IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

BARRY NOTMEYER,

Plaintiff,

v.

STRYKER CORPORATION, et al.,

Defendants.
_____/

No. C 06-04096 SI

ORDER DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

On June 15, 2007, the Court heard argument on defendants' motion for summary judgment. Having considered the arguments of the parties and the papers submitted, and for good cause shown, the Court hereby DENIES defendants' motion.

BACKGROUND

On March 4, 2004, Dr. Warren Ayers performed total left hip arthroplasty on plaintiff Barry Notmeyer. Plaintiff was implanted with a prosthetic hip replacement system called the Trident. On May 21, 2004, the Alumina C-Taper Head, which is part of the Trident system, shattered and plaintiff underwent revision surgery. Plaintiff subsequently filed suit for personal injuries and damages against the manufacturers of the Alumina C-Taper Head, defendants Stryker Corporation and Howmedica Osteonics Corporation ("HOC"), for strict liability, negligence, breach of warranty, misrepresentation, concealment, and violation of the California Consumer Legal Remedies Act.

The first model of the Alumina C-Taper Head component was approved for use by the Food and Drug Administration ("FDA") in 1997 pursuant to the 510(k) process, by which the FDA determines that a device is suitable for marketing as substantially equivalent to another already-approved device.

In 2000, under the 510(k) process again, the FDA approved the particular size of the Alumina C-Taper Head component implanted in plaintiff. The FDA approved these components for use only with polyethylene inserts, which the Trident system does not use; instead the Trident system uses "Alumina" inserts.

In 1999, HOC submitted to the FDA a premarket approval ("PMA") application for the Trident hip replacement system, which included the Alumina C-Taper Head component.[1] After three years of PMA review, the FDA approved the device. A day later, HOC submitted a PMA supplement to include additional Alumina C-Taper Head sizes, including the size used by plaintiff. The FDA approved the additional sizes via a special 30-day supplemental review process.

Defendants now move for summary judgment on the ground that section 360k of the Medical Device Amendments ("MDA") preempts plaintiff's claims.

LEGAL STANDARD

The Federal Rules of Civil Procedure provide for summary adjudication when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

On a motion for summary judgment, "[i]f the party moving for summary judgment meets its initial burden of identifying for the court those portions of the materials on file that it believes demonstrate the absence of any genuine issues of material fact," the burden of production then shifts so that "the nonmoving party must set forth, by affidavit or as otherwise provided in Rule 56, '*specific facts* showing that there is a genuine issue for trial.'" *T.W. Elec. Service, Inc. v. Pacific Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986)); *Kaiser Cement Corp. v. Fischbach & Moore, Inc.*, 793 F.2d 1100, 1103-04 (9th Cir.), *cert. denied*, 479 U.S. 949 (1986).

[1] Three years prior to the PMA submission, the Trident underwent clinical testing and laboratory testing pursuant to an Investigational Device Exemption application, filed with the FDA. *See* 21 U.S.C. § 360j(g).

In judging evidence at the summary judgment stage, the Court does not make credibility determinations or weigh conflicting evidence, and draws all inferences in the light most favorable to the nonmoving party. *T.W. Electric*, 809 F.2d at 630-31 (citing *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574 (1986)); *Ting v. United States*, 927 F.2d 1504, 1509 (9th Cir. 1991). The evidence the parties present must be admissible. Fed. R. Civ. P. 56(e). Conclusory, speculative testimony in affidavits and moving papers is insufficient to raise genuine issues of fact and defeat summary judgment. *See Falls Riverway Realty, Inc. v. Niagara Falls*, 754 F.2d 49 (2d Cir. 1985); *Thornhill Pub. Co., Inc. v. GTE Corp.*, 594 F.2d 730, 738 (9th Cir. 1979). Hearsay statements found in affidavits are inadmissible. *See, e.g., Fong v. American Airlines, Inc.*, 626 F.2d 759, 762-63 (9th Cir. 1980). The party who will have the burden of proof must persuade the Court that it will have sufficient admissible evidence to justify going to trial.

