No. 15-15653

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

KATHRYN MARIE JONES,
Plaintiff-Appellant,

v.

MEDTRONIC, ET AL.,
Defendants-Appellees.

Appeal from the United States District Court
for the District of Arizona

SUPPLEMENTAL REPLY BRIEF OF APPELLANT KATHRYN MARIE JONES

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Other Authorities

PMA Approval Database: P000058 – Infuse/LT-Cage:

INTRODUCTION

Parsing Medtronic's brief, two things stand out. First, the company never comes to grips with the fundamental problem with its preemption defense: it claims immunity based on the very regulatory scheme that it has allegedly evaded. Medtronic's position thus makes a farce of federal-preemption doctrine, which is premised on the supremacy of federal *regulation*, not its *absence*.

Second, and relatedly, Medtronic never confronts the human impact of its preemption argument—that is, how its preemption argument would harm Kathryn Jones and others like her. Judging by Medtronic's brief, no one would know that this case involves a real person grievously injured by the company's misconduct. Ms. Jones was implanted with a host of unapproved Medtronic products, placed in her body using unapproved methods, that Medtronic promoted to her doctors. A Medtronic sales representative stood alongside her surgeons in the operating room, SER 678-79, likely assisting with the spine surgery that has left her permanently disabled. *See* Ms. Jones's Opening Br. 23-26, 32.

Medtronic induced Ms. Jones's doctors into using the company's biologics, cages, and other hardware in ways and combinations never approved by FDA. SER 677-83, 688-91, 694-707. As a result, her spine failed to fuse so catastrophically that, according to national spine specialists, she would likely not survive any corrective surgery. SER 711-12. Ms. Jones now suffers from unceasing, debilitating pain. Medtronic's products have forever changed her body chemistry, while its hardware has migrated, making her

feel "as though she is full of sharp, jagged slivers of broken glass." SER 711. The pain prevents her from driving and limits her mobility, all but ending meaningful independence. SER 712; *see* Supp. Opening Br. 9-10.

Ms. Jones is not asking this Court to vindicate her allegations of wrongful conduct and grave injury now. She is asking only for a full opportunity to press these claims on the merits under Arizona law on remand.

In the following pages, we first address our principal argument—that Medtronic cannot gain preemption while evading federal regulation—and explain why Medtronic's contrary arguments fail. We next show that Medtronic's efforts to gain preemption for injuries caused by its Class II products are foreclosed by controlling precedent. We then separately demonstrate that Ms. Jones's state-law claims are non-preempted "parallel" claims. Finally, we explain that Ms. Jones's pro se complaint is well-pleaded and, even if it is not, that she is entitled to re-plead (a proposition that Medtronic does not contest).

STATUTORY AND REGULATORY ADDENDUM

Pertinent statutes and regulations not reproduced in the Supplemental Opening Brief appear in an addendum to this brief.

ARGUMENT

I. Ms. Jones's claims are not preempted because the products Medtronic promoted for use in her surgeries had not been approved by FDA.

A. FDA does not impose device-specific "requirements" on products promoted for unapproved uses.

1. A product's premarket approval under the MDA is limited to the product's uses authorized on its FDA-approved label. Therefore, when FDA grants marketing approval, it does not impose preemptive "requirements" under 21 U.S.C. § 360k on products marketed for uses other than those on the label.

Medtronic's key contrary argument—that Section 360k applies regardless of how a product is promoted because "FDA approves devices, not uses," Ans. Br. 23-30—is at odds with the MDA. When a manufacturer seeks premarket approval to sell a new Class III product, its application to FDA must include proposed labeling. 21 U.S.C. § 360e(c)(1)(F). The statute demands that FDA "rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance" of the product's "safety and effectiveness" when marketed. *Id.* § 360e(d)(1)(A). FDA "shall deny" an application if the proposed labeling does not provide assurance that a product will be safe and effective when marketed for its proposed uses. *Id.* § 360e(d)(2)(A)-(B).

FDA approval includes approval of the product's label, which limits marketing to only those uses approved as safe and effective. Even Medtronic acknowledges that FDA's approval of "design, manufacture, and *labeling*" are integral to approval of "*devices*

themselves." Ans. Br. 23 (first emphasis added). The statute bars manufacturers from promoting or advertising a product inconsistent with its label. 21 U.S.C. §§ 331(a), 352. Therefore, marketing approval authorizes a manufacturer to promote a product only for the uses on its approved label.

Medtronic's "devices, not uses" theory is also incompatible with the MDA's regulatory requirements for marketing new uses of existing PMA products. Manufacturers must seek supplemental approval for changes to a previously approved product, 21 U.S.C. § 360e(d)(5), including new uses not approved in the original PMA, 21 C.F.R. § 814.39(a)(1). If Medtronic believed that FDA's initial approval of Infuse/LT-Cage authorized it to market *any* use of that product, as it now argues (Ans. Br. 23-26), the company would not have sought new approvals to market new uses of that same product. But it has. *See, e.g.*, FDA PMA Approval Database: P000058/S002, (extending approved levels of use in the spine up to L2).[1]

2. Medtronic's focus on the word "device" in Section 360k, Ans. Br. 22-30, is beside the point. A product promoted for unapproved uses is no longer "the device" approved by FDA because the agency approves a "device" as safe for marketing only for the uses listed on its label. This understanding dovetails with FDA guidance discussed in our Supplemental Opening Brief (at 23-24) and ignored in Medtronic's brief. When a manufacturer intends to promote a product for uses that are significantly

