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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

PLAINTIFF'S OPPOSITION TO MEDTRONIC'S MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, SUMMARY ADJUDICATION

Date: August 20, 2012
Time: 8:30 a.m.
Dept.: 10

[Filed concurrently with Declaration of Bijan Esfandiari; Separate Statement of Undisputed Facts; Notice of Lodging Out-of-State Authorities; (Proposed) Order; Proof of Service]

Action Filed: July 13, 2011
Trial Date: October 9, 2012

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

STATUTES

MEMORANDUM OF POINTS AND AUTHORITES

The central issue in this case is whether federal law preempts products liability claims against manufacturers of a medical device 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. Cases that have addressed this specific issue, including those cited by defendants, have held that such claims are not preempted. Medtronic, however, through a distorted and illogical interpretation of the facts and applicable precedent, argues it is entitled to *complete* immunity. In rejecting similar arguments, a Court of Appeals cogently stated: "The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive." *Bausch v. Stryker Corp*., 630 F.3d 546, 549 (7th Cir. 2010) cert. denied, 132 S. Ct. 498 (U.S. 2011); *see also Steele v. Collagen Corp*., 54 Cal.App.4th 1474, 1486 (1997) ("it is clear preemption does not apply to a state claim based on a manufacturer's violation of FDA requirements"). The *Bausch* court observed that, while manufacturers who *comply* with federal law may be entitled to immunity, those who *violate* federal law cannot hide behind the shield of immunity and are liable under state tort law for any personal injuries caused by their violations.

Medtronic's arguments are even more suspect given it is a defendant in a *certified* class action wherein investors claim they suffered financial losses as a result of the same conduct (i.e., Medtronic's illegal promotion of Infuse) at issue in this case. *Minneapolis Firefighters' Relief Ass'n v. Medtronic, Inc*., 278 F.R.D. 454 (D. Minn. Dec. 12, 2011). The investors' class action was never found to be preempted and it does not even appear Medtronic ever sought preemption/immunity. Medtronic recently settled the investor class action for $85 million. It is thus curious that Medtronic would argue it is entitled to full immunity against the claims of a patient who suffered personal injuries as a result of its illegal promotion, yet concedes that no such immunity exists *vis-a-vis* claims brought by investors who merely suffered financial losses as a result of the same illegal conduct. A review of the facts and the applicable authorities confirms that Medtronic is not entitled to preemption/immunity.

I. STATEMENT OF FACTS

To remedy her lower back pain, 31-year-old April C. Cabana, met with orthopedic surgeon Ali Mesiwala, M.D for medical consultation. See Plaintiff's Separate Statement of Undisputed Material

Facts ("SSUF") 16.[1] Dr. Mesiwala recommended surgery and, on September 26, 2008, Cabana was admitted to Pomona Valley Hospital to receive surgery on her lower back. SSUF 17. A humanitarian device that was utilized in the September 26, 2008 surgery caused the development and migration of excess bone growth in Cabana's spine which necessitated a second remedial surgery. SSUF 18. The remedial surgery occurred on July 9, 2009 and was, once again, performed by Dr. Mesiwala. SSUF 19. To achieve spinal fusion, in the July 9, 2009 surgery, Dr. Mesiwala used Infuse Bone Graft ("Infuse"), a recombinant bone morphogenetic protein ("BMP") that is supposed to stimulate bone growth. SSUF 20.[2] Infuse is a liquid substance produced by a genetically engineered Chinese hamster ovary cell line. SSUF 21. Medtronic is the manufacturer and distributor of Infuse. SSUF 22. [3]

The FDA approved Infuse in 2002 for single-level *anterior* lumbar interbody fusions (ALIF) to be used in conjunction with a titanium metallic cage device known as LT-Cage – meaning that Infuse could only be promoted for use in spinal surgeries that were performed from a frontal (i.e., anterior) procedure. SSUF 23. Importantly, to date, Infuse has not been approved for *posterior* lumbar fusions. SSUF 24. While Medtronic initially intended to obtain approval for posterior procedures, it never did because its clinical trials for posterior uses had to be prematurely halted due to patients' development of unwanted (heterotopic) bone growth and other serious side effects. SSUF 25.

As discussed in greater detail below, because Infuse has not been approved for posterior uses, Medtronic is prohibited from promoting its use for posterior procedures.[4] In order to enhance sales, however, Medtronic engaged in substantial illegal promotional efforts to encourage physicians to use Infuse for unapproved/off-label posterior procedures. SSUF 30-37. Specifically, to drive sales, Medtronic retained paid consultants (also known as "key opinion leaders") to promote Infuse for off-

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[1] Concurrently herewith, Cabana is filing an opposition to Medtronic's Separate Statement and as permitted under Rule 437c(b)(3), she is including her own additional material disputed facts.

[2] Infuse is the trademark name for *recombinant human bone morphogenic protein-2* (rhBMP-2). In medical literature, Infuse is usually referred to by its non-trademark name rhBMP-2.

[3] As used in this opposition brief, "Medtronic" refers collectively to defendants Medtronic, Inc., and Medtronic Sofamor Danek USA, Inc.

[4] The use of a device for a non-FDA approved use is referred to as an "off-label" or "unapproved" use. While physicians are permitted to use devices for off-label uses, device manufacturers are expressly prohibited for promoting devices for off-label uses.

label procedures and/or to train other physicians in such off-label uses. SSUF 30-37.[5] Specific to this case, Medtronic retained Todd H. Lanman, M.D., a well regarded Beverly Hills surgeon, to make presentations regarding the benefits of using Infuse for off-label posterior procedures. In that regard, in 2003, Medtronic paid for Dr. Mesiwala's trip to attend a Medtronic-sponsored seminar at the Hotel Del Coronado. At that seminar, Medtronic's paid consultant and key opinion leader, Dr. Lanman, utilized cadavers, and provided training and instructions to Dr. Mesiwala regarding the off-label use of Infuse for posterior procedures (the same type of procedure Dr. Mesiwala eventually performed on plaintiff). SSUF 33-38. Thus, through its paid consultants and sponsored courses, Medtronic directly promoted the off-label use of Infuse to Dr. Mesiwala.

