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Novel Claims: How Plaintiffs Are Using Off-Label Promotion of Medical Devices to Avoid Preemption and Dismissal of Their Claims

by Brett A. Tarver

I. Introduction

Plaintiffs constantly seek new ways to elude preemption or dismissal of their claims. After each new court decision defining the pleading requirements to survive preemption or dismissal, plaintiffs revise their approach in order to rescue their claims from dismissal. In the past few years, plaintiffs have made a concerted effort to carve out claims that are not subject to preemption or dismissal in a new area, specifically, claims based upon a defendant's alleged promotion of off-label uses for a medical device.

Standing alone, "'off-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350, 121 S. Ct. 1012, 1018, 148 L. Ed. 2d 854 (2001). However, "[a] device may not be . . . advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. Plaintiffs have asserted—and some courts have agreed—that this regulation amounts to a prohibition of promoting off-label use of a medical device. From 2013 to 2015 alone, courts have evaluated claims related to defendants' alleged promotion of off-label use in approximately 42 cases, giving plaintiffs a plethora of language to use in crafting new arguments that escape preemption and dismissal.

Of the issues being addressed regarding promotion of off-label uses for medical devices, this article will focus on two separate grounds where plaintiffs have introduced—and found some acceptance for—new theories to evade both preemption and dismissal of their claims. First, in *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 993 (D. Ariz. 2013), the court ruled that preemption under 42 U.S.C. § 360k did not apply as a defense to claims related to a defendant's alleged promotion of an off-label use for a device as the FDA never evaluated or approved the device for the off-label use and, therefore, there were no federal requirements that may conflict with the state law requirements. Though many courts have addressed the holding in *Ramirez* and disagreed with the overall premise, others have followed *Ramirez*'s reasoning, encouraging plaintiffs to continue asserting this argument.

Second, plaintiffs have crafted a "fraud-on-the-market" theory by using defendants' alleged promotional marketing activities to survive dismissal of their fraud claims for failure to plead such claims with particularity as required by Federal Rule of Civil Procedure 9(b). *See, e.g.*, *Garross v. Medtronic, Inc.*, No. 14-CV-0134, 2015 WL 264903, at *3 (E.D. Wis. Jan. 21, 2015); *Arvizu v. Medtronic Inc.*, No. CV-14-00792, 2014 WL 4204933, at *6 – 7 (D. Ariz. Aug. 25, 2014); *Houston v. Medtronic, Inc.*, No. 2:13-CV-01679, 2014 WL 1364455, at *8 – 9 (C.D. Cal. Apr. 2, 2014).

Despite the headway plaintiffs have made in bringing and arguing the above-described theories in some courts, many other courts have rejected these theories and still found plaintiffs' claims to be subject to preemption or dismissal. Thus, there are many authorities counsel may rely upon in defending against these novel claims.

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II. *Ramirez* and the Rejection of Applying Preemption.

In *Ramirez v. Medtronic Inc.*, plaintiff Cristina Ramirez's surgeon "used Infuse, a bio-engineered liquid bone graft substitute" to perform "a lumbar fusion procedure to alleviate [plaintiff's] back pain." 961 F. Supp. 2d 977, 981 (D. Ariz. 2013). At the time of her surgery in 2009, the "Infuse device consist[ed] of three components: (1) a metallic spinal fusion cage (the LT–Cage), (2) the bone graft substitute, which consists of liquid rhBMP–2, and (3) a spongy carrier or scaffold for the protein that resides in the fusion cage." *Id.* Medtronic received premarket approval from the FDA for the Infuse devise in 2001. *Id.*

FDA's approval of the device indicated that the device "was intended for a single-level anterior lumbar interbody fusion performed with all three components in a specific spinal region." *Id.* at 981. Although the device was not approved for a spinal fusion surgery conducted through a posterior approach, Ramirez's surgeon elected to use a posterior approach during her procedure. *Id.* at 982. Her surgeon also only made use of the bone graft component of the device and did not use the other component parts. *Id.* at 983. After the surgery, the plaintiff began to experience severe pain and it was discovered that "she had developed uncontrolled bone growth" in the spinal area where the device was implanted. *Id.*

