14-3491

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

KOLEEN OTIS-WISHER,

Plaintiff-Appellant,

— v. —

MEDTRONIC, INC., and MEDTRONIC SOFAMOR DANEK USA, INC.,

Defendants-Appellees,

FLETCHER ALLEN HEALTH CARE, INC.,
AKA Fletcher Allen Health Care,

Defendant.

ON APPEAL FROM THE U.S. DISTRICT COURT
FOR THE DISTRICT OF VERMONT
IN CASE NO. 1:11-CV-64-JGM (MURTHA, *J.*)

BRIEF FOR APPELLEES

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Defendants-Appellees state as follows:

1. Defendant-Appellee Medtronic Sofamor Danek USA, Inc. is a wholly-owned subsidiary of Medtronic Sofamor Danek, Inc., and no other publicly traded corporation owns 10% or more of its stock;

2. Medtronic Sofamor Danek, Inc. is a wholly-owned subsidiary of Defendant-Appellee Medtronic, Inc., and no other publicly traded corporation owns 10% or more of its stock;

3. Defendant-Appellee Medtronic, Inc. is a wholly-owned subsidiary of Medtronic plc, and no other publicly traded corporation owns 10% or more of its stock; and

4. Medtronic plc—the ultimate parent of Defendants-Appellees Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc.—is a publicly traded corporation with no parent company, and no publicly held corporation owns 10% or more of its stock.

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INTRODUCTION

Plaintiff-appellant Koleen Otis-Wisher alleges that she was injured by Medtronic's Infuse® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device ("Infuse"), a Class III prescription medical device whose design, manufacture, and labeling were approved by the U.S. Food and Drug Administration through the agency's Premarket Approval (PMA) process.[1]

Two types of preemption limit the claims that can be brought against manufacturers of PMA-approved medical devices:

First, the Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act (FDCA) expressly preempt any claim that would impose a state-law requirement that is "different from, or in addition to" the federal requirements imposed by the FDA through the PMA process. 21 U.S.C. § 360k(a); *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316, 323 (2008), *aff'g* 451 F.3d 104 (2d Cir. 2006). Claims challenging the safety or effectiveness of a PMA-approved device can survive express preemption under § 360k(a) only if they are "parallel"

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[1] Otis-Wisher's complaint often refers to Infuse as "Infuse/BMP" or simply "BMP." JA19. Infuse is an implantable device that includes a recombinant human bone morphogenetic protein (rhBMP-2), an absorbable collagen sponge, and a titanium cage. JA37.

claims based on a state-law duty that is "identical" to a specific federal requirement. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996).

Second, the FDCA's no-private-right-of-action clause, 21 U.S.C. § 337(a), declares that all actions to enforce the FDCA "shall be by and in the name of the United States," and thus requires that the FDCA and its implementing regulations be "enforced exclusively by the Federal Government"—not by private plaintiffs. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). Federal law therefore impliedly preempts any private claim for which the existence of the FDCA or its implementing regulations is "a critical element." *Id.* at 353.

Together, "'*Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption.'" *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010); *Caplinger v. Medtronic, Inc.*, 921 F.Supp.2d 1206, 1215 (W.D. Okla. 2013). To avoid preemption, "'[t]he plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA ([because] such a claim would be impliedly preempted under *Buckman*).'" *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (quoting *Bryant*, 623 F.3d at 1204).

Agreeing with the well-reasoned analysis in *Caplinger*, in which "[c]laims almost identical to those raised here—also concerning alleged off-label promotion and posterior use of Infuse—were recently rejected as preempted" (JA42), the district court correctly found that Otis-Wisher's claims do not fit through that narrow gap. JA42-44. As the *Caplinger* court explained, these claims would "establish … requirements different from, or in addition to, federal requirements for the Infuse Device" and are therefore "the exact type of claim that is expressly preempted under § 360k(a)." 921 F.Supp.2d at 1221, 1222, 1223. Moreover, any claim "based upon defendants' promotion and marketing of the Infuse Device for off-label uses" is "impliedly preempted under *Buckman* and § 337(a)." *Id.* at 1219, 1223.

The district court also correctly recognized that, in the alternative, Otis-Wisher's fraud claims must be dismissed "[b]ecause Otis-Wisher has failed to plead her misrepresentation and fraud claims with the particularity required by Federal Rule of Civil Procedure 9(b)." JA45.

Because the district court's decision is both correct and consistent with the thorough analysis in *Caplinger* and numerous other decisions dismissing claims arising from the alleged off-label promotion of the Infuse device, the decision below should be affirmed.

Preemption and particularity aside, the district court's judgment also should be affirmed on the ground (presented, but not reached, below) that Otis-Wisher's claims are barred by statute of limitations.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

Congress enacted the MDA in 1976, granting the FDA exclusive authority to regulate medical devices and creating a comprehensive "regime of detailed federal oversight." *Riegel*, 552 U.S. at 316. In enacting the MDA, Congress sought to ensure that safe and effective medical devices are readily available to treat patients in need of life-saving or disability-averting care. Recognizing the "undu[e] burden[]" imposed by differing state regulation, Congress adopted a "general prohibition on non-Federal regulation" of medical devices, in the form of an express-preemption clause. H.R. Rep. No. 94-853, at 45 (1976). That express-preemption provision specifies that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable … to the device" under federal law. 21 U.S.C. § 360k(a).

Under the MDA, different types of devices receive different levels of FDA scrutiny. Devices that "support[] or sustain[] human life" or

"present[] a potential unreasonable risk of … injury" are designated "Class III" devices. 21 U.S.C. § 360c(a)(1)(C)(ii). Innovative Class III devices, like the Infuse device at issue here, "incur the FDA's strictest regulation" and must receive Premarket Approval (PMA) from the FDA before being sold. *Buckman*, 531 U.S. at 344.

"Premarket approval is a 'rigorous' process." *Riegel*, 552 U.S. at 317. To obtain premarket approval, a manufacturer "must submit a detailed PMA application" that contains, among other things, "specimens of the proposed labeling for the device." *Riegel*, 451 F.3d at 109. The FDA closely scrutinizes PMA applications, "'weig[hing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318. "The FDA spends an average of 1,200 hours reviewing each application" and "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.*

If the FDA decides that the device's proposed design, manufacturing methods, or labeling is inadequate, it can deny approval or require revisions prior to approval. *See id.* at 319; *see also Riegel*, 451 F.3d at 109-10 (The decision "whether or not to approve the device for marketing …. is not binary; the FDA has means to impose additional

requirements."). The FDA "thus has quite broad authority to approve, deny, and effectuate modifications of an application throughout the PMA process." *Riegel*, 451 F.3d at 110.

"Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319. Before making such changes, a manufacturer must submit a PMA supplement and generally may not implement the proposed changes without FDA approval. *Id.*

B. Off-Label Use Of Medical Devices

While the FDA approves *devices* through the PMA process, it does not approve *how* such devices may be *used*. This follows from a critical and overarching limitation imposed by Congress: The FDA is prohibited by law from "limit[ing] or interfer[ing] with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease." 21 U.S.C. § 396. Thus, while Congress established the premarket approval system to help ensure that innovative Class III devices possess a reasonable assurance of

safety and effectiveness, Congress also was adamant that the federal government not regulate the practice of medicine. Congress therefore empowered the FDA to decide whether a new device may be sold, but forbade the agency to regulate how an approved device may be *used*.

Otis-Wisher is therefore mistaken when she refers to "unapproved uses" of Infuse. *E.g.*, Br.8, 19, 22. The FDA has said that "[t]he term 'unapproved uses' is … misleading," because the agency does not regulate the use of medical products. U.S. Food & Drug Admin., *Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bull. 4, 5 (1982). The FDA approves (or disapproves) *devices* and their labeling; it does not mandate how approved devices may be *used*. *See Nightingale Home Healthcare, Inc. v. Anodyne Therapy, LLC*, 2008 WL 4367554, at *6 (S.D. Ind. 2008) ("[T]he FDA does not approve or disapprove the use of medical devices for specific treatments."), *aff'd*, 589 F.3d 881 (7th Cir. 2009); *Harris v. Medtronic, Inc.*, 2013 WL 4011624, at *2 (Cal. Super. Ct. 2013) ("PMA covers devices—not applications."). Accordingly, "[o]nce the FDA has cleared a device …, physicians may use the device in any manner they determine to be best." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 197 (4th Cir. 2001).

The FDA does not ignore that an approved device may—and likely will—be used in ways other those indicated on its label. To the contrary, in deciding whether to grant premarket approval, the FDA's "approval process generally contemplates that approved [devices] will be used in off-label ways." *United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012). This is because "off-label use is not illegal or even disfavored" but "an accepted and valuable part of the practice of medicine" (*Caplinger*, 921 F.Supp.2d at 1218 n.3) and often constitutes the prevailing "'standard of care'" (*Caronia*, 703 F.3d at 153). Thus, "'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." *Buckman*, 531 U.S. at 350.

The FDCA anticipates that the FDA will consider potential off-label uses and their associated risks when deciding whether to grant premarket approval. A manufacturer seeking premarket approval must submit all "data … relevant to an evaluation of the safety and effectiveness of the device …, *including information derived from investigations other than those proposed in the application*." 21 C.F.R. § 814.20(b)(8)(2)(ii) (emphasis added); *see also* 21 U.S.C. § 360e(c)(1)(A). In turn, when determining whether to grant a PMA application, the

FDA must consider not only the "conditions of use … suggested in the [proposed] labeling," but also "*other intended conditions of use*."[2] 21 C.F.R. § 860.7(b)(2) (emphasis added); *see also* 21 U.S.C. § 360e(d)(1)(A)(ii).

The FDA may therefore determine that the proposed labeling for a device does not adequately discourage off-label uses or warn of their risks, and may condition PMA approval on the addition or strengthening of such warnings. And, if the FDA becomes concerned about off-label use after approval, it may require post-approval changes to the device. The agency may, for example, "require a manufacturer to provide additional labeling that addresses potential off-label uses." *Reeves v. AcroMed Corp.*, 44 F.3d 300, 305-06 (5th Cir. 1995) (citing 21 C.F.R. § 895.25)); *accord* 21 C.F.R. § 814.82; *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 931 (5th Cir. 2006).

