UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

SUSAN SCHOUEST,	§	
	§	
Plaintiff,	§	
VS.	§	CIVIL ACTION NO. 3:13-CV-203
	§	
MEDTRONIC, INC., *et al*,	§	
	§	
Defendants.	§	

MEMORANDUM AND ORDER

Plaintiffs seeking to bring state law claims against the manufacturer of a medical device that the Food and Drug Administration (FDA) has approved must navigate a narrow path between two federal preemption doctrines. If the claims rely on state law that imposes duties different from or in addition to federal requirements, express preemption bars the claims. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). While state law claims that impose obligations parallel to federal requirements escape express preemption, such claims are impliedly preempted, and can only be brought by the FDA in its enforcement capacity, if they would not exist absent the federal regulatory scheme. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347–48, 353 (2001).

Relying primarily on these Supreme Court preemption rulings, Defendant Medtronic seeks dismissal of this lawsuit that challenges the use of its Infuse device in an "off-label" procedure—that is, in a way not expressly approved by the

FDA. Plaintiff Susan Schouest asserts various state causes of action against Medtronic, most of which rely on allegations that it fraudulently promoted the off-label use of the Infuse device or failed to warn physicians that off-label use could be dangerous. The Court must therefore determine which, if any, of her state tort claims are able to navigate the path between express and implied preemption and emerge unscathed.

I. BACKGROUND[1]

A. FDA Oversight Of Medical Devices

Under the Medical Device Amendment (MDA) to the Food, Drug, and Cosmetic Act (FDCA), the FDA has the authority to regulate medical devices. If a device "support[s] or sustain[s] human life" or "presents a potential unreasonable risk of illness or injury," it is designated a "Class III" device. 21 U.S.C. § 360c(a)(1)(C)(ii). New Class III devices must receive premarket approval (PMA) from the FDA before they can be sold. To obtain that approval, a manufacturer must submit a detailed application that contains "specimens of labeling proposed to be used for such device." § 360e(c)(1); *Riegel*, 552 U.S. at 317–18. The FDA reviews the device's labeling to evaluate the "safety and effectiveness under the conditions of use set forth on the label." *Id.* at 318 (citing § 360c(a)(2)(B)). It also

[1] The Background section (apart from the discussion of the FDA's oversight of medical devices, as well as the brief mention of Medtronic's profits from off-label uses) is based on Plaintiff's Original Complaint, *see* Docket Entry No. 1, which the Court must assume to be true at this stage.

"must determine that the proposed labeling is neither false nor misleading." *Id.* (citing § 360e(d)(1)(A)). After this evaluation, the FDA "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* (citing § 360e(d)). "Once a device has received [premarket] approval, the manufacturer cannot make changes to any feature of the device without obtaining FDA permission." *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 765–66 (5th Cir. 2011) (citing § 360e(d)(6)).

B. FDA Approval Of The Infuse Device

In January 2001, Defendants Medtronic Inc. and Medtronic Sofamor Danek USA, Inc. (collectively "Medtronic") filed a premarket approval application for the INFUSE Bone Graft product, which the FDA categorized as a Class III medical device. The Infuse device utilizes an injured person's bone-building cells to stimulate bone growth in a process referred to as bone grafting. After an extensive review that lasted over a year and a half, the FDA approved the Infuse device for limited use in spinal fusion surgeries. The Infuse device consists of two component parts: (1) the LT-CAGE® Lumbar Tapered Fusion Device Component, which is a hollow metal cylinder, and (2) the Infuse Bone Graft Component, which includes an absorbable collagen sponge that carries a genetically-engineered liquid bone protein (rhBMP-2). Docket Entry No. 1 ¶ 9.

According to the Infuse device's FDA-approved labeling, the device can only be used in an anterior lumber interbody procedure, involving a single-level fusion in the L4-S1 region of the lumber spine. This approval was limited to the use of rhBMP-2 in combination with the LT-Cage. Schouest alleges that despite knowing that the Infuse device could be dangerous if not used in that limited manner, Medtronic actively promoted off-label use of the Infuse device by "providing doctors with information about other doctors using the product off-label" and directing its "sales force personnel to provide doctors with fraudulent, deceptive, incomplete and/or incorrect information and instruction" concerning the off-label applications of the Infuse device. *Id.* ¶ 19. For instance, Medtronic allegedly paid "key opinion leaders" to author articles about the Infuse device's efficacy and safety when used off-label without disclosing those relationships. Medtronic allegedly encouraged one doctor to represent that using the Infuse device off-label was safer and superior to any existing alternatives. Docket Entry No. 1 ¶¶ 24, 40.

This promotion had an impact. Off-label uses of the Infuse device generate significant revenue for Medtronic: "close to 90% of the $800 million dollars in revenue" that the Infuse device produced in 2011. *Ramirez v. Medtronic Inc.*, --- F. Supp. 2d ----, 2013 WL 4446913, at *2 (D. Ariz. Aug. 21, 2013), *clarified on denial of reconsideration*, 2013 WL 4007811. This met with controversy even

before the wave of lawsuits, including this one, brought by patients allegedly injured by off-label use of the Infuse device. For instance, the official journal of the North American Spine Society, *The Spine Journal*, dedicated an entire 2011 issue to the risks of using the Infuse device. Docket Entry No. 1 ¶ 22. And after a 16-month investigation, the Senate Committee on Finance issued a 2,315-page report criticizing Medtronic for its heavy involvement in "drafting, editing and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic." Staff of S. Comm. on Finance, 112th Cong., Staff Report on Medtronic's Influence on Infuse Clinical Studies 6 (Comm. Print 2012).

