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United States Court of Appeals
Tenth Circuit

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PUBLISH

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

PATRICIA CAPLINGER,

Plaintiff-Appellant,

v.

MEDTRONIC, INC., a Minnesota corporation; MEDTRONIC SOFAMOR DANEK USA, INC., a Tennessee corporation,

Defendants-Appellees.

THE PRODUCT LIABILITY ADVISORY COUNCIL, INC.,

Amicus Curiae.

No. 13-6061

Appeal from the United States District Court
for the Western District of Oklahoma
(D.C. No. 5:12-CV-00630-M)

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Andrew E. Tauber of Mayer Brown LLP, Washington, D.C. (Daniel L. Ring of Mayer Brown LLP, Washington, D.C. and Scott M. Noveck, formerly of Mayer Brown LLP, Washington, D.C., and Michael K. Brown, James C. Martin, and Lisa M. Baird of Reed Smith LLP, Los Angeles, California, with him on the brief), for Defendants-Appellees.

Alan Untereiner and Donald Burke of Robbins, Russell, Englert, Orseck, Untereiner & Sauber LLP, Washington, D.C., and Hugh F. Young, Jr., of the Product Liability Advisory Council, Inc., Reston, Virginia, on the brief for amicus curiae Product Liability Advisory Council, Inc., in support of Defendants-Appellees.

Before **LUCERO**, **HARTZ**, and **GORSUCH**, Circuit Judges.

GORSUCH, Circuit Judge.

Some medical devices are so risky they can't be sold without the federal government's prior approval. While even relatively simple things like bandages face some degree of federal oversight, manufacturers of pacemakers, heart valves, and the like must prove the "safety and effectiveness" of their devices to the FDA's satisfaction before offering them for sale. Batteries of tests must be performed and presented and the agency's premarket approval process can take years. Beyond guarding the gate to the market square, the FDA also acts as censor for those allowed to enter. A manufacturer must receive the agency's approval for any instructional or warning label associated with its device. And once the device and label are approved, the manufacturer usually may not change them without the agency's consent. *See* 21 U.S.C. § 360e(d)(1)(A), (d)(6)(A)(i); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319 (2008).

As with most federal regulatory regimes, Congress had to balance competing goods when it enacted the Medical Device Amendments (MDA) to the

Federal Food, Drug, and Cosmetics Act (FDCA). Perhaps most notably, it had to weigh the good of ensuring that proposed medical devices are carefully scrutinized for safety against the good of preserving the freedom of patients and doctors to use potentially life-saving technology as they see fit and without undue delay. One arena in which these objectives clashed during the legislative process involved this question: to what extent (if any) should states be able to layer additional rules on top of Congress's? Allowing more regulation of medical devices could yield benefits for patient safety. But it could also mean forcing manufacturers to abide not one but fifty-one sets of requirements, a prospect that could deter or delay access to innovative devices and wind up hurting more patients than it helps.

Exercising its authority under the Supremacy Clause, Congress chose to balance these competing considerations by instructing that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The question we face is whether this provision forecloses Patricia Caplinger's state law tort suit against Medtronic. Medtronic produces Infuse, a device that stimulates bone growth to repair damaged or diseased vertebrae. When it approved the device for sale, the FDA required the company to include a warning label instructing that Infuse should "be implanted via an anterior" surgical approach. The label further cautioned that the device's "safety and effectiveness . . . in surgical techniques other than anterior open or anterior laparoscopic approaches have not been established" and that "[w]hen degenerative disc disease was treated by a posterior lumber [sic] interbody fusion procedure with cylindrical threaded cages, posterior bone formation was observed in some instances." Medtronic Sofamor Danek, *InFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device Important Medical Information* (2002).

Despite this warning, Ms. Caplinger alleges, Medtronic and its representatives promoted Infuse for use in a posterior surgical approach — an "off-label" use as it's known in the industry. Ms. Caplinger alleges that a Medtronic representative personally recommended using the device in this particular way to her and her doctor. All the while, Ms. Caplinger asserts, the company harbored evidence documenting dangers associated with posterior surgical approaches that it kept hidden. According to Ms. Caplinger, she and her doctor relied on Medtronic's representations and elected to implant the device using a posterior approach — only to watch complications emerge that could have

been avoided had they known the truth about Infuse. Ms. Caplinger alleges that Medtronic's conduct exposed the company to liability under a variety of state tort theories. But the district court held all of these state law claims either insufficiently pleaded or preempted, and it's this decision we're now asked to revisit.

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At first glance the answer to this appeal might appear easy enough. Section 360k(a) preempts "any requirement" imposed by states on manufacturers that differs from or adds to those found in the FDCA. Given this expansive language one might be forgiven for thinking all private state law tort suits are foreclosed. After all, a "requirement" usually means a request, need, want, or demand. *See* 13 *The Oxford English Dictionary* 682 (2d ed. 1989). And an adverse tort judgment seems to involve just that: a demand that a defendant appear to answer for its conduct and pay damages for failing some state law duty. Certainly some commentators have argued that the obligation to pay state law judgments amounts to an additional state law requirement warranting preemption under § 360k(a). *See, e.g.*, Mark Herrmann & Geoffrey J. Ritts, *Preemption and Medical Devices: A Response to Adler and Mann*, 51 Food & Drug L.J. 1, 15-16 (1996).

But the answer to this appeal isn't so simple. The Supreme Court has issued a number of opinions that embody "divergent views" about the proper role of the MDA's preemption provision, a fact that has yielded considerable

"uncertainty" among the lower courts seeking to apply the statute to cases like this one. Max N. Helveston, *Preemption Without Borders: The Modern Conflation of Tort and Contract Liabilities*, 48 Ga. L. Rev. 1085, 1124 (2014); *see also Martin v. Medtronic, Inc.*, 254 F.3d 573, 578-79 (5th Cir. 2001) (observing the difficulty in "extracting the final meaning" of the Supreme Court's cases in this area); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 700 (S.D. Tex. 2014) ("Courts have struggled with applying the Supreme Court's preemption rulings to cases involving the Infuse device."); *Carrelo v. Advanced Neuromodulation Sys., Inc.*, 777 F. Supp. 2d 303, 310 (D.P.R. 2011) (noting "the present struggle . . . to determine whether state-law claims are preempted by the MDA").

The Supreme Court's first significant encounter with the MDA's preemption provision came in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). There the Court rejected the notion that state law tort suits are always preempted. It held that tort suits do not impose new "requirements" on manufacturers and are not preempted so long as the duties they seek to impose "parallel" duties found in the FDCA. *Id.* at 495. The fact that a manufacturer is "required" to defend itself against a damages remedy nowhere provided for in federal law is, the Court indicated, neither here nor there.

But the Court's answer only invited the next question: when exactly does a state law duty "parallel" a federal law duty enough to evade preemption? That

term doesn't appear in the statute, so its meaning was left entirely to judicial exposition. And in *Lohr* itself five justices took the view that state and federal law duties "parallel" each other not only when they are identical, but also when state law imposes duties on the defendant that are "narrower, not broader" than those found in the FDCA. *Id.* So, for example, a state claim requiring a plaintiff to prove that a manufacturer negligently breached a duty of care might survive preemption if a federal regulation would impose strict liability in the same situation.