C. Premarket Approval Of The Infuse Device

Otis-Wisher admits (Br.2), and FDA records confirm, that the FDA granted premarket approval to the Infuse device in 2002 after nearly 1½ years of agency scrutiny. *See* JA52-55, 60. FDA records also

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[2] A device's "intended use" can include "uses other than the ones for which [the manufacturer] offers it." 21 C.F.R. § 801.4.

confirm the text of the device's FDA-approved label, the InFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device Important Medical Information. *See* JA65-80. These public records establish that Infuse was approved by the FDA through the PMA process and that this approval remains in effect today.[3]

As relevant here, the device's FDA-approved labeling instructed Otis-Wisher's surgeon that the Infuse device should not be implanted "at locations other than the lower lumbar spine" (JA68) and "is to be implanted via an anterior … approach" (JA67). The label also warns that "the potential for ectopic … or undesirable exuberant bone formation exists" and that "[e]ctopic and/or exuberant bone formation" are "potential adverse events which may occur with spinal fusion surgery with the InFUSE Bone Graft." JA69, 73-74.

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[3] The district court was authorized to take judicial notice of these materials because they are official records published by the agency and cannot reasonably be questioned. Fed. R. Evid. 201(b); *see, e.g.*, *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (judicial notice of device's premarket approval); *Martin v. Medtronic, Inc.*, 32 F.Supp.3d 1026, 1031 n.8 (D. Ariz. 2014) (judicial notice of Infuse premarket approval and labeling); *Chapman v. Abbott Labs.*, 930 F.Supp.2d 1321, 1323 (M.D. Fla. 2013) (judicial notice of FDA-approved drug label published on FDA website).

D. Otis-Wisher's Claims Against Medtronic

This case began as a medical-malpractice action by Otis-Wisher against a medical provider whose treatment allegedly violated accepted standards of care. *See* ECF #1; JA22-23. Otis-Wisher later amended her complaint to plead various claims against Medtronic, the manufacturer of the Infuse device that her physicians allegedly used off-label. JA24-34.

According to her amended complaint, Otis-Wisher was seriously injured in an April 2007 motor-vehicle accident that fractured her cervical spine (*i.e.*, the section of the spine that passes through the neck). JA12. She alleges that in March 2008 she underwent "posterior C1-[C]2 instrumented fusion using cables and an H-shaped iliac crest bone allograft," which does not involve Infuse, with "[a]dditional bone grafting performed in the right side" using Infuse. JA13. This procedure was contrary to the instructions and warnings given by Medtronic on the device's FDA-approved label, which warn that Infuse should be used only in the lumbar spine and implanted only via an anterior approach. *See supra* p. 10.

Shortly after her surgery, Otis-Wisher allegedly began experiencing neck pain and muscle spasms, which she called to her

doctors' attention on at least four separate occasions in 2008. *See* JA14-16. She alleges that, during her follow-up visits, she specifically "expressed her frustration and concern about the use of [Infuse]." JA16. Soon after, she alleges, her physicians confirmed that she has "exuberant bone growth in [her] cervical spine," which she believed to be caused by the alleged "off-label use of Infuse." JA17.

Otis-Wisher filed her medical-malpractice complaint against Fletcher Allen Health Care, Inc. in March 2011, shortly before the three-year statute of limitations expired. JA3. It was not until February 2012, nearly four years after her Infuse procedure and more than three years after she began experiencing the symptoms she complains of, that Otis-Wisher amended her complaint to assert claims against Medtronic. JA4, 11. Her claims against Medtronic are for fraudulent misrepresentation and constructive fraud; strict-liability design defect, manufacturing defect, and failure to warn; negligence and negligent misrepresentation; and consumer fraud. JA24-34. The gravamen of each claim is that Medtronic should have designed Infuse differently or should have made different or additional statements about Infuse beyond those required by the FDA.

E. Proceedings Below

The district court (Murtha, *J.*) granted Medtronic's motion to dismiss. JA39-46.

Applying § 360k(a), the district court determined that all of Otis-Wisher's claims are expressly preempted by federal law. JA42-44. "A state law claim may survive" express preemption only "if the claim relies on a state requirement that 'parallels' the federal requirement." JA42. Here, however, "none of Otis-Wisher's common-law claims allege any specific federal requirement," and a plaintiff "cannot state a parallel claim without stating a violation of federal law." JA43-44.

The district court also held, in the alternative, that Otis-Wisher's fraud claims must be dismissed because she failed to allege fraud with particularity. JA44-45. Otis-Wisher's "[b]are bones allegations" "failed to plead her misrepresentation and fraud claims with the particularity required by Federal Rule of Civil Procedure 9(b)," because she "has not alleged any particular statements or speaker(s)[,] let alone when and where any such statements were made." JA45.

The court further held that Otis-Wisher "has not stated a claim for violation of the Vermont Consumer Fraud Act" because implantable medical devices are not "consumer" goods under the Act. JA45-46.

Because the court dismissed all of Otis-Wisher's claims against Medtronic on the merits, it did "not consider Medtronic's remaining arguments concerning the statute of limitations." JA45.

Otis-Wisher's claims against her healthcare provider, Fletcher Allen Health Care—which "agree[d] to be responsible for, and liable for, any deviation from the standard of care by Dr. [John] Braun," who performed her surgery (JA11)—proceeded for another 14 months, then settled for an undisclosed amount. JA10. This appeal followed.

SUMMARY OF THE ARGUMENT

Congress has—through § 360k(a) as interpreted in *Riegel*—expressly preempted state-law claims challenging the design, manufacture, or labeling of a medical device approved by the FDA through the PMA process, and has—through § 337(a) as interpreted in *Buckman*—impliedly preempted private claims seeking to enforce the FDCA or its implementing regulations.

Otis-Wisher does not allege that Medtronic failed to provide any warnings required by the FDA, and she does not allege that the design of her Infuse device was anything other than the design approved by the FDA. Instead, she contends that Medtronic was required under state tort law to give *additional* warnings about risks purportedly

associated with off-label use of Infuse or to employ a *different* design. Those claims are expressly preempted under § 360k(a) because they would impose state-law requirements "different from, or in addition to" the federal requirements imposed by the FDA.

Although there is a narrow exception to § 360k(a) for claims that "parallel" the federal requirements, none of Otis-Wisher's claims is a parallel claim. To be "parallel," the state-law duty at issue must be "identical" to a specific federal requirement. But Otis-Wisher did not plead a parallel claim in her complaint, which does not allege the violation of any specific federal requirement. And her effort on appeal to construct a parallel claim based on off-label promotion fails because she has not identified any federal prohibition on off-label promotion, has not identified any state-law prohibition on off-label promotion, and cannot identify a causal connection between any off-label promotion and her alleged injury.

Otis-Wisher's claims also are impliedly preempted. Through § 337(a), Congress vested the FDA with exclusive power to enforce the FDCA and its implementing regulations. Any duty to abstain from off-label promotion exists, if at all, solely under the FDCA, and private actions to enforce the FDCA are forbidden. Moreover, any state-law

claim that would require Medtronic to communicate with the FDA about a possible design or labeling change would be impliedly preempted because States have no power over the relationship between a federal agency and the entities it regulates.

Otis-Wisher's fraud claims are also inadequately pleaded. Her bare-bones allegations do not identify with particularity the time, place, speaker, or contents of any false statement, nor does she allege how her physicians came to rely on any such (unidentified) misstatement.

In the alternative, Otis-Wisher's claims should be dismissed as time-barred. Although the complaint establishes that Otis-Wisher knew of her injuries in 2008 and had attributed them to Infuse by 2009, she did not assert any claims against Medtronic until 2012, after the three-year limitations period and two-year discovery period had expired.

ARGUMENT

I. OTIS-WISHER'S CLAIMS ARE PREEMPTED.

The MDA's express-preemption clause, 21 U.S.C. § 360k(a), forbids States from maintaining any safety or effectiveness requirement that is "different from, or in addition to" those imposed by the FDA. Seeking to ensure "that innovations in medical device technology are not stifled by unnecessary restrictions," and recognizing the "undu[e]

burden[]" on device manufacturers when "differing requirements … are imposed by jurisdictions other than the Federal government," Congress enacted § 360k(a) as a "general prohibition on non-Federal regulation" of medical devices. H.R. Rep. No. 94-853, at 12, 45. The MDA thus "swept back some state obligations and imposed a regime of detailed federal oversight," enforced by an expert federal agency rather than by private plaintiffs and lay juries applying state tort law. *Riegel*, 552 U.S. at 316.

In addition, 21 U.S.C. § 337(a), the FDCA's no-private-right-of-action clause, impliedly preempts any private action to enforce the FDCA. Congress granted the FDA exclusive authority to enforce the FDCA and gave it "complete discretion" to decide "how and when [its enforcement tools] should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). The Supreme Court has recognized that "this authority is used … to achieve a somewhat delicate balance of statutory objectives," a balance that "can be skewed" if private tort suits are allowed. *Buckman*, 531 U.S. at 348. Thus, while "citizens may report wrongdoing and petition the agency to take action" (*id.* at 349), § 337(a) forbids private claims that cannot be established without reliance on the FDCA and that thereby amount to private enforcement of its provisions.

Although Congress's preemption of state tort claims may leave some individuals who are injured by FDA-approved medical devices "'without … judicial recourse,'" the loss to those comparatively few individuals was, in Congress's estimation, outweighed by the benefit to the far greater number "who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." *Riegel*, 552 U.S. at 326; *see also Scott v. CIBA Vision Corp.*, 44 Cal.Rptr.2d 902, 914 (Ct. App. 1995). As an alternative to private tort suits, Congress granted the FDA substantial authority to police device manufacturers under federal law. *See Buckman*, 531 U.S. at 349; *Scott*, 44 Cal.Rptr. 2d at 913.

Otis-Wisher should not be allowed to circumvent this carefully crafted regulatory scheme. Congress recognized that state tort litigation poses a grave risk to public health by inhibiting the development of life-sustaining medical treatment. In deciding to "swe[ep] back some state obligations and impose[] a regime of detailed federal oversight" (*Riegel*, 552 U.S. at 316), to be enforced by an expert federal agency rather than lay juries, Congress further recognized that private tort suits are ill-suited to regulating complex medical devices. In particular, Congress was concerned that "[a] jury … sees only the cost of a more dangerous

design, and is not concerned with its benefits," because "the patients who reaped those benefits are not represented in court." *Id.* at 325. Congress's determination that medical devices should be regulated by an expert federal agency, rather than through individual tort verdicts issued by lay juries across 50 states, must be respected. *See Riegel*, 451 F.3d at 124 ("Should Congress conclude that the preemption of the state tort actions at issue in this case [is] undesirable," that is "a policy issue for the legislative and executive branches rather than a legal question.").[4]

A. No Presumption Against Preemption Applies Here.

Contrary to Otis-Wisher's contention that her claims survive under a "presumption against preemption" (Br.7, 13-14), the Supreme

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[4] Contrary to Otis-Wisher's assertion, preemption is not "immunity" (Br.4, 5) and does not mean that medical-device manufacturers are "excused and immune from all liability" (Br.30). On the contrary, although many private tort claims are barred, the government may bring civil and criminal charges against a manufacturer who violates the FDCA. *See Buckman*, 531 U.S. at 349. Moreover, as discussed below, not all tort claims are preempted: A person injured by a PMA-approved device may still sue the manufacturer, notwithstanding § 360k(a), if the manufacturer violated the device's PMA requirements—*e.g.*, by failing to provide the FDA-mandated warnings—and that violation caused the person's injuries. Nevertheless, the regulatory scheme enacted by Congress does preclude Otis-Wisher from pursuing the claims asserted here.