C. Schouest's Surgery

In December 2006, before this public controversy concerning off-label use of the Infuse device, Schouest underwent a laminectomy and discectomy and multilevel interbody fusion. To achieve fusion, her surgeon used a posterior approach, mixing rhBNP-2 with allograft and placing the mixture inside a Hollywood cage rather than the FDA-approved LT-Cage. In other words, the doctors performed an off-label procedure with the Infuse device.

In June 2009, Schouest was diagnosed with bony overgrowth and a host of other injuries arising out of the surgery, for which she has had to undergo additional extensive medical treatment.

D. Schouest's Claims

Schouest asserts nine state law claims, including negligence, strict liability, breach of express and implied warranties, and fraud. All of her claims include allegations that Medtronic promoted the Infuse device for off-label uses. But two primary theories underpin her hopes of prevailing. The first is that Medtronic failed to warn—in other words, that Medtronic should have provided more information concerning the dangers of using the Infuse device in off-label procedures. The second is that, rather than saying too little by failing to provide additional warnings, Medtronic actually said too much by fraudulently representing that the Infuse device could be used safely in off-label procedures.

II. RULE 12 STANDARD OF REVIEW

Medtronic raises its preemption defense and others in a motion brought under Federal Rule of Civil Procedure 12(b)(6), which allows dismissal if a plaintiff fails to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). In evaluating a Rule 12(b)(6) motion, the "court accepts 'all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff.'" *Martin K. Eby Constr. Co. v. Dallas Area Rapid Transit*, 369 F.3d 464, 467 (5th

Cir. 2004) (quoting *Jones v. Greninger*, 188 F.3d 322, 324 (5th Cir. 1999)). The court does not look beyond the face of the pleadings to determine whether the plaintiff has stated a claim. *Spivey v. Robertson*, 197 F.3d 772, 774 (5th Cir. 1999). To survive a motion to dismiss, a claim for relief must be "plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). If the face of the complaint makes apparent that federal law preempts a plaintiff's claims, dismissal is warranted at the Rule 12 stage. *See Fisher v. Halliburton*, 667 F.3d 602, 609 (5th Cir. 2012) (explaining that if "the complaint itself establishes the applicability of a federal-preemption defense," the issue "may properly be the subject of a Rule 12(b)(6) motion); *Frank v. Delta Airlines, Inc.*, 314 F.3d 195, 203 (5th Cir. 2002) (reversing trial court and rendering judgment on motion to dismiss because federal law preempted plaintiff's state law claims).

III. PREEMPTION

A. An Overview of Express and Implied Preemption

When Congress enacts a law that appears to preempt—or supersede—areas of the law that have been "traditionally occupied by the States," courts must "start with the assumption 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." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). By beginning with that assumption, courts assure "that 'the federal-state balance' will not be

disturbed unintentionally by Congress or unnecessarily by the courts." *Id.* (citation omitted). But because of the Supremacy Clause's command that the "Laws of the United States . . . shall be the Supreme Law of the land," U.S. Const., art. VI, cl. 2, when Congress has "'unmistakably . . . ordained' that its enactments alone are to regulate a part of commerce, state laws regulating that aspect of commerce must fall." *Jones*, 430 U.S. at 525 (citation omitted).

Congress has unmistakably preempted certain state law claims pertaining to medical devices. *See* 21 U.S.C. § 360k(a). Because of the FDA's extensive regulation in this area, states cannot "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 . . . 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." *Id.* Congress enacted this express preemption clause to prevent manufacturers from being subject to inconsistent laws and regulations. *See Riegel*, 552 U.S. at 326 (explaining that without the FDA's central oversight, juries would "apply the tort law of 50 States to all innovations," thus subjecting medical device manufacturers to the whims of juries in all 50 states); *see also Gavin v. Medtronic, Inc.*, 2013 WL 3791612, at *4 (E.D. La. July 19, 2013) (noting that express preemption "preserve[s] federal regulatory

authority over medical devices and thereby enable[s] the FDA to balance various statutory objectives").

The express preemption analysis proceeds in two steps: first, courts "must determine whether the Federal Government has established requirements applicable to" a medical device. *Riegel*, 552 U.S. at 321. As a Class III device, the Infuse device was subjected to specific requirements as part of the FDA's premarket approval process. *Id.* at 322–23; *Gavin*, 2013 WL 3791612, at *4. Schouest contends, however, that because the Infuse device's "PMA does not establish device-specific federal requirements for the rhBMP-2 bone protein used alone and without the LT-Cage™, it cannot provide a basis for express preemption under" section 360k(a). Docket Entry No. 20 at 16–17. Numerous federal courts have rejected this argument on the basis that "requirements set forth in the premarket approval for the entire device are just as applicable to the components that together form the FDA-approved device as the device itself." *Hawkins v. Medtronic, Inc.*, 2014 WL 346622, at *5 (E.D. Cal. Jan. 30, 2014); *see, e.g.*, *Eidson v. Medtronic, Inc.*, --- F. Supp. 2d ----, 2013 WL 5533081, at *3 n.3 (N.D. Cal. Oct. 3, 2013) (citing cases and noting that "the preemption analysis should not be applied differently to the component parts of a medical device and the medical device that received PMA"); *see also Bass v. Stryker Corp.*, 669 F.3d 501, 508 (5th Cir. 2012) (holding that district court did not err in determining that device as a

whole was subject to PMA approval even though some evidence indicated only certain components of the device were at issue). This Court concurs with that analysis.

Once the first step of the express preemption analysis is met—as it is here—courts must determine whether state law claims asserted against a medical device manufacturer are based on requirements "with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Riegel*, 552 U.S. at 321–22 (quoting 21 U.S.C. § 360k(a)). Because express preemption is aimed at avoiding inconsistent regulation at the state and federal law, the FDCA "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." *Id.* at 330. (quoting *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996)). A state requirement is parallel to a federal requirement, and thus not expressly preempted under section 360k(a), if the plaintiff shows "that the requirements are 'genuinely equivalent.' State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law." *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1174 (C.D. Cal. 2013) (quoting *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011)).