[1] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000058S002

different from the uses on its label—including, as here, using a different surgical procedure—it must submit a new PMA device application because that product is a new device.[2]

Look no further than Medtronic's own practices for proof that new intended uses of a product require separate approval. For example, Medtronic itself points to two approvals of one physical product—the Infuse biologic in a sponge without a cage—each for a different use. Ans. Br. 7 n.1. This product was approved as "Infuse® Bone Graft" through a PMA device application (P000054) for use only in the tibia.[3] The identical physical product was later approved through *a separate PMA device application* (P050053), with different, use-specific labeling for use only in the face.[4] Indeed, the latter was approved for marketing as "Infuse® Bone Graft *for Certain Oral Maxillofacial and Dental Regenerative Uses*." *Id.* (emphasis added). (The Infuse-biologic-and-sponge

[2] FDA, Guidance for Industry and Staff: Modifications to Devices Subject to Premarket Approval 5-6 (2008), https://perma.cc/BBX3-KGXE.

[3] SER 558 (FDA approval letter); Label 0381204E Rev. C (Sep. 16, 2013), https://perma.cc/2KDW-ZDS2. *See* PMA Approval Database: P000054, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000054. *See also* Ms. Jones's Opening Br. 22.

[4] SER 566 (FDA approval letter); Label M704819B001E Rev. B (Aug. 29, 2012), https://perma.cc/K726-RW49. *See* PMA Approval Database: P050053, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P050053. *See also* Ms. Jones's Opening Br. 23.

combination has *never* been approved for use as implanted in Ms. Jones—without a cage and in the spine.)

Here, Medtronic's products were not intended for use as they were used in Ms. Jones: at seven consecutive levels of the spine, for nineteen total applications, without a cage, with unapproved cages, at spine levels above L2, and via a non-anterior surgical approach. *See* Supp. Opening Br. 11-12. The Infuse/LT-Cage label stated that the safety of many of these deviations "has not been established." SER 632. By promoting these radically new uses, Medtronic promoted new, unapproved products for use in Ms. Jones's surgeries.[5]

For this reason, it cannot be correct—as Medtronic appears to argue, Ans. Br. 51-52—that FDA's approval of a label that includes statements about unapproved uses preempts claims based on promotion of those same unapproved uses. Quite the contrary, the label, by its very terms, underscores why Medtronic's promotion of unapproved uses exceeds the scope of FDA's approval. Under Medtronic's theory, a manufacturer could receive marketing approval for a benign use only to leverage that approval as a preemptive shield against claims arising from its promotion of dangerous, unapproved uses of the same product. That result would undermine "the primary issue

[5] Medtronic suggests that it received supplemental approvals for Infuse/LT-Cage (PMA P000058) that approved the Infuse biologic without a cage. Ans. Br. 7 n.1. That is not true. The two approvals Medtronic cites (*see* SER 558, 566) are entirely separate PMAs for separate devices, for use in the tibia and in the face, respectively—not in the spine.

motivating the MDA's enactment: the safety of those who use medical devices." *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013) (en banc) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 491 (1996)).

That new intended uses of PMA products require new FDA approvals also shows why *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335 (10th Cir. 2015), is wrong. *See* Supp. Opening Br. 28-29. The *Caplinger* majority's basic mistake was to equate "the device" with the physical product alone rather than the product as intended for use. 784 F.3d at 1343-44. Though seeking to examine the question "[t]extually," *id.*, *Caplinger* misread Section 360k's text and overlooked the rest of the interlocking statutory provisions comprising premarket approval. *See* Supp. Opening Br. 28-29. As explained, what constitutes a "device" under the FDCA depends on how the product is "intended for use." *See* 21 U.S.C. § 360c(a)(2)(B); 21 C.F.R. § 801.4 (manufacturer's post-approval actions can create new intended uses).

3. Medtronic's contention, based on 21 U.S.C. § 396, that FDA does not approve uses because the statute recognizes that doctors may use devices in unapproved ways is a non sequitur. Ans. Br. 24-26. That argument erroneously conflates a doctor's *use* with the manufacturer's *promotion* of unapproved uses. Though the FDCA does not regulate the former, it prohibits the latter. Section 396 says *both* that the statute does not "interfere with the authority of a health care practitioner" to use products *and* that recognizing this authority "shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices." And so, Medtronic's assertion that

FDA "contemplates" unapproved use by doctors, Ans. Br. 24-26, simply reflects that federal regulation of manufacturer promotion coexists with federal non-regulation of doctors (who are regulated by state laws concerning licensing and professional discipline).

Medtronic's selective quotation of an FDA Bulletin to suggest that FDA does not "approve or disapprove particular *uses*" is driven by the same misunderstanding. Ans. Br. 9 (citing FDA, Use of Approved Drugs for Unlabeled Indications, Drug Bulletin, April 1982, 4, 5, https://perma.cc/G9J9-2FCC). The Bulletin acknowledges that doctors might use products off-label. Bulletin, at 5. But, just lines before, the Bulletin says that products "may be labeled, promoted, and advertised by the manufacturer *only for those uses* for which the [product's] safety and effectiveness have been established and which the FDA has approved." *Id.* at 4 (emphasis added).

