UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA – SACRAMENTO DIVISION

ADAM PHILLIPPI, Plaintiff, v. STRYKER CORPORATION, a Michigan corporation; STRYKER SALES CORPORATION, a Michigan Corporation; and DOES 1 through 50, Defendants.	Case No. 2:08-CV-02445-JAM-KJN **ORDER RE: SUMMARY JUDGMENT AND SANCTIONS**

Before the Court is the motion of Defendants Stryker Corporation and Stryker Sales Corporation (collectively "Stryker") for summary judgment, or in the alternative for partial summary, as to Plaintiff Adam Phillippi's products liability action against Stryker. Having considered the moving, opposing and reply papers, various evidentiary objections, and after having heard oral argument by each of the parties at the hearing held June 16, 2010, the Court rules that Stryker's motion is GRANTED as to Plaintiff's entire action for the reasons set forth below. Further, the Court imposes sanctions against Plaintiff's counsel, Leslie O'Leary, Esq., and Thomas Powers, Esq., in the amounts of $500 and $200 respectively, for the reasons detailed below.

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A. Procedural Posture

1. Plaintiff Adam Phillippi, a resident of Sacramento County, California, sues Stryker, a Michigan corporation, in strict products liability and negligence, for personal injuries suffered, he alleges, as a consequence of the use of Stryker infusion pump, the PainPump 2.0, by his surgeon, Dr. Eric Younger, M.D., following arthroscopic surgery on his shoulder in July, 2005. Plaintiff alleges that the continuous infusion of local anesthetics into his shoulder joint space, via the Stryker pump, caused chondrolysis, the complete and global destruction of the cartilage in his shoulder joint. Plaintiff's claim is based on Stryker's alleged failure to provide adequate warnings with its device. This Court has diversity jurisdiction, and will apply California substantive law.

2. Stryker now moves for summary judgment, advancing four primary arguments: (1) There is no admissible evidence that at the time of Plaintiff's surgery Stryker either knew or in the application of scientific knowledge could have known that there was any risk that use of the pump with local anesthetics would cause chondrolysis of the shoulder; (2) That as a matter of law a manufacturer of a medical device has no duty to include in its labeling information about the device's regulatory history; (3) That as a matter of law there is no liability for an alleged failure to conduct testing of a medical device available only through the prescription of a licensed physician; and (4) There is no admissible evidence that Stryker's conduct caused Dr. Younger to use the pump in the manner that he did, and hence there is no causal link between Stryker's allegedly defective labeling and Plaintiff's injury. Plaintiff opposed Stryker's motion with a 40 page memorandum, declarations and exhibits, and a response to Stryker's separate statement. Stryker filed a reply memorandum and evidentiary objections. Oral argument was held on June 16, 2010.

B. Rulings on Stryker's Motion and Evidentiary Objections.

3. Evidentiary objections: With the exception of Stryker's objections to Dr. Younger's declaration, the Court overrules all of the Stryker's other evidentiary objections. As to the doctor's declaration, Stryker's objections are sustained on the grounds

that the declaration is self-serving, clearly drafted by counsel (in view of the transmittal email accompanying the declaration in the record), lacks foundation, and is inconsistent with the declarant's prior deposition testimony, and therefore cannot be used by a party (and particularly by a party whose counsel has drafted the declaration) to in any way create a triable issue of fact in this case. *Kennedy v. Allied Mutual Insurance Co.*, 952 F.2d 262, 266 (9th Cir. 1991).

4. Applicable Law: California law recognizes three theories of product liability: design defect, manufacturing defect, and failure to warn. *Brown v. Superior Court*, 44 Cal.3d 1049, 1057 (1988) ("*Brown*"). Plaintiff's claim here against Stryker is based solely on an alleged failure to warn, whether under the strict liability or negligence claims for relief. The manufacturer of a medicine or medical device, which is available only through the prescription of a licensed physician, must give adequate warnings of dangerous propensities in its product of which the manufacturer knows or should know in the application of existing scientific knowledge at the time of distribution. *Id.* 1069; *Carlin v. Superior Court*, 13 Cal.4th 1104, 1109 (1996) ("*Carlin*"). The manufacturer of a prescription medicine or medical device satisfies its duty to provide an appropriate warning about the product's risks when it informs the patient's physician of those risks. *Carlin*, 13 Cal. 4th at 1116. There is no duty to warn physicians of a product's regulatory history. When the warnings accompanying a prescription product adequately inform the physician of dangers inherent in its use, the manufacturer's alleged failure to test that product cannot, by itself, either cause injury or be a source of liability of the manufacturer. Imposing liability for breach of a purported "independent duty to conduct long-term testing" would be beyond the pale of any known California tort doctrine, because, *inter alia*, the causal link between Plaintiff's known harm, and the unknown outcome of the hypothetical testing is entirely speculative. *See Valentine v. Baxter Healthcare Corporation*, 68 Cal.App.4th 1467, 1485-1486 (1999), *citing Kociemba v. G.D Searle & Co.,* 707 F.Supp 1517, 1527 (D. Minn. 1989). To find a manufacturer liable for failing to warn, a plaintiff must prove that the manufacturer's failure to warn was the proximate cause of the plaintiff's injuries. *Ramirez v. Plough, Inc.*, 6 Cal.4th

539, 555 (1994); *Motus v. Pfizer, Inc.*, 196 F.Supp.2d 984, 991 (C.D. Cal. 2001), *aff'd* 358 F.3d 659, 661 (9th Cir. 2004).

