ORAL ARGUMENT REQUESTED

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 a Final Judgment of the United States District Court for the Western District of Oklahoma, Hon. Judge Miles-Lagrange

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REPLY BRIEF FOR PLAINTIFF-APPELLANT

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GLOSSARY

Appx.	Appendix of Record Excerpts filed August 9, 2013
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, *et seq*.
MAUDE	Manufacturer and User Facility Device Experience database
MDA	Medical Device Amendments of 1976, 21 U.S.C. §§ 360c, *et seq*.
PMA	Premarket approval

INTRODUCTION

The implications of Medtronic's arguments are far-reaching. According to Medtronic, premarket approval (PMA) by the Food and Drug Administration (FDA), based on a determination that a medical device is safe and effective for *one* use, allows a manufacturer to promote the device for any *other* use and to do so free from any liability under state law for injury resulting from its off-label promotion. Nothing in the Medical Device Amendments (MDA) or the Supreme Court's preemption jurisprudence grants a manufacturer such immunity when acting outside the scope of PMA, which allows marketing of the device according to the design and labeling for the particular uses for which the FDA has found it safe and effective.

Medtronic's position distorts the MDA's preemption provision, 21 U.S.C. § 360k(a), "beyond recognition by transforming its protection for FDA-approved devices that comply with federal law into a grant of civil immunity for FDA-approved devices that violate federal law." *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 832 (S.D. Ind. 2009). When a manufacturer markets a device for uses other than those evaluated by the FDA in granting PMA, state-law remedies for patients injured as a result of the device's unsuitability for an unapproved use do not interfere with any applicable requirements of federal law. Thus, "[i]t would make little sense to allow Medtronic to receive the protection of

preemption when it is actively promoting off-label uses that have not been reviewed by the FDA." *Ramirez v. Medtronic Inc.*, __ F. Supp. 2d __, 2013 WL 4446913, at *11 (D. Ariz. Aug. 21, 2013). "When the device is not being used in the manner the FDA preapproved and the manufacturer is actually promoting such use, there is no law or policy basis on which to pre-empt the application of state law designed to provide … protection" to patients. *Id.* at *10.

Medtronic's contrary arguments are unavailing. Ms. Caplinger did not waive her argument that claims arising from off-label promotion are not preempted; indeed, the district court expressly acknowledged and addressed the argument. Appx. 56, 58. Moreover, although Medtronic is correct that *doctors* are permitted to use devices for off-label indications, that point is irrelevant. The issue is not physicians' off-label use, but *Medtronic*'s off-label *marketing*. And Medtronic's assertion that marketing devices for unapproved uses is not prohibited by federal law is manifestly incorrect and based on a misreading of the Second Circuit's decision in *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), which held only that the First Amendment does not permit a criminal prosecution based solely on the defendant's speech. Ultimately, Medtronic cannot evade the fact that, in granting Infuse PMA for anterior use, the FDA imposed *no* requirements on the design or labeling of the device *for posterior use.* Ms. Caplinger's state-law claims

are, thus, not preempted because they impose no requirements that are different from or in addition to any *applicable* federal requirements.

To the extent that Infuse is subject to applicable federal requirements, Ms. Caplinger's claims nonetheless escape preemption because they are based on violations of state-law duties that parallel federal requirements. Medtronic offers a particularly restrictive view of parallel claims that is divorced from the factual context of the Supreme Court cases on which Medtronic purports to rely and would, as Medtronic acknowledges, require this Court to hold that influential decisions of two other Circuits—in *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013), and *Hughes v. Boston Scientific Corp.*, 631 F.3d 672, 770-71 (5th Cir. 2011)—were wrongly decided. Moreover, under Medtronic's view, any parallel claim would be impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), because enforcing a state requirement identical to a federal requirement would, it argues, constitute an impermissible attempt to enforce the Food, Drug, & Cosmetic Act (FDCA) through a private right of action.

In fact, Ms. Caplinger's claims are not expressly preempted because they are based on state-law duties that parallel federal requirements—namely, duties not to market a device for a use for which it is unsafe and for which proper warnings have not been provided, and not to conceal information about the risks posed by that use. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Medtronic, Inc.*

v. Lohr, 518 U.S. 470, 496-97 (1996). At the same time, her claims are not impliedly preempted under *Buckman* because they do not seek to enforce federal requirements, but rest on "traditional state tort law principles of the duty of care" that differ fundamentally from the "fraud-on-the-agency" claim that *Buckman* held to be preempted. *Buckman*, 531 U.S. at 352.

ARGUMENT

I. Ms. Caplinger's State-Law Claims Are Not Expressly Preempted by § 360k(a).

A. Claims Based on a Manufacturer's Marketing of a Device for Unapproved Uses Do Not Impose Requirements Different from or in Addition to Applicable Federal Requirements.

