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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

SACRAMENTO DIVISION

TERRI LYNN TODD,

Plaintiff,

v.

STRYKER CORPORATION, a Michigan corporation; and STRYKER SALES CORPORATION, a Michigan corporation,

Defendants.

Case No. 2:09-cv-01509-JAM-GGH

ORDER GRANTING DEFENDANTS' SUMMARY JUDGMENT MOTION

On March 9, 2011, the Court brought on for hearing the motion for summary judgment of Defendants Stryker Corporation and Stryker Sales Corporation ("Stryker"). (Doc. no. 45). Appearing on behalf of Plaintiff Terri Lynn Todd ("Todd") were C. Brooks Cutter and Thomas B. Powers. Appearing on behalf of Stryker were Hall R. Marston and Wayne A. Wolff.

Following oral argument, the motion was taken under submission to consider Todd's request to defer the entry of judgment. Subsequently, the Court issued an order deferring the entry of judgment for Stryker pending the decision of the Ninth Circuit Court of Appeals in the matter entitled *Phillippi v. Stryker Corporation*, 2:08-CV-02445-JAM-KJN, 2010 U.S. Dist. LEXIS 66470 (E.D. Cal. 2010) ("*Phillippi*"), in which the Court granted summary judgment for Stryker on issues substantially similar to those raised in the present motion for summary judgment.[1] (*See* Doc. no.84). On March 9, 2012, the Ninth Circuit issued its order affirming this Court's order in *Phillippi*, in all respects. *See Phillippi v. Stryker Corporation*, Ninth Circuit Case No. 10-16651, 2012 U.S. App. LEXIS 4940 (9th Cir. March 9, 2012). At the Court's direction, the parties submitted a joint status report (Doc. nos. 88-89) following the Ninth Circuit's decision, in which Todd requested leave to file supplemental briefing concerning the effect of "newly acquired evidence," and to which Stryker objected. The Court DENIES Todd's request for leave to file supplemental briefing and "newly-acquired evidence," (Doc. no. 90) and for the reasons set forth below GRANTS Stryker's motion for summary judgment.

A. Procedural Posture

Todd, a resident of Sacramento County, California, sues Stryker, a Michigan corporation, in strict products liability and negligence, for personal injuries suffered, she alleges, as a consequence of the use of a Stryker infusion pump, the PainPump 2.0, by her surgeon, Dr. Edward Younger, following arthroscopic surgery on her shoulder in September, 2006. (Doc. no. 1 and Doc. no. 51-1 at 24). Todd further alleges that the continuous infusion of local anesthetics into her shoulder joint space, via the Stryker pump, caused chondrolysis, the complete or nearly complete loss of cartilage, in her shoulder joint. (Doc. no. 1 at 2). Todd'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.

In support of its summary judgment motion, Stryker advances the following primary

[1] In her complaint, Todd specifically identified *Phillippi* as a related case. *See* Eastern District Local Rule 123(a)(3) (matter related when "both actions involve similar questions of fact and the same question of law and their assignment to the same Judge or Magistrate Judge is likely to effect a substantial savings of judicial effort, either because the same result should follow in both actions or otherwise. . . ."). (Doc no. 1 at 1).

arguments: (1) There is no admissible evidence that Stryker's conduct caused Dr. Younger to use the pump in the manner that he did, i.e., catheter placement, medication selected, dose and duration of administration prescribed, and hence there is no causal link between Stryker's allegedly defective labeling and Todd's injury; (2) There is no admissible evidence that at the time of Todd's surgery Stryker either knew or in the application of existing scientific knowledge could have known that there was any risk that the use of its device with local anesthetics would cause chondrolysis of the shoulder; (3) As 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) As a matter of law, a manufacturer of a prescription medical device has no duty to include in its labeling information about the device's regulatory history. (Doc. no. 46.)