4. Medtronic argues that limiting a product's approval to its approved uses "cannot be reconciled" with *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), because the preempted claim there involved a doctor's off-label use. Ans. Br. 27-28. Wrong. Although the plaintiff in *Riegel* sued a manufacturer, she never claimed that the manufacturer promoted uses beyond FDA's approval, so the Court never addressed that issue. *See* Complaint, *Riegel v. Medtronic, Inc.*, No. 99–CV–0649 (N.D.N.Y. 2003), 1999 WL 34824712. The doctor's use of the product was simply irrelevant to the Court's preemption analysis, which, as noted, had nothing to do with how the doctor used the product. *Riegel*, 552 U.S. at 322.

Although not entirely clear, Medtronic appears to say it would be anomalous if the outcome of claims against a manufacturer turned on whether the doctor's use of a product was (or was not) induced by the manufacturer's off-label promotion. Ans. Br. 29. There is no anomaly. If the doctor's off-label use was induced by the manufacturer's off-label promotion, there would be no preemption for the reasons given above: when a manufacturer promotes a product for uses that were never approved by FDA, then FDA has not imposed device-specific requirements on the product as promoted by the manufacturer. And if the doctor's off-label use was not induced by the promotion, there would be no preemption for the same reason: the manufacturer promoted an unapproved product. (But in that situation the manufacturer would not be liable because it would not have *caused* the plaintiff's injuries.)

Medtronic's concern that manufacturers will be "discouraged" from seeking approval of products with beneficial off-label uses for fear of incurring civil liability based on doctors' off-label use is seriously misguided. *See* Ans. Br. 63 n.18. As long as a manufacturer's promotional activity remains within the scope of FDA's PMA as embodied in the label, there is no risk of liability under *Riegel*, regardless of off-label use by doctors. But here, unlike in *Riegel*, Medtronic promoted its products for uses that FDA *had not* approved for marketing.

B. Ms. Jones's claims are not preempted even under Medtronic's (incorrect) view that preemption attaches to physical products regardless of how they are promoted.

1. Medtronic's preemption defense is premised entirely on FDA's approval of a physical product that was never implanted in Ms. Jones: Infuse/LT-Cage (PMA P000058). *See, e.g.*, Ans. Br. 22-23, 32. Even under Medtronic's misguided view that "the device" means the physical product when put to *any* use, its preemption defense fails because Ms. Jones was *not* implanted with Infuse/LT-Cage.[6]

Ms. Jones has steadfastly maintained that she was not implanted with the physical product approved as Infuse/LT-Cage. SER 680 (complaint); SER 421 (opp. to MTD); Ms. Jones's Opening Br. 3; Ms. Jones's Reply Br. 3; Supp. Opening Br. 11-12. The Infuse/LT-Cage combination product was approved only with a titanium cage, SER 632, but Ms. Jones was never implanted with any titanium cages, SER 680.

Instead, Ms. Jones was repeatedly implanted with (among other things) two variations of a makeshift intervertebral body fusion device consisting of a non-titanium cage with the Infuse biologic in a sponge. SER 680 (complaint), SER 421-23 (opp. to MTD). Any intervertebral body fusion device that includes the Infuse biologic is a Class III device that must, by law, undergo PMA approval. 21 C.F.R. § 888.3080. But these

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[6] Only *after* Ms. Jones's surgeries did Medtronic seek and obtain a supplemental PMA to promote use of one (but not both) of the PEEK cages with the Infuse biologic. Even then, the cage was *not* approved to be marketed for use in the unapproved ways employed in Ms. Jones's surgery. *See* PMA Approval Database: P000058/S059 (Dec. 4, 2015), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000058S059; *see also* Ms. Jones's Reply Br. 11.

products promoted by Medtronic and implanted in Ms. Jones did *not* receive that approval—and Medtronic does not argue otherwise. For this reason alone, there is no preemption.

2.a. In response to this problem, Medtronic asserts that, because the statutory definition of "device" contains the phrase "including any component, part, or accessory," each part of an approved "device" is itself sheltered by Section 360k preemption when used either in isolation *or even with other parts and products not PMA-approved by FDA*. Ans. Br. 54-56.

The statute does not support this anything-goes approach, which would allow a manufacturer to gain approval for one physical product and then add all manner of other physical appurtenances with regulatory impunity. If anything, the statute's definition of "device" shows that all parts must be approved together, 21 U.S.C. § 321(h) (a "device" "include[s] any component, part, or accessory"). The statute certainly does not indicate that a product regulated as a Class III "device" may include new, unapproved parts, which is Medtronic's argument here. And the statute mandates supplemental premarket approval even for any "incremental change" to a device. 21 U.S.C. § 360e(d)(5)(B). Indeed, Medtronic's own conduct in seeking separate FDA approval when adding unapproved parts belies its argument.[7]

[7] For example, Medtronic sought approval for "inclusion of additional [InterFix] fusion cage component designs" with Class III Infuse/LT-Cage. PMA Approval Database: P000058/S004 (Dec. 1, 2003), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000058S004.

b. FDA regulations demonstrate that the specific combination of products used in Ms. Jones's surgeries must be approved as a new Class III device. When a new product combines pieces that fall into different regulatory categories—like a nicotine patch, which combines a drug (nicotine) with a device (a patch)—FDA can specify through regulation how the entire "combination product" must be approved. *See* 21 C.F.R. §§ 3.2(e), 3.4; *see also* Supp. Opening Br. 10-11. FDA has done just that with some of the products used in Ms. Jones's surgeries: 21 C.F.R § 888.3080 requires that whenever a bone-growth protein like the Infuse biologic is part of a spinal-fusion combination product, the whole product *must* receive premarket approval as a Class III device.