Even after clearing the express preemption hurdle, state claims still face the possibility of implied preemption. This additional source of preemption is based on the fact that any suit to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). In *Buckman Co. v. Plaintiffs' Legal Committee*, the Supreme Court held that claims that "exist solely by virtue" of the federal regulatory scheme—"[s]tate-law fraud-on-the-FDA claims"—are impliedly preempted by federal law because they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." 531 U.S. at 350, 353. Thus, "[t]he conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

The *Riegel* and *Buckman* preemption scheme therefore creates a narrow path for plaintiffs asserting state law claims against medical device manufacturers. In order to survive preemption, such claims "must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA." *Id.*

Courts have struggled with applying the Supreme Court's preemption rulings to cases involving the Infuse device. Though they uniformly agree that the

PMA process imposes requirements on the Infuse device, both the second step of the *Riegel* analysis and the scope of *Buckman* have prompted disagreement. This Court's view is that some of these cases have read *Riegel* and *Buckman*—especially *Buckman*—too broadly, *see, e.g.*, *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1219 (W.D. Okla. 2013) (finding that fraud claims are impliedly preempted by *Buckman* because "even the concept of 'off-label use' is a creature of the FDCA"),[2] while others have read *Riegel* too narrowly, *see, e.g.*, *Ramirez*, 2013 WL 4446913, at *8–10 (holding that *Riegel*'s shield drops if plaintiff alleges off-label promotion and that most claims, including design defect claims, evade preemption).[3] At least one court has read *Riegel* and *Buckman* to establish a distinction between claims premised on false misrepresentations and those premised on omissions.[4] *See Houston*, 957 F. Supp. 2d at 1176–79. For the reasons that follow, the Court generally agrees with this analysis that the key dividing line is between claims alleging affirmative misrepresentations and those alleging that Medtronic should have done more.

[2] *See also Gavin*, 2013 WL 3791612, at *17 (dismissing all claims except a failure-to-report adverse events to FDA claim); *Ledet v. Medtronic, Inc.*, 2013 WL 6858858, at *4–6 (S.D. Miss. Dec. 30, 2013) (dismissing all claims as expressly or impliedly preempted).

[3] *See also McDonald-Lerner, M.D. v. Neurocare Assocs., P.A.*, No. 373859-V (Md. Cir. Ct. Aug. 29, 2013) (adopting *Ramirez*'s reasoning and denying motion to dismiss).

[4] Courts have drawn this same distinction in other areas of preemption law. *See, e.g.*, *Martin v. Ford Motor Co.*, 914 F. Supp. 1449, 1454 (S.D. Tex. 1996) (holding in preemption case involving car manufacturer that material omission claims were preempted but that false representation claims survived).

B. Off-Label Promotion

The reason the Court believes that dividing line is critical to resolving the difficult question of which state claims survive *Riegel* and *Buckman* is the second step of the express preemption analysis—whether any of Schouest's state law claims would impose requirements "different from, or in addition to," federal requirements applicable to the Infuse device. The affirmative misrepresentation/omission distinction is representative of the two types of claims Schouest is asserting: on the one hand, that Medtronic did not do enough, and on the other, that Medtronic did too much. Medtronic allegedly failed to do enough when it did not include additional warnings that off-label procedures could be dangerous or when it did not add design features to account for off-label uses. And Medtronic allegedly said too much when it made false and misleading representations concerning the safety of using the Infuse device in off-label procedures. Because all of these claims are largely based on allegations of off-label promotion, they prompt the following question: what is the status of off-label promotion under federal law? [5]

The answer is not clear. Federal law does not expressly define, or ban, off-label promotion; rather the FDCA prohibits "[t]he adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce." 21

[5] Because of the importance of this issue, the Court requested supplemental briefing on the lawfulness of off-label promotion. Docket Entry No. 27.

U.S.C. § 331(b). Class III devices may be misbranded if their "labeling is false or misleading in any particular," 21 U.S.C. § 352(a), of if they use "false or misleading advertising," *id.* § 352(q). Devices can also be misbranded if their labeling does not bear "adequate directions for use," § 352(f), defined by the FDA as "directions under which the layman can use a device safely and for the purposes for which it is intended." 21 C.F.R. § 801.5. A device's intended use is determined by "the objective intent of the persons legally responsible for the labeling of devices," and can be demonstrated by "oral or written statements by such persons or their representatives." 21 C.F.R. § 801.4.

Despite this statutory uncertainty on the question whether off-label promotion is *per se* unlawful, the FDA's position is that it is prohibited because it constitutes misbranding. *See United States v. Caronia*, 703 F.3d 149, 155 (2d Cir. 2012) (citing FDA, *Draft Guidance, Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* 2–3 (2009) ("An approved drug that is marketed for an unapproved use (whether in labeling or not) is misbranded")); *see also* Dina McKenney, Note, *Off-Label Drug Promotion and the Use of Disclaimers*, 92 TEXAS L. REV. 231, 231–32 (2013) (explaining the FDA's view that "promoting a drug for an off-label use is a violation" of the FDCA's misbranding provisions). Based on this view, the FDA

has recovered millions of dollars in settlements from drug manufacturers that have engaged in off-label promotion. *See, e.g.*, *id.* at 232 (citing Press Release, U.S. Dep't of Justice, *Justice Department Announces Largest Health Care Fraud Settlement in Its History*, (Sept. 2, 2009) (trumpeting a multi-billion dollar fine imposed against a drug company that promoted its drugs for uses and dosages that the FDA specifically declined to approve)). The FDA's informal interpretation of a statute it administers is entitled to some deference from courts. *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) (holding that an agency's informal interpretation of a statute it administers is entitled to deference to the extent it has the "power to persuade").