Now, you might ask, why isn't a narrower state law requirement at least "different from" a broader federal requirement — and thus preempted by § 360k(a)'s express terms? The *Lohr* majority acknowledged that a state duty imposing a "narrower requirement" is indeed "'different from' the federal rules in a literal sense." *Id.* And when it comes to interpreting the text of a statute, that's often the sense that matters most. *See, e.g.*, *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000) (noting that "when the statute's language is plain, the sole function of the courts — at least where the disposition required by the text is not absurd — is to enforce it according to its terms" (internal quotation marks omitted)). But all the same the *Lohr* majority adopted a test that leaves it to lower courts to try to resolve whether a state duty is "literally different" but "narrower" (and thus permissible) or "too different" and "broader" (and thus impermissible). Lower courts have struggled ever since when it comes

to trying to decide whether particular state claims do or don't "parallel" putative federal counterparts. *See, e.g., In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (noting that the "contours of the parallel claim exception" are "as-yet ill defined"); Mark Herrmann, David Booth Alden, & Bradley W. Harrison, *The Meaning of the Parallel Requirements Exception Under* Lohr *and* Riegel, 65 N.Y.U. Ann. Surv. Am. L. 545, 546 (2010) ("This parallel requirements exception is far from clear."); David Chang, Note, *Internalizing the External Costs of Medical Device Preemption*, 65 Hastings L.J. 283, 295 (2013) (noting that the Court's decisions have not "provide[d] much guidance as to what constitutes a parallel claim").

Neither are these the only directions *Lohr* left us to contend with. Section 360k(a) provides that state laws are preempted to the extent they conflict with "any [federal] requirement applicable under this chapter to the device." The chapter in question is chapter 9 of title 21 of the U.S. Code, which contains the whole of the FDCA. So, again read literally, it would seem "any" federal requirement imposed by the FDCA is capable of preempting any different or additional state requirement. But again the *Lohr* majority held otherwise, instructing lower courts that for preemption to take place the FDA must first issue some regulation "specific" to a "particular device." 518 U.S. at 498-99 (quoting 21 C.F.R. § 801.1(d)). Put differently, a device must undergo the premarket approval process — or, the Court suggested, perhaps something like it. *See id.*;

Riegel, 552 U.S. at 322-23. Lawsuits aimed at less highly regulated devices — like those subject only to "general" FDA regulatory requirements applicable to all devices — are not preempted. *See Lohr*, 518 U.S. at 500. To be sure, *Lohr* itself wasn't unequivocal on this point: the Court acknowledged the possibility that "general" federal requirements might sometimes preempt state requirements. *Id.* But when it comes to when and what kinds of "general" requirements have preemptive effect, or what sort of device-specific regulations beyond the premarket approval process might bear that same power, *Lohr* told us little. *See* Scott W. Sayler & Steven M. Thomas, *Post-Decision Diagnosis: Medical Device Preemption Alive and Mostly Well After* Medtronic, Inc. v. Lohr, 6 Annals Health L. 185, 196 (1997).

Since *Lohr*, the Supreme Court has twice revisited and cut back the scope of its initial decision. The first blow fell in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). There the Court addressed 21 U.S.C. § 337(a), a provision authorizing the federal government to enforce the MDA. In that statute's language and structure the Court found "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." *Id.* at 352. For this reason, *Buckman* concluded, § 337(a) preempts any state tort claim that exists "solely by virtue" of an FDCA violation — say, a claim against a manufacturer for violating the FDCA's prohibition against making false statements to the FDA during the device-approval process. *Id.* at 353. At the

same time, the Court left undisturbed the portion of *Lohr* allowing state lawsuits based on "traditional state tort law" that "predate[s]" the FDCA but happens to "parallel" it. *Id.* So it is that lower courts must now accept both the notion that § 337(a) shows Congress intended the federal government to enjoy exclusive enforcement authority over the MDA and the notion that § 360k(a) permits private tort suits that do no more than parallel the MDA. *See* Catherine M. Sharkey, *Tort-Agency Partnerships in an Age of Preemption*, 15 Theoretical Inquiries L. 359, 369-70 (2014) (noting the tension in allowing private tort suits in light of § 337(a)'s grant of exclusive enforcement authority).

The Court retreated further from *Lohr* in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). As *Riegel* saw it, the clause in § 360k(a) providing that "any [state] requirement . . . which relates to the safety or effectiveness of the device" should be read literally: *any* state requirement, whether device specific or generally applicable, is preempted when it differs from or adds to federal requirements. 552 U.S. at 327-28. While perhaps unremarkable on its own terms, this invited a new tension with *Lohr* and its suggestion that (at least usually) only device-specific federal requirements bear preemptive power even though the statute's literal language suggests "any" federal requirement hold that power. True, *Lohr* and *Riegel* formally addressed different clauses in § 360k(a) — *Lohr* interpreted the "any" federal requirements clause and *Riegel* discussed the "any" state requirements clause. But it's no small mystery why the same word — "any"

— should bear such different meanings in two such similar clauses that lie cheek by jowl in the same statutory subsection.

How are we supposed to apply all these competing instructions? It's "no easy task." *Martin*, 254 F.3d at 579. Even the usually straightforward job of laying out the rules governing our review is a real "struggle[]" in this area. *Schouest*, 13 F. Supp. 3d at 700. One can't help but wonder if perhaps some of those rules warrant revisiting and reconciliation. But if we understand our directions, it seems we aren't supposed to ask whether Ms. Caplinger wishes to use state tort law to impose on Medtronic a safety requirement that is "different from, or in addition to" a federal requirement so much as whether she seeks to vindicate a state duty that is "narrower" or "broader" than a federal duty. To the extent the state law duty is narrower than or equal to the federal duty it survives, through what seems a sort of Venn diagram approach to preemption. Still, even if the state claim fails that test because it would impose a "broader" duty than can be found in federal law, it appears we may not find the claim preempted just because it conflicts with "any" federal requirement. Instead, we may find the state law claim preempted only if there exists a device-specific federal requirement, though this test admittedly finds no analogue when it comes to the state requirement clause interpreted in *Riegel*. Finally, should the state claim survive this far, we must ask whether it exists "solely by virtue" of the federal statutory scheme (unacceptable) or "predates" the scheme (acceptable). It's no

wonder that the difficulty of crafting a complaint sufficient to satisfy all these demands has been compared to the task of navigating between Scylla and Charybdis. Jean Macchiaroli Eggen, *Navigating Between Scylla and Charybdis: Preemption of Medical Device "Parallel Claims,"* 9 J. Health & Biomedical L. 159, 161 (2013). Certainly the task we face in trying to apply the Court's directions faithfully feels something like that.

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How do Ms. Caplinger's pleadings measure up to the Court's announced preemption principles? Her complaint raises claims for strict products liability (alleging defective design and inadequate warning), breach of warranty, negligent misrepresentation, and negligence.[1] There's no dispute in our case that device-specific federal requirements apply to Infuse: the device endured the premarket approval process. So the MDA will preempt all of Ms. Caplinger's claims unless federal requirements impose duties that are at least as broad as those she seeks to vindicate through state law. *See Riegel*, 552 U.S. at 322-24.

It's here the problems begin. When it comes to her design defect and breach of warranty claims, Ms. Caplinger has not attempted, in either the district

[1] Ms. Caplinger also pursues claims for fraud, but we don't have to consider whether they survive preemption because we agree with the district court that Ms. Caplinger's complaint doesn't identify the who, what, when, where, and how of the alleged fraud with the specificity required by Federal Rule of Civil Procedure 9(b). *See, e.g.*, *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 726-27 (10th Cir. 2006).

court or this one, to identify a single parallel federal statute or regulation. For her failure to warn, negligence, and negligent misrepresentation claims, Ms. Caplinger has at least offered candidates for a parallel federal duty: 21 U.S.C. § 352 and 21 C.F.R. § 801.5. Through the combined effect of these provisions, a device's warning label must not be "false or misleading in any particular," 21 U.S.C. § 352(a), and generally must bear "directions under which the layman can use a device safely and for the purposes for which it is intended," 21 C.F.R. § 801.5. But on inspection these regulations do not provide parallels to most of the state claims she seeks to pursue. They don't because the federal regulations Ms. Caplinger cites govern only a device's labeling and her state law claims go well beyond that, attacking not just Infuse's label but also Medtronic's advertising and oral and written representations to her, her doctor, and others. So as a matter of law Ms. Caplinger's state law claims substantially exceed the potential scope of any federal regulation she's identified.