Indeed, in promulgating the classification regulation for these combination products, 21 C.F.R. § 888.3080, FDA expressly rejected public comments to classify this type of combination product as a Class II device because, in the agency's view, the function of a bone-growth protein like Infuse is inseparable from the other constituent parts. 72 Fed. Reg. 32170, 32171 (June 12, 2007). To market the products together, the entire combination must be approved through PMA. Allowing Medtronic to dodge PMA requirements for intervertebral body fusion devices by promoting new, unapproved combination products as "modified" versions of the Infuse/LT-Cage product would thus unravel FDA's regulatory regime for these products.[8]

[8] Because Section 888.3080 demands whole-device Class III approval here, the Third Circuit's recent decision in *Shuker v. Smith & Nephew*, ___ F.3d. ___, 2018 WL 1096185, at *7 (3d Cir. Mar. 1, 2018), is inapposite on this point. The plaintiff there

II. Ms. Jones's claims regarding Class II products are not preempted.

Ms. Jones's claims involve Class II devices implanted during her surgery, including the PEEK cages and the CD Horizon spinal fixation system, that were cleared through the 510(k) process. SER 706, 718; *see also* Supp. Opening Br. 3-4. State-law claims involving 510(k) products are not preempted. *Medtronic Inc., v. Lohr* 518 U.S. 470, 492-503 (1996).

As our Supplemental Opening Brief (at 33-34) shows, the district court mistakenly found Ms. Jones's failure-to-warn claims involving Class II devices impliedly preempted. SER 17-18. Medtronic does not dispute the district court's finding that Ms. Jones was, in fact, implanted with Class II devices. SER 17. Nor does it defend the district court's flawed, implied-preemption analysis. Instead, it advances two new, equally-flawed theories.[9]

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claimed that a set of Class II hip-replacement parts was promoted for use with a substitute part from a Class III PMA-approved product. *Id.* at *4. Rather than analyze the resulting system as "the device," the court considered preemption from the perspective of each part individually. But, as just explained, applying a component-by-component preemption analysis here would short-circuit the Class III PMA approval demanded by Section 888.3080. Moreover, the Third Circuit was not presented with and did not consider Ms. Jones's principal argument here: that when a manufacturer promotes unapproved uses, claims based on that promotion are outside the scope of Section 360k altogether. *See supra* at 3-12.

[9] The district court did not address Ms. Jones's fraud claim with respect to Class II products. *See* SER 720 (complaint alleging fraud involving Class II products). And, as the district court noted, Medtronic ignored the Class II products below. SER 16 n.7. Before this Court, it continues to ignore all Class II products implanted in Ms. Jones other than the PEEK cages.

A. Medtronic first says that although these claims involve Class II products, they are expressly preempted because Ms. Jones's surgeries included a part from a PMA-approved product (the protein-soaked sponge). Ans. Br. 54-56. This one part, Medtronic asserts, cloaks the entire ordeal with preemption. *Id.* at 56. As explained above (at 10-12), extending preemption to products not approved by FDA is inconsistent with the FDCA and FDA's regulation of spinal-fusion products. And as the Third Circuit recently recognized, claims concerning Class II products are not preempted simply because they are combined with a constituent part from a Class III product. *Shuker v. Smith & Nephew*, ___ F.3d ___, 2018 WL 1096185, at *10 n.15 (3d Cir. Mar. 1, 2018).

Nor does Ms. Jones have to show, as Medtronic asserts, that a Class II product *alone* caused her injury to escape preemption. Ans. Br. 56. The one district court opinion Medtronic cites for this proposition confused proximate causation, an element of the underlying state-law claim, with preemption. *See Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d. 246, 254-57 (E.D.N.Y. 2014). Under Arizona law, "there may be more than one proximate cause" of an injury, *Kennecott Copper Corp. v. McDowell*, 413 P.2d 749, 753 (Ariz. 1966), and Ms. Jones plans to prove at trial that Class II products proximately caused her injuries. But she need not prove proximate causation to defeat preemption, much less do so on a motion to dismiss, and nothing in Section 360k(a) suggests otherwise.

B. Medtronic also says that FDA's 510(k) "substantial equivalence" determination for the Class II products impliedly preempts any design-defect claim because the "ongoing federal duty of sameness bars any claim that would require a manufacturer to change" the device's design. Ans. Br. 57-58. Medtronic presented—and the Supreme Court rejected—this exact argument in *Lohr*. *See* Brief for Petitioner, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), 1996 WL 88789, at 27-28, 44-46. There, the Court held that "the 'substantial equivalence' provision did not pre-empt the Lohrs' design claims." *Lohr*, 518 U.S. at 493-94. The Court reasoned that FDA's examination of a 510(k) application does not require devices "to take any particular form for any particular reason," *id.* at 493, and so seeking clearance through the 510(k) process "included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design," *id.* at 494. *See also Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1230-31 (9th Cir. 2013) (en banc) (viewing *Lohr* as holding no express or implied preemption for 510(k) products).

III. Ms. Jones's claims are not preempted because they are based on state-law duties that parallel federal requirements.

Section 360k does not preempt Ms. Jones's state-law claims for another reason: they do not impose duties "different from, or in addition to" federal requirements and are therefore non-preempted "parallel" claims under *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1226 (9th Cir. 2013) (en banc). Medtronic does not even cite this unanimous, en-banc decision—which is definitive on the parallel-claims issue.