Medtronic knew, through the previously halted clinical trials and other adverse event reports, that the off-label use of Infuse (such as use in posterior procedures) had not been approved by the FDA, had not been shown to be effective, could result in migration of bone growth onto nerve roots, and could increase the risk of radiculitis and cancer. SSUF 41. Despite this knowledge, Medtronic never warned the medical community or public about these risks and instead falsely touted and actively promoted the off-label use of Infuse as safe and effective. SSUF 30-37. The off-label use of Infuse during Cabana's surgery has not been effective. SSUF 39. Following her surgery, Cabana has developed radiculitis, escalating radiating pain through her lower extremities, she remains permanently disabled and has been informed that she will need additional curative surgery. SSUF 39 & 40.

II. STANDARD FOR ADJUDICATING SUMMARY JUDGMENT

The rules for adjudicating summary judgment motions are well settled. In ruling upon a motion for summary judgment, the Court must view the evidence in a light favorable to plaintiff as the non-moving party, liberally construe plaintiff's evidentiary submission while strictly scrutinizing defendant's own showing, and resolve any evidentiary doubts or ambiguities in plaintiff's favor. *Shin v. Ahn*, 42 Cal. 4th 482, 499 (2007); *Yanowitz v. L'Oreal USA, Inc.*, 36 Cal. 4th 1028, 1037 (2005); *Mann v. Cracchiolo*, 38 Cal. 3d 18, 35-36 (1985). The Supreme Court has cautioned that "[t]he

[5] These illegal promotional efforts proved to be highly effective and, "eventually more than 85% of Infuse sales involved off-label uses." *Minneapolis Firefighters*, 278 F.R.D. at 456.

summary judgment procedure, inasmuch as it denies the right of the adverse party to a trial, is drastic and should be used with caution." *Mann*, 38 Cal. 3d at 35.

III. PLAINTIFFS' CLAIMS ARE NOT PREEMPTED BY FEDERAL LAW

In its Motion for Summary Judgment, Medtronic generally argues that it is immune from liability on the grounds that all of plaintiff's causes of action are preempted by federal law. In seeking blanket immunity, Medtronic makes the following two arguments: *First*, relying on the Supreme Court's ruling in *Riegel v. Medtronic*, 552 U.S. 312 (2008), Medtronic contends that, because it obtained FDA approval for the use of Infuse for one indication, it is entitled to preemption/immunity even though it illegally marketed Infuse for off-label indications the FDA had not approved. Medtronic's argument is flawed. *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. *Riegel*, 552 U.S. at 330 (state tort claims premised on violations of FDA regulations are not preempted because such claims "parallel" federal requirements); *Bausch*, 630 F.3d at 552 ("state law claims based on violations of federal law are not expressly preempted"); *Cornett v. Johnson & Johnson*, 414 N.J.Super. 365, 402-03 (2010), *cert granted*, 205 N.J. 317 (2011) (products liability claims arising out of device manufacturer's off-label promotion of the device are not preempted).

Second, no doubt realizing Cabana's illegal off-label promotion allegations would escape preemption under *Riegel* and its progeny, Medtronic alternatively argues that any attempt by Cabana to allege that Medtronic violated federal law (i.e., through its illegal off-label promotion) is preempted by the 2001 Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In essence, Medtronic argues that the "parallel claims" exception the *Riegel* court carved out is itself preempted by a previous Supreme Court decision. Medtronic fails to explain why the Supreme Court in *Riegel* would go through the trouble of creating an illusory exception. Courts which have considered similar arguments as those advanced by Medtronic, have rejected such arguments. *Bausch*, 630 F.3d at 557 (*Buckman* did not preempt plaintiffs' state law tort claims against device manufacturer that failed to comply with FDA regulations); *Cornett*, 414 N.J.Super. at 402 (claims that device manufacturer illegally promoted its device for off-label uses and failed to provide adequate warnings would not be preempted by *Riegel* or *Buckman*). Indeed, even the case on which Medtronic relies

rejected such a proposition. *Riley v. Cordis Corp*., 625 F. Supp. 2d 769, 784 (D. Minn. 2009) (neither *Riegel* nor *Buckman* preempt a properly pled claim that device manufacturer engaged in illegal off-label promotion and failed to provide adequate warnings regarding the off-label use it was promoting).

As outlined herein, the Supreme Court has consistently held there is a strong presumption against preemption, especially in fields (e.g., products liability litigation) traditionally occupied by States. Medtronic has failed to overcome this presumption and has failed to establish that, in passing the Medical Device Amendments to the Food, Drug and Cosmetic Act ("FDCA"), Congress intended to prohibit injured plaintiffs from seeking tort recovery when harmed by a manufacturer's violation of FDCA and FDA regulations. Furthermore, the Supreme Court, through its decisions in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and *Riegel* has confirmed that state law tort claims arising out of a device manufacturer's violations of FDCA and FDA regulations are not preempted.

A. The FDCA and FDA Regulations Prohibit Medical Device Manufacturers From Promoting Their Devices for Unapproved/Off-Label Uses

To understand the full scope of Cabana's allegations, a brief general background regarding the applicable FDCA provisions is warranted, as well as an application of those laws to the present case. When the FDA approves a medical device, the agency approves the product for the specific use set out in the product's approved labeling. A use approved by the FDA is usually referred to as an "approved" or "labeled" use. A use that does not appear in the labeling is not approved as safe and effective and is known as an "unapproved," "off-label" or "new use." For the sake of consistency, in this motion, Cabana will refer to such unapproved uses as "off-label" use. A central feature of the FDCA is that it generally prohibits medical device companies from promoting their devices for off-label uses.[6] The FDA has made it clear that a medical device that is promoted for off-label uses is deemed misbranded

