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 BRIEF OF APPELLANT KATHRYN MARIE JONES

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INTRODUCTION

This appeal concerns allegations of Medtronic's unlawful promotion of unapproved uses of its medical products. Plaintiff-Appellant Kathryn Jones was severely injured, and is now permanently disabled, because of three spine surgeries in which Ms. Jones's doctors implanted Medtronic products "off-label"—that is, for uses that had not been approved by the Food and Drug Administration. Ms. Jones sued Medtronic under Arizona law, alleging that the company unlawfully promoted these unapproved uses and fraudulently induced her doctors to perform dangerous surgeries.

One of the relevant products is Medtronic's Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion Device. The district court dismissed all but one of Ms. Jones's state-law claims regarding Medtronic's unlawful promotion of this product as expressly preempted by 21 U.S.C. § 360k(a), the preemption clause of the Medical Device Amendments to the Food, Drug, and Cosmetic Act. The court also dismissed all but one of Ms. Jones's claims regarding another set of Medtronic's products—cages made of a polymer called PEEK—as impliedly preempted by the MDA. As we show below, both preemption holdings are wrong.

The district court dismissed the two remaining claims as inadequately pleaded. This decision also was wrong. Ms. Jones's pro se complaint adequately alleges both claims. And even if it does not, the court should have granted her leave to amend the complaint to address any deficiencies.

STATEMENT OF THE ISSUES

1. Are Ms. Jones's claims preempted by the Medical Devices Amendments to the Food, Drug, and Cosmetic Act?

2.a. Did Ms. Jones's pro se complaint adequately allege fraud and design defect under Arizona law?

b. If not, was it proper for the district court to dismiss Ms. Jones's fraud and design-defect claims without leave to amend?

STATUTORY AND REGULATORY ADDENDUM

Pertinent statutes and regulations appear in an addendum to this brief.

JURISDICTIONAL STATEMENT

This suit was filed in Arizona state court. SER 671. Defendant removed under 28 U.S.C. § 1441(a), claiming diversity, *see* 28 U.S.C. § 1332(a)(1). SER 660 (notice of removal). Defendant was then a Minnesota corporation with its principal place of business in Minnesota. SER 663. Plaintiff is an Arizona citizen. *See id.* The amount in controversy exceeds $75,000. SER 662-63. The district court entered judgment disposing of all claims of all parties on March 6, 2015. SER 7. The notice of appeal was filed on April 2, 2015. SER 1. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE CASE

I. Legal background

A. Federal regulation under the Medical Device Amendments

In 1976, Congress passed the Medical Device Amendments (MDA), 21 U.S.C. § 360c *et seq.*, to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.* The MDA sought to ensure the safety and effectiveness of medical devices by expanding federal oversight, with particular emphasis on regulating the entry of devices into the market. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-76 (1996).

The MDA divides medical devices into three classes based on their risk to the public. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316-17 (2008). The least risky products, such as bandages, fall into Class I and are subject only to the general regulatory controls that apply to all devices, such as recordkeeping requirements and good manufacturing practices. 21 U.S.C. §§ 360c(a)(1)(A), 360i(a); *Riegel*, 552 U.S. at 316; *Lohr*, 518 U.S. at 497. Riskier products, such as powered wheelchairs, fall into Class II and may be subject to special controls, such as postmarket surveillance, if the agency issues any controls for the product. 21 U.S.C. §§ 360c(a)(1)(B), 360*l*(a); *Riegel*, 552 U.S. at 316-17. The riskiest products, such as pacemakers, fall into Class III. *Riegel*, 552 U.S. at 317. As explained below, some products regulated as Class III devices are subject to intensive review and must be officially approved by FDA before they may be marketed at all. *Id.*

Most medical devices are marketed without extensive safety and effectiveness scrutiny by FDA. Instead, they go through procedures known as the "510(k) process,"

named after Section 510(k) of the 1976 Act. *See Lohr*, 518 U.S. at 478-79. For Class I devices, the manufacturer need only notify FDA that the product is being marketed. *See* 21 U.S.C. §§ 360(k), 360c(a)(1)(A). For Class II devices, a manufacturer must notify FDA and certify compliance with special controls, if any apply. *See id.* §§ 360(k), 360c(a)(1)(B). Even for most Class III devices, before marketing, a manufacturer need only receive FDA's determination that the device is "substantially equivalent" to a pre-1976 device or a post-1976 device that was itself found substantially equivalent. *See id.* §§ 360(k), 360e(b)(1)(B); *Lohr*, 518 U.S. at 477-78.

By contrast, a minority of Class III devices are not "substantially equivalent" and thus may not be marketed through the 510(k) process. FDA requires those Class III devices to undergo a premarket approval (PMA) process before they may be marketed. *Lohr*, 518 U.S. at 477. To obtain premarket approval, a manufacturer must submit an application to FDA. 21 U.S.C. § 360e(c). That application must include, among other things, clinical studies about the device's safety and effectiveness, a statement of the device's components, a description of how the device is manufactured and how it operates, and "specimens of the labeling proposed to be used" for the device. *Id.* § 360e(c)(1); *Riegel*, 552 U.S. at 317-18. If FDA determines that there is a reasonable assurance that the device is safe and effective, it will approve the device for marketing and notify the manufacturer of the approval and any conditions of the approval. 21 U.S.C. § 360e(d)(1), (d)(2)(A)-(B).

In approving a PMA product for marketing, FDA determines whether it is safe and effective only with respect to the uses set forth on its proposed label. FDA does not consider or evaluate the safety of other potential uses for the product. As Congress put it, "[i]n making the determination whether to approve or deny the [PMA] application, the Secretary shall 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 safety and effectiveness." 21 U.S.C. § 360e(d)(1)(A). As FDA explains in its guidance to manufacturers, it "determines whether a medical product is safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling submitted to the FDA." FDA, Medical Product Communications That Are Consistent With the FDA-Required Labeling — Questions and Answers, Draft Guidance for Industry 2 (proposed Jan. 2017) (FDA Labeling Guidance), https://perma.cc/7489-YRR4.

A prescription device is approved only if the proposed label provides enough information so that doctors can use the device safely for its intended purposes. *See* 21 C.F.R. § 801.109(c). Although the MDA does not regulate how doctors may use devices, *see* 21 U.S.C. § 396, it prohibits a manufacturer from advertising a product for uses inconsistent with its label, *see id.* §§ 331(a), 352(q). The MDA also prohibits a manufacturer from altering or removing the device's label or doing anything that would make the label false or misleading. *Id.* §§ 331(k), 352(a). The MDA further mandates that all changes to a PMA device, including changes to labeling, be approved through a

supplemental PMA application. *Id.* § 360e(d)(5)(A)(i). However, the manufacturer may unilaterally make labeling changes that enhance the safety of the device while the supplemental application is pending. 21 C.F.R. § 814.39(d).

B. Preemption under the MDA

The MDA contains an express preemption provision, 21 U.S.C. § 360k(a), which says that no state can impose any requirement applicable to a medical device that is "different from, or in addition to" the requirements applicable to the device under the MDA. A potentially preemptive "requirement" under Section 360k(a) means only "specific requirements applicable to a particular device under" the MDA. *See* 21 C.F.R. § 808.1(d).

1. Two Supreme Court decisions establish the framework for evaluating state-law damages claims under Section 360k(a). In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court held that Section 360k(a) generally does not preempt state-law damages claims concerning products that enter the market through the 510(k) process. *See id.* at 492, 498-501.

The plaintiff in *Lohr* sued Medtronic for injuries caused by a product cleared through the 510(k) process, alleging failure to warn, defective manufacturing, and defective design under state law. 518 U.S. at 480-81. With regard to the failure-to-warn and defective-manufacturing claims, the Court explained that products cleared under Section 510(k) are subject only to general federal manufacturing and labeling requirements applicable to a "host of different devices." *Id.* at 497-98, 501. These

requirements reflect "generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 501. Because Section 360k(a) preempts state requirements only when FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act," the Court held that the general requirements imposed through the Section 510(k) process did not preempt the plaintiff's state-law claims. *Id.* at 498-500, 498 n.18 (quoting 21 C.F.R. § 808.1(d)).

As to the plaintiff's state-law design-defect claim, the Court held that because "[t]he 510(k) process is focused on *equivalence*, not safety," FDA "did not 'require'" the product "to take any particular form for any particular reason." *Lohr*, 518 U.S. at 493. The Court therefore concluded that the 510(k) process did not create specific preemptive requirements under Section 360k(a) and thus federal regulation of these products "included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design." *Id.* at 493-94.

Lohr further held that states are entitled to provide traditional damages remedies for violation of state-law duties where the conduct at issue also violates federal law. *Id.* at 494-97. In that situation, the state-law duties "parallel" federal duties, and thus state law does not impose requirements "different from, or in addition to" federal requirements within the meaning of Section 360k(a). *Id.*

The Court elaborated on Section 360k(a) preemption in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). There, the Court held that a Class III product formally approved through the PMA process is subject to device-specific "requirements," because that process imposes specific conditions on, for example, a product's design and label. *Id.* at 321-23. Thus, Section 360k(a) can preempt state-law damages claims based on duties different from or in addition to those specific "requirements" imposed through that process. *Id.*

Riegel emphatically reaffirmed *Lohr*'s holding regarding parallel claims. The Court thus noted that Section 360k(a) does not preempt a state-law damages claim where the underlying conduct also violates FDA regulations, because "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (citing *Lohr*, 518 U.S. at 495); *see also Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc) ("[I]nsofar as the state-law duty parallels a federal-law duty under the MDA, [it] is not preempted.").

