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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

APRIL CHRISTINE CABANA, Plaintiff, vs. STRYKER BIOTECH, LLC; STRYKER CORPORATION; MEDTRONIC SOFAMOR DANEK USA, INC., MEDTRONIC, INC.; and DOES 1 through 100, inclusive, Defendants.	Case No.: BC 465 313 Hon. Michael Paul Linfield NOTICE OF RULING RE DENIAL OF MEDTRONIC'S MOTION FOR SUMMARY JUDGMENT **Date: August 20, 2012** **Time: 8:30 A.M.** **Dept.: 10** Action Filed: July 13, 2011 Trial Date: October 9, 2012

TO ALL PARTIES AND TO THEIR ATTORNEYS OF RECORD:

NOTICE IS HEREBY GIVEN that, on August 20, 2012 at 8:30 a.m. in Department 10 of the above-entitled Court, the Honorable Michael P. Linfield presiding, the motion for summary judgment by Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively "Medtronic") came on for a regularly scheduled hearing. Appearances were made by Bijan Esfandiari for plaintiff April C. Cabana and Michael K. Brown and Lisa M. Baird for Medtronic. Prior to the hearing, the Court had issued its tentative ruling on Medtronic's motion, a copy of which is attached hereto as Exhibit A. Following the argument of counsel, the Court adopted its tentative ruling (Exhibit A) as the Court's final ruling,

which became the order of the Court with the modification that the parties' requests to seal exhibits submitted in connection with the motion will be the subject of a separate order.

DATED: August 22, 2012

BAUM HEDLUND ARISTEI & GOLDMAN, PC

By: _____
Bijan Esfandiari, Esq.

Attorneys for Plaintiff
April Christine Cabana

EXHIBIT A

Civil · Tentative Rulings

DEPARTMENT 10 LAW AND MOTION RULINGS

Case Number: BC465313 **Hearing Date:** August 20, 2012 **Dept:** 10

The motion of defendants Medtronic Sofamor Danek USA, Inc. and Medtronic, Inc. (collectively "Medtronic") for Summary Judgment is DENIED.

The alternative Motion for Summary Adjudication is MOOT as to Issues 3, 5, 6 and 8 because Plaintiff has agreed to dismiss her 4th cause of action for strict liability and her 6th cause of action for breach of implied warranty.

The alternative motion for summary adjudication is DENIED as to Issues 1, 2, 4, 7, 9, and 10.

A ruling on Medtronic's motion to file Exh. A (or Exhs. A and B) under seal is deferred to the hearing on the motion for summary judgment.

Plaintiff's request to file medical records under seal is GRANTED.

Plaintiff's request to file tax records under seal is GRANTED.

Defendants' Objections Nos. 1-33:

Objection Ruling
1 Overruled
2 Overruled
3 Overruled
4 Overruled
5 Overruled
6 Overruled
7 Overruled
8 Overruled
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23 Overruled
24 Overruled
25 Overruled
26 Overruled

27 Sustained
28 Sustained
29 Sustained
30 Sustained
31 Sustained
32 Overruled
33 Overruled

MOTION FOR SUMMARY JUDGMENT AND/OR SUMMARY ADJUDICATION

Medtronic moves for summary judgment, or alternatively summary adjudication, of each of the five causes of action asserted against Medtronic in the complaint on the ground that the claims are preempted by federal law pursuant to the express preemption provision of the Medical Device Amendments ("MDA") contained in the federal Food, Drug and Cosmetic Act, 21 USC § 360k, et seq., by application of implied preemption principles, or by the Food, Drug and Cosmetic Act's bar against private actions enforcing its provision, 21 USC § 337. Because Medtronic manufactured, designed and labeled plaintiff's Premarket Approved device in accordance with the specifications mandated by the FDA, any state-law claim that would impose requirements on the device that are contrary to those imposed by the FDA is prohibited by the express preemption provision, 21 U.S.C. Section 360k(a), as articulated by the Supreme Court in Riegel v. Medtronic, Inc. (2008) 552 U.S. 312, implied preemption principles articulated in Buckman Co. v. Plaintiff's Legal Committee (2001) 531 U.S. 341, and by the Food, Drug and Cosmetic Act's bar against private actions enforcing its provisions, 21 U.S.C. § 337. Therefore, Medtronic is entitled to judgment under CCP § 437c.