Court has twice *rejected* the argument that such a presumption applies in the medical-device context. In *Riegel*, the Court rejected the dissent's reliance on that presumption because "the text of [§ 360k(a)]" plainly evinced Congress's intent to displace "the tort law of 50 States." 552 U.S. at 326; *see also id.* at 316 (Congress intended the MDA's express preemption clause to "swe[ep] back some state obligations" and replace them with "a regime of detailed federal oversight."); *cf. id.* at 334 (Ginsburg, J., dissenting). And in *Buckman*, the Court held that there is "no presumption against pre-emption" for state-law claims seeking to enforce FDCA requirements. 531 U.S. at 347-48. Accordingly, no presumption against preemption applies here.

B. Otis-Wisher's Claims Are Expressly Preempted.

Section 360k(a) creates a two-step test for determining whether state-law claims are expressly preempted. *See, e.g.*, *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300-01 (11th Cir. 2011). First, the court must consider whether "the Federal Government has established requirements applicable to" the medical device. *Riegel*, 552 U.S. at 321. If it has, the court must then determine whether the state-law claims would impose "requirements with respect to the device that are 'different from, or in addition to'" the federal requirements. *Id.* at 322.

Otis-Wisher does not dispute that the FDA has imposed device-specific federal requirements on the Infuse device. Nor could she. "Premarket approval … imposes [federal] 'requirements'" under § 360k(a). *Riegel*, 552 U.S. at 321-23. Accordingly, "[d]evices that are approved through PMA procedures," like Infuse, "automatically satisfy the 'federal requirements' prong" of § 360k(a). *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012).[5]

Riegel also held that state common-law claims impose "requirements … 'with respect to devices'" as that term is used in § 360k(a). 552 U.S. at 327. Thus, under *Riegel*, § 360k(a) expressly preempts any state-law claims that would impose requirements

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[5] *See also, e.g.*, *Beavers-Gabriel v. Medtronic, Inc.*, 15 F.Supp.3d 1021, 1032-33 & n.6 (D. Haw. 2014); *Brady v. Medtronic, Inc.*, 2014 WL 1377830, at *4-5 (S.D. Fla. 2014); *Kashani-Matts v. Medtronic, Inc.*, 2013 WL 6147032, at *3 (C.D. Cal. 2013); *Gavin v. Medtronic, Inc.*, 2013 WL 3791612, at *11-12 (E.D. La. 2013). One widely criticized decision incorrectly suggests that the federal-requirements prong is not satisfied if the plaintiff alleges that the device was promoted for off-label use. *Ramirez v. Medtronic, Inc.*, 961 F.Supp.2d 977 (D. Ariz. 2013). But "the majority of other courts … have rejected *Ramirez*" (*Martin*, 32 F.Supp.3d at 1036) as "not consistent with the text of §360k(a) [or] the scope of federal requirements imposed on Class III devices." *Houston v. Medtronic, Inc.*, 2014 WL 1364455, at *5 (C.D. Cal. 2014); *accord, e.g.*, *Thorn v. Medtronic Sofamor Danek, USA, Inc.*, --- F.Supp.3d ---, 2015 WL 328885, at *7-8 (W.D. Mich. 2015); *Beavers-Gabriel*, 15 F.Supp.3d at 1035-36 & n.8; *see also Caplinger*, 921 F.Supp.2d at 1218.

respecting the safety or effectiveness of a device with premarket approval that are "'different from, or in addition to'" the requirements imposed by federal law. *Id.* at 321 (quoting 21 U.S.C. § 360k(a)(1)).

The only remaining question is whether Otis-Wisher properly alleged claims that "parallel" a specific federal requirement, as required to survive express preemption under § 360k(a). The district court correctly held (JA41-44) that she failed to do so.

1. To avoid preemption, Otis-Wisher must plead a parallel claim.

The only claims that survive express preemption under *Riegel* and § 360k(a) are those that "'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (quoting *Lohr*, 518 U.S. at 495). But to be "parallel," the Supreme Court has said, a claim must rest on the violation of a state-law requirement that is "identical" to an existing federal requirement. *Lohr*, 518 U.S. at 495; *accord McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) (parallel requirements must be "'*genuinely* equivalent'"). Establishing liability through a parallel claim is therefore "more difficult than it would be in a typical product liability case." *White v. Striker Corp.*, 818 F.Supp.2d 1032, 1037 (W.D. Ky. 2011).

To state a "parallel" claim, Otis-Wisher must allege (1) the violation of a specific federal requirement applicable to the Infuse device; (2) the violation of an *identical* state-law duty; and (3) that the predicate federal violation caused her injuries. *See, e.g.*, *Wolicki-Gables*, 634 F.3d at 1300-01; *McMullen*, 421 F.3d at 488-89; *Caplinger*, 921 F.Supp.2d at 1214; *White*, 818 F.Supp.2d at 1039-40. It is not enough that a manufacturer's conduct violated some requirement under federal law and at the same time violated some other requirement under state law. Rather, to avoid preemption under § 360k(a), the "[s]tate … *requirement*" at issue must be identical to a specific "*requirement* … under [the FDCA]." 21 U.S.C. § 360k(a) (emphasis added).

Citing *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), Otis-Wisher insists that "while manufacturers who comply with federal law are entitled to preemption, those who violate federal law are not." Br.5-6; *see also* Br.19-20.[6] But it is not the law, and *Bausch* did not hold, that the presence of *any* alleged federal violation allows *any* state-law claim to escape preemption. On the contrary, the Supreme Court has held

[6] Otis-Wisher also attributes this position to *Riegel* (*see* Br.5), but *Riegel* held that a private tort claim may proceed only if it "parallels" a specific federal requirement, not whenever there has been *any* violation of federal law.

that "although [§ 360k(a)] can be read to allow certain state-law causes of action that parallel federal safety requirements, it does not and cannot stand for the proposition that *any* violation of the FDCA will support a parallel claim." *Buckman*, 531 U.S. at 353 (emphasis added). Instead, as *Bausch* acknowledges, state requirements escape preemption under § 360k(a) only if "*the plaintiff can show that the requirements are 'genuinely equivalent'*" to a specific federal requirement. 630 F.3d at 552 (emphasis added); *see also Wolicki-Gables*, 634 F.3d at 1300; *McMullen*, 421 F.3d at 489.[7]

Instead, all that *Riegel* and *Lohr* permit a State to do is to "duplicate[] the federal rule[]" and attach "a traditional damages remedy" to it. *Lohr*, 518 U.S. at 495; *accord Riegel*, 552 U.S. at 330 (States may simply "provid[e] a damages remedy" for "a violation of FDA regulations").[8] But § 360k(a) prevents States from maintaining

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[7] Unlike Otis-Wisher's claims, the claim in *Bausch* was deemed to be a parallel claim because the plaintiff's state-law *manufacturing*-defect claim rested on allegations that the defendant violated federal *manufacturing* requirements. *See* 630 F.3d at 558-59. In this case, however, the district court correctly recognized that no such parallel claim is presented.

[8] Even then, because § 337(a) bars any claim for which "the existence of [the FDCA] is a critical element," the parallel state-law requirement must be found in "traditional state tort law which had predated" the

any requirement regarding the safety or effectiveness of a PMA-approved medical device that is not "identical" to a federal requirement. *Lohr*, 518 U.S. at 495. Indeed, a central purpose of the MDA, made clear through its legislative history, was to forbid States from creating a patchwork of differing state standards. *See* H.R. Rep. No. 94-853, at 12, 45; *Riegel*, 451 F.3d at 122-23.

2. Otis-Wisher did not plead a parallel claim in her complaint.

The district court correctly dismissed Otis-Wisher's claims as preempted because her complaint did not allege the violation of any specific federal requirement applicable to the Infuse device. *See* JA43-44.

It is well established that "[p]arallel claims must be specifically stated in the initial pleadings." *Wolicki-Gables*, 634 F.3d at 1301; *see also, e.g.*, *Rodriguez v. Am. Med. Sys., Inc.*, --- F.App'x ---, 2014 WL 7399048, at *3-4 (5th Cir. 2014) (per curiam); *Herron v. Smith & Nephew, Inc.*, 7 F.Supp.3d 1043, 1049, 1051-52 (E.D. Cal. 2014). Courts across the country agree that "[w]hen facing MDA preemption, a

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FDCA. *Buckman*, 531 U.S. at 353. Thus, some claims that escape preemption under § 360k(a) might still be barred by § 337(a). *See id.* at 352 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000)).

plausible cause of action requires … a showing that the alleged violation of state law parallels a violation of federal law." *White*, 818 F.Supp.2d at 1037; *see id.* at 1037-39 (collecting cases). Here, however, "[i]n the face of the narrow pleading window required to avoid preemption," Otis-Wisher's complaint "d[id] virtually nothing." *Id.* at 1039.

As the district court observed, "none of Otis-Wisher's common-law claims allege[s]" the existence, much less the violation, of "any specific federal requirement." JA43. For example, her complaint "does not allege [that] the design of Infuse was anything other than the design approved by the FDA," and "does not aver [that] any … alleged misrepresentations or omissions were in violation of any specific federal law." JA44. Notably, Otis-Wisher "ma[de] no allegations of misbranding" in her complaint. JA44 n.9.

In fact, most of Otis-Wisher's claims do not even *mention* federal law. The sole exception is a vague and conclusory allegation in her negligence claim that Medtronic "[f]ail[ed] to exercise reasonable care by not complying with federal law and regulations." JA32.[9] But, as the district court observed, "this allegation does not state a device specific

[9] "None of the other common law claims even include[s] a reference to federal law." JA43.

violation of federal law" and therefore "is not sufficient to avoid preemption" under § 360k(a). JA43. To satisfy Rule 8 as construed in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), "a plaintiff must do more than 'simply incant the magic words "Medtronic violated FDA regulations" in order to avoid preemption.'" JA42 (quoting *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F.Supp.2d 1147, 1158 (D. Minn. 2009), *aff'd sub nom. Bryant*, 623 F.3d 1200); *accord, e.g.*, *Wolicki-Gables*, 634 F.3d at 1301. Otis-Wisher made no effort to cure the deficiency by amending her complaint to articulate a specific violation of federal law.