[6] Congress created a very limited "safe harbor" for certain off-label promotion between 1997 and 2006. The "safe harbor" allowed manufacturers to provide copies of peer reviewed scientific articles to physicians. See 21 U.S.C. §§360aaa, 360aaa-1 (these statutes had a sunset clause of September 30, 2006 and were never renewed, see *Riley v. Cordis Corp*., 625 F. Supp. 2d 769, 781, n.6 (D. Minn. 2009)); *see also* 21 C.F.R. §§ 99.101 (current FDA regulations on this issue). Cabana, however, alleges that Medtronic's off-label promotional efforts far exceeded these "safe harbor" activities (i.e., redistribution of peer reviewed articles) and included other impermissible acts, including using paid consultants, key opinion leaders, seminars and presentations to actively promote off-label uses. SSUF 30-38 & 41; *Cornett*, 414 N.J. Super. at 402 ("A claim that promotion of off-label use beyond the safe harbor was coupled with a failure to warn would not be preempted.")

in violation of 21 U.S.C. §352(f) (misbranding) and distribution is prohibited pursuant to 21 U.S.C. §331(a) and (k). See 65 Fed.Reg. 14286 (Mar. 16, 2000) ("a medical device that is distributed for a 'new use' is 'adulterated'…and 'misbranded'…"); *United States v. Caputo*, 288 F. Supp. 2d 912, 920 (N.D. Ill. 2003) ("the FDCA and the corresponding FDA regulations prohibit manufacturer promotion of off-label uses."); *Riley*, 625 F. Supp. 2d at 784, n.8 ("The reason a medical device that is distributed for an unapproved new use is considered 'misbranded' is that the device fails to include adequate directions and warnings.").

Once the FDA has approved a medical device (such as Infuse) through the premarket approval application ("PMA") process, the manufacturer/applicant is required to comply with the standards in the PMA approval order. 21 C.F.R. § 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."). Any changes the manufacturer believes could affect the safety or effectiveness of the device, including any intention to promote the device for new uses, must be submitted, via a "PMA supplement," to the FDA for approval. 21 C.F.R. § 814.39(a) ("After FDA's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA....While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant *shall* submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device: (1) *New indications for use of the device*…") (emphasis added); *see also Riegel v. Medtronic, Inc.*, 451 F.3d 104, 110 (2d Cir. 2006) *aff'd*, 552 U.S. 312 (2008).[7]

As Medtronic concedes, while its Infuse device has obtained approval for use in *anterior* lumbar procedures, it has never received approval for *posterior* lumbar procedures. SSUF 24. Thus, posterior use is considered a "new indication" for which Medtronic was obligated to obtain FDA

[7] *See also* 21 C.F.R. §801.4 ("if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, *he is required* to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.") (emphasis added).

approval if it sought to promote such use. 21 C.F.R. § 814.39(a).[8] Medtronic, however, never obtained approval for posterior use because the clinical trial Medtronic performed for use of Infuse in posterior procedures had to be prematurely halted due to the excess amount of side effects the Infuse patients were suffering. SSUF 25. As such, the FDA only approved Infuse for anterior procedures and specifically asked Medtronic to take measures to prohibit the off-label use and off-label promotion of posterior uses. SSUF 27-28. Instead of heeding the FDA's prohibitions against off-label promotion, Medtronic began a national campaign of utilizing paid consultants and "key opinion leaders," such as the aforementioned Todd H. Lanman, M.D., to promote and train the medical community (including Dr. Mesiwala) to use Infuse for off-label procedures, including posterior procedures. SSUF 30-38.

If Medtronic wanted to *legally* promote Infuse for off-label posterior uses, it was obligated to obtain FDA approval for posterior uses. 21 C.F.R. § 814.39(a). Having failed to obtain said approval, Medtronic's promotion of Infuse for such off-label uses was in violation of state and federal laws, thus, it is not entitled to the preemption defense.

B. There is a Strong Presumption Against Preemption

The Supreme Court has repeatedly recognized there is a "basic presumption *against* preemption" because preemption upsets the balance of power between the federal government and the states as independent sovereigns. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (emphasis added); *see also Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008). The presumption applies in tort cases such as this because, historically, the several States have possessed broad powers to protect the "lives, limbs, health, comfort and quiet of all persons." *Slaughter House Cases*, 16 Wall 36, 62 (1873); *Lohr*, 518 U.S. at 485 (stating that "[t]hroughout our history the several States have exercised their police powers to protect the health and safety of their citizens" and, thus, applying a presumption against preemption in a products liability case filed against Medtronic); *see also In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1088 (2008) (there is a "strong presumption against preemption"); *Steele*, 54 Cal. App. 4th at 1479 (refusing to find the claims against a device manufacturer preempted, and noting that "[t]here is a presumption against federal preemption.")

[8] In essence, the promotion of Infuse for unapproved posterior uses is akin to promoting a device that has never been approved by the FDA.

The Supreme Court has emphasized that the presumption against preemption equally applies to federal statutes, including the Medical Device Amendments, which contain an express preemption clause. *Lohr*, 518 U.S., at 485*; see also Altria Group*, 555 U.S. at 77 ("[w]hen addressing questions of express or implied pre-emption, we begin our analysis with the assumption that the historic police powers of the States are not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."). Medtronic's motion fails to make *any* mention of the presumption against preemption and it has failed to overcome the presumption.

C. Under Under Established Supreme Court Authority, As Espoused in *Lohr* and *Riegel*, Cabana's "Parallel Claims" Arising Out of Medtronic's Illegal Off-Label Promotion Are Not Preempted By Federal Law

The Medical Device Amendments of 1976 to the FDCA include an express, but limited, preemption provision for claims against manufacturers of Class III medical devices:

> [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). The Supreme Court has twice addressed the limited scope of this preemption provision. Its decisions show that Cabana has stated a legally viable claim based on alleged violations of federal law. *First*, in 1996, the Court held that lawsuits brought under state law against medical device manufacturers who submit "premarket notification" to the FDA – a process described below – are not preempted by 21 U.S.C. § 360k(a) when liability is premised on theories that the device was defective and unreasonably dangerous and that the manufacturer failed to use reasonable care in the device's design, manufacture, assembly, and sale. *Lohr*, 518 U.S. at 481, 494–95. *Second*, in 2008, the Court held that lawsuits brought under state law against medical device manufacturers who obtain the full federal "premarket approval" are preempted by section 360k(a) when liability is premised on violations of state law requirements that are in addition to or different from federal requirements regulating the devices. *Riegel*, 552 U.S. at 330. Neither case held that state lawsuits premised on *violations* of federal law are preempted under section 360k(a). In fact, *Lohr* and *Riegel* expressly left the door open for state law claims based on violations of federal law.

