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IN THIS ISSUE

David W. O'Quinn, Douglas J. Moore, and Carlos A. Benach provide a basic overview of federal preemption and parallel claims related to Class III medical devices, an understanding of off-label promotion claims within the framework of federal preemption, and insights and observations on off-label promotion claims at the pleading stage.

Off-Label Promotion of Class III Medical Devices: Parallel Claims and Preemption at the Pleading Stage

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Manufacturers of Class III, PMA approved medical devices are entitled to the dismissal of state based claims that seek to impose requirements that are "different from, or in addition to" federal requirements for the device which relate to safety and efficacy, based on the doctrine of federal preemption. However, a claimant can circumvent preemption by asserting a parallel claim by pleading violation of a state based duty which parallels a federal requirement under the Federal Drug and Cosmetic Act ("FDCA"). Within this legal framework, claims based on a manufacturer's alleged off-label promotion have created a spectrum of precedent that can assist evaluation of the viability of such claims at the pleading stage.

This article will provide a basic overview of federal preemption and parallel claims related to Class III medical devices, an understanding of off-label promotion claims within the framework of federal preemption, and insights and observations on off-label promotion claims at the pleading stage.

I. Federal Preemption Applicable to Class III Medical Devices

Courts analyze off-label promotion claims by testing a claimant's causes of action and allegations under the doctrine of federal preemption. The US Supreme Court decisions *Riegel*, *Lohr* and *Buckman* are the precedential foundation governing federal preemption regarding FDA approved Class III medical devices. The FDCA's express preemption clause, 21 USCA §360(k), contemplates two major queries: (1) is the device subject to FDCA requirements, and (2) do the state based claims relate to the safety and efficacy of the device and impose requirements "different from, or in addition to" federal requirements? *Riegel v. Medtronic*, *Inc.*, 552 U.S. 312, 323 (2008). Courts have dismissed claims against manufacturers of Class III medical devices when the claims seek to impose different or additional requirements from those imposed by the FDCA. *Id.*; *see generally Shuker v. Smith & Nephew, PLC*, 885 F.3d 760 (3rd Cir. 2018); *Caplinger v. Medtronic*, *Inc.*, 784 F.3d 784 F.3d 1335 (10th Cir. 2015); *Perez v. Nidek*, 28 F.Supp.3d 282 (9th Cir. 2014); *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013 (en banc); *Bass v. Stryker Corp.,* 669 F.3d 501 (5th Cir. 2012); *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010).

Courts will also evaluate a claimant's causes of action based on implied preemption. The enforcement of the FDCA regulatory scheme is within the sole province of the federal government, and thus private litigants have no private right of action under the FDCA. *See* 21 U.S.C.A. § 331 *et seq*.; *see also Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348-53 (2001). Thus, if a plaintiff's claims are based solely on violation of the FDCA, and do not involve a parallel state based cause of action, the claims are impliedly preempted. For example, if a claimant seeks a medical device manufacturer's liability as a result of the

manufacturer's misrepresentations to the FDA during the premarket approval process, this claim is impliedly preempted under the FDCA because a private cause of action cannot "be based solely on a violation of federal law." *Buckman,* 531 U.S. at 352-53.

Nevertheless, a claimant can find a "narrow gap" in preemption if they can successfully assert a parallel claim. *Perez*, 28 F.Supp.3d at 1120. A parallel claim is a state law tort claim based on a device manufacturer's violation of federal regulations under the FDCA. *See Medtronic, Inc. v. Lohr*, 518 U.S. 460, 488; *see also Bausch*, 630 F.3d at 558. Thus, to properly assert a parallel claim, "[t]he plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by §360(k)(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim could be impliedly preempted under *Buckman*)." *Perez,* 711 F.3d at 1120 (citing *In re Medtronic, Inc., Sprint Fidelis Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010).