In opposition, plaintiff contends that the central issue in this case is whether federal law preempts products liability claims against manufacturers of a medical devoice where the patient claims she was harmed as a result of the manufacturer's illegal promotion of the medical device for uses not approved by the FDA.

Complaint

In the complaint, it is alleged that this is a products liability action arising out of injuries caused by the illegal off-label promotion of two medical device manufacturers. (Complaint ¶1.) To cure her back pain, plaintiff underwent a surgery in which her surgeon used a mixture of two products manufactured by defendant Stryker Biotech. (¶1.) The mixed use of these two products (Calstrux and OP-1) had not been approved by the FDA and Stryker knew that the mixed used of these two products was ineffective and could lead to unwanted bone growth. (¶1.)

Nonetheless, Stryker engaged in extensive and illegal off-label promotion of the mixed use of these two products. (¶1.) Plaintiff eventually had to undergo a second surgery to remove the excessive bone growth. (¶1.) In the second surgery, plaintiff's surgeon removed the "bone of unknown origin" and, in order to fuse the bone, the surgeon used INFUSE Bone Graft manufactured by defendant Medtronic. (¶2.) The INFUSE Bone Graft had only been approved for a limited surgical procedure, yet Medtronic illegally promoted it for a number of off-label procedures. (¶2.) The surgeon used the INFUSE Bone Graft in an off-label manner and the surgery failed to remedy plaintiff's condition and exacerbated her pain. (¶2.) As a

result of the untested, unapproved, and off-label use of materials during her surgeries, her condition and pain has worsened and necessitated additional surgeries. (¶3.)

Medtronic acquired the exclusive rights to recombinant human bone morphogenetic protein-2 ("rhBMP-2") for spinal applications. (¶64.) rhBMP-2 is a genetically engineered version of a naturally occurring protein that stimulates bone growth, developed as a commercially viable bone morphogenetic protein ("BMP") technology. (¶64.) On January 12, 2001, Medtronic filed the INFUSE Bone Graft PMA and was granted expedited review status by the FDA. (¶65.)

On July 2, 2002, the FDA approved INFUSE Bone Graft for certain limited uses. (¶66.) Although these two components are sold separately, the initial approved labeling for the product indicates that the INFUSE Bone Graft must be used with the LT-CAGE component. (¶68.) The labeling also directs the specific manner in which both components are to be used in a fusion procedure. (¶69.) INFUSE Bone Graft can only be used in an Anterior Lumbar Interbody Fusion ("ALIF") procedure, involving a single-level fusion in the L4-S1 region of the lumbar spine. (¶70.) ALIF is performed by approaching the spine from the front through an incision in the abdomen and is primarily used to treat pain resulting from disc collapse. (¶71.) There are numerous other lumbar spine surgical procedures for which INFUSE had not been approved but for which it was promoted and/or utilized, such as (a) Posterior Lumbar Interbody Fusion ("PLIF"); (b) Posterolateral Fusion; and (c) Transforaminal Lumbar Interbody Fusion ("TLIF"). (¶71.) Use of rhBMP-2 in other applications revealed instances of adverse events. (¶72.) At the FDA Advisory Committee panel hearing on January 10, 2002 concerning FDA approval of Medtronic's INFUSE Bone Graft, the panel members stressed concerns regarding potential off-label use of the product and asked Medtronic presenters repeated questions about how the Company would seek to guard against off-label applications of the product. (¶¶74-75.) At the time of its FDA approval, Medtronic and its senior management, were well aware of the concern regarding off-label uses of INFUSE Bone Graft and the potential dangers posed by them. (¶76.) Subsequent medical studies confirmed the fears of the FDA Advisory Panel that use of INFUSE Bone Graft outside of the studied application sought in the PMA could present severe risks to patient safety. (¶¶77-78.)