In *Lohr*, the Court rejected a preemption defense as applied to a medical device where the plaintiff based her claims on allegations the manufacturer violated federal regulations:

> [I]t is clear that [plaintiffs'] allegations may include claims that Medtronic has, to the extent that they exist, violated FDA regulations. At least these claims, they suggest, can be maintained without being pre-empted by § 360k, **and we agree**.
>
> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

Lohr, 518 U.S. at 495 (emphasis added). The pacemaker leads at issue in *Lohr* had not been approved through the FDA's premarket approval process. Instead, the FDA confirmed that the leads were "substantially equivalent" to a device that was already on the market through what is known as a "premarket notification" or "§ 510(k) process." *Id*. at 478–80. The section 510(k) process is less rigorous than the pre-market approval process, so much so that *Lohr* held that such generally applicable standards are not "requirements" sufficient even to trigger preemption under section 360k(a). *Id*. at 492–93. The Court went on to explain that section 360k(a) does not preempt state rules that merely duplicate federal requirements. *Id*. at 494–95. Thus, the above quoted language in *Lohr* discussing parallel claims also applies to products such as Infuse that have gone through the more rigorous premarket approval. *See Bausch*, 630 F.3d at 551 (discussing same).

Nothing in the more recent *Riegel* case (a case upon which Medtronic anchors its arguments) calls into question the ability of a patient to sue a Class III device manufacturer under state law for violations of federal law. In fact, *Riegel* emphasized that such claims are not preempted. In *Riegel*, the plaintiffs alleged that a medical device that failed was designed, labeled, and manufactured in breach of duties imposed by state common law, and that the defects caused the plaintiffs to suffer severe and permanent injury. *Riegel*, 552 U.S. at 320. The trial court held that section 360k preempted the plaintiffs' claims of strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing and sale of the device. *Id*. at 320–21. The trial court also

held that section 360k preempted the Riegels' negligent manufacturing claim, but only to the extent the claim was not premised on the theory that Medtronic had violated federal law. *Id*. at 321. But the trial court allowed the Riegels to go forward on claims that Medtronic was negligent in manufacturing by failing to comply with federal standards and had breached an express warranty. Those claims were not preempted by section 360k. The trial court later granted summary judgment on those claims, apparently on the merits, and those claims were not before the Supreme Court. *Id*. at 321, n. 2.

On review, the Supreme Court held that the premarket approval process imposed federal "requirements" that triggered the preemption clause of section 360k. *Id*. at 322–23. The Court further held that the tort duties implicit in a finding of liability under the common law claims brought by the Riegels would also constitute "requirements" under section 360k. *Id*. at 323–25. Ultimately, the Court concluded that, to the extent state tort law underlying the Riegels' claims would require a manufacturer's device to be safer (but perhaps less effective) than the model device approved by the FDA, those requirements would "disrupt[ ] the federal scheme no less than state regulatory law to the same effect." *Id*. at 325. Thus, the Court found that the state requirements implicit in the Riegels' common law claims were different from or in addition to the federal requirements and were preempted under section 360k.[9]

The Supreme Court took care, however, to limit its holding to claims that the device at issue "violated state tort law *notwithstanding compliance with the relevant federal requirements*." *Riegel*, 552 U.S. at 330 (emphasis added). The Court gave lower courts clear instructions to allow claims to proceed when they are based on claimed violations of federal law: "§ 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." *Riegel*, 552 U.S. at 330.

Riegel and *Lohr* thus confirm that state law claims based on violations of federal law are not expressly preempted by section 360k. *Lohr*, 518 U.S. at 495 ("Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties

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[9] Importantly, while the doctor in *Riegel* used the device in an off-label manner, the issue of off-label *promotion* was not before the Court in *Riegel*. *See Cornett*, 414 N.J.Super. at 392 ("*Lohr* and *Riegel* did not involve a claim that a device's manufacturer had intended or promoted an off-label use.")

parallel federal requirements."); *accord Riegel*, 552 U.S. at 330; *see also* 21 C.F.R. § 808.1 ("[the Medical Device Act] does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.") Like most states, for well over a century, California has provided common law tort remedies to consumers injured as a result of the negligence of others, *see e.g.*, *Lewis v. Terry*, 111 Cal. 39, 44-45 (1896) ("It is well settled that a man who delivers an article, which he knows to be dangerous or noxious, to another person, without notice of its nature and qualities, is liable for any injury which may reasonably be contemplated as likely to result, and which does in fact result, therefrom, to that person or any other who is not himself in fault.") (internal quotes and citations omitted); *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 66 (1973) (holding pharmaceutical manufacturer liable for over-promoting its drug for unapproved uses); *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1108 (1996) (applying doctrine of strict liability to pharmaceutical cases), and California has long recognized the theory of negligence per se and has provided tort remedies to those who have been injured as a result of a defendant's violations of safety statutes, *Siemers v. Eisen*, 54 Cal. 418, 421 (1880) ("It is an axiomatic truth, that every person while violating an express statute is a wrong-doer, and as such is ex necessitate negligent in the eye of the law; and every innocent party whose person is injured by the act which constitutes the violation of the statute is entitled to a civil remedy for such injury, notwithstanding any redress the public may also have."); *Toole v. Richardson–Merrell Inc*., 251 Cal.App.2d 689, 703–704 (1967) (holding that a violation of FDCA requirements can form the basis for civil liability on a negligence per se theory); *see also Evraets v. Intermedics Intraocular, Inc.*, 29 Cal. App. 4th 779, 791-92 (1994) (medical device manufacturer who violated the FDCA can be liable for negligence per se). Thus, under both *Riegel* and *Lohr*, Cabana's claims for a traditional damages remedy under California law are not preempted.