Even with respect to her remaining labeling attack that falls within the arguable (Venn diagram) scope of the regulations she's cited, another problem quickly emerges. Infuse is a prescription device. As federal regulations explain, that usually means it isn't possible to prepare adequate directions for its safe use by laymen. *Id.* § 801.109. And for precisely this reason, 21 C.F.R. § 801.109 generally absolves manufacturers from liability under § 352 and § 801.5 so long as they label their prescription devices in a certain manner approved by the FDA.

More than that, once the FDA approves a device's label as part of the premarket approval process (as it has here), the manufacturer usually may not alter the label's warnings without prior agency approval. *See* 21 U.S.C. § 360e(d). So in the end Ms. Caplinger relies exclusively on a legally inapplicable provision in her effort to establish a parallel claim (§ 801.5), fails anywhere to discuss the apparently applicable one (§ 801.109), and offers no answer to the conundrum how she might impose a state tort duty on Medtronic to revise a label that federal regulation precludes it from revising.

In these circumstances, we cannot see how the district court can be faulted for dismissing her claims. A district court may grant judgment as a matter of law under Federal Rule of Civil Procedure 12(b)(6) on the basis of an affirmative defense like preemption when the law compels that result. *See Jones v. Bock*, 549 U.S. 199, 212-15 (2007); 5B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1357 (3d ed. 2004 & Supp. 2014) (collecting cases). Here, Medtronic argued for just that result. It didn't dispute the veracity of any of Ms. Caplinger's factual pleadings. Instead, it contended that, even taking all her factual pleadings as true, not a single regulation or statute exists in all the federal law books parallel to the state law claims she sought to pursue. In reply, Ms. Caplinger didn't identify any viable parallel federal duty and so the district court quite reasonably concluded that the Medtronic had met its burden of showing that the law compelled dismissal of the complaint. *See, e.g., Wolicki-*

Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301-03 (11th Cir. 2011) (affirming the dismissal of a complaint where the plaintiff failed to identify a parallel federal duty); *Sprint Fidelis*, 623 F.3d at 1206-07 (same); *cf. Nelson v. State Farm Mut. Auto. Ins. Co.*, 419 F.3d 1117, 1120-21 (10th Cir. 2005) (noting that the plaintiff "made no suggestion of a proper accrual date at the trial-court level" in response to the defendant's statute-of-limitations affirmative defense).[2]

That's not to say another plaintiff won't ever be able to succeed where Ms. Caplinger has failed. For example, we don't question the possibility that buried somewhere in the heap of federal law parallel provisions exist to save claims like Ms. Caplinger's. After all, the FDA's medical device regulations alone cover 592 pages of eight-point type and the Supreme Court has suggested that in searching for a parallel federal duty a plaintiff may scour them all as well as the statute itself. *See Lohr*, 518 U.S. at 495. And lurking in there somewhere might be some answer to the apparent conundrum of how a plaintiff might use state law to require more label warnings that federal law seems to prohibit. But despite the

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[2] One might read some of these cases as suggesting that a plaintiff's complaint must anticipate the affirmative defense of preemption and identify parallel federal requirements. *See, e.g., Wolicki-Gables*, 634 F.3d at 1301-03; *Sprint Fidelis*, 623 F.3d at 1206-07. That far we do not go. After all, it is for defendants to prove their affirmative defenses in their motions, not for plaintiffs to disprove them in their complaints. *See Jones*, 549 U.S. 212-14; *Bausch v. Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010). But all the same it remains the case that a defendant may win dismissal as a matter of law with an affirmative defense if it can show that, without respect to any material dispute of fact, the law compels that result — exactly what happened here. *See, e.g., Jones*, 549 U.S. at 215; Wright & Miller, *supra*, § 1357 (collecting cases).

challenge of Medtronic's motion to dismiss, Ms. Caplinger has never — in all her voluminous briefs in the district court or this one — identified any legally viable federal requirement that might parallel and thus permit her claims. Neither are the courts under an obligation to perform that work for her, searching out theories and authorities she has not presented for herself. Indeed, we are especially hesitant to try that here, where Ms. Caplinger has been ably represented by counsel and the effort to supplement their efforts would require us to venture into a field in which so many others who've come before have struggled to find their way and there exists so much risk of going astray. *See, e.g.*, *Aquila, Inc. v. C.W. Mining*, 545 F.3d 1258, 1268 (10th Cir. 2008).[3]

Not only do we acknowledge others might succeed where Ms. Caplinger has failed. We also acknowledge that there's always the possibility an antecedent dispute of material fact will preclude a court from being able to render judgment as a matter of law on an affirmative defense like preemption. In *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), for example, the court found that the

[3] Ms. Caplinger's warranty claims, both express and implied, also fail because they depend on conclusory allegations. The operative complaint contains no well-pleaded facts suggesting, for example, what Medtronic expressly promised her, how those promises related to the Infuse device, or how they became part of the basis of the bargain. Likewise, the complaint doesn't allege any facts that would suggest any species of implied warranty claim. Regardless whether Oklahoma or Missouri state law happens to apply to this case (a question the parties debate but proves immaterial), Ms. Caplinger simply hasn't alleged "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also* Okla. Stat. Ann. tit. 12A, §§ 2-313 to -315; Mo. Ann. Stat. §§ 400.2-313 to -315.

plaintiff lacked access to the certain confidential premarket approval documents for the device in question. *Id.* at 561. According to the court, the plaintiff didn't and couldn't know at the time of the motion to dismiss what federal requirements applied to the device in question. And without knowing, as a factual matter, what federal requirements did and didn't apply to the device the court held it couldn't resolve the legal question whether the state torts the plaintiff wished to pursue did or didn't parallel those federal requirements. In other words, a material question of fact (what federal requirements exist related to the device?) precluded the ability to issue a definitive ruling on the legal question (do the plaintiff's state law claims parallel federal requirements?).

But, once again, Ms. Caplinger has never suggested anything like that here. She's never argued that she lacks access to any relevant documents for the Infuse device and she has never identified any other missing material fact essential to analyzing the preemption question. She has not so much as cited *Bausch* to suggest the preemption question presented in our case raises anything less than a purely legal question. In these circumstances we can again hardly fault the district court for granting judgment as a matter of law when no one has suggested a material dispute of fact exists that might require otherwise.[4]

[4] Our colleague states that Ms. Caplinger's efforts to identify a parallel federal requirement have not proven "model[s] of clarity" but suggests that we should still remand the case to allow Ms. Caplinger one more chance to crack open the federal register and unearth some parallel requirement or perhaps amend her complaint. *See post* at 7-8; *id.* at 14. Respectfully, however, Ms. Caplinger

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Still, that doesn't come close to ending our encounter with this case. So far we've hewed to the path the Supreme Court mapped out in *Lohr*, *Riegel*, and *Buckman*, asking whether Ms. Caplinger's state law claims seek to impose duties that parallel federal duties but do not depend solely on federal law. Recognizing the weakness of her position under the tests announced by the Supreme Court, she now seeks to suggest they don't much matter. Even if no parallel federal requirements exist for her state tort claims, Ms. Caplinger argues that's immaterial and her tort claims should survive preemption anyway. As she sees it, the fact that her suit concerns an off-label use is enough all by itself to insulate all her claims from preemption. Her reasoning goes something like this: When weighing whether a medical device is sufficiently safe to enter the market, the FDA usually examines the use the manufacturer intends the device to be put — its "on-label" use. *See* 21 U.S.C. §§ 360c(a)(2), 360e(d)(1)-(2). Because the agency's studies and safety assessments generally focus on the device's intended or on-label uses, she argues, it isn't appropriate to preempt claims concerning off-

