FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ROBERT PEREZ; NANCY ART; BRETT HARBACH, on behalf of themselves and all others similarly situated, *Plaintiffs-Appellants*, v. NIDEK CO., LTD.; NIDEK INCORPORATED; NIDEK TECHNOLOGIES INCORPORATED; MANJOV V. MOTWANI, M.D.; GARY M. KAWESCH, M.D.; LINDA VU, M.D.; JOSEPH LEE, M.D.; FARZAD YAGHOUTI, M.D.; RANDA M. GARRANA, M.D.; THOMAS S. TOOMA, M.D.; PAUL C. LEE, M.D.; KEITH LIANG, M.D.; ANTOINE L. GARABET, M.D.; WILLIAM ELLIS, M.D.; GREGG FEINERMAN, M.D.; MICHAEL ROSE, M.D.; JOHN KOWNACKI, M.D.; STEVEN MA, M.D.; ESTATE OF GLENN A. KAWESCH, M.D.; TLC VISION CORPORATION, DBA TLC Laser Eye Center, Inc.; CALIFORNIA CENTER FOR REFRACTIVE SURGERY, a medical corporation; LASER EYE CENTER MEDICAL OFFICE, INC.; SOUTHWEST EYE CARE CENTER INC.; DOES, 1 through 1000, inclusive, *Defendants-Appellees*.	No. 10-55577 D.C. No. 3:08-cv-01261-BTM-JMA OPINION

Appeal from the United States District Court
for the Southern District of California
Barry T. Moskowitz, District Judge, Presiding

Argued and Submitted
October 10, 2012—Pasadena, California

Filed March 25, 2013

Before: Stephen S. Trott, Andrew J. Kleinfeld, and
M. Margaret McKeown, Circuit Judges.

Opinion by Judge McKeown

SUMMARY*

Medical Law

The panel affirmed the district court's dismissal of a complaint brought by patients who suffered no injuries but who were subject to the off-label use of a medical device for eye surgeries, where the Food and Drug Administration status of the device was not disclosed to the patients.

The panel held that the complaint did not state a claim under the California Protection of Human Subjects in Medical Experimentation Act because the surgeries were not "medical experiments" subject to the protection of the Act. The panel also held that plaintiff Robert Perez did not have standing to

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

sue for injunctive relief under the California Consumers Legal Remedies Act, and his other substantive claim—a common law fraud by omission claim—was preempted by the Federal Food, Drug, and Cosmetic Act. The panel held that the claim of omission was expressly preempted by the preemption provision in the Medical Device Amendments; and even if it were not, it was impliedly preempted because it amounted to an attempt to privately enforce the Food, Drug and Cosmetic Act.

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OPINION

McKEOWN, Circuit Judge:

We are asked to decide whether patients who suffered no injuries but who were subject to the off-label use of a medical device for eye surgeries may bring suit solely because the Food and Drug Administration ("FDA") status of the device was not disclosed to them. The Third Amended Complaint ("the Complaint") does not state a claim under the California Protection of Human Subjects in Medical Experimentation Act ("the Human Subjects Act") because the surgeries were not "medical experiments" subject to the protection of the

Act. Robert Perez does not have standing to sue for injunctive relief under the California Consumers Legal Remedies Act ("CLRA"), and his other substantive claim is preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"). We affirm the district court's dismissal of the Complaint.

BACKGROUND[1]

Robert Perez, Nancy Art, and Brett Harbach (collectively, "Perez") each sought and received Laser in Situ Keratomileusis ("LASIK") eye surgery with a Nidek EC-5000 Excimer Laser System ("the Laser") to correct farsightedness. They claim that, at the time of their surgeries, they did not know the FDA had not approved the Laser for this use. According to the Complaint, had they known, they would not have consented to the surgeries.

