship to the claim for relief or the defenses being pleaded" and "'[i]mpertinent' matter consists of statements that do not pertain, and are not necessary, to the issues in question.'" *See Fantasy, Inc. v. Fogerty*, 984 F.2d 1524, 1527 (9th Cir.1993) (reversed on other grounds *sub nom. Fogerty v. Fantasy, Inc.*, 510 U.S. 517 (1994)).

The allegations defendants seek to strike are neither immaterial, impertinent nor improper. Instead defendants move to "strike" the allegations as legally barred under California law. The Ninth Circuit recently held that a motion to strike is neither an authorized or proper way to procure dismissal of all or part of a complaint. *Whittlestone, Inc. v. Handi-Craft Co.*, 618 F.3d 970, 974, 976 (9th Cir. 2010)("We hold that Rule 12(f) of the Federal Rules of Civil Procedure does not authorize a district court to dismiss a claim for damages on the basis it is

precluded as a matter of law."). Accordingly, defendants' motion to strike under Rule 12(f) will be denied.

E. Conclusion

For the reasons set forth above, **IT IS ORDERED**

1. Defendant Guidant's motion to dismiss plaintiff's complaint is **GRANTED WITHOUT PREJUDICE**.

2. Defendant Guidant's motion to strike allegations concerning failure to warn is **DENIED.**

3. Plaintiff is **GRANTED** until April 11, 2011 in which to file a First Amended Complaint that cures the deficiencies of the pleading noted above. The First Amended Complaint must be complete in itself without reference to the superseded pleading. *See* Civ. L. R. 15.1. Defendants not named and all claims not re-alleged in the First Amended Complaint will be deemed to have been waived. *See King v. Atiyeh*, 814 F.2d 565, 567 (9th Cir. 1987).

4. In the event plaintiff does not file a timely First Amended Complaint, plaintiff and defendant Daniel Cepin, M.D. are **DIRECTED** to contact the assigned magistrate judge by April 18, 2011 to arrange an Early Neutral Evaluation conference of a Case Management conference at his discretion.

IT IS SO ORDERED.

DATED: March 3, 2011

M. James Lorenz
United States District Court Judge

COPY TO:

HON. ANTHONY J. BATTAGLIA
UNITED STATES MAGISTRATE JUDGE

ALL PARTIES/COUNSEL