DISCUSSION

I. Preemption

The principal dispute between the parties on this motion for summary judgment is whether section 360k of the MDA preempts plaintiff's state common-law and statutory claims. Defendants argue that once a device receives PMA approval, the entire device and all of its components are subject to PMA regulatory requirements, which effectively preempt state law tort actions under section 360k.

A. The PMA process

Congress enacted the MDA in 1976 to allow the FDA to regulate medical devices. *See* 21 U.S.C. § 360c. The Act classifies medical devices into three categories based on risk to the public. The most strict FDA regulation is reserved for Class III devices, which pose "a potential unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." *Id.* § 360c(a)(1)(C).

Before introducing a new Class III device into the market, the device must undergo PMA review, during which the manufacturer must provide the FDA with "reasonable assurance" that the device is

safe and effective. *Id.* § 360e(d)(2). Accordingly, the FDA conducts a rigorous review, for which "manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). The PMA application must show reasonable assurance of safety by including a description of the device's components, manufacturing processes, proposed instructions for use, clinical data and information, design, testing methods, manufacturing methods, performance standards, package inserts, and associated labeling. 21 U.S.C. § 360e(c). The application is subject to withdrawal if at any point the device is found unsafe or inadequate. § 360e(e)(1).

Once the manufacturer demonstrates that the device conforms to FDA requirements for safety and effectiveness, the device is approved. *Id.* § 360e(d)(2). If the manufacturer intends to make changes that "affect the safety or effectiveness of the device," then the manufacturer must submit a PMA supplement for FDA approval. 21 C.F.R. § 814.39(a). If the change does not affect the safety or effectiveness of the device, then the manufacturer submits a special PMA supplement that is approved or disapproved within 30 days. *Id.* § 814.39(e).

There are two exceptions to the full PMA process: (1) a pre-1976 Class III device may be "grandfathered in," and (2) a Class III device may be approved by a 510(k) process provided that it is "substantially equivalent" to pre-existing devices. 21 U.S.C. § 360e(b)(1)(A)-(B). Unlike PMA review, "the 510(k) review is completed in an average of only 20 hours." *Lohr*, 518 U.S. at 479. Most Class III devices are "introduced to the market through the 510(k) process and without PMA review." *Id.*

B. Preemption by PMA approval

When Congress enacted the MDA, it sought to establish "national uniformity in product regulation." *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 797 (8th Cir. 2001), *cert. denied*, 535 U.S. 1056 (2002). To ensure this uniformity, Congress provided an express preemption clause under section 360k of the MDA, which states in pertinent part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use 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 under this chapter.

21 U.S.C. § 360k(a).

In *Medtronic, Inc. v. Lohr*, the Supreme Court analyzed the scope of the MDA's express preemption clause on state tort lawsuits in the context of a 510(k) approved device. *See* 518 U.S. at 485. The *Lohr* case involved claims of negligence and strict liability for a malfunctioning pacemaker that was 510(k) approved. In a five to four decision, with Justice Breyer writing separately, the Court found that the MDA did not preempt state-law tort claims with respect to a 510(k) approved device. *Id.* at 501-02.

On the issue of whether state common-law actions constitute state requirements for the purposes of MDA preemption, the four justice plurality found that they almost never do. *Id.* at 502-03 (Stevens, J., Kennedy, J., Souter, J., and Ginsburg, J.). They concluded that Congress intended to preempt "device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries." *Id.* at 489. Reaching the opposite conclusion, another four justices found that "state common-law damages do impose 'state requirements' and are therefore preempted where such requirements would differ from those imposed by the FDCA." *Id.* at 509 (O'Connor, J., Rehnquist, J., Scalia, J., and Thomas, J., concurring and dissenting). Finally, Justice Breyer wrote separately, agreeing with Justice O'Connor's opinion that a state common-law action constitutes a state requirement, insofar as the MDA preempts a requirement that "takes the form of a standard of care or behavior imposed by state-law tort action." *Id.* at 504-05.