5. Rulings on Grounds For Summary Judgment:

a. Duty To Warn: Stryker's undisputed facts 1 through 11 establish, as a matter of law, that of the time of Plaintiff's surgery in July, 2005 there existed no duty to warn relating to any asserted association between intra-articular pain pump use and development of chondrolysis. The additional facts submitted by Plaintiff on this issue, even assuming them to be true, do not support a conclusion that the FDA's decision not to clear the indication for "synovial cavity" created a known or knowable risk of chondrolysis. The February, 2005, communications from Dr. Paulos are also not sufficient to establish that Stryker either knew or should have known in the application of existing scientific knowledge that there was a risk of chondrolysis in patients whose physicians chose to place its infusion pumps in the intra-articular space of the shoulder. Those communications concerned the use of the drug epinephrine when mixed with other drugs in the pain pump, and that epinephrine might cause injury. Stryker warned about the use of epinephrine in its labeling at the time of Plaintiff's surgery. It is undisputed that Stryker thoroughly investigated this potential issue and reached a conclusion that the existing warning was sufficient. Further, there was no mention whatsoever in these Paulos' communications regarding pain pump placement. Evidence presented by Plaintiff to the contrary all post-dates his surgery and thus does not establish what Stryker knew or should have known at or before the time of Plaintiff's operation. As recently as November, 2009, the FDA issued a statement to the effect that the cause of chondrolysis in the shoulder, even when infusion pumps are prescribed, is unknown. Plaintiff offers no admissible evidence to establish that Stryker knew or should have known in the application of scientific knowledge of a risk of chondrolysis from the use of its infusion pumps in the intra-articular space at or before the time of Plaintiff's July, 2005 surgery.

b. Duty To Test: Plaintiff offers no admissible evidence as to what testing would have been conducted before Plaintiff's surgery in July, 2005, and what the results of that unknown testing would have shown. Accordingly, even were an independent

duty to test found in law to exist (as to which the Court finds there is no such duty), it would be completely speculative as to what the consequences would be of any purported failure to fulfill this supposed duty.

c. Causation: Plaintiff is required to establish by admissible evidence a causal connection between the alleged inadequacy of Stryker's warnings and his injuries. Plaintiff has not disputed Stryker's facts 12 through 23 which establish as a matter of law that no alleged acts or omissions by Stryker were a proximate cause of Plaintiff's alleged injury. By virtue of these undisputed facts, it is without controversy that the decision to use Stryker's infusion pump in the fashion that it was used during Plaintiff's surgery was solely and exclusively Dr. Younger's, who received no direction or instruction from Stryker as to the placement of the catheter, the type of anesthetic utilized, the amount of anesthetic utilized, the rate at which the anesthetic was administered via the pump, or the duration of time during which the anesthetic was administered. Because all these variables were within the doctor's discretion, Stryker cannot be liable as a matter of law for an injury which, assuming that medical causation were established, would be due solely to the doctor's decisions on these factors.

d. Conclusion: The undisputed evidence clearly shows that the scientific and medical knowledge available at the time of Plaintiff's surgery did not and could not require Stryker in any way to change the warnings that accompanied its PainPump 2.0 infusion pump. Accordingly, summary judgment is required as a matter of law based on the lack of duty to warn or test as discussed above. It is further undisputed that Dr. Younger independently made the decision to use the product in the manner it was used during Plaintiff's surgery, and that Stryker did not promote any particular use or catheter placement. As Plaintiff has failed to raise any triable issue of material fact with respect to causation between Stryker's labeling and purported promotion and Plaintiff's alleged injury, summary judgment is also required on this independent ground. The court therefore grants summary judgment as a matter of law in favor of Stryker as to each of Plaintiff's claims.

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C. Orders As To Sanctions.

6. Plaintiff submitted a 40 page response in opposition to Stryker's motion. Plaintiff's counsel, Ms. O'Leary, did so without seeking leave of court. On January 9, 2009, the Court signed a scheduling order which explicitly limited the length of any memoranda submitted to the Court to 25 pages, and admonished counsel to not circumvent this limitation through the filing of multiple memoranda. On May 14, 2010, Stryker submitted an ex parte application seeking leave to exceed this 25 page limitation for its summary judgment motion, a copy of which was served on Plaintiff's counsel. On May 17, 2010, the court denied Stryker's request, giving notice to all counsel electronically. Stryker complied with the court's orders in connection with its summary judgment motion. Ms. O'Leary subsequently submitted a declaration explaining her conduct with respect to the page limitation.

7. The Court imposes sanctions against Ms. O'Leary for breach of the specific orders limiting briefing to 25 pages. The court sanctions Ms. O'Leary in the amount of $500, payable to the clerk of the United States District Court, Eastern District of California, Sacramento Division, within ten days following the issuance of the Court's order of June 29, 2010 (Document No. 93). Ms. O'Leary is further ordered to advise Plaintiff personally of the sanctions order and the reasons therefore and to provide proof to this Court, within ten days of the Court's June 29, 2010 order, that she has informed her client of the Court's sanctions order against her.

8. Mr. Powers' request to appear telephonically at the hearing on the motion for summary judgment was made on the morning of the hearing, without any showing of good cause for his untimely request to do so. The Court sanctions Mr. Powers in the amount of $200, payable to the clerk of the United States District Court, Eastern District of California, Sacramento Division, within ten days following the issuance of the Court's order of June 29, 2010, referenced above.

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9. Counsel for Stryker is ordered to prepare an order reflecting the Court's rulings, which is to be submitted to Plaintiff's counsel for approval as to form.

IT IS SO ORDERED.

Dated: June 30, 2010

/s/ John A. Mendez
Honorable John A. Mendez
United States District Court Judge