1. Section 360k(a) preempts state requirements with respect to a medical device that are "different from, or in addition to," federal requirements "applicable under [the MDA] to the device, and" relate "to the safety and effectiveness of the device" or other matters "included in a requirement applicable to the device under" the MDA. Section 360k(a) does not preempt claims based on a manufacturer's marketing of a device for an *unapproved* use because such claims do not implicate requirements "applicable to the device" under federal law. FDA approval is based on a determination of safety and effectiveness for the device "under the conditions of use included in the proposed labeling" submitted by the manufacturer in the PMA application, 21 U.S.C. § 360e(d)(1), and approval imposes design, labeling,

and other requirements on the marketing of the device for those "conditions of use." *See id*. §§ 360c(a)(2), 360e(d)(2).

Here, Medtronic does not dispute that the FDA did not approve Infuse as safe and effective for posterior surgery or that Ms. Caplinger adequately pleaded that Medtronic extensively promoted Infuse for off-label use. Rather, the FDA imposed requirements, including design, labeling, and reporting requirements, in connection with Medtronic's marketing of the device for uses specified in the proposed labeling—on which the FDA "rel[ied]" in granting PMA. *Id.* § 360e(d)(1). The FDA imposed no similar requirements with respect to other uses, including posterior-approach use, because it did not "mak[e] a determination whether to approve or deny the [PMA] application" for other uses. *Id.* Because the PMA did not impose federal requirements on marketing for the unapproved use, state-law claims based on Medtronic's marketing of the device for that use do not impose requirements that are "different from, or additional to," any federal requirements applicable to the device. *See Lohr*, 518 U.S. at 493 (no preemption where FDA marketing clearance did not involve a determination of safety and effectiveness).

2. Medtronic contends that Ms. Caplinger's argument is waived. Its contention, however, rests largely on the mistaken notion that Ms. Caplinger argues that § 360k(a) "does not apply" or "does not govern her claims at all."

Medtr. Br. 18, 19. Ms. Caplinger is not asserting that § 360k(a) "does not apply," but that the application of § 360k(a) does not result in preemption of her claims because they are not "different from, or in addition to," any "applicable" requirement of federal law, in light of Medtronic's off-label promotion. This argument was made below and addressed by the district court, which ruled on the merits of Ms. Caplinger's argument that Medtronic's off-label promotion for an unapproved use placed her claims outside the preemptive effect of § 360k(a). *See* Appx. 56 ("Because defendants failed to obtain said approval, plaintiff contends defendants' intentional promotion of the Infuse Device for such off-label uses was in violation of federal law and FDA regulations and, thus, defendants are not entitled to the preemption defense."); *id*. 58 ("In other words, plaintiff contends that § 360k(a) does not preempt any claim that arises out of the promotion of an off-label use of a device.").[1] The court rejected Ms. Caplinger's argument on the merits, holding that PMA is a sufficient predicate for preemption under § 360k(a), regardless of whether the PMA addresses the use at issue. *Id*. 58-59.

The district court's opinion makes clear that Ms. Caplinger's argument was presented and addressed below. Waiver principles do not prohibit a party from

[1] The district court understood that this argument was distinct from the argument that Ms. Caplinger asserts parallel claims under *Riegel* and *Lohr*. *See* Appx. 56-57 (separately discussing Ms. Caplinger's parallel claims arguments); Appx. 59 & n.4 (same).

"refin[ing] his argument" on appeal, *United States v. MacKay*, 715 F.3d 807, 844 (10th Cir. 2013), or making points that are "an extension of … arguments before the district court." *Ass'ns Working for Aurora's Residential Env't v. Colo. Dep't of Transp.*, 153 F.3d 1122, 1127 n.3 (10th Cir. 1998); *see also Yee v. City of Escondido*, 503 U.S. 519, 534 (1992) ("Once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below."). Indeed, where a district court interprets a statute, this Court may review and correct the interpretation (even if a party failed to make clear its own view) because "it is necessary to correct misconceptions of statutory meaning at the earliest opportunity for the benefit of all who must operate under a statute's purview." *WWC Holding Co. v. Sopkin*, 488 F.3d 1262, 1276 n.10 (10th Cir. 2007) (citation omitted). Here, there is not even a close question of waiver.

3. Asserting that the FDA approves "devices, not uses," Medtronic (at 19-20) cites authorities for the uncontested propositions that a *purchaser* of a device may use it for uses not approved by the FDA and that doctors may use devices for "any condition or disease." The freedom of doctors to put a device to off-label uses does not, however, reflect FDA approval for those uses. It reflects that the FDA does not regulate the practice of medicine. *See, e.g.*, FDA, Guidance for Industry—Responding to Unsolicited Requests for Off-Label Information About Prescription

Drugs and Medical Devices 2 (2011), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf (FDA 2011 Guidance).

