IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

KARL L. SANDA,

Plaintiff,

v.

MEDTRONIC, INC., MEDTRONIC SOFAMOR DANEK USA, INC., NORTHWESTERN MEMORIAL HOSPITAL, NORTHWESTERN ORTHOPAEDIC INSTITUTE, LLC, and MARK T. NOLDEN, M.D.,

Defendants.

Civil Action No. 2013L000305

Judge Eileen M. Brewer

PLAINTIFF'S RESPONSE IN OPPOSITION TO DEFENDANTS MEDTRONIC, INC. AND MEDTRONIC SOFAMOR DANEK USA, INC.'S JOINT MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Plaintiff Karl L. Sanda, by and through counsel, respectfully submits this memorandum of law in opposition to Defendants Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc.'s Joint Motion to Dismiss.

INTRODUCTION

The central issue in this motion is whether federal law preempts products liability claims against manufacturers of a medical device where the patient claims he was harmed as a result of the manufacturer's *illegal* promotion of the medical device for uses *not approved* by the Food and Drug Administration ("FDA"). Cases that have addressed this specific issue, including those cited by Defendants Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. ("Medtronic") have held that such claims are not preempted. Medtronic, however, through a distorted and illogical interpretation of the allegations and applicable precedent, argues it is entitled to *complete* immunity. In rejecting similar arguments, the United States Court of Appeals for the Seventh Circuit cogently stated while interpreting Illinois State Law that "[t]he 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 (2011). 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 Illinois tort law for any personal injuries caused by their violations. A review of the facts and the applicable authorities confirms that Medtronic is not entitled to preemption.

STATEMENT OF FACTS

This is a product liability and medical malpractice lawsuit alleging negligence, strict liability, breach of warranty, and willful-wanton conduct causes of action against Medtronic and negligence causes of action against Northwestern Memorial Hospital, Northwestern Orthopaedic Institute, LLC, and Mark T. Nolden, M.D.

Dr. Nolden diagnosed the plaintiff with, among other things, advanced subaxial cervical spondylosis and degenerative cervical stenosis from C-2 through C-7 of the cervical spine. On

January 10, 2011, Dr. Nolden performed a posterior cervical fusion, C2 through C6, which is a procedure utilized to fuse the cervical vertebral body with the sacrum (sacralisation). During this procedure, the center of the diseased disc is removed, and bone growth material is inserted in its place with the intention that it will stimulate bone growth over time in order to "fuse." To achieve fusion, Dr. Nolden performed a procedure using Infuse in the cervical spine instead of limiting the cervical surgery to an autograft or allograft procedure. The FDA had not approved Infuse to be used in a cervical fusion procedure.

Plaintiff alleges that Medtronic, through its sales representatives and paid Key Opinion Leaders (individuals who are respected within the medical community but are not directly associated with Medtronic) directly and indirectly promoted, trained, and encouraged Dr. Nolden to use the Infuse Bone Graft in an off-label manner, including utilizing it in posterior cervical spine surgery.

Following the January 10, 2011 cervical spine surgery, plaintiff developed a massive seroma (a pocket of clear serous fluid that sometimes develops in the body after surgery) caused by the use of Infuse. When diagnosed on January 16, 2011, the massive seroma was life-threatening and required an emergency corrective surgery. Although the seroma was evacuated, it left Plaintiff partially paralyzed with permanent disability and pain. The Plaintiff has never recovered from his two surgeries and continues to have daily severe disabling pain and paralysis. The primary allegation against Medtronic in this case is that, among other things, Medtronic illegally and untruthfully promoted the use of Infuse in cervical fusion procedures to Dr. Nolden, which caused Dr. Nolden to use the Infuse device in Plaintiff's surgery, which, in turn, led to Plaintiff's injuries.

STANDARD OF REVIEW

I. MOTION TO DISMISS

Medtronic moves to dismiss all claims alleged against it pursuant to 735 ILCS 5/2-615. A motion to dismiss pursuant to section 2-615 "attacks the sufficiency of a complaint, and is to be decided solely on the allegations set forth in the complaint." *People ex rel. Peters v. Murphy-*

Knight, 248 Ill. App. 3d 382, 386-87 (1st Dist. 1993). In deciding the motion, the Court must accept as true all well pleaded facts. *See Knox Coll. v. Celotex Corp.*, 88 Ill. 2d 407 (Ill. 1981). Accordingly, the claims in a complaint should be dismissed "only if it appears that plaintiff can prove no set of facts under the pleadings which would entitle him to the relief sought." *Murphy-Knight*, 248 Ill. App. 3d at 387. Thus, in reviewing a motion to dismiss, "the question is whether, when viewed in the light most favorable to the plaintiff, the facts alleged in the complaint adequately state a cause of action." *Id.*; *Holloway v. Meyer*, 311 Ill. App. 3d 818, 823, (2nd Dist. 2000).

