ORAL ARGUMENT NEITHER REQUESTED NOR OPPOSED

No. 13-6061

IN THE
UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

PATRICIA CAPLINGER,

Plaintiff-Appellant,

v.

MEDTRONIC, INC., et al.

Defendants-Appellees.

On Appeal from the United States District Court
for the Western District of Oklahoma
in Case No. 5:12-cv-00630-M (Miles-Lagrange, 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:

Defendant-Appellee Medtronic Sofamor Danek USA, Inc. is a wholly-owned subsidiary of Medtronic Sofamor Danek, Inc., which is a wholly-owned subsidiary of Defendant-Appellee Medtronic, Inc., a publicly held corporation with no parent corporation. No publicly held corporation owns 10 percent or more of the stock of Medtronic, Inc.

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STATEMENT OF RELATED CASES

Pursuant to Tenth Circuit Rule 28.2(C)(1), Defendants-Appellees state that there are no prior or related appeals.

GLOSSARY

Br.__ Brief for Plaintiff-Appellant Patricia Caplinger

Dkt.__ Refers to district court pleadings as numbered in the district court docket (W.D. Okla. Case No. 5:12-cv-00630-M)

FDA U.S. Food and Drug Administration

FDCA Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*.

JA__ Joint Appendix

MDA Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. §§ 360 to 360n)

MDR Medical Device Report, also known as an adverse-event report (*see* 21 C.F.R. Part 803)

PMA Premarket Approval (*see* 21 U.S.C. § 360e; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-20 (2008))

STATEMENT OF THE ISSUES

1. Whether the district court correctly held that 21 U.S.C. § 360k(a) governs claims challenging the safety or effectiveness of a medical device that has been granted premarket approval by the FDA, as the Supreme Court held in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), irrespective of any allegation that the device was used or promoted in an off-label manner.

2. Whether the district court correctly held that all of the plaintiff's state-law tort claims are expressly preempted under § 360k(a) and *Riegel*, because they do not "parallel" any federal requirement and would impose state-law requirements that are "different from, or in addition to" the federal requirements, and/or impliedly preempted under 21 U.S.C. § 337(a) and *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), because federal law forbids private plaintiffs from bringing any action to enforce the federal medical-device regulations.

3. Whether the district correctly held in the alternative that the plaintiff's fraud claims must be dismissed because the complaint fails to plead fraud with particularity as required by Rule 9(b), and

whether the plaintiff's express-warranty claims must likewise be dismissed as deficiently pleaded.

INTRODUCTION

Plaintiff-Appellant Patricia Caplinger alleges that she was injured by a Class-III prescription medical device—Medtronic's Infuse® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device ("Infuse")—whose design, manufacture, and labeling were approved by the Food and Drug Administration (FDA) through the agency's Premarket Approval (PMA) process.

Two types of preemption limit the claims that can be brought against the manufacturer of a PMA-approved medical device:

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 through the PMA process. 21 U.S.C. § 360k(a); *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316, 323 (2008). Claims challenging the safety or effectiveness of a PMA-approved device survive express preemption under § 360k(a) only if they are "parallel" claims based on both a traditional state cause of

action *and* a specific federal requirement that *each* impose the *same* requirement.

Second, because 21 U.S.C. § 337(a) gives the federal government exclusive authority to enforce the FDCA, any claim for which "the existence of these federal enactments is a critical element"—that is, where liability cannot be established without reliance on the FDCA—is impliedly preempted. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

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). The 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*).'" *Id.*

As the district court found here, Caplinger's claims do not fit through the "narrow gap" between § 360k(a) and *Riegel*, on the one hand, and § 337(a) and *Buckman*, on the other. Each claim is expressly

and/or impliedly preempted, and the decision below should therefore be affirmed.

STATEMENT OF THE FACTS

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 in the MDA. H.R. Rep. No. 94-853, at 45 (1976). That express-preemption clause provides 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 illness or injury" are

designated "Class III" devices. 21 U.S.C. § 360c(a)(1)(C)(ii). Innovative Class III devices, like Infuse, "incur the FDA's strictest regulation" and must receive premarket approval (PMA) from the FDA before they are sold. *Buckman*, 531 U.S. at 344.

"Premarket approval is a 'rigorous' process." *Riegel*, 552 U.S. at 317. A manufacturer "must submit a detailed PMA application" that contains, among other things, "specimens of the proposed labeling for the device." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 109 (2d Cir. 2006), *aff'd*, 552 U.S. 312 (2008). 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, manufacture, or labeling is inadequate, it can require revisions prior to approval. *See id.* at 319.

The FDA's regulatory role does not end with approval of a PMA application. "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." *Id.* at 319.

The FDA has exclusive enforcement authority under the FDCA. Congress has specified that all actions to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Although "citizens may report wrongdoing and petition the agency to take action," private plaintiffs cannot enforce the FDCA. *Buckman*, 531 U.S. at 349 & n.4. Instead, the FDA is authorized to investigate violations and "has at its disposal a variety of enforcement options that allow it to make a measured response" to any wrongdoing, including "injunctive relief, 21 U.S.C. § 332, and civil penalties, 21 U.S.C. § 333(f)(1)(A); seizing the device, § 334(a)(2)(D); and pursuing criminal prosecutions, § 333(a)." *Id.* at 349.

B. Off-Label Use Of Medical Devices

The FDA's oversight of medical devices is subject to 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 administer a legally marketed device to any patient for

any condition or disease." 21 U.S.C. § 396. Thus, while Congress established the premarket approval system to help ensure that certain devices present a reasonable assurance of safety and effectiveness, Congress was also 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*.

Caplinger alleges that her physician used Infuse in an "off-label" manner—*i.e.*, in a manner not indicated on the device's FDA-approved labeling. *See, e.g.*, JA6, 21. Caplinger refers to such uses as "unapproved uses," but 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). Rather than approve or disapprove particular *uses*, the FDA instead approves or disapproves *devices*.

Off-label use of medical devices is lawful and commonplace. The Supreme Court has explained that "'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; *see also Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 197 (4th Cir. 2001) ("Once the FDA has cleared a device … physicians may use the device in any manner they determine to be best"). Accordingly, 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).

C. Premarket Approval Of The Infuse Medical Device

Caplinger admits that the FDA granted premarket approval to Infuse in 2002 after nearly 1½ years of agency scrutiny. JA10; *see* JA75, 80. Upon approval, the agency published the InFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device Important Medical Information, which reflects the text of Infuse's FDA-approved labeling.[1] JA91-106.

D. Caplinger's Claims And The Proceedings Below.

Caplinger alleges that she underwent a "posterior lumbar interbody fusion surgery" using Infuse in 2010. JA20. According to

[1] 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).

Caplinger, a "Medtronic representative" was "present prior to and during the surgery … and provided information regarding Infuse." JA21. Caplinger alleges that her surgeon "used an off-label posterior approach to place the Medtronic Infuse bone graft into the lumbar region" of her spine. *Id.* The alleged posterior approach was off-label because Infuse's label instructs that the device "is to be implanted via an anterior … approach." JA93, 107. Caplinger further alleges that following surgery she experienced various "symptoms … resulting from … exuberant bone growth caused by the use of Infuse." JA21.

Caplinger asserted claims against Medtronic for fraudulent misrepresentation, fraud in the inducement, constructive fraud, strict-liability failure to warn, strict-liability design defect, breach of express and implied warranty, negligence, and negligent misrepresentation. JA26-39. The gravamen of each claim is that Medtronic should have designed Infuse differently or should have given different or additional warnings.

The district court granted Medtronic's motion to dismiss, concluding in its extensive analysis that all of Caplinger's claims are preempted and, in addition, that her fraud claims are not pleaded with

the required particularity. JA43-70. It held that Caplinger's 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)." JA60, 63, 64, 65, 67. It further held that any claim "based upon defendants' promotion and marketing of the Infuse Device for off-label uses" is "impliedly preempted under *Buckman* and § 337(a)." JA55-56, 60-61, 67-68. And as to Caplinger's fraud claims, the district court also held that they "should be dismissed because [they are] not pled with particularity as required by Federal Rule of Civil Procedure 9(b)." JA61-62, 62-63.

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 federal medical-device regulations.

There is no merit to Caplinger's argument that § 360k(a) does not apply when a device is used or promoted in an off-label manner. To

start, Caplinger waived this argument by failing to present it to the district court. But even if it were not waived, it is wrong. Nothing in § 360k(a) turns on how a device is used or promoted after FDA approval. When the FDA grants premarket approval to a device, § 360k(a) governs *any* state-law claim challenging the device's safety or effectiveness. Caplinger's contrary position misrepresents the premarket approval process; is inconsistent with the statutory text as well as *Riegel*; and would undermine Congress's goal of protecting innovation in the development of life-saving and life-enhancing medical devices.