2. The Supreme Court also has recognized one type of state-law claim that is impliedly preempted by the MDA (even if not expressly preempted by Section 360k(a)). In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the plaintiffs alleged that their device-related injuries stemmed from the defendant's fraudulent statements to FDA that had convinced the agency to clear the product for marketing. *Id.* at 343. The Court called this claim "fraud-on-the-agency" and noted that, although the claim was styled as "fraud," it did not stem from "traditional state tort law principles," because

the duty to be truthful to FDA in regulatory communications "exist[s] solely by virtue of the FDCA disclosure requirements." *Id.* at 352-53. By contrast, a claim based on a traditional state-law duty, the Court noted, is not impliedly preempted by the MDA. *See id.* at 351-52; *see also McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040-41 (9th Cir. 2015).

II. Factual background

A. Ms. Jones's medical conditions and her failed surgeries

Before the surgeries giving rise to this case, Ms. Jones suffered from several spinal disorders: spinal curvature (scoliosis), a slipped vertebra (spondylolisthesis), and spinal-nerve damage. SER 676-77, 764-69.[1]

Over two days in 2010, she underwent three spinal fusion surgeries to treat these disorders. According to her surgeons, the goal of the surgeries was to reconstruct her spine by fusing multiple vertebrae in her lower back into a single, continuous mass of bone. *See* SER 676-77, 764.

Spinal fusion surgery normally involves removing a spinal disc (a piece of cartilage between two vertebrae) followed by installation of implants that stimulate bone growth where the disc once was. SER 814. In theory, new bone will grow in the space where the disc had been and fuse the two vertebrae together. *See* SER 683, 814.

Ms. Jones's surgeries were unsuccessful, and her spine failed to fuse. SER 708, 711. Her spinal conditions worsened and other complications developed, such as abnormal

[1] Unless otherwise indicated, all citations to the SER are to Ms. Jones's complaint and its exhibits.

bone growth. SER 707-09, 713. Because of these failed surgeries and complications, Ms. Jones is permanently disabled. SER 707-08. She is plagued by muscle spasms that cause stabbing pain. SER 713. Because certain postures trigger unbearable pain, she sometimes must remain standing for an entire day. SER 714. At other times, she cannot lie down in bed and must sleep in a kneeling position with her head on the mattress. *Id.* She suffers a painful and embarrassing bowel condition. *Id.* Her balance has been compromised, resulting in a serious fall and creating the risk of further, potentially fatal falls. SER 713. And further spine surgeries, which could alleviate her symptoms, carry a high risk of heart attack. SER 712.

B. Ms. Jones discovers that her surgeons used Medtronic products in risky, unapproved ways.

Ms. Jones naturally wanted to know what had gone wrong. So, she obtained her medical records and learned that her surgeons had implanted several Medtronic products. *See* SER 677, 681-82. She then located the FDA-approved labels and other materials for the products implanted in her. *See* SER 689.

One of the relevant Medtronic products is Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion Device. SER 688-89; SER 574 (Infuse/LT-Cage label); SER 595 (Summary of Safety and Effectiveness Data). Infuse/LT Cage is a combination product consisting of multiple components: a synthetic protein known as Infuse rhBMP, a collagen sponge, and a titanium cage. *See* SER 823; SER 574-76 (Infuse/LT-Cage label). *See generally* 21 C.F.R. § 3.2(e) (defining "combination product"). FDA regulates the

Infuse/LT-Cage combination product as a Class III PMA device. *See* SER 542 (PMA approval letter). As contemplated by FDA's approval, a surgeon would soak the sponge in a mixture of the protein and water, place the sponge into the titanium cage, and implant the cage into the patient, adjacent to existing bone. *See* SER 588 (Infuse/LT-Cage label). Ideally, over time, the protein would stimulate the patient's body to build bone where the product was placed. SER 823, 574-75 (Infuse/LT-Cage label).

FDA's 2002 PMA order approved Infuse/LT-Cage as a spinal fusion product, but only for implantation through the patient's front side, only at one spinal level in the L4-S1 range of vertebrae, *id.* at 576, and only using the titanium LT-Cage, *id.* at 574. Each of these limitations appeared on Infuse/LT-Cage's FDA-approved label. *Id.* at 574-77.[2]

Reviewing her medical records, Ms. Jones discovered that her doctors had not observed these requirements. Rather, her surgery had been done "off label," meaning the Medtronic products were used in ways the FDA-approved label did not authorize. Instead of implanting the Infuse rhBMP protein from the front (an "anterior approach") as the Infuse/LT-Cage label demands, the surgeons implanted it from the side (a "lateral approach") and from the back (a "posterior approach"). SER 678-80. Instead of implanting it at only one level in the spine as the label demands, the surgeons implanted the protein at seven consecutive levels along her spine, for a total of nineteen applications. *Id.* In the first and second surgeries, instead of using the protein with the

[2] FDA later approved use of Infuse/LT-Cage in the L2-S1 range, but still at only one level of the spine. SER 683.

titanium LT-Cage as the label demands, the surgeons used it with two different Medtronic cages regulated as Class II devices: the Capstone and Clydesdale cages, made of PEEK polymer and approved only for use with the patient's bone rather than Infuse rhBMP. *Id.*; *see also* SER 789-90, 795-96 (PEEK cages' labels). And in Ms. Jones's third surgery, the surgeons did not use any cage at all, implanting the protein-soaked sponge by itself, directly between her vertebrae. SER 678-80.

These unapproved uses are dangerous. For example, implanting Infuse rhBMP via a posterior or lateral surgical approach may cause "severe uncontrolled or ectopic bone growth, severe inflammatory reaction, adverse back and leg pain events, radiculitis, retrograde ejaculation in men, urinary retention, bone resorption, and implant displacement." *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1028 (D. Haw. 2014). Since her failed surgeries, Ms. Jones has suffered from several of these complications. SER 708-09, 711, 713, 714-15.

C. Ms. Jones investigates Medtronic's role in her off-label surgeries.

With more research, Ms. Jones discovered that Medtronic had actively promoted dangerous uses of its spinal-fusion products. *See* SER 682, 694-707. She also learned that she was not the only patient injured by these unapproved uses. *See* SER 681-82. Indeed, whistleblowers and patients have alleged that Medtronic aggressively pushed its

products by systematically paying illegal bribes to doctors—leading in one case to a $40 million settlement with the United States.[3]

After studying her medical records and Medtronic's promotional materials, Ms. Jones began to suspect that Medtronic had induced her doctors to use Medtronic products in unapproved ways in her surgeries. *See* SER at 700-05, 707. She became more certain that Medtronic had influenced her surgeons when she learned that her surgeons appeared in directories published by Medtronic and that Medtronic salespeople were in the operating room during her three surgeries for more than thirteen total hours. *See* SER 678-79, 701-703, 772-73.

[3] *See e.g.*, *Hornbeck v. Medtronic, Inc.*, 2014 WL 2510817, at *1–2 (N.D. Ill. June 2, 2014) (noting allegation that Medtronic paid prominent surgeons to influence other surgeons to use Infuse/LT-Cage in unapproved ways); Compl. ¶¶ 57–68, *Foster v. Medtronic, Inc.*, 2012 WL 3202835 (N.D. Fla. July 27, 2012) (alleging that Medtronic unlawfully paid doctors to both use and promote Infuse rhBMP and other Medtronic spinal products, primarily for unapproved applications); Compl., *United States* ex rel. *[Under Seal] v. Medtronic, Inc.*, No. 2:02-cv-02709 (W.D. Tenn. Nov. 21, 2007) (alleging that Medtronic bribed doctors to use its spinal products), *settled as announced in* Dep't of Justice, *Medtronic to Pay United States $40 Million to Settle Kickback Allegations* (July 18, 2006), https://www.justice.gov/archive/opa/pr/2006/July/06_civ_445.html; *cf. Beavers-Gabriel*, 15 F. Supp. 3d at 1028 (noting allegation that "[o]ff-label uses of the Infuse Device account for 85 to 90 percent of all spine surgeries using the Infuse Device"); Jim Spencer et al., *Question of Risk: Medtronic's Lost Study*, StarTribune (Apr. 10, 2016) (describing Medtronic's failure to report over 1,000 cases of Infuse/LT-Cage complications to FDA and describing an alleged cover-up); David Armstrong & Thomas M. Burton, *Medtronic Product Linked to Surgery Problems*, Wall St. J. (Sept. 4, 2008) (noting serious complications from Infuse rhBMP and financial relationships between Medtronic and doctors who promoted off-label uses of Infuse rhBMP).

III. Procedural background

Represented by counsel, Ms. Jones and another patient sued Medtronic in California state court. Later, her attorney withdrew, and, later still, the state court dismissed her claims with leave to refile in Arizona state court. *See* Ms. Jones's Opening Br. 11-12. Proceeding pro se, Ms. Jones then sued Medtronic in Arizona court under Arizona common law and the Arizona Consumer Fraud Act, Ariz. Rev. Stat. Ann. § 44-1521 *et seq*. *See* SER 671, 675. Her complaint sets forth six substantive counts: (I) fraud in the inducement, (II) actual fraud, (III) constructive fraud, (IV) willful and gross negligence, (V) design defect, and (VI) negligence per se. SER 719-35. Counts I, III, IV, V, and VI allege that Medtronic violated Arizona law in several ways by promoting unapproved uses of Infuse/LT-Cage, the PEEK cages, and other products, inducing her doctors to perform injurious, off-label surgeries on her. *See id.* Count II alleges that Medtronic charged Ms. Jones for more products than were implanted in her and failed to give her a list of implanted products on request. *See* SER 720-23. Count VII maintains that Ms. Jones is entitled to punitive damages. *See* SER 735.

Medtronic removed the case to U.S. district court and moved to dismiss the complaint, arguing that the MDA preempts Ms. Jones's claims and that her fraud claims were insufficiently pleaded. SER 8, 9 (dist. ct. op.). The district court granted the motion and dismissed the case with prejudice. *Id.* at 32. Part A below discusses the claims the district court dismissed as preempted. Part B discusses the claims the court dismissed as improperly pleaded.