The district court was therefore correct to dismiss Otis-Wisher's claims as preempted, because a plaintiff "cannot state a 'parallel' claim without stating a violation of federal law." JA43; *accord* JA44.

3. Otis-Wisher does not present a parallel claim on appeal.

On appeal, Otis-Wisher contends that "[t]he FDCA generally prohibits medical device companies from promoting their devices for off-label uses" and that "[a] medical device promoted for off-label uses is deemed misbranded in violation of 21 U.S.C. § 352(f)." Br.8. But, because "Otis-Wisher ma[de] no allegations of misbranding" in her

complaint (JA44 n.3), that argument has been waived. *See, e.g.*, *In re Nortel Networks Corp. Sec. Litig.*, 539 F.3d 129, 132-33 (2d Cir. 2008) (per curiam). And even if she had properly pleaded and preserved a misbranding claim, Otis-Wisher still fails to satisfy any—much less all—of the elements required to state a parallel claim.

a. Otis-Wisher has not identified any federal prohibition on off-label promotion.

Otis-Wisher's contention that federal law prohibits off-label promotion as misbranding is contrary to this Court's precedent, the FDA's own representations, and a growing number of other decisions.

As this Court recently held, "[w]hile the FDCA makes it a crime to misbrand," federal law "does not expressly prohibit"—and cannot be construed to prohibit—"off-label promotion." *Caronia*, 703 F.3d at 160; *see also id.* at 154, 162, 168-69. That follows the FDA's representations to this Court that off-label promotion is not itself prohibited by the FDCA. And it is consistent with the decisions of numerous other courts rejecting the argument that federal law somehow prohibits off-label promotion. *See, e.g.*, *Brady v. Medtronic, Inc.*, 2014 WL 1377830, at *5 (S.D. Fla. 2014) ("the FDCA does not expressly prohibit off-label marketing"); *Schuler v. Medtronic, Inc.*, 2014 WL 988516, at *1 (C.D.

Cal. 2014) ("federal law does not bar off-label promotion"); *Dawson v. Medtronic, Inc.*, 2013 WL 4048850, at *6 (D.S.C. 2013) (refusing to "accept Plaintiff's premise that off-label promotion is illegal under the FDCA"); *Underwood v. Rhone-Poulenc Rorer Pharm., Inc.*, 890 So.2d 429, 431 (Fla. Dist. Ct. App. 2004) ("[N]othing in the FDCA actually prohibits manufacturers from promoting off-label uses.").

i. The FDA has represented to this Court that off-label promotion does not violate the FDCA.

Otis-Wisher's position that off-label promotion constitutes misbranding has been refuted by the FDA itself. In *Caronia*, the FDA represented to this Court that "[p]romoting an approved [medical product] for off-label uses is not itself a prohibited act under the FDCA, nor is it an element of any prohibited act." Brief for United States at 51, *Caronia*, 703 F.3d 149 (No. 09-5006-cr) ("FDA *Caronia* Brief"), *at* 2010 WL 6351497, *quoted in Caronia*, 703 F.3d at 160. Thus, according to the FDA itself, off-label promotion is not misbranding.[10] In fact, off-label promotion is not even "an element of" misbranding. FDA *Caronia*

[10] According to the FDA, "the promotion of off-label uses plays" only "an *evidentiary* role in determining whether a [device] is misbranded." FDA *Caronia* Br.51.

Br.51.[11]

ii. This Court has held that the FDCA cannot be construed to prohibit off-label promotion.

Construing the same provision that Otis-Wisher purports to rely on, this Court in *Caronia* held, as a matter of statutory interpretation, that the FDCA's misbranding provision cannot be construed to prohibit off-label promotion. That decision is controlling here. *See, e.g.*, *Adams v. Zarnel*, 619 F.3d 156, 168 (2d Cir. 2010) (panel bound by prior decision of another panel).

The *Caronia* court first observed that nothing in the FDCA or its implementing regulations expressly prohibits off-label promotion. *See, e.g.*, 703 F.3d at 154 ("The FDCA and its accompanying regulations do not expressly prohibit the 'promotion' or 'marketing' of drugs for off-label use."); *id.* at 160 ("[T]he [FDCA] and its accompanying regulations do not expressly prohibit or criminalize off-label promotion."); *id.* at 161 (district court erred by "flatly stat[ing] to the jury that pharmaceutical representatives are prohibited from engaging in off-label promotion").

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[11] The Government recently reiterated that "off-label promotion by a manufacturer is not by itself a violation of federal law" and "no[t] … among the comprehensive list of prohibited acts in the [FDCA]." U.S. Statement of Interest at 2, ECF #141, *United States v. Millennium Pharm., Inc.*, No. 2:09-cv-03010 (E.D. Cal. Aug. 28, 2014).

In fact, *Caronia* noted, the FDA has recognized that "'[o]ff-label uses or treatment regimens may be important and may even constitute a medically-recognized standard of care.'" *Id.* at 153. If Congress wished to take the drastic step of prohibiting off-label promotion, it presumably would have said so clearly and explicitly, but it has not done so.[12] *Cf. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress … does not … hide elephants in mouseholes.").

Applying the doctrine of constitutional avoidance, the Court then held that the misbranding provision must not be *construed* to prohibit off-label promotion, because such an interpretation would raise grave First Amendment problems: "[U]nder the principle of constitutional avoidance, … we construe the FDCA as not criminalizing the simple promotion of a drug's off-label use[,] because such a construction would raise First Amendment concerns." *Caronia*, 703 F.3d at 160. The promotion or marketing of medical products, including promotion of off-label uses, is speech protected by the First Amendment. *Id.* at 161-62 (citing *Sorrell v. IMS Health Inc.*, 131 S.Ct. 2653, 2659 (2011)); *see also*

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[12] For example, in 21 U.S.C. § 353a(c) (1997), Congress prohibited "advertis[ing] or promot[ing] the compounding of any particular drug," although that provision was later struck down by the Supreme Court. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002).

Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002) (prohibition on advertising of compounded drugs violates the First Amendment). Thus, "[t]o the extent there is any ambiguity as to whether off-label promotion is tantamount to illegal misbranding," courts must "construe the FDCA narrowly to avoid a serious constitutional question." *Caronia*, 703 F.3d at 162; *see id.* at 162-69 (explaining that a prohibition on off-label promotion would potentially violate the First Amendment).

Caronia therefore "decline[d] … to construe the FDCA's misbranding provisions to criminalize the simple promotion of a drug's off-label use by pharmaceutical manufacturers." 703 F.3d at 162. Accordingly, the court held, the FDCA and its misbranding provision do not prohibit "speech promoting the lawful, off-label use of an FDA-approved [device]." *Id.* at 169. That decision forecloses Otis-Wisher's attempt to construct a parallel claim predicated on off-label promotion.

Otis-Wisher argues that *Caronia* is inapplicable—either because she alleges that Medtronic's purported off-label promotion was misleading rather than truthful, or because *Caronia* construed the FDCA in a criminal rather than civil case. Br.10. But there is no merit to either suggestion, because 21 U.S.C. § 352(f)—the misbranding

provision that Otis-Wisher relies on—does not differentiate between true and false statements or between civil and criminal cases. Supreme Court precedent holds that a statutory construction adopted to avoid constitutional concerns with respect to one category of conduct (such as the making of truthful statements) applies equally to all other categories (such as the making of supposedly misleading statements) where, as here, "the statutory text provides for no distinction" between the categories, because "[t]o give the same words a different meaning for each category would be to invent a statute rather than interpret one." *Clark v. Martinez*, 543 U.S. 371, 378-79 (2005).[13] And the Supreme

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[13] Otis-Wisher's categorical declaration that "[a] defendant making such 'untruthful' statements enjoys no First Amendment protection" (Br.10) is also contrary to Supreme Court precedent. *See, e.g.*, *N.Y. Times Co. v. Sullivan*, 376 U.S. 254 (1964) (First Amendment protects allegedly false statements in a paid newspaper advertisement); *IMS Health*, 131 S.Ct. at 2664-65 (observing that "the burdened speech" in *Sullivan* "result[ed] from an economic motive" and suggesting that its heightened scrutiny applies to regulation of pharmaceutical information). But even if misleading commercial speech did not enjoy any *constitutional* protection, Otis-Wisher's claim fails as a *statutory* matter: To state a parallel claim, Otis-Wisher must identify a predicate federal violation, but, as *Caronia* held, federal law does not prohibit off-label promotion as such. Although dictum in a footnote assumed that "a defendant may be prosecuted for untruthfully promoting the off-label use of an FDA-approved drug" (703 F.3d at 165 n.10), the government's authority to prosecute untruthful promotion was not before the court in *Caronia*, and the court was not confronted with any argument on that

Court has likewise held that, when interpreting a statute, courts "must interpret the statute consistently, whether [they] encounter its application in a criminal or noncriminal context." *Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004). *Caronia* therefore cannot be distinguished on either ground.

iii. Otis-Wisher's contrary authorities are unavailing.

Otis-Wisher cites two authorities as purportedly recognizing a federal prohibition on off-label promotion (Br.8, 19), but neither offers her support. First, Otis-Wisher cites the district court decision in *United States v. Caputo*; but when the Seventh Circuit reviewed that decision, it expressly *refused* to adopt the position Otis-Wisher urges. *See* 517 F.3d 935, 940 (7th Cir. 2008) ("[W]e need not decide today whether a seller of … medical devices has a … right to promote off-label uses."). Second, Otis-Wisher cites a single, unexplained sentence—from an FDA document summarizing a D.C. Circuit decision that *declined* to consider whether the First Amendment would permit a hypothetical

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issue. Nor must the Court address the government's authority to prosecute untruthful promotion (either of on- or off-label uses) in this case, which involves a private tort suit rather than a government prosecution, because it is well established under § 337(a) and *Buckman* that private tort litigants face many limitations under the FDCA that the government does not. *See infra* pp. 41-51.

restriction on off-label promotion—stating that a product "distributed for a 'new use'" could be misbranded. Dep't of Health & Human Servs., Food & Drug Admin., *Notice of Decision in* Washington Legal Foundation v. Henney, 65 Fed. Reg. 14,286 (Mar. 16, 2000). Neither citation overcomes the FDA's recent representations to this Court, this Court's reasoned decision in *Caronia*, or the other cases holding that federal law does not prohibit off-label promotion.

b. Otis-Wisher has not identified any state-law prohibition on off-label promotion.