Caplinger does not allege that the design or labeling of her Infuse device was anything other than what was required by the FDA. Instead, she alleges that Medtronic should have designed Infuse differently, or should have given different or additional warnings about the device. But such 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 Caplinger's claims is a

parallel claim. To be "parallel," the state-law duty must be "identical" to an existing federal requirement. In the district court, Caplinger argued that her claims parallel a purported federal restriction on off-label promotion; but that assertion fails because, among other reasons, there is no state-law duty "identical" to any federal requirement to abstain from off-label promotion. In this Court, Caplinger also argues that her claims parallel the federal duty to report adverse events to the FDA. That argument is waived, because Caplinger did not raise it below, and cannot be sustained, because her complaint does not allege *any* supporting facts. Even if it were adequately alleged and not waived, however, the argument fails because, among other reasons, there is no state-law duty to report information *to the FDA*.

Caplinger's claims also are impliedly preempted. Through § 337(a), Congress gave exclusive power to enforce the FDCA and its implementing regulations to the FDA. Caplinger's claims do not rest on any independent state-law duty; any duty to abstain from off-label promotion and any duty to report information to the FDA exist solely under the FDCA. Private actions to enforce these federal requirements are forbidden.

Finally, Caplinger's fraud and express-warranty claims fail for the additional reason that they are inadequately pleaded. The district court correctly held that the fraud claims are not pleaded with the required particularity. And the express-warranty claim fails because Caplinger's complaint does not identify any express warranty and because Medtronic validly disclaimed all warranties regarding Infuse.

ARGUMENT

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" (H.R. Rep. No. 94-853, at 12), and recognizing the "undu[e] burden[]" on device manufacturers when "differing requirements … are imposed by jurisdictions other than the Federal government" (*id.* at 45), Congress enacted § 360k(a) as a "general prohibition on non-Federal regulation" of medical devices (*id.*). 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.[2]

In addition, the FDCA's no-private-right-of-action clause, 21 U.S.C. § 337(a), impliedly preempts any private action to enforce the FDCA. Congress granted the FDA exclusive authority to enforce the medical-device regulations 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

[2] Contrary to Caplinger's contention that her claims survive under a "presumption against preemption," the *Riegel* Court rejected the argument that such a presumption applies in the medical-device context. The Court rejected the dissent's reliance on that presumption because "the text of the statute" 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).

reliance on the FDCA and that thereby amount to private enforcement of its provisions.

Although Congress's broad 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.[3]

Caplinger cannot be allowed to circumvent Congress's carefully crafted regulatory scheme. Congress recognized that state tort litigation poses a grave risk to public health by inhibiting the

[3] A person injured by a PMA-approved device may still sue the manufacturer, notwithstanding § 360k(a), if the manufacturer failed to adhere to the device's PMA requirements—*e.g.*, by failing to provide the FDA-mandated warnings or to adhere to the FDA-mandated manufacturing process.

development of life-saving 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 tort suits are ill-suited for 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.

I. SECTION 360k(a) GOVERNS CAPLINGER'S CLAIMS.

The Supreme Court held in *Riegel* that when "the federal government has established requirements applicable to" a medical device, 21 U.S.C. § 360k(a) governs any state-law claim challenging the safety or effectiveness of the device. *Riegel*, 552 U.S. at 321. The Court further held that "[p]remarket approval … imposes [federal] 'requirements'" as that term is used in § 360k(a). *Id.* at 322-23.

Finally, the Court held that state common-law claims impose "requirements … 'with respect to devices'" as that term is used in § 360k(a). *Id.* at 327.

Thus, *Riegel* establishes that § 360k(a) governs any state-law claim involving the safety or effectiveness of a PMA-approved device. Since *Riegel*, "courts across the country have applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence, to breach of warranty, to failure to warn and manufacturing-and-design-defect, to negligence *per se*." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (internal citations omitted), *aff'd sub nom. Bryant*, 623 F.3d 1200.

Because the FDA's premarket approval of Infuse established federal requirements for the Infuse device, the district court was correct that Caplinger's claims are governed by § 360k(a) and *Riegel*. Caplinger did not even dispute this below: She argued that § 360k(a) permits her to bring claims that "parallel" the federal requirements, but did not deny that her claims must be analyzed under § 360k(a) and *Riegel*. *See generally* Dkt.33.

Unable to convince the district court that her claims are in fact parallel claims, Caplinger now changes course and argues that her claims are not governed by § 360k(a) after all. She now insists that § 360k(a) does not apply when a PMA-approved device is used or promoted in an off-label manner.

Caplinger waived this argument by failing to raise it below; but even if not waived, it is wrong. Nothing in § 360k(a) turns on how a device is used or promoted. When the FDA grants premarket approval to a device, § 360k(a) governs *any* state-law claim challenging the device's safety or effectiveness.

A. Caplinger Waived The Argument That § 360k(a) Does Not Apply.

Caplinger has forfeited the argument that § 360k(a) does not govern her claims. Arguments not raised in the district court are "waived for purposes of appeal." *Quigley v. Rosenthal*, 327 F.3d 1044, 1068 n.13, 1069, 1072 (10th Cir. 2003). Waiver applies when "'a litigant changes to a new theory on appeal that falls under the same general category as an argument presented at trial' or presents 'a theory that was discussed in a vague and ambiguous way.'" *Bancamerica Commercial Corp. v. Mosher Steel of Kan., Inc.*, 100 F.3d 792, 798-99

(10th Cir. 1996). Caplinger's argument that § 360k(a) does not govern her claims at all was not raised below; accordingly, it has been waived. *Shrock v. Wyeth, Inc.*, 2013 WL 4529359, at *9 (10th Cir. 2013).

B. Section 360k(a) Applies Regardless How An FDA-Approved Device Is Used.

Caplinger's principal argument on appeal is that the FDA's premarket approval of Infuse was supposedly limited to indicated uses, and that § 360k(a) does not apply when a device is used in an off-label procedure. *See, e.g.*, Br.25 ("The FDA has never approved [Infuse] for [posterior-approach surgery] and hence has never imposed requirements … for that use."). Even if she had not waived this argument, she is wrong on both counts.

1. The FDA approves *devices*, not *uses*.

Contrary to Caplinger's representations, when the FDA grants premarket approval to a device, that approval establishes requirements for *the device* in general, and is not limited to particular *uses* of the device. *See, e.g.*, *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) ("The PMA covers devices—not applications.").

That the FDA grants premarket approval to devices rather than uses is a necessary consequence of Congress's decision to forbid the FDA from regulating the practice of medicine. Although Congress created the premarket approval process to allow the FDA to review devices before they may be sold, Congress explicitly forbade the FDA from restricting how a device may be used once approved. *See* 21 U.S.C § 396 ("Nothing in this chapter shall … limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease"); *Buckman*, 531 U.S. at 350. Doctors may use approved devices in any manner they deem appropriate. *Cooper*, 259 F.3d at 197. The FDA's approval process imposes federal requirements on the *device*, irrespective of how it is later *used* by physicians.

Also contrary to Caplinger's suggestion, the FDA *does* consider off-label uses when deciding whether to grant premarket approval. As the Second Circuit recently recognized, the FDA's "approval process generally contemplates that approved [medical products] will be used in

off-label ways." *Caronia*, 703 F.3d at 166. Indeed, Caplinger acknowledges that the FDA considered possible off-label uses before approving the Infuse device. *See* JA12 ("[B]efore the product was approved … an FDA advisory committee reviewing Infuse asked agency staff for recommendations on 'guarding against off-label use of this product.'"). And when the FDA ultimately approved Infuse, the agency required that the device's label include warnings regarding off-label uses. *See* JA94 ("The safety and effectiveness of [Infuse] … used in surgical techniques other than anterior … approaches have not been established."); *see also*, *e.g.*, JA91 (warning against use without the LT-Cage component); JA94 (warning against use "at locations other than the lower lumbar spine").

Caplinger's assertion (Br.7-8, 27-28) that off-label uses are not considered during the PMA process rests on statutory language directing the agency to evaluate the safety and effectiveness of a device under "the conditions of use included in the proposed labeling." 21 U.S.C. § 360e(d)(1)(A). But the fact that premarket approval requires a finding that there is a reasonable assurance that the device is safe and effective under "the conditions of use included in the proposed labeling"

does not mean that potential off-label uses are not considered during the approval process. On the contrary, the FDA could determine that a device would not be safe and effective under "the conditions of use included in the proposed labeling" precisely *because* the proposed labeling does not adequately discourage off-label use, and can mandate the inclusion of warnings regarding off-label use as a condition of approval—as it did for Infuse.

2. Limiting application of § 360k(a) to particular uses is contrary to the statutory text and *Riegel*.

Caplinger's argument that the application of § 360k(a) somehow depends on how a device is used is inconsistent with the statutory text. By its plain terms, § 360k(a) applies whenever the FDA has established requirements that apply "to the *device*." 21 U.S.C. § 360k(a)(1) (emphasis added). Nothing in § 360k(a) limits its application to particular *uses* of the device. That is as it must be, because the FDA approves only devices themselves—not how approved devices may be used, a decision Congress committed to doctors' professional judgment.