But courts have not always agreed with the FDA position. One divided court of appeals recently observed that under the FDCA framework, off-label promotional statements are not prohibited by federal law but instead could constitute "evidence of [a drug's] intended use." *Caronia*, 703 F.3d at 155. That same court ruled that interpreting the FDCA to make "the simple promotion of a drug's off-label use" a crime violates the First Amendment.[6] *Id.* at 160; *but see id.*

[6] This raises an interesting question: should *Caronia*'s analysis of the First Amendment implications of a criminal conviction for off-label promotion apply to determining whether misbranding violates the FDCA so that parallel state tort liability for misbranding would not be preempted? Medtronic points to cases that have held that when a statute must be interpreted narrowly in the criminal context to avoid constitutional problems, the same construction of the statute should apply to civil enforcement of the same provision. But preemption is a defense in which the question is whether Congress unmistakably evinced its intent to preempt the traditional domain of state tort law. Whether it would be proper to rely on the constitutional

at 178 (Livingston, J., dissenting) (arguing that the FDCA's prohibition on off-label marketing is constitutional in part because prohibiting such promotion is "one of the few mechanisms available to encourage participation in the [FDA] approval process" (internal quotation marks and citation omitted)).

Out of this muddy statutory and regulatory framework, the Court can make this determination: federal law bars off-label promotion when it is false or misleading. *See Houston*, 957 F. Supp. 2d at 1179 & n.8 (noting that federal law "certainly prohibits false or misleading off-label promotion" (citing 21 U.S.C. §§ 331(a), 352(q)(1)). Far less doubt exists on this question than the proposition discussed above that federal law bans truthful off-label promotion, on which courts have come to differing conclusions. *Compare Ramirez*, 2013 WL 4446913, at *9 ("While permitting health care providers to use devices in ways other than those anticipated by the FDA, the FDA prohibits device manufacturers from promoting the off-label use of their product."); *Carson v. Depuy Spine, Inc.*, 365 F. App'x 812, 815 (9th Cir. 2010) ("[W]hile doctors may use a drug or device off-label, the marketing and promotion of a Class III device for unapproved use violates Section 331 of the FDCA."), *with Dawson v. Medtronic, Inc.*, 2013 WL 4048850, at *6

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avoidance principle in this context, which would likely not involve First Amendment concerns, is a question the Court need not resolve because of the analysis below that only misleading off-label promotion can escape preemption. Sanctions on misleading off-label promotion, criminal or otherwise, do not implicate First Amendment concerns. *Edenfield v. Fane*, 507 U.S. 761, 768 (1993) ("[T]he State may ban commercial expression that is fraudulent or deceptive without further justification.").

(D.S.C. Aug. 9, 2013) ("This 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" (citing 21 U.S.C. § 360k(a))); *Caronia*, 703 F.3d at 154 ("The FDCA and its accompanying regulations do not expressly prohibit the 'promotion' or 'marketing' or drugs for off-label use.").

C. Express Preemption Applied to the Infuse Device: The Divide Between Failure-to-Warn And Affirmative Misrepresentation Claims

That failure-to-warn claims premised on truthful off-label promotion may not allege a violation of federal law, in which case they would be barred by *Riegel*, is one obstacle such claims face in avoiding express preemption. But the Court need not decide this difficult question because a failure-to-warn claim premised on such a theory faces another problem. The FDA proscribed the precise labeling that the Infuse device was required to carry. Medtronic cannot deviate from that labeling without the FDA's permission. Under *Riegel*, a Texas jury finding that labeling inadequate would be tantamount to a requirement that Medtronic do something "different from, or in addition to," what the FDA already approved. As the *Houston* court observed, for a plaintiff to prevail on a failure-to-warn claim, "a jury would have to find either that Defendants were required to include warnings beyond those in the FDA-approved label for the Infuse Device, or that Defendants

were obligated to issue post-sale warnings about potential adverse effects of using the Infuse Device in an off-label manner." 957 F. Supp. 2d at 1177. Either scenario would violate *Riegel*'s express preemption framework. *Id.* For this reason, even courts that have found, or assumed, that federal law bans off-label promotion have held that failure-to-warn claims face preemption. *See, e.g.*, *Hawkins*, 2014 WL 346622, at *15 ("An affirmative duty to *provide* adequate warnings is not genuinely equivalent to a federal requirement to *refrain* from a particular type of promotion.") (emphasis in original).

One district court recently disagreed and found that failure-to-warn claims premised on off-label promotion evade preemption. *See Ramirez*, 2013 WL 4446913, at *11. The court relied in large part on the fact that the FDA had not considered or approved the off-label uses that the medical device manufacturer was promoting. *See id.* (finding that the concerns underlying section 360k's express preemption provision "vanish[] 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"). But though the FDA might not have approved the off-label procedures at issue here, it "generally contemplates that approved [devices] will be used in off-label ways." *Caronia*, 703 F.3d at 166. In fact, "'off-label' usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering

with the practice of medicine." *See Buckman*, 531 U.S. at 350. A successful failure-to-warn claim premised on inadequate labeling would therefore disturb the FDA's policy with respect to the regulation of these devices. *See id.* ("[T]he FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals.").