Even if federal law did prohibit off-label promotion, that still would not be enough for Otis-Wisher to state a parallel claim, because there is no state-law duty to abstain from off-label promotion as such. Nothing in Vermont law purports to prohibit off-label promotion. That is because "even the concept of 'off-label use' is a creature of the FDCA, is defined by the FDCA, and is not a part of [state] substantive law." *Caplinger*, 921 F.Supp.2d at 1219-20, 1224; *accord Gavin v. Medtronic, Inc.*, 2013 WL 3791612, at *17 (E.D. La. 2013) ("There is no … state law claim premised on off-label promotion."); *In re Zyprexa Prods. Liab. Litig.*, 2008 WL 398378, at *5 (E.D.N.Y. 2008) ("[T]here is no state-law equivalent of 'off-label.'"). Thus, even courts that have assumed that

federal law does prohibit off-label promotion still have held that state-law claims predicated on off-label promotion are expressly preempted by § 360k(a). *See, e.g.*, *Zaccarello v. Medtronic, Inc.*, --- F.Supp.3d ---, 2014 WL 3866607 (W.D. Mo. 2014); *Houston v. Medtronic, Inc.*, 957 F.Supp.2d 1166 (C.D. Cal. 2013); *Hawkins v. Medtronic, Inc.*, 2014 WL 346622 (E.D. Cal. 2014); *Caplinger*, 921 F.Supp.2d 1206.

Unable to identify any state-law duty to abstain from off-label promotion, Otis-Wisher instead relies on the state-law duty to warn. *See* Br.19 ("Medtronic's … failure to provide adequate warnings … subjects it to state law tort liability."); JA21, 27-28, 31. But allegations that a manufacturer violated federal law by promoting off-label use and allegations that it violated state law by failing to issue certain warnings are not "parallel." The state-law duty Otis-Wisher invokes is a duty to provide warnings—*i.e.*, *to make statements*—about off-label use of Infuse, while the federal duty she invokes is a purported duty *to abstain from making statements* about off-label use of Infuse. But, as various courts have recognized, "[a]n affirmative duty to *provide* adequate warnings is not genuinely equivalent to a federal requirement to *refrain* from a particular type of promotion." *Hawkins*, 2014 WL 346622, at

*15.[14] Because "the federal requirement that manufacturers not promote devices for off-label uses is not genuinely equivalent to the state law requirements that a manufacturer provide adequate warnings," "off-label promotion allegations do not somehow turn plaintiff's claims into 'parallel' claims that are not preempted." *Caplinger*, 921 F.Supp.2d at 1218 n.4.[15]

Seeking to resist this conclusion, Otis-Wisher points (Br.8, 12, 19-25, 30) to *Riley v. Cordis Corp.*, 625 F.Supp.2d 769 (D. Minn. 2009), and *Cornett v. Johnson & Johnson*, 48 A.3d 1041, 1057 (N.J. 2012), but neither case offers her any persuasive support. In dictum, the *Riley*

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[14] Nor is the state-law duty to warn parallel to the federal prohibition on misbranding: Whereas "[t]he FDCA defines misbranding in terms of whether a drug's labeling is adequate for its *intended* use" (*Caronia*, 703 F.3d at 162 (emphasis added)), intent is not an element of either strict liability or negligence. That is critical, because "[s]tate and federal requirements are not genuinely equivalent"—and thus are not parallel for purposes of § 360k(a)—if, as here, "a manufacturer could be held liable under the state law without having violated the federal law." *McMullen*, 421 F.3d at 488-89; *Wolicki-Gables*, 634 F.3d at 1300.

[15] "To the extent [they] complain[] about the information provided to patients and physicians regarding" Infuse, Otis-Wisher's fraud and misrepresentation claims are each "'at bottom, a failure to warn claim'" (*Timberlake v. Synthes Spine, Inc.*, 2011 WL 711075, at *7 (S.D. Tex. 2011)), and therefore fail for the same reason. *See, e.g.*, *Perez*, 711 F.3d at 1118 (fraud claim based on alleged off-label promotion "is expressly preempted by § 360k(a)").

court speculated about whether it might be "possible" for a failure-to-warn claim coupled with an off-label-promotion allegation to escape preemption, but expressly declined to reach the issue. 625 F.Supp.2d at 783. Most courts to reach the issue have relied on *Riley* to conclude that allegations of off-label promotion do *not* save state-law claims from preemption. *See Caplinger*, 921 F.Supp.2d at 1218 & n.4 (citing *Riley* and holding that "off-label promotion allegations do not somehow turn plaintiff's claims into 'parallel' claims that are not preempted"); *see also, e.g.*, *Dawson*, 2013 WL 4048850, at *6; *Gavin*, 2013 WL 3791612, at *11. And *Cornett*'s sole authority for allowing a failure-to-warn claim to proceed based on allegations of off-label promotion was the very dictum in *Riley* that reserved rather than resolved the issue.[16] It is not surprising, therefore, that *Cornett* is at odds with other cases to consider the issue and has not been followed. *See, e.g.*, JA42-43 (deeming *Cornett* unpersuasive in light of the analysis in *Caplinger*).

[16] Otis-Wisher actually cites a lower-court decision in *Cornett* that has been superseded. Like the superseding decision, the lower court's decision offers no persuasive explanation for why claims predicated on off-label promotion are not both expressly and impliedly preempted.

c. Otis-Wisher cannot identify a causal connection between any alleged off-label promotion and her alleged injury.

To state a parallel claim that avoids express preemption under § 360k(a), "a plaintiff must allege facts … 'establishing a causal nexus between the alleged injury and the [alleged federal] violation.'" *Erickson v. Bos. Scientific Corp.*, 846 F.Supp.2d 1085, 1092 (C.D. Cal. 2011).

Here, Otis-Wisher's allegations do not establish the requisite causal link between any alleged federal violation and her alleged injury. She alleges that her physicians used Infuse in an off-label manner by implanting the device in the cervical (rather than lumbar) spine and by using a posterior (rather than anterior) approach. JA12-13, 19. And she alleges that she now suffers "exuberant bone growth in [her] cervical spine" and "ectopic bone formation"—in other words, "excess bone growth"—that she attributes to "the off-label use of Infuse." JA17, 19, 27; *see also* JA20.

But Otis-Wisher cannot say that these alleged injuries resulted from any failure to warn, because she and her physicians *were* warned about these risks and against this off-label use. Infuse's FDA-approved label specifically instructs that the device should not be implanted "at

locations other than the lower lumbar spine" (JA68) and "is to be implanted via an anterior … approach" (JA67), and explicitly warns that "[t]he safety and effectiveness of the InFUSE Bone Graft component … implanted at locations other than the lower lumbar spine, or used in surgical techniques other than anterior … approaches have not been established" (JA68). The FDA-approved label further warns that "the potential for ectopic … or undesirable exuberant bone formation exists," and identifies "[e]ctopic and/or exuberant bone formation" as "potential adverse events which may occur with spinal fusion surgery with the InFUSE Bone Graft." JA69, 73-74.

Given that the Infuse label explicitly warned of the very risks Otis-Wisher supposedly encountered, she does not allege any injuries that can be causally connected to off-label promotion. *See Rounds v. Genzyme Corp.*, 440 F.App'x 753, 754-55 (11th Cir. 2011) (per curiam) (no liability where manufacturer "expressly and clearly warned [the plaintiff's physician] … about the risk of the exact injury of which the [plaintiff] now complain[s]"); *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) (similar).

C. Otis-Wisher's Claims Are Impliedly Preempted.

Even if Otis-Wisher had stated a parallel claim that escaped express preemption under 21 U.S.C. § 360k(a), her claims would nonetheless have to be dismissed as "impliedly preempted under *Buckman* and [21 U.S.C.] § 337(a)." *Caplinger*, 921 F.Supp.2d at 1219; *see also, e.g.*, *Zaccarello*, 2014 WL 3866607, at *5-6; *Dawson*, 2013 WL 4048850, at *6; *Lawrence v. Medtronic, Inc.*, 2013 WL 4008821, at *4-5 (Minn. Dist. Ct. 2013).

Otis-Wisher conspicuously ignores 21 U.S.C. § 337(a), the FDCA's no-private-right-of-action clause, which the Supreme Court identified in *Buckman* as the statutory basis for implied preemption of private claims seeking to enforce the FDCA. In enacting this provision, Congress not only declined to create a private cause of action under the FDCA, but affirmatively required that any action to enforce the FDCA "be by and in the name of the United States." 21 U.S.C. § 337(a). Thus, the FDCA and its implementing regulations are to be "enforced exclusively by the Federal Government"—not by private plaintiffs. *Buckman*, 531 U.S. at 352.

Moreover, Congress granted the FDA "complete discretion" to decide "how and when [its enforcement tools] should be exercised." *Heckler*, 470 U.S. at 835. That discretion is necessary "to achieve a somewhat delicate balance of statutory objectives," a balance that "can be skewed" if private tort suits are allowed. *Buckman*, 531 U.S. at 348. Indeed, because "the FDA pursues difficult (and often competing) objectives," that administrative "flexibility is a critical component of the statutory and regulatory framework." *Id.* at 349. Thus, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Id.* at 349 n.4.

Otis-Wisher also ignores the implied-preemption analysis set forth in *Riley* and *Caplinger*. *See Caplinger*, 921 F.Supp.2d at 1214-15; *Riley*, 625 F.Supp.2d at 776-77. As *Riley* explains, § 337(a) forbids private plaintiffs from asserting any "state claim [that] would not exist if the FDCA did not exist," or any claim for which "'the existence of [the] federal enactments is a critical element,'" because such a claim "is in substance (even if not in form) a claim for violating the FDCA" and may be enforced only by the federal government. 625 F.Supp.2d at 777, 790 (quoting *Buckman*, 531 U.S. at 353); *see also Loreto v. Proctor & Gamble*

Co., 515 F.App'x 576, 579 (6th Cir. 2013) (following *Riley*); *Dawson*, 2013 WL 4048850, at *3. Moreover, it is not enough that a claim be a "traditional state tort law claim[]." Br.22. Rather, the specific "'conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law.'" *Caplinger*, 921 F.Supp.2d at 1214 (quoting *Riley*, 625 F.Supp.2d at 777); *accord Pinsonneault v. St. Jude Med., Inc.*, 953 F.Supp.2d 1006, 1016 (D. Minn. 2013).

1. Claims predicated on off-label promotion are impliedly preempted.

Otis-Wisher's claims, which rest on allegations of off-label promotion, are impliedly preempted "because promoting the off-label use of an FDA-approved medical device is not unlawful under 'traditional state tort law which[] had predated the federal enactments in question.'" *Dawson*, 2013 WL 4048850, at *6 (quoting *Buckman*, 531 U.S. at 353). There is no traditional state-law duty to abstain from off-label promotion. Indeed, the very *concept* of off-label promotion—which did not and could not exist until Congress required manufacturers to obtain FDA approval of devices and their labeling—"is a creature of the FDCA, is defined by the FDCA, and is not a part of [state] substantive

law." *Caplinger*, 921 F.Supp.2d at 1219-20, 1224; *accord Gavin*, 2013 WL 3791612, at *17 ("[T]he very concept of 'off-label' use and promotion is derived from the regulatory system imposed by the MDA and the FDCA."); *In re Zyprexa*, 2008 WL 398378, at *5 ("The [off-label] concept is entirely federal.").