Other courts have held that the language of § 360k(a) applies irrespective of how an approved device is used. As explained by one court, and followed by the district court here (JA58-59),

> under § 360k(a)(1), the question is not whether there are federal requirements applicable to a particular *use* of a device; the question is whether there are federal requirements applicable 'to the *device*.' If there are—and, as *Riegel* makes clear, the PMA process unquestionably imposes such requirements—then any state requirements that are different from, or in addition to, those federal requirements are preempted. *Nothing in the statute suggests that the preemption analysis somehow depends on how the device is used.*

Riley v. Cordis Corp., 625 F. Supp. 2d 769, 779 (D. Minn. 2009) (emphasis added); *accord Gavin v. Medtronic, Inc.*, 2013 WL 3791612, at *11 (E.D. La. 2013) (same). Accordingly, allegations of off-label use do not remove claims from the preemptive scope of § 360k(a).[4]

Caplinger's assertion that § 360k(a) does not govern claims arising from the off-label use of an approved device is also contrary to the Supreme Court's decision in *Riegel*. The claims held preempted in *Riegel* arose from an off-label procedure: The label stated that the device was not to be used in patients with diffuse or calcified stenoses and was not to be inflated above 8 atmospheres of pressure, yet the

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[4] *See also Houston v. Medtronic, Inc.*, 2013 WL 3927839, at *7 (C.D. Cal. 2013) ("[E]ven though Plaintiff was not implanted with the Infuse Device in an approved manner, her state claims are oriented 'with respect to' the off-label promotion and use of a device that is covered by federal requirements. This suffices to bring her state law claims within the ambit of express preemption under *Riegel*."); *Lawrence v. Medtronic, Inc.*, 2013 WL 4008821, at *3 (Minn. Dist. Ct. 2013) (similar).

plaintiff had diffuse and calcified stenoses and the physician inflated the device to 10 atmospheres. 552 U.S. at 320. If § 360k(a) did not apply to off-label uses of a device, as Caplinger argues, then the claims in *Riegel* would not have been preempted. But *Riegel* applied § 360k(a) and held the plaintiff's claims expressly preempted thereunder. Thus, Caplinger's "argument is clearly inconsistent with *Riegel* which also involved the off-label use of a medical device." *Gavin*, 2013 WL 3791612, at *12.[5]

Capliner's argument is also inconsistent with *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013), in which the plaintiffs alleged that the defendant had promoted and facilitated off-label use of a device. *Id.* at 1113. Notwithstanding these allegations, the Ninth Circuit applied § 360k(a) and held that the plaintiffs' fraud-by-omission claim was expressly preempted. *Id.* at 1118. The same conclusion follows here.

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[5] For these reasons, *McDonald-Lerner v. Neurocare Associates, P.A.*, No. 373859-V (Md. Cir. Ct. 2013), erred in holding that § 360k(a) does not apply when a device is used off-label. As other courts have recgonized, the "federal requirements 'applicable … to the device' for purposes of § 360k … are not 'use-specific'; they do not purport to apply only to approved uses of Infuse." *Ramirez v. Medtronic, Inc.*, 2013 WL 4446913, at *7 (D. Ariz. 2013). "[B]ecause the requirements are not use-specific, a claim arising solely from the off-label use of a device could face preemption." *Id.* at *8. *But see infra* note 8 (explaining that *Ramirez* erred on other grounds).

3. Limiting application of § 360k(a) to particular uses would undermine Congress's goals.

There is good reason why Congress did not limit preemption under § 360k(a) to particular uses of a device. Once a device is approved, the FDA does not control how it is used, since Congress explicitly forbade the FDA from regulating the practice of medicine. *See supra* pp.5-7.

If preemption applied only when a device is used for labeled indications, as Caplinger contends, device manufacturers would be denied the protection that Congress afforded them under § 360k(a) whenever a physician decides to use a device in an off-label manner—even though the physician can make that decision unilaterally, and can do so after the device has left the manufacturer's control. If that were so, manufacturers of innovative medical devices would be "expose[d] … to unpredictable civil liability" (*Buckman*, 531 U.S. at 350)—precisely the scenario that Congress, determined to foster the development of life-enhancing medical devices, sought to avoid by enacting § 360k(a). *See* H.R. Rep. No. 94-853, at 12, 45; *Riegel*, 552 U.S. at 316.[6]

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[6] A patient injured through a physician's off-label use of a PMA-approved device is not without recourse. The patient may sue his or her physician if the treatment was, under the circumstances, contrary to recognized standards of medical care.

C. Section 360k(a) Applies Regardless How An Approved Device Is Promoted.

Perhaps recognizing that application of § 360k(a) cannot turn on how physicians decide to *use* an approved device, Caplinger at times frames her argument in terms of how the device is *promoted*. *Cf.* Br.29-30. But, as the district court correctly concluded (JA59), application of § 360k(a) does not depend on how a device is promoted.

The suggestion that off-label promotion renders § 360k(a) inapplicable finds no support in the statutory text, which does not condition preemption on how a device is promoted. As another court has stated, "nothing in § 360k(a) or *Riegel* suggests that applicability of the preemption analysis depends on how the device is being promoted to be used." *Gavin*, 2013 WL 3791612, at *11.

Indeed, conditioning application of § 360k(a) on how a device is promoted would produce logically inconsistent results that cannot be reconciled with the statute as interpreted in *Riegel*. If preemption turned on how a device is promoted, then claims arising from a doctor's unilateral decision to use an approved device in an off-label manner would be subject to § 360k(a), but claims arising from another doctor's decision to make the *same* use of the *same* device would *not* be subject

to § 360k(a) if that doctor's decision resulted from off-label promotion. That cannot be correct, because, as the Supreme Court stated in *Riegel*, whether § 360k(a) applies depends on "whether the Federal Government has established requirements applicable to" the device. 552 U.S. at 321. For any given device at any given time, the federal government either has established requirements applicable to that device or it has not.[7] It is not possible for there to be federal requirements "applicable … *to the device*" (21 U.S.C. § 360k(a) (emphasis added)) when the device is used by one doctor, but not when the *same* device is put to the *same* use by a different doctor.[8]

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[7] Caplinger attempts to reconcile her argument with § 360k(a) by contending that there are federal requirements "applicable" to a device only when it is marketed for on-label uses. Br.29. But if that were correct, then a device promoted for off-label use would not be subject to—and need not comply with—*any* "requirement[s] applicable under [the FDCA]." 21 U.S.C. § 360k(a)(1). That is plainly incorrect, and is contradicted by Caplinger's own contentions that Medtronic violated federal requirements applicable to the Infuse device.

[8] For these reasons, *Ramirez* erred in holding that off-label promotion renders § 360k(a) inapplicable. *See Alton v. Medtronic, Inc.*, 2013 WL 4786381, at *22 (D. Or. 2013) (explaining that *Ramirez* rests "on a flawed premise" because it fails to recognize that premarket approval "impos[es] … device-specific requirements on a medical device without regard to the application or use in connection with which the FDA issued such approval").

II. CAPLINGER'S CLAIMS ARE EXPRESSLY PREEMPTED UNDER § 360k(a).

Caplinger's claims are expressly preempted. Caplinger does not allege that Medtronic failed to provide any of the warnings required by the FDA, and does not allege that the design of her Infuse device was anything other than that approved by the FDA. Instead, she claims that Medtronic was, as a matter of state law, required to give *additional* warnings or to employ a *different* design. But because this would impose state-law requirements "different from, or in addition to," the federal requirements imposed by the FDA through the PMA process, Caplinger's claims are barred by § 360k(a). *See Riegel*, 552 U.S. at 320, 329; *Bryant*, 623 F.3d at 1205-06; *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489-90 (7th Cir. 2005).[9]

There is a narrow exception to express preemption for claims that "'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330. But to be "parallel," the Supreme Court has said, a state-law requirement must be "identical" to an existing federal requirement. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996); *accord McMullen*, 421

[9] In fact, these claims would affirmatively *conflict with* federal law. *See infra* pp.56-57.

F.3d at 489 (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. Styker Corp.*, 818 F. Supp. 2d 1032, 1037 (W.D. Ky. 2011).

To state a "parallel" claim, a plaintiff must allege (1) the violation of a specific federal requirement applicable to the device; (2) the violation of an identical, but independent, state-law duty; and (3) that the predicate federal violation caused his or her injuries. *See, e.g.*, *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300-01 (11th Cir. 2011); *McMullen*, 421 F.3d at 488-89.[10]

Caplinger is therefore wrong when she asserts that state-law claims constitute parallel claims that escape preemption whenever a

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[10] *Alton*, a recent but erroneous magistrate decision, holds that "*Lohr* and its progeny contemplate two types of 'parallel' state-law claims"—claims predicated on identical federal and state duties, and claims "premised on conduct that contravenes state-law duties of such generality as not to present any risk of interference with the federal medical-device regulatory scheme." 2013 WL 4786381, at *23. But the purported second type of parallel claim does not exist. On the contrary, *Riegel* expressly *rejected* the contention that claims based on general state-law duties escape preemption under § 360k(a), holding that "[n]othing in the statutory text suggests that the pre-empted state requirement must apply *only* to the relevant device, or only to medical devices and not to all products and all actions in general." *Riegel*, 552 U.S. at 328.

plaintiff alleges that "the same conduct that violated federal device requirements [also] violated … state-law duties." Br.32. 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). Caplinger's focus on *conduct* misunderstands the law.