A. Claims dismissed as preempted

1. Express preemption. The district court treated one of the fraud claims and the negligence claims (Counts III, IV, and VI) as "virtually identical," reasoning that each claim rested on Medtronic's alleged duty to "(1) limit[] … its promotion materials to the anterior surgical approach, and (2) provid[e] additional safety information to the surgeons for the off-label use of its devices." SER 24 (dist. ct. op.). The court held that these claims are expressly preempted as to Infuse/LT-Cage because Ms. Jones "seek[s] to add to the FDA requirements" by requiring Medtronic to "affirmatively tell patients when medical devices have not been approved for a certain use." *Id.* at 24-25.

The court also dismissed Ms. Jones's claim that Infuse/LT-Cage was defectively designed (Count V). SER 26-27 (dist. ct. op.). Reasoning that an attack on the design of a product approved as a PMA device amounts to second-guessing FDA's risk-benefit analysis, the court held this claim expressly preempted. *Id.*

2. Implied preemption. The court observed that claims involving the PEEK cages are not subject to express preemption because (a) those cages are Class II devices approved through the Section 510(k) process, and (b) the parties had "not identified any device-specific requirements" applicable to those cages. SER 17-18 (dist. ct. op.). The court nonetheless held Ms. Jones's claims concerning the PEEK cages impliedly preempted. Based on its understanding of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the court stated that to "survive implied preemption, Plaintiff has to show that Defendant violated state tort law and the MDA." SER 25 (dist. ct. op.). The

court concluded that no MDA violation occurred, stating that federal law does not require additional instructions for or warnings against off-label uses. *Id.* On this basis, the court dismissed Ms. Jones's constructive-fraud and negligence claims about the PEEK cages (Counts III, IV, and VI). *Id.*

B. Claims held not preempted but dismissed as improperly pleaded

1. Fraud. The court concluded that Ms. Jones's claim for fraudulent, off-label promotion (Count I) is a parallel claim under the Supreme Court's precedents in *Lohr* and *Riegel* and therefore is not expressly preempted. SER 21 (dist. ct. op.) (citing *Beavers-Gabriel v. Medtronic*, 15 F. Supp. 3d 1021, 1034 (D. Haw. 2014)). In reaching this conclusion, the court observed that a regulation implementing the MDA prohibits manufacturing, packaging, storing, labeling, distributing, or advertising a device "in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." *Id.* (quoting 21 C.F.R. § 814.80). This regulation, the court reasoned, prohibits off-label promotion, paralleling the state-law duty not to fraudulently promote a product. The court further held that Ms. Jones's fraud claim is not impliedly preempted because it does not "seek to enforce an exclusively federal requirement not grounded in traditional state tort law." *Id.*

But the district court dismissed the claim nonetheless, reasoning that Ms. Jones's pro se complaint had "failed to allege that Defendant had induced her or her surgeon directly" or that "she would not have consented to the surgery" absent misrepresentations by Medtronic. SER 22 (dist. ct. op.). The court further reasoned that

any curative amendment would be "contradictory" because Ms. Jones had purportedly alleged that she did not know what caused her injuries. *Id.* at 22-23.

2. Design defect. As noted above, the court dismissed as preempted Ms. Jones's claim that Infuse/LT-Cage was defectively designed (Count V). In her opposition to Medtronic's motion to dismiss, Ms. Jones sought to particularize her design-defect claim by focusing her arguments on the Clydesdale cage—one of the Class II PEEK cages used off-label in her surgeries. *See* SER 429-30 (opp. mot. dismiss). The court did not consider the PEEK-related allegations in Count V of Ms. Jones's complaint, declined to consider new facts alleged in her opposition, and dismissed Count V. SER 27-28 (dist. ct. op.).

* * *

Reasoning that no amendment would change the preemption analysis and that Ms. Jones could not support her fraud claim without contradicting her original allegations, the court dismissed the case with prejudice. *See* SER 31-32 (dist. ct. op.).[4]

SUMMARY OF THE ARGUMENT

I. The district court's express-preemption holdings are wrong. Section 360k(a) preempts only state-law claims that impose requirements "different from, or in addition

[4] The court dismissed Ms. Jones's actual fraud claim (Count II), reasoning that her allegations of overcharging lacked factual support and that Medtronic had no duty to give her a list of implanted products. SER 29 (dist. ct. op.). The court also dismissed Ms. Jones's claim for punitive damages, reasoning that a plaintiff can seek punitive damages only as a remedy, rather than as a standalone claim. *Id.* at 30.

to" federal requirements "applicable under [the FDCA] to the device." 21 U.S.C. § 360k(a)(1). To have preemptive effect, federal requirements must be specific to the device and must cover the same subject matter as the state requirement. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 498-500 (1996); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322-23 (2008). But where a state-law claim concerns uses or characteristics of the product that are not subject to specific federal requirements, the claim is not preempted. *Lohr*, 518 U.S. at 500-02.

Ms. Jones's state-law claims are exactly that. Because PMA review assesses and approves a product only for the use described in a PMA application, it imposes specific federal requirements only as to that use. Ms. Jones's claims concern Medtronic's promotion of *unapproved* uses of its products—which did not undergo PMA review and so are not subject to any PMA-imposed requirements. Thus, none of her claims is expressly preempted. Allowing Medtronic to benefit from preemption after it circumvented the premarket approval process cannot be squared with the MDA's text, structure, or purposes.

II. Nor are Ms. Jones's claims as to the PEEK cages impliedly preempted. Under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), implied preemption occurs only when vindication of the state-law duty on which the plaintiff relies would interfere with the agency's exclusive authority to police its relationship with regulated parties. Such a claim would be based solely on federal law. Ms. Jones's claims do not interfere

with FDA's relationship with Medtronic and are based on traditional state-law principles.

III. Even assuming that the MDA may preempt state-law claims based on the promotion of medical products for unapproved uses, the MDA does not preempt Ms. Jones's claims for fraud and negligence with respect to Infuse/LT-Cage because they are "parallel" claims.

State-law claims are "parallel," and thus are not preempted under the MDA, if they are based on traditional state law and the conduct giving rise to them also violates the MDA. Ms. Jones's fraud and negligent-warning claims are based on the traditional state-law duties owed by a product manufacturer to those who use its products. And the alleged conduct underlying her claims also violates the MDA. The MDA prohibits Medtronic from advertising Infuse/LT-Cage in a manner inconsistent with the conditions of its PMA, but Medtronic did just that by promoting the product for unapproved uses. The MDA also requires Medtronic to provide adequate warnings about the dangers associated with Infuse/LT-Cage, and Medtronic's promotion of unapproved uses made the warnings on the product's label inadequate because it did not warn of those dangers.

IV. The district court erroneously dismissed two non-preempted claims as inadequately pleaded. First, Ms. Jones adequately pleaded that the PEEK cages were defectively designed. The district court's failure even to consider this claim requires reversal. Second, Ms. Jones's fraud claim was adequately pleaded. Drawing all inferences

in her favor, Ms. Jones pleaded causation by alleging that Medtronic's pervasive off-label promotion reached her surgeons and that Medtronic representatives were present during her surgery. But even if these two claims were not well pleaded, Ms. Jones should be permitted to amend her pro se complaint to remedy any deficiencies.

STANDARDS OF REVIEW

This Court reviews de novo the preemption holdings discussed in Parts I, II, and III below, and the sufficiency-of-pleading holdings discussed in Part IV, because each was decided as a matter of law on a motion to dismiss. *See Knievel v. ESPN*, 393 F.3d 1068, 1072 (9th Cir. 2005). In reviewing a grant of a motion to dismiss, the Court must draw "all reasonable inferences" in the plaintiff's favor. *Ass'n for L.A. Deputy Sheriffs v. Cty. of L.A.*, 648 F.3d 986, 991 (9th Cir. 2011). A pro se complaint must be construed liberally, "however inartfully pleaded," and it must be "held to less stringent standards than formal pleadings drafted by lawyers." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *see also Nordstrom v. Ryan*, 762 F.3d 903, 908 (9th Cir. 2014).

This Court should review the district court's denial of leave to amend, discussed in Part IV below, for abuse of discretion. *See Pierce v. Multnomah County*, 76 F.3d 1032, 1043 (9th Cir. 1996). "It is an abuse of discretion to apply the wrong legal standard." *United States v. Emmett*, 749 F.3d 817, 819 (9th Cir. 2014). Generally, leave to amend should be granted "with extreme liberality" and denied only when there is good reason, such as prejudice to the opposing party. *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1051-52 (9th Cir. 2003). A pro se complaint must not be dismissed without leave to

amend unless "it is absolutely clear that the deficiencies of the complaint could not be cured by amendment." *Nordstrom*, 762 F.3d at 908 (quoting *Schucker v. Rockwood*, 846 F.2d 1202, 1203-04 (9th Cir. 1988)). Absent a showing of prejudice or another strong reason for denial, "there exists a *presumption* under Rule 15(a) in favor of granting leave to amend." *Eminence Capital*, 316 F.3d at 1052.

ARGUMENT

I. Ms. Jones's claims are not preempted because Medtronic bypassed the MDA by promoting unapproved uses of its products.

None of Ms. Jones's state-law claims is preempted because each arises from Medtronic's promotion of unapproved uses of its products. Because unapproved uses have never run "the gauntlet of the PMA process," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 494 (1996), there are no device-specific federal requirements applicable to the unapproved uses that would preempt Ms. Jones's claims. Medtronic's expansive reading of preemption—that the existence of *any* device-specific federal requirement has across-the-board preemptive effect—cannot be squared with *Lohr, Riegel*, or the text, structure, and purpose of the MDA.