Consequently, claims predicated on off-label promotion "exist," if at all, "solely by virtue of the FDCA." *Buckman*, 531 U.S. at 353. Private enforcement of such claims is barred by § 337(a) because it would "usurp the FDA's regulatory oversight role for policing purported violations of" the statutes and regulations it has exclusive authority to administer. *Dawson*, 2013 WL 4048850, at *7. This Court should therefore reject Otis-Wisher's attempt to enforce a purported federal restriction on off-label promotion as intruding on the FDA's "complete discretion … to decide how and when" to enforce its regulations. *Heckler*, 470 U.S. at 835.[17]

[17] Allowing Otis-Wisher's claims to proceed would be particularly inappropriate here, where the Government took no action after a multiyear investigation of Medtronic's alleged conduct. *See* Medtronic, Inc., Form 8-K (May 16, 2012), *at* http://www.sec.gov/Archives/edgar/data/64670/000119312512236814/d355299d8k.htm

Observing that the *Buckman* Court described the claim before it as a fraud-on-the-FDA claim, Otis-Wisher argues that her claims are "unlike those in *Buckman*" because she "does not complain of fraud on the FDA" but instead claims that "she[] herself … was deceived and injured by" the alleged conduct. Br.22. But like Otis-Wisher, the *Buckman* plaintiffs "sought damages from [the manufacturer] under state tort law" for "injuries resulting from the use of" an allegedly unsafe device. *Buckman*, 531 U.S. at 343; *see also id.* at 346-47 (plaintiffs brought "a state-law cause of action" alleging that "the devices were … used to the plaintiffs' detriment"). Otis-Wisher's claims, which seek damages under state tort law for injuries allegedly caused by the Infuse device, are not materially distinguishable in this respect from the private tort claims held preempted in *Buckman*.

In fact, Otis-Wisher's contention that she does "does not complain of fraud on the FDA" (Br.22) is belied by her own brief. Her theory is that "Medtronic effectively circumvented the FDA [approval] process by having Infuse approved for a very limited purpose and then engaging in promotion activity to encourage physicians to use it in ways not approved by the FDA." Br.3; *see also* Br.30 (arguing Medtronic "did an 'end run'

around the FDA"). Yet that is what the *Buckman* plaintiffs alleged too: They alleged that they were injured after a manufacturer obtained FDA approval for use of a device in "the arms and legs" while actually intending that the device be used "in spinal surgery." 531 U.S. at 346.

Just as in *Buckman*, moreover, Otis-Wisher's claims would interfere with the FDA's "difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals." *Buckman*, 531 U.S. at 350. As in *Buckman*, the claims here could "discourage[]" manufacturers "from seeking … approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer … to unpredictable civil liability," and thus could "deter off-label use despite the fact that the FDCA expressly disclaims any intent to directly regulate the practice of medicine, and even though off-label use is generally accepted." *Id.* at 350-51 (citing 21 U.S.C. § 396). Indeed, because off-label use can constitute the standard of care for some patients (*see Caronia*, 703 F.3d at 153), allowing private suits predicated on the promotion of such uses would ultimately harm patients by "inhibit[ing], to the public's detriment, informed and intelligent treatment decisions" (*id.* at 166).

Courts have therefore rejected attempts to distinguish *Buckman* as "only appl[ying] to" claims labeled "fraud-on-the-FDA claims," holding that "*Buckman* cannot be read that narrowly." *Martin v. Medtronic, Inc.*, 32 F.Supp.3d 1026, 1034 n.22 (D. Ariz. 2014). For example, in *Perez*, 711 F.3d at 1119-20, the Ninth Circuit "appl[ied] *Buckman* to [a] fraud by omission claim based on a failure to disclose information to patients." *Martin*, 32 F.Supp.2d at 1034 n.22.

Finally, Otis-Wisher incorrectly contends that adhering to *Buckman* would "[i]n essence" preempt all claims that survive express preemption under *Riegel*. Br.6. Not so. As many courts have held, there remains a "narrow gap" between *Riegel* and *Buckman*. *Bryant*, 623 F.3d at 1204; *see also, e.g.*, *Perez*, 711 F.3d at 1120; *Caplinger*, 921 F.Supp.2d at 1215. A plaintiff can navigate that gap by asserting a traditional state-law cause of action based on conduct that violates a requirement imposed by the FDA through the PMA process and an identical state-law requirement.[18] That Otis-Wisher has failed to plead a non-preempted claim in this case does not mean that such claims do not exist.

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[18] For example, the plaintiff in *Bausch* was able to allege a traditional state-law manufacturing-defect claim based on a duty held to parallel federal manufacturing requirements. *See supra* note 7. Other plaintiffs

2. Claims that would impose a duty to seek FDA approval for additional warnings are impliedly preempted.

Otis-Wisher suggests that Medtronic was required to submit a PMA supplement seeking to modify Infuse's design or labeling. *See, e.g.*, Br.8-9, 10 (citing 21 C.F.R. § 814.39(a)). That suggestion rests upon a misreading of the federal regulations.[19] But even if federal law required Medtronic to submit a PMA supplement seeking to change the device or its labeling, any private claim based on that duty would be impliedly preempted.

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have also successfully navigated this gap. *See, e.g.*, *Purcel v. Advanced Bionics Corp.*, 2008 WL 3874713 (N.D. Tex. 2008); *Rollins v. St. Jude Med.*, 583 F.Supp.2d 790 (W.D. La. 2008).

[19] The regulation on which Otis-Wisher relies, 21 C.F.R. § 814.39(a), requires a PMA supplement *only* "before making a change affecting the safety or effectiveness of the device"—*i.e.*, before modifying the device's FDA-approved design or amending its FDA-approved label. But Medtronic never "ma[de]" any "change" to "the device" requiring FDA permission, and thus was never required to submit a PMA supplement. That Medtronic *could* have proposed a labeling change by submitting a PMA supplement cannot save Otis-Wisher's claims from preemption, because § 360k(a) prevents States from requiring an act that federal law merely "permits, but does not require." *McMullen*, 421 F.3d at 489; *see, e.g.*, *Scanlon v. Medtronic Sofamor Danek USA, Inc.*, --- F.Supp.3d ---, 2014 WL 3737501, at 6 n.10 (D. Del. 2014); *cf. Nat'l Meat Ass'n v. Harris*, 132 S.Ct. 965, 970-71 (2012) (preemption of state-law requirements "different from, or in addition to" federal requirements precludes state-law requirements that transform a "may" into a "must").

Any duty to communicate with the FDA about a possible design or labeling change "exist[s] solely by virtue of the FDCA," and thus may be enforced only by "the Federal Government rather than private litigants." *Buckman*, 531 U.S. at 349 n.4, 353. Accordingly, any claim based on that duty is preempted under *Buckman*, which holds that "federal … medical device laws pre-empt[] a state tort-law claim based on [a manufacturer's] failure to properly communicate with the FDA." *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, 2578 (2011).

As *Buckman* explains, "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Buckman*, 531 U.S. at 347. State-law claims that would require a manufacturer to communicate information to the FDA, such as by submitting a PMA supplement, "conflict with, and are therefore impliedly pre-empted by, federal law," because they interfere with the agency's authority to police its own requirements. *Id.* at 348. Such claims would create an "incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA[],"and would be inconsistent with the agency's decision not to punish certain violations on the ground that excessive

enforcement would "discourage[]" device manufacturers from entering the market by threat of "unpredictable civil liability." *Id.* at 350-51. Thus, private claims alleging that a manufacturer did not make required communications to the FDA "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350.

Moreover, the mere submission of a PMA supplement would not have resulted in the modification of Infuse's design or warning label, as purportedly demanded by state law. *Cf. Mensing*, 131 S.Ct. at 2578 (2011) ("State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label."). Instead, any change would have been dependent on the FDA's approval of the application. *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6) and 21 C.F.R. § 814.39(c)).

But any state-law claim requiring a manufacturer to change a device's design or labeling is impliedly preempted under *Mensing* unless the defendant manufacturer "could *independently* do under federal law what state law requires of it." 131 S. Ct. at 2579 (emphasis added). The mere possibility that "the Federal Government *might*" have approved a design or labeling change if Medtronic were to have submitted a PMA

supplement does not "suffice to prevent federal and state law from conflicting for Supremacy Clause purposes." *Id.* (emphasis in original). As *Mensing* explains, accepting a plaintiff's "conjectures" about what the FDA would have done if a PMA supplement had been submitted would "render[] … pre-emption all but meaningless" and deprive "the Supremacy Clause [of] any force." *Id.* Otis-Wisher therefore cannot pursue a claim that turns on whether the FDA would have approved a design or labeling change.

II. THE DISTRICT COURT CORRECTLY HELD IN THE ALTERNATIVE THAT OTIS-WISHER'S FRAUD CLAIMS ARE DEFICIENT.

A. The Fraud Claims Are Not Pleaded With Particularity.

A plaintiff alleging fraud "must state *with particularity* the circumstance constituting fraud or mistake." Fed. R. Civ. P. 9(b) (emphasis added). "The purpose of Rule 9(b)" is "to provide a defendant with fair notice of a plaintiff's claim, to safeguard a defendant's reputation from 'improvident charges of wrongdoing,' and to protect a defendant against the institution of a strike suit." *O'Brien v. Nat'l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991). To plead fraud with particularity, a complaint "must," at minimum, "(1) detail the statements (or omissions) that the plaintiff contends are fraudulent,

(2) identify the speaker, (3) state where and when the statements … were made, and (4) identify why the statements … are fraudulent." *Harsco Corp. v. Segui*, 91 F.3d 337, 347 (2d Cir. 1996).[20]

Applying this standard, the district court correctly held that Otis-Wisher's "[b]are bones allegations" are insufficient to satisfy Rule 9(b). JA45.