That the FDA imposes no requirements on doctors does not speak to the nature of the requirements it imposes on device manufacturers. As to that question, Medtronic's slogan that the FDA approves "devices, not uses" poses a false dichotomy. The FDA approves the marketing of devices under the "conditions of use included in the proposed labeling" submitted with the PMA application. 21 U.S.C. § 360e(d)(1), (2); *see id*. § 360c(a)(2); *see generally Riegel*, 552 U.S. at 317-19. A PMA device marketed for the uses specified in its labeling is subject to the design and labeling requirements imposed by the FDA upon approval, and under § 360k(a), a manufacturer that markets the device for its approved use may not be subjected to state requirements that differ from or add to those requirements. *See Riegel*, 552 U.S. at 323-25. By contrast, because the FDA "rel[ies] on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness," 21 U.S.C. § 360e(d)(1), PMA does not represent a finding that the device is safe and effective in some general sense, disconnected from the approved use(s). And PMA does not impose requirements on how a manufacturer can design and label a device for a use not specified in the proposed labeling, as such uses have not been found

safe and effective by the FDA. Rather, "requirements applicable to the device" are "premised on the manufacturer's intended use," and when a manufacturer markets a device for an off-label use, "it [has] departed the realm of federal regulation and returned to the area of traditional state law remedies." *Ramirez*, 2013 WL 4446913 at *7, *11. "In the absence of federal approval of the new use, there is nothing to preempt state law requirements." *Id*. at *11. *Accord McDonald-Lerner v. Neuro-care Assocs., P.A.*, No. 373859-V (Md. Cir. Ct. Aug. 29, 2013).

4. Contrary to Medtronic's assertion (at 25), recognition that PMA imposes design and labeling requirements on a device with respect to approved uses, but not unapproved uses, does not threaten manufacturers with liability whenever doctors "unilaterally" decide to use the products off-label. A PMA device marketed by its manufacturer for approved uses is indisputably subject to applicable federal design and labeling requirements, and a physician's decision to use the device for an off-label purpose for which the manufacturer has not promoted it does not alter the preemptive effect of § 360k(a). As explained in *Ramirez*, when the manufacturer confines itself to marketing the device for approved uses and complies with the requirements applicable to the device when marketed for those uses, a claim that the manufacturer "should have provided additional warnings or designed the product differently in light of [an] unapproved use … is asking the manufacturer to do something 'different from, or in addition

to' federal law." *Ramirez*, 2013 WL 4446913, at *8. In such cases, "[t]he doctor's off-label use is not a result of the manufacturer's conduct; indeed, the manufacturer in this situation is adhering to federal law." *Id*.

Thus, Medtronic's observation (at 23-24) that the use to which the doctor put the device in *Riegel* was unapproved is irrelevant. The plaintiffs in *Riegel* did not allege that the manufacturer had marketed the device for an unapproved use. *See Riegel*, 552 U.S. at 320 (describing facts). The Supreme Court decided the case on the premise that the manufacturer had complied with the terms of the PMA, which imposed design and labeling requirements applicable to the device when marketed for the approved uses. *See id.* at 339. In those circumstances, *Riegel* held, state-law claims based on a duty to design and label the device differently from the federal requirements would impose different or additional requirements on the manufacturer. *See id*. at 323-34.

Similarly, *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013), does not address the consequences of a manufacturer's marketing its device for an unapproved use. *Perez* holds that § 360k(a) preempts state-law fraud claims premised on the theory that a manufacturer should have provided warnings in addition to those required by the PMA, because the manufacturer "knew or should have known" that doctors were using the device for unapproved indications

without telling their patients that the uses were not FDA approved. *Id*. at 1117.[2] A manufacturer that markets its product only for approved uses, the court held, cannot be held liable for failure to take steps not required by the FDA to warn against unapproved uses. *See id.* at 1118-19. Thus, "[t]here is a crucial difference between a claim premised on a physician's use of a device that is unsanctioned by both the FDA and the manufacturer, and one based on a use that still lacks FDA scrutiny but is actively promoted by the manufacturer." *Ramirez*, 2013 WL 4446913, at * 11.

Medtronic (at 26) argues that it makes no sense to hold that claims against a manufacturer arising from a doctor's "unilateral" off-label use are preempted, while claims against a manufacturer arising from a doctor's decision "to make the *same* use of the *same* device" are not preempted where the manufacturer has promoted the unapproved use. This result, however, follows directly from the Supreme Court's decisions in *Lohr*, 518 U.S. at 493-94 (no preemption where no FDA determination of safety and effectiveness), and *Riegel*, 552 U.S. at 322-23 (preemption where device marketed pursuant to PMA). As those cases held, preemption under § 360k(a) looks first to the existence of an applicable federal

[2] *Perez* recognized that the device was subject to the requirement that the manufacturer not "introduce[] [it] into commerce" for unapproved uses. *Perez*, 711 at 1118.

requirement, *Riegel*, 552 U.S. at 322-23, and, if such a requirement exists, then looks to whether the plaintiff's claim would impose a duty "different from, or in addition to," that federal requirement. *Id*. at 323. Because FDA approval of the device for the uses specified in its labeling does not impose requirements applicable to the device *as marketed for other uses*, there is no preemption here.