Perez sued on behalf of himself and a class of similarly situated individuals who received hyperopic surgery (surgery to correct farsightedness) with the Laser between February 1996 and October 2006. Perez does not allege any injury stemming from surgery. Nor does Perez claim that his or any other surgery was ineffective. Instead, he asserts claims under the Human Subjects Act and the CLRA, as well as common-law claims of fraud by omission, civil conspiracy, and aiding and abetting. Perez brought these claims against various Nidek corporate entities ("Nidek"), named and unnamed physicians who allegedly used the Laser for unapproved purposes on individuals in the purported class

[1] This background is taken from the factual allegations in the Complaint, which we treat as true for purposes of evaluating the motion to dismiss. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

("Physician Defendants"), named and unnamed medical centers where these procedures were allegedly performed, and other unnamed persons and entities who allegedly participated in the conduct at issue. Of the named Physician Defendants, only two performed LASIK surgery on the named plaintiffs.

The Laser is a Class III medical device under the FDCA, as amended by the Medical Device Amendments of 1976 ("MDA"). 21 U.S.C. § 360c. For that reason, Nidek was required to get premarket approval ("PMA") from the FDA before it could sell or distribute the Laser. 21 U.S.C. § 360e. Between 1998 and 2000, Nidek obtained three PMAs for treating nearsightedness with the Laser, but the Laser was not approved for treating farsightedness until October 2006. The PMAs restricted the Laser from being used for hyperopic corrections outside of approved investigations. During the class period, use of the Laser for farsightedness was being investigated in FDA-approved clinical trials, which required full disclosure of the device's experimental use and informed consent from patients receiving treatment.

Perez alleges that the defendants engaged in a nationwide scheme to modify the approved Laser to enable it to correct farsightedness before it was approved for that purpose. He claims that Physician Defendants used the modified Lasers to perform hyperopic surgeries without informing patients that the Laser was not approved for that use outside of approved clinical trials, and that Nidek knew about the improper use of the Laser. Perez further alleges that the defendants conspired and aided and abetted each other in their unlawful conduct.

The FDA was aware of claims that the Laser was being put to unauthorized uses, and it took steps to halt abuses. In

late 2000, the FDA sent Nidek a letter expressing concern that chips in Laser units were being replaced with chips that enable the device for "unapproved applications, such as hyperopia." The letter addressed allegations that Nidek employees were providing the replacement chips and that Nidek had fired at least one employee for doing so. It also noted that Nidek had waited several months after becoming aware that some Lasers had been tampered with before reporting the problem, in violation of the PMA conditions.

In 2001, the FDA sent two sets of warning letters to certain physicians after an investigator determined that the Lasers they were using for hyperopia were manufactured before Nidek's PMA was effective and that the Lasers contained software not approved for commercial distribution in the United States. The first letter stated, "Because an approved PMA or an approved IDE [Investigational Device Exemption] does not cover this laser, it is adulterated within the meaning of the Act. Therefore, you should not be using this laser to treat patients." The second letter reiterated the information in the first letter and added that the modified lasers needed to be certified as in compliance with the federal laser product performance standard. In addition, the FDA published an Import Alert addressing the problem of Lasers with software not approved under the PMAs.

Perez alleges that, "[d]espite these actions by [the] FDA, Defendants continued to sell, distribute, lease, use, service, and market the Lasers in the United States with the capacity to perform hyperopic procedures." He alleges that Nidek "continued to install, service and enable the Lasers to perform hyperopic corrections outside of sanctioned clinical trials" and that Nidek falsified many service records indicating that it had removed the software. In October 2006, the Laser was

approved for hyperopic use with improved and updated software and treatment parameters.

ANALYSIS

I. STANDING

Perez sued two groups of doctors: the two doctors who performed surgery on the named plaintiffs, and named and unnamed doctors who performed no surgery on the named plaintiffs, but who allegedly performed surgery on other individuals in the proposed class. With respect to the first group, standing is not at issue, but the second group raises a serious standing question.[2] *See Easter v. Am. W. Fin.*, 381 F.3d 948, 961–62 (9th Cir. 2004) (holding that borrowers of second mortgage loans had no standing to sue those investment trusts that did not hold a named plaintiff's note because they could not trace the alleged injury in fact to those defendants' actions).