II. THERE IS A STRONG PRESUMPTION AGAINST PREEMPTION

The United States Supreme Court and Illinois Supreme Court have 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 Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008); *Weiland v. Telectronics Pacing Sys., Inc.*, 188 Ill. 2d 415, 417 (Ill. 1999) ("[T]he starting point for our analysis is the presumption 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.") (quotations omitted); *People v. Williams*, 235 Ill. 2d 178, 184 (Ill. 2009). The presumption applies in all tort cases, particularly those involving products liability, because states have historically possessed broad powers to protect the "lives, limbs, health, comfort and quiet of all persons." *Slaughter House Cases*, 16 Wall 36, 62 (1873); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (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). The United States Supreme Court and Illinois Supreme Court have 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."); *Weiland*, 188 Ill. 2d at 417. Medtronic's motion fails to make *any* mention of this important presumption against preemption precisely because it cannot overcome it.

ARGUMENT

Medtronic's Motion to Dismiss takes an extreme position—that, regardless of whether Medtronic has violated federal law or whether those violations also violate state law, Medtronic is immune from any state tort liability because all causes of action are preempted by federal law. In seeking blanket immunity, Medtronic makes two specious arguments: *First*, relying on a tortured reading of 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. This argument, however, is predicated on a misreading of *Riegel*. *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); *see 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 Sanda's illegal off-label promotion allegations would escape preemption under *Riegel* and its progeny, Medtronic alternatively argues that any attempt by Sanda 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 ("MDA") 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 *Lohr* 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.

I. FEDERAL LAW DOES NOT EXPRESSLY PREEMPT STATE CAUSES OF ACTION ARISING OUT OF VIOLATIONS OF FEDERAL LAW

Medtronic's first argument in its Motion to Dismiss is that all state causes of action alleged against a medical device manufacturer are expressly preempted by the FDCA because state law imposes requirements that are different from or in addition to those imposed by federal law. This exact argument, however, has been considered by numerous state and federal courts, including the United States Supreme Court and the Illinois Supreme Court, and has been rejected. The fundamental flaw with Medtronic's position is that, at its core, Plaintiff is not seeking to enforce state law that would impose requirements that conflict with federal law. In

fact, the basis of Plaintiff's Complaint is that, by violating federal law, Medtronic also violated Illinois product liability law. Plaintiff's claims run parallel to, not against, federal law.

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

The starting point in determining whether Plaintiff's claims run contrary to federal law is by understanding what federal law requires of medical device manufacturers. Thus, a brief general background regarding the applicable FDCA provisions is warranted, as well as an application of those laws to the present case.

The Medical Device Amendments of 1976 ("MDA"), 90 Stat. 539, classifies medical devices in three categories based on the risk that they pose to the public. Devices that present no unreasonable risk of illness or injury are designated Class I. 21 U.S.C. § 360c(a)(1)(A). Devices that are potentially more harmful are designated Class II. 21 U.S.C. § 360c(a)(1)(B). Devices that either "presen[t] 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," are designated Class III. 21 U.S.C. § 360c(a)(1)(C). Infuse is a Class III device.

Before a Class III device can be put to market, it must undergo a premarket approval ("PMA") by the FDA. 21 U.S.C. § 360e(d)(2). The PMA process "is a rigorous one" because "[m]anufacturers 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." *Lohr*, 518 U.S. at 477. When the FDA approves a medical device as part of the PMA process, the agency approves the product for a specific use or indication. This is the *sine qua non* of federal regulation. The manufacturer is required to comply with the standards in the PMA approval order, which specifies for which uses the device is safe and effective. 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 other, non-approved 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); *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 110 (2d Cir. 2006) *aff'd*, 552 U.S. 312 (2008); *see also* 21 C.F.R. §801.4 ("[I]f 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).

By approving a device for a specific indication, the FDA can ensure that the device, as it was purposed to be used in the PMA or PMA supplement, is safe and effective. Thus, 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, Plaintiff 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.[1] The FDA has made it clear that a medical

[1] 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). Plaintiff, 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. *See Cornett*, 414 N.J. Super. at 402 ("A claim that promotion of off-label use beyond the safe harbor was coupled with a

device that is promoted for off-label uses is deemed misbranded 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.").