Because § 360k(a) does not permit States to impose different or additional requirements on medical devices, the most that States may do under § 360k(a) is provide a damages remedy for violation of a requirement that exists under both federal and state law.[11] *Riegel*, 552 U.S. at 330; *Lohr*, 518 U.S. at 495. "Thus, although [*Lohr*] 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 state-law claim." *Buckman*, 531

[11] 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 FDCA. *Buckman*, 531 U.S. at 353. Thus, a claim that escapes preemption under § 360k(a) might still be barred by § 337(a). *See infra* pp.43-45 & n.17.

U.S. at 353 (emphasis added).[12]

A. Caplinger's Claims Do Not Parallel Any Federal Requirement To Abstain From Off-Label Promotion.

Caplinger contends that her claims parallel a purported federal prohibition on off-label promotion. That argument fails because she cannot satisfy any of the three elements of a parallel claim.

First, as held by the Second Circuit subsequent to the decision below, federal law does not expressly prohibit—and cannot be construed to prohibit—off-label promotion. *See Caronia*, 703 F.3d at 154 ("The FDCA and its accompanying regulations do not expressly prohibit the 'promotion' or 'marketing' of [devices] for off-label use."); *id.* at 160 (the FDCA does "not criminaliz[e] the simple promotion of a [device]'s off-

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[12] Caplinger quotes dictum in *Bausch v. Styker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010), stating that § 360k(a) "provides immunity for manufacturers … to the extent that they comply with federal law, but … does not protect them if they have violated federal law." Br.40; *see also* Br.34-35. But that gross oversimplification is an incomplete statement of the law, and *Bausch* did not purport to hold that *any* federal violation supports *any* state-law claim. On the contrary, *Bausch* recognized that a claim escapes preemption under § 360k(a) only if it rests on a state-law duty that is "'genuinely equivalent'" to a federal requirement. 560 F.3d at 552. In *Bausch*, the plaintiff's state-law *manufacturing*-defect claim was deemed a parallel claim because it rested on allegations that the defendant had violated federal *manufacturing* requirements. *See id.* at 558-59. No such parallel claim is presented here.

label use"); *see also Dawson v. Medtronic, Inc.*, 2013 WL 4048850, at *6 (D.S.C. 2013) ("[F]or any of these claims to survive …, the court must accept Plaintiff's premise that off-label promotion is illegal under the FDCA, and this court cannot do so."). Absent a federal requirement that manufacturers abstain from off-label promotion, Caplinger cannot state a parallel claim based on off-label promotion.[13]

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[13] Caplinger attempts to derive an implicit federal prohibition on off-label promotion from the FDCA's misbranding provision (Br.8-9), but that is exactly the argument *Caronia* and *Dawson* rejected. *See Caronia*, 703 F.3d at 160 ("While the FDCA makes it a crime to misbrand … a [device], the statute and its accompanying regulations do not expressly prohibit … off-label promotion."); *Dawson*, 2013 WL 4048850, at *6 ("Federal law clearly prohibits misbranding, but … [t]his court is not convinced that off-label promotion violates the FDCA.") (citation omitted). We anticipate that Caplinger will argue that *Caronia* is inapplicable because she contends that the purported off-label promotion was misleading rather than truthful and because *Caronia* applied the canon of constitutional avoidance in a criminal case. There is no merit to either suggestion, because the "misbranding" provision that purportedly prohibits off-label promotion, 21 U.S.C. § 352(f), does not differentiate between true and false statements. Supreme Court precedent holds that a statutory construction adopted to avoid constitutional concerns with respect to one category of conduct applies with respect to all other categories 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); *see also Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004) (courts "must interpret the statute consistently, whether [they] encounter its application in a criminal or noncriminal context").

Second, even if federal law did restrict off-label promotion, that restriction could not give rise to a parallel claim because there is no independent *state-law* prohibition on off-label promotion. As the district court correctly observed, "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." JA61, 68; *accord, e.g.*, *Lawrence v. Medtronic, Inc.*, 2013 WL 4008821, at *5 (Minn. Dist. Ct. 2013) ("There is no … state cause of action that addresses … off-label promotion of a device which has received the FDA's premarket approval."); *Gavin*, 2013 WL 3791612, at *17 ("There is no Louisiana state law claim premised on off-label promotion. Indeed, the very concept of 'off-label' use and promotion is derived entirely from the federal regulatory system"); *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.' The concept is entirely federal."); *see also Eidson v. Medtronic, Inc.*, 2013 WL 5533081, at *15 (N.D. Cal. 2013) ("Defendants' conduct is only allegedly 'negligent' because the FDCA [allegedly] bans off-label promotion."). Nowhere in Caplinger's brief does she challenge that conclusion or identify any state-law authority recognizing such a claim.

Unable to identify a state-law prohibition on off-label promotion, Caplinger instead relies on "the state-law duty to warn." Br.35; *see also* Br.37 (invoking "the duty to warn under state law"). 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," because a manufacturer could fully comply with the federal requirement by abstaining from any off-label promotion, yet be held in violation of state law for failing to warn about risks associated with foreseeable off-label uses. Thus, as the district court correctly observed,

> 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 … [and] not produce a product with a defective design. It is possible to violate the state law requirement while complying with the federal requirement and vice versa.

JA59 n.4. The district court's analysis echoes the Seventh and Eleventh Circuits' holdings that "[s]tate and federal requirements are not genuinely equivalent"—and thus are not parallel—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.

Finally, Caplinger cannot satisfy the third requirement for a parallel claim because she cannot establish the requisite causal link between the alleged federal violation and her alleged injury. Caplinger, who alleges that she suffered injury caused by exuberant bone growth following implantation of the Infuse device via a posterior approach to the spine (*see* JA8, 21), cannot claim that her alleged injury resulted from any failure to warn, because she and her surgeon *were* warned of the relevant risks. Infuse's FDA-approved label explicitly warns that the device "is to be implanted via an anterior … approach" and that its "safety and effectiveness … in surgical techniques other than anterior … approaches have not been established." JA93-94. The label further warns that "exuberant bone formation" is among the "potential adverse events which may occur." JA99-100. Given these warnings, Caplinger cannot show injury resulting from a failure to warn about the risks of a posterior approach or of exuberant bone growth, or her physician justifiably relied on any unspecified misrepresentations regarding these risks. *See Rounds v. Genzyme Corp.*, 440 F. App'x 753, 754-55 (11th

Cir. 2011) (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]"); *Giannacopoulos v. Credit Suisse*, 37 F. Supp. 2d 626, 633 (S.D.N.Y. 1999) ("[W]here parties have access to information that could expose a misrepresentation, courts will not find their reliance sufficiently justifiable to merit legal protection.").

B. Caplinger Does Not And Cannot Assert Claims Parallel To FDA Reporting Requirements.

Although Caplinger did not argue in the district court that her claims are parallel to FDA reporting requirements, her brief to this Court contends (without explanation) that her claims "parallel[] the applicable federal requirement[] to submit required reports of data from clinical investigations." Br.35. Her brief also includes two cursory citations to 21 C.F.R. § 803.50, which requires device manufacturers to report adverse events to the FDA. *See* Br.36, 38. Yet even if these passing references were adequate to present an argument never pressed below, her state-law tort claims are not in fact parallel to any federal reporting requirements.

As a threshold matter, Caplinger waived reliance on these provisions by failing to invoke them in the district court, and by failing

to address them in any detail in her brief to this Court. Caplinger's brief in the district court did not mention any failure to file adverse-event reports and did not make any reference to § 803.50. *See generally* Dkt.33. And she has never explained, in the district court or in this Court, how any of her claims parallel federal reporting requirements. Caplinger has therefore forfeited any argument based on an alleged failure to file adverse-event reports. *Shrock*, 2013 WL 4529359, at *9.

Waiver aside, the argument must be rejected because Caplinger's complaint fails to allege *any* supporting facts. The complaint does not allege that Medtronic knew of any relevant adverse events that it failed to report to the FDA; that Caplinger's surgeon would have seen any adverse-event reports had they been submitted to the FDA; or that her surgeon would have acted differently had he seen them. Thus, the complaint does not adequately allege either a violation or causation. Its conclusory allegation that Medtronic "violated 21 C.F.R. § 803.50 by failing to report adverse events" (JA40) is insufficient to survive a motion to dismiss. *See Ashcroft v. Iqbal*, 556 U.S. 662, 677-79 (2009);

Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).[14]

In any event, none of Caplinger's claims is "parallel" to the federal reporting requirement.