A. Promoting unapproved uses bypasses premarket approval.

As explained above (at 3-6), the MDA imposes a rigorous process for approving Class III PMA devices. But this process is limited to a product's specific proposed use. As Congress put it, FDA "shall 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

safety and effectiveness." 21 U.S.C. § 360e(d)(1)(A) (emphasis added). Thus, every PMA application must begin with the new product's "indications for use" and include a "complete description" of the "functional components" of the product; the "properties" of the product "relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition" it is intended to address; and the product's "principles of operation." *See* 21 C.F.R. § 814.20(b). A PMA application must also include an explanation of all clinical and nonclinical studies, *see id.* § 814.20(b)(6), and from these studies, FDA must fairly conclude that the product "will have the effect it purports or is represented to have *under the conditions of use* prescribed," 21 U.S.C. § 360c(a)(3)(A). *See generally Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-18 (2008) (explaining PMA process).

A PMA application must also contain a specimen of the product's labeling, 21 U.S.C. § 360e(c)(1)(F), because labeling is the "primary tool that FDA uses to communicate the essential information needed for the safe and effective use of the product," FDA Labeling Guidance, *supra*, at 2. For products approved as prescription devices, like the products in this case, labeling must include "indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions" under which practitioners can use the product "safely and for the purposes for which it is intended." *See* 21 C.F.R. § 801.109(c).

A use that is *not* included in a new product's PMA application is *not* reviewed by FDA. *See, e.g.*, FDA, Procedures for Meetings of the Medical Devices Advisory Committee, Guidance for Industry and Food and Drug Administration Staff 11-12 (2017), https://perma.cc/45N3-AVEZ (explaining that panel review evaluating the safety and effectiveness of a new product's use relies only on "what was submitted by the applicant in the original submission, unless the submission was amended in a subsequent submission."). Indeed, as if to underscore this point, the agency advises against "bundling" multiple indications for use for one product in a single PMA application "because each indication is usually supported by a clinical study that requires significant review resources." FDA, Bundling Multiple Devices or Multiple Indications in a Single Submission, Guidance for Industry and Food and Drug Administration Staff 9 (2007), https://perma.cc/C3QX-MKNJ.[5]

Instead, additional uses must be approved through a supplemental PMA. 21 C.F.R. § 814.39(a)(1). FDA guidance further explains that changes to a product's approved use at a particular anatomical site or for a particular surgical procedure—the same changes at issue in this case—"generally require significant labeling changes for which new clinical data are generally needed to support those changes." FDA, Guidance for Industry and Staff, Modifications to Devices Subject to Premarket Approval 7-8 (2008), https://perma.cc/BBX3-KGXE. And, when a significant change to a product's use

[5] By contrast, FDA permits bundling multiple uses for products cleared through the 510(k) process. *Id.* at 9.

requires "new preclinical testing and new clinical testing to demonstrate reasonable assurance of safety and effectiveness," FDA considers the product a "new device" for PMA purposes, requiring an entirely new PMA application. *Id.* at 5.

Like a lock and key, premarket approval is thus matched to a product's proposed use and only its proposed use. FDA's final premarket approval order does not reflect any determination about how safe or effective a product may be for uses beyond those approved by PMA. When, for example, FDA approves a drug-delivery pump intended for use in the back, it has determined *only* that the product is safe and effective *when used in the back*. FDA does not consider whether the same pump is safe and effective when used in the brain. A manufacturer that promotes that product for use in the brain promotes a use never subjected to PMA review and has thus bypassed the regulatory process. In the statute's terms, promoting an approved device for an unapproved use amounts to promoting a new—and unregulated—device.

B. There are no device-specific requirements that preempt a state-law claim based on promotion of unapproved uses.

Because unapproved uses are never evaluated during premarket approval, there are no preemptive federal requirements "applicable to" a product promoted for unapproved uses. *See Riegel*, 552 U.S. at 322-23; *Lohr*, 518 U.S. at 492-94. Granting the protection of preemption to manufacturers that skirt the MDA by promoting unapproved uses cannot be reconciled with the statute's text, structure, or purposes.

1.a. *Lohr* and *Riegel* held that the touchstone for preemption under Section 360k(a) is the existence of specific federal requirements applicable to a device. *Lohr*, 518 U.S. at 493-94, 498-502; *Riegel*, 552 U.S. at 322-23. These federal requirements have preemptive effect only when the federal requirements are both "'applicable to the device' in question" and "relevant"—that is, when the federal requirements are specific to the device and cover the same subject matter as the state-law claim. *Lohr*, 518 U.S. at 496, 500 (quoting 21 U.S.C. § 360k(a)); *see also* 21 C.F.R. § 808.1(d) (federal requirements preempt state requirements only when there are "specific counterpart regulations"). Federal requirements imposed through PMA may preempt state-law claims challenging the design, manufacturing, or labeling of a product approved as a PMA device because PMA requirements embody FDA's final risk-benefit determination that the product's "approved form provides a reasonable assurance of safety and effectiveness" for the stated "conditions of use." *Riegel*, 552 U.S. at 318, 322-23.

Absent premarket approval, however, federal requirements do not preempt state-law claims. Thus, in *Lohr*, the Court unanimously rejected Medtronic's argument that FDA clearance under Section 510(k) preempts a design-defect claim. 518 U.S. at 492-94; *id.* at 513 (O'Connor, J., concurring in part). This is so because Section 510(k)'s "substantial equivalency" process "merely evaluates whether the Class III device at issue is substantially equivalent to a device that was on the market before 1976," and this "places no 'requirements' on a device" as to its design. *Id.* General federal requirements,

such as general labeling and manufacturing duties, also do not preempt because these "reflect entirely generic concerns about device regulation generally." *Id.* at 501-02.

Lohr's reasoning decides this case. Much like Section 510(k) clearance "is focused on equivalence, not safety," and therefore does not preempt state-law claims about safety, *Lohr* 518 U.S. at 493-94, premarket approval of a product's proposed use is focused on the proposed use alone—not on all of a product's potential but unapproved uses. Thus, premarket approval as to the safety of one use does not preempt state-law claims for the unlawful promotion of unapproved uses. As the United States has recognized, it is an "oversimplification" to assume that "the act of premarket approval itself establishes device-specific requirements on all possible subjects, thus preempting additional or different state requirements whatever their subject." Br. for the United States as Amicus Curiae at 16, *Medtronic, Inc. v. Stengel*, 134 S. Ct. 2839 (2014) (No. 12-1351), 2014 WL 2111719. And, as the government explained, state compensation laws are "an important complement to the FDCA's regulatory framework." *Id.* at 11. Were a state-law claim preempted absent a device-specific federal requirement on the same subject, "the MDA would have the ironic effect of 'provid[ing] less public protection from unsafe and ineffective medical devices' than pre-MDA law." *Id.* at 11 (quoting 43 Fed. Reg. at 18,663).[6]

[6] In *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013) (en banc), this Court held that a state-law claim concerning Medtronic's failure to report adverse events to FDA was not preempted. *Id.* at 1232-33. In its amicus brief responding to Medtronic's

b. Here, Ms. Jones alleges that Medtronic promoted numerous unapproved uses of its products. At the time of Ms. Jones's surgery, FDA had approved Infuse rhBMP for specific uses: to treat acute tibial shaft fractures; to promote bone growth for sinus augmentations; and in spinal fusion surgery, at one level of the spine and with the LT-Cage, a titanium intervertebral spacer cage. SER 558, 566, 542 (PMA approval letters). FDA's 2002 PMA of the combination Infuse/LT-Cage product was expressly restricted to the use of its components together. *See id.* at 574 (Infuse/LT-Cage label). The label read: "**These components must be used as a system. The InFuse™ Bone Graft component must not be used without the LT-CAGE™ Lumbar Tapered Fusion Device component.**" *Id.* (bold and underline in original). And, the label instructed that the product be implanted "via an anterior open or an anterior laparoscopic approach," at no more than one spinal level. *Id.* at 576.

FDA's premarket approval imposed design and labeling requirements as to the approved use of Infuse/LT-Cage, but it imposed no requirements on the uses employed in Ms. Jones's surgeries: at five levels of the spine with polymer PEEK cages (rather than the required titanium LT-Cage); by itself (without any cage) directly between her vertebrae for seven consecutive levels; and implanted via unapproved lateral and posterior approaches. *See* SER 678, 764-65, 775-78. FDA never considered

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petition for certiorari, the government reasoned that because the adverse reporting requirement is governed by FDA's generally applicable regulations rather than the terms of the device's premarket approval order, under *Lohr* and *Riegel*, the state-law claim was not preempted. Br. for United States at 10-12.

or approved the safety or effectiveness of Infuse/LT-Cage's design for these uses, nor did it evaluate the adequacy of its labeling for these uses. By promoting the components of Infuse/LT-Cage for use in these ways, Medtronic circumvented the PMA process. Once outside of the PMA regime, Medtronic is not shielded by Section 360k(a) preemption.

c. For these reasons, the Tenth Circuit's decision in *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335 (10th Cir. 2015), is wrong. *Caplinger* held that state-law claims concerning unapproved uses may be expressly preempted because Section 360k(a) does not distinguish between FDA-approved uses and the unapproved uses a manufacturer promotes. *Id.* at 1344. Because Section 360k(a)(1) refers broadly to requirements "applicable … to the *device*," the court maintained, preemption applies across-the-board to all potential uses of a product approved as a Class III PMA device. *Id.*

That reasoning cannot be squared with the MDA, particularly given the longstanding principle that "the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Roberts v. Sea-Land Servs., Inc.*, 566 U.S. 93, 101 (2012) (citation and quotation marks omitted). "It is necessary and required that an interpretation of a phrase of uncertain reach is not confined to a single sentence when the text of the whole statute gives instruction as to its meaning." *Maracich v. Spears*, 133 S. Ct. 2191, 2203 (2013).