The Justices were unanimous in finding that the 510(k) approval process does not create MDA preemption of state claims based on defective design. *Id.* at 513. In addition, five justices agreed that federal requirements "preempt state law only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.'" *Id.* at 500 (Breyer, J. concurring). Those five justices found that no regulation at issue in the case created specific regulations with respect to the design, manufacturing, or labeling of the particular device at issue. *Id.* at 501. In dissent, Justice O'Connor disagreed with the "specificity" requirement imposed by the Court, and opined that the FDA's non-device specific "Good Manufacturing Practice" regulations, and the "extensive labeling requirements imposed by the FDA," would preempt the plaintiff's manufacturing defect and failure to warn claims. *Id.* at 514. None of the

three opinions in *Lohr* addressed whether the PMA process would create a "requirement" for purposes of MDA preemption.

Subsequent to *Lohr*, circuit courts have split on the issue as to whether the PMA approval process creates specific FDA requirements for purposes of MDA preemption. Five out of six circuit courts that have faced this issue have ruled that the PMA process creates FDA requirements. *See Riegel v. Medtronic, Inc.*, 451 F.3d 104, 118 (2d Cir. 2006); *Gomez v. St. Jude Medical Daig Div., Inc.*, 442 F.3d 919, 930 (5th Cir. 2006); *Horn v. Thoratec Corp.*, 376 F.3d 163, 169-70 (3d Cir. 2004); *Brooks*, 273 F.3d at 799; *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 226-28 (6th Cir. 2000), *reh'g denied*, 2001 WL 91119 (6th Cir. Jan. 26, 2001), *cert. denied*, 122 S. Ct. 48 (2001); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998). In *Mitchell*, the Seventh Circuit held: "We agree that the PMA process, as opposed to the 'substantially equivalent' process at issue in [*Lohr*], can constitute the sort of specific federal regulation of a product that can have preemptive effect." *Mitchell*, 126 F.3d at 911.

Post-*Lohr*, only the Eleventh Circuit court has explicitly found that the PMA review process does not create specific federal requirements. *See Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1375-80 (11th Cir. 1999). In *Goodlin*, the plaintiff sued the manufacturer of a PMA-approved pacemaker lead. The Eleventh Circuit held that "neither the FDA's actual review of a device and its supporting information nor the agency's eventual approval of the device imposes any ascertainable requirement on the device." *Id.* at 1375. In reaching this holding, the court engaged in a thorough review of Congressional intent, and noted that "several highly publicized incidents involving defective medical devices . . . gave rise to Congress's legislation in this area. It would have been inconsistent for the same Congress that enacted these sweeping reforms . . . then to preempt product liability suits when those devices caused injury." *Id.* at 1378. The court continued: "We . . . are reluctant to conclude that Congress sought to remove all remedies available to the very class of persons that it sought to protect when it enacted the MDA." *Id.* at 1379.

Though the Ninth Circuit has not directly addressed this issue post-*Lohr*, it did address the issue pre-*Lohr*, in *Kennedy v. Collagen Corporation*, 67 F.3d 1453 (9th Cir. 1995). In *Kennedy*, the plaintiff brought suit against the manufacturer of a PMA-approved prescription medical device used to treat soft

tissue defects. In addressing defendant's preemption argument, the Ninth Circuit stated: "We must address two threshold questions: (1) what constitutes a 'State . . . requirement' and (2) what constitutes a 'requirement' under the MDA." *Id.* at 1457 (quoting case). With respect to the first inquiry, the Ninth Circuit held that state common-law causes of action do not constitute state requirements for the purposes of MDA preemption. *See id.* at 1459. As discussed above, the Supreme Court in *Lohr* overruled this first holding of *Kennedy*. The Ninth Circuit recognized this much in *Papike v. Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir. 1997), stating: "To the extent we concluded in *Kennedy* that the MDA cannot preempt any state common-law causes of action, the conclusion cannot survive in light of the concurring and dissenting opinions in [*Lohr*]."