Perez apparently endeavors to sidestep the traceability hurdle for the second group of doctors through his allegations of conspiracy and aiding and abetting. A look at those allegations reveals virtually nothing because they are no more than conclusory and bare bones words and phrases without any factual content. Such vacuous claims are insufficient to establish standing or to survive a motion to dismiss. *See Lujan*, 504 U.S at 561 (explaining that the elements of standing "must be supported in the same way as any other

[2] Although Perez, as the party invoking federal jurisdiction, has the burden of establishing Article III standing, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992), he did not respond to the argument that he had no standing to sue the second group of doctors.

matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation"); *Iqbal*, 556 U.S. at 678 ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" (citation omitted)).

Because Perez's substantive claims fail, amendment would be futile. For the same reason, we do not need to reach the more difficult chicken-and-egg question of whether class certification should be decided before standing. *See Easter*, 381 F.3d at 962 (explaining that the district court correctly addressed standing before class certification and that *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999), "does not require courts to consider class certification before standing").

Nor does Perez have standing to sue any of the defendants under the CLRA. The Complaint requests only injunctive relief under that statute. Perez has not demonstrated that he faces "a *real or immediate threat* of an irreparable injury." *Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1021 (9th Cir. 2004) (emphasis in original) (citation and internal quotation marks omitted); *see also Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983). Perez does not allege that he intends to have further hyperopic surgery and, more importantly, the Laser has been approved for hyperopic use since 2006. No post-2006 conduct is alleged. Although the district court dismissed the CLRA claim on the basis of preemption, we affirm on the alternate ground of standing, which is a threshold determination. *See Thompson v. Paul*, 547 F.3d 1055, 1058–59 (9th Cir. 2008) (explaining that we can affirm a dismissal under Rule 12(b)(6) "on any ground supported by the record"); *Bates v. United Parcel Serv., Inc.*,

511 F.3d 974, 985 (9th Cir. 2007) (en banc) ("Standing is a threshold matter central to our subject matter jurisdiction.").

II. CALIFORNIA PROTECTION OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTATION ACT ("HUMAN SUBJECTS ACT") CLAIM

The California legislature enacted the Human Subjects Act "to provide minimum statutory protection for the citizens of [the] state with regard to human experimentation and to provide penalties for those who violate such provisions." Cal. Health & Saf. Code § 24171. The Act lays out detailed guidelines for informed consent, which is required before a person can be "subjected to any medical experiment." *Id.* § 24175(a); *see id.* § 24173. For purposes of the informed consent provisions, "medical experiment" is defined as follows:

> (a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, as defined in Section 109920 or 109925, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.
>
> (b) The investigational use of a drug or device as provided in Sections 111590 and 111595.
>
> (c) Withholding medical treatment from a human subject for any purpose other than

> maintenance or improvement of the health of the subject.

Id. § 24174. Perez's claims do not fit the definition of "medical experiment" under either provision at issue here—§ 24174(a) or § 24174(b).

A. SECTION 24174(a)

As to § 24174(a), there is no dispute that the laser eye surgeries involved the use of a device upon a human subject. Where the parties disagree is whether the surgeries were performed "in the practice . . . of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject."[3]

Only one published California case has addressed the interpretation of "medical experiment" under § 24174(a). *Trantafello v. Medical Center of Tarzana*, 182 Cal. App. 3d 315, 320 n.2 (Cal. Ct. App. 1986). In *Trantafello*, an orthopedic surgeon implanted a piece of acrylic in Trantafello's neck to fill the space once occupied by a removed cervical disk. *Id.* at 318. The surgeon did not advise Trantafello that he planned to use an acrylic implant or that this was an innovative procedure not generally accepted in the United States. *Id.* at 319. In holding that the patient could not rely on the Human Subjects Act to extend the statute of limitations for his medical malpractice claim, the court stated in a footnote that the Act was "irrelevant" to

[3] With regard to this and other claims, Nidek raises defenses that are unique to its corporate entities. Because we hold that Perez's claims fail on grounds common to all of the defendants, we do not address Nidek's other arguments.