1. Otis-Wisher has not adequately alleged any false statement.

The district court correctly held that Otis-Wisher's complaint fails to satisfy Rule 9(b) because it does not allege the time, place, speaker, or contents of any particular false statement by Medtronic. JA44-45. Otis-Wisher merely alleges in conclusory terms that some unspecified person supposedly associated with Medtronic made some unspecified misrepresentation about Infuse in some unspecified manner at some

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[20] Otis-Wisher's negligent-misrepresentation claim must satisfy Rule 9(b) because it is "premised upon a course of [allegedly] fraudulent conduct." *Borsellino v. Goldman Sachs Grp., Inc.*, 477 F.3d 502, 507 (7th Cir. 2007). "Rule 9(b) applies to 'averments of fraud,' not claims of fraud, so whether the rule applies will depend on the plaintiffs' factual allegations." *Id.* Here, Otis-Wisher's negligent-misrepresentation claim is premised on the same factual allegations as her fraud claim and thus "implicate[s] Rule 9(b)'s heightened pleading requirements." *Id.* Having failed to satisfy those requirements, the claim is—as this Court held in *Harsco*—subject to dismissal. *See* 91 F.3d at 347-48 (affirming dismissal of negligent-misrepresentation claim under Rule 9(b) where claim was premised on same allegations as fraud claim).

unspecified time in some unspecified place to some other unspecified person or persons. JA44 (citing JA24-25, 32). She "has not alleged any particular statements or speaker(s) let alone when and where any such statements were made." JA45.

These "[b]are bones allegations" (JA45) are insufficient. "[F]raud allegations ought to specify the time, place, speaker, and content of the alleged misrepresentations." *DiVittorio v. Equidyne Extractive Indus.*, 822 F.2d 1242, 1247 (2d Cir. 1987). Allegations "which fail to specify the time, place, speaker, and … content of the alleged misrepresentations[] lack the 'particulars' required by Rule 9(b)." *Luce v. Edelstein*, 802 F.2d 49, 54 (2d Cir. 1986). Otis-Wisher's complaint specifies none of these things.

Conclusory allegations that "contain[] little by way of embellishment" do "not pass muster under Rule 9(b)." *Stern v. Leucadia Nat'l Corp.*, 844 F.2d 997, 1004 (2d Cir. 1988). Here, Otis-Wisher's "allegations of fraud are entirely conclusory and unsupported by assertions of facts." *Luce*, 802 F.2d at 54.

Recognizing that "off-label marketing … is itself not inherently fraudulent" (*In re Actimmune Mktg. Litig.*, 614 F.Supp.2d 1037, 1051 n.6 (N.D. Cal. 2009), *aff'd*, 464 F.App'x 651 (9th Cir. 2011)), other courts

have dismissed similar claims arising from alleged off-label promotion of the Infuse device where, as here, the complaint "is lacking in substantive, nonconclusory facts." *Kashani-Matts v. Medtronic, Inc.*, 2013 WL 6147032, at *5 (C.D. Cal. 2013). In *Kashani-Matts*, for example, the court dismissed a complaint that "fail[ed] to identify what specific misrepresentations or omissions form[ed] the basis for [the] [p]laintiff's claims," noting that "[t]he specific 'who, what, when, where, and how' of the alleged fraud … is not alleged." *Id.* Likewise in *Brady*, the court dismissed a complaint that did "not allege[] with specificity when, where, and by whom [any] representations were made, or the content of those representations." 2014 WL 1377830, at *8. And in *Zaccarello*, the court dismissed a complaint that "fail[ed] to identify (among other things) the particular misrepresentations and knowingly false statements that were made to [the plaintiff] and his physician." 2014 WL 3866607, at *7.

Rather than identify an allegation in her complaint that specifies a particular, purportedly false statement by Medtronic, Otis-Wisher now rests her claims on two insufficient bases, a Senate staff report that never resulted in any action against Medtronic and a securities action that was settled without any determination or admission of

liability. Br.28. As other courts have recognized, the staff report is "not relevant" (*Beavers-Gabriel v. Medtronic, Inc.*, 15 F.Supp.3d 1021, 1026 n.1 (D. Haw. 2014)) and suffers from "possible reliability issues" (*Caplinger*, 921 F.Supp.2d at 1226). Regardless, even if the staff report had been incorporated in Otis-Wisher's complaint, it would not help her, as it does not identify any purportedly false statement by Medtronic. Nor would Otis-Wisher's fraud claim be saved by any allegation in the securities action: Although the plaintiffs there alleged that Medtronic had falsely denied engaging in off-label promotion of Infuse, they did not allege that Medtronic made any false statements in the course of that alleged promotion. *See Minneapolis Firefighters' Relief Ass'n v. Medtronic, Inc.*, 278 F.R.D. 454 (D. Minn. 2011).

2. Otis-Wisher has not adequately alleged reliance.

Otis-Wisher's fraud allegations are insufficient in yet another respect: Having failed to identify any particular misrepresentation by Medtronic, she is unable to allege how she or her physicians *relied on* any such misrepresentations. "Missing from the complaint … is the connection between Defendants' alleged misdeeds and Plaintiff and Plaintiff's physicians—*i.e.*, that Plaintiff and Plaintiff's physicians relied on these misrepresentations." *Beavers-Gabriel*, 15 F.Supp.2d at

1038. Even if Otis-Wisher had alleged "who made misrepresentations about the Infuse device and when and where those misrepresentations were made," she still "has not alleged which misrepresentations were relied on by her and her surgeon." *Martin*, 32 F.Supp.3d at 1040.[21]

Instead, Otis-Wisher asks this Court to effectively dispense with the reliance requirement. She argues that "the scope of misconduct … was … 'so pervasive'" that the Court must "infer that the alleged practices tainted" her surgery despite her inability to allege any direct reliance. Br.28. But Otis-Wisher cannot evade her burden of alleging facts that, if true, would establish reliance by her physician on a specific misrepresentation by Medtronic. Arguing that Medtronic "'saturated' the market for information regarding [Infuse]" is insufficient, because that "'fraud on the market' theory" has been overwhelmingly rejected in the medical context. *In re Actimmune Mktg. Litig.*, 2009 WL 3740648, at *14 (N.D. Cal. 2009), *aff'd*, 464 F.App'x 651 (9th Cir. 2011); *Heindel v. Pfizer, Inc.*, 381 F.Supp.2d 364, 380 (D.N.J. 2004); *Coleman v. Danek Med., Inc.*, 43 F.Supp.2d 629, 635 n.4 (S.D. Miss. 1998); *cf. In re*

[21] Otis-Wisher's failure to allege reliance is especially glaring given that she filed her claims against Medtronic *after* deposing her physician. *See* ECF #71, at 22.

Sofamor Danek Grp., Inc., 123 F.3d 394, 403-04 (6th Cir. 1997) (refusing to allow state-law fraud and misrepresentations claims that "rest[] on a fraud-on-the-market theory"). To plead a fraud claim, Otis-Wisher must allege how she or her physicians *directly* relied on a particular false statement by Medtronic.

Otis-Wisher therefore errs in relying (Br.26-28) on a securities case, *Dexia SA/NV v. Bear, Stearns & Co.*, 929 F.Supp.2d 231 (S.D.N.Y. 2013), where—unlike here—the fraud-on-the-market doctrine did apply. A "fraud-on-the-market" presumption applies in securities-fraud cases because the securities markets "are efficient processors of public information" and "[i]f a market is generally efficient in incorporating publicly available information into a security's market price, it is reasonable to presume that a particular public, material misrepresentation will be reflected in the security's price." *Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 133 S.Ct. 1184, 1192 (2013). That presumption, which depends on the "unique nature of the public securities market," has no application to "other claims of garden-variety fraud." *Sikes v. Teleline, Inc.*, 281 F.3d 1350, 1363 (11th Cir. 2002). Thus, the fraud-on-the-market theory "has been resoundingly rejected outside the context of federal securities fraud litigation." *In re Schering-*

Plough Corp. Intron/Temodar Consumer Class Action, 2009 WL 2043604, at *20 (D.N.J. 2009).

The fraud-on-the-market theory has repeatedly been rejected in products-liability actions in particular, because it "is based on concepts and policies that simply do not apply in a products liability case." *Chudasama v. Mazda Motor Corp.*, 123 F.3d 1353, 1369 n.39 (11th Cir. 1997).[22] Consistent with national authority, this Court too has rejected application of the fraud-on-the-market doctrine in a personal injury case. *See McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 224 (2d Cir. 2008) (presumption of reliance inapplicable because cigarette market "anything but efficient").

Indeed, courts in other Infuse cases have held that plaintiffs "cannot pursue a 'fraud on the market' theory," because "courts have generally found such theories inapplicable to product liability cases." *Martin v. Medtronic, Inc.*, --- F.Supp.3d ---, 2014 WL 6633540, at *7 (D.

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[22] *See, e.g.*, *In re Gen. Motors Corp. Pick-Up Truck Fuel Tank Prods. Liab. Litig.*, 55 F.3d 768, 783 (3d Cir. 1995); *In re Cessna 208 Series Aircraft Prods. Liab. Litig.*, 2009 WL 274509, at *6 (D. Kan. 2009); *Gonzalez v. Proctor & Gamble Co.*, 247 F.R.D. 616, 624-25 (S.D. Cal. 2007); *Miller v. Gen. Motors Corp.*, 2003 WL 168626, at *4 (N.D. Ill. 2003); *Graham v. Am. Cyanamid Co.*, 2000 WL 1911431, at *6 (S.D. Ohio 2000), *aff'd*, 350 F.3d 496 (6th Cir. 2003).

Ariz. 2014). "[A]llegations of generalized misinformation in the marketplace [are] insufficient to satisfy" Rule 9(b), because such "allegations are little more than allegations of 'fraud on the market,' which … cannot carry the day in this type of case." *Butts v. Medtronic, Inc.*, 2014 WL 4762279, at *5 (Minn. Dist. Ct. 2014).

Unable to invoke the fraud-on-the-market presumption, Otis-Wisher must identify a specific misrepresentation and allege how she or her physician *actually* relied on it. Notably, Otis-Wisher filed her amended complaint against Medtronic *after* she had opportunity to depose her physician (*see* ECF #71, at 22), yet still is unable to say what, if any, misrepresentations her physician relied upon. Given that Otis-Wisher never sought to amend her claims against Medtronic, even after conducting discovery against Fletcher Allen Health Care (*see* ECF #105, at 1-2), one can only infer that her failure to plead facts sufficient to support her fraud claims is because she has no factual basis to support those claims.

3. Otis-Wisher has not adequately alleged agency.

In a last-ditch effort to save her claims, Otis-Wisher argues (Br.3-4, 5, 22, 29-30) that Dr. Braun was Medtronic's agent and that Medtronic is vicariously responsible for his actions (even though she

has settled her claims against Fletcher Allen Health Center, which "agree[d] to be responsible for, and liable for, any deviation from the standard of care by Dr. Braun" (JA11)).

But Otis-Wisher has not identified any fraudulent representation by Dr. Braun, much less alleged facts showing that Dr. Braun was acting as Medtronic's agent or acting within the scope of any agency when he treated her. Her argument rests on a single unsupported assertion (repeated several times) that "Dr. Braun had a financial and developmental relationship with Medtronic such that he actively promoted the use of that company's products." JA13, 24. That is insufficient to establish agency under Rule 8, much less under Rule 9(b).