Todd opposed Stryker's motion (doc. no. 51), submitted her own statement of material facts in opposition (doc. no. 51-1), and submitted counsel's declaration with 113 exhibits (doc. no. 51-2). Among those exhibits was the Declaration of Edward W. Younger, M.D., dated May 28, 2010. This is the same declaration to which the Court sustained Stryker's objection in *Phillippi*, on the grounds that it was "self-serving, clearly drafted by counsel (in view of the transmittal email accompanying the declaration in the record), lack foundation, and is inconsistent with 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)." *Phillippi*, 2010 U.S. Dist. LEXIS 66470, *4-5 (E.D. Cal. 2010).[2] This Court's ruling on Dr. Younger's declaration was upheld on review, citing *FTC v. Publ'g Clearing House, Inc.*, 104 F.3d 1168, 1171 (9th Cir. 1997) ("A conclusory, self-serving affidavit, lacking detailed facts and any supporting evidence is insufficient to create a genuine issue of material fact.") *Phillippi v. Stryker Corporation,* 2012 U.S. App. LEXIS 4940, *3 (9th Cir. 2012).

Stryker filed a reply to Todd's opposition (doc. no. 61), counsel's declaration (Doc. no.

[2] Although not included in Todd's submission of the declaration, the transmittal email from Mr. Phillippi's counsel was submitted by Stryker in its counsel declaration in support of Stryker's reply to Todd's opposition to Stryker's motion. (doc. no. 65 at 2 and 48.).

65), a reply in support of its separate statement of material facts (doc. no. 62), evidentiary objections and a motion to strike Dr. Younger's declaration (doc. no. 64), and evidentiary objections to the declaration of Todd's counsel in support of Todd's opposition to Stryker's motion (doc. no. 63). As indicated above, oral argument was held on March 9, 2011.

B. Rulings on Evidentiary Objections.

Preliminary to ruling on Stryker's evidentiary objections, the Court notes that counsel's declaration in opposition to the summary judgment motion attaches 113 exhibits, roughly two telephone books thick. (Doc. nos. 51-1 through 53-32). An avalanche of paper, submitted in the hope that somewhere buried in the bulk of documentation there may be a genuine disputed fact issue lurking, whether done to defeat the motion itself, or to hedge one's bet on appellate review, is not helpful to the Court. As Judge Shubb noted in his opinion in *Burch v. Regents of the University of California*, 433 F.Supp.2d 1110, 1122 (E.D. 2006), the objective of modern summary judgment practice is to promote judicial efficiency and avoid costly litigation, citing *Roberts v. Browning*, 610 F.2d 528, 531 (8th Cir. 1979). In the same vein, however, the response to such a tidal wave of evidence (to mix the metaphor) should not be an equally daunting host of evidentiary objections, directed primarily at issues of form and authentication. As Judge Shubb ably explained in his exhaustive commentary on the subject in *Burch*, the bulk of these kinds of objections are unnecessary under Ninth Circuit jurisprudence. *Id.* at 1118-1122. The Court joins Judge Shubb to urge counsel, whether representing movants or non-movants in summary judgment proceedings, to be both circumspect in the submission of evidence and considered in lodging only necessary objections. The Court further echoes Judge Shubb's request for greater clarity from the appellate courts to give both bench and bar better guidance in the efficient oversight of consideration of admissible evidence in Rule 56 litigation.

The foregoing notwithstanding, the Court overrules all of Stryker's evidentiary objections, save for those directed to the Younger Declaration. The Court sustains Stryker's objections to the declaration 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 the case. *Kennedy v. Allied Mutual Insurance Co.*, 952 F.2d 262, 266 (9th Cir. 1991); *FTC v. Publ'g Clearing House, Inc.*, 104 F.3d 1168, 1171 (9th Cir. 1997); *Phillippi v. Stryker Corporation*, 2012 U.S. App. LEXIS 4940, *2-3 (9th Cir. 2012) (considering identical declaration submitted in *Phillippi*).

C. Ruling on Stryker's Summary Judgment Motion.

As it did in *Phillippi*, the Court summarizes the applicable California law: Of the three theories of product liability recognized in California (design defect, manufacturing defect, and failure to warn defect), Todd's claims here raise only the alleged failure to warn, whether under either her strict liability or negligence claims for relief. *See Brown v. Superior Court*, 44 Cal.3d 1049, 1057 (1988) (available theories under California products liability law). It is undisputed that Stryker's continuous infusion pump is available only through the prescription of a licensed physician (here, Todd's surgeon, Dr. Younger). A maker of a medicine or medical device, available pursuant to 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 of the medicine or device. *Id.; Carlin v. Superior Court*, 13 Cal.4th 1104, 1109 (1996); *Hufft v. Horowitz*, 4 Cal.App.4th 8, 18 (1992) (rule for prescription drugs applicable to medical devices available via prescription). Were a maker of a prescription medical device held liable for an alleged failure to warn of dangerous propensities that were not known according to the state of existing scientific knowledge at the time of distribution, doing so would transform the manufacturer into a guarantor of its products and a virtual insurer of the product. *Brown* at 1066.