5. The FDA has repeatedly made clear that PMA, far from imposing requirements as to how a device marketed for an *unapproved* use must be designed and labeled, forbids off-label marketing by device manufacturers. As the FDA has explained, "the [FDCA] and FDA's implementing regulations generally prohibit manufacturers of new drugs or medical devices from distributing products in interstate commerce for any intended use that FDA has not approved as safe and effective," and "a medical device that is promoted for a use that has not been approved or cleared by FDA is adulterated and misbranded." FDA, Guidance for Industry—Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (2009), http://www.fda.gov/regulatoryinformation/guidances/ucm125126.htm (FDA 2009 Guidance).

Contrary to Medtronic's assertion, the Second Circuit's decision in *United States v. Caronia* does not reverse the FDA's longstanding position in this respect. *Caronia* held that a criminal prosecution based on promotional speech *alone*

violated the First Amendment. *See* 703 F.3d at 152. It also recognized that when a manufacturer *intends* a drug or device for an off-label use, the product is misbranded because its label does not contain adequate directions for that use. *See id*. at 154, 160-62. *Caronia* thus does not hold that federal law permits (let alone authorizes) a manufacturer to market a device for unapproved uses.

That the FDA sometimes "considers" unapproved uses in the sense that, for a particular product, it might require that the labeling *discourage* a particular use (Medtr. Br. 22) does not mean that FDA approval establishes design and labeling requirements under § 360k(a) that are applicable when the device is marketed for those unapproved uses. Such labeling requirements presuppose that the manufacturer is *not* marketing the device for the unapproved use, and the requirements apply when the device is being marketed for its approved use. When the manufacturer acts affirmatively to subvert those requirements by marketing the device for the very use that the labeling sought to discourage, it acts outside the requirements imposed by the FDA. To hold otherwise would turn the law upside down and allow manufacturers to claim that, by telling them *not* to do something, the FDA has given them protection when they do it. Medtronic cannot "cite[] the existence of federal regulations it is allegedly circumventing to justify" preemption. *Ramirez*, 2013 WL 4446913, at *10.

B. Ms. Caplinger's Claims Are Not Preempted to the Extent That They Are Based on State-Law Duties that Parallel Federal Requirements.

1. The parties agree that § 360k(a) does not preempt state-law claims based on duties that parallel federal requirements. Here, to the extent that there are applicable federal requirements, they parallel the state-law duties on which Ms. Caplinger's claims are based.

Both state and federal law required that Medtronic's Infuse labeling not be false or misleading, and that it bear adequate directions for use. On the federal side, a manufacturer is prohibited from marketing a "misbranded" device, and a device is misbranded if "its labeling is false or misleading in any particular" or if its labeling does not bear "adequate directions for use." 21 U.S.C. § 352(a), (f). On the state side, a manufacturer owes a duty to warn of dangers presented by the product when used as the manufacturer expected. *See* Opening Br. 33-34 n.9 (defining strict liability and negligent failure to warn). And a manufacturer is liable for fraudulent or negligent misrepresentation if it makes a false representation on which the hearer relies, causing injury. *Id*. 37 n.11. These federal and state requirements—to provide adequate warnings for use, and not to give false or misleading statements about the product—are equivalent here.

Likewise, both federal and state law provide that a medical device can be marketed only if there is reasonable assurance that it is safe and effective for its

intended use(s). A class III medical device cannot be marketed without either PMA or 510(k) clearance, Opening Br. 6-7, and a manufacturer who wants to promote a PMA device for a use that has not been considered and approved by the FDA must "submit a PMA supplement for review and approval by FDA." 21 C.F.R. § 814.39(a). Otherwise, when the product is marketing for the unapproved indication, the product is adulterated, 21 U.S.C. § 351(f), and its sale is prohibited, *id*. § 331(a), (b). Here, the PMA for Infuse authorized marketing only for anterior use, not for posterior use. *See* Appx. 10, 75, 80. It thus lacked a determination under federal law that it was reasonably safe for the use for which it was marketed—posterior use. The federal requirement that a device not be sold absent an FDA finding of safety and effectiveness parallels the state-law duty that the manufacturer not sell unreasonably dangerous products. *See* Opening Br. 34 n.9.

As the FDA has reiterated, PMA represents a finding of sufficient evidence to assure that the device is safe and effective "for its intended use[s]." FDA 2009 Guidance; *see* 21 U.S.C. § 360e(d)(1), (2). Therefore, here, Medtronic cannot shield itself behind the PMA for anterior use, as that PMA does not represent a determination that the product was safe and effective for posterior use, that the labeling provided adequate warnings for posterior use, or that Medtronic's promotion for posterior use was not false or misleading. Accordingly, Ms. Caplinger's claims, which seek to enforce state-law duties of care, would not

impose requirements "different from or in addition to," 21 U.S.C. § 360k(a), federal requirements. Her state-law claims provide a remedy for conduct that violated both federal and parallel state requirements.