Applying that principle here, the word "device" cannot be understood "in a contextual vacuum." *Lohr*, 518 U.S. at 485. First, though Section 360k(a) refers to "the

device," the FDCA's definition of "device" depends on its "primary intended purposes." 21 U.S.C. § 321(h). And *Caplinger*'s cramped understanding of "device" is at war with the MDA's provisions implementing the PMA process. As just explained, the statute instructs that when a new "device" is approved through PMA, the product's proposed use—and only its proposed use—is approved. *See id.* §§ 360e(d)(1)(A), 360c(a)(2)(B), 360e(d)(2)(A), (B). Clinical investigations must support the safety and effectiveness of the product for that use, *id.* § 360e(c)(1)(A), and the product's labeling must bear adequate warnings about dangers associated with that use, *id.* § 352(f)(2). So, whether a federal requirement is "applicable under this chapter to [a] device," *see id.* § 360k(a), necessarily depends on the *use* for which the product was approved. PMA creates preemptive federal requirements—but only as to FDA-approved uses. *See Riegel*, 552 U.S. at 322-23.

Other courts have reached similar conclusions. *See Ramirez v. Medtronic, Inc.*, 961 F. Supp. 2d 977 (D. Ariz. 2013); *Hornbeck v. Medtronic, Inc.*, 2014 WL 2510817 (N.D. Ill. June 2, 2014); *McDonald-Lerner v. Neurocare Associates, P.A.*, 2013 WL 7394926 (Md. Cir. Ct. Aug. 29, 2013). *Ramirez* held that Medtronic could not benefit from preemption because, absent federal approval of the promoted—but unapproved—use, no regulations preempted state-law requirements. 961 F. Supp. 2d at 993. Put another way, promoting products for unapproved uses removes a manufacturer "from whatever protection federal oversight of medical devices would have provided." *Hornbeck*, 2014 WL 2510817, at *3. "There is no legitimate federal concern with state judges or state

juries meddling with the decisions of the FDA when the state law claims, as alleged in this case, arise 'out of a use that has not been reviewed by the FDA but has been promoted by the manufacturer.'" *McDonald-Lerner*, 2013 WL 7394926, at *6 (quoting *Ramirez*, 961 F. Supp. 2d at 991).

Though *Ramirez* correctly embraced the principle that unapproved uses do not trigger preemption, *see Ramirez*, 961 F. Supp. 2d at 922-93, it did not adequately distinguish between the argument advanced here (that PMA-imposed requirements preempt only state-law claims about PMA-approved uses) and a separate parallel-claim argument, explained further in Part III below (that Ms. Jones's state-law claims are not preempted because Medtronic's alleged off-label promotion violated both state and federal law). This confusion has led other courts to incorrectly reject *Ramirez* on the basis that federal law *does* impose requirements regarding off-label use, like prohibiting manufacturers from promoting off-label uses. *See, e.g.*, *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1035-36 (D. Haw. 2014) (citing *Houston v. Medtronic, Inc.*, 2014 WL 1364455, at *5 (C.D. Cal. Apr. 2, 2014)). Although the MDA indeed imposes *general* requirements on products regulated as devices regardless of intended use—such as prohibiting "misbranded" products—these requirements are not preemptive. *See Lohr*, 518 U.S. at 501. General requirements do not, as *Lohr* emphatically held, preempt state-law claims because they are "not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.*; *accord* 21 C.F.R. § 808.1(d).

2. Nor can immunizing manufacturers that skirt the PMA regulatory scheme be squared with the MDA's structure and purpose. As *Lohr* emphasized, "interpretation of [Section 360k(a)'s] language does not occur in a contextual vacuum." 518 U.S. at 484-85. Rather, the preemption analysis is guided by the presumption against preemption, premised on the understanding that "the States are independent sovereigns in our federal system," *id.* at 485, and Congress's purpose, which can be discerned by the statute's language and the "'statutory framework' surrounding it," *id.* at 485-86. That framework pairs rigorous premarket approval with preemption to ensure, first, that medical products are safe and effective and, second, that FDA generally has the final say as to each product's risk-benefit safety assessment. *See id.* at 490-91; *see also Riegel*, 552 U.S. at 315-16, 325.

Neither purpose is served when manufacturers sidestep regulatory approval with impunity. *Unapproved* uses are *unregulated* uses that can—as alleged here—seriously harm the people the statute aims to protect. The MDA was intended to "prevent the marketing of medical devices which have not had adequate premarket testing." H.R. Rep. 94-853, 94th Cong., 2d Sess. 8 (1976). Indeed, Congress enacted the statute following a series of public health tragedies in which patients died or were seriously injured by unregulated products that had been promoted as safe and effective by manufacturers. *See id.* To now shield manufacturers that promote untested and unregulated uses of products as safe and effective simply because these products were approved for a different use runs headlong into this history.

Nor is regulatory uniformity—arguably a goal of Section 360k(a) preemption—served by allowing manufacturers to promote unapproved uses. *Riegel* explained that Section 360k(a) preemption is intended to protect FDA's device-specific determinations of a product's safety and effectiveness from second-guessing under state law. *See Riegel*, 552 U.S. at 323-25. Preemption ensures that no other entities "arrive at a determination regarding a device's safety that conflicts with the conclusion the FDA made after the rigorous PMA process." *Ramirez*, 961 F. Supp. 2d at 991.

But FDA has come to no "conclusion" regarding an unapproved use because it has never reviewed that use, much less approved and imposed "requirements" on it. Instead of ensuring the supremacy of federal regulation, preemption under these circumstances provides manufacturers a perverse safe-haven: escape from "the gauntlet of the PMA process," *Lohr*, 518 U.S. at 494, *and* immunity from state law. If preemption broadly covered both approved and unapproved uses, "device manufacturers might be faced with an incentive to seek FDA approval for the most minimal contemplated use—and thereafter market the product for additional, perhaps largely untested, uses—with impunity." Marcia Boumil, *FDA Approval of Drugs and Devices: Preemption of State Laws for "Parallel" Tort Claims*, 18 J. Health Care L. & Pol'y 1, 40 (2015). The MDA does not shelter manufacturers who evade regulatory scrutiny, and this Court should therefore reject any invitation to insulate them from accountability under state law. Put simply, Medtronic may not be shielded by the very process it circumvented.

II. Ms. Jones's claims regarding the Class II PEEK cages are not preempted.

Separate and apart from any ruling regarding the Class III Infuse/LT-Cage combination product, this Court should reverse the district court's erroneous ruling regarding the Class II polymer PEEK cages. Ms. Jones alleged that Medtronic committed constructive fraud and was negligent in failing to warn doctors and patients about the dangers associated with using polymer PEEK cage implants with the synthetic protein component of Infuse/LT-Cage, rather than with bone harvested from the patient, as required by the PEEK cages' labeling (Counts III and IV). SER 725-26; *see also* SER 789-90, 795-96. Ms. Jones also alleged that Medtronic was per se negligent by violating federal prohibitions against selling mislabeled products (Count VI). SER 728; *see* 21 U.S.C. §§ 331(a), 352(a)(1). The district court correctly held that these claims are not expressly preempted under *Lohr*, but the court erred in finding these claims impliedly preempted. SER 17-18, 25 (dist. ct. op.).[7]

According to the district court, to avoid implied preemption, Ms. Jones needed to show that Medtronic violated both state tort law and the MDA, and, in the court's view, Medtronic's actions did not violate the MDA. SER 25 (dist. ct. op.). This holding confused implied preemption with the "parallel claims" doctrine. That doctrine, explained above (at 7-8), allows certain state-law claims regarding a product approved

[7] Ms. Jones also raised a design-defect claim regarding the PEEK cages. As discussed below (at 45-47), Ms. Jones adequately pleaded this claim, and even if she did not, she should have been granted leave to amend.

as a PMA device to defeat *express* preemption under 21 U.S.C. § 360k(a) if the claims are "parallel," meaning they do not impose duties "different from, or in addition to" an FDCA requirement. *See Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013).

As noted earlier (at 8-9), a state-law claim is *impliedly* preempted under the narrow rationale of *Buckman Co. v. Plaintiffs' Legal Committee* only where the claim does not stem from "traditional state tort law principles." 531 U.S. 341, 352-53 (2001). In *Buckman*, the impliedly preempted "fraud-on-the-agency" claim was based on statements made by a consulting company to FDA during the agency's internal market-clearance process. *Id.* at 343. Because "policing fraud against the agency is hardly a field which the States have traditionally occupied," no presumption against preemption applies, and state law "would inevitably conflict with FDA's responsibility to police fraud consistently with [its] judgment and objectives." *Id.* at 347-48, 350 (internal quotations and citations omitted).

By contrast, Ms. Jones's claims—including those involving the Class II PEEK cages—sound in "traditional state tort law principles," *Buckman*, 531 U.S. at 352. Ms. Jones alleges that Medtronic had a state-law duty to provide an adequate warning about the use of PEEK cages with the Infuse rhBMP protein. SER 723-76, 728. Like the claims in *Lohr*, Ms. Jones's claims are grounded in a traditional state-law duty: the general duty owed by a manufacturer to a consumer to use due care. *See* 518 U.S. at 501; *see also McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040-41 (9th Cir. 2015) (state law failure-to-warn and negligence per se theories not impliedly preempted). Unlike fraud-on-the-

agency, these claims do not "arise solely by virtue of the MDA" and are therefore not impliedly preempted. *See McClellan*, 776 F.3d at 1040-41. For these reasons, Ms. Jones's claims regarding Medtronic's Class II PEEK cages are not preempted.[8]

III. Ms. Jones's Infuse/LT-Cage claims are non-preempted parallel claims.

Even if preemption under the MDA extends to uses not approved by FDA, Ms. Jones's particular state-law claims as to the Infuse/LT-Cage product are not preempted because they are parallel claims under *Lohr* and *Riegel*.