Trantafello's claim because the Act "deals with experiments on human subjects in the course of *pure research*. . . . Here [the doctor] used the acrylic implant not in the course of a medical research program but in a course of therapeutic treatment for plaintiff." *Id.* at 320 n.2 (emphasis added).

Perez quibbles with *Trantafello*'s restriction of the Act to experiments done in the course of pure research. According to Perez, "the fact that a procedure is meant to impart *some* benefit to a patient does not mean that it cannot also constitute a 'medical experiment' under the Act." Without deciding whether there is any more play in the joints of § 24174(a) than *Trantafello* signals, the eye surgeries fell well outside the scope of subsection (a). Perez alleges that the procedures were undertaken "to attempt to correct [] farsightedness." Perez admits that the surgeries had a therapeutic purpose. He does not claim that this therapeutic purpose was merely incidental to a broader research goal—in fact, he does not claim that there was any research goal whatsoever. Without doubt, the hyperopic surgeries at issue here were "reasonably related" to "improving [Perez's] health" and "directly benefiting" him. *See* § 24174(a).

Perez is unable to explain why his broad definition of "medical experiment" would not swallow up all off-label use. As the Supreme Court has recognized, "'off-label' usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate [in the area of medical devices] without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001). The legislative history of the Human Subjects Act reflects that California purposefully excluded therapeutic off-label use from the scope of § 24174. The Assembly Bill originally included off-label use and the use of a drug or

device for which an application had been denied or withdrawn by the FDA or the California Department of Health as falling within the definition of "medical experiment." A.B. 1752, Assemb. Reg. Sess. (Cal. 1977–78) [revisions to AB 1752 as amended in Assembly, May 23, 1977] at 7; Assembly member Herschel Rosenthal, Letter to Governor Edmund G. Brown, Jr., re Assemb. Bill No. 1752 (1977–78 Reg. Sess.), June 28, 1978, at 2 ["Rosenthal Letter"]. Those provisions were deleted before the bill became law, at least in part in response to the California Medical Association's opposition to the bill. Rosenthal Letter 2.

Perez's remaining arguments—that the eye surgeries were not "reasonably related" to improving the proposed class members' health because the doctors performed the surgeries "to line their own pockets" and because the surgeries were elective—are unpersuasive. Both arguments attempt to import requirements into § 24174(a) that are not found in the text and have nothing to do with medical experimentation. The standard under § 24174(a) is objective, not subjective; the doctors' alleged motivations do not come into play. Nor does the statute embody any requirement of altruism. A doctor's desire to profit from a procedure hardly transforms that procedure from therapeutic to experimental. Finally, the elective nature of a procedure is not a component of the statutory definition. Many elective surgeries are performed to improve the patient's health. The term often is used merely to distinguish emergency procedures from those that can be scheduled at the convenience of doctor and patient.[4]

[4] The medical dictionary available through MedlinePlus, a service of the U.S. National Library of Medicine and the National Institutes of Health, defines "elective" as "beneficial for the patient but not necessary for

And even elective surgery that is not health related may be "reasonably related" to "directly benefiting" a patient. For example, elective cosmetic surgery that ostensibly has no health component, that is solely undertaken for aesthetic reasons, and that may be lucrative for certain physicians nonetheless may be performed to benefit a patient and thus fall outside of the Act. Perez is unable to advance a rationale that places these LASIK surgeries within the requirements of the Human Subjects Act.

B. SECTION 24174(b)

The term "medical experiment" also includes, under § 24174(b), the "investigational use of a drug or device as provided in Sections 111590 and 111595." These latter referenced sections, respectively, govern investigations, commonly dubbed clinical trials, conducted in accordance with the requirements of the FDCA, and investigations conducted under conditions specified by state law.