As a result of her injuries, plaintiff brought suit against Medtronic, asserting six causes of action based on Medtronic's alleged promotion of the off-label use of the Infuse device that was employed her in surgery. *Id.* Plaintiff asserted that Medtronic actively promoted the off-label use of the Infuse device that caused her injuries by: (1) "promot[ing] th[e] off-label uses through its sales personnel;" (2) "establishing consulting/royalty agreements with physicians who advocated off-label uses to fellow surgeons;" (3) "conceal[ing] the[] risks by funding biased studies and articles by opinion leaders in key medical journals that showed a lower incidence of off-label adverse effects;" and, (4) "allegedly fail[ing] to report certain adverse events to the FDA." *Id.* at 982. Medtronic filed a motion to dismiss the plaintiff's claims, asserting that each of her claims were both expressly and impliedly preempted pursuant to 42 U.S.C. § 360k and *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001). *Id.* at 985.

The *Ramirez* court ruled that plaintiff's claims were neither expressly nor impliedly preempted under federal law. In so doing, the court acknowledged that "[t]here is no dispute that the federal government heavily regulates Infuse, and there are a number of federal requirements 'applicable . . . to the device' for purposes of § 360k." *Id.* at 987. The court also recognized, as discussed above, that the FDA "does not seek to control how physicians use regulated devices" and that "off-label use is expressly permitted as 'an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.'" *Id.* at 988 (citing *Buckman*, 531 U.S. at 350, 121 S.Ct. 1012). Thus, if the plaintiff's claims were simply premised upon her surgeon's off-label use of the device, her claims against the manufacturer would be preempted. *Id.* at 989.

However, the court expressed that the claims brought by plaintiff presented a "different scenario." *Id.* at 990. First, citing to 42 U.S.C. § 331(a), the court premised that "[a] manufacturer is . . . prohibited from promoting a use of the product that is not the specified use," thus concluding that the action of off-label promotion alone—whether or not such promotion was false or misleading—violated the FDCA. *Id.* at 986. Second, the court explained that "the FDA reviewed Infuse's safety and effectiveness *only for the uses Medtronic specified in its PMA application*, and the regulations are premised on that review." *Id.* at 988 (emphasis added). The court therefore reasoned that, "while the requirements applicable to the device are not explicitly use-specific, they are premised on the manufacturer's intended use." *Id.* Explaining that the "fundamental purpose of § 360k's express preemption provision is to avoid having another entity (jury, state regulators, or state legislatures) arrive at a determination regarding a device's safety that conflicts with the conclusion the FDA made after the rigorous PMA process," the court concluded that the "concern vanishes when the plaintiff brings a claim against a manufacturer that arises out of a use that has not been reviewed by the FDA but has been promoted by the manufacturer." *Id.* at 991.

Thus, "[w]hen the device is not being used in the manner the FDA pre-approved and the manufacturer is actually promoting such use, there is no law or policy basis on which to pre-empt the application of state law designed to provide that protection." *Id.* Because the plaintiff alleged that the defendant had engaged in

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active promotion of the off-label use of the Infuse device, the court ruled that the defendant had "departed the realm of federal regulation and returned to the area of traditional state law remedies." *Id.* Without any federal regulations applicable to the "new use," the court held that "there is nothing to preempt the state law requirements" and none of plaintiff's claims were expressly preempted. *Id.* at 993. Under similar reasoning, the court also found the plaintiff's claims were not impliedly preempted, finding that the "state law claims here exist[] independent of federal law." *Id.* at 994.