While Schouest's claims that Medtronic failed to provide sufficient warnings cannot overcome the MDA's express preemptive force, her claims premised on fraudulent representations about off-label procedures can avoid *Riegel*. As discussed above, making false or misleading statements about medical devices is prohibited by federal law. This means that Schouest's state law fraud claims based on false off-label promotion would, if proven, also amount to a violation of federal law, and thus such claims could survive preemption. *See Houston*, 957 F. Supp. 2d at 1179–80 (holding that state fraud-based claims "are parallel or 'genuinely equivalent' to federal law"); *cf. In re Epogen & Aranesp Off-Label Marketing & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1292 (C.D. Cal. 2008) (observing in fraud case based on drug manufacturer's alleged misrepresentations that "insofar as Plaintiffs can identify specific representations by Defendants that are literally false, misleading, or contain material omissions, the claims are actionable" under California law).

D. Implied Preemption Applied to the Infuse Device

For any affirmative misrepresentation claims that are not expressly preempted, the question will remain whether they can avoid *Buckman*'s implied preemption bar. In this case, that seems to be the easier determination. Medtronic reads *Buckman* broadly to mean that state law claims predicated on alleged off-label promotion are impliedly preempted because they "seek to enforce FDCA provisions" that the FDA has the exclusive authority to enforce. Docket Entry No. 14 at 12. But the claim asserted in *Buckman* was a "fraud-on-the-FDA" claim in which fraudulent misrepresentations were allegedly made during an FDA approval process. Though the plaintiffs brought a state law fraud claim, the fraudulent actions for which they sought recovery would not have occurred in a world without the FDCA. That is, the challenged conduct only occurred during the FDA approval process. The reason the plaintiffs found the manufacturer's conduct so objectionable was that, in their view, the FDA would not have approved the manufacturer's device if not for the misrepresentations made during the preapproval process. Thus, *Buckman* appears only to preempt the rather limited set of claims that are based on conduct that could not have occurred in the absence of the FDCA regulatory scheme. *See Buckman*, 531 U.S. at 353 (noting that the claims at issue "exist[ed] solely by virtue of the FDCA disclosure requirements"). Adopting a broader reading of *Buckman* that would bar state claims imposing

obligations parallel to FDCA obligations would be "inconsistent with the Supreme Court's reasoning in *Riegel*, decided long after *Buckman*." *Hughes*, 631 F.3d at 775.

Most of the state tort claims asserted in this case would exist in a world without the FDCA. Fraud, breach of express warranty, and negligence are venerable common law claims. They can be asserted against a seller who misleads one into buying or using its product for an improper purpose. *Crocker v. Winthrop Lab., Div. of Sterling Drug, Inc.*, 514 S.W.2d 429, 433 (Tex. 1974) (affirming recovery for plaintiff when drug manufacturer "positively and specifically" misrepresented that its prescription drug could be used without causing physical dependence); *Church & Dwight Co., Inc. v. Huey*, 961 S.W.2d 560, 567 (Tex. App.—San Antonio 1997, pet. denied) (affirming jury verdict that company engaged in misrepresentations where it falsely assured plaintiff that paint remover could be used safely on any surface). Take a product far removed from FDA regulation: ladders. If a ladder company told consumers that its step ladder could be used not just to reach high places, but also could be used safely as a high chair for babies, that could give rise to a misrepresentation claim if the company knew the "off-label" use of its ladders was not safe.

Thus the distinction between truthful and fraudulent off-label matters also matters when it comes to implied preemption. Mere "off-label" promotion,

divorced from any negligent or fraudulent misrepresentations, would likely not run afoul of state tort law. *See Gavin*, 2013 WL 3791612, at *7; *Caplinger*, 2013 WL 453133, at *11. But Schouest's affirmative misrepresentation claims are based on independent state law duties that Medtronic allegedly violated after the initial PMA process. Because these claims would apply to a seller of a product not subject to any federal regulations who engaged in similar alleged misconduct, they are not impliedly preempted. *See Houston*, 957 F. Supp. 2d at 1179 (holding that state fraud-based claims that include off-label promotion allegations are not impliedly preempted under *Buckman* "because they are moored in traditional state common law that exists independently from the FDCA"); *Eidson*, --- F. Supp. 2d ----, 2013 WL 5533081, at *11 (finding that fraud claims based on off-label promotion escape preemption because such claims "are based on state common law tort duties that exist independently from the FDCA and not solely by virtue of the FDCA").

E. Claim-by-Claim Analysis

Having discussed the larger preemption scheme established by *Riegel* and *Buckman* and how it applies to the particular facts alleged in this case, the Court can now consider each of Schouest's claims and determine where they fit within that framework.

1. Negligence and Negligence Per Se (Counts I and VIII)

Schouest alleges that a proximate cause of her injuries is "the negligence and misrepresentations" of Medtronic concerning the marketing of the Infuse device for off-label uses. *Id.* ¶ 66. She also alleges that Medtronic "[n]egligently, carelessly and recklessly represent[ed] that the off-label use of INFUSE Bone Graft was safe when, in fact, it was unsafe." *Id.* ¶ 66f. Limited to a negligent misrepresentation claim, her claim is not preempted by federal law. But to the extent her claim it is premised on "failing to disclose . . . that the promoted off-label use of" the Infuse device can cause injuries, *id.* ¶ 66d, the claim is expressly preempted. As explained above, such a claim would add warning requirements additional to the ones already imposed by federal law.

Schouest's negligence per se claim is more accurately labeled a negligence claim given that "[n]egligence per se is not itself a cause of action, but actually a way to prove a party's negligence as a matter of law, through the violation of a penal statute." *de Pacheco v. Martinez*, 515 F. Supp. 2d 773, 779 n.7 (S.D. Tex. 2007) (quoting *Zavala v. Trujillo*, 883 S.W.2d 242 (Tex. App.—El Paso 1994, writ denied).[7] As part of that claim, Schouest seeks to hold Medtronic liable for withholding information from the FDA during the premarket approval process.