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has already amended her complaint once and in this appeal she does not seek another chance to do so. Indeed, she nowhere challenges the district court's ruling denying her motion to file a second amended complaint; instead, she chooses to stand and fight on the basis of her existing pleadings. Neither do we see a lawful basis for remanding the case for further proceedings on the present pleadings. Ms. Caplinger has been repeatedly challenged to identify some federal regulation or statute on the books that parallels her state law claims and she has repeatedly failed to do so. Accordingly, Medtronic is now entitled to the judgment it has long sought on its affirmative defense.

label uses. Parallelism may be one way to avoid preemption, but in Ms. Caplinger's estimation attacking off-label uses should be another entirely separate way around the problem. In not a single one of its many and involved encounters with the MDA has the Supreme Court so much as hinted at this alternative path around preemption. But Ms. Caplinger says its past obscurity shouldn't stop us from recognizing it now.

This we decline to do.[5] Textually, § 360k(a) simply does not contain the distinction Ms. Caplinger would have us draw between suits addressing on- and off-label uses. The MDA says that a plaintiff may not invoke state law to impose "*any* requirement" that "relates to the safety or effectiveness of [a] *device*" that is "different from, or in addition to, any requirement applicable . . . to the *device*" under the FDCA. 21 U.S.C. § 360k(a) (emphasis added). Nothing depends on whether the plaintiff seeks to use state law to impose requirements for off-label uses or on-label uses. Rather, by its terms, the statute preempts *any* effort to use state law to impose a new requirement on a federally approved medical device.

Neither was Congress oblivious to the potential pitfalls (and promises) of off-label uses when it wrote such a broad preemption provision. Congress spoke directly to off-label uses in 21 U.S.C. § 396. There legislators went out of their way to protect the liberty of doctors and patients to use approved devices in any

[5] Neither do we understand our colleague's separate writing as taking a different view. His difference of opinion appears to be confined to the question whether a parallel federal requirement might exist to save this suit.

manner they wish — including off-label — instructing that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device." 21 U.S.C. § 396. Congress added this language aware that experiments with off-label uses often prove vital to patients and wary about granting the federal government the power to deny doctors and patients the freedom to use approved devices in any way they think might help improve health or extend life. *See Buckman*, 531 U.S. at 351 n.5. But in preserving the liberty of doctors and patients to use approved devices however they wish, Congress also appeared to place a good deal of the risk on them rather than on manufacturers. Knowing about (even encouraging) off-label uses in § 396, Congress proceeded in § 360k(a) to preempt any state tort suit challenging the safety of a federally approved device without qualification about the manner of its use. Given that Congress well understood the difference between on- and off-label uses and exhibited its facility with those terms in § 396, the absence of any mention of them in § 360k(a) becomes all the harder to ignore, a sort of dog that didn't bark. *See, e.g.*, *Roberts v. Sea-Land Servs., Inc.*, 132 S. Ct. 1350, 1357 n.5 (2012) (explaining that when Congress uses "different language" in different parts of the same statute, we normally "assume[] different meanings were intended" (quoting *Sosa v. Alvarez-Machain*, 542 U.S. 692, 711 n.9 (2004)) (internal quotation mark omitted)).

At this point in the proceedings and recognizing the absence of any textual authority for limiting § 360k(a)'s preemptive effect to challenges concerning on-label uses, Ms. Caplinger offers yet another amendment to her position, even as she continues to aim in the same direction. Now she says preemption should occur only when a state requirement differs from or adds to a federal regulation covering the "same subject." And because there are no federal regulations on the "subject" of off-label uses, she reasons, off-label claims should not be preempted.

This theory faces a similar textual dead-end. Section 360k(a) doesn't preempt only those state safety requirements addressing the "same subject" as federal requirements. Instead and again, the statute requires preemption whenever state law is used to impose "any requirement . . . which relates to the safety or effectiveness of the device." To accommodate Ms. Caplinger's view, a serious revision would be required, mandating preemption only when the state imposes "any requirement . . . which relates to the safety and effectiveness of the device *and concerns the same subject matter as a federal requirement*." We discern nothing in the judicial power that might permit us to undertake such a revamping of Congress's handiwork.

Not only does the statute lack Ms. Caplinger's latest precondition to preemption, it once again contains evidence suggesting that Congress knew how to prescribe ones exactly like it when it wished. Section 360k(a) preempts any state requirement that (1) adds to or differs from federal requirements and (2)

relates either to (a) a device's "safety or effectiveness" or (b) "any other matter included in a [federal] requirement applicable to the device." The category we've labeled (b) is noteworthy because there a federal requirement concerning the "same subject" as a state requirement may be a necessary precondition to preemption. Meanwhile, none of this is true of the first category — what we've labeled (a). That category specifies its preemptive reach plainly and broadly: any state requirement that adds to federal requirements and that relates to the safety or effectiveness of the device is preempted. No other qualification exists. It seems pretty clear, then, that Congress knew not only how to impose a "same subject" precondition to preemption but actually chose to do so in an adjacent clause. In this light, its decision not to include a "same subject" precondition in the clause under review seems all the more deliberate and difficult for a court to disregard. *See Roberts*, 132 S. Ct. at 1357 n.5.

Beyond these textual impediments, Ms. Caplinger's theories face precedential problems. Like Ms. Caplinger, the plaintiff in *Riegel* argued that a medical device was poorly designed for the particular off-label use his doctor made of it. The plaintiff in *Riegel* claimed, too, that the manufacturer failed to provide sufficient warnings about off-label uses. Even so, the Court didn't hesitate to find all of his claims preempted. Once a device endures the premarket approval process, *Riegel* held, any state safety requirement differing from or adding to the body of federal regulations is preempted, even if that requirement

comes in the guise of a general tort suit addressing only safety issues relating to off-label uses. *See* 552 U.S. at 322-24. Indeed, the Court told us unequivocally that "[s]tate tort law that requires a manufacturer's [device] to be safer . . . than the model the FDA has approved disrupts the federal scheme." *Id.* at 325. And the Court proceeded to dismiss the plaintiff's design defect and failure to warn claims addressing off-label uses. We fail to see how we might faithfully reach a different view here.

Our conclusion finds support in circuit precedent too. Several circuits have already recognized that once a device survives premarket approval it's immune from state tort suits that seek to impose different or additional safety-related duties like those alleged here. *See, e.g.*, *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc); *Walker v. Medtronic, Inc.*, 670 F.3d 569, 577 (4th Cir. 2012); *Hughes v. Bos. Scientific Corp.*, 631 F.3d 762, 768 (5th Cir. 2011); *Wolicki-Gables*, 634 F.3d at 1301; *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 439-40 (6th Cir. 2010); *Bausch*, 630 F.3d at 552-53; *Sprint Fidelis*, 623 F.3d at 1205; *see also* Helveston, *supra*, at 1111 (explaining that "the MDA grants manufacturers of devices that have gone through the pre-market approval process immunity from nearly all state law claims"). On the other side of the ledger, Ms. Caplinger cites no circuit authority supporting any of her various arguments for reversal.