However, *Lohr* did not have any discernable impact on the Ninth Circuit's answer to the second of the two "threshold questions." In this strongly-worded second holding, the Ninth Circuit stated:

> [I]t makes little sense to hold that the FDA's premarket approval process qualifies as a "*specific* requirement applicable to a *particular* device." 21 C.F.R. § 808.1(d) (emphasis added). All Class III devices are required to obtain premarket approval before being sold in interstate commerce. 21 U.S.C. § 360e; 21 C.F.R. § 814.1. The fact that the premarket approval process involves specific requirements, *see* 21 C.F.R. § 814, 820, must not be confused with the premarket approval requirement itself acting as a specific requirement. The result of holding that the premarket approval process is a "specific requirement applicable to a particular device" is the preemption of claims which, if barred, leave injured plaintiffs without any remedy in state or federal law.

Id. (emphasis in original). The court reasoned that to hold otherwise "flies in the face of congressional intent behind the MDA legislation: consumer protection." *Id.* It concluded:

> The federal law requiring the premarket approval of Class III devices was not enacted in order to free manufacturers from the everyday burdens of the marketplace after they are permitted to enter it. Premarket approval is supposed to benefit consumers, not create a rose garden, free from liability, for manufacturers. Courts which have held to the contrary have done so in contravention of the FDA's regulations and statements concerning the preemptive scope of the MDA.

Id. at 1459-60.

Nothing in *Lohr*, *Papike*, or any other Ninth Circuit case, overrules this half of *Kennedy*. In fact, *Papike* supports a conclusion that the Ninth Circuit would reaffirm the second holding of *Kennedy*, post-*Lohr*. *See* 107 F.3d at 737. In *Papike*, the Ninth Circuit concluded that under the MDA, the specific and extensive FDA code regulations mandating Toxic Shock Syndrom ("TSS") warning labeling on tampons, preempted the plaintiff's state law failure to warn claims against a tampon manufacturer. *See*

id. at 740-42. The court explained: "The regulation is not only device-specific (tampons), but also disease-specific (TSS). This fact distinguishes Papike's case from prior relevant MDA preemption cases, including [*Lohr*, *Kennedy*, and other cases]." *Id.* at 740. "Unlike the general federal requirements in [*Lohr*], the warning requirements here reflect 'the sort of concerns regarding a specific device of field of device regulation which the . . . regulations were designed to protect from potentially contradictory state requirements.'" *Id.* Consequently, "preemption results in this case because the FDA has established specific counterpart regulations with respect to labeling tampons." *Id.* at 741. In an especially helpful passage to the issues faced here, the court stated:

> In summary, preemption is triggered by and "the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device." *Anguiano*, 44 F.3d at 809 (internal quotation omitted). The tampon labeling regulation is device- and disease-specific and preemption is warranted in this case. This result is entirely consistent with [*Lohr*], which did not involve device-specific federal requirements. *Kennedy* does not support Papike's position because not only did it involve general federal requirements, but also because its conclusion that a common-law claim cannot be preempted does not survive the five Justices' contrary conclusion in [*Lohr*].

Id. at 742. The Ninth Circuit's statement that *Kennedy* "involve[d] general federal requirements," almost conclusively establishes that in its view, even after *Lohr*, the PMA process at issue in *Kennedy* and here, constitutes and generates "general federal requirements" insufficient to allow MDA preemption.

In light of *Kennedy*, *Papike*, and the persuasive analysis of the Eleventh Circuit in *Goodlin*, this Court finds that the PMA process does not constitute or create "specific FDA requirements applicable to a particular device," *id.*, and cannot, therefore, be used to preempt related state law causes of action.[2] Here, defendants' Trident system went through the full PMA review process and received approval on

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[2]The Court is also mindful of the Supreme Court's instruction that:

> because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied," *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 91 L. Ed. 1447, 67 S. Ct. 1146 (1947), we "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Ibid.*

Lohr, 518 U.S. at 485 (citing additional cases).