Perez does not claim that he or any proposed class member was part of a clinical trial or that Physician Defendants performed their surgeries under the conditions specified in § 111595 (such as submitting reports to the state Department of Health Services). With respect to this claim, Perez's undoing is that he affirmatively pled that he and the proposed class members were *not* participants in officially sanctioned clinical trials. The defendant doctor class is defined as "[a]ll physicians who performed Hyperopic LASIK and/or PRK in California with the Nidek Laser during

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survival"—for example, "an *elective* appendectomy." *Elective Definition*, MedlinePlus, http://www.merriam-webster.com/medlineplus/elective (last visited Mar. 13, 2013).

the Class Period, other than during an approved FDA clinical trial." According to the Complaint, those "Defendants knew and understood that the Lasers were being used on Plaintiffs and the Class without their informed consent to be subjected to the investigational use of the Laser, and without including them in a sanctioned clinical trial." Perez cannot argue both that he was not included in clinical trials and that the procedure falls under the clinical trial provisions of the Human Subjects Act. *See Huntman v. Danek Medical, Inc.*, No. 97-2155-IEG (RBB), 1998 WL 663362, at *6–*7 (S.D. Cal. July 24, 1998) (explaining that because there was no evidence that the plaintiff was part of an Investigational Device Exemption, the defendant did not need to comply with the informed consent provisions of the IDE regulations).

Perez's allegation that the "Laser was being investigated . . . under FDA approved clinical trials by both NIDEK and independent physician groups" during the class period does not convert his own surgery—which falls outside of the provisions of sections 111590 and 111595—into part of a clinical trial. For this reason, Perez's reliance on *Daum v. Spinecare Medical Group, Inc.*, 52 Cal. App. 4th 1285 (Cal. Ct. App. 1997), is misplaced. The plaintiff in *Daum* was part of a clinical investigation conducted under the requirements of the FDCA. *Id.* at 1308.

Although Perez may find it "perverse and inequitable," as he puts it, to provide patients admitted to clinical trials with "more protection than those who are subjected to the same experimental procedures outside the gaze of the FDA," § 24174(b), by its terms, applies only to investigations conducted under the requirements of the FDCA or state law. Perez was not subject to the "investigational use" of a device within the meaning of § 24174(b).

III. FRAUD BY OMISSION CLAIMS

Perez also alleges a common-law fraud by omission claim. The theory is that the defendants misled the proposed class by failing to disclose that the Laser was not FDA approved for hyperopic surgeries, even though Nidek and the doctors knew or should have known that the proposed class members believed the Laser was FDA approved for such surgeries. This claim of omission is expressly preempted by the preemption provision in the Medical Device Amendments ("MDA"). Even if it were not, it is impliedly preempted because it amounts to an attempt to privately enforce the FDCA.

A. EXPRESS PREEMPTION

The FDCA has long provided for premarket approval of new drugs. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). Before 1976, states were left to supervise the introduction of new medical devices. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). California was among a number of states that adopted regulatory measures governing devices. *Id.* In 1976, Congress enacted the Medical Device Amendments to the FDCA, which "swept back some state obligations and imposed a regime of detailed federal oversight." *Id.* at 316. These amendments include an express preemption provision:

> Except as provided in subsection (b) of this section, 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.

21 U.S.C. § 360k(a). An implementing regulation provides that state and local requirements are only preempted by the MDA when the FDA "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." 21 C.F.R. § 808.1(d).

A trio of Supreme Court cases address preemption under the MDA: *Lohr*, *Buckman*, and *Riegel*. *Lohr* and *Riegel* involved the MDA's express preemption provision, and *Buckman* involved implied preemption. As we explained in a recent en banc decision, the "rule that emerges from these cases is that the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA." *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc).