The Infuse device obtained approval for use in *anterior* lumbar procedures, but it has never been approved for posterior cervical fusion procedures. In fact, the FDA specifically published a public health notification linking the off-label use of Infuse in the cervical spine with life-threatening swelling in patient's throats and necks—the very injury Plaintiff sustained as a result of the off-label use of Infuse. (*See* Complaint at ¶ 56.) Thus, use of Infuse for cervical fusion is considered a "new indication" for which Medtronic was obligated to obtain FDA approval if it sought to promote such use. 21 C.F.R. § 814.39(a).[2] Medtronic, however, never obtained approval for posterior cervical fusion procedures and, instead, engaged in a national campaign of utilizing paid consultants and "key opinion leaders" to promote and train the medical community (including Dr. Noland) to use Infuse for off-label procedures, including posterior cervical fusion procedures. (Complaint at ¶ 14.) If Medtronic wanted to *legally* promote Infuse for posterior cervical fusion procedures, it was obligated to obtain FDA approval for that specific indication. 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 clear violation of state and federal laws.

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failure to warn would not be preempted.")

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

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

The MDA includes 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 Plaintiff 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 "require-ment" 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. 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. *Id.*

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.[3]

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 parallel federal requirements."); *Riegel*, 552 U.S. at 330; *see also* 21 C.F.R. § 808.1 ("[the Medical Device Act] does not preempt State or

[3] 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.")

local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.")

In Illinois, courts have long recognized that common law tort remedies arise out of violations of regulatory law, most notably in the area of negligence *per se*. *See, e.g., Kalata v. Anheuser–Busch Companies, Inc.,* 144 Ill.2d 425, 434 (Ill. 1991) (violation of public safety ordinance regulating handrails is *prima facie* evidence of negligence); *Batteast v. Wyeth Lab., Inc.,* 137 Ill.2d 175, 193 (Ill. 1990) (violation of safety statute is *prima facie* evidence of negligence); *First Natn'l Bank in DeKalb v. City of Aurora,* 71 Ill. 2d 1, 7 (Ill. 1978); *Hartje v. Moxley,* 235 Ill. 164, 166 (Ill. 1908) (driving over speed limit is *prima facie* evidence of negligence). Accordingly, Plaintiff can bring a state law cause of action against Medtronic to the extent that it has violated federal law. The Seventh Circuit Court of Appeals engaged in this exact analysis in *Bausch* and held that:

> 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.

630 F.3d at 553 (emphasis added). This analysis of Illinois law was again confirmed last week in the United States District Court for the Northern District of Illinois by the Honorable Robert W. Gettleman in *Elmore v. Smith & Nephew, Inc.*, 12 C 8347, 2013 WL 1707956 (N.D. Ill. Apr. 19, 2013). In *Elmore*, Judge Gettleman rejected nearly identical preemption arguments raised by Medtronic, stating:

> Medical device manufactures that receive PMA are protected from civil liability to the extent that they comply with federal law, but this protection does not foreclose claims based on violations of federal law. *See* [*Bausch*, 630 F.3d at 549]. ("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.").

> Plaintiffs' negligence and strict liability claims are not expressly preempted because they do not impose requirements that are "different from or in addition to" the federal requirements on which they are based. Like the strict liability and negligence claims in *Bausch,* plaintiffs' claims run parallel to underlying federal regulations. Under Illinois law, violation of a statute designed to protect human life is *prima facie* evidence of negligence. [citation omitted] In addition, Illinois "imposes strict liability on sellers of unreasonably dangerous products where the dangerous condition existed when it left the manufacturer's control." *Apperson v. E.I. du Pont de Nemours & Co.,* 41 F.3d 1103, 1106 (7th Cir.1994). Design or manufacturing defects may cause a product to become "unreasonably dangerous." *Id.* Because plaintiffs' common-law claims are based on alleged violations of federal law, they impose no requirement "different from, or in addition to" the requirements of the federal regulations, and are not expressly preempted.

Elmore, 2013 WL 1707956, at *3 (N.D. Ill. Apr. 19, 2013).