Recall that a state-law claim is expressly preempted only if it seeks to impose a requirement on a manufacturer that is "different from, or in addition to" the requirements imposed on the manufacturer by the MDA. 21 U.S.C. § 360k(a). But Section 360k(a) does not deny states "the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). Put differently:

> Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is "different from, or in addition to," requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.

[8] For the same reasons, Ms. Jones's fraud claim as to the PEEK cages (Count I) is also not impliedly preempted, as the district court correctly held. SER 21 (dist. ct. op.). As discussed below (at 47-51), the district court erroneously dismissed this fraud claim as inadequately pleaded.

Id. at 513 (O'Connor, J., concurring in relevant part).

Thus, as this Court held in *Stengel v. Medtronic, Inc.*, so long as a state-law claim about a Class III device is based on "traditional state tort law principles," *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 352-53 (2001), and the conduct giving rise to the claim also violates the MDA, *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008), the claim survives preemption as a parallel claim. *See Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc).

A. Ms. Jones's fraud claim is a parallel claim and so is not preempted.

The district court correctly held that Ms. Jones's claim against Medtronic for fraud in promoting unapproved uses of Infuse/LT-Cage (Count I) is a parallel claim. SER 21 (dist. ct. op.).[9] As explained earlier (at 10-12), Infuse/LT-Cage is approved for use only in anterior surgical approaches and for use on only one level of the spine between L2 and S1. SER 576 (Infuse/LT-Cage label); *see also supra* note 2. Ms. Jones alleges that, despite these restrictions, Medtronic posted information on its websites misrepresenting Infuse/LT-Cage as "approved for use with all surgical approaches," SER 719-20, and misrepresenting Medtronic's spinal products as enabling "fixation over many levels," even though no Medtronic fusion product has received FDA approval for use at "many levels," SER 705-06. In particular, Ms. Jones alleges that

[9] Ms. Jones's pro se complaint referred to this fraud claim as "fraud in the inducement." SER 719. Fraud in the inducement and simple fraud are the same under Arizona law. *See* SER 21-22 (dist. ct. op.).

these misrepresentations were made to her surgeons, both through "Medtronic's all-reaching promotion of the off-label use of" Infuse/LT-Cage and by Medtronic representatives in the operating room during Ms. Jones's surgeries. *See* SER 702-03.

1. State-law violation. This claim is based on traditional state-law duties. Ms. Jones alleges that Medtronic fraudulently misrepresented Infuse/LT-Cage as safer than it actually was, *see* SER 719-20, and fraud in the advertisement of merchandise violates the Arizona Consumer Fraud Act (CFA), Ariz. Rev. Stat. Ann. § 44-1522(A). In particular, a misrepresentation about the safety of a medical product in connection with the promotion of that product violates the CFA. *See Watts v. Medicis Pharm. Corp.*, 365 P.3d 944, 952-53 (Ariz. 2016). Fraud claims have a deep pedigree in Arizona law, *see, e.g.*, *Moore v. Meyers*, 253 P. 626, 627 (Ariz. 1927), and such claims are based on the traditional duty of care owed to individuals, not on a duty to be truthful to a federal agency, *cf. Buckman*, 531 U.S. at 351-53. Thus, the district court correctly held that Ms. Jones's fraud claim is "grounded in traditional state tort law" and is a "valid state-law claim." SER 21 (dist. ct. op.).

2. Federal-law violation. Medtronic's alleged fraud also violates the FDCA. The FDCA prohibits a manufacturer from selling "misbranded" medical products. 21 U.S.C. § 331(a). A product is misbranded if its advertising is misleading, 21 U.S.C. § 352(q), and FDA regulations state that a product regulated as a Class III device cannot be advertised in any manner inconsistent with the conditions of its PMA, 21 C.F.R. § 814.80. Medtronic's promotion of Infuse/LT-Cage for spinal surgeries with non-

anterior approaches and on multiple discs—both of which were inconsistent with its PMA—constituted the "promotion of a Class III device for an unapproved use [and] violates Section 331 of the FDCA." *Carson v. Depuy Spine, Inc.*, 365 F. App'x 812, 815 (9th Cir. 2010); *accord* SER 20-21 (dist. ct. op.).

* * *

In sum, because Ms. Jones's complaint alleges off-label promotion that would violate both independent state law and the FDCA, the district court correctly held that her fraud claim based on Medtronic's promotion of unapproved uses of Infuse/LT-Cage is a non-preempted parallel claim. SER 20-21 (dist. ct. op.); *see also Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 704 (S.D. Tex. 2014) ("state law fraud claims based on false off-label promotion would, if proven, also amount to a violation of federal law, and thus such claims could survive preemption"); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1037 (D. Haw. 2014) ("fraudulent statements to promote off-label uses of [Infuse/LT-Cage] lies 'parallel' to federal requirements") (quoting *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1179 (C.D. Cal. 2013)).

B. Ms. Jones's negligent failure-to-warn claims are parallel claims and so are not preempted.

Although the district court was correct that Ms. Jones's fraud claim is not preempted, it erred in holding that her claims alleging negligent failure-to-warn (Counts III, IV, and VI) are preempted. Ms. Jones brings two theories against Medtronic: nullification and failure to provide new labeling. Both theories flow from Medtronic's

off-label promotion of Infuse/LT-Cage, and Ms. Jones's claims survive preemption under either theory.

First, Ms. Jones alleges that Medtronic was negligent because its promotion of unapproved uses nullified the label on Infuse/LT-Cage, rendering it ineffective for its purpose of "promot[ing] the safe and effective use of medical devices." SER 728. The labeling on Infuse/LT-Cage is supposed to ensure that doctors and patients are warned about the dangers associated with the product. *See id.* By promoting unapproved uses—in contravention of the warnings on the label—Medtronic rendered the label ineffective at providing the adequate warning intended by the law. In a word, Medtronic's promotion *nullified* the existing labeling.

Second, Ms. Jones alleges that Medtronic was negligent when it failed to correct labeling deficiencies that resulted from the company's promotion of unapproved uses. Specifically, she alleges that once Medtronic decided to promote Infuse/LT-Cage for new uses that had not been approved by FDA, it incurred a duty to provide "information necessary for the safe use of [Infuse/LT-Cage] in an off-label surgery," and she alleges that Medtronic was negligent under Arizona state law in failing to provide this information to her or her doctors. SER 725-26.

Put simply, Medtronic was, first, negligent in creating a mess—by deciding to promote Infuse/LT-Cage for unapproved uses, it rendered its existing labeling inadequate under federal law. Then, Medtronic was negligent in failing to clean up its mess—by engaging in unlawful promotion, it had a further duty to provide new

warnings and instructions as to those unapproved uses, and it was negligent in failing to do that too.

1. State-law violation. Both of Ms. Jones's negligence theories are rooted in Arizona law. Under Arizona law, a medical product manufacturer is liable for defects in warnings about the dangers associated with its product. *See Watts v. Medicis Pharm. Corp.*, 365 P.3d 944, 948 (Ariz. 2016). In particular, the manufacturer has a duty to provide "adequate" warnings. *Id.*; *see also, e.g.*, *Tucson Indus., Inc. v. Schwartz*, 501 P.2d 936 (Ariz. 1972) (en banc).

Ms. Jones is alleging that Medtronic's warnings about Infuse/LT-Cage were inadequate, both because the existing labeling was nullified by Medtronic's promotion of unapproved uses and because new warnings were required to render the labeling adequate once the promotion had commenced. Ms. Jones is thus bringing a straightforward Arizona-law claim alleging negligent failure to provide adequate warnings, and so her negligence claims are "valid state-law claims." *See* SER 24 n.19 (dist. ct. op.).

2. Federal-law violation. On the federal side of the parallel-claim analysis, nullification of an existing warning and failure to provide new warnings each violates the FDCA.

a. Nullifying an existing warning through promotion of unapproved uses violates 21 U.S.C. § 331(k). That section prohibits a person from doing anything that would result in the product's labeling becoming false or misleading, like making misleading

statements intended to accompany the product in commerce. *See Kordel v. United States*, 335 U.S. 345, 346-48 (1948) (holding that where information intended to supplement and explain the use of a product was misleading, the product's labeling was misleading); *United States v. Harkonen*, 2009 WL 1578712, at *8, *10-11 (N.D. Cal. 2009) (applying *Kordel* to hold that promotion of unapproved uses of a drug violates Section 331(k)).

Here, Ms. Jones's claims are based on Medtronic's promotion of Infuse/LT-Cage as safe for unapproved uses—promotion that was inconsistent with warnings on the product's label. SER 683-84, 705-06, 719-20. These promotions were intended to reach doctors and to "supplement[] or explain[]" the use of Infuse/LT-Cage. *Kordel*, 335 U.S. at 350. Thus, Medtronic's promotion of unapproved uses, in addition to violating a state-law duty, constitutes an alteration of the Infuse/LT-Cage label that renders the product misbranded in violation of 21 U.S.C. § 331(k). And so, a negligence claim based on the nullification theory is a non-preempted parallel claim. *See Mendez v. Shah*, 28 F. Supp. 3d 282, 299-300 (D.N.J. 2014) (nullification-based negligence claim with respect to Infuse/LT-Cage not preempted); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 827-28 (E.D. Pa. 2016) (rejecting preemption where state-law claim is based in part on the theory that overpromotion of a product can "nullify otherwise adequate warnings").