2. Although Medtronic (at 29) argues that the state and federal requirements must be "identical," the Supreme Court has not applied the very rigid approach that Medtronic prefers. *Lohr* held that § 360k(a) does not preempt state-law duties that "parallel federal requirements," or that are "substantially identical" to federal requirements," 518 U.S. at 495, 497, and *Riegel* that § 360k(a) does not preempt "parallel claims," 552 U.S. at 330 (no preemption where claims alleged to violate state law "notwithstanding compliance with relevant federal requirements"). Likewise, construing a "similarly worded" preemption provision applicable to pesticides, *Bates v. Dow AgroSciences* held that state requirements "equivalent to, and fully consistent with," the statute's misbranding provision were not preempted. 544 U.S. 431, 447 (2005). Applying the Supreme Court's repeated description of non-preempted parallel state-law claims, both the Fifth and Ninth Circuits have held that § 360k(a) does not preempt claims analogous to Ms. Caplinger's. *See Hughes*, 631 F.2d at 770-71; *Stengel*, 704 F.3d at 1232-33; *see also Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) (holding that claims based on "allegations of harm caused by violations of federal law" are not preempted because such claims would not impose "any requirement 'different from, or in

addition to, any requirement' imposed by federal law"); *cf. Walker v. Medtronic*, 670 F.3d 569, 571 (4th Cir. 2012) ("In light of Walker's concession that the device was designed, manufactured, and distributed in compliance with the terms of its premarket approval, given by the [FDA] as required under the MDA, however, we are compelled to affirm [the finding of preemption].").

Medtronic (at 33-34) further errs in stating that the violation for which Ms. Caplinger seeks to hold it accountable under state law is its off-label promotion. To begin with, Medtronic is wrong to state that federal law does not prohibit off-label promotion. In reality, as the FDA has expressly stated, a manufacturer's off-label promotion renders a device adulterated and misbranded. *See supra* p. 12. In any event, Ms. Caplinger is not suing *for* off-label promotion. Rather, her suit is for claims such as failure-to-warn, fraudulent misrepresentation, and design defect, which are based on state-law duties that parallel the federal prohibitions against adulteration and misbranding. The bar on off-label promotion is not the parallel federal and state requirement itself; off-label promotion is evidence that Medtronic violated federal and state requirements.

Next, Medtronic (at 35) argues that, to state a parallel claim, Ms. Caplinger must establish that its failure to warn caused her injury. Medtronic's argument here is not about parallel requirements but that, in Medtronic's view, it should prevail on the merits. Ms. Caplinger, of course, disagrees that Medtronic provided

adequate warnings. Indeed, as her complaint details, Medtronic aggressively promoted posterior use, knowing that it was unapproved and created undue risks to the patient, and without adequate disclosure of those risks—conduct that led to investigations by the Department of Justice, the United States Senate Committee on Finance, and a leading journal of spinal medicine. Appx. 12-20, ¶¶ 35-63. Regardless of who is right, causation is not an element of the preemption analysis. *See Hughes*, 631 F.3d at 776 (holding no preemption, declining to address causation, and remanding).

3. Medtronic argues that a duty to warn a patient's doctor is not exactly the same as the duty to report to the FDA. Here, Medtronic errs in several respects. First, Medtronic suggests that the only way in which a device manufacturer may warn a physician is through product labeling. In addition to labeling, however, physicians get information about risks posed by devices from adverse event reports submitted by manufacturers to the FDA, from journal articles, and directly from manufacturer representatives.

Second, Medtronic (at 39) argues that adverse event reports submitted to the FDA cannot be considered when assessing failure to warn, because the adverse events are reported to the FDA, not to physicians. Yet the FDA makes adverse events publicly available through its online MAUDE (Manufacturer and User Facility Device Experience) database (at http://www.accessdata.fda.gov/scripts/

cdrh/cfdocs/cfmaude/search.cfm). The database provides another source of public information about risks posed by medical devices. As the Fifth Circuit held in *Hughes*, 631 F.3d at 771, a state-law "failure-to-warn claim is not expressly preempted to the extent that it is based on [the manufacturer's] violation of applicable FDA regulations requiring accurate reporting of serious injuries and malfunctions of the [medical] device."

Third, Medtronic heavily promoted Infuse for posterior use, in part by sponsoring articles that reported only successful procedures and low rates of complications, "which led to the 'off-label' use of Infuse" and "may have promoted widespread poorly considered on- and off-label use, eventual life-threatening complications and deaths." Appx. 19, ¶ 61 (quoting The Spine Journal). Medical journal articles promoting Infuse, without adequate disclosure of risks, misled physicians and provide further evidence of misrepresentation and failure-to-warn.

Fourth, a Medtronic representative, Lisa Mitchell, "was present prior to and during the surgery" and "was actively involved and provided information regarding Infuse as it applied to Patricia Caplinger's particular surgery." *Id*. ¶ 66. Direct communications from Medtronic's representative provided yet another opportunity to warn of the undue risks associated with off-label, posterior use of Infuse. *See Medtronic v. Malander*, __ N.E.2d __, 2013 WL 5583573, at *7 (Ind.