The duty to warn of a prescription product maker runs to the patient's physician, not directly to the patient. *Carlin*, 13 Cal. 4th at 1116.

There is no duty to warn the patient's physician of a prescription product's regulatory history, because the history is not a "dangerous propensity" about which an adequate warning must be given under *Brown*. The Court agrees with and adopts the reasoning of other courts considering pain pump suits that have come to similar conclusions. *See Rodriguez v. Stryker*

Corporation, 2011 U.S. Dist. LEXIS 1252, *22-25 (M.D. Tenn. 2010), and opinions cited therein.[3]

When the warnings accompanying a prescription product adequately inform the prescribing physician of dangers inherent in its use, the manufacturer's alleged failure to test that product cannot, by itself, either cause injury to be a source of liability for the manufacturer. *Taylor v. Elliott Turbomachinery Co.,* 171 Cal.App.4th 564, 571 (2009) (no duty to warn of hazards inherent in product manufactured or supplied by third parties); *Johnson v. American Standard, Inc.*, 43 Cal.4th 56, 64 (2008) (duty to warn limited to hazards inherent in the manufacturer's product). 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).

The Court agrees with and adopts the reasoning of other courts that have come to similar conclusions on the purported duty to test as it concerns pain pumps. *See Rodriguez*, at *30-31 (applying Tennessee law); *Krumpelbeck v. Breg, Inc.*, 759 F.Supp.2d 958, 973 (S.D. Ohio 2010) ("[G]iven` the risk profile of pain pumps, and the history regarding the intra-operative injection of anesthetics in orthopedic procedures, there was simply no reason for Defendant to have developed specific testing protocols to uncover the supposed link between pain-pump use and postarthroscopic glenohumeral chondrolysis."); *Meharg v. I-Flow Corporation*, 2010 U.S. Dist. LEXIS 18517, **14-15, n. 9 (S.D. Ind. 2010) (no duty of maker of drug used in pain pumps to conduct or sponsor studies necessary to ensure that the promoted use was safe, under Indiana law).[4]

As to causation, to find a manufacturer of a prescription product liable for failing to warn, a plaintiff must prove that the maker's failure to warn was the proximate cause of the plaintiff's

[3] Since the submission of the matter for decision, another court has come to a similar conclusion, in a matter where the plaintiff was represented by the same counsel representing Todd in the present matter. *Pavelko v. Breg, Inc.*, 2011 U.S. Dist. LEXIS 19380, *19 (D. Colo. 2011).

[4] *See also Pavelko*, referenced in footnote 3, supra, at *23-24.

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). The Court agrees with and adopts the reasoning of other courts who have ruled, in the context of the pain pump litigation, that when the physician independently makes the decision to prescribe the device based on his or her own separately developed protocol, uninfluenced by the pump manufacturer, that there is no causal link between either an alleged defect in the pump, or the alleged negligence of the manufacturer and plaintiff's injury. *See Rodriguez* at *34-35, n. 9.

1. There Is No Genuine Dispute That Stryker Knew or Should Have Known of any Dangerous Propensity in the Use of Its Pain Pump Related to Chondrolysis of the Shoulder.

Applying these principles to the record before it, the Court first considers Todd's claim that Stryker had a duty to warn physicians of the purported association between continuous infusion of local anesthetics and chondrolysis of the shoulder as of the date of her surgery in September, 2006. As in *Phillippi,* Todd essentially did not dispute, albeit with numerous caveats which are insufficient to raise a genuine disputed fact issue, the following: Stryker's labeling for the PainPump 2.0 does not recommend any particular use or medication for the pump, and that the device requires the prescribing physician to select the medication and its rate of medication over a physician-selected period of time. Stryker's pump was cleared by the FDA under the 510(k) process for the general indication of "intraoperative use." In February 2005, Stryker received an email from Dr. Lonnie Paulos, M.D., expressing concerns of cartilage injury potentially associated with use of the drug epinephrine used in infusion pumps. In response to those communications Stryker investigated its files, reports by manufacturers of infusion pumps to the FDA, and literature concerning the use of a local anesthetic with epinephrine and necrosis; further it consulted with a prominent anesthesiologist, and found no mention of the condition Dr. Paulos mentioned. Because Stryker's labeling already warned about possible risks posed by epinephrine (and had since 2002), no other action was indicated. As of the date of the Dr. Paulos communications, there is no evidence that there were any other reports that catheter placement of the pump as a possible contributing cause. In August 2005, Stryker received a report from Dr. Charles Beck, M.D., regarding cases of chondrolysis in patients who were prescribed pain