Medtronic's senior management concealed the company's surreptitious effort to promote the widespread off-label use of INFUSE Bone Graft. Medtronic provided millions of dollars in undisclosed payments to doctors (including so-called "Key Opinion Leaders") who published articles in medical journals, delivered presentations at continuing medical education courses, and appeared at consulting engagements addressing off-label applications of INFUSE Bone Graft. (¶¶81, 84.) Under applicable FDCA and FDA regulations, device and drug manufacturers such as Medtronic are prohibited from actively promoting products for uses not approved by the FDA. (¶82.)

Dr. Mesiwala performed a surgical procedure on plaintiff on September 26, 2008, including the off-label procedure of the mixed use of the two Stryker products. (¶¶87-88.) In the July 13, 2009 surgery, Dr. Mesiwala removed the Stryker bone graft and used the INFUSE Bone Graft in an off-label manner (instead of performing an anterior procedure, Dr. Mesiwala opted for a posterior procedure). (¶¶94-95.) The Medtronic defendants, directly and indirectly promoted, trained, and encouraged Dr. Mesiwala to perform this procedure. (¶96.) Dr. Mesiwala never informed plaintiff that he would be using the product at all or in that manner, that the procedure was not FDA approved, that it could result in adverse affects, etc.

(¶97.) Plaintiff has never recovered from her two surgeries and continues to have daily severe disabling pain in her lower back and nerve pain throughout her right leg. (¶98.)

The five causes of action brought against Medtronic are: (2) negligence; (4) strict liability; (6) breach of express and implied warranty; (8) fraud; and (9) negligence per se. (As indicated above, plaintiff has agreed to dismiss her 4th cause of action for strict liability and her 6th cause of action for implied warranty.)

Express Preemption

Medtronic argues that pursuant to Riegel, supra, 552 U.S. 312, plaintiff's claims must be dismissed. (Motion p. 7.) In opposition, plaintiff argues that Riegel and its progeny held that, while manufacturers who comply with federal law may be entitled to preemption, those who violate federal law are not entitled to preemption. (Opposition p. 4.) Plaintiff's argument is persuasive.

In Riegel, a cardiac patient sued the manufacturer of a balloon catheter used in his angioplasty, asserting state-law claims including strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, sale and manufacture. The US Supreme Court held that the FDA's premarket approval process established federal requirements and that the patient's New York common-law claims of negligence, strict liability, and implied warranty against manufacturer were preempted.

Plaintiffs "alleged that Medtronic's catheter was designed, labeled, and manufactured in a manner that violated New York common law, and that these defects caused Riegel to suffer severe and permanent injuries. The complaint raised a number of common-law claims." Riegel, supra, 552 U.S. at 320. "Since the MDA expressly pre-empts only state requirements 'different from, or in addition to, any requirement applicable ... to the device' under federal law, [21 USCA] § 360k(a)(1), we must determine whether the Federal Government has established requirements applicable to Medtronic's catheter. If so, we must then determine whether the Riegels' common-law claims are based upon New York requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness. § 360k(a)." Id. at 321-322.

"State requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements. [Citations.] The District Court in this case recognized that parallel claims would not be pre-empted, [citation], but it interpreted the claims here to assert that Medtronic's device violated state tort law notwithstanding compliance with the relevant federal requirements, [citation]. Although the Riegels now argue that their lawsuit raises parallel claims, they made no such contention in their briefs before the Second Circuit, nor did they raise this argument in their petition for certiorari. We decline to address that argument in the first instance here." Riegel, supra, 552 U.S. at 330.

Here, as discussed above, plaintiff's claim is not based on allegations that Medtronic's device violated state tort law notwithstanding compliance with the relevant federal requirements. In contrast, plaintiff here is alleging that Medtronic promoted the use of its device in violation of federal requirements. (See Complaint

cited above; see also plaintiff's responses to Separate Statement of Undisputed Facts ("SSUF") 6, 8, 10, 13-15; Plaintiff's Additional Material Facts ("AMF") 23-39.) Accordingly, Riegel is not authority that plaintiff's claims against Medtronic are preempted here.