A. Medtronic's sweeping implied-preemption theory is inconsistent with controlling precedent.

Medtronic appears to argue that whenever a state-law claim is "[p]remised" or "predicated" on a duty that parallels an FDCA requirement, the claim is impliedly preempted. Ans. Br. 58-60. This argument makes no sense. Accepting it would effectively eliminate the parallel-claims doctrine—repeatedly endorsed by the Supreme Court—which holds that a claim premised on a state-law duty is *not* preempted when the plaintiff identifies a corresponding, or "parallel," federal duty. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

Medtronic's expansive view of implied preemption is at odds with this doctrine. This Court explained in *Stengel* that the plaintiffs in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), lost on implied-preemption grounds because, under their "fraud on the FDA" theory, they had "alleged no state-law claim." *Stengel*, 704 F.3d at 1230. By contrast, the Stengels' failure-to-warn claim was not expressly or impliedly preempted because it was based on a traditional state-law duty that paralleled the FDCA duty to report adverse events to FDA. *Id.* at 1233. Ms. Jones's Arizona failure-to-warn and fraud claims parallel their FDCA counterparts, and thus are neither expressly nor impliedly preempted. Indeed, her failure-to-warn claims are based on the *same* "settled Arizona law" recognized by this Court in *Stengel*. *Id.* at 1233. And so, in Medtronic's words, her state-law claims would arise "even if the FDCA had never been enacted." Ans. Br. 59.

It is therefore irrelevant that 21 U.S.C. § 337 says there is no federal private right of action to enforce a federal duty under the FDCA, Ans. Br. 58-60, for the simple reason that Ms. Jones does not claim a right to sue under federal law. As just noted, her claims are traditional Arizona state-law claims that this Court has upheld against express- and implied-preemption defenses. *See* Supp. Opening Br. 37, 40 (explaining traditional nature of Ms. Jones's state-law claims). And as Ms. Jones aptly noted in her pro se complaint, "[t]hese Arizona laws and statutes parallel FDA regulations." SER 730. *See also* Ariz. Rev. Stat. Ann. §§ 32-1965, 32-1967 (Arizona Pharmacy Act prohibiting device manufacturers from misbranding their products); *Sisk v. Ball*, 371 P.2d 594 (Ariz. 1962) (violation of an Arizona public-safety statute is negligence per se in common-law damages action).

B. Ms. Jones's state-law claims parallel two FDCA requirements.

Ms. Jones's state-law fraud and negligent failure-to-warn nullification claims parallel the FDCA's prohibition on misbranding. And her other negligent failure-to-warn claims parallel the FDCA's requirement that manufacturers provide adequate warnings when their promotion renders existing labeling ineffective. *Compare Stengel*, 704 F.3d at 1230 (finding a failure-to-warn claim parallel with the federal duty to report adverse events), *with Perez v. Nidek Co.*, 711 F.3d 1109, 1118-20 (9th Cir. 2013) (rejecting a claim that purported to parallel a non-existent federal duty to "disclose lack of FDA approval").

1. Medtronic's off-label promotion resulted in misbranding, which is prohibited by the FDCA.

The FDCA prohibits a manufacturer from selling "misbranded" medical products. 21 U.S.C. § 331(a). A product is misbranded if its label is inadequate or its advertising is misleading. *Id.* § 352(a), (f), (q). And a product regulated as a Class III device cannot be promoted in a manner inconsistent with conditions of its premarket approval, 21 C.F.R. § 814.80, including the intended uses established by its label, *id.* § 801.4.

FDA has long made clear that when manufacturers "promote a use that is inconsistent with the product's approved labeling, the product is misbranded" under 21 U.S.C. § 352. 62 Fed. Reg. 64074, 64075 (Dec. 3, 1997). After this Court held that, under Section 352, labeling must establish intended uses, *Alberty Food Prod. Co. v. United States*, 185 F.2d 321, 325-26 (9th Cir. 1950), FDA issued 21 C.F.R. § 801.4 ("Meaning of intended uses"). *See* 59 Fed. Reg. 59820, 59820-22 (Nov. 18, 1994). That regulation explains that whether conduct constitutes misbranding turns on the "objective intent of the persons legally responsible for the labeling," which may be shown by their "expressions" or "the circumstances surrounding the distribution of the article." 21 C.F.R. § 801.4. Thus, whether off-label promotion is expressly prohibited by federal law, Ans. Br. 40, is not the point (though it is prohibited). Rather, off-label promotion is evidence of *misbranding*, which is expressly prohibited by federal law (and is one of the federal duties that parallels Ms. Jones's state-law claims). *See* 21 U.S.C. § 352.

The Third and Eleventh Circuits recently concluded that a state-law claim based on a manufacturer's promotion of a product beyond the limits of its federally-mandated label is neither expressly nor impliedly preempted. *Shuker v. Smith & Nephew*, ___ F.3d. ___, 2018 WL 1096185, at *11-12 (3d Cir. Mar. 1, 2018); *Godelia v. Doe*, 881 F.3d 1309, 1320-22 (11th Cir. 2018). The district court here likewise agreed with "the majority of courts in this Circuit" that have held that state-law claims based on off-label promotion parallel federal misbranding requirements. SER 20-21. This Court, too, has concluded that "marketing and promotion of a Class III device for an unapproved use" is misbranding under the FDCA. *Carson v. Depuy Spine, Inc.*, 365 F. App'x 812, 815 (9th Cir. 2010) (non-precedential).