The district court did not analyze Ms. Jones's negligent failure-to-warn claim under her nullification theory, but rather only under the theory that Medtronic was negligent in failing to provide new labels. *See* SER 23-25 (dist. ct. op.); *cf. Hawkins v. Medtronic, Inc.*, 62 F. Supp. 3d 1144, 1164 (E.D. Cal. 2014) (similar analysis). But the two theories are

analytically distinct. Ms. Jones's nullification theory is not based on Medtronic's duty to provide *new* warnings; it alleges only that Medtronic must faithfully adhere to its *existing* label by not nullifying it through other, unlawful statements.

b. In any event, Ms. Jones's claim survives preemption under the district court's mode of analysis. The district court held that Ms. Jones's negligent-warning claim is preempted because liability for failure to provide new warnings was tantamount to a requirement that Medtronic provide more labels than those already approved, which would be a requirement "different from, or in addition to" requirements imposed by the MDA. SER 24-25 (dist. ct. op.). This holding was wrong because, in these circumstances, Medtronic was required to provide new warnings by the MDA as well as by state law—a classic "parallel" claim. *Stengel*, 704 F.3d at 1233.

As explained earlier (at 5-6, 21-24), FDA considers only uses listed on the label when it decides whether to approve the product. However, a manufacturer may subsequently intend to put the product to a different use, as evidenced by the manufacturer's "advertising matter" and "oral or written statements by [the manufacturers] or their representative." 21 C.F.R. § 801.4. Under FDA regulations, a product regulated as a prescription device must bear information about "hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and *for the purpose for which it is intended*." 21 C.F.R. § 801.109(c) (emphasis added). Because intended uses that arise after premarket approval were never vetted through the initial PMA process, *see supra* at 5-6,

21-24, a manufacturer is "required to supply adequate labeling in accordance with the new intended uses." 21 C.F.R. § 801.4.

Therefore, when Medtronic decided to promote Infuse/LT-Cage for unapproved uses, it created new intended—albeit unapproved—uses for Infuse/LT-Cage. In doing so, it incurred a duty to provide adequate warnings about the risks of those new, unapproved uses. As FDA has emphasized, "FDA-required labeling is the primary tool that FDA uses to communicate the essential information needed for the safe and effective use of the product." FDA Labeling Guidance, *supra*, at 2. Therefore, Medtronic has "an obligation to update their FDA-required labeling as needed to ensure it is not false or misleading," *id.*, and it violated the MDA by failing to do so, *see Alton v. Medtronic, Inc.*, 970 F. Supp. 2d 1069, 1101-02 (D. Or. 2013) (holding that a failure-to-warn claim regarding unapproved use of Infuse/LT-Cage was not premised on a "state-law duty different from or in addition to Medtronic's FDCA labeling obligations").

The district court was wrong to suggest that Medtronic could not change its labeling without supplemental premarket approval. *See* SER 13 (dist. ct. op.). Medtronic need not wait for supplemental approval before providing new warnings—it may unilaterally make label changes that strengthen warnings while supplemental approval is pending. 21 C.F.R. § 814.39(d)(2)(i); *cf. Wyeth v. Levine*, 555 U.S. 555, 568-70 (2009) (arriving at same conclusion under identical regulatory language about supplemental drug labeling).

* * *

By promoting Infuse/LT-Cage for unapproved uses, Medtronic incurred both a state and a federal duty to provide adequate warnings about those uses. Failure to provide these warnings violates both state law and the MDA, so Ms. Jones's negligent failure-to-warn claims are non-preempted parallel claims.

3. Negligence per se. The parallel nature of Ms. Jones's negligence claims—under either negligent failure-to-warn theory—is underscored by Ms. Jones's negligence per se claim. *See* SER 728. In Arizona, it is generally per se negligent to fail to comply with a statutory standard of care. *Gunnell v. Ariz. Pub. Serv. Co.*, 46 P.3d 399, 403 (Ariz. 2002) (en banc). Thus, when Medtronic "failed to comply with FDA labeling regulations" by nullifying its label and failing to provide new labels, SER 728, it was per se negligent under Arizona law.

Negligence per se is the quintessential parallel claim—a claim based independently on a state-law duty of care where breach is determined by a violation of federal law. Such a claim is not expressly preempted by Section 360k(a) because the state is providing a damages remedy "premised on a violation of FDA regulations." *Riegel*, 552 U.S. at 330. Nor is it impliedly preempted even though Ms. Jones's negligence per se claim uses "federal law to establish a standard of care." *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1041 (9th Cir. 2015). Under *Buckman*, implied preemption occurs only where the state-law claims "arise solely by virtue of the MDA." *Id.* at 1040-41. Like the non-preempted claim in *McClellan*, Ms. Jones's negligence per se claim arises under state law

and not by virtue of the MDA. That is so because her claim concerns conduct "outside the context of the regulatory process"—meaning, her claim "has little to do with [Medtronic's] direct regulatory interaction with the FDA." *Id.* at 1041. It is therefore not preempted.

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

The district court erred when it found pleading defects in Ms. Jones's pro se complaint and dismissed her claims for design defects in the PEEK cages (Count V) and for fraud as to all products (Count I). The court compounded this error by denying leave to amend.[10]

A. Ms. Jones adequately pleaded claims for design defects in the PEEK cages, but even if she did not, she should be permitted to amend.

1. Sufficiency of pleading. In dismissing Ms. Jones's design-defect claim, the district court erred by focusing solely on her allegations about Infuse/LT-Cage and ignoring her allegations about Medtronic's PEEK cages. *See* SER 26-28 (dist. ct. op.). As the district court correctly recognized, claims about the Class II PEEK cages would not be expressly preempted by federal law. *See id.* at 17-18. The court implied, however, that Ms. Jones had not alleged a defect in the PEEK cages until her opposition to Medtronic's motion to dismiss. *See id.* at 27.

[10] The district court also dismissed Ms. Jones's actual fraud claim (Count II) as insufficiently pleaded. SER 29 (dist. ct. op.). Ms. Jones may replead this claim if this Court remands.

But Ms. Jones's pro se complaint does allege this defect. At the beginning of her complaint, she explains: "This is a products liability case pertaining to … Capstone Spinal System [PEEK] Cages … Clydesdale Spinal System [PEEK] cages, PEEK Intervertebral Cages … and any and all other Medtronic devices … implanted in or used upon the body of Plaintiff Kathryn Marie Jones." SER 673. Under "Fifth Cause of Action: Design Defect," Ms. Jones alleges that the "design of the Medtronic devices … was defective." SER 726-27. And finally, she alleges that a PEEK cage has migrated and is "no longer in the space between the vertebrae." SER 711.

That Ms. Jones does not mention PEEK cages specifically under the "Design Defect" heading does not make her pro se complaint defective. Her reference to "the Medtronic devices" in the plural under that heading refers to the products identified at the beginning of her complaint. These products, as noted, include the PEEK cages—a point that Ms. Jones amplified in her opposition to Medtronic's motion to dismiss. *See* SER 429-34 (opp. mot. dismiss). The district court's failure even to consider this claim is reversible error, especially under the liberal pleading standard for pro se complaints. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *see also supra* at 20 (standards of review).

2. Leave to amend. Even if Ms. Jones did not sufficiently plead that the PEEK cages were defectively designed, the district court was wrong not to grant leave to amend. In her response to Medtronic's motion to dismiss, Ms. Jones sought to further particularize Count V (design defect), focusing her arguments on the Clydesdale PEEK cage. *See* SER 429-34 (opp. mot. dismiss). The court refused to consider Ms. Jones's

new allegations, stating that complaints "may not be amended through an opposition to a motion to dismiss." SER 27-28 (dist. ct. op.). The court dismissed Ms. Jones's PEEK design-defect claim without leave to amend. *See id.* at 32.

Although a trained lawyer presumably would have used Rule 15 to make additional allegations, Ms. Jones, a pro se litigant, chose a different vehicle. But that was no reason to prohibit her from amending, particularly given the strong presumption in favor of leave to amend. *See Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1051 (9th Cir. 2003). Indeed, the allegations Ms. Jones made in her opposition show that she has new, relevant information to put in an amended complaint.

B. Ms. Jones adequately pleaded her fraud claim, but even if she did not, she should be permitted to amend.

1. Sufficiency of pleading. After holding that Ms. Jones's fraud claim (Count I) survives preemption, the district court dismissed that claim as insufficiently pleaded. SER 21-23 (dist. ct. op.). According to the court, Ms. Jones failed to allege a causal link between her surgeons' off-label uses of Medtronic's products and Medtronic's off-label promotion. *Id.*

Not so. Drawing all reasonable inferences in Ms. Jones's favor, *see Ass'n for L.A. Deputy Sheriffs v. Cty. of L.A.*, 648 F.3d 986, 991 (9th Cir. 2011), and construing her complaint liberally, *see Erickson*, 551 U.S. at 94, Ms. Jones sufficiently alleges causation. First, Ms. Jones alleges that "since FDA approval in 2002, Medtronic has overwhelmingly, willfully, and continuously promoted its Infuse Bone Graft/LT-Cage

Lumbar Tapered Fusion Device (and other Medtronic devices, products, and therapies) for off-label spinal surgeries." SER 691. Second, she alleges that Medtronic promoted her specific surgeon through its websites, and that "surgeons promoted by Medtronic" received off-label promotions. SER 701, 702. Third, she alleges "[i]t would be impossible for any spine surgeon to not come into contact with Medtronic's all-reaching promotion of the off-label use of" Infuse/LT-Cage. SER 702. Fourth, she alleges that Medtronic employees were in the operating room for the entirety of her three surgeries. SER 678-79. Hospital records show these visits totaled over thirteen hours. *See* SER 772-73. Fifth, Ms. Jones alleges, in two rhetorical questions, "What inducements did Medtronic provide to Drs. Denning and Jackson that enticed the doctors into performing three entire fusions on one patient? And was a Medtronic Clinical Specialist present during those fusions - standing side-by-side with Plaintiffs surgeons - actively, clinically participating?" SER 703.