II. Federal Regulation of Off-Label Promotion

Under this preemption framework, courts evaluate whether a claimant's state court causes of action properly set forth a parallel claim based on a manufacturer's alleged off-label promotion of a Class III medical device. In assessing express preemption under the FDCA, courts consider whether the state based claims "are different from, or in addition to" the federal regulations about Class III devices set forth in the FDCA. 21 U.S.C.A. § 360(k). This analysis requires the identification of FDCA regulations that prohibit medical device manufacturers from promoting their devices for off-label uses.

There are no FDCA regulations which explicitly prohibit off-label promotion. Nevertheless, courts have identified different statutes empowering the FDCA's authority to regulate, and thereby prohibit off-label promotion of Class III medical devices. Courts have relied upon the FDCA's prohibition on misbranding of medical devices. 21 USC §§ 331(a), 333, 321(n). The term "misbranded" is defined as "labeling or advertising [that] is misleading," which is evaluated by considering "representations made or suggested by statement, word, design, device, or any combination thereof," or if the devices "labeling is false or misleading in any particular." *Id.*; 21 USC § 352(f)(1); *see also Perez*, 711 F.3d at 1118; *Carson v. Depuy Spine, Inc*., 365 Fed.Appx. 812, 815 (9th Cir. Feb. 16, 2010); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F.Supp.3d 1021, 1034 (D. Haw. April 10, 2014); *Eidson v. Medtronic, Inc.*, 981 F.Supp.2d 868, 884, n. 4, (N.D. Cal. Oct. 3, 2013)*; Alton v. Medtronic, Inc.* 960 F. Supp.2d 1069, 1078 (D. Oreg. Sept. 6, 2013); *Houston v. Medtronic, Inc.*, 957 F.Supp.2d 1166, 1179 (C.D. Cal. July 30, 2013); *In re Epogen & Aranesp Off–Label Marketing & Sales Practices Litig*., 590 F.Supp.2d 1282, 1287 (C.D.Cal. Dec. 17, 2008). Under this provision, off-label promotion is deemed to have misbranded the device by creating a new intended use outside the FDA approval.

Although courts have identified that the FDCA does not expressly prohibit device manufacturers from promoting off-label uses of their products, only a minority of courts have relied upon this absence of express federal regulation to dismiss off-label promotion claims. *See Dawson v. Medtronic Inc.*, 2013 WL 4048850, at *6 (D.S.C. Aug. 9, 2013) (explaining "[t]his court is not convinced that off-label promotion violates the FDCA. Consequently, any state laws proscribing off-label promotion would establish requirements 'different from[] or in addition to[] any requirement' under the MDA and would be expressly preempted"); *see also U.S. v. Caronia*, 703 F.3d 149, 160 (2nd Cir. 2012); *Schuler v. Medtronic, Inc*., No. CV 14-00241-R, 2014 WL 988516, at *1 (C.D. Cal. Mar. 12, 2014).

Furthermore, courts have made a distinction between a manufacturer's off-label promotion of a Class III medical device and a physician's discretion to use a medical device in an off-label manner. *See Mendez v. Shah*, 28 F.Supp.3d 282, 292 (D.N.J. June 27, 2014). The FDCA is not intended to interfere with the practice of medicine. 21 U.S.C.A § 396; *see also Buckman*, 531 U.S. at 350 (explaining that "'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"). Moreover, the FDCA statute concerning the "practice of medicine" specifically provides that "…this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices." *Id.*

These commonly cited statutes and interpretive case law provide the foundation for parallel claims based on off label promotion. Each court's analysis of off-label promotion claims turns on the facts alleged and the state-based cause of action's requirements in light of federal requirements. Awareness of your appellate and district court decisions as to off-label promotion claims will guide jurisdiction specific analyses regarding the viability of these claims.

III. Preemption and Pleading Parallel Off-Label Promotion Claims: Observations

Many courts have evaluated preemption of claims based on alleged off-label promotion at the pleading stage. The courts evaluate the alleged parallel claims by testing their legal adequacy under preemption standards [21 USC §360(k)] and their factual adequacy based on pleading standards. Fed. R. Civ. Proc. 8. Because many plaintiffs will allege fraud and/or fraudulent or intentional misrepresentation claims based on allegations of off-label promotion, Federal Rules of Civil Procedure ("FRCP") Rule 9 should also be raised to challenge the sufficiency of factual allegations. Here are some observations, trends, and common issues appearing in the case law.