Instead, she notes that the FDA recently submitted a legal brief in another case that arguably endorses her view that § 360k(a) preempts only claims concerning on-label uses and allows any claim concerning off-label uses to proceed. *See* Brief for the United States as Amicus Curiae at 8-9, *Medtronic, Inc. v. Stengel*, No. 12-1351 (U.S. 2014). But Ms. Caplinger neglects to mention that the agency itself not long ago read the MDA preemption provision just as we have, as preempting any claim that seeks to impose a state law duty that differs from or adds to federal duties, whether those duties concern on- or off-label uses. *See* Brief for the United States as Amicus Curiae Supporting Respondent at 8, *Riegel*, 552 U.S. 312 (2008) (No. 06-179). Neither does the agency's latest brief mention — let alone seek to explain why it has deviated from — its prior litigating position. And the FDA acknowledges candidly that its (current) litigating position would require a court to reject "every [circuit] case since *Riegel*" because none has suggested that § 360k(a)'s preemptive effect depends on a dichotomy between on- and off-label uses. *See* Brief for the United States as Amicus Curiae, *Stengel*, *supra*, at 15-16. Without any good reason to defer to the FDA's current position over its previous position — and the textual and precedential acrobatics that would be required to land there — we decline the attempt.

Aside from statutory terms, structure, and precedent there remains the question of statutory purpose. The business of hazarding a guess about the intent

of a legislative body composed of more than 500 individuals, each with his or her own interests and ends, always bears its risks. But as explored by the parties and amicus, the legislative history suggests that to the extent Congress considered any of the questions here it opted for the broadest available preemption provision in circulation during the drafting process. *Compare* H.R. 11124, 94th Cong. § 2 (as reported by H. Comm. on Interstate & Foreign Commerce, Feb. 29, 1976), *with* S. 510, 94th Cong. § 704 (as passed by Senate, April 17, 1975).

It's easy to imagine, too, why Congress adopted a preemption provision that doesn't distinguish between on- and off-label uses. Any additional state duties on top of those imposed by federal law, even if nominally limited to off-label uses, might check innovation, postpone access to life-saving devices, and impose barriers to entry without sufficient offsetting safety gains. For example, a state's judgment that a device is unsafe for a particular off-label use could require design changes that adversely affect the device's safety for on-label uses. Requiring manufacturers to comply with fifty states' warning requirements concerning off-label uses, on top of existing federal on-label warning requirements, might introduce sufficient uncertainty and cost that manufacturers would delay or abandon at least some number of life-saving innovations. *See, e.g.*, Sharkey, *supra*, at 361; Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L. Rev. 1353, 1385-86 (2006); Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 Geo.

Wash. L. Rev. 449, 483 (2008). Regulating any aspect of a device also raises the possibility of "spillover effects" from rules that "benefit in-state residents" at the expense of out-of-staters. Issacharoff & Sharkey, *supra*, at 1386-87. In short, we can see a number of ways in which a lawsuit nominally limited to attacking an off-label use might have knock-on effects for those seeking access to a device for its on-label use. And the Supreme Court has explained that "the text of the statute . . . suggests that the solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those 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.

Not everyone may agree with how Congress balanced the competing interests it faced in this sensitive and difficult area. We can surely imagine a different statute embodying a different judgment. But strike a balance Congress had to and did, and it is not for this court to revise it by beating a new path around preemption nowhere authorized in the text of the statute and nowhere recognized in any of the Supreme Court's many forays into this field.

Affirmed.

13-6061, Caplinger v. Medtronic

LUCERO, J., concurring in part and dissenting in part.

According to the majority, Patricia Caplinger cannot recover for harms, long cognizable under state law, that flow directly from Medtronic's alleged violations of federal laws forbidding the introduction of misbranded or adulterated medical devices into the market. This result is compelled neither by binding precedent nor by the plain text and clear purpose of the Federal Food, Drug, and Cosmetic Act as amended by the Medical Devices Amendments of 1976 ("MDA"), which were enacted to promote the safety of medical devices through honest labeling and promotion.[1]

Federalism concerns caution against rushing to preempt state law. See The Federalist No. 33, at 206-08 (Alexander Hamilton) (J. Cooke ed. 1961). Those concerns are heightened when, as here, the district court misapprehended the scope of relevant law. Although I agree with most of the majority's preemption analysis, I write separately to express these concerns, discuss how the district court misapprehended law, and explain why some of Caplinger's claims are at least plausibly parallel and should survive a motion to dismiss at this early stage of the litigation.

[1] Ensuring the truthful labeling and promotion of medical devices has been a federal priority for decades. See S. Rep. No. 94-33, at 17 (1976), reprinted in 1976 U.S.C.C.A.N. 1070, 1086 (stating that "[t]he Committee believes that the Secretary of Health, Education, and Welfare should have authority to regulate prescription medical device advertising"); id. at 2-3, reprinted in 1976 U.S.C.C.A.N. at 1072 (explaining that in the Federal Food, Drug, and Cosmetic Act of 1938, "the major concern with these devices was assuring truthful labeling").

I

Caplinger alleges that Medtronic promoted and marketed uses of its Infuse product to Caplinger and her physicians that were not approved by the Food and Drug Administration ("FDA"). This "off-label" promotion allegedly induced Caplinger and her physicians to implant Infuse in Caplinger's spine using a technique that had never been evaluated by the FDA.[2] A Medtronic representative, acting in the course of her employment, actively provided information regarding Infuse as it applied to Caplinger's particular surgery and was present during her surgery. Caplinger's complaint details extensive evidence suggesting that Medtronic intentionally introduced Infuse into the market for misbranded or adulterated uses, including the specific off-label use that harmed Caplinger. This includes evidence that Medtronic improperly bribed physicians, paid "kickbacks" to promote these off-label uses, and funded misleading scientific studies that misrepresented the safety of these uses.[3] Caplinger alleges that Medtronic's conduct violated the MDA, FDA regulations, and state tort law.[4]

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[2] In considering Medtronic's motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), we must assume that Caplinger's factual allegations are true. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007).

[3] Caplinger also proffers well-substantiated allegations that Medtronic was subjected to a bipartisan Senate investigation for its marketing practices.

[4] The parties dispute which state law applies. Caplinger argues that determining the relevant state law should not affect the preemption analysis. This is incorrect. The specific requirements and duties imposed by state law are so central to the preemption analysis that this issue on its own merits a remand. See Bates v. Dow Agrosciences LLC, 544 U.S. 431, 453 & n.27 (2005). There is some evidence suggesting that the district court applied Oklahoma law, and in illustrating why I would conclude that some of Caplinger's claims are not preempted at this stage of the litigation, I will discuss the

II

After a device has been submitted for Premarket Approval ("PMA"), the FDA carefully studies its safety "under the conditions of use prescribed, recommended, or suggested in the proposed labeling" by the manufacturer. 21 U.S.C. § 360e(d)(2)(A). A device can be safe for one use but unsafe for many others. For instance, an artificial heart valve safe for use in adults may not be safe for pediatric use. Immunizing from liability a medical device company that sells or markets a device for untested, unapproved, and potentially unsafe uses would completely subvert the purpose of the PMA process and provide perverse incentives for device companies as they seek federal approval.

The FDA guards against this danger by forbidding manufacturers from introducing "misbranded" or "adulterated" devices into the marketplace. §§ 351, 352; see also 21 C.F.R. § 814.80 (forbidding devices to be "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device"). An otherwise approved device is misbranded if, among other things, "its labeling is false or misleading in any particular," its label does not bear "adequate directions for use," or the manufacturer of a restricted device uses "false or misleading advertising." 21 U.S.C. § 352. The FDA has sensibly concluded that a manufacturer who introduces a medical device into the market for uses not contemplated in the PMA process violates the prohibition on selling devices with false, misleading, and/or inadequate labeling. See 21 C.F.R. §§ 801.5, 801.109.