pumps, where the anesthetic was mixed with epinephrine. Stryker reported these events to the FDA, which did not require any further action from Stryker. In late 2005, Stryker consulted with an orthopedic surgeon about this recently reported phenomenon, and the surgeon responded that he was unaware of any association between use of epinephrine or intra-articular catheter placement and chondrolysis. In May, 2006, after Stryker learned that Dr. Beck had presented his cases of chondrolysis patients at a medical conference, it received an opinion from another orthopedic surgeon, who advised Stryker that "it is difficult to determine a cause for chondrolysis in many cases," and that he was "unaware of any large study linking shoulder chondrolysis and pain pump infusion. . . ." (Doc. no. 62).

Given the similarity between this case and *Phillippi*, during argument the Court pressed Todd's counsel to identify the genuine disputed fact issues in this record that distinguished it from the record in *Phillippi*. Counsel pointed to the date of Todd's surgery in September, 2006, which was 14 months later than the surgery in *Phillippi*, an August, 2005 report by Dr. Beck to Stryker of cases of chondrolysis where epinephrine was used in pain pumps, and a podium presentation by Dr. Beck of his experience in March, 2006. But it is undisputed that upon receiving those reports Stryker undertook investigations, medical literature reviews, consulted three independent physicians (one anesthesiologist, and two orthopedic surgeons), and reported the events to the FDA (which undertook no action in response). None of the papers published in the summer of 2006, cited by Todd, come to the conclusion that continuous infusion of local anesthetics causes chondrolysis, or indeed that chondrolysis was even related to continuous infusion, particularly where, as in Todd's treatment, epinephrine was not prescribed. These additional facts are not sufficient to create a genuine disputed fact issue whether Stryker should have known at the time of Todd's surgery, based on existing scientific knowledge, that there was a risk of chondrolysis associated with the use of continuous infusion of local anesthetics into the shoulder joint.[5]

[5] The Court also notes that to the extent that the purported facts to which Todd points might prompt such a duty, all of those supposed facts concern the use of epinephrine with the local anesthetic administered via the pain pump. Todd does not dispute that Dr. Younger did not use epinephrine in the pump prescribed to her, rendering moot any alleged duty to warn that she claims arose based on the information Stryker received from Dr. Beck in the intervening period. (Doc. no 62 at 44 [Undisputed Fact no. 16]).

Todd cites actions by the FDA in response to applications by Stryker and its predecessor to secure an expanded clearance of indications for which the pain pump could be marketed for use in the synovial cavity as evidence of a risk that required Stryker to supply a warning. As the Court held in *Phillippi*, even assuming that these "facts" are true, they do not support a conclusion that the FDA's decision not to clear this applied-for indication created a known or knowable risk of chondrolysis. *Phillippi*, 2010 U.S. Dist. LEXIS 66470 at *7. The FDA status of a product is not a medical risk, nor can the regulatory status support an inference that the product is unsafe, much less defective. *Broderick v. Sofamor Danek Group, Inc.*, 1999 U.S. Dist. LEXIS 6434, *24-25 (S.D. Fla. 1999) (FDA status not a medical risk); *Minisan v. Danek Medical, Inc.*, 79 F.Supp.2d 970, 978 (N.D. Ind. 1999) (Lack of FDA clearance of a particular use does not mean that device is unsafe or defective). *See also Forslund v. Stryker Corporation*, 2010 U.S. Dist. LEXIS 104227, *12, n.5 (D. Minn. 2010) ("[The allegation that the FDA did not approve the pain pump for use in shoulder joint] is not probative of whether Stryker knew or should have known of the risks relating to the use of the pain pump in the shoulder joint space and therefore that Stryker had a duty to warn about that potential use."); *Haley v. I-Flow*, --- F.Supp.2d ---, 2012 WL 1185680, *7-8 (D. Minn. April 10, 2012) (That FDA did not clear pain pump for use in the intra-articular site did not establish that the "FDA [had] concluded that the use of the [pain pump] in the intra-articular joint space after orthopedic surgery was *not* safe and effective." (Emphasis in original)).