A few courts have adopted *Ramirez*'s reasoning and holding in evaluating claims premised upon a defendant's alleged promotion of off-label uses for a device. *See, e.g.*, *McDonald–Lerner v. Neurocare Assocs., P.A.*, No. 373859–V, 2013 WL 7394926 (Md. Cir. Ct. Aug. 29, 2013). Relying on *Ramirez*, the court in *McDonald-Lerner* explained that "[t]here is no legitimate federal concern with state judges or state juries meddling with the decisions of the FDA when the state law claims, as alleged in this case 'arise out of a use that has not been reviewed by the FDA, but has been promoted by the manufacturer.'" *Id.* at *12 (quoting *Ramirez*, 961 F.Supp.2d at 991). Thus, the court concluded that "preemption under § 360k is not even an issue because the PMA for 'the Infuse® Bone Graft/L–T Cage Device' does not establish device-specific requirements for the bone protein alone and without the LT–Cage, or the implantation of any or all of the device through a posterior approach." *Id.*

However, the majority of courts faced with arguments by plaintiffs to adopt the holding in *Ramirez* have declined to do so. These courts differentiate their reasoning from that adopted in *Ramirez* by identifying that premarket approval of a device by the FDA imposes requirements on the device itself, not upon a *specific use* of the device. *See, e.g.*, *Wright v. Medtronic, Inc.*, No. 1:13-CV-716, 2015 WL 328596, at *8 (W.D. Mich. Jan. 23, 2015) ("The reasoning of *Ramirez* has been rejected as inconsistent with the text of § 360(k), which applies if federal requirements are applicable 'to the device,' not merely to specific uses of devices."); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F.Supp.3d 1021 (D. Haw. 2014); *Houston v. Medtronic, Inc.*, No. 2:13-CV-01679-SVW, 2014 WL 1364455, at *5 (C.D. Cal. Apr. 2, 2014) ("If § 360k(a) does not distinguish between uses of a device, it surely does not distinguish between whether a particular use of a device was promoted by the manufacturer."); *Alton v. Medtronic, Inc.*, 970 F. Supp. 2d 1069, 1096 (D. Or. 2013) ("PMA approval constitutes—impliedly but necessarily—imposition of device-specific requirements on a medical device without regard to the application or use in connection with which the FDA issued such approval."); *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 431, 167 Cal. Rptr. 3d 300, 314, as modified (Feb. 3, 2014), *dismissed, remanded and ordered published sub nom. Coleman v. Medtronic*, 331 P.3d 178 (Cal. 2014) ("We find the approach taken in *Ramirez* unpersuasive. To avoid preemption, a plaintiff must state a cause of action based on state law that parallels a federal requirement.").

Additionally, courts have rejected the premise set forth in *Ramirez* that off-label promotion alone is violative of federal law. *See, e.g.*, *Alton*, 970 F. Supp. 2d at 1096 ("Finally, the reasoning of *Ramirez*, although largely persuasive, . . . depend[s] in part on a flawed premise . . . in connection with the court's finding that Medtronic violated federal law specifically by promoting off-label applications of the Infuse device."). Instead, courts have identified that Section 331(a) "does not expressly prohibit such promotion," but rather prohibits manufacturers from introducing into interstate commerce any device that is misbranded. *Thorn v. Medtronic Sofamor Danek, USA, Inc.*, No. 1:13-CV-239, 2015 WL 328885, at *8 (W.D. Mich. Jan. 23, 2015). Thus, off-label promotion "'itself did not violate any provision of the FDCA, but rather constituted evidence material to the question whether the . . . device was misbranded.'" *Id.* (quoting *Alton*, 970 F. Supp. 2d at 1096).