February 3, 2003. The FDA issued a document entitled "Conditions of Approval," which required that the manufacturer submit proposed labeling before marketing, submit PMA supplements before making any changes affecting safety or effectiveness, submit post-approval reports annually, and report any adverse reactions. *See* Cymbaluk, Ex. B. As *Goodlin* explains: "The 'Conditions of Approval' . . . set forth rules and regulations generally applicable to all devices approved through the PMA process." 167 F.3d at 1377. Ultimately, the only requirements imposed on the Trident system were these generic "Conditions of Approval." Defendants provide no evidence here of a requirement applicable specifically to the Trident, the Alumina C-Taper Head, or to prosthetic hips or joints more generally, such as the Tampon- and TSS-specific requirement at issue in *Papike*. Therefore, even if the device at issue here was PMA approved, plaintiff's state law claims are not subject to MDA section 360k preemption.[3]

II. Design defect claims

In addition to the preemption argument, defendants briefly argue that plaintiff's claims independently fail, for failure to provide evidence of essential claim elements.

With respect to plaintiff's first two claims, for strict liability, defendants argue that under California law, manufacturers of implanted prescription medical devices such as the Trident cannot be held strictly liable for defective design. The Court agrees. The California courts announced this limitation in *Hufft v. Horowitz*, 4 Cal. App. 4th 8, 17 (Cal. Ct. App. 1992), stating: "We hold that a

[3]Though the Court need not do so in light of the foregoing, it is worth noting that the particular facts of the device approval process in this case cast further doubt on whether plaintiff's state law claims are preempted. In particular, it is not clear to the Court that the device at issue here received the benefit of the full FDA PMA approval process.

Though the FDA approved the Alumina C-Taper Head component via the PMA process as part of the Trident, the FDA approved the particular size of the head component used by plaintiff via the special 30-day PMA supplemental process. *See* Cymbaluk Decl., Ex. B. As described above, the FDA approves changes to PMA-approved devices via the special 30-day PMA supplemental process only when the FDA determines that the change does not affect the safety or effectiveness of the device. Furthermore, in their application for PMA supplemental approval of additional Alumina C-Taper Head component sizes, defendants cited to the FDA the fact that the other head sizes had been previously approved by the FDA, apart from the Trident system, pursuant to the 510(k) process. *See* Parisian Decl. ¶ 57, Ex. D. Given these facts, it is not clear to the Court that the device at issue here can be considered to have gone through the full PMA process. Thus even if the PMA process were to create or constitute a device-specific federal requirement for MDA preemption purposes, the Court would not necessarily apply that preemption to the device at issue here.

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." Strict liability is thus limited to manufacturing defect cases (products which are not "properly made"). Accordingly, the Court GRANTS defendants' motion with respect to plaintiff's strict liability design defect claims.

With respect to plaintiff's negligence-based product liability claim, defendants argue generally that "Plaintiff has produced no evidence that the design of the Trident system or any component was in any way defective." Mot. at 22:17-18. Under California law,

> in a products liability action based on negligence in the design of a product "placed on the market," the test of negligent design "involves a balancing of the likelihood of harm to be expected from a machine with a given design and the gravity of harm if it happens against the burden of the precaution which would be effective to avoid the harm."

Merrill v. Navegar, Inc., 26 Cal. 4th 465, 479 (Cal. 2001) (quoting *Pike v. Frank G. Hough Co.*, 2 Cal. 3d 465, 470, 85 Cal. Rptr. 629, 467 P.2d 229 (Cal. 1970)). In a negligence case, unlike a strict liability case, "the jury's focus is properly directed . . . to the reasonableness of the manufacturer's conduct," rather than "the condition of the product itself." *Barker v. Lull Enq'q, Co.*, 20 Cal. 3d 413, 434 (Cal. 1978). Here, there is sufficient, and undisputed, evidence that the Trident system involved some likelihood of grave harm. It is for the jury to weigh this harm "against the burden of the precaution which would be effective to avoid the harm." *Merrill*, 26 Cal. 4th at 479.

In their motion, defendants also suggest, without explicitly saying so, that the FDA's review of the Trident precludes plaintiff's negligence claims. While this may be one factor in the fact-finder's consideration of the weighing test described above, it is not dispositive. The Court therefore DENIES defendants' motion to dismiss plaintiff's negligent product liability claim.