From these allegations, it follows that Ms. Jones's spine surgeons encountered the promotion, and that the Medtronic employees encouraged, or at least sanctioned, the unapproved uses of Medtronic's products that they witnessed during the surgeries. In other words, these allegations permit the reasonable inference that Medtronic induced her doctors to use Medtronic's products in unapproved ways.

2. Leave to amend. Even if Ms. Jones failed to plead causation, the district court should not have denied leave to amend. In denying leave, the court relied on Ms. Jones's acknowledgments that she "may" ultimately be unable to prove which Medtronic

products caused which of her injuries or how interactions among them might have contributed. SER 22-23 (dist. ct. op.); SER 674, 690. On this basis, the court concluded that Ms. Jones "cannot cure the deficiencies with additional non-contradictory allegations." SER 23 (dist. ct. op.). That is, the court thought any further particularization of Ms. Jones's causation theory would contradict her earlier acknowledgement of uncertainty. This purported inconsistency, the court reasoned, would make any amended complaint futile. *Id.* at 22-23. This reasoning was flawed in three ways.

First, contrary to the district court's conclusion, new allegations particularizing Ms. Jones's causal theory would not contradict her original complaint. That complaint, filed in 2014, acknowledges uncertainty about questions of medical fact. But since then, Ms. Jones has learned much more that she could include in an amended complaint. She has learned that spinal fusion is likely to fail when Infuse/LT-Cage is used without the LT-Cage, contrary to the FDA-approved label—which is precisely what Ms. Jones's doctors did. *See* Opp. Mot. Strike, Dist. Ct. ECF 31, at 7-10. She has also learned that these failures to fuse often cause abnormal bone resorption. *See id.* She now knows that Medtronic gave her doctors an outdated label that contained only half as many warnings as the then-current label and, unlike the latter, did not mention the risk of bone resorption. *See* SER 51-53 (pl. mot. for jud. notice). And she has learned that she suffers from abnormal bone resorption that has seriously damaged her spine and caused other complications, such that the only possible treatment is a surgery with a three-in-four

chance of killing her. *See* Opp. Mot. Strike, Dist. Ct. ECF 31, at 8-10. Adding these facts—and others that she has learned since filing her complaint—would not result in a contradiction. There is no inconsistency between the propositions that (a) Ms. Jones was uncertain about her medical situation in 2014, and (b) she now has a clearer picture of it.

Second, the district court's reasoning was wrong even on its own terms. Inconsistency in pleading ordinarily "is not a basis for dismissal." *Shirley v. Univ. of Idaho, College of Law*, 800 F.3d 1193, 1194 (9th Cir. 2015) (Kozinski, C.J., concurring). As this Court has observed, "the parties are often uncertain about the facts and the law" when a complaint is first filed. *PAE Gov't Servs., Inc. v. MPRI, Inc.*, 514 F.3d 856, 858 (9th Cir. 2007). But "over the passage of time, and through diligent work, they [learn] more about the available evidence and viable legal theories, and wish to shape their allegations to conform to these newly discovered realities." *Id.* at 859. It is legitimate and normal for an amended complaint to be in tension with the original complaint, *see id.*, especially with pro se plaintiffs.

Third, Ms. Jones's acknowledgment of uncertainty should not prejudice her, particularly given the liberal construction afforded pro se pleadings, *see Nordstrom v. Ryan*, 762 F.3d 903, 908 (9th Cir. 2014). The passages on which the district court relied simply are candid observations about the difficulties inherent in proving complex medical facts. They are not concessions that her case is unwinnable. That a plaintiff might fail to persuade a factfinder at trial should go without saying. Although a

represented plaintiff usually would not acknowledge this truism in her complaint, a pro se plaintiff should not be punished for doing so.

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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December 11, 2017

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

STATEMENT OF RELATED CASES

Appellant knows of no related cases pending before this Court. In 2015, this Court decided *Jones v. Dallas Neurological Spine Associates*, No. 13-15488, a medical-malpractice case brought by Ms. Jones and her husband against their doctors. The malpractice claims arose in part from the surgeries at issue here. On November 18, 2015, this Court affirmed the district court's order dismissing the case. The Joneses are now litigating their malpractice claims in Arizona state court. *See Jones v. Denning*, No. CV 2016-054241 (Ariz. Sup. Ct. Maricopa Cty.).

Form 8. Certificate of Compliance Pursuant to 9th Circuit Rules 28.1-1(f), 29-2(c)(2) and (3), 32-1, 32-2 or 32-4 for Case Number 15-15653

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Signature of Attorney or Unrepresented Litigant: /s Brian Wolfman

Date: 12/11/2017

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

STATUTORY AND REGULATORY ADDENDUM

TABLE OF CONTENTS

Statutes

Regulations

21 U.S.C. § 321(h) - Definitions; generally.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 360j(o) of this title.

21 U.S.C. § 331 - Prohibited acts.

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

* * *

(k) 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 food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

* * *

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.

* * *

(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. § 360c – Classification of devices intended for human use.

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

* * *

(B) Class II, Special Controls.

A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) Class III, Premarket Approval. A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii) (I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or (II) presents a potential unreasonable risk of illness or injury, is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 360d and 360e of this title, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

* * *

21 U.S.C. § 360e – Premarket approval.

* * *

(c) Application for premarket approval

(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

* * *

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may

be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device;

* * *

(d) Action on application for premarket approval

(1)

(A) As promptly as possible, but in no event later than one hundred and eighty days after the receipt of an application under subsection (c) (except as provided in section 360j(l)(3)(D)(ii) of this title or unless, in accordance with subparagraph (B)(i), an additional period as agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

In making the determination whether to approve or deny the application, the Secretary shall 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 safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.

* * *

(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that—

(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(C) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 360j(f) of this title;

(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular;

* * *

(5)

(A)

(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 360j(f) of this title.

* * *

21 U.S.C. § 360k – State and local requirements respecting devices.

(a) General rule. Except as provided in subsection (b), no 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.

(b) Exempt requirements. Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 C.F.R. § 801.109(c) – Prescription devices.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions 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: Provided, however, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

21 C.F.R. § 801.4 – Meaning of intended uses.

The words intended uses or words of similar import in 801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. 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. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

21 C.F.R. § 808.1(d) – Scope. [Under Part 808 – Exemptions from federal preemption of state and local medical device requirements]

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6) (i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good

manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

21 C.F.R. § 814.20 – Application. [Under Subpart B, Premarket Approval Application]

* * *

(b) Unless the applicant justifies an omission in accordance with paragraph (d) of this section, a PMA shall include:

* * *

(3) A summary in sufficient detail that the reader may gain a general understanding of the data and information in the application. The summary shall contain the following information:

(i) Indications for use. A general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

(ii) Device description. An explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device. A brief description of the manufacturing process should be included if it will significantly enhance the reader's understanding of the device. The generic name of the device as well as any proprietary name or trade name should be included.

* * *

(v) Summary of studies. An abstract of any information or report described in the PMA under paragraph (b)(8)(ii) of this section and a summary of the results of technical data submitted under paragraph (b)(6) of this section. Such summary

shall include a description of the objective of the study, a description of the experimental design of the study, a brief description of how the data were collected and analyzed, and a brief description of the results, whether positive, negative, or inconclusive. This section shall include the following:

(A) A summary of the nonclinical laboratory studies submitted in the application;

(B) A summary of the clinical investigations involving human subjects submitted in the application including a discussion of subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures and replacements, results of statistical analyses of the clinical investigations, contraindications and precautions for use of the device, and other information from the clinical investigations as appropriate (any investigation conducted under an IDE shall be identified as such).

(vi) Conclusions drawn from the studies. A discussion demonstrating that the data and information in the application constitute valid scientific evidence within the meaning of 860.7 and provide reasonable assurance that the device is safe and effective for its intended use. A concluding discussion shall present benefit and risk considerations related to the device including a discussion of any adverse effects of the device on health and any proposed additional studies or surveillance the applicant intends to conduct following approval of the PMA.

(4) A complete description of:

(i) The device, including pictorial representations;

(ii) Each of the functional components or ingredients of the device if the device consists of more than one physical component or ingredient;

(iii) The properties of the device relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition;

(iv) The principles of operation of the device;

* * *

(9) One or more samples of the device and its components, if requested by FDA. If it is impractical to submit a requested sample of the device, the applicant shall name the location at which FDA may examine and test one or more devices.

(10) Copies of all proposed labeling for the device. Such labeling may include, e.g., instructions for installation and any information, literature, or advertising that constitutes labeling under section 201(m) of the act.

* * *

21 C.F.R. § 814.39 – PMA supplements.

(a) After FDA's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA, unless the change is of a type for which FDA, under paragraph (e) of this section, has advised that an alternate submission is permitted or is of a type which, under section 515(d)(6)(A) of the act and paragraph (f) of this section, does not require a PMA supplement under this paragraph. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device:

(1) New indications for use of the device.

(2) Labeling changes.

* * *

(6) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device.

* * *

(d)(1) After FDA approves a PMA, any change described in paragraph (d)(2) of this section to reflect newly acquired information that enhances the safety of the device or the safety in the use of the device may be placed into effect by the applicant prior to the receipt under 814.17 of a written FDA order approving the PMA supplement provided that:

* * *

(ii) The PMA supplement provides a full explanation of the basis for the changes;

* * *

(2) The following changes are permitted by paragraph (d)(1) of this section:

(i) Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association.

(ii) Labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device.

(iii) Labeling changes that delete misleading, false, or unsupported indications.

* * *

21 C.F.R. § 814.80 – General. [Under Subpart E – Postapproval Requirements]

A device may not 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.

Arizona Revised Statutes § 44-1522 – Unlawful practices; intended interpretation of provisions.

(A) The act, use or employment by any person of any deception, deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice.

* * *

9th Circuit Case Number(s) 15-15653

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