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elements of Oklahoma tort law. I express no opinion regarding the proper resolution of this choice of law dispute or whether its resolution would change the result.

Specifically, § 801.5 explains that "[a]dequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended" Id. (emphasis added). Another regulation, § 801.4, explains that references to intended use in § 801.5 "refer to the objective intent of the persons legally responsible for the labeling of devices" and are "determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article." § 801.4. The regulation further provides:

> This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.

Id. For prescription devices, such as Infuse, the labeling must include adequate information "under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented." § 801.109(c) (emphasis added).

If a manufacturer wishes to sell a device for an intended use not analyzed in the PMA process, it must generally "submit a PMA supplement for review and approval by FDA." § 814.39. A device sold in violation of that requirement is considered "adulterated." 21 U.S.C. § 351.

These prohibitions against misbranding or adulteration do not limit the ability of doctors to exercise professional judgment in their use of approved devices. As the majority notes, a medical practitioner does not violate federal law by using a medical device off-label. See § 396. However, practitioners who use devices off-label are not

excused from their legal responsibilities. Traditional state tort remedies such as negligence and malpractice ensure that those practitioners employ off-label devices in line with the professional standard of care.

Unlike the patient protection achieved by practitioner liability for off-label use, the result of allowing injured individuals to pursue state tort remedies against medical device manufacturers who legally sold and marketed FDA-approved devices would be an undue burden on those manufacturers. To avoid federal liability, each modification made to a device in order to forestall such a state tort claim would need to comply with the exacting PMA process. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 344-45 (2001) (explaining that "the PMA process is ordinarily quite time consuming because the FDA's review requires an 'average of 1,200 hours [for] each submission'" (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996))). Congress' solution to this problem was enacting § 360k(a). Pursuant to this provision, a medical device manufacturer who complies with the PMA process and the FDA's marketing regulations cannot be held liable under state law for injuries resulting from a physician's off-label use of a medical device. Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (holding state law tort claims preempted when plaintiff asserted "that Medtronic's device violated state tort law notwithstanding compliance with the relevant federal requirements" (emphasis added)); Walker v. Medtronic, Inc., 670 F.3d 569, 581 (4th Cir. 2012) (explaining that state law tort claims stemming from the failure of "devices that were designed, manufactured, and sold in accordance with the terms of their premarket approval were preempted" (emphasis added)).

In contrast, when a plaintiff alleges harms predicated on a manufacturer's violation of both FDA regulations and "parallel" state law duties, the enforcement of state tort law complements the federal scheme. See Riegel, 552 U.S. at 330; see also Lohr, 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part) ("[T]he threat of a damages remedy will give manufacturers an additional cause to comply . . . . Section 360k does not preclude States from imposing different or additional remedies, but only different or additional requirements."). This is a form of "cooperative federalism" that invites, but does not require, states to deploy their traditional police powers to provide remedies that reinforce federal standards. See New York v. United States, 505 U.S. 144, 167-68 (1992) (discussing cooperative federalism); see generally Jessica Bulman-Pozen & Heather K. Gerken, Uncooperative Federalism, 118 Yale L.J. 1256 (2009) (explaining how cooperative federalism structures the relationship between states and the federal government). With the MDA, Congress has provided a powerful example of how our federal system can work to efficiently implement national regulations while simultaneously respecting the role of states in that system.

Thus, § 360(k)(a) does not expressly preempt the state law claims of a plaintiff like Caplinger who alleges that: (1) the medical device that injured her was misbranded or adulterated in violation of federal law; (2) the violation of federal law that caused the product to become misbranded or adulterated is also a violation of state law; and (3) her use of the device resulted in harms with parallel state law remedies. See Bausch v. Stryker Corp., 630 F.3d 546, 553 (7th Cir. 2010) (concluding that "section 360k provides

immunity for manufacturers of new Class III medical devices to the extent that they comply with federal law, but it does not protect them if they have violated federal law").

To hold otherwise would "have the perverse effect of granting complete immunity" from state law torts stemming from misbranding and adulteration practices forbidden by federal law and regulation "to an entire industry that, in the judgment of Congress, needed more stringent regulation in order to provide for the safety and effectiveness of medical devices intended for human use." Lohr, 518 U.S. at 487 (quotation omitted). Moreover, allowing medical device companies to escape state tort liability in such a situation would improperly shift the risk of liability from device companies that intentionally mislead physicians to the physicians who rely upon that misleading advice when deciding to utilize a device off-label. Congress sensibly refused to establish such a dystopic regime.

III

I suspect that the majority would not disagree with the above preemption analysis. Our disagreement in this case stems primarily from our varying characterization of Caplinger's complaint and her appellate briefing. In my view, the majority holds Caplinger's complaint and appellate briefing to an excessively stringent standard that places the onus on her to affirmatively demonstrate that state law claims are parallel to federal requirements. The majority does this by minimizing the scope of her state tort claims and their relationship with the relevant federal laws. I admit that Caplinger's briefing on the topic, especially before the district court, was not a model of clarity, but the presence of parallel state claims in Caplinger's complaint is certainly more apparent

than in the operative complaint in Lohr, where the Supreme Court allowed a suit to proceed on remand. See 518 U.S. at 495 (allowing the Lohrs' suit against Medtronic to proceed despite the fact that "the precise contours of their theory of recovery have not yet been defined" because "it is clear that the Lohrs' allegations may include claims that Medtronic has, to the extent that they exist, violated FDA regulations"). Moreover, because the district court based its dismissal on a mistaken understanding of the MDA and relevant FDA regulations, and failed to compare the elements of state tort law with the federal requirements, Caplinger should be provided an opportunity to make her case with the regulatory regime properly understood.

A

As the majority explains, federal law "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." Riegel, 552 U.S. at 330. Such a claim seeks a "parallel" remedy and is not expressly preempted by § 360k(a) if it does not impose any requirements with respect to safety or effectiveness that are "different from, or in addition to, federal requirements." Id. at 328 (quotation and citation omitted). Preemption is an affirmative defense, and the defendant bears the burden of proof. See Emerson v. Kan. City S. Ry. Co., 503 F.3d 1126, 1133-34 (10th Cir. 2007); see also De Buono v. NYSA-ILA Med. & Clinical Servs. Fund, 520 U.S. 806, 814 (1997); Stengel v. Medtronic Inc., 704 F.3d 1224, 1227 (9th Cir. 2013) (en banc) (explaining that "[p]arties seeking to invalidate a state law based on preemption bear the considerable burden of overcoming the starting presumption that Congress does not intend to supplant state law" (quotation omitted)). Caplinger has properly alleged facts in

her complaint "demonstrating the presence of the elements of a parallel claim" and she has pointed "to specific PMA requirements that have been violated." Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1302 (11th Cir. 2011). To establish that Caplinger's claims are expressly preempted, Medtronic must affirmatively show that her state tort claims are not "parallel" to the alleged federal violation. And to judge whether a plaintiff's state law claims are genuinely parallel, a district court must consider the elements "to determine whether these claims impose requirements that differ from or are in addition to federal requirements." Hughes v. Boston Scientific Corp., 631 F.3d 762, 768 (5th Cir. 2011).