Medtronic was obligated to obtain FDA approval for all of the uses for which it intended to promote Infuse (i.e., posterior procedures) and once Medtronic chose to intentionally promote Infuse for off-label/unapproved uses, it resulted in a violation of both state and federal law. 65 Fed.Reg. 14286 (Mar. 16, 2000) ("a medical device that is distributed for a 'new use' is 'adulterated'…and 'misbranded'…"); *Caputo*, 288 F. Supp. 2d at 920 ("the FDCA and the corresponding FDA regulations prohibit manufacturer promotion of off-label uses."); *see also* 21 U.S.C. §§331(a) and 352(f)

(federal law prohibiting the sale and promotion of misbranded devices) *and* CAL. HEALTH & SAFETY CODE §§ 110390, 110398, 111330, 111375, 111440, 111445 & 111450 (California's "Sherman Law" prohibiting the sale and promotion of misbranded devices). Medtronic's failure to obtain approval for posterior use of Infuse, its intentional off-label promotion of Infuse, and its failure to provide adequate warnings for the off-label/unapproved uses, thus, subjects it to state law tort liability. *Stevens*, 9 Cal. 3d at 66 (manufacturer whose sales agents over-promoted pharmaceutical products for unapproved and unjustified uses were liable to injured patients); *see also Riley*, 625 F.Supp.2d at 783-84 (preemption would not apply to a claim wherein plaintiff alleges that medical device manufacturer promoted its drug for off-label uses and failed to provide warnings associated with such off-label use). As the Seventh Circuit Court of Appeals recently observed:

> Section 360k provides immunity for manufacturers of new Class III medical devices to the extent that they comply with federal law, but it does not protect them if they have violated federal law. Just as a plaintiff in an auto accident may use the other driver's speeding violation as evidence of negligence, plaintiff Bausch claims that she was injured by Stryker's violations of federal law in manufacturing the device implanted in her hip. It remains to be seen whether she can prove those allegations, including causation and damages. But if she can prove those allegations of harm caused by violations of federal law, her claims under state law would not impose on defendants any requirement "different from, or in addition to, any requirement" imposed by federal law. Her claims are not preempted.

Bausch, 630 F.3d at 553. The *Bausch* Court's finding of non-preemption in such cases is not only consistent with the Supreme Court's decisions in *Lohr* and *Riegel*, but is also in line with numerous other courts which have addressed this issue. *See Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769 (5th Cir. 2011) ("To the extent that Hughes asserts a failure to warn claim based only on Boston Scientific's failure to comply with FDA regulations, however, such a claim is not expressly preempted."); *Howard v. Sulzer Orthopedics, Inc*., 382 Fed.Appx. 436 (6th Cir.2010) (same); *Gelber v. Stryker Corp*., 788 F. Supp. 2d 145, 165 (S.D.N.Y. 2011) (same); *Hofts v. Howmedica Osteonics Corp*., 597 F.Supp.2d 830, 832 (S.D.Ind.2009) (same); *Prudhel v. Endologix, Inc.*, 2009 WL 2045559 (E.D.Cal. Jul. 9, 2009) (same); *Purcel v. Advanced Bionics Corp*., 2008 WL 3874713 (N.D.Tex. Aug. 13, 2008) (same); *Rollins v. St. Jude Medical*, 583 F.Supp.2d 790 (W.D.La.2008) (same); *Riley*, 625 F.Supp.2d at 783-84 (same); *Cornett*, 414 N.J. Super. at 402 (claims that medical device manufacturer promoted its devices for off-label uses was not preempted by *Riegel*).

California case law is in accord. For example, in *Steele*, a case which, like Infuse, involved a pre-market approved ("PMA") device, the California Court of Appeal refused to find preemption because the device manufacturer failed to establish that it complied with all applicable federal law. *Steele*, 54 Cal. App. 4th at 1489-90. The Court emphasized that preemption does not apply to device manufacturers who failed to comply with FDA regulations and federal laws:

> it is clear preemption does not apply to a state claim based on a manufacturer's violation of FDA requirements…Thus, if the manufacturer does not abide by a federal requirement, preemption does not prevent a state award of damages on a tort claim based on the violation of that federal requirement, even if the device has undergone the PMA process, if the state requirement is equal to, or substantially identical to, the federal requirement.

Steele, 54 Cal. App. 4th at 1486. Likewise, in *Evarets*, the California Court of Appeal, Second District, held that plaintiff's claims of breach of express warranty, fraud and negligence per se against a medical device manufacturer were not preempted by the FDCA:

> It seems fair to say that for a medical device manufacturer to claim the shield of preemption, the manufacturer must 'play by the rules.'… There is no reason to believe that the federal government intended to insulate medical device producers from longstanding rules governing fraud.

Evraets, 29 Cal. App. 4th at 790-91. While *Steele* and *Evraets* predate *Riegel*, their holding (i.e., refusal to extend preemption to manufacturers who have violated federal laws) is consistent with both *Lohr* and *Riegel*. In sum, *Riegel* does not foreclose Cabana's right to seek state tort remedies for injuries caused as a result of Medtronic's *illegal* off-label promotion of Infuse, but rather *Riegel* and its progeny, including *Bausch*, *Riley* and *Cornett* confirm that such parallel claims are not preempted.

D. The Supreme Court's *Buckman* Decision Does Not Impliedly Preempt Cabana's "Parallel Claims" of Illegal Off-Label Promotion

Ostensibly recognizing that Cabana has pled a viable parallel claim based upon Medtronic's off-label promotion violations, Medtronic alternatively argues that such parallel claims are impliedly preempted under the Supreme Court's ruling in *Buckman*, 531 U.S. 341. This is a most curious proposition. Namely, Medtronic spends the bulk of its brief arguing that, to survive preemption under the 2008 *Riegel* decision, a plaintiff must show a "parallel" claim, and then in the tail end of its motion, it argues that any attempt to show a parallel claim would be preempted by the 2001 *Buckman* decision. See Motion at 15-17. Medtronic, thus, argues that the *exception* to preemption enunciated by *Riegel* in 2008 (i.e., the parallel claim exception) is itself preempted by the 2001 *Buckman* decision. Medtronic

fails to explain why the *Riegel* Court would go through the trouble of creating an illusory exception. A review of the applicable authority confirms that *Buckman*, which concerned a sole "fraud on the FDA" claim, is not at all applicable to this case.