First, a state-law duty to warn *a patient's doctor* is not "identical" (*Lohr*, 518 U.S. at 495)—and thus not parallel—to a federal duty to report adverse events to *the FDA*.[15] A manufacturer could report such events to the FDA, and thus satisfy the federal requirement, without having communicated those events to physicians, and thus without having fulfilled its state-law duty to warn. Accordingly, the state-law duty to warn a patient's doctor does not "parallel" the federal duty to submit adverse-event reports to the FDA. *McClelland v. Medtronic,*

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[14] Caplinger thus is wrong (Br.39, 46) that her claims would be able to proceed under *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013) (en banc), or *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011)—even if (contrary to fact) those cases were consistent with *Riegel*, *Buckman*, § 360k(a), and § 337(a), and even if *Stengel* were not CVSG'd by the Supreme Court (*see* 2013 WL 5507351 (U.S. Oct. 7, 2013)). As *Hughes* admonishes, "*conclusory* allegations of an FDA regulatory violation are impermissible." 631 F.3d at 773; *accord Simmons v. Bos. Scientific Corp.*, 2013 WL 1207421, at *5 (C.D. Cal. 2013) ("unsupported allegations" of failure to report adverse events are "insufficient [to] state a claim" under *Stengel*).

[15] Under the learned intermediary doctrine, any duty to warn is owed to the doctor, not the patient. *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 419 (Mo. Ct. App. 1999); *Edwards v. Basel Pharm.*, 933 P.2d 298, 300 (Okla. 1997).

Inc., 2012 WL 5077401, at *6 (M.D. Fla. 2012) (a "state law duty to warn the [patient] or her physician" is not parallel to "manufacturer reporting requirements to the FDA"); *see also Pinsonneault v. St. Jude Med., Inc.*, 2013 WL 3717780, at *8 (D. Minn. 2013) (same); *Lake v. Kardjian*, 874 N.Y.S.2d 751, 755 (Sup. Ct. 2008) (same).

Second, doctors are warned of the risks associated with a medical device through a device's FDA-approved labeling, not through adverse-event reports submitted to the FDA. Unlike the device labeling, anecdotal adverse-event reports (known as "Medical Device Reports" or "MDRs") are not necessarily made public. *See* 21 C.F.R. § 803.9(a) (FDA "*may* disclose" adverse-event reports) (emphasis added). Moreover, MDRs do not necessarily result in labeling changes and cannot be used by a manufacturer to unilaterally change the label. Labeling changes require FDA approval (*see* 21 C.F.R. § 814.39), and the FDA may not approve a safety-related labeling change absent sufficient scientific data (*see* 21 U.S.C. § 360e(d)(6)(B)). Because MDRs are inherently anecdotal, and because they do not "constitute[] an admission that the device … caused or contributed" to an injury (21

C.F.R. § 803.16), they are not by themselves sufficient grounds for a labeling change.

Because the filing of MDRs with the FDA does not alter a device's labeling, and thus does not alter the warnings given to doctors, the federal duty to submit MDRs to the FDA is not identical to any state-law duty to warn doctors. Therefore, a state-law failure-to-warn claim premised on the failure to submit MDRs to the FDA is not a "parallel" claim and does not survive express preemption under § 360k(a). *See In re Medtronic*, 592 F. Supp. 2d at 1162 (because federal "post-sale *reporting* requirements" do not "even remotely suggest[] an obligation" on the manufacturer's part "to improve the safety of the [device]" via labeling changes "upon receiving adverse-event reports," tort claims based on a state-law duty to do so would "impose conditions … 'different from, or in addition to' those under federal law"); *cf. PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 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.").

C. The Complaint Must Allege Facts Sufficient To State A Parallel Claim.

In a final effort to avoid dismissal, Caplinger contends that a plaintiff asserting claims challenging the safety or effectiveness of a PMA-approved medical device need not allege the basis for a parallel claim in her complaint *at all*. Br.41-42. That novel proposition must be rejected.

In effect, Caplinger argues that preemption under § 360k(a) can *never* be decided on a motion to dismiss. That would be contrary to the Supreme Court's admonition that "when the allegations in a complaint … could not raise a claim of entitlement to relief, 'this basic deficiency should … be disposed of at the point of minimum expenditure of time and money by the parties and the court.'" *Twombly*, 550 U.S. at 558. It would subject medical-device manufacturers to "the potentially enormous expense of discovery in cases with no 'reasonably founded hope that the discovery process will reveal relevant evidence.'" *Id.* at 559 (alteration omitted). And allowing plaintiffs to omit essential facts when filing a complaint in hopes of discovering them later would condone the "unadorned, the-defendant-unlawfully-harmed-me accusation[s]" that *Twombly* and *Iqbal* forbid. *Iqbal*, 556 U.S. at 678.

Notably, Caplinger does not identify a single case adopting her position. Indeed, the case law is to the contrary: "Parallel claims must be specifically stated in the initial pleadings." *Wolicki-Gables*, 634 F.3d at 1301. Although the circuits are not in complete agreement about "the precise level of … specificity" required, all agree that "[w]hen facing MDA preemption, a 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). Accordingly, courts around the country have dismissed claims on the pleadings for failing to allege a parallel claim. *See, e.g.*, *id.* at 1039-40.[16]

Caplinger cites *Lohr* and *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), in support of her assertion that to avoid preemption under § 360k(a), "a plaintiff does not need to plead in her complaint the federal requirements that her claims parallel." Br.41. But neither case

[16] *See also, e.g.*, *Desai v. Sorin CRM USA, Inc.*, 2013 WL 163298, at *4-8 (D.N.J. 2013); *Cooley v. Medtronic, Inc.*, 2012 WL 1380265, at *2-6 (E.D. Ky. 2012); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 482-501 (W.D. Pa. 2012); *Franklin v. Medtronic, Inc.*, 2010 WL 2543579, at *4-10 (D. Colo. 2010); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582 (E.D.N.Y. 2009); *In re Medtronic*, 592 F. Supp. 2d 1147; *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1299-303 (D. Colo. 2008).

supports her position: The claims in *Lohr* were not governed by § 360k(a) because the device at issue did not have premarket approval, and those in *Bates* were not governed by § 360k(a) because they did not involve medical devices at all—and in any event, *Lohr* and *Bates* were both decided before the Court tightened federal pleading standards in *Twombly* and *Iqbal*.

III. CAPLINGER'S CLAIMS ARE IMPLIEDLY PREEMPTED.

Caplinger conspicuously ignores—indeed, fails to even cite—the FDCA's no-private-right-of-action clause, 21 U.S.C. § 337(a), which the Supreme Court identified in *Buckman* as the statutory basis for implied preemption of private claims seeking to enforce the FDCA.[17]

In enacting the FDCA, Congress not only declined to create a private cause of action, but affirmatively required that any action to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). This provision requires that the FDCA and its implementing regulations be "enforced exclusively by the Federal

[17] Caplinger suggests that all "parallel claims, not expressly preempted by the MDA, are also not impliedly preempted under *Buckman*." Br.46. But it is well established that the existence of an express-preemption provision does not foreclose application of implied-preemption principles. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000); *see also Buckman*, 531 U.S. at 352-53.

Government." *Buckman*, 531 U.S. at 352. Moreover, Congress granted the FDA "complete discretion" in deciding "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; *see also id.* at 349 ("This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives."). 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.

In holding that Caplinger's claims are impliedly preempted, the district court followed (JA51-52)—yet Caplinger ignores—the analysis set forth in *Riley*, which the Sixth Circuit subsequently adopted in *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013). 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); *accord Loreto*, 515 F. App'x at 579; *Dawson*, 2013 WL 4048850, at *3.[18]

A. Claims Predicated On Off-Label Promotion Are Impliedly Preempted.

1. Insofar as Caplinger's claims rest on allegations of off-label promotion, the claims 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

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[18] In dictum, *Riley* left open the possibility that a plaintiff "might" attempt to escape preemption by coupling a failure-to-warn claim with allegations of off-label promotion. 625 F. Supp. 2d at 780-85. But *Riley* expressly declined to reach the issue, stating that "*[i]f* Riley successfully pleads such a claim, the Court *will then decide* whether that claim is expressly or impliedly preempted." *Id.* at 785 (emphasis added); *see also Coleman v. Medtronic Corp.*, 2012 WL 2335532 (Cal. Super. Ct. 2012) ("this portion of *Riley* was purely dicta"). Caplinger's reliance (Br.37, 51) on *Cornett v. Johnson & Johnson*, 48 A.3d 1041 (N.J. 2012), is misplaced for the same reason: *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. It is not surprising, therefore, that *Cornett* is at odds with other cases to consider the issue. *See, e.g.*, *Otis-Wisher v. Fletcher Allen Health Care, Inc.*, 2013 WL 3214714, at *5 (D. Vt. 2013) (deeming *Cornett* unpersuasive in light of the district court decision in this case).