[7] Schouest's gross negligence claim (Count IX) seeks to recover punitive damages and asserts that Medtronic's actions were "reckless and without regard for the public's safety and welfare." Docket Entry No. 1 ¶ 141. This claim hinges on the predicate negligence claim; if Schouest's negligence claim can survive preemption, her gross negligence claim can as well. And because the negligent misrepresentation claim survives preemption, so does the gross negligence claim.

See Docket Entry No. 1 ¶ 133 ("Defendants, both before and after pre-market approval of INFUSE Bone Graft, withheld from and/or misrepresented to the FDA required information that was material and relevant to the performance, safety and efficacy of the product."). A claim that Medtronic withheld information from the FDA during the premarket approval process would not exist, of course, absent the FDCA regulatory scheme that gave the FDA the power to approve medical devices. So to the extent that this is a "fraud-on-the-FDA" claim, Schouest cannot avoid *Buckman*'s implied preemption holding.

The negligence claims also involve one exception to the Court's general holding that claims premised on a failure to do something are either expressly or impliedly preempted: a negligence allegation predicated on Medtronic's failure to submit adverse-event reports to the FDA after the FDA granted the Infuse device premarket approval. Indeed, the Fifth Circuit directly held in *Hughes* that such a claim could survive. 631 F.3d at 775. This particular claim survived in *Hughes* because the defendants had an independent duty under Mississippi law to "warn about the dangers or risks of a product." *Id.* The court determined that because the plaintiff was asserting a recognized state tort claim through an FDA violation, her claim survived *Buckman*. So to the extent Schouest can point to a state law duty to report adverse events, and, critically, what FDA reporting regulations Medtronic

allegedly violated, this claim could escape preemption.[8] As with her other claims, Schouest will be given an opportunity to make those allegations in an amended complaint.

2. Fraud and Constructive Fraud (Counts IV and V)

Schouest's allegation that Medtronic "knowingly and intentionally misrepresented material facts regarding the safety and effectiveness of using INFUSE Bone Graft off-label with the intent that the public and physicians would rely upon those representations" is the paradigmatic affirmative misrepresentation claim that would survive preemption. Docket Entry No. 1 ¶ 92. And her constructive fraud claim that Medtronic had unique knowledge about the Infuse device's safety yet intentionally misrepresented that information would also get past a preemption defense. *Id.* ¶ 111.

3. Strict Liability (Count II)

Schouest alleges that Medtronic "knew that the INFUSE Bone Graft manufactured, designed, and sold by it, when used off-label . . . as promoted and instructed" by Medtronic, was defective and dangerous. *Id.* ¶ 81. Medtronic

[8] In *Hughes*, the Fifth Circuit was thus reading *Buckman* far more narrowly than Medtronic does. In *Hughes*, the Fifth Circuit read *Buckman* to only bar claims that "assert a freestanding federal cause of action based on a violation of the FDA's regulations." 631 F.3d at 775. But *Buckman* did involve a cause of action asserted under state law, what the Supreme Court described as a "state-law fraud-on-the-FDA claim[]." *Buckman*, 531 U.S. at 348. The state claim was still preempted, *Buckman* concluded, because it "exist[ed] solely by virtue of the FDCA disclosure requirements." *Id*. at 352. The claim in *Hughes* similarly seemed to involve a "fraud on the FDA," in the form of failing to notify the FDA about adverse events, but this Court is bound to follow *Hughes* in assessing this claim.

allegedly "acted []with conscious disregard of the safety of the public, including Plaintiff, when it placed the product on the market without warning of the defect." *Id.* By alleging that Medtronic failed to distribute an adequate warning concerning the Infuse device's design, Schouest seeks a determination that Medtronic's warnings were insufficient, even though the FDA preapproved them. This is exactly the kind of failure-to-warn claim that is preempted under federal law.

Schouest's strict liability claim based on design and manufacturing defect theories is also clearly barred by *Riegel* because it would require the Infuse device to be designed or manufactured differently than the FDA authorized. *Id.* ¶ 88; *Houston*, 957 F. Supp. 2d at 1177 (finding design defect claim subject to preemption because it would "attack[] the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device" (internal quotation marks and citation omitted)).

4. Breach of Express and Implied Warranties (Count III)

Although Schouest's breach of express warranty allegation might survive, her breach of implied warranty claim does not. Schouest alleges that Medtronic "expressly and impliedly warranted to physicians and other members of the general public and medical community that [] off-label uses, including the type of off-label procedure that Plaintiff underwent, [were] safe and effective." Docket Entry No. 1 ¶ 85. Any implied warranty claim would be based on statements that Medtronic

did not actually make. *See Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 435 (Tex. 1997) ("An implied warranty is a representation about the implied quality or suitability of a product that the law implies and imports into a contract . . . ."); *Western Tank & Steel Corp. v. Gandy*, 385 S.W.2d 406, 409 (Tex. Civ. App.—Texarkana 1964, no writ) ("An implied warranty is an inherent term of a sale contract . . . ."). Federal law governs all statements that Medtronic is obligated to make concerning the Infuse device, and therefore preempts Schouest's breach of implied warranty claim.