In *Buckman*, patients claimed they suffered injuries from implantation of orthopedic bone screws into their spines. The patients settled their claims against the device manufacturer and proceeded on a suit solely against a *regulatory consultant* they alleged made fraudulent representations to the FDA in the course of the FDA approval process. The Supreme Court held that the FDCA as amended by the Medical Devices Amendments impliedly preempted the patients' sole cause of action for "fraud on the FDA." *Buckman*, 531 U.S. at 348. But, *Buckman* specifically distinguished such "fraud-on-the-agency" claims, i.e., claims not related to a field of law that states traditionally occupied, from claims based on state law tort principles such as in *Silkwood v. Kerr–McGee Corp*., 464 U.S. 238 (1984) (state tort action against federally licensed nuclear plant), and *Lohr*, 518 U.S. 470 (state tort action against device manufacturer). *Buckman*, 531 U.S. at 352-53.

Cabana's claims, like those in *Lohr*, and unlike those in *Buckman*, are traditional state tort law claims based on warning defects, not fraud on a federal agency. Cabana does not complain of fraud on the FDA, rather, she claims she, herself (and her treating surgeon) were deceived and injured by: (a) Medtronic's actions in illegally promoting Infuse for off-label/ unapproved uses; (b) utilizing paid consultants, such as Dr. Lanman, to market the off-label use of Infuse; and (c) failing to provide adequate warning regarding the risks and dangers associated with the promoted off-label uses. Multiple courts, including courts on whose decisions Medtronic relies, have held that such claims are not preempted by *Buckman*. *Riley*, 625 F.Supp.2d at 784 (neither *Riegel* nor *Buckman* would preempt a properly pled claim based on off-label promotion); *Cornett*, 414 N.J.Super. at 402 (claims that device manufacturer illegally promoted its device for off-label uses and failed to provide adequate warnings would not be preempted by *Riegel* or *Buckman*); *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 899 (D. Minn. 2006) (*Buckman* did not preempt plaintiff's state tort law claims against Medtronic and further holding: "States may not be concerned about protecting federal agencies, but states have a strong interest in protecting their citizens from fraud and personal injuries."); *Bausch*, 630 F.3d at 557 (*Buckman* did not preempt plaintiffs' claims against manufacturer

that failed to comply with FDA regulations); *Knipe v. SmithKline Beecham*, 583 F.Supp.2d 553, 583, 597-98 (E.D.Pa. 2008) (*Buckman* does not preempt plaintiff's state tort law claims that pharmaceutical manufacturer failed to issue adequate warnings of risks associated with off-label uses); *Phillips v. Stryker Corp*., 2010 WL 2270683 (E.D. Tenn. June 3, 2010) (*Buckman* did not preempt plaintiff's ability to establish a "parallel claim" as mandated by *Riegel*).

Finally, and most importantly, Medtronic's implied preemption arguments premised on *Buckman* conflict with California Supreme Court precedent. In *Farm Raised Salmon*, the Court held that plaintiffs' false advertising claims against a defendant who sold a misbranded food product in violation of the federal and state law, including the FDCA and the state Sherman Food Drug and Cosmetic Act ("Sherman Law") were not preempted. *In re Farm Raised Salmon Cases*, 42 Cal. 4th at 1091. Defendants, like Medtronic does in this case, argued that any attempt by plaintiff to seek remedies for violations of the federal FDCA were impliedly preempted by *Buckman* since only the FDA can enforce the FDCA. *Id*. at 1089. In rejecting preemption, the Court recognized that there is a strong presumption against preemption, *id*. at 1088, and held that *Buckman* did not preempt plaintiffs' right to seek remedies against a defendant that violated both the FDCA and California's Sherman Law. *Id*. at 1091. Here, Cabana has likewise shown that Medtronic's off-label promotion caused Infuse to be misbranded under the FDCA (*see e.g.* 21 U.S.C. §§331(a) and 352(f)) and California's Sherman Law (CAL. HEALTH & SAFETY CODE §§ 110390, 110398, 111330, 111375, 111440, 111445 & 111450) and common law (*see e.g.*, *Stevens, Toole, Steele* and *Evraets*).

E. The Additional Authorities On Which Medtronic Relies Are Inapposite

The additional authorities Medtronic has marshaled to support its arguments are either factually distinguishable (as they do not relate to off-label promotion claims) or actually support Cabana's arguments. Medtronic places great stock in the Ninth Circuit's decision in *Stengel v. Medtronic Inc*., 676 F.3d 1159 (9th Cir. 2012).[10] Importantly, *Stengel* did not concern the issue of off-label promotion and thus has no application to this case. In *Stengel*, the plaintiff's initial complaint was deemed

[10] On July 25, 2012, the Ninth Circuit decided to rehear the *Stengel* case *en banc* and, in its order, it held that the *Stengel* decision "shall not be cited as precedent by or to any court of the Ninth Circuit." *Stengel v. Medtronic Inc*., 2012 WL 3039710 (9th Cir. July 25, 2012).