The *Bausch* and *Elmore* 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*). In addition, several state courts that have evaluated whether Medtronic's off-label promotion of Infuse was preempted by federal law have held that the parallel state causes of action were *not preempted. Martinez v. Oppenhimer*, No. 12-31442 CA 06 (Fla. Cir. Ct. 2013); *Huggins v. Medtronic, Inc.*, No. 12CV40 (Colo. Dist. Ct. 2013); *Cabana v. Stryker Biotech LLC*, 2012 WL 3876245 (Cal. Super. Ct. 2012)[4] (rejecting nearly verbatim Medtronic arguments regarding preemption stating that "plaintiff's claim is not based on

[4] These cases are also cited as opposing authority in Medtronic's Motion to Dismiss.

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. [citation omitted] Accordingly, *Riegel* is not authority that plaintiff's claims against Medtronic are preempted here.").

Moreover, to the extent that the Illinois Supreme Court has addressed this issue, the Court has indicated that the MDA does not preempt state law causes of action. *See Weiland*, 188 Ill. 2d at 417. In *Weiland*, the Illinois Supreme Court directly addressed "whether the MDA preempts plaintiff's state common law claims." *Id.* at 417. While *Weiland* was decided before *Riegel*, the Court expressed a clear policy of avoiding broad interpretation of the MDA to find state law tort claims preempted. *Id.* at 421-22 ("[A]sweeping interpretation of federal preemption under section 360k would also produce a serious intrusion into state sovereignty."). The Court engaged in a careful analysis of federal regulation including the PMA process under the FDCA and MDA and concluded that:

> The premarket approval process allows the FDA to assure the minimal safety of medical devices which are marketed for human consumption; the premarket approval process simply does not address the appropriate standards of liability once the medical device enters the market. [Citation omitted] There is simply no support for [defendant]'s assertion that Congress intended to preempt almost all state common law claims against the manufacturers of medical devices which receive premarket approval from the FDA.

Id. at 422. Although the Illinois Supreme Court did not have access to the United States Supreme Court's decision in *Riegel*, there is no indication that the Illinois Supreme Court would suddenly abrogate the policy and law articulated in *Weiland* to find, in contravention of the federal authority in Illinois, *i.e.*, *Bausch* and *Elmore*, that "all state common law claims against the manufacturers of medical devices which receive premarket approval from the FDA" are preempted.

II. THE SUPREME COURT'S *BUCKMAN* DECISION DOES NOT IMPLIEDLY PREEMPT PLAINTIFF'S PARALLEL CLAIMS OF ILLEGAL OFF-LABEL PROMOTION

Ostensibly recognizing that Plaintiff has pled a viable parallel claim based upon Medtronic's off-label promotion, Medtronic alternatively argues that such parallel claims are

impliedly preempted under the Supreme Court's ruling in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). This is a curious proposition. Namely, Medtronic argues on one hand that to survive preemption under the 2008 *Riegel* decision, a plaintiff must show a "parallel" claim, and then, on the other hand, argues that any attempt to show a parallel claim would be preempted by the 2001 *Buckman* decision.[5] The practical effect of this *non sequitur* argument, of course, is to immunize Medtronic against any possible civil liability for violating federal and state law.

A review of the applicable authority confirms that *Buckman*, which concerned a "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. 531 U.S. at 343. 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. *Id.* The Supreme Court held that the FDCA as amended by the MDA 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.

Plaintiff'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. Plaintiff does not complain of fraud on the FDA, rather, he and his treating physician were deceived and injured by: (a) Medtronic's actions in illegally promoting Infuse for off-label/ unapproved uses; (b) utilizing paid consultants to market the off-label use of Infuse; and (c) failing to provide

[5] Moreover, Medtronic's argument fails to explain why the Court, in 2008, would go through the trouble of creating the parallel claim exception in *Riegel*, which was, according to Medtronic, prohibited by its *earlier* 2001 *Buckman* decision.

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*).

In the recent *Elmore* decision, Judge Gettleman similarly recognized the distinction between those claims alleging that a manufacturer committed fraud on the FDA and those claims alleging that the manufacturer's violation of federal law constituted similar violations of state law. *Elmore*, 2013 WL 1707956, at *4. Echoing the same rationale expressed in the cases cited above, the *Elmore* Court reasoned:

> Plaintiffs' claims are not impliedly preempted because they are based on common-law duties of care that exist independently of the FDA regulations. As in *Bausch*, plaintiffs' common-law claims do not conflict with the primary objective of the FDA's regulatory scheme—ensuring the safety and effectiveness of medical devices. Rather, plaintiffs' negligence and strict liability claims are based on the breach of well-recognized duties already owed under state law. Under *Bausch*, such claims are permissible provided that the plaintiff can show he or she "was harmed by a violation of applicable federal law." *Bausch*, 630 F.3d at 558. Although plaintiffs' claims are premised on alleged violations of federal regulations, they are also capable of existing independent of those regulations.