The Court also notes, as a distinction between the present and the record in *Phillippi*, that Todd submitted an expert declaration of Dr. David S. Bailie, dated August 1, 2010. (Doc. no. 52-21).[6] Putting aside statements in the report that are clearly beyond the proper scope of expert opinion (such as assumptions by others about the pump), it is notable that in Dr. Bailie's view, the use of pain pumps by the orthopedic community was "ubiquitous in the orthopedic

[6] Todd also submitted an affidavit of Dr. Stephen F. Badylak, D.V.M.LA/1165637v1, Ph.D., M.D. (Doc no. 53-1). The affidavit addresses only whether certain types of tests or studies were scientifically feasible prior to Todd's surgery. Because California law does not impose a duty to test on makers of prescription products, this affidavit does not raise a genuine issue of disputed fact as to the duty to warn. Under Rule 702, *Federal Rules of Evidence*, the affidavit is irrelevant to the duty question, and hence there is no "fit" under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993).

community across the country," amounting to the standard of care. *Id.* at 5. Even Dr. Bailie reports that his own first experience with chondrolysis following continuous infusion was in March, 2006, and that because he only had a "hunch" that the local anesthetic was implicated in the condition, he "did not feel obligated to initiate contact with company engineers or executives." *Id.* at 5-6. "Hunches," even if held by experts, are not scientific knowledge. Stryker is held to the standard of an expert in the field of pain pumps. *Vermeulen v. Superior Court*, 204 Cal.App.3d 1192, 1204 (1988). California law does not require Stryker to know more than any other expert at any given point in time, and Todd's evidence shows that no other expert thought in September of 2006 that the use of continuous infusion of local anesthetics without epinephrine posed a risk of chondrolysis or other cartilage injury to patients to whom it was prescribed for postarthroscopic pain management. Further, at no point does Dr. Bailie render an opinion that as of the date of Todd's surgery medical science knew that the treatment protocol selected for her by Dr. Younger (that is, continuous infusion of local anesthetics without epinephrine) posed any risk to the patient's cartilage.[7]

Finally, Todd, as did plaintiff in *Phillippi*, submitted multiple medical articles as support for her argument that there was sufficient information in the scientific literature to put Stryker on notice that continuous infusion posed a risk to patients. First, as many other courts have noted, counsel's bald advocacy about the significance of complex medical literature, unsupported by an admissible and sufficient expert opinion, cannot raise a genuine disputed fact issue. *See Krumpelbeck*, 759 F.Supp.2d at 968 ("This Court has reviewed the proffered articles and finds that on their face, they did not put Defendant on notice of a risk of chondrolysis from the continuous infusion of bupivacaine into an intra articular space prior to March 2005. . . . [T]he Court is not willing to rely on counsel's interpretation of the literature. *Daubert v. Merrell Dow Pharms., Inc.,* 43 F.3d 1311, 1318, n. 8 (9th Cir. 1995)."); *Monroe v. Zimmer US Inc.*, 766 F.Supp.2d 1012, 1034 (E.D. Cal. 2011) (Damrell, J.) ("The court cannot accept *counsel's* interpretation of the medical literature, counsel's unsupported determination that defendants had

[7] The Court notes that the substance of Dr. Bailie's report addresses the question of general causation—is continuous infusion capable of causing chondrolysis—an issue Stryker did not raise in its summary judgment motion.

a duty to investigate the medical literature, nor counsel's unsupported determination that the medical literature triggered defendants' alleged duty to 'further investigate [the] risk or at least warn of [the] risk.'") (emphasis in original); *Meharg v. I-Flow Corporation*, 2010 U.S. Dist. LEXIS 18517, *10-13, n. 7 & 8 (S. D. Ind. 2010).