Based on the Second Circuit's divided decision in *U.S. v. Caronia*, 703 F.3d 149 (2d Cir. 2012), Medtronic argues that the FDCA should not be interpreted to prohibit off-label promotion because that promotion is protected commercial speech. Ans. Br. 39-41; *but see* Public Citizen Am. Br. 23 (explaining that *Caronia* recognized that when a manufacturer intends a drug or device to be used off-label, the product is misbranded). But the First Amendment does not prohibit use of speech as evidence "to prove motive or intent." *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993); *see also, e.g.*, *In re Atossa Genetics Inc. Sec. Litig.*, 868 F.3d 784, 791 (9th Cir. 2017) (holding cognizable misbranding-based claims premised on a manufacturer's speech without suggesting any constitutional concern). Thus, Medtronic acknowledges, Ans. Br. 63, as it must, that FDA may consider speech and other promotional conduct as evidence of a violation of the

FDCA's misbranding provisions. *See* 21 C.F.R. § 801.4. Medtronic's effort to undermine FDCA labeling requirements here would "call[] into question the very foundations of our century-old system of drug [and device] regulation." *Caronia*, 703 F.3d at 169 (Livingston, J., dissenting).

Medtronic also relies on what it calls FDA's "nuanced approach" to regulating off-label promotion, which it asserts impliedly preempts Ms. Jones's claims because any state-law claim would interfere with FDA regulatory discretion. Ans. Br. 63-64. This assertion is based on a misleading use of an FDA guidance document. The guidance explains that promoting unapproved uses would in fact "generally violate the law" and that manufacturers may only provide "non-promotional scientific or medical information" in response to unsolicited requests. FDA, Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices 2, 6 (2011), https://perma.cc/UK3U-USMM. Indeed, the guidance says that, to avoid promotional misbranding, "sales and marketing personnel" should have "no input" when manufacturers respond to requests for "off-label information." *Id.* at 9. Here, by contrast, "Medtronic agent, District Sales Manager James Sherman was present in the OR" during all of Ms. Jones's surgeries in their entirety. SER 678-79. This allegation is but one of many manifestations of Medtronic's "objective intent" to establish new unapproved uses, thereby misbranding its products. *See* 21 C.F.R. § 801.4.

2. The FDCA required Medtronic to provide adequate warnings that addressed new intended uses created by its promotion.

Ms. Jones's failure-to-warn claims also find a federal counterpart in the FDCA's requirement that manufacturers provide warnings about dangers associated with new intended uses. 21 U.S.C. § 352(f) (a product is misbranded if its label is inadequate for intended uses); 21 C.F.R. § 801.4. A manufacturer may change a label to add new warnings by seeking approval of a PMA supplement (21 U.S.C. § 360e(d)(5)(A)(i); 21 C.F.R. § 814.39(a)(1)), and may unilaterally change the label while a supplemental application is pending (if the change would enhance the safety of the product), 21 C.F.R. § 814.39(d)(2). *See* Supp. Opening Br. 42-43.

Medtronic does not deny that this federal requirement exists, but says it impliedly preempts Ms. Jones's failure-to-warn claims. Ans. Br. 67-69. This Court has already rejected all three variations of Medtronic's argument.

a. Medtronic says that *Buckman* demands preemption any time the conduct underlying the state-law claim is a "failure to properly communicate with the FDA." Ans. Br. 68 (citing *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001)). This argument is just a variant on Medtronic's sweeping implied-preemption theory, rebutted above (at 16-17). Medtronic made the same argument, nearly verbatim, in *Stengel*. Medtronic Supp. Rep. Br. at 7-8 in *Stengel*, 2012 WL 3911696. The Court should reject it here for the same reason the en banc Court has already rejected it: the state-law duty to warn parallels—and does not interfere with—the FDCA's requirement that

manufacturers inform FDA of risks associated with intended uses so that doctors and patients are appropriately warned. *Stengel*, 704 F.3d at 1233.

b. Medtronic asserts that because Ms. Jones cannot be sure that FDA will take any particular action to warn doctors and patients, the state-law duty conflicts with the federal duty and therefore is impliedly preempted, Ans. Br. 68-69, or is not parallel, *id.* at 45. Again, Medtronic made, and this Court rejected, this argument in *Stengel*. Medtronic Supp. Rep. Br. at 5 n.2 in *Stengel*, 2012 WL 3911696. Judge Watford, writing for a concurring majority, explained that this is a causation argument dressed up as implied preemption and accepting it would "require an unwarranted expansion of *Buckman*'s rationale." *Stengel,* 704 F.3d at 1234-35 (Watford, J., concurring).

c. Finally, Medtronic argues that it cannot unilaterally change its label to strengthen warnings lest it violate the FDCA. Ans. Br. 67. This argument ignores 21 C.F.R. § 814.39(d)(2)(i), which allows Medtronic to "add or strengthen" warnings pending FDA approval of the new warnings. *See also Stengel,* 704 F.3d at 1234 (Watford, J., concurring) (a device manufacturer may issue these warnings "even without receiving prior approval from the FDA"); *cf.* Ans. Br. 45 (acknowledging elsewhere that "a manufacturer '*may* unilaterally make changes' under 21 C.F.R. § 814.39(d)"). The Supreme Court emphatically rejected this argument when interpreting an identical regulation concerning changes to drug labels, *Wyeth v. Levine*, 555 U.S. 555, 568-70 (2009), holding that any other outcome would undermine a "central premise" of the

FDCA—that manufacturers are responsible for ensuring that warnings remain adequate as long as their products are marketed, *id.* at 570-71.