Under Rule 9(b), "a plaintiff seeking to hold a principal liable for an agent's fraud must plead not only fraud but also agency with particularity." *Abels v. Farmers Commodities Corp.*, 259 F.3d 910, 916 (8th Cir. 2001). "The test of the relationship of principal and agent is the right to control. … There must be submission by the one giving service to the directions and control of the one receiving it as to the manner of performance." *Stevens v. Nurenburg*, 97 A.2d 250, 253 (Vt. 1953); *accord Kimco Leasing Co. v. Lake Hortonia Props.*, 640 A.2d 18, 20 (Vt. 1993) ("The agent must … be subject to the principal's control.")

(internal quotation marks omitted). Moreover, a principal can be held liable for the actions of its agent only as to "matter[s] within the scope of that agency." *State v. Ogden*, 640 A.2d 6, 11 (Vt. 1993).

Otis-Wisher contends that her surgeon, Dr. Braun, was Medtronic's agent "by virtue of his financial ties to Medtronic" (Br.29-30), but that is insufficient to establish agency as to the practice of medicine (which is the only type of agency relevant here), because Otis-Wisher nowhere alleges that Medtronic had a right to control the manner in which Dr. Braun treated patients. A financial relationship is not enough: Without the right to control the specific manner in which Dr. Braun performed his work, Dr. Braun would at most be an independent contractor—not an agent. *See Hathaway v. Tucker*, 14 A.3d 968, 976, 978 (Vt. 2010) (citing Restatement (Second) of Agency § 220(1) (1958)); *Morrisville Lumber Co. v. Okcuoglu*, 531 A.2d 887, 889 (Vt. 1987).

Nor has Otis-Wisher alleged that Dr. Braun was acting within the scope of any purported agency when he decided to use Infuse in her spinal-fusion surgery. Reaching outside the allegations in her complaint, Otis-Wisher points (Br.3-4) to a lawsuit filed by Dr. Braun against Medtronic. But the allegations in that lawsuit *contradict* her argument that Dr. Braun was paid to promote Infuse. The complaint

reveals that the subject of Dr. Braun's "developmental relationship" with Medtronic was "a system and method that is designed to treat scoliosis surgically *without need for a spinal fusion*"—in other words, a technology that *competes with* Infuse. Complaint at 2, *Braun v. Medtronic Sofamor Danek, Inc.*, No. 2:10-cv-01283 (D. Utah filed Dec. 30, 2010) (emphasis added). Even if Dr. Braun was Medtronic's agent with respect to the development of *that* device, the Infuse device and the surgery performed on Otis-Wisher were well outside the scope of that agency. *Cf. Talley v. Danek Med., Inc.*, 179 F.3d 154, 164 (4th Cir. 1999) (no liability where doctor's "consulting relationship with [the manufacturer] involved devices other than" the one at issue).

B. The Vermont Consumer Fraud Act Claim Also Fails Because Infuse Is Not A Consumer Good.

Vermont restricts claims under its Consumer Fraud Act (which has now been renamed the Consumer Protection Act) to claims that a plaintiff files in his or her capacity as a "consumer," defined as a "person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services … for his or her use or benefit or the use or benefit of a member of his or her household." Vt. Stat. Ann. tit. 9, § 2451a(a). The district court recognized that Otis-Wisher did not

receive Infuse as a "consumer" as defined under the statute, "because Infuse, a prescription medical device, is not purchased for personal use, but is instead prescribed by a doctor and installed in a patient." JA45-46.

The district court's conclusion is correct. As a prescription medical device sold only to licensed healthcare practitioners, Infuse cannot even be purchased by consumers.[23] While Medtronic is aware of no other cases addressing the applicability of Vermont's Consumer Fraud Act to medical-device manufacturers, courts in other jurisdictions applying similar laws have repeatedly held that medical devices such as Infuse are not consumer goods.[24] The dismissal of the Consumer Fraud Act claim should therefore be affirmed.

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[23] Otis-Wisher admits that "she did not directly purchase the Infuse [device] and that it was instead obtained and implanted by Dr. Braun." Br.29. She argues, however, that she qualifies as a consumer because she alleges "an agency relationship between Medtronic and Dr. Braun." *Id.* But even if an agency relationship allowed her to attribute *Dr. Braun's actions to Medtronic*, it would not allow *Otis-Wisher to stand in the shoes of Dr. Braun*, who she admits was the one who purchased and used the device.

[24] *See, e.g.*, *Smith v. Smith & Nephew, Inc.*, 5 F.Supp.3d 930, 932 (S.D. Ohio 2014); *Pease v. Abbott Labs., Inc.*, 2013 WL 174478, at *2 (D. Md. 2013); *Reeves v. PharmaJet, Inc.*, 846 F.Supp.2d 791, 798 n.2 (N.D. Ohio 2012); *Hogan v. Md. State Dental Ass'n*, 843 A.2d 902, 906 (Md. Ct. Spec. App. 2004); *Kanter v. Warner-Lambert Co.*, 122 Cal.Rptr.2d 72, 86 (Ct. App. 2002); *In re Minn. Breast Implant Litig.*, 36 F.Supp.2d 863, 876 (D. Minn. 1998); *Goldsmith v. Mentor Corp.*, 913 F.Supp. 56, 63

III. OTIS-WISHER'S CLAIMS ARE TIME-BARRED.

Because Otis-Wisher's claims are preempted, the district court did not reach Medtronic's argument that her claims against Medtronic are barred by the statute of limitations. *See* JA45. This Court, however, may affirm on any ground supported by the record. *See, e.g.*, *McCall v. Pataki*, 232 F.3d 321, 323 (2d Cir. 2000).

On the face of the amended complaint, all of Otis-Wisher's claims against Medtronic are time-barred. Under Vermont law, the statute of limitations for any "action[] to recover damages for injuries to the person arising out of any medical or surgical treatment or operation" is "three years [from] the date of the incident or two years from the date the injury is or reasonably should have been discovered." Vt. Stat. Ann. tit. 12, § 521.[25] Otis-Wisher's Infuse surgery took place in March 2008, and she began experiencing symptoms shortly thereafter. JA13-15. Yet it was not until February 2012, nearly *four years* after her Infuse procedure and more than three years after she began experiencing the

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(D.N.H. 1995); *Kemp v. Pfizer, Inc.*, 835 F.Supp. 1015, 1024 (E.D. Mich. 1993).

[25] Otis-Wisher's claims are also barred if they are construed as personal-injury claims. *See* Vt. Stat. Ann. tit. 12, § 512(4) (three-year limitations period for personal-injury claims).

symptoms she complains of, that Otis-Wisher amended her complaint to assert claims against Medtronic. JA4, 11. Those claims are untimely.

Nor can Otis-Wisher's claims be salvaged under the relevant discovery rule, which permits suit within "two years from the date the injury is or reasonably should have been discovered" (Vt. Stat. Ann. tit. 12, § 521), because the amended complaint establishes that Otis-Wisher knew of, and certainly "should have … discovered," her injury more than two years before she asserted claims against Medtronic. Otis-Wisher alleges that she began experiencing symptoms shortly after her surgery in March 2008, and specifically admits that she complained of these symptoms to her doctors in May, June, July, and August of 2008. *See* JA14-15. She further admits that by May 2009 she attributed these alleged injuries to Infuse, "express[ing] … frustration and concern about the use of BMP"—the active ingredient in Infuse—to her doctor. JA16. And Infuse's FDA-mandated warning label, which is public and published on the FDA's website, specifically warned that "[t]he safety and effectiveness of [Infuse] … implanted at locations other than the lower lumbar spine, or used in surgical techniques other than anterior … approaches, have not been established" (JA68), and that the injury Otis-Wisher allegedly experienced—"[e]ctopic and/or exuberant bone

formation"—is a known "potential adverse event[] which may occur with spinal fusion surgery with the InFUSE Bone Graft" (JA73-74).

Moreover, Otis-Wisher has admitted that in July 2008, the FDA issued a Public Health Notification (PHN) warning of serious complications from the use of Infuse in the cervical spine. ECF #71, at 3 n.1; *see* U.S. Food & Drug Admin., *Public Health Notification: Life-Threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion*, http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062000.htm (July 1, 2008). The PHN specifically warned of "the risks associated with the use of rhBMP products in the cervical spine," including "difficulty swallowing, breathing or speaking." *Id.* As Otis-Wisher admitted below (ECF #71, at 3), she experienced those same symptoms shortly after her surgery. *See, e.g.*, JA15 ("difficulty swallowing"); JA16 ("difficulty swallowing food and speaking"). Yet she did not assert any claims against Medtronic until well over three years after the PHN was made public.

All this establishes beyond dispute that Otis-Wisher knew of her injuries, and even attributed them to the off-label use of Infuse, in the year 2008, yet she did not assert claims against Medtronic until 2012—

after the three-year limitations period and the two-year discovery-rule period both expired. Those claims are therefore time-barred. *Cf. Raborn v. Albea*, 144 So.3d 1066 (La. Ct. App. 2014) (holding Infuse-related claims time-barred because device label placed plaintiff on notice of his claims).

Otis-Wisher argued below that some of her claims are nonetheless timely because they are supposedly governed by the six-year limitations period for fraud. *See* ECF #71, at 18. That is incorrect: "[I]t is the nature of the harm done, rather than the plaintiff's characterization of the cause of action, that determines which statute of limitations governs." *Eaton v. Prior*, 58 A.3d 200, 257 (Vt. 2012) (internal quotation marks omitted). The Vermont Supreme Court has accordingly held that the six-year limitations period for fraud does not apply when "the nature of the harm done" falls under another limitations provision, such as § 521. *See, e.g.*, *Stevers v. E.T. & H.K. Ide Co.*, 527 A.2d 658, 659 (Vt. 1987) (per curiam). Under the three-year limitations period established by § 521, all of Otis-Wisher's claims against Medtronic are time-barred.

CONCLUSION

The judgment below should be affirmed.

Dated: February 23, 2015

Respectfully submitted,

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/s/ *Andrew E. Tauber*
Andrew E. Tauber
Counsel for Defendants-Appellees

CERTIFICATE OF FILING AND SERVICE

I hereby certify, pursuant to Federal Rule of Appellate Procedure 25(c) and Second Circuit Rule 25.1, that on this 23rd day of February 2015, I caused a copy of the foregoing Brief for Appellees to be electronically filed with the Clerk of Court of the United State Court of Appeals for the Second Circuit by using the appellate CM/ECF system. All participants in this appeal are registered CM/ECF users and will be served by the appellate CM/ECF system. I further certify, pursuant to Second Circuit Rule 31.1, that I caused six paper copies of the foregoing brief to be filed with the Clerk of Court by overnight delivery.

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