Crucially, federal law and state law remedies need not be identical in order to be parallel and thus avoid express preemption. See Lohr, 518 U.S. at 495; see also Bates, 544 U.S. 431, 454 (2005) (holding that "to survive pre-emption, the state-law requirement need not be phrased in the identical language as its corresponding [statutory] requirement; it would be surprising if a common-law requirement used the same phraseology as [the statute]"). As the Court explained in Lohr, "additional elements of the state-law cause of action" requiring plaintiffs to show that "violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product . . . would make the state requirements narrower, not broader, than the federal requirement." 518 U.S. at 494. For example, in the context of misbranded or adulterated medical devices, a state may permissibly determine that it only wishes to provide private remedies to individuals who can demonstrate that they relied upon false statements or

omissions about the safety of the misbranded products, or that the misbranding or adulteration created an unreasonable hazard for its citizens.

B

The majority does not reach the question of implied preemption, because it holds that all of Caplinger's claims were either insufficiently pled or expressly preempted. The district court did reach the question, incorrectly holding that several of Caplinger's claims relating to Medtronic's "off-label marketing" would be impliedly preempted. Some otherwise parallel state claims are impliedly preempted because Congress has determined that actions to enforce FDA requirements related to medical devices "shall be by and in the name of the United States." § 337(a). This language has been interpreted by the Supreme Court to impliedly preempt claims that "exist solely by virtue" of federal requirements. Buckman, 531 U.S. at 353. This language does not, however, preempt claims that would traditionally sound in state tort law, such as Lohr's "common-law negligence action against the manufacturer of an allegedly defective pacemaker lead." Buckman, 531 U.S. at 352.

The contours of implied preemption are eloquently explained by the Sixth Circuit in Loreto v. Procter & Gamble Co., 515 F. App'x 576 (6th Cir. 2013) (unpublished). Loreto held that Buckman preempted a claim alleging that Procter & Gamble failed to tell consumers that its products were "illegal" when that claim's theory of liability depended "entirely upon an FDCA [Federal Food, Drug, and Cosmetic Act] violation—i.e., the only reason Procter & Gamble's products were allegedly 'illegal' was because they failed to comply with FDCA labeling requirements." 515 F. App'x at 579. But the court

allowed a claim to proceed alleging that Procter & Gamble made false or misleading statements regarding the same product, because the false-or-misleading "theory relies solely on traditional state tort law predating the FDCA, and would exist in the absence of the Act." Id. at 580; see also Hughes, 631 F.3d at 775 (holding that state tort law failure-to-warn claim was not impliedly preempted); Bausch, 630 F.3d at 557 (holding that tort law claims based on manufacturing defects were not impliedly preempted).

As discussed below, it is clear that at least some of Caplinger's claims are not dependent entirely upon a violation of federal law. Instead, they are grounded in traditional state-law duties that predate the MDA and would be cognizable even if the MDA did not exist. These claims are not impliedly preempted.

IV

According to the district court, Caplinger's state law claims were either not genuinely parallel to the federal laws relating to off-label promotion or were impliedly preempted because they were entirely based upon those laws and "even the concept of 'off-label use' is a creature of the FDCA, is defined by the FDCA, and is not part of Oklahoma substantive law." Caplinger v. Medtronic, Inc., 921 F. Supp. 2d 1206, 1219-20 (W.D. Okla. 2013). This misstates the scope of federal-law violations alleged in Caplinger's complaint, artificially narrowing their grounds. Federal regulations prohibit the promotion of off-label uses, which might itself form the basis of an appropriately parallel state law claim. But that act of forbidden promotion does not capture the extent of Medtronic's alleged federal violations, or the state tort claims Caplinger specifically raised in her complaint. Instead, Medtronic's allegedly illegal promotion of Infuse,

including Medtronic's advertising and oral and written statements made by its representatives, is properly viewed as evidence that Infuse was misbranded and/or adulterated in violation of the law. See United States v. Caronia, 703 F.3d 149, 154 (2d Cir. 2012) (explaining that misbranding may be proven by, "among other evidence, oral or written statements by [persons legally responsible for the labeling of drugs] or their representatives and the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised" (quotation omitted)); see also 21 C.F.R. § 801.4 (explaining that "intended use" of a device may be shown "by the circumstances that the article is . . . offered and used for a purpose for which it is neither labeled nor advertised"). Caplinger explicitly alleges violations of 21 U.S.C. § 331, which prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." Id. As a result, if Caplinger can prove that Infuse was misbranded or adulterated, her state law claims are not preempted so long as the federal violation that caused the devices to be misbranded is also a violation of some state law that does not impose requirements "different from, or in addition to" the federal prohibitions concerning misbranded or adulterated devices.

Applying this analysis, I would hold that Caplinger's claims based on failure to warn and negligence have been sufficiently pled to avoid preemption at this stage of the litigation. For each of these claims, Caplinger alleges that exactly the same conduct that violated federal device requirements also violated state law.

Although Caplinger's claims could end up being preempted as the case proceeds, the burden of establishing preemption at this stage falls upon Medtronic, and in my view it has not met that burden.

A

As a preliminary matter, I agree with the majority that Caplinger's complaint currently fails to state her fraud claims with the particularity required by Fed. R. Civ. P. 9(b). I also agree that her warranty claim was not sufficiently pled. However, these issues are closer than the majority concludes. Federal law explicitly forbids medical device manufacturers from engaging in false or misleading advertising. See §§ 331(a), 352(q)(1). With this in mind, and as the majority acknowledges, adequately pled state-law fraud claims bottomed on a device manufacturer's false or misleading advertising may escape preemption. Moreover, an adequately pled warranty claim should easily escape preemption. As the court in Houston v. Medtronic, Inc., 957 F. Supp. 2d 1166 (C.D. Cal. 2013), explained:

> [F]ederal law already prohibits false or misleading off-label promotion. Therefore, to the extent that Plaintiff seeks to impose liability on Defendants for voluntarily making misleading warranties outside the label, Plaintiff is not imposing any requirement different from or additional to what federal law already requires. In other words, to avoid state law liability on this claim, Defendants need only to refrain from making misleading warranties, which adds no burden beyond what federal law already imposes. Nor is the express warranty claim impliedly preempted under Buckman, as a claim for express breach of warranty finds its origin in traditional state law that predates the FDCA.

Id. at 1180-81. This conclusion is consistent with the developing consensus regarding the scope of preemption in this context. See Beavers-Gabriel v. Medtronic, Inc., 15 F. Supp.

3d 1021 (D. Haw. 2014) (holding that express warranty claim survives preemption); Schouest v. Medtronic, Inc., 13 F. Supp. 3d. 692, 707 (S.D. Tex. 2014) (same); Arvizu v. Medtronic Inc., 41 F. Supp. 3d 783, 793 (D. Ariz. 2014) (explaining that "[s]everal courts have found that claims for breach of express warranty are neither expressly nor impliedly preempted in the context of off-label promotion"); see also Scovil v. Medtronic Inc., No. 2:14-CV-00213-APG, 2015 WL 880614, at *12 (D. Nev. Mar. 2, 2015) (unpublished) (similar); Wright v. Medtronic, Inc., No. 1:13-CV-716, 2015 WL 328596, at *15 (W.D. Mich. Jan. 23, 2015) (unpublished) (similar); Arthur v. Medtronic, Inc., No. 4:14-CV-52 (CEJ), 2014 WL 3894365, at *8 (E.D. Mo. Aug. 11, 2014) (unpublished) (similar).

The district court denied Caplinger's motion to reconsider or, in the alternative, for leave to amend because it concluded many of her claims were necessarily preempted. Remand for the district court to apply a proper understanding of preemption would allow Caplinger to amend her complaint and possibly state viable fraud and warranty claims. See Fed. R. Civ. P. 15; Grossman v. Novell, Inc., 120 F.3d 1112, 1126 (10th Cir. 1997) (holding that it is an abuse of discretion for a district court to refuse leave to amend if the stated reasons are "incorrect as a matter of law").