Despite the many district court rulings that have declined to follow *Ramirez*, plaintiffs have continued to raise this argument and can be expected to do so until decisive rulings are made by the circuit courts. For example, in *Martin v. Medtronic, Inc.*, the "plaintiffs argue[d] that the federal requirements were imposed only for [the use approved in the PMA]. Plaintiffs insist[ed] that the PMA does not establish federal requirements applicable to the unreviewed, unapproved uses of the bone protein component by itself," relying primarily upon *Ramirez* to support their theory. 32 F.Supp.3d 1026, 1035 (D. Ariz. 2014); *see also Houston v. Medtronic, Inc.*, No. 2:13-CV-01679, 2014 WL 1364455, at *5 (C.D. Cal. Apr. 2, 2014) ("[Plaintiff] asserts that this Court should follow Ramirez, and find that § 360k(a) does not apply where a manufacturer actually promotes off-label uses of a device."). The court soundly rejected this argument,

concluding that "'§ 360(k) applies broadly to "devices" as opposed to particular "uses" of such devices.'" *Id.* (quoting *Beavers-Gabriel,* 15 F.Supp.3d at 1035). Most recently in *Wright v. Medtronic, Inc*., the plaintiff urged the court to follow *Ramirez* and argued "that the FDA's express preemption provision does not apply when a manufacturer engages in off-label promotion." No. 1:13-CV-716, 2015 WL 328596, at *8 (W.D. Mich. Jan. 23, 2015). The court declined to follow *Ramirez*. *Id.*

III. The Use of the "Fraud-On-The-Market" Theory to Avoid Dismissal of Fraud Claims.

In cases premised upon a defendant's alleged promotion of off-label use for a medical device, nearly all plaintiffs have asserted claims for fraud. Under Federal Rule of Civil Procedure 9(b), plaintiffs are required to "state with particularity the circumstances constituting fraud or mistake" in their pleadings. In order to plead fraud with the requisite particularity, plaintiffs must identify "(1) a specific false representation of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his damage." *U.S. ex rel. Atkinson v. Pennsylvania Shipbuilding Co*., 255 F. Supp. 2d 351, 407 (E.D. Pa. 2002). When dealing with a defendant's alleged promotion of a device's off-label use, plaintiffs have struggled to identify the precise "who, what, where, when, and why" of the alleged misrepresentation that is typically required to satisfy the particularity requirements of Rule 9(b). However, plaintiffs have found traction in satisfying Rule 9(b) by pleading what has been identified by one court as a "fraud-on-the-market" theory. *See Martin v. Medtronic, Inc.*, No. 2:14-CV-0385, 2014 WL 6633540, at *7 (D. Ariz. Nov. 24, 2014).

Under this theory, plaintiffs are not required to identify precisely what statements were made to their individual surgeons, when these statements were made, or why their surgeons relied upon these statements from the defendant in determining to use the medical device in an off-label manner. Instead, courts have "found that the general allegation that a plaintiff's doctor relied upon misrepresentations made by [defendant] sponsored medical literature, conferences, and statements by sales representatives—despite the failure to plead what statements were relied upon, who made the misstatements, when they were made—were sufficient to plead reliance." *Hawkins v. Medtronic, Inc*., No. 1:13-CV-00499 AWI, 2014 WL 6611876, at *13 (E.D. Cal. Nov. 20, 2014) (finding plaintiff's allegations that the defendant made misrepresentations during the course of actively promoting the off-label use of the device were sufficient to satisfy Rule 9(b), even where the plaintiff did not identify the precise statement(s) made to his physician); *see also Eidson v. Medtronic, Inc*., No. 13-CV-01502, 2014 WL 1996024, at *22 (N.D. Cal. May 13, 2014) (ruling that plaintiff's allegations of misrepresentation about off-label use of a device in scientific articles funded by defendant, misleading statements made by "opinion leaders" supported by the defendant, and false statements made by defendant's sales representatives were enough to plead fraud even though the plaintiff did not identify a particular statement made to his physician); *Garross v. Medtronic, Inc*., No. 14-CV-0134, 2015 WL 264903, at *6 (E.D. Wis. Jan. 21, 2015) (same).