Off-Label Allegations

Medtronic argues that the fact that plaintiff makes off-label promotion allegations does not immunize her claims under section 360k(a). Medtronic cites McGuan v. Endovascular Technologies, Inc. (2010) 182 Cal.App.4th 974, 978, 983 and Wolicki-Gables (M.D. Fla. 2009) 641 F.Supp.2d 1270, 1292. (Motion pp. 12-13.)

In its reply brief, Medtronic states that McGuan "is the controlling California decision." (Reply, p. 2:11.) But McGuan is not apposite. In McGuan, patients brought product liability and personal injury actions against manufacturers and designers of abdominal aortic aneurysm treatment device after patients suffered severe injuries after they were implanted with the device. The Court of Appeal held that the MDA preempted the patients' state law claims and any claims for fraud on the FDA and fraud on patients and their physicians. As the court noted, "Plaintiffs' complaints focus on defects in the design, testing, and manufacture of the Ancure Device, the failure to warn of all possible adverse side effects, and the fraudulent concealment of the dangers and defects of the product. The complaints do not refer to violations of federal law." Id. at 980. The court later repeats this all-important qualifier: "[H]ere, though plaintiffs' complaints are based, in part, on alleged defects in the design, testing, and manufacture of the Ancure Device, as well as the failure to warn of all possible adverse side effects, they do not allege that defendants violated FDA regulations." Id at p. 983. In contrast here, plaintiff's claims are based on the promotion and use of the product in a manner that has not been approved by the FDA.

Also, as to Wolicki-Gables, the portion of the case cited is not relevant to plaintiff's claims in this action. (See id. at 1292 ["As to Plaintiffs' claim based on an alleged 'off label' use of the pain pump, Dr. Reese testified that Dr. James' decisions on 7/15/2003 resulted in an "off label" use of the pain pump and Defendant Nelson should have advised Dr. James as such during the procedure. Dr. Reese, who is not a medical doctor, testified that Dr. James should have removed and replaced everything originally implanted: pump, catheter connector, and intrathecal catheter. According to Dr. Reese, the exercise of medical judgment by Dr. James went beyond the product labeling and resulted in an off label use, although Dr. Reese acknowledges that the replacement catheter connector itself was used exactly as indicated in the FDA approved labeling to connect the pump to the catheter. [¶] The Court has already recognized that 'off label use,' within the context of medical treatment is not prohibited, as the FDCA does not regulate the practice of medicine. [¶] The Court notes that a claim for negligence based on "off label use" is not pleaded [as to one defendant] . . . and there is a complete lack of evidence as to any claim for negligence based on "off label" marketing and promotion [by the other defendant]."])

Parallel Claims

Medtronic also argues that plaintiff's state law claims do not amount to genuine "parallel claims." Medtronic fails to cite to any submitted evidence in support of its argument that the exception under Riegel does not apply here. Instead, Medtronic

seems to be placing the burden upon plaintiff to prove her claims; however, this is not plaintiff's burden in opposing a motion for summary judgment. (See Opposition p. 14.)

Implied Preemption

Medtronic next argues that even if plaintiff's claims were not expressly preempted, they would still be barred because they are impliedly preempted under Buckman, supra, 531 U.S. 341 and 21 USC § 337(a). (Motion p. 15.) In opposition, plaintiff correctly points out that Buckman concerned a "fraud on the FDA" claim, which is not applicable to this case.