In *Lohr*, the Court held that plaintiffs' common-law claims stemming from a pacemaker failure were not preempted under § 360k. The allegations included claims that Medtronic had violated FDA regulations, and "[n]othing in § 360k denies Florida the right to provide a traditional

damages remedy for violations of common-law duties *when those duties parallel federal requirements*." 518 U.S. at 495 (emphasis added). Although a plurality of the Court emphasized the generality of the state laws giving rise to the plaintiffs' claims, "five Justices concluded that common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." *Riegel*, 552 U.S. at 323–24 (citing *Lohr*, 518 U.S. at 512 (opinion of O'Connor, J., joined by Rehnquist, C.J., and Scalia and Thomas, JJ.); *id.* at 503–05 (opinion of Breyer, J.)). None of the federal laws or regulations at issue imposed device-specific requirements. *Lohr*, 518 U.S. at 492–94, 500–01.

In contrast, the Court in *Riegel* held that § 360k preempted common-law claims challenging the safety and effectiveness of a medical device that had received premarket approval from the FDA. Unlike the federal laws and regulations at issue in *Lohr*, premarket approval imposes device-specific requirements. *Id.* at 322–23. Because the state common-law claims related to the safety and effectiveness of the device and because the plaintiffs alleged that the device violated state tort law notwithstanding compliance with the federal requirements, the state claims were preempted. *Id.* at 323, 330. It did not matter that the common-law claims involved general tort duties of care applicable to other products besides medical devices. *Id.* at 327–29.

In *Stengel*, we "clarified preemption law under the MDA." 704 F.3d at 1233. Plaintiffs' proposed negligence claim for failure to warn the FDA was not preempted "insofar as the state-law duty parallels a federal-law duty under the MDA." *Id.* We distinguished an Eighth Circuit case holding

plaintiffs' claims were preempted because, in that case, "plaintiffs sought to enforce state-law requirements that would have required Medtronic 'to give additional warnings, precisely the type of state requirement that is "different from or in addition to" the federal requirement.'" *Id.* at 1232 (quoting *In re Medtronic, Inc., Spring Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1205 (8th Cir. 2010)) (citation and internal quotation marks omitted). In a concurring opinion joined by six other judges, Judge Watford explained that, had the plaintiffs predicated their claim on a failure to warn doctors directly—an action not required by FDA regulations—that claim would have been preempted because it would have been an addition to the federal requirement. *Stengel*, 704 F.3d at 1234 (Watford, J., concurring).

The teachings from the Supreme Court cases plus our application of MDA preemption in *Stengel* lead to an obvious result: Perez's fraud by omission claim is expressly preempted by § 360k(a). To begin, the disclosure requirement at issue is "different from, or in addition to" the requirements applicable to the Laser under the MDA. § 360k(a)(1). Like the device in *Riegel*, the Laser was subject to device-specific requirements under the PMAs—including that it was not to be used for hyperopic corrections and was not permitted to be introduced into commerce for such corrections unless it was used in connection with an approved investigational use. And like the claim in *Riegel*, the claim here depends on a requirement that is "in addition to" those federal requirements. Perez effectively seeks to write in a new provision to the FDCA: that physicians and medical device companies must affirmatively tell patients when medical devices have not been approved for a certain use. We do not pass judgment on whether this would be a wise

rule for the FDA to adopt. It is sufficient for our inquiry that it has not done so. Just as significant, the alleged missing disclosure—that hyperopic use was not within the scope of the Laser's PMAs—"relates to the safety or effectiveness" of the Laser. § 360k(a)(2). In *Riegel*, the Court explained that premarket approval "*is* federal safety review." 552 U.S. at 323. The sought-after disclosure also relates to "other matter[s] included in a requirement applicable to the device": the Laser's use in hyperopic surgeries. § 360k(a)(2). In sum, the fraud by omission claim is expressly preempted under the FDCA.

B. IMPLIED PREEMPTION

Perez faces another hurdle—even without express preemption, Perez's fraud by omission claim is impliedly preempted because it conflicts with the FDCA's enforcement scheme. The FDA is responsible for investigating potential violations of the FDCA, and the Act provides the agency with a range of enforcement mechanisms, such as injunction proceedings, civil and criminal penalties, and seizure. 21 U.S.C. §§ 332–34, 372. Although citizens may petition the FDA to take administrative action, 21 C.F.R. §§ 10.25(a) and 10.30, private enforcement of the statute is barred: "all such proceedings for the enforcement, or to restrain violations, of [the Act] shall be by and in the name of the United States." 21 U.S.C. § 337(a).