The district courts are currently split over whether the "fraud-on-the-market" approach can fulfill the plaintiff's duty to plead a fraud claim with particularity. Numerous courts have disagreed with the defense argument that a plaintiff fails to plead fraud with the requisite particularity when he or she fails to identify "an actual representation or omission that was made by [defendant] and relied upon by [plaintiff's] physician." W*right v. Medtronic*, *Inc.,* No. 1:13-CV-716, 2015 WL 328596, at *14 (W.D. Mich. Jan. 23, 2015). Courts have instead relied upon a plaintiff's description of a defendant's "course of conduct that promotes [the off-label use] as safe" to support a finding that the plaintiff plead her fraud claim with the required particularity. *Id.*; *see also Arvizu v. Medtronic Inc.*, No. CV-14-00792, 2014 WL 4204933, at *6 – 7 (D. Ariz. Aug. 25, 2014); *Houston v. Medtronic, Inc*., No. 2:13-CV-01679, 2014 WL 1364455, at *8 – 9 (C.D. Cal. Apr. 2, 2014).

On the other hand, several courts have agreed with defendants that a "fraud-on-the-market" theory is simply not sufficient to meet the requisite pleading standards under Rule 9(b). *See Martin,* No. 2:14-CV-0385, 2014 WL 6633540, at *7. In *Martin*, the plaintiff argued that her complaint was "replete with allegations that the representations that defendants made that the [] device was safe for off-label use was false and that defendants made these representations to induce physicians . . . to use the [] device off-label." *Id.* The court determined these allegations were not sufficient to plead a claim for fraud as they were not specifically "tied" to plaintiff or plaintiff's physician. *Id.* "Rather, these allegations

suggest that what plaintiffs are attempting to do here is advance a 'fraud-on-the-market' theory, with the 'market' being the medical community at large" and do not meet the pleading requirements as set forth in Rule 9(b). *Id*.

These courts have required the plaintiff to precisely identify what source his or her physician relied upon in deciding to use the device in an off-label manner in order for the fraud claim to survive dismissal. *See, e.g., Beavers-Gabriel v. Medtronic, Inc*., No. CIV. 13-00686, 2015 WL 143944, at *7 – 10 (D. Haw. Jan. 9, 2015) (ruling that several of plaintiff's allegations regarding scientific journal articles and talks by "key opinion leaders" were still "too vague" to support a claim for fraud and only allowing the fraud claim to stand upon the plaintiff's identification of a specific talk her physician testified he attended where one of defendant's key opinion leaders specifically discussed off-label use of the device); *Dunbar v. Medtronic, Inc*., No. CV 14-01529, 2014 WL 3056026, at *7 (C.D. Cal. June 25, 2014) (ruling that plaintiff's "general statements that [defendant] manipulated medical literature and paid opinion leader consultants to misrepresent the safety and efficacy of INFUSE's off-label use . . . fail to meet the heightened pleading requirements"). Thus, some courts have confirmed that where a "[p]laintiff provides detailed allegations on studies, journal articles, investigations, and media reports, but [] fails to identify (among other things) the particular misrepresentations and knowingly false statements that were made to him and his physician," the fraud claim cannot survive dismissal. *Zaccarello v. Medtronic, Inc*., No. 3:13-CV-01161-BCW, 2014 WL 3866607, at *7 (W.D. Mo. Aug. 6, 2014).

IV. Conclusion

In sum, the district court decisions that have been entered in the past two years addressing claims based upon defendants' alleged promotion of off-label uses for medical devices have provided plaintiffs with plenty of ammunition to use in making arguments to survive preemption or dismissal of their claims. Fortunately, many courts have also provided a roadmap for defendants in defending against these novel theories being embraced by plaintiffs. Until the circuit courts take up these theories and provide further guidance for their legitimacy, it can be expected that plaintiffs will continue to argue for the application of *Ramirez* to avoid preemption of their claims and the "fraud-on-the-market" theory to elude the particularity requirements of Federal Rule of Civil Procedure 9(b). In the meantime, defense counsel can arm themselves with the various rulings rejecting these novel theories and be prepared for these tactics in attempting to bring about the dismissal of plaintiffs' claims.

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