Ct. App. Oct. 11, 2013) (claim based on oral representations of Medtronic representatives to plaintiff's physician not preempted).

In sum, Medtronic had available to it several means of warning physicians and patients, but it failed to avail itself of them. Instead, it aggressively promoted Infuse as safe for the unapproved posterior use to such an extent that it triggered federal investigations, a special issue of the Spine Journal, and hundreds of patient injuries.

4. Medtronic argues that Ms. Caplinger is wrong to rely on the unanimous holdings in two Supreme Court cases, *Lohr*, 518 U.S. at 495 (majority); *id*. at 513 (O'Connor, J., concurring in part and dissenting in part), and *Bates*, 544 U.S. at 447, to show that, to avoid preemption, a complaint need not specify the federal requirements that parallel her state requirements. Misunderstanding both § 360k(a) and *Lohr*, Medtronic (at 43) asserts that the holding in *Lohr* does not apply because the "claims in *Lohr* were not governed by § 360k(a)." In *Lohr*, the Supreme Court held that § 360k(a) did not expressly preempt the Lohrs' claims for several independent reasons, one of which was that state-law requirements are not preempted to the extent that they parallel federal requirements. This part of the majority opinion assumes that both state and federal requirements exist and is not based on the separate holding that the Medtronic device at issue, which had not undergone PMA, was not subject to federal device requirements. Similarly, while

Medtronic tries to dismiss *Bates* on the ground that it did not involve a medical device, the Court's opinion expressly noted that the preemption provision for pesticides is "similarly worded" to 360k(a), and expressly applied *Lohr*'s holding with regard to parallel claims. *Bates*, 544 U.S. at 447-48.

Medtronic (at 43) also suggests that *Lohr* and *Bates* have been undercut by *Twombly* and *Iqbal*, which "tightened federal pleading standards." But the pleading standards apply to the plaintiff's affirmative case, and neither *Lohr*, *Bates*, nor *Riegel* suggest that the identification of a parallel federal requirement is an element of the plaintiff's claim. Rather, identification of the parallel federal requirement is an issue pertinent to an affirmative defense—preemption. *Emerson v. Kansas City So. Ry.*, 503 F.3d 1126 (10th Cir. 2007) (noting that federal preemption is an affirmative defense on which the defendant bears the burden of proof).

In any event, Ms. Caplinger's amended complaint specifically identifies the federal requirements that parallel the state-law duties underlying her claims. *See* Appx. 39, ¶ 154. Accordingly, although Medtronic's argument could be accepted only by disregarding the Supreme Court's opinions in *Lohr*, *Bates*, and *Riegel*, this Court need not reach the issue to rule in favor of Ms. Caplinger here.

II. Ms. Caplinger's Claims Are Not Impliedly Preempted.

A. *Buckman* Does Not Preempt Traditional State-Law Causes of Action.

Ms. Caplinger's opening brief describes in detail the Supreme Court's opinion in *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, which addressed a state-law claim for "fraud-on-the-FDA." The theory of the claim was that the defendant, a consultant that worked with a device manufacturer, had made misrepresentations to the FDA and that, had it not made misrepresentations, the FDA would not have cleared the device for marketing. The claim was not based on state-law duties of care owed by a manufacturer to patients; it rested entirely on alleged duties arising from "the relationship between a federal agency and the entity it regulates." *Id*. at 352. By contrast, Ms. Caplinger alleges traditional state-law claims based on traditional state-law duties of care owed by a manufacturer to customers or patients. Like the claims in *Lohr*, her "claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely form violation of FDCA requirements." *Id*.

Medtronic's argument on implied preemption is largely a series of red herrings. First, Medtronic derides Ms. Caplinger for not discussing 21 U.S.C. § 337(a), which provides that an action to enforce the FDCA "shall be by and in the name of the United States." Ms. Caplinger did not discuss that provision, however, because it is both undisputed and irrelevant. That the state-law duties

underlying her common-law claims parallel federal requirements does not convert them into claims for noncompliance with federal requirements. The existence of parallel federal requirements *allows* Ms. Caplinger to pursue her state-law claims, but those requirements are not the *basis* for her claims.

Medtronic next argues that claims predicated on its marketing of Infuse for an unapproved use or on its failure to submit required adverse event reports are preempted because off-label promotion was not barred by state law before enactment of the MDA and such claims are an attempt to enforce the MDA. Here, Medtronic makes several mistakes. First, as explained above, Ms. Caplinger has not asserted claims for "off-label promotion" or failure to submit reports. She has asserted claims such as failure-to-warn, negligence, and misrepresentation, all of which are indisputably traditional state-law causes of action. Off-label promotion shows that Medtronic cannot avoid preemption by relying on its PMA for anterior use (*see* supra I.A.) and that Medtronic has violated parallel federal and state requirements (*see* supra I.B.), but off-label promotion is not itself a claim. Similarly, failure to submit adverse event reports shows that the violation of the state-law duty to warn has a parallel in a federal requirement, as Medtronic had the means of warning, of which a reasonable manufacturer would have availed itself.