The California Court of Appeal in McGuan, supra, summarized Buckman:

"In Buckman, the plaintiffs suffered injuries after orthopedic bone screws were implanted in their spines. (Buckman, supra, 531 U.S. at p. 343, 121 S.Ct. 1012.) The plaintiffs then brought state tort law claims in which they alleged that the defendant made fraudulent representations to the FDA in obtaining approval to market these CLASS III devices, and they would not have been injured if these representations had not been made. (Ibid.) The Buckman court began its discussion by observing that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' [citation]" and thus the nature of the plaintiffs' claims was insufficient to warrant a presumption against preemption. (Buckman, at p. 347, 121 S.Ct. 1012.) The court based this conclusion on the principle that 'the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.' (Ibid.)

Based on this "analytical framework," the court held that the state law fraud-on-the-FDA claims conflicted with, and thus, were impliedly preempted by federal law. (Buckman, supra, 531 U.S. at p. 348, 121 S.Ct. 1012.) As the court explained, "[t]he conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." (Ibid.) After reviewing the extensive disclosure requirements of the MDA and the provisions governing the detection, deterrence and punishment of false statements made during the approval process, the court concluded that state tort law fraud-on-the-FDA claims would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." (Buckman, at pp. 349–350, 121 S.Ct. 1012.) Since the court held that the claims were impliedly preempted, it did not consider whether the claims were expressly preempted under 21 U.S.C. § 360k. (Buckman, at p. 348, fn. 2., 121 S.Ct. 1012)." McGuan, supra, 182 Cal.App.4th at 984-985.

Buckman is inapposite to plaintiff's claims as plaintiff has not brought a claim for "fraud-on-the-FDA" against Medtronic.

The Court notes that the recently-decided case of Cornett v. Johnson & Johnson, __ A.3d ____, 2012 WL 3210943 (N.J., Aug. 9, 2012) reaches a similar conclusion. The New Jersey Supreme Court analyzed the preemption doctrine and concluded that failure to warn claims and breach of express warranty claims are not necessarily preempted as a matter of law. If "plaintiffs' failure to warn claim is founded on

promotion by defendants of off-label uses of the device . . . the claim is not preempted." (Id. at p. *13.) Similarly, the court concluded that "to the extent . . . defendants have deviated from the labeling and instructions for use through voluntary statements to third parties in the course of its marketing efforts, this claim [for breach of express warranty] is not preempted." (Id. at p. *15.)

(Lastly, the court notes that on page 1 of defendants' reply brief, Medtronic cites to the Los Angeles Superior Court case of Coleman v. Medtronics Corp. (Reply, p. 1:11-13.) Medtronic states that "[I]n Coleman, the court sustained Medtronic's demurrer without leave to amend on federal preemption grounds in another LA Suerior [sic] Court case involving the Infuse Device. Medtronic recognizes the trial court decision in Coleman does not have binding precedential value and is not submitting it for that purpose but merely to alert this court to a decision in a similar case." (Reply, p. 1, fn. 1.) Such an effort to "alert" this court is improper. It might behoove the managing partner on this case, the next time he reviews such a brief, not only to correct the typographical error, but to delete the allusion to uncitable cases altogether.)

For the aforementioned reasons, the motion for summary judgment is DENIED.

As to the alternative motion for summary adjudication, the motion is DENIED as to Issues 1, 2, 4, 9 and 10 for the same reasons. (The court would deny the alternative motion for summary adjudication as to issue No. 5 for the same reason; however since plaintiff has agreed to withdraw her 6th cause of action, this issue is now moot.)

Independent State Law Grounds

Medtronic also argues that: (A) the fourth cause of action for strict liability is barred by the application of the Restatement (Second) of Torts § 402A, Comment K (MSA: Issue 3); (B) that the sixth cause of action for breach of implied warranty of fitness is barred by Civil Code § 1793.02(e)(3) (MSA: Issue 6); and (C) the sixth cause of action for breach of express and implied warranty fails due to lack of privity (MSA: Issues 7 (express warranty) and 8 (implied warranty)). (Motion pp. 18-20.)

Plaintiff has agreed to dismiss her strict liability design defect claim and her breach of implied warranty claim. (Opposition p. 19.) Therefore, as to issues Nos. 3, 6 and 8, the motion for summary adjudication is moot.