preempted because the complaint was "without any hint of an allegation that Medtronic's conduct violated FDA regulations." *Stengel*, 676 F.3d at 1162. Cabana, however, has specifically alleged and has established that Medtronic, through the utilization of its paid-consultants and key opinion leaders, violated the law and FDA regulations by distributing and promoting Infuse for non-FDA approved uses (i.e., off-label uses). See SSUF 30-38. Thus, *Stengel* is factually inapposite. The Ninth Circuit further noted that plaintiff's proposed amended complaint, which contained allegations that defendant failed to adequately report adverse events, was impliedly preempted by *Buckman*. The Ninth Circuit admitted that its conclusion on this ground is in direct conflict with decisions from other courts. *Stengel*, 676 F.3d at 1166 ("We acknowledge that there is a division among the circuits whether state failure-to-warn claims are preempted by *Buckman*.").[11] Cabana, like the dissenting judge in *Stengel*, respectfully contends that the majority's decision in *Stengel* was in error.[12] Nonetheless, even under *Stengel*, Cabana's claims are not preempted because she is not claiming that Medtronic failed to file adverse event reports as required by federal law (and which apparently has no state counterpart), rather, she claims she was injured as a result of Medtronic's false and illegal off-label promotion of Infuse (rendering the off-label promoted use of Infuse *defective* and *misbranded*) which is a violation *of both* state and federal law and for which California has traditionally provided damages remedies. 65 Fed.Reg. 14286 ("a medical device that is distributed for a 'new use' is 'adulterated'…and 'mis-branded'…"); 21 U.S.C. §§331(a) and 352(f) (prohibiting the sale/promotion of misbranded devices); CAL. HEALTH & SAFETY CODE §§ 110390, 111330, 111375, 111440 & 111450 (prohibiting the sale/promotion of misbranded devices); *Steele*, 54 Cal. App. 4th at 1486 ("it is clear preemption does not apply to a state claim based on a manufacturer's violation of FDA requirements").[13]

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[11] Numerous other courts have refused to find *Buckman* preemption. See *supra* at 4-5.

[12] The dissenting judge in *Stengel* disagreed with the majority's preemption ruling and found it to be "strange" and in conflict with Supreme Court precedent. *Stengel*, 676 F.3d at 1168-69.

[13] For similar reasons, Medtronic's reliance upon *McGuan v. Endovascular Technologies, Inc*., 182 Cal.App.4th 974 (2010) is also misplaced as *McGuan* did not involve the issue of off-label promotion and as the Court emphasized, plaintiff's "do not allege that defendants violated FDA regulations." *Id*. at 983. Aside from being factually distinguishable, *McGuan's* non-binding preemption ruling *conflicts* with the authorities cited herein (such as *Bausch, Riley* and *Cornett*), as well as the California Supreme Court's *In re Farm Raised Salmon Cases* (holding that *Buckman* did not preempt plaintiffs claims based on FDCA violations) and the California Court of Appeal decisions in *Steele* and *Evraets*.

Medtronic also cites to *Riley*, 625 F.Supp.2d 769. *Riley* supports Cabana's arguments. *Riley* held that adequately pled off-label promotion claims such as Cabana's would not be preempted*:*

> It seems possible, though, that Riley could plead a narrow failure-to-warn claim that would escape preemption. Specifically, if Riley pleaded that (1) Cordis affirmatively promoted the off-label use of the Cypher stent in a manner that violated federal law, and (2) that, while promoting the device in violation of federal law, Cordis failed to include adequate warnings and directions about the off-label use that it was promoting, then Riley's claim might survive. Arguably, the first allegation would protect the claim from being expressly preempted by § 360k(a), because Cordis's conduct in promoting the off-label use of the stent violated federal law. And arguably the second allegation would protect the claim from being impliedly preempted under *Buckman*, because traditional state tort law imposes a duty to warn on a supplier of a product if it is reasonably foreseeable that an injury could result from the use of the product-and this duty includes the duty to give adequate instructions for the safe use of the product….Insofar as Riley sufficiently alleges that, in the course of unlawfully promoting the Cypher stent for off-label use, Cordis failed to adequately warn of foreseeable dangers of that use, Riley may succeed in asserting a claim that is neither expressly nor impliedly preempted.

Riley, 625 F. Supp. 2d at 783-84 (internal citations omitted). Cabana's claims are identical to the claims *Riley* found would escape preemption. Specifically, Cabana has established that Medtronic engaged in a vast campaign to illegally market Infuse for off-label uses; and in the course of this off-label promotion, Medtronic failed to provide adequate warnings about the risks associated with the off-label use it was promoting. SSUF 30-38 & 41. Such claims are not preempted. *Riley*, 625 F. Supp. 2d at 783-84; *see also Cornett*, 414 N.J. Super. at 402 (adopting *Riley's* reasoning and holding claims against a medical device manufacturer who promoted its device for off-label uses are not preempted).

IV. THE DANGERS OF REGULATORY CAPTURE

Cabana has demonstrated that, under established Supreme Court and California precedent, her claims arising out of Medtronic's illegal off-label promotion are neither expressly nor impliedly preempted. Cabana, however, would like to take a moment to discuss a pertinent historical backdrop to the preemption story. Congress' primary motivation for enacting the FDCA and creating the FDA was to protect the health and safety of the public. However, an administrative agency set up to protect the public from certain industries can be "captured" by those industries and turned against the public. This has been referred to as "regulatory capture." It is a phenomenon that has been discussed and analyzed by numerous commentators, including Nobel Prize winning economists George Stigler and Milton Friedman. *See* George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971); MILTON FRIEDMAN, FREE TO CHOOSE: A PERSONAL STATEMENT 201 (1990).

In 1887, Congress created the first ever federal agency, the Interstate Commerce Commission (ICC). The ICC's purpose was to control railroads and their unfair business practices. However, the ICC was soon staffed with employees with ties to the railroad industry. In 1893, Richard Olney, a prominent business lawyer, became the Attorney General. Once appointed, Olney's former clients, the railroad tycoons, asked him if he would help eliminate the hated ICC. In response, Olney replied:

> The Commission ...is, or can be made, of great use to the railroads... the older such a commission gets to be, the more inclined it will be found to take the business and railroad view of things. It thus becomes a sort of barrier between the railroad corporations and the people and a sort of protection against hasty and crude legislation hostile to railroad interests...The part of wisdom is not to destroy the Commission, but to utilize it.