III. Manufacturing defect claims

With respect to plaintiff's manufacturing defect theory, defendants contend that plaintiff has failed to raise a triable issue as to whether "any component of the device differed from other typical units of the same product line when it left HOC's control." Mot. at 23:7-8. Under California law, a manufacturing defect occurs where the "product differs from the manufacturer's intended result or from

other ostensibly identical units from the same product line." *Barker*, 20 Cal.3d at 429. At this stage, on a motion for summary judgment brought and argued before the close of discovery, plaintiff has provided sufficient evidence that the product at issue "differ[ed] from the manufacturer's intended result." Defendants are correct that under California law, "a defect in manufacture or design defect must be affirmatively established, and an inference of defect solely from the fact of an accident cannot be drawn." *Hinckley v. La Mesa R.V. Center, Inc.*, 158 Cal. App. 3d 630, 642 (Cal. Ct. App. 1984). However, this rule does not preclude a plaintiff from proving a manufacturing defect using only circumstantial evidence. *See, e.g., id.* at 643 ("Where a product fails to such an extent that its examination can furnish no clue as to the specific part that failed, the facts (1) the accident occurred shortly after sale, (2) plaintiffs did nothing to bring about the accident, and (3) expert testimony suggests a defect in fact was responsible for the accident, allow the issue of whether defendants are strictly liable for plaintiffs' injuries to be submitted to the jury."). Here, even before the close of fact and expert discovery, plaintiff has presented sufficient circumstantial evidence to raise a triable issue of fact as to whether the subject femoral head contained a manufacturing defect.

IV. Failure to warn claims

"A medical product manufacturer fulfills its duty to warn of risks by providing adequate information to the physician." *Hufft v. Horowitz*, 4 Cal. App. 4th 8, 21 n.14 (1992). Here, defendants argue that the Trident package labeling included FDA-approved warnings, and that "the undisputed evidence establishes that these warnings were provided to the implanting physician." Mot. at 24:6. Defendants cite to no such evidence, however, and it is their burden to do so. Accordingly, the Court DENIES defendants' motion for summary judgment on plaintiff's failure to warn claims.

V. Breach of warranty, misrepresentation, concealment

Finally, in a page-long smattering of arguments, defendants attack plaintiff's five remaining causes of action. First, defendants argue that plaintiff "cannot establish the existence of any evidence that any representations were made by defendants concerning the safety of the device other than the information contained in the FDA-approved labeling that his doctor may have discussed with him."

Mot. at 24:16-18. In response, plaintiff argues that his claims are based on omission of information, rather than active misrepresentation. For example, plaintiff argues that defendants failed to disclose to plaintiff and his physician that the femoral head of the size and neck angle used in plaintiff was more likely to fracture than other sizes, or that there was a superior material available to defendants at the time. Plaintiff's omission claims thus tie directly in with his design and manufacturing defect claims, as to which plaintiff has raised material issues of fact.

Defendants also rely in this section on the "undisputed" fact that HOC provided the FDA-approved warnings to plaintiff's physician. As discussed above, defendant provides no such evidence. Furthermore, defendants cite no authority for the proposition that FDA approval of warnings precludes claims based on inadequate warnings. Accordingly, the Court DENIES defendants motion for summary judgment on these claims.

CONCLUSION

For the foregoing reasons and for good cause shown, the Court hereby DENIES defendants' motion for summary judgment on plaintiff's claims.[4]

IT IS SO ORDERED.

Dated: August 6, 2007

SUSAN ILLSTON
United States District Judge

[4]The parties bring several objections to each other's evidence. The Court DENIES defendants' objections to Exhibit C of the Abrams declaration, and SUSTAINS defendants' objections as to Exhibit D. The Court did not rely upon any other objected-to exhibits, or the actual declarations of Suzanne Parisian or Rachel Abrams, in reaching the conclusions contained in this order. The Court therefore DENIES defendants' additional objections as moot. Plaintiff's evidentiary objections are DENIED AS MOOT.