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 use or promotion did not exist—and could not exist—until Congress required manufacturers to obtain FDA approval of devices and their labels. *See Gavin*, 2013 WL 3791612, at *17; *Lawrence*, 2013 WL 4008821, at *5; *In re Zyprexa*, 2008 WL 398378, at *5.

Thus, insofar as her claims are predicated on alleged off-label promotion, Caplinger is seeking to hold Medtronic liable for conduct that was not unlawful under "traditional state tort law which had predated the federal enactments," and is attempting to pursue a claim that, if it exists at all, "exist[s] 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; *see also Wendt v. Bernstein*, 2013 WL 3199361, at *1, *2 (Ill. Cir. Ct. 2013) (citing *Franklin v. Medtronic, Inc.*, 2010 WL 2543579, at *8 (D. Colo. 2010)); *Raborn v. Albea*, 2012 WL 6600475 (La. Dist. Ct. 2012).

This Court should reject Caplinger'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.

2. Observing that *Buckman* involved a "fraud-on-the-FDA" claim, Caplinger argues that her claims survive implied preempted because her claims are supposedly "wholly unlike the claim … impliedly preempted in *Buckman*." Br.43. There is no merit to that assertion.

First, Caplinger is incorrect that her case is unlike *Buckman* because she alleges a breach of "duties [owed] *to her*," whereas *Buckman* supposedly involved "duties [owed] *to the FDA*." Br.44. On the contrary, as in *Buckman*, Caplinger "s[eeks] damages … under state tort law" for "injuries resulting from the use of" an allegedly unsafe device. 531 U.S. at 343; *see also id.* at 346-47 (*Buckman* involved "a state-law cause of action" alleging that "the devices were … used to the plaintiffs' detriment.").

Second, the fact that Caplinger's tort claims are predicated on an alleged violation of a supposed federal prohibition on off-label promotion rather than on an alleged violation of federal disclosure requirements

does not alter the fact that "the existence of [the FDCA] is a critical element in [her] case." *Buckman*, 531 U.S. at 353. As the district court observed, the very "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." JA61, 68.

Third, as in *Buckman*, Caplinger'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*, Caplinger's claims 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 might "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, given that off-label use often constitutes the standard of care (*see* 12 FDA Drug Bull. at 5), allowing private suits predicated on the promotion of such uses will ultimately harm patients by "inhibit[ing], to

the public's detriment, informed and intelligent treatment decisions." *Caronia*, 703 F.3d at 166.

B. Claims Predicated On FDA Reporting Requirements Are Impliedly Preempted.

1. Even if it were not waived and were adequately alleged (*but see supra* pp.36-38), any claim premised on Medtronic's alleged failure to submit (unspecified) MDRs to the FDA likewise is impliedly preempted as an impermissible attempt to enforce federal requirements with no counterpart in state law. *See, e.g.*, *Bryant*, 623 F.3d at 1205 (claim that manufacturer was negligent for "not timely fil[ing] adverse event reports, as required by federal regulations" was "simply an attempt by private parties to enforce the MDA"); *Littlebear v. Advanced Bionics, LLC*, 896 F. Supp. 2d 1085, 1092 (N.D. Okla. 2012) ("All claims predicated on the failure to comply with adverse event reporting requirements are impliedly pre-empted."); *McClelland*, 2012 WL 5077401, at *7 ("[C]laims based upon FDCA disclosure requirements … are impliedly preempted."); *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 696 (W.D. Tenn. 2011) ("[P]rivate rights of action to enforce FDA administrative and reporting requirements are prohibited by 21 U.S.C. § 337(a).").

As *Buckman* teaches, "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." 531 U.S. at 347; *see also Dawson*, 2013 WL 4048850, at *7 ("these regulations relate to information that manufacturers are required to provide to the FDA, and Plaintiff cannot usurp the FDA's regulatory oversight role for policing purported violations of the agency's regulations"). Any tort claim based on a failure to submit MDRs to the FDA "would not be relying on traditional state tort law which had predated" the FDCA (*Buckman*, 531 U.S. at 353), because no duty to submit MDRs to the FDA would exist if the FDA and the FDCA did not exist. Since "the existence of these federal enactments" is therefore "a critical element" of any such claim, the claim is impliedly preempted. *Id.*

2. Just as *Buckman* held that the claim that a manufacturer withheld information to *obtain* FDA approval is an impermissible "fraud-on-the-FDA" claim (531 U.S. at 348, 350), Caplinger's allegation that Medtronic withheld adverse-event reports to *maintain* FDA approval is "a disguised fraud on the FDA claim" and is equally

impermissible. *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424-25 (6th Cir. 2005); *see also McGuan v. Endovascular Techs., Inc.*, 106 Cal. Rptr. 3d 277, 286-87 (Ct. App. 2010). *Buckman* teaches that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law," because they interfere with the FDA's exclusive discretion to enforce the FDCA "consistently with [its] judgment and objectives." 531 U.S. at 348, 350. Any private action predicated on a violation of FDA reporting requirements is therefore preempted.[19]

3. Any attempt to prove a claim based on an alleged failure to comply with federal reporting requirements also fails because it necessarily rests on an impermissible theory of causation. Although Caplinger does not articulate her theory of causation, it must be that, upon submission of the allegedly missing MDRs, either (1) the FDA would have required Medtronic to issue additional warnings, or

[19] *Buckman* underscores the importance of the FDA's discretion. It is not always clear whether an adverse-event report is required, and the threat of "unpredictable civil liability" from excessive enforcement of claimed violations could "discourage[]" manufacturers from entering the market and create an "incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA[]." 531 U.S. at 350-51.

(2) Caplinger's surgeon would have altered his conduct on his own. But neither theory avoids implied preemption.

Caplinger cannot rely on assertions of what the FDA would have done had any allegedly unsubmitted MDRs been submitted. As she admits, *Buckman* forbids any claim that would "require … hypothetical consideration about what regulatory action the agency would have taken if the agency had not been 'defrauded.'" Br.45-46. Indeed, in the recent *Mensing* decision, the Supreme Court again rejected an FDA-would-have-acted theory of causation as impliedly preempted because accepting a plaintiff's "conjectures" about what the FDA would have done would "render[] … pre-emption all but meaningless" and deprive "the Supremacy Clause [of] any force." 131 S. Ct. at 2579. Instead, "[t]he question" for preemption purposes "is whether the [manufacturer] could *independently* do under federal law what state law requires of it." *Id.* (emphasis added).[20] Accordingly, Caplinger cannot rely on what the FDA would have done had any (unspecified) MDRs been submitted. *See Hughes*, 631 F.3d at 776 n.12.

[20] As noted above, a manufacturer is not permitted to issue additional warnings without FDA approval. *Riegel*, 552 U.S. at 319.

Nor can Caplinger rely on the theory that, upon submission of the (unspecified) MDRs, her surgeon would have altered his conduct on his own, because that theory, too, ultimately depends on action by the FDA. To have altered his conduct based on the MDRs, Caplinger's surgeon would have had to have known of the MDRs prior to Caplinger's surgery. In other words, to establish causation, Caplinger must allege (and ultimately prove) "that if Medtronic had properly reported the adverse events to the FDA …, that information would have reached [her] doctors in time to prevent [her] injuries." *Stengel*, 704 F.3d at 1234 (Watford, J., concurring) (citing *Hughes*, 631 F.3d at 770 n.5, 776). The problem for Caplinger is that although manufacturers are required by 21 C.F.R. § 803.50 to submit MDRs *to the FDA*, manufacturers do not control whether or when the FDA makes MDRs available *to the public*. Although the agency "*may* disclose" MDRs (21 C.F.R. § 803.9(a) (emphasis added)), whether and when it does so—and thus whether and when it makes MDRs accessible to doctors and the public—rests entirely in the FDA's discretion. Accordingly, because such claims depend on action that a manufacturer cannot "independently"

undertake (*Mensing*, 131 S. Ct. at 2579), any failure-to-warn claim premised on a failure to submit MDRs is impliedly preempted.[21]

C. The Warranty Claims Are Impliedly Preempted.

The district court correctly held (JA65-66) that Caplinger's breach-of-warranty claims conflict with the FDA's determination that Infuse is safe and effective. This claim would require a jury to find that Infuse "was *not* safe and effective" as labeled. *Gavin*, 2013 WL 3791612, at *15-16 (emphasis added); *Lawrence*, 2013 WL 4008821, at *5 (same). But that would conflict with the FDA's conclusive determination in granting premarket approval that "there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 318; *see, e.g.*, *Gavin*, 2013 WL 3791612, at *15 (warranty claims involving Infuse are preempted because they would require a finding that "the Device was not safe and effective, a finding that would be contrary to the FDA's approval").[22]

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[21] *Stengel* and *Hughes* are wrongly decided because, *inter alia*, they fail to recognize that manufacturers do not independently control the release of MDRs.