In *Buckman*, the Court held that the plaintiffs' "fraud-on-the-FDA" claims were impliedly preempted by the FDCA because they conflicted with the federal statutory scheme, which "amply empowers the FDA to punish and deter fraud against the Administration." 531 U.S. at 348. "[C]omplying with the FDA's detailed regulatory regime in the shadow of

50 States' tort regimes w[ould] dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA." *Id.* at 350. The Court distinguished the plaintiffs' claims from those in *Lohr*. In *Lohr*, the claims "arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements." *Id.* at 352. In contrast, the fraud-on-the-FDA claims "exist solely by virtue of the FDCA disclosure requirements." *Id.* at 353. *Lohr* "does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." *Id.*

Like the fraud-on-the-FDA claims in *Buckman*, Perez's fraud by omission claim "exist[s] solely by virtue of the FDCA . . . requirements," 351 U.S. 353, with respect to approved use of the Laser. As in *Buckman*, "the existence of these federal enactments is a critical element in their case." *Id.* Although Perez is not barred from bringing *any* fraud claim related to the surgeries, he cannot bring a claim that rests solely on the non-disclosure to patients of facts tied to the scope of PMA approval. While courts have acknowledged that some fraud and false advertising claims related to FDA status may go forward,[5] Perez cites to no case

[5] *See, e.g.*, *Photomedex, Inc. v. Irwin*, 601 F.3d 919, 924–25 (9th Cir. 2010) (explaining that, "[i]f . . . it was clear that an affirmative statement of approval by the FDA was required before a given product could be marketed and that no such FDA approval had been granted, a Lanham Act claim could be pursued for injuries suffered by a competitor as a result of a false assertion that approval had been granted"); *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 940 (8th Cir. 2005) (allowing a plaintiff's false advertising claims to go forward where the plaintiff "alleged reasonably clear claims of FDA approval" by the defendant).

where a court has allowed a plaintiff to bring suit solely for failure to disclose lack of FDA approval.[6]

The FDA knew about the allegations that the Laser was being used for unapproved hyperopic use and took steps to address the allegations by issuing warning letters and an Import Alert, but it did not take final action against the defendants. The district court explained that

> [w]hether Defendants' use of the laser was in violation of the FDCA depends on, among other things, the scope of the PMAs, whether the Lasers were modified so that they were "adulterated" under section 501(f)(1)(B) of the FDCA, whether Defendants were engaged in a permissible "off-label" use of the Laser, and whether re-certification of the device was required under 21 C.F.R. § 1040.10. All of these matters rest within the enforcement authority of the FDA, not this Court.

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[6] In *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993), the Fourth Circuit dismissed a Lanham Act claim where the plaintiff contended that the very act of placing the drug on the market falsely implied that the drug had been properly approved by the FDA. Allowing such a claim would permit the plaintiff to "use the Lanham Act as a vehicle by which to enforce the [FDCA] and the regulations promulgated thereunder." *Id. See also Summit Tech., Inc. v. High-Line Medical Instruments Co.*, 922 F. Supp. 299, 307 (C.D. Cal. 1996) (holding that, although "a plaintiff may bring a Lanham Act cause of action for affirmatively misrepresenting facts, even if the truth of those facts may be governed by FDA regulations," he may not sue for "failure to disclose a 'fact,' the truth of which is *currently* being reviewed and determined by the FDA").

The Eighth Circuit has aptly described the "narrow gap" through which a state-law claim must fit to escape preemption by the FDCA: "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic*, 623 F.3d at 1204 (citation and internal quotation marks omitted). Perez's fraud by omission claim does not squeeze through this gap.

AFFIRMED.