B

In contrast, I would hold that Caplinger's failure-to-warn and negligence claims are not clearly preempted at this stage of the litigation and are also plausibly stated. Caplinger contends that Medtronic had a state law duty to warn both the plaintiff and her physician about the dangers associated with off-label use of Infuse. The district court concluded that this claim was expressly or impliedly preempted. To the extent that her

claim is predicated on a general failure to warn about off-label uses or asserts a state-imposed duty to include different or additional labeling, I agree with the majority and the district court that it is preempted by § 360k(a) or Buckman.

However, in my judgment, Caplinger may be advancing a more specific failure-to-warn claim that survives preemption. A medical device must contain directions that are adequate for its intended use. See 21 C.F.R. §§ 801.5, 801.109. A device's "intended use" is determined by "the objective intent of the persons legally responsible for the labeling of devices." § 801.4. Successful traversal of the PMA process means that the FDA has conclusively determined that a device is adequately labeled with respect to the intended use for which it was approved. See 21 U.S.C. § 360c(a)(1)(C)(ii)(II), 360c(a)(2)(B). But in her complaint, Caplinger incorporated allegations, supported by facts, that Medtronic misbranded Infuse in violation of federal law because it sold Infuse for an intended use not approved by the FDA. This would render its labeling no longer necessarily "adequate" under federal law. See 21 C.F.R. § 801.109(c). Caplinger's assertions relating to "advertising and oral and written representations to her, her doctor, and others" (Majority Op. 13), which the majority seems to read as irrelevant to the question at hand, likely have the purpose of demonstrating the existence of improper "purposes for which [Infuse] is intended." § 801.5.

Caplinger also alleged that even as it promoted Infuse in violation of those requirements, Medtronic failed to include adequate warnings and directions for the misbranded product that it was promoting. Other courts have imagined just this scenario

as the type of "narrow failure-to-warn claim that would escape preemption." Riley v. Cordis Corp., 625 F. Supp. 2d 769, 783 (D. Minn. 2009).

In Oklahoma, the elements of a product liability failure-to-warn claim are: (1) "the product was the cause of the injury"; (2) "the defect existed in the product, if the action is against the manufacturer, at the time the product left the manufacturer's possession and control"; and (3) the defect "made the article unreasonably dangerous." Kirkland v. Gen. Motors Corp., 521 P.2d 1353, 1363 (Okla. 1974). That defect "can stem from either a dangerous design or an inadequate warning about the product's dangers." Braswell v. Cincinnati Inc., 731 F.3d 1081, 1085 (10th Cir. 2013) (applying Oklahoma law); see also Tansy v. Dacomed Corp., 890 P.2d 881, 886 (Okla. 1994) (observing that "inadequate warnings" can render a product defective). Like federal medical device law, Oklahoma law considers an object's intended use when determining if a warning is sufficient to avoid making the product unreasonably dangerous. See Smith v. U.S. Gypsum Co., 612 P.2d 251, 256 (Okla. 1980); Kirkland, 521 P.2d at 1366 (holding that "[i]f the plaintiff is using the product for some purpose for which it was not intended and is consequently injured, he should not recover"). Moreover, like federal law, Oklahoma law specifically extends protection from defective design claims, including failure-to-warn claims, when "the product is properly manufactured and contains adequate warnings." Tansy, 890 P.2d at 886. The additional Oklahoma requirements that a plaintiff show injury and show that any warning was inadequate when the product "left the manufacturer's possession and control" are exactly the kind of "narrower" conditions that the Lohr court held were not preempted.

Comparing the relevant elements of federal and Oklahoma law makes it clear that Oklahoma imposes no requirements that are "different from, or in addition to" federal requirements. Cf. Riegel, 552 U.S. at 330. The district court incorrectly determined that this claim would be preempted because it would "permit a finding that defendants were required to provide warnings above and beyond those on the Infuse Device's label and accompanying the device." Caplinger, 921 F. Supp. 2d at 1221. This determination misstates the elements of Oklahoma law. Nothing in Oklahoma failure-to-warn law requires that Medtronic provide additional warnings or labeling in order to escape state tort liability. Once the specific elements of state law are apprehended, it becomes clear that Oklahoma is merely providing a mechanism for recovery if Medtronic violates federal law by introducing Infuse for an adulterated or misbranded use and the warnings accompanying Infuse are inadequate for that adulterated or misbranded use. The state duty, like the federal duty, requires that Medtronic provide adequate directions for use. It does not attach "liability to statements on the label that do not produce liability under [federal law]." See Bates, 544 U.S. at 456 (Thomas, J., concurring in part and dissenting in part). Permitting recovery would properly hold Medtronic accountable for its alleged violations of state and federal law. To hold otherwise would allow Medtronic to shift liability for its illegal misbranding and adulteration to patients and physicians and provide a strong disincentive for Medtronic to seek supplemental FDA approval when the intended use of a device changes.

Because Caplinger's failure-to-warn claim is at least arguably parallel to her claim that Medtronic's misbranded device failed to contain adequate directions for its intended

use, I would hold that it is not preempted at this juncture. Cf. Alton v. Medtronic, Inc., 970 F. Supp. 2d 1069, 1101 (D. Or. 2013) (holding that plaintiff's similar failure-to-warn claim against Medtronic regarding misbranding of Infuse was not preempted).

Caplinger also alleged claims sounding in negligence and negligent misrepresentation. In response to a certified question from our Circuit, the Oklahoma Supreme Court has explicitly acknowledged "the distinction between attempting to enforce a federal regulation and allowing a parallel claim for negligence per se bottomed on violation of the regulation." It held that Oklahoma negligence law provides a preexisting remedy for many of the harms caused by "adulterated" medical devices. Howard v. Zimmer, Inc., 299 P.3d 463, 470-74 (Okla. 2013). The remedy provided is not merely an enforcement action based on the violation of a federal regulation, which would be preempted by Buckman. Id. Caplinger claims that Medtronic provided untrue or misleading information about the safety and efficacy of the particular off-label use of Infuse that Medtronic allegedly promoted. Such conduct is a clear violation of federal law forbidding adulteration and misbranding, including 21 U.S.C. § 352 and 21 C.F.R. § 814.80. To the extent that Caplinger's negligence and negligent misrepresentation claims parallel these requirements, and her pleadings suggest they well might, those claims should not be preempted.

V

Although I would hold that several of Caplinger's claims are not preempted at this early stage of the litigation, and would remand the remaining claims with instructions to permit amendment, I would also echo the Sixth Circuit in reminding Caplinger that over

the course of her lawsuit, the "arguments she makes, the proofs she offers, and the evidence she submits are all subject to limitation by preemption principles." Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 588 (6th Cir. 2013). My disagreement with the majority opinion does not turn on the substance of federal preemption law. Instead, our disagreement turns on our respective characterization of Caplinger's pleadings and understanding of the proper burden at this stage of the litigation, as described by the Supreme Court in cases such as Lohr and Bates. I suspect that the majority would say that I am "trying out arguments and searching out legal theories [Caplinger] has not presented for herself" (Majority Op. 16). However, in light of the important federalism concerns at the heart of this case, the district court's misapprehension of relevant federal law, and its failure to examine the specific elements of state tort law at issue, I would remand for the district court to revisit its analysis with a proper understanding of this regulatory regime.

Ultimately, Caplinger's allegations need not be conclusive at this stage of the litigation. They need only state a plausible claim for relief. Twombly, 550 U.S. at 556. Although I disagree with the majority's interpretation of Caplinger's complaint, the text of the majority's opinion properly advises that a future plaintiff alleging similar harms can avoid preemption by carefully explicating the parallels between the alleged federal violations and state tort remedies.