Id. Here, Plaintiff has likewise alleged that Medtronic's illegal off-label promotion of Infuse for use in cervical spinal fusion procedures violated federal law *and* Illinois state tort law. Accordingly, although Plaintiff's claims are premised on alleged violations of federal law, they exist independently as state law causes of action. They are not impliedly preempted by *Buckman.*

III. MEDTRONIC'S PRIMARY AUTHORITY, *CAPLINGER V. MEDTRONIC, INC.*, WAS WRONGLY DECIDED

Medtronic's Motion to Dismiss relies heavily on *Caplinger v. Medtronic, Inc.*, CIV-12-630-M, 2013 WL 453133 (W.D. Okla. Feb. 6, 2013), *reconsideration denied* (Apr. 8, 2013) to support its argument that all state law causes of action are either expressly or impliedly preempted by federal law. *Caplinger*, however, is a deeply flawed non-binding decision that this Court should not follow. In *Caplinger*, an Oklahoma Federal Court held that the plaintiff's Oklahoma state law claims alleging that the plaintiff sustained injuries from the off-label use of Infuse were preempted by federal law. *Id.* at *10-16. The decision hinged on a finding that "nothing in [Section] 360k(a) suggests that the preemption analysis somehow depends on how the device is being promoted or used." *Id.* at *10. Relying heavily on *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009), the *Caplinger* Court concluded that

> [O]ff-label promotion allegations do not somehow turn plaintiff's claims into "parallel" claims that are not preempted. Specifically, the Court finds that the federal requirement that manufacturers not promote devices for off-label uses is not genuinely equivalent to the state law requirements that a manufacturer provide adequate warnings to physicians about the risks of its medical device and that a manufacturer not produce a product with a defective design.

Caplinger, 2013 WL 453133, at *10 n.4. Putting aside, for a moment, that this finding directly conflicts with any logical reading of *Riegel* or that "equivalence" is not the standard in preemption, it also fundamentally conflicts with *Riley*, the case upon which the *Caplinger* Court was relying. In *Riley*, the court specifically indicated that off-label promotion could give rise to state-law causes of action that are not preempted:

> It seems possible, though, that [plaintiff] could plead a narrow failure-to-warn claim that would escape preemption. Specifically, if [plaintiff] pleaded that (1) [defendant] 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, [defendant] failed to include adequate warnings and directions about the off-label use that it was promoting, then [plaintiff]'s claim might survive. Arguably, the first allegation would protect the claim from being expressly preempted by § 360k(a), because [defendant]'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 [plaintiff] sufficiently alleges that, in the course of unlawfully promoting the Cypher stent for off-label use, [defendant] failed to adequately warn of foreseeable dangers of that use, [plaintiff] may succeed in asserting a claim that is neither expressly nor impliedly preempted.

Riley, 625 F. Supp. 2d at 783-84 (internal citations omitted). *Caplinger* simply ignored that it is possible for a state law cause of action to exist, based on violations of federal law, that run parallel to federal regulation.

What the *Caplinger* Court failed to recognize is that federal regulation only creates standards for medical devices that it has approved for a specific use. Thus, to the extent that state law imposes additional or different obligations relating to that device and its approved use, it would conflict with federal regulation. However, when a device is promoted for off-label use in violation of federal law, federal regulation does not dictate how that product should be used. Thus, state law imposing liability for engaging in off-label promotion and use would not run counter to federal regulation or undermine the FDA's ability to regulate approved medical devices. In other words, state claims arising from the off-label promotion of a medical device are neither expressly nor impliedly preempted.

IV. PLAINTIFF'S FAILURE-TO-WARN CLAIMS ARE SUFFICIENTLY PLEADED

In addition to its misguided preemption arguments, Medtronic also argues that Plaintiff's failure-to-warn claims "must be dismissed under Illinois law because the alleged risk he supposedly encountered were already known by the medical community." (Motion to Dismiss at 23.) This argument, however, is improper for two reasons.