FRIEDMAN, *supra*, at 197. The phenomenon of regulatory capture has not been limited to the ICC or the theories of Nobel Prize winning economists. Indeed, the FDA has at times also been the victim of regulatory capture. For instance, on August 20, 2001, Daniel Troy, Esq. was appointed as Chief Counsel of the FDA. Prior to his appointment, Mr. Troy worked in the private sector representing large pharmaceutical companies. See Exh. 27. Once appointed, Mr. Troy began taking unorthodox steps to promote the doctrine of preemption. These steps included filing multiple *amicus* briefs on behalf of the FDA in personal injury cases (including cases wherein his former client's were defendants) arguing that the plaintiff's claims against the pharmaceutical manufacturer should be preempted. See Exhs. 28 & 29. Troy and his successors further altered regulations and issued "Preambles" to regulations to bolster the pharmaceutical industry's preemption arguments. See e.g., Exh. 30 .[14] The machinations of Mr. Troy and his cohorts were not lost on legislators and members of the Supreme Court. *See Wyeth v. Levine*, 555 U.S. 555, 579, n. 11 (2009) (the Supreme Court rejected the preemption arguments advanced by FDA attorneys and cited to Congressional documents observing that "The Office of Chief Counsel ignored the warnings from FDA scientists and career officials that the preemption language of the 2006 preamble was based on erroneous assertions about the ability

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[14] Notably, prior to Mr. Troy's arrival, the FDA, in *Lohr*, filed an *amicus* brief *supporting* the plaintiff and arguing plaintiff's claims were not preempted. *See Medtronic, Inc. v. Lohr*, 1996 WL 118035 (U.S.Amicus.Brief, 1996). Yet, following Mr. Troy's arrival (and the regulatory capture of the FDA by the industry), the FDA in *Riegel* filed an *amicus* brief in support of the medical device defendant advocating preemption. Both the majority and the dissent in *Riegel* noted FDA's flip-flop position. *Riegel*, 552 U.S. at 326 ("the dissent is correct …that… the degree of deference might be reduced by the fact that the agency's earlier position was different.")

of the drug approval process to ensure accurate and up-to-date drug labels").[15] This aforementioned history of regulatory capture and the risks associated with such capture deserve consideration in assessing the merits of any preemption defense.

V. PLAINTIFFS' BREACH OF EXPRESS WARRANTY CLAIM IS VALID UNDER CALIFORNIA LAW

In addition to its misguided preemption arguments, Medtronic also argues that plaintiff's (a) strict liability design defect; (b) breach of implied warranty; and (c) breach of express warranty claims must be dismissed on independent state-law grounds. See Motion at 18-20. While not fully agreeing with Medtronic's legal arguments, Cabana agrees to the voluntary dismissal of her (a) Strict Liability *Design* Defect Claim; and (b) her Breach of *Implied* Warranty Claim. Cabana however, does not agree to the dismissal of her breach of express warranty claim.

Medtronic contends that plaintiff's *express* warranty claim must be dismissed due to lack of privity. Medtronic neglects to mention that, in this very action, Judge Sinanian rejected an identical argument that had been advanced by co-defendant Stryker. See Exh. 32. There is a strong basis for Judge Sinanian's ruling given that the California Supreme Court has long held that privity is not required for breach of express warranty claims. *Hauter v. Zogarts*, 14 Cal. 3d 104, 115 (1975) ("The fact that [plaintiff] is not in privity with defendants does not bar recovery. Privity is not required for an action based upon an express warranty."); *Rodrigues v. Campbell Indus*., 87 Cal. App. 3d 494, 500 (1978) ("privity is not a requirement for actions based upon an express warranty.") Indeed, even the case cited by Medtronic (*Evraets*) states "We note that privity is *not* a requirement for actions based upon an express warranty." *Evraets*, 29 Cal.App.4th at 789, n.4.[16] Accordingly, Medtronic's request to dismiss the breach of express warranty cause of action should be denied.

VI. CONCLUSION

Legend has it that when the thirteenth century poet, Saadi, was asked why he ceased traveling to a neighboring town, he responded by regaling what he had observed in the courtroom of that town:

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[15] Following his stint as Chief Counsel of the FDA, Mr. Troy left the FDA and became Senior Vice-President and General Counsel for the pharmaceutical company GlaxoSmithKline. See Exh. 31.

[16] *See also* 21 C.F.R. § 808.1(d) (breach of warranty claims are not preempted).

> While robbing a house, a thief, surprised by the presence of the homeowner's son, picked up a loose brick and fatally struck the homeowner's son on the head. The homeowner pressed charges and a judicial proceeding got underway. In defense the thief argued that he is merely a thief and not a killer and the death of the son was not his fault but rather the fault of the bricklayer who had built a house with a loose brick. The magistrate summoned the bricklayer and asked him why he should not be punished. The bricklayer in defense testified that it is not his fault as he did his job well and the cement must have been of poor quality. The wrath of the magistrate then descended on the cement mixer who is accused of pouring too much water during mixing. The cement maker admits he poured too much water, but attributes it to his required mandatory greeting of the passing King, a legally justifiable diversion that diluted the cement. The magistrate could not punish the King and did not want to leave the death of the homeowner's son unpunished so to ensure that justice was dispensed he punished the homeowner (the decedent's father) for purchasing a house with a loose brick.[17]

The various arguments made by the multiple defendants in this case are, in some respects, reminiscent of Saadi's tale. Pomona Hospital in its overruled demurer argued that it was an "innocent victim" of the acts of the other defendants (Court's 1/31/12 Ruling, Exh. 33); Dr. Mesiwala in discovery responses argued that he was merely following the Infuse instructions provided to him by Medtronic's consultants (SSUF 37); and now Medtronic proclaims it was simply giving the instructions approved by the FDA (i.e. the King) and, thus, contends it should be excused and immune from all liability. Putting aside the logical and normative flaws inherent in Medtronic's immunity argument, Medtronic's argument also suffers from a significant factual flaw: namely, contrary to Medtronic's contentions, Medtronic was *not* providing the instructions approved by the FDA, but was actually promoting and providing instructions for non-approved off-label uses. Thus, Medtronic was violating the King/FDA's decrees. As countless authorities have recognized, including *Lohr*, *Riegel*, *Steele*, *Evraets*, *Bausch, Riley* and *Cornett*, Medtronic cannot hide behind the cloak of immunity. Its motion should be denied and Cabana should be allowed to proceed with her meritorious claims.

Dated: August 6, 2012

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[17] Variations of this tale are also attributed to other authors including for example the renowned 19th Century Indian playwright Bharatendu Harishchandra and his play "Dark Is the Nation."