However, the express warranty claim could survive. "Federal law permits, but does not require, manufacturers like [Medtronic] to make warranties, as long as those warranties are truthful and accurate." *Riley*, 625 F. Supp. 2d at 788. Schouest's express warranty claim can survive to the extent she seeks to recover based on false warranties that Medtronic voluntarily and falsely made beyond the federally approved warning because "[f]ederal law already requires [Medtronic] to ensure that any warranty statements it voluntarily makes are truthful, accurate, not misleading, and consistent with applicable federal and state law." *Id.; see also Houston*, 957 F. Supp. 2d at 1180–81 (holding that breach of express warranty claim could survive preemption because by "seek[ing] to impose liability on Defendants for voluntarily making misleading warranties outside the label, Plaintiff is not imposing any requirement different from or additional to what

federal law already requires"). While conceptually an express warranty claim could avoid express preemption, what is missing from Schouest's complaint, in its current form, is a description of what specific warranties Medtronic made to Schouest or her physicians. Because she has asked for an opportunity to replead, the Court will preserve ruling on whether her breach of express warranty claim survives the Rule 12 motion.

5. Texas Consumer Protection Laws (Count VI)

Schouest alleges that Medtronic has a "statutory duty to refrain from unfair or deceptive acts or practices in the development, manufacture, promotion and sale of INFUSE Bone Graft." *Id.* ¶ 116. A claim that Medtronic should have acted differently in the manufacturing or development of the Infuse device would be preempted, given that the FDA approved the Infuse device in its current form. However, a deceptive act in the promotion of the Infuse device would survive a preemption challenge for the same reasons that Schouest's fraud and negligent misrepresentations claim would. Because Schouest does not specify which statutory duties Medtronic violated, the Court will give Schouest an opportunity to replead before ruling on her Texas Consumer Protection Statutes claim.

For these reasons, the strict liability and implied warranty claims will be dismissed with prejudice. The portions of the negligence claim that rely on a failure-to-warn theory will also be dismissed. The other claims avoid the

preemption defense, but must withstand other challenges—including the specificity of the fraud allegations—that the Court now addresses.

IV. OTHER GROUNDS FOR DISMISSAL

A. Statute of Limitations

Even if the claims brought against it are not preempted, Medtronic argues that the statute of limitations bars them. Schouest underwent the lumber surgery in December 2006 and was diagnosed with bony overgrowth in June 2009. She did not bring suit until May 2013. If the two-year statute of limitations applies to her claims (and there is some dispute over whether the applicable statute of limitations is two or four years), then her claims would be barred if they accrued in either 2006 or 2009. Anticipating this problem, Schouest asserts in her Complaint that the "discovery rule" applies because the nature of her injury was both "inherently undiscoverable and objectively verifiable." *Shell Oil Co. v. Ross*, 356 S.W.3d 924, 929–30 (Tex. 2011); Docket Entry No. 1 ¶ 59. If applicable, the discovery rule would "defer[] accrual of [her] cause[s] of action" until the time that she "knew, or exercising reasonable diligence, should have known of the facts giving rise to the cause of action." *Computer Assocs. Int'l v. Altai, Inc.*, 918 S.W.2d 453, 455 (Tex. 1996). She also asserts the "fraudulent concealment" doctrine, which tolls the statute of limitations "where a party affirmatively conceals the responsible party's identity, if there is a duty to disclose." *Dougherty v. Gifford*, 826 S.W.2d 668, 674

(Tex. App.—Texarkana 1992, no writ) (internal citation omitted). This doctrine would defer the accrual of Schouest's causes of action "until the right of action is, or in the exercise of reasonable diligence should [have been], discovered." *Nichols v. Smith*, 507 S.W.2d 518, 519 (Tex. 1974).

As the party asserting a statute of limitations defense, Medtronic must negate the discovery rule as a matter of law. *See Weaver v. Witt*, 561 S.W.2d 792, 794 (Tex. 1977); *Doe v. Linam*, 225 F. Supp. 2d 731, 735 (S.D. Tex. 2002) ("The burden rests upon the defendant not only to plead limitations but also to negate the discovery rule."); *Trigo v. TDCJ-CID Officials*, 2010 WL 3359481, at *9 (S.D. Tex. Aug. 24, 2010) ("A defendant asserting a limitations defense at the pleading stage has the burden to establish the accrual date, including negating the applicability of the discovery rule."). When an evidentiary record can be considered, the statute of limitations may prove a successful defense, but at the Rule 12 stage, it is insufficient to warrant dismissal of Schouest's claims given her allegation that the discovery rule tolled her claims until some point within the statute of limitations. *See Milton v. Stryker Corp.*, 2014 WL 31393, --- F. App'x ----, at *2 (5th Cir. Jan. 6, 2014) (reversing trial court that converted motion to dismiss on limitations grounds into a summary judgment motion and dismissing case because evidence regarding whether plaintiff's injury was "inherently undiscoverable" was insufficient to meet defendant's burden).

B. Rule 9(b) Particularity Requirement

One final ground for Rule 12 dismissal remains. The same feature that allowed many of the claims to avoid express preemption—that they are based on false representations about off-label use, which would also violate federal law—subjects most of them to Rule 9(b)'s heightened pleading standard requiring that they be alleged "with particularity."[9] That rule usually requires that the plaintiff identify "the who, what, when, where, and how of the alleged fraud." *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 266 (5th Cir. 2010) (internal quotation marks and citations omitted). That information should be readily available prior to discovery to the typical fraud plaintiff who was the direct recipient of fraudulent information. *See* 5A Charles Alan Wright et. al., Federal Practice and Procedure § 1297 (3d ed. 2004) (explaining that requiring that fraud be pled with precision allows defendants to understand "the acts or statements or failures to disclose" on which the plaintiff actually relied).