[22] *See also Bryant*, 623 F.3d at 1207-08, *aff'g In re Medtronic*, 592 F. Supp. 2d at 1163-64; *Gomez v. St. Jude Med. Diag Div., Inc.*, 442 F.3d 919, 932 (5th Cir. 2006); *Williams v. Cyberonics, Inc.*, 388 F. App'x 169 171 (3d Cir. 2010); *Smith v. Depuy Orthopaedics, Inc.*, 2013 WL

Caplinger contends that no such conflict exists because, she insists, the FDA does not consider the possibility of off-label use when granting premarket approval. Br.51-52. But, as previously noted (*supra* pp.6-8), the premise of her argument is incorrect. As the Second Circuit has observed, "the FDA's … approval process generally contemplates that approved [devices] will be used in off-label ways." *Caronia*, 703 F.3d at 166. When deciding whether to grant premarket approval, the FDA knew that medical devices in general often are—and that Infuse in particular foreseeably would be (*see* JA12)—put to off-label uses. *See supra* pp.20-22. Thus, contrary to Caplinger's assertion, a finding that Infuse was not safe and effective as labeled would conflict with the FDA's determination that Infuse is safe and effective for sale as labeled. *See Timberlake v. Synthes Spine, Inc.*, 2011 WL 711075, at *6-7 (S.D. Tex. 2011).

Because warranty claims involving safety and effectiveness essentially "'require[] a manufacturer's [device] to be safer, but hence

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1108555, at *10 (D.N.J. 2013); *Hinkel v. St. Jude Med., S.C., Inc.*, 869 F. Supp. 2d 739, 746-48 (E.D. La. 2012); *Cooley*, 2012 WL 1380265, at *4; *Gross*, 858 F. Supp. 2d at 488-92; *Kinetic Co. v. Medtronic, Inc.*, 2011 WL 1485601, at *4 (D. Minn. 2011); *Timberlake v. Synthes Spine, Inc.*, 2011 WL 711075, at *6-7 (S.D. Tex. 2011).

less effective, than the model the FDA has approved,'" they necessarily "'disrupt[] the federal scheme'" and must be preempted. JA49 (quoting *Riegel*, 552 U.S. at 325). Were such claims not preempted, lay juries would, contrary to Congress's intent, have license to substitute their own "cost-benefit analysis" in place of "that applied by the experts at the FDA"; and patients would, as Congress feared, "suffer without new medical devices" because "[a] jury … sees only the cost of a more dangerous design, and is not concerned with its benefits" given that "the patients who reaped those benefits are not represented in court." *Riegel*, 552 U.S. at 325-26. Thus, although not every warranty claim is preempted, those that implicate the *safety or effectiveness* of a PMA-approved medical device are expressly preempted by § 360k(a).[23]

D. The Design-Defect And Failure-To-Warn Claims Conflict With Federal Law.

Finally, Caplinger's design-defect and failure-to-warn claims affirmatively conflict with federal law. The design-defect claim alleges that Medtronic should have "adopt[ed] a reasonabl[e] alternative

[23] *Cf. Kinetic Co.*, 2011 WL 1485601, at *5 (breach of promise to "pay certain costs associated with removing and replacing" device at issue not preempted because it had "nothing to do with the safety or effectiveness of the devices and thus is not preempted by § 360k").

design" (JA33), but federal law prohibits manufacturers of PMA-approved devices from departing in any way from the approved design. *See Riegel*, 552 U.S. at 319. Similarly, any state-law claim that Medtronic or its representative should have given additional warnings about Infuse and any off-label uses would conflict with 21 U.S.C. § 360e(d)(6)(A)(i) and 21 C.F.R. § 814.39(c), which affirmatively *prohibit* manufacturers from issuing warnings other than those prescribed by the FDA. *See id.* When federal law prohibits a manufacturer from independently complying with obligations imposed by state law, the state-law claims are preempted. *See Mensing*, 131 S. Ct. at 2579 (state-law claims that would require a manufacturer to take action that requires FDA approval are preempted).

* * *

At bottom, Caplinger's contention that Infuse is unsafe is an attack on the FDA's premarket approval decision itself. Because Congress forbade the FDA from regulating how approved devices may be used (*see supra* pp.6-8), Caplinger's real objection must be that the FDA should not have granted premarket approval *at all*, or should have withdrawn its approval, or should have mandated different warnings,

because of the possibility that the device might be used in an off-label manner. But, as Caplinger's complaint acknowledges (JA12), the FDA considered the possibility that Infuse would be used in off-label procedures and granted premarket approval nonetheless. If Caplinger believes that the FDA did not give adequate consideration to off-label risks, that concern should be directed to the FDA, not the courts. Because the FDA's premarket approval of Infuse remains in effect, and because Caplinger has not asserted any claim that escapes express and implied preemption, all of her claims challenging the safety and effectiveness of Infuse must be dismissed.

IV. CAPLINGER'S FRAUD AND EXPRESS-WARRANTY CLAIMS ARE INADEQUATELY PLEADED.

Caplinger's fraud and express-warranty claims also must be dismissed because they are inadequately pleaded.

A. Caplinger's Fraud Claims Are Not Pleaded With Particularity.

Plaintiffs alleging fraud "must state *with particularity* the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b) (emphasis added). "'Rule 9(b) requires that a plaintiff set forth the "who, what, when, where and how" of the alleged fraud,' and must 'set forth the time, place, and contents of the false representation, the

identity of the party making the false statements and the consequences thereof.'" *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 726-27 (10th Cir. 2006) (citations omitted). The district court correctly held (JA 61-62, 63) that Caplinger's complaint fails to comply with this requirement.

1. The Affirmative-Fraud Claims Are Not Pleaded With Particularity.

The complaint fails to identify with particularity the time, place, or contents of any particular affirmative representation by Medtronic, and alleges no facts showing that any such representation was fraudulent. "[O]ff-label marketing … is itself not inherently fraudulent," and "courts have routinely refused to find promotional marketing of off-label uses fraudulent when they are directed at sophisticated audiences, like physicians." *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1051 n.6, 1054 (N.D. Cal. 2009), *aff'd*, 464 F. App'x 651 (9th Cir. 2011). Caplinger's allegation "that the trials and reports suffered from idiosyncratic trial design, reporting bias, and peer-review and publication shortfalls" (Br.13; JA19) does not plead any affirmative misrepresentation, let alone do so with particularity. That "journal and newspaper articles, lawsuits, … and letters from senators"

might suggest that "fraudulent misrepresentations were made" (Br.53-54) does not suffice. Under Rule 9(b), the complaint must identify a *particular* false statement and its contents. *See Koch v. Koch Indus.*, 203 F.3d 1202, 1237 (10th Cir. 2000).[24]

Caplinger also fails to allege—with particularity or otherwise—how she or her physician *relied on* any fraudulent representation. She does not allege that she or her physician ever read any studies about Infuse, or that they justifiably believed and acted on any particular representation, let alone any alleged misrepresentation, contained in such studies—or anywhere else, for that matter. *Cf. Evans v. Pearson Enters.*, 434 F.3d 839, 852-53 (6th Cir. 2006).

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[24] Caplinger's reliance on hearsay and allegations in other complaints in place of "knowledge, information, and belief[] formed after an inquiry reasonable under the circumstances" (Fed. R. Civ. P. 11(b)) is inadequate even under notice pleading, and potentially violates Rule 11. *See, e.g.*, *Garr v. U.S. Healthcare, Inc.*, 22 F.3d 1274, 1280 (3d Cir. 1994) (relying on allegations in a complaint prepared by another lawyer violates Rule 11); *Geinko v. Padda*, 2002 WL 276236, at *6 (N.D. Ill. 2002) ("hearsay allegations … are improper, and therefore superfluous, and they will not be considered"); *SSDD Enters. v. Vill. of Lansing*, 1996 WL 238931, at *2 n.7 (N.D. Ill. 1996) (disregarding allegations based on hearsay in newspaper articles as "violative of Rule 11"); *Three Crown Ltd. P'ship v. Caxton Corp.*, 817 F. Supp. 1033, 1041 n.13 (S.D.N.Y. 1993) ("[A]llegations made in … complaints submitted by other plaintiffs do not satisfy the Rule 9(b) pleading requirement.").

Caplinger cannot evade the requirement that she plead reliance with particularity by "argu[ing] … that [Medtronic] 'saturated' the market for information regarding [Infuse]," and that her doctor therefore "necessarily relied upon [Medtronic's] misrepresentations when choosing to prescribe" the device, 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); *see also*, *e.g.*, *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. Chudasama v. Mazda Motor Corp.*, 123 F.3d 1353, 1369 n.39 (11th Cir. 1997) ("The fraud on the market theory … is based on concepts and policies that simply do not apply in a products liability case."). To plead a fraud claim, Caplinger was required to allege with particularity that her physician *directly* relied on a *particular* misrepresentation about Infuse; "a generalized daisy chain of causation does not meet the requirements of Rule 9(b)." *Sikkenga*, 472 F.3d at 728 n.34.