C. Medtronic's argument that state-law claims must parallel an "identical" federal requirement conflicts with *Lohr* and *Stengel*.

Medtronic argues that "a state law claim must be 'identical' to an existing [federal] requirement for such a claim to survive Section 360k(a) preemption." Ans. Br. 33. For example, Medtronic insists that "even the concept of 'off-label use' is a creature of the FDCA," so no state law can possibly be "identical." *Id.* at 42. This argument cannot be squared with controlling precedent.

For starters, an "identical requirement" test would have required a contrary outcome in *Stengel*. This Court found the Stengels' Arizona failure-to-warn claim parallel to the FDCA's requirement that manufacturers report adverse events to FDA, even though the two are not literally identical. *See Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1232 (9th Cir. 2013) (en banc).

Lohr recognized that parallel common-law duties cannot be literally "identical" to federal statutory requirements. Like Lora Lohr, Ms. Jones "claims that Medtronic negligently failed to comply with duties 'equal to, or substantially identical to, requirements imposed' under federal law." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 497 (1996) (quoting 21 C.F.R. § 808.1(d)(2)). But *Lohr* observed that even if a state-law claim is "'different from' the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates

the federal rule." 518 U.S. at 470. Indeed, in re-affirming the parallel-claims doctrine, the Court in *Bates v. Dow Agrosciences* noted that "it would be surprising if a common-law requirement used the same phraseology" as the parallel federal requirement. 544 U.S. 431, 454 (2005); *see also Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1352 (10th Cir. 2015) (Lucero, J., concurring in relevant part) ("Crucially, federal law and state law remedies need not be identical in order to be parallel and thus avoid express preemption.") (citing *Lohr* and *Bates*).

D. Ms. Jones may pursue her parallel failure-to-warn claims based on nullification.

Arizona recognizes failure-to-warn claims, including those premised on misleading medical-product promotion. *Watts v. Medicis Pharm. Corp.*, 365 P.3d 944 (Ariz. 2016). And nullification—in which overpromotion renders existing warnings inadequate—is a well-established theory for pursuing failure-to-warn claims. *See, e.g.*, *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1363 (4th Cir. 1975); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) (en banc). Indeed, the Arizona Supreme Court has held that overpromotion of medical products violates the Arizona Consumer Fraud Act, *Watts*, 365 P.3d at 953, and Ms. Jones brings her failure-to-warn claims under both that Act and Arizona common law, *see* SER 725, 730.

Watts's recent embrace of the nullification theory is hardly an outlier. In just the last few years, courts have held that failure-to-warn claims based on nullification survive Section 360k preemption. *See, e.g.*, *Mendez v. Shah*, 28 F. Supp. 3d 282, 299-300 (D.N.J.

2014) (Infuse/LT-Cage); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 827-28 (E.D. Pa. 2016) (Class III birth-control device). And an MDL court noted last year that failure-to-warn claims based on nullification are recognized broadly. *In re Testosterone Replacement Therapy Prod. Liab. Litig.*, No. 14 C 1748, 2017 WL 1836435, at *16-17 (N.D. Ill. May 8, 2017) (also holding the claim non-preempted). At the end of the day, Medtronic cites no case from any jurisdiction rejecting nullification as a species of failure-to-warn. For all these reasons, Ms. Jones may press it.

Medtronic is also wrong that Ms. Jones has "waived" nullification as way of proving failure to warn. Ans. Br. 48. Ms. Jones alleges that Medtronic's promotion of uses beyond the approved label rendered the label's existing warnings inadequate, SER 725-28 (complaint); SER 434-35 (opp. to. MTD), and that is easily sufficient. Preservation of an issue does not require "incantation of particular words," *Nelson v. Adams*, 529 U.S. 460, 469 (2000), such as "nullification," particularly given that pro se complaints are construed liberally, *Erickson v. Pardius*, 551 U.S. 89, 94 (2007).[10]

E. This Court endorsed Ms. Jones's negligence per se theory in *McClellan*.

No state-law claim could be more parallel to a federal duty than one founded on a per se violation of a federal statute. *See* Supp. Opening Br. 44. Medtronic argues that Ms. Jones's state-law negligence per se theory would undermine the prohibition on a

[10] If this Court finds that Ms. Jones did not delineate the nullification theory sufficiently to survive preemption, she should be granted leave to amend her complaint to do so. *See Stengel*, 704 F.3d at 1233-34 (plaintiffs may be permitted to amend a complaint after the court "clarifie[s] preemption law under the MDA").

federal right of action to enforce the FDCA. Ans. Br. 66 n.19; *see* 21 U.S.C. § 337. But *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1041 (9th Cir. 2015), held otherwise. *McClellan* did not, as Medtronic asserts, approve an instruction that the jury "could, but did not have to, consider an FDCA violation." Ans. Br. 66 n.19. Rather, *McClellan* flatly rejected the proposition that "use of federal law to establish a standard of care is an attempt to enforce the underlying federal provisions" and found that the district court erred by not providing a negligence per se instruction—precisely the kind of instruction to which Ms. Jones would be entitled. 776 F.3d at 1041.