[9] While Schouest's fraud claim clearly is subject to Rule 9(b) and her breach of express warranty claim clearly is not, whether her constructive fraud or negligent misrepresentation claims are subject to Rule 9(b) is unsettled in the Fifth Circuit. *See Schroeder v. Wildenthal*, 2011 WL 6029727, at *4 (N.D. Tex. Nov. 30, 2011) ("[T]he Fifth Circuit has not decided whether a claim of constructive fraud must satisfy the higher pleading standards under Rule 9(b)"); *Am. Realty Trust, Inc. v. Travelers Cas. and Sur. Co. of Am.*, 362 F. Supp. 2d 744, 749–52 (N.D. Tex. 2005) (thoroughly reviewing Fifth Circuit precedent and concluding that negligent misrepresentation is only subject to Rule 9(b) in limited circumstances). This confusion illustrates another reason why the Court should avoid resolving the Rule 9(b) issue at this juncture: Medtronic can offer its arguments for why heightened pleading standards apply to all of Schouest's claims in a renewed motion to dismiss if it continues to regard her amended complaint as defective.

A number of courts, however, have recognized that the heightened pleading standards of Rule 9(b) should be relaxed "upon a showing by the plaintiff that he or she is unable, without pretrial discovery, 'to obtain essential information' peculiarly in the possession of the defendant." *Freitas v. Wells Fargo Home Mortg.*, Inc., 703 F.3d 436 (8th Cir. 2013) (citation omitted) (though declining to relax the particularity requirement in the context of that case). In *qui tam* cases, for example, the Fifth Circuit has explained that Rule 9(b) is not a "straitjacket" because relators often do not possess the billing information submitted to the federal government at the pleading stage—"a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); *but see U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 768 (S.D. Tex. 2010) (citing *U.S. ex rel. Rafizadeh v. Cont'l Common, Inc.*, 553 F.3d 869, 873 n.6 (5th Cir. 2008)) ("In the Fifth Circuit, the pleading standard is not relaxed when such information is available from third party entities and individuals."). The Seventh Circuit has relaxed the pleading requirement for certain RICO cases under the same lack-of-pre-discovery-access rationale. *See Corley v. Rosewood Care Ctr., Inc. of Peoria*, 142 F.3d 1041, 1050–51 (7th Cir. 1998) (relaxing particularity requirements of

Rule 9(b) when RICO plaintiff lacked access to all facts necessary to detail claim), *cited in Rotella v. Wood*, 528 U.S. 549 (2000); *see also Emery v. Am. Gen. Fin., Inc.*, 134 F.3d 1321, 1323 (7th Cir. 1998) (Posner, J.) (citing cases). This is a case in which the alleged fraudulent misrepresentations were not made directly to the plaintiff. The fraud allegations are based on an "intermediary theory" in which Schouest's doctor allegedly received the false information and relied on it in performing the off-label surgery that harmed her. *See Crocker*, 514 S.W.2d at 433 ("[W]hen the drug company positively and specifically represents its product to be free and safe from all dangers of addiction, and when the treating physician relies upon that representation, the drug company is liable when the representation proves to be false and harm results.").

But before addressing the proper scope of the Rule 9 requirement in this case and applying it to Schouest's allegation, the efficient course is to allow Schouest one opportunity to amend her complaint. Judicial economy would be ill served if the Court were to engage in the labor-intensive process of scrutinizing the specific allegations at this point, find them insufficient, and then follow the usual pattern of allowing the plaintiff at least one opportunity to replead. *See Siddiqui v. Nationwide Prop. & Cas. Ins. Co.*, 2011 WL 722208, at *2 (S.D. Tex. Feb. 21, 2011) (quoting *Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 329 (5th Cir. 2002)) ("[D]istrict courts often afford plaintiffs at least one

opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable or the plaintiffs advise the court that they are unwilling or unable to amend in a manner that will avoid dismissal."). The better course is to allow Schouest to put her best foot forward and then engage in the Rule 9(b) analysis if Medtronic continues to believe the pleading is insufficient and files another Rule 12 motion.

V. CONCLUSION

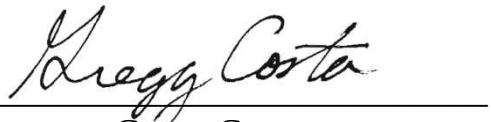
For the reasons explained above, Schouest's claims against Medtronic can be grouped into two general categories: (a) failure-to-warn or otherwise do some additional act (such as employ a different design); and (b) affirmative misrepresentations. The claims premised on a failure-to-warn theory do not survive preemption, while the fraud claims based on affirmative misrepresentations could survive preemption if they meet Rule 9(b)'s heightened pleading standards.

Medtronic raises concerns that allowing any claims to go forward will undermine manufacturers' reliance on the FDA approval process and inhibit the development of new medical devices. Docket Entry No. 14 at 19–20. But the claims that the Court is finding avoid preemption are ones involving false representations, to which liability will attach only if Medtronic acted in a negligent, if not intentional, manner. Schouest is a long way from proving these claims, but if she can do so, Medtronic will only be liable for conduct that federal

law prohibits and for which the FDA premarket approval process does not provide immunity from state law obligations.

Accordingly, Medtronic's Motion to Dismiss (Docket Entry No. 14) is **GRANTED IN PART** and **DENIED IN PART**. Schouest's strict liability claim (Count II), breach of implied warranty claim (part of Count III) and the part of her negligence claim based on Medtronic's "fail[ure] to adequately warn" about the off-label uses of the Infuse device (part of Count I) are **DISMISSED WITH PREJUDICE**. As she requested, Schouest will be given an opportunity to replead her negligence (Count I), breach of express warranty (Count III), Texas consumer protection laws (Count VI), fraud (Count IV) and constructive fraud (Count V) claims in conformity with this opinion in terms of which claims avoid preemption and, where required, Rule 9(b). That amended complaint shall be filed within thirty days of the issuance of this order. After that time Medtronic can reurge its motion to dismiss if it continues to believe the claims are not alleged with sufficient particularity.

SIGNED this 24th day of March, 2014.



Gregg Costa
United States District Judge