Medtronic's response to Ms. Caplinger's point (Opening Br. 44) that *Buckman* involved a claimed violation of a duty owed to the FDA, whereas the

claim here is that Medtronic violated a duty owed directly to Ms. Caplinger, is a non sequitur. Medtronic relies on a sentence from *Buckman* explaining that the plaintiffs there claimed that the device manufacturer and its consultant made fraudulent representations to the FDA about the intended use of the device and that, as a result, the device was improperly cleared for marketing and then "subsequently used to the plaintiffs' detriment." *Buckman*, 531 U.S. 347. That sentence, however, underscores Ms. Caplinger's point that the claims alleged in *Buckman* turned on violation of a duty owed *to the FDA*, not to the plaintiffs. To be sure, the *Buckman* plaintiffs sought damages for *injuries* to them, but those injuries did not result from the violation of *duties owed* to them. The duty was owed to the FDA, and the fraud was directed at the FDA. In contrast, the damages here resulted from violation of duties owed to Ms. Caplinger. Although it confuses the point, Medtronic does not actually argue otherwise.

Medtronic (at 50-51) tries to analogize the failure-to-warn claim here to the fraud-on-the-FDA claim in *Buckman* by arguing that the *Buckman* claim alleged that the defendant withheld information to "obtain FDA approval," whereas here the claim is that the defendant withheld information to "maintain approval." But unlike the claim in *Buckman*, Ms. Caplinger's claims do not turn on why Medtronic failed to warn or on the consequences of that failure for the marketing status of Infuse.

Disagreeing with the Fifth and Ninth Circuits, *see Hughes*, 631 F.3d 672, and *Stengel*, 704 F.3d 1224, Medtronic asserts that Ms. Caplinger cannot prove causation because, even if it had complied with reporting requirements, the FDA might not have posted the reports in its publicly accessible database, MAUDE. Aside from its failure to offer any reason why the FDA would alter its usual practice, Medtronic's argument again goes to causation, not to preemption, and disregards other avenues for providing warnings. *See supra* pp. 18-19.

B. The Warranty, Design-Defect, and Failure-to-Warn Claims Do Not Conflict With the PMA.

Medtronic (at 54) argues that Ms. Caplinger's warranty claims would require a jury to find that the device was not safe and effective as labeled, which would conflict with the FDA's determination in granting PMA that "there is a reasonable assurance of safety and effectiveness." Again, Medtronic misunderstands the regulatory scheme. PMA is a determination that the manufacturer has demonstrated reasonable assurance of safety and effectiveness "under the conditions of use prescribed, recommended, or suggested in the proposed labeling" submitted with the PMA application. 21 U.S.C. § 360e(d)(2); *see id*. § 360e(d)(1). Thus, Ms. Caplinger's warranty claims, like her other claims, do not pose a conflict with any FDA determination concerning Infuse, including its decision to grant PMA for anterior use.

Looking to *United States v. Caronia*, 703 F.3d 149, in which the Second Circuit considered criminal charges brought by the FDA against a pharmaceutical sales representative who engaged in off-label promotion, Medtronic responds that the FDA approval process "contemplated" off-label use. Medtronic errs by relying on a decision with which the FDA disagreed as evidence of the FDA's views on off-label promotion. Putting that aside, Medtronic errs in conflating FDA acceptance of the fact that physicians sometimes prescribe or use approved drugs and devices for unapproved uses with FDA acceptance of off-label promotion. The FDA does not regulate physicians' practice of medicine, but it does regulate manufacturers' marketing of medical devices. *See* FDA 2011 Guidance. The FDA has stated clearly that off-label promotion by manufacturers is strictly limited and renders the product misbranded. *See* FDA 2009 Guidance. Moreover, the MDA makes explicit that the approval decision is based on the safety and effectiveness of the device for uses specified in the labeling, as opposed to off-label uses. *See supra* pp. 4-5, 8. Medtronic's argument thus runs directly counter to the federal regulatory scheme.

Finally, Medtronic (at 56-57) argues very briefly that the design-defect and failure-to-warn claims are impliedly preempted. Its argument here is not based on *Buckman*. Rather, Medtronic argues that it could not comply with the state-law duties underlying Ms. Caplinger's claims without running afoul of federal law.

First, Medtronic's argument is based on the false premise that the FDA has evaluated Infuse for posterior use, found it safe and effective for that use, and approved marketing for that use. It has not. Thus, a state-law duty requiring Medtronic to refrain from marketing Infuse for uses for which it is defectively designed and inadequately labeled would not require the company to take any action that "affirmatively conflicts with federal law," Medtr. Br. 56, but to comply with federal law. Second, as explained above, the duties underlying these claims parallel federal law. Accordingly, complying with those duties, or paying damages for failing to comply with them, poses no conflict with federal law. *See Lohr*, 518 U.S. at 495 (majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part) (MDA "does not preclude States from imposing different or additional remedies, but only different or additional requirements.").