IV. Ms. Jones's claims are well-pleaded, but even if they are not, she is entitled to amend her complaint.

A. Medtronic argues that Ms. Jones's pleadings are inadequate for three reasons, none correct.

First, Medtronic argues that Ms. Jones impermissibly relies on a general fraud-on-the-market theory to allege that Medtronic's off-label promotion caused her doctors' off-label use. Ans. Br. 70-71. Not so. Her pro se complaint pleads specific facts alleging that Medtronic's off-label promotion reached *her* doctors, *see* Supp. Opening Br. 47-48, including allegations that Medtronic publicized *her* surgeons through its web sites, and that those surgeons received off-label promotions, SER 701-02. She further alleges that a Medtronic sales representative was in the operating room for the entirety of *her* surgeries. SER 678-79.

Second, Medtronic apparently argues that Ms. Jones cannot allege a failure-to-warn claim under state law because statements on the Infuse/LT-Cage's label warned against the unapproved methods and product configurations used in her surgeries. Ans. Br. 51-53, 57. Even assuming (illogically) that one product's label could somehow adequately warn about unapproved uses of the *other* products used in Ms. Jones's surgeries, this argument misunderstands her failure-to-warn claims. Ms. Jones alleges that Medtronic, through its off-label promotion, rendered the label inadequate and incurred a duty to provide additional information necessary for safe use in an off-label surgery. SER 725-26. And that the label stated that the safety of the promoted uses had "not been established," SER 632, or that other component configurations were not approved, Ans. Br. 57, did not immunize Medtronic from complying with its state-law duties not to promote unsafe uses and products beyond the label. *See supra* 17, 24-25.

Finally, Medtronic wrongly suggests (Ans. Br. 55) that Ms. Jones has not alleged a specific misrepresentation regarding the Class II PEEK cages. Ms. Jones's allegations that Medtronic promoted its products for unapproved uses apply to both Medtronic's Class II and Class III products used in her surgeries, and she specifically alleges that Medtronic promoted Class II devices for unapproved uses. SER 673-74, 718 (identifying Class II products overpromoted by Medtronic); *see also* SER 685-86, 689 (detailing unapproved uses of PEEK cages). Ms. Jones also alleges that she "has been directly and proximately harmed" by the PEEK cages. SER 689 (Capstone PEEK cage); SER 690 (Clydesdale PEEK cages). Ms. Jones further alleges, for example, that a Class

II PEEK cage "migrated" and is "no longer in the space between her vertebrae." SER 711.

Taken together—and construed under the liberal pleading standards for pro se complaints, *Erickson v. Pardius*, 551 U.S. 89, 94 (2007)—Ms. Jones's allegations permit reasonable inferences that Medtronic's promotion reached her doctors and influenced them to use Medtronic's products in unapproved ways, and that unapproved uses of Class II devices contributed to her injuries. *See* Supp. Opening Br. 47-48.

B. If Ms. Jones's pleadings are found inadequate, she should be granted leave to amend her complaint, a proposition that even Medtronic does not contest. Ms. Jones should be allowed to amend to reflect the information she has learned about Medtronic's products, Medtronic's promotion, and her injuries since filing her original complaint. *See* Supp. Opening. Br. 45-51 (detailing this information).

CONCLUSION

This Court should reverse the district court's order dismissing the complaint and remand the case for further proceedings.*

Respectfully submitted,

/s/Brian Wolfman

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March 20, 2018

* This is a supplemental reply brief, not a replacement reply brief. Ms. Jones understands that this Court will not strike her original briefs and will consider them alongside this brief and her supplemental opening brief.

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Signature of Attorney or Unrepresented Litigant: /s Brian Wolfman

Date: 3/20/2018

("s/" plus typed name is acceptable for electronically-filed documents)

STATUTORY AND REGULATORY ADDENDUM

TABLE OF CONTENTS

Statutes

Regulations

21 U.S.C. § 352 – Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

(a) False or misleading label
(1) If its labeling is false or misleading in any particular.

* * *

(f) Directions for use and warnings on label
Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

* * *

(q) Restricted devices using false or misleading advertising or used in violation of regulations
In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title.

21 U.S.C. § 396 – Practice of medicine.

Nothing 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 to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

21 C.F.R. § 888.3080 – Intervertebral body fusion device.

(a) Identification. An intervertebral body fusion device is an implanted single or multiple component spinal device made from a variety of materials, including titanium and polymers. The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion.

(b) Classification.

(1) Class II (special controls) for intervertebral body fusion devices that contain bone grafting material. The special control is the FDA guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device." See § 888.1(e) for the availability of this guidance document.

(2) Class III (premarket approval) for intervertebral body fusion devices that include any therapeutic biologic (e.g., bone morphogenic protein). Intervertebral body fusion devices that contain any therapeutic biologic require premarket approval.

(c) Date premarket approval application (PMA) or notice of product development protocol (PDP) is required. Devices described in paragraph (b)(2) of this section shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Arizona Revised Statutes Annotated § 32-1965

Prohibited acts

The following acts or the causing of any thereof, in addition to any others so specified in this chapter, are prohibited:

1. The manufacture, sale, holding or offering for sale of any drug, device, poison, or hazardous substance that is adulterated or misbranded.

2. The adulteration or misbranding of any drug, device, poison, or hazardous substance.

3. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a drug, device, poison, or hazardous substance, if such act is done while such article is held for sale and results in such article being adulterated or misbranded.

* * *

Arizona Revised Statutes Annotated § 32-1967

Acts constituting misbranding of a drug or device; exceptions; interpretation of misleading label; definition

A. A drug or device is misbranded:

1. If its labeling is false or misleading in any particular.

* * *

9th Circuit Case Number(s) 15-15653

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