Second, even if the Court were to consider the literature written before Plaintiff's September 2006 surgery, not a single article states that continuous infusion of local anesthetics via pain pump causes chondrolysis. In fact, the only article that actually studied bupivacaine (the generic name for the anesthetic selected by Dr. Younger for the prescription for Todd) concluded that as of 1985, "[t]here does not appear to be *any* contraindication to the use of intraarticular bupivacaine based on these findings." (Doc no. 53-9 at 1, Nole (1985), emphasis added). The only cited article published before Todd's surgery involving a clinical report of glenohumeral chondrolysis of the shoulder in a patient treated with a pain pump did not mention the device as related to the condition, and explicitly ruled out "chemical trauma" as a causative factor. (Doc. no. 52-21 at 8, Petty (2004)). Much of this literature was also submitted in *Phillippi*, without any explication via expert declaration, and the Ninth Circuit has affirmed this Court's order determining that the literature did not raise a genuine issue of disputed fact on the duty issue. *Phillippi v. Stryker Corporation*, 2012 U.S. App. LEXIS 4940, *2 (9th Cir. 2012).

2. There Is No Genuine Disputed Fact Issue Regarding The Purported Duty to Test.

In addition to the absence of a genuine disputed fact on Stryker's alleged duty to warn of the date of Todd's surgery, since Stryker's warnings are adequate in the light of its actual or constructive knowledge that continuous infusion of local anesthetics posed a risk of chondrolysis of the shoulder in patients treated by a doctor's prescription of pain pumps, a manufacturer's alleged failure to test the product cannot, by itself, either cause injury or be a source of liability of the manufacturer. *Phillippi* at *6. Todd has offered no admissible evidence as to either the type of testing that would have been conducted before her surgery in September, 2006, or what the results of that unknown testing would have shown. Even if there were such a testing duty (which the Court finds there is none), it would be completely speculative as to what the

consequences would be of any purported failure to fulfill this supposed duty.

3. There Is No Genuine Disputed Fact Issue That Stryker Caused Todd's Injury.

In *Phillippi*, the plaintiff did not make any response to Stryker's undisputed material facts regarding Dr. Younger's decision to prescribe the pain pump. *Phillippi* at *9. Todd, however, has responded to the corresponding facts identified by Stryker, but has rarely actually disputed them. These facts are essentially undisputed in any material sense: Dr. Younger, who was aware of and followed Stryker's warning concerning the risk of using epinephrine in the pump, learned to inject local anesthetics directly into the joint space as part of his residency training. He began using infusion pumps a decade ago, used whatever manufacturer's pump was available as stocked by the surgical facility, and selected the medication, its concentration, its flow rate and its duration of administration based on his own medical judgment. Dr. Younger made these clinical decisions, including placement of the pump catheter, based on his determination of the severity of the underlying problem and the needs of the patient. Dr. Younger recalled no conversations or promotion by a Stryker representative concerning direct placement of the pump catheter into the articulating joint. Neither of the Stryker sales representatives that called on Dr. Younger spoke with him about catheter placement for the pump. (*See generally* Doc. no. 62 at 44-55).[8]

These differences from the record in *Phillippi* notwithstanding, the conclusion is the same. There is no dispute that Dr. Younger's decision to use Stryker's pain pump in the fashion that he prescribed for Todd was solely and exclusively his. He 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. As with *Phillippi*, "[b]ecause 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

[8] In addition, Dr. Younger testified that if the FDA was aware of intra-articular placement and took no action in response (such as requiring Stryker to change warnings or notify physicians) he could not say he would have changed his treatment protocol for Todd. (Doc no. 46-7 at 45-50).

the doctor's decision on these factors." *Phillippi* at *9-10.

D. Conclusion.

Even though the record here is somewhat different from that in *Phillippi*, and Todd's surgery is months later, these differences in the record and the intervening events between the two surgery dates do not present genuine disputed fact issues or change the outcome on Stryker's motion. Even with the podium presentation by Dr. Beck, the actual notice of his patients received by Stryker, and the articles published in 2006 before Todd's surgery, there is no evidence that scientific and medical knowledge available at the time of her surgery required Stryker in any way to change the warning that accompanied its PainPump 2.0 device. There are no genuine disputed facts on either the duty to warn, or the purported duty to test (which the Court has held does not exist under California law). Beyond the issues of duty, it is undisputed that Dr. Younger independent made the decision to use the device in the manner was used during Todd's surgery, and that Stryker did not promote any particular medication or placement of the catheter. Thus summary judgment in Stryker's favor is required on the independent grounds of duty and causation, and the Court therefore grants judgment as a matter of law in favor of Stryker as to each of Todd's claims.

IT IS SO ORDERED

Dated: May 1, 2012

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