Some decisions have identified the factual allegations necessary for an off-label promotion claim to survive a motion to dismiss. Claims based on fraud or misrepresentation require specific allegations of affirmative promotion and misrepresentation regarding a particular off-label use of a device. *See Shuker*, 885 F.3d 760, 778-79 (3rd Cir. 2018); *see also Shuker v. Smith & Nephew*, 211 F.Supp.3d 695, 703-04 (E.D. Penn. Sept. 29, 2016), *rev'd and affirm'd*, 885 F.3d 760 (3rd Cir. 2018); *Raab v. Smith & Nephew, Inc.*, 150 F.Supp.3d 671, 698 (S.D.W.V. Dec. 15, 2015); *Schouest v. Medtronic, Inc.*, 13 F.Supp.3d 692, 705 (S.D. Tex. March 24, 2014); *Alton*, 970 F.Supp.2d at 1102-03. As one court explained "plaintiffs do not allege how any of the defendant's promotion activities violated federal law because they [do not] identify any specific conduct on the part of the defendant in marketing its products… On such allegations, defendant (and this Court) are left to guess as to the manner in which the defendant was negligent..." *Raab*, 150 F.Supp.3d at 698. In this view, alleged omissions cannot support an off-label promotion claim because state law cannot require disclosures in addition to those required by the FDA. *Perez*, 711 F.3d at 1118-19.

Another court has explained how allegations of off-label promotion could fulfill the pleading requirements for a general negligence claim. *See Shuker*, 885 F.3d. at 776-77. The court explained that a manufacturer's duty was premised on the FDA's approval of the medical device, and that the manufacturer had a duty to "refrain from publishing 'false or misleading' advertising" about the device, in line with the FDCA. *Id*. For the element of liability (i.e. breach of duty), the court explained that a claimant must allege facts that "give rise to the reasonable inference that [the manufacturer] was 'misleading' regarding FDA approved uses of the [device]." *Id.* at 777. As to causation, a claimants allegations should demonstrate that a manufacturer's marketing materials "caused [the plaintiff's] surgeon to recommend [the device] and to install it within [the plaintiff], a course of action which in turn caused [plaintiff's] subsequent injuries." *Id.* at 777. The *Shuker* court concluded that the claimant's factual allegations allowed for the reasonable inference that "each of the three legal elements of the [plaintiff's] parallel negligence claim" were satisfied, and thereby validly asserted on the petition.

Courts have been critical of claimants' parallel claims based on of off-label promotion allegations which are unaccompanied by any citations to FDCA regulations. *See Dawson,* 2013 WL 4048850 at *6; *Raab*, 150 F.Supp.3d at 698. A claimant's failure to identify relevant off-label promotion federal regulations "is not sufficient to avoid preemption" because these claims fail to demonstrate how the manufacturer violated federal regulations. *Otis-Wishner*, 951 F. Supp. 2d 592, 599 (D. Ver. 2013); *see also Wolicki-Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) (explaining "Parallel claims must be specifically stated in the initial pleadings. A

plaintiff must alleged that '[the] defendant violated a particular federal specification referring to the device at issue.") (internal citations omitted).