III. The Fraud and Warranty Claims Are Adequately Pleaded.

A. With respect to pleading under Rule 9(b), the parties agree on the standard and disagree only about whether Ms. Caplinger has pleaded sufficient facts. The complaint sets forth considerable detail, as is evident from the complaint itself and summarized in Ms. Caplinger's opening brief (at 52-54). Because the complaint informs Medtronic of the who, what, and when of the misrepresentations—both representations made to the medical community at large and to Ms. Caplinger's physician in particular (in the operating room on August

25, 2010, by Medtronic representative Lisa Mitchell)—the claims are adequately pleaded.

B. Medtronic briefly makes three arguments, not argued below, in connection with the warranty claims. First, Medtronic (at 65-66) argues that the express warranty claim must meet Rule 9(b)'s heightened pleading standard for pleading a fraud claim because it "rests on the same allegations as her fraud claims." In fact,

> [T]he elements for a breach of express warranty claim are: (1) the defendant sold goods to the plaintiff; (2) the seller made a statement of fact about the kind or quality of those goods; (3) the statement of fact was a material factor inducing the buyer to purchase the goods; (4) the goods did not conform to that statement of fact; (5) the nonconformity injured the buyer; and (6) the buyer notified the seller of the nonconformity in a timely fashion.

Renaissance Leasing, LLC v. Vermeer Mfg. Co., 322 S.W.3d 112 (Mo. 2010). Ms. Caplinger's complaint reflects these standard elements. In contrast to the proof needed to prevail on her fraudulent misrepresentation claim, to prevail on her express warranty claim Ms. Caplinger will not have to prove Medtronic's knowledge of the falsity of its representations or its intent that the falsity induce her physician to use the product for the promoted off-label use. *See* Opening Br. 37 n.11 (setting forth elements of fraudulent misrepresentation claim). Because her claim does not require proof of fraud, it is not subject to Rule 9(b). *See, e.g., Two Old Hippies, LLC v. Catch the Bus, LLC*, 784 F. Supp. 2d 1200, 1207 (D.N.M. 2011) ("[C]laims based on negligent or innocent misrepresentation, to the extent

those claims do not require proof of fraud, may be pled in accordance with the more relaxed standards of rule 8(a).").

In addition, as explained above, the complaint includes sufficient particularity to satisfy Rule 9(b). The Rule's purpose is "to afford defendant fair notice of plaintiff's claims and the factual ground upon which [they] are based." Ms. Caplinger's complaint easily fulfills that purpose. *U.S. ex rel. Lemmon v. Envirocare of Utah*, 614 F.3d 1163, 1172 (10th Cir. 2010). Accordingly, even if Medtronic were correct that the warranty claim "sounds in fraud," the claim would satisfy Rule 9(b).

Second, Medtronic argues that the express warranty claim lacks sufficient detail under Rule 8 because it supposedly does not allege that Medtronic made an affirmation of fact or description of Infuse that was a basis for its use. The warranty claim incorporates allegations describing Medtronic's scheme to pay kickbacks and other incentives to physicians to influence clinical studies, prevent publication of adverse events, and encourage an unduly dangerous off-label use and allegations that Medtronic representative Mitchell discussed the use with Ms. Caplinger's physicians and was present at her surgery. *See* Appx. 12-20, ¶¶ 35-63; *id*. 30, ¶¶ 129, 131. These allegations satisfy the Rule 8 standard.

Third, Medtronic states that it disclaimed any warranties. The effect of the disclaimer (including whether it accompanied the actual product, whether it

reached off-label uses, and whether representative Mitchell made warranties) is a matter to be raised as an affirmative defense and appropriately resolved by the district court in the first instance. Furthermore, a disclaimer of implied warranties of merchantability is effective only if it is conspicuous. Mo. Rev. Stat. 400.2-316(2); *see Nester Commercial Roofing, Inc. v. Am. Builders and Contractors Supply Co*., 250 F. Appx. 852, 854 (10th Cir. 2007) (unpublished; Oklahoma law). Medtronic's disclaimer was not. Rather, the language to which Medtronic (at 68) points appears on page 7 of a 16-page document. *See* Appx. 91-106. Although the underlying and bold type appear in many places throughout the document to make certain text stand out, the "no warranties" statement appears in regular type at the end of a 2½-page discussion called "Description." *Id*. at 91, 93.

CONCLUSION

This Court should reverse the district court decision and remand for further proceedings.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE-STYLE REQUIREMENTS OF FED. R. APP. P. 32(a) AND WITH THIS COURT'S ELECTRONIC FILING REQUIREMENTS

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6,995 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and the Rules of this Court.

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word 2010 in 14-point Times New Roman.

3. This brief complies with the requirements for redaction of private information; it is identical to the paper copy of the brief; and the electronic file containing it has been scanned for viruses with an updated version of a commercial virus scanning program (VIPRE Business, version 6.2.5530.0, 2013 update) and is free from viruses.

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November 1, 2013

CERTIFICATE OF SERVICE

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