Medtronic cites Fieldstone Co. v. Briggs Plumbing Products, Inc. (1997) 54 Cal.App.4th 357 (superseded by statute on other grounds) for the proposition that privity of contract is a required element of an express breach of warranty cause of action. (Motion p. 20.) However, the court actually stated that "As a general rule, privity of contract is a required element of an express breach of warranty cause of action. [Citation.] However, there is an exception where plaintiff's decision to purchase the product was made in reliance on the manufacturers' written representations in labels or advertising materials. [Citations.]" Id. at p. 369, fn. 10. In opposition, plaintiff cites cases in which courts stated that privity is not required for breach of express warranty claims. (Opposition p. 19.) "We note that privity is not a requirement for actions based upon an express warranty." In Evraets v. Intermedics Intraocular, Inc. (1994) 29 Cal.App.4th 779, 789, citing Seely v. White

Motor Co. (1965) 63 Cal.2d 9, 14 and Rodrigues v. Campbell Industries (1978), 87 Cal.App.3d 494, 500; see also Hauter v. Zogarts (1975) 14 Cal.3d 104, 115 ("The fact that Fred Hauter is not in privity with defendants does not bar recovery. Privity is not required for an action based upon an express warranty.)

Plaintiff's argument, as indicated by the above cases, is persuasive. Plaintiff also argues that Judge Sinanian has already rejected an identical argument that was advanced by co-defendant Stryker. (Opposition p. 19, citing Exhibit 32.) This argument is not persuasive: a previous rejection of a similar argument on demurrer is not relevant at the Summary Judgment stage.)

Plaintiff's claim for breach of express warranty is not barred as a matter of law.

The motion for summary adjudication is DENIED as to Issue 7.

SEALING OF PORTIONS OF THE RECORD

The court has three requests for filing various documents under seal:
1) Medtronic requests to file Exh. A (or Exhs. A and B) under seal
2) Plaintiff requests to file medical records under seal
3) Plaintiff's request to file tax records under seal

The trial court "may order that a record be filed under seal only if it expressly finds facts that establish: [¶] (1) There exists an overriding interest that overcomes the right of public access to the record; [¶] (2) The overriding interest supports sealing the record; [¶] (3) A substantial probability exists that the overriding interest will be prejudiced if the record is not sealed; [¶] (4) The proposed sealing is narrowly tailored; and [¶] (5) No less restrictive means exist to achieve the overriding interest." (Cal. Rules of Court, rule 2.550(d).)

Medtronic's Request to File Exhibit(s) Under Seal:

Medtronic has filed a motion to file under seal Exhibit A to the Declaration of William Garth Conrad submitted in support of Medtronic's motion. This exhibit was filed conditionally under seal on December 15, 2011 and the motion is made pursuant to CRC 2.550 and 2.551 and the stipulation and protective order entered in this action. Both the moving papers (filed December 15, 2011) and the reply (filed August 13, 2012) refer to an Exhibit A to the Declaration of William Garth Conrad; however, the "Amended Declaration of Michelle L. Cheng," filed April 25, 2012, refers to two documents, Exhibits A and B, that were filed under seal.

Exhibit A to the Declaration of William Garth Conrad apparently contains highly confidential and proprietary information about Medtronic's method of tracking each of the devices through the proprietary manufacturing process and their extensive inspections, all of which ensure the device's quality standards and conformance with the design requirements. (Memo of P&A p. 3; Barry Declaration. ¶¶5-10.)

Exhibits A and B to the Amended Declaration of Michelle L. Cheng are plaintiff's medical records from the July 13, 2009 surgery.

It is not clear to the court which document(s) Medtronics is requesting be filed under seal.

The court request clarification on this issue at the summary judgment hearing.

Plaintiff's Requests to File Exhibits Under Seal:

Cabana requests that two documents be filed under seal: part of her own medical records, and a third-party tax return. The court finds that all five requirements of Cal. Rules of Court, rule 2.550(d) are met and grants her request.

Plaintiff to prepare the Order.