First, the assertion that the medical community was already aware of the risk associated with the off-label use of Infuse in cervical fusion procedures is a factual question that cannot be addressed at this stage. Medtronic's argument is predicated on the learned intermediary doctrine,

a legal defense which allows a drug and device manufacturer to discharge their duty to warn consumers of known risks by giving those adequate warnings to the physician. *See Kirk v. Michael Reese Hosp. & Med. Ctr.*, 117 Ill. 2d 507, 519 (Ill. 1987). "The underlying rationale of the learned intermediary doctrine is that, with regard to prescription drugs, which are likely to be complex medicines, it is the prescribing physician who knows both the propensities of the drug and the susceptibilities of his patient, and who therefore is in the best position to prescribe a particular drug for the patient." *Happel v. Wal-Mart Stores, Inc.*, 199 Ill. 2d 179, 191 (Ill. 2002). Thus, "[t]he doctor, functioning as a learned intermediary between the prescription drug manufacturer and the patient, decides which available drug best fits the patient's needs and chooses which facts from the various warnings should be conveyed to the patient, and the extent of disclosure is a matter of medical judgment." *Kirk*, 117 Ill. 2d at 519. The central question, therefore, in determining whether a defendant is entitled to the learned intermediary defense, is whether sufficient warnings were given to the treating physician. Having no evidence before the Court about whether Dr. Nolden was given proper warnings about the off-label use of Infuse in cervical fusion procedures, this issue cannot be resolved here. Although the FDA published a public health notification linking the off-label use of Infuse in the cervical spine with life-threatening swelling in patient's throats and necks (*see* Complaint at ¶ 56), there is no indication that Dr. Noland received that notice or was aware of it prior to using Infuse in the Plaintiff. Moreover, Medtronic's aggressive promotion of infuse for off-label use effectively diluted or nullified the FDA's notification. Indeed, absent Medtronic's off-label promotion of Infuse, Plaintiff's orthopedic surgeon would not have performed the off-label surgery. See Complaint, ¶¶ 88-89.

Second, even if Dr. Nolden had received the FDA's public notice regarding the use of Infuse in cervical fusion procedures, that alone would be insufficient to avoid liability. Plaintiff alleges that Medtronic engaged in off-label promotion to Dr. Nolden and indicated that Infuse was safe in cervical fusion procedures. It was this illegal conduct that gives rise to Medtronic's liability for failure-to-warn. Whether there was publically available information warning of the

risks of using Infuse in cervical fusion procedures is not dispositive. It was the illegal statements made to Dr. Nolden, *i.e.*, Medtronic's off-label promotion, which led to Plaintiff's injuries.

V. PLAINTIFF'S WARRANTY CLAIMS ARE SUFFICIENTLY PLEADED

Medtronic also argues that Plaintiff's warranty claims should be dismissed because "Medtronic specifically disclaimed any express or implied warranties for the Infuse device, as permitted by Illinois law (*see* 810 ILCS 5/2-316). The FDA approved labeling for Infuse plainly states: 'No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.'" (Motion to Dismiss at 24.) This argument is disingenuous and plainly wrong.

First, Medtronic argues, in the page proceeding its argument to dismiss Plaintiff's warranty claims, that "the intended audience for product warnings is not the patients on whom the [medical] devices are ultimately used[.]" Medtronic then argues on the next page that Infuse's label acts as a warrant disclaimer. It is black letter law that before a warranty can be disclaimed, the disclaimer must actually reach the consumer before the contractual relationship is created. *See, e.g., Midland Supply Co., Inc. v. Ehret Plumbing & Heating Co.*, 108 Ill. App. 3d 1120, 1125 (5th Dist. 1982) (relying on *Gideon Service Division v. Dunham-Bush, Inc.* 80 Ill. App. 3d 633 (1st Dist. 1980) (holding that warranty disclaimer provided at time of delivery but not at time of contract formation is invalid). Thus, if the drug label is not directed to the consumer, as Medtronic argues on page 23, then its disclaimer is, by law, invalid. If the drug label is directed at the consumer, there is no proof that the warranty disclaimer reached Plaintiff before delivery of the product.

Second, Medtronic's attempt to direct the Court to a warranty disclaimer that is on the drug label is simply, again, a misapprehension of the Plaintiff's claims. Plaintiff is not suing for conduct related to on-label promotion. The crux of Plaintiff's Complaint rests on Medtronic's illegal off-label conduct. Thus, the warranties at issue here are not those provided on the label, but those expressed to Dr. Nolden by Medtronic through its off-label promotion.

CONCLUSION

For the reasons stated above, Medtronic's Motion to Dismiss should be DENIED.

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