2. The Constructive-Fraud Claim Is Inadequately Pleaded And Does Not State A Claim.

Caplinger insists that she has adequately pleaded a constructive-fraud claim based on her allegation that a Medtronic representative was present during her surgery and omitted or failed to disclose some unspecified fact about the safety of Infuse. Because this claim is deficient in multiple respects, it was properly dismissed.

First, Caplinger fails to allege with particularity *what material fact* the representative was required to, but did not, disclose. She alleges only in general terms that Medtronic did not "fully disclose all pertinent information" and "fail[ed] to provide *[sic]* known dangers." JA29. That is insufficient under Rule 9(b). Also insufficient is Caplinger's argument that Medtronic "fail[ed] to disclose that using the Infuse device for Ms. Caplinger's posterior-approach surgery was unreasonably dangerous." Br.53. The contention that a device was "unreasonably dangerous" is not a *fact*, but rather a legal conclusion to be drawn from facts. Caplinger has never identified what *particular*, material *facts* bearing on the safety of her surgery were not disclosed.

Second, Caplinger fails to allege with particularity that her physician *justifiably relied on* any omission. Caplinger offers no facts to

show that additional disclosures during the surgery would have caused her surgeon to alter or stop the procedure. On the contrary, because "'[o]ff-label use of a medical device is a matter of medical judgment,'" it "is patently unreasonable for [a physician] to rely on a sales representative's opinion about the type of procedure that should be employed in operating on a patient's spine." *Hall v. Horn Med., L.L.C.*, 2012 WL 1752546, at *3 (E.D. La. 2012) (quoting *Uribe v. Sofamor, S.N.C.*, 1999 WL 1129703, at *6 (D. Neb. 1999)); *cf. Heindel*, 381 F. Supp. 2d at 382 (discussing physicians' duty when prescribing drugs).[25]

Third, Caplinger does not allege a confidential relationship giving rise to a duty to disclose, which is required for a constructive-fraud claim under Missouri law (which she asserts applies here). *See, e.g.*, *In re Estate of Dawes*, 891 S.W.2d 510, 523 (Mo. Ct. App. 1994); *cf.* Br.14 n.7. As other courts have recognized, manufacturer representatives do not assume a duty to ensure proper use of the device or to warn against

[25] *See also* U.S. Food & Drug Admin., *"Off-Label" And Investigational Use Of Marketed Drugs, Biologics, and Medical Devices—Information Sheet* (Aug. 10, 2011), http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm ("If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects.").

dangers relating to the surgery. *See Kennedy v. Medtronic, Inc.*, 851 N.E.2d 778, 786-87 (Ill. App. Ct. 2006). Caplinger has not identified any case imposing such a duty under Missouri law, and doing so would be detrimental to patients. If manufacturers assumed liability for doctors' decisions simply by making a representative available to provide technical assistance, they would cease to provide that assistance, leaving doctors without access to important technical information during surgery.[26]

Finally, Caplinger's constructive-fraud claim is preempted in any event. Caplinger argues that a claim based on statements or omissions by a company representative in the operating room "'does not challenge the … labeling of the [] device so as to implicate *Riegel* preemption.'" Br.30-31 (quoting *Adkins v. Cytyc Corp.*, 2008 WL 2680474, at *2-3 (W.D. Va. 2008)). But had the representative given the (unspecified)

[26] Leading medical authorities embrace the benefits provided by manufacturer representatives during surgery, yet continue to instruct that physicians must always exercise their own medical judgment. *See, e.g.*, Am. Coll. of Surgeons, *Statement on Health Care Industry Representatives in the Operating Room* (Sept. 2005), http://www.facs.org/fellows_info/statements/st-33.html; Pa. Patient Safety Auth., *Healthcare Industry Representatives: Maximizing Benefits and Reducing Risks*, 3 PA-PSRS Patient Safety Advisory 13 (Mar. 2006), *at* http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2006/Mar3(1)/Documents/mar;3(1).pdf.

additional warnings Caplinger seeks, she would have been in violation of the federal prohibition on giving warnings not approved by the FDA. *See Riegel*, 552 U.S. at 319; *see also supra* pp.56-57. Moreover, requiring the representative *to make additional statements* about purported risks of off-label use is not parallel to—and indeed conflicts with—any purported federal requirement *to abstain from making statements* about off-label use. *Cf. Lawrence*, 2013 WL 4008821, at *4-5; *see also Perez*, 711 F.3d at 1118 (fraud-by-omission claim preempted); *Littlebear*, 896 F. Supp. 2d at 1091 (claim of "fraud by nondisclosure" is "expressly preempted"). Caplinger does not and cannot explain how additional disclosures were required by federal law, and thus this claim is preempted under § 360k(a).

B. Caplinger's Express-Warranty Claim Is Inadequately Pleaded.

Lastly, because the Caplinger's complaint fails to identify any specific express warranty that Medtronic made, and because Medtronic in fact disclaimed all warranties, her express-warranty claim fails.

1. The Express-Warranty Claim Is Not Pleaded With The Required Particularity.

Although Caplinger does not explicitly identify her express-warranty claim as a fraud-based claim, it rests on the same allegations

as her fraud claims and is therefore subject to the same particularity requirement under Rule 9(b). As the Seventh Circuit has explained, "Rule 9(b) applies to 'averments of fraud,' not claims of fraud, so whether the rule applies will depend on the plaintiffs' factual allegations." *Borsellino v. Goldman Sachs Grp., Inc.*, 477 F.3d 502, 507 (7th Cir. 2007). Thus, any "claim that 'sounds in fraud'—in other words, one that is premised upon a course of fraudulent conduct—can implicate Rule 9(b)'s heightened pleading requirements." *Id.* (citing *Rombach v. Chang*, 355 F.3d 164, 170-71 (2d Cir. 2004), and *Sears v. Likens*, 912 F.2d 889, 893 (7th Cir. 1990)).

Caplinger's express-warranty claim arises from the same allegations as her fraud claims—allegations that Medtronic somehow misrepresented the safety and effectiveness of Infuse for off-label procedures. *Compare, e.g.*, JA27 *with* JA34. Accordingly, this claim too sounds in fraud and must be pleaded with particularity. Because Caplinger fails to identify with particularity the time, place, or contents of any particular affirmative representation constituting an express warranty, this claim must be dismissed under Rule 9(b).

2. The Express-Warranty Claim Fails Under Any Pleading Standard.

As Medtronic argued below (*see* Dkt.32 at 14 n.10), Caplinger's express-warranty claim fails even under ordinary pleading rules, because her complaint fails to identify any specific express warranty that Medtronic made. Caplinger does not identify "[a]ny affirmation of fact or promise made by" Medtronic nor any "description of the" Infuse device, let alone any affirmation, promise, or description which allegedly was "part of the basis of the bargain." Mo. Rev. Stat. § 400.2-313(1); 12A Okla. Stat. § 2-313(1); *cf.* JA34.

Under *Twombly*, a "passing mention of a breach [of] an express warranty, without factual allegations supporting this claim"—*i.e.*, allegations substantiating the "elements of a breach of express warranty cause of action"—does not constitute an actionable claim. *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 502 (W.D. Pa. 2012); *accord Williams v. Cyberonics, Inc.*, 654 F. Supp. 2d 301, 308 (E.D. Pa. 2009), *aff'd*, 388 F. App'x 169 (3d Cir. 2010). Absent such allegations, the claim must be dismissed. *See Houston v. Medtronic, Inc.*, 2013 WL 3927839, at *11 (C.D. Cal. 2013) (dismissing express-warranty claim in an Infuse case because "Plaintiff has alleged no facts demonstrating

that Defendants made any affirmations specifically to Plaintiff or her physician so as to form the basis of the bargain").

3. Medtronic Disclaimed Any Warranties.

Finally, the warranty claims fail because Medtronic disclaimed any warranties, as both Missouri and Oklahoma law permit. *See* Mo. Rev. Stat. § 400.2-316; 12A Okla. Stat. § 2-316; *Karr-Bick Kitchens & Bath, Inc. v. Gemini Coatings, Inc.*, 932 S.W.2d 877, 799 (Mo. Ct. App. 1996); *Bundren v. Car Connection, Inc.*, 963 P.2d 634, 637 (Okla. Civ. App. 1998). Infuse's FDA-approved label states that "[n]o warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded." JA93. This unambiguous declaration defeats any warranty claim.

CONCLUSION

The judgment of the district court should be affirmed.

STATEMENT WITH RESPECT TO ORAL ARGUMENT

Medtronic does not oppose Caplinger's request for oral argument if the Court believes that oral argument would be helpful.

Dated: October 15, 2013

Respectfully submitted,

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s/ *Andrew E. Tauber*
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I certify that on October 15, 2013, I electronically filed the foregoing using the Court's CM/ECF system, which will serve copies on all parties or their counsel of record. I further certify that I caused seven paper copies of the foregoing to be filed with the Clerk of Court within two business days.

s/ *Andrew E. Tauber*
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