In some instances, courts have acknowledged that the elements/ requirements of the state-based cause of action imposes requirements "different from, or in addition to" federal requirements, and thereby are expressly preempted under the FDCA. *See e.g. Mendez,* 28 F.Supp.3d at 298; *Gomez v. St. Jude Medical Diag. Division Inc.,* 442 F.3d 919, 928 (5th Cir. 2006). Some courts have also considered policy arguments that off-label promotion claims frustrate the FDCA's purpose and the FDA's review and approval of Class III medical devices. For example, in *Caplinger v. Medtronic, Inc.*, the court explained that

> "Any additional state duties on top of those imposed by federal law, even if nominally limited to off-label uses, might check innovation, postpone access to life-saving devices, and impose barriers to entry without sufficient offsetting safety gains. For example, a state's judgment that a device is unsafe for a particular off-label use could require design changes that adversely affect the device's safety for on-label uses. Requiring manufacturers to comply with fifty states' warning requirements concerning off-label uses, on top of existing federal on-label warning requirements, might introduce sufficient uncertainty and cost that manufacturers would delay or abandon at least some number of life-saving innovations."

784 F.3d at 1346. These policy arguments prove helpful when dealing with allegations related to failure-to-warn and negligence claims based on a manufacturer's off-label promotion of the device. *See e.g.* Catherine M. Sharkey*, Tort–Agency Partnerships in an Age of Preemption,* 15 Theoretical Inquiries L. 359, 361 (2014); Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 Geo. Wash. L.Rev. 449, 483 (2008); Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L.Rev. 1353, 1385–87 (2006).

Off-label promotion allegations do not eliminate federal requirements for the device itself. The outlier decision, *Ramirez v. Medtronic Inc.*, exemplifies this issue. *In Ramirez*, the court concluded that allegations of the manufacturer's off-label promotion of an unapproved new use of a Class III medical device misbranded the device and thereby removed it from "the realm of federal regulation and returned it to the area of traditional state law remedies." 961 F.Supp.2d 977, 991 (D. Ariz. 2013). As a result, the *Ramirez* court concluded that Plaintiff's claims (e.g. design defect, failure to warn, misrepresentation, fraud, and warranty) all survived preemption because the manufacturer promoted the *device's use* in an off-label manner inconsistent with the FDCA. The *Ramirez* decision has been

roundly criticized as an outlier. *See Beavers-Gabriel,* 15 F.Supp. at 1035; *Scovil v. Medtronic, Inc.*, 995 F.Supp.2d 1082, 1096 n.12 (D. Ariz. Feb. 7, 2014); *Alton*, 970 F.Supp.2d at 1096-97; *Schouest*, 13 F.Supp.3d at 700. As one decision critical of *Ramirez* explained "off-label promotion is in fact regulated by the FDA - §360(k) applies broadly to "devices" as opposed to particular "uses" of such device. If §360(k)(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 a manufacturer." *Houston*, 2014 WL 1364455 at *5.

Finally, and although courts are obliged to perform the preemption and FRCP Rule 8 and 9 analyses required by law, some courts have allowed claimants to move past the pleading stage because they are not in possession of the factual information that would more properly support their claims. As a result, courts have denied motions to dismiss on the bases that a plaintiff should be entitled to discovery. In support of these arguments, claimants argue that manufacturers are in sole possession of off-label promotion information, which could be contained in their device records and regulatory submissions. *See e.g. Bausch v. Stryker Corp.*, 630 F.3d 546, 560-61 (7th Cir. 2010)*; Swisher v. Stryker Corp.*, 2014 WL 1153716 at *2 (W.D. Ok. March 14, 2014); *Killen v. Stryker*, 2012 WL 4482371 *8-9 (W.D. Penn. Aug. 21, 2012); *James v. Diva Int'l, Inc*., 803 F. Supp. 2d 945, 949 (S.D. Ind. 2011); *Burgos v. Satiety, Inc.,* No. 10-CV-2680 JG RLM, 2011 WL 1327684, at *4 (E.D.N.Y. Apr. 5, 2011); *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp.2d 830 (S.D. Ind. 2009). A counter to this argument, though, is that an off-label promotion claim requires affirmative representations to the claimant or his physician, information that a plaintiff has better access to than a manufacturer.

Although the law regarding off-label promotion claims is still developing, an understanding of federal preemption premised on the FDCA, the elements of state based causes of action, and the factual and legal issues plaguing claimants petitions provides the basic foundation for challenging off-label promotion claims.

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