FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RICHARD STENGEL; MARY LOU STENGEL, *Plaintiffs-Appellants,* v. MEDTRONIC INCORPORATED, a foreign corporation, *Defendant-Appellee.*	No. 10-17755 D.C. No. 4:10-cv-00318-RCC OPINION

Appeal from the United States District Court
for the District of Arizona
Raner C. Collins, District Judge, Presiding

Argued and Submitted
January 13, 2012—San Francisco, California

Filed April 16, 2012

Before: J. Clifford Wallace, John T. Noonan, and Milan D. Smith, Jr., Circuit Judges.

Opinion by Judge Wallace;
Dissent by Judge Noonan

COUNSEL

Thomas G. Cotter, Stanley G. Feldman, and Stephen T. Portell; Haralson Miller, Pitt, Feldman & McAnally, P.L.C., Tucson, Arizona, for the plaintiffs-appellants

Michael K. Brown, Ginger F.H. Pigott, and Lisa M. Baird, Reed Smith LLP, Los Angeles, California, for the defendant-appellee.

OPINION

WALLACE, Senior Circuit Judge:

Richard and Mary Lou Stengel brought several state causes of action in Arizona state court against Medtronic Incorporated (Medtronic) for injuries sustained by Richard Stengel (Stengel) from his use of a pain pump manufactured by Medtronic. Medtronic timely removed the case to the United States District Court for the District of Arizona. The district court dismissed the Stengels' claims as preempted by federal law and the Stengels appealed. We have jurisdiction under 28 U.S.C. § 1291. We affirm.

I.

Medtronic's pain pump is a medical device that infuses prescription medication through a catheter into the intrathecal

space within the spine to help control severe pain. In 1988, the Food and Drug Administration (FDA) gave premarket approval as a Class III medical device for Medtronic's SynchroMed Pump & Infusion System. In 1999, the FDA gave supplemental premarket approval for Medtronic's SynchroMed EL Pump and intrathecal catheter, which are the versions of Medtronic's device at issue in this action.

In 2000, Stengel had a Medtronic pump surgically implanted in his abdomen and began receiving medication through the catheter tip implanted in his spine. In 2005, Stengel began experiencing ascending paralysis in his lower extremities caused by a granuloma (a type of inflammation) in his spine that had formed at the tip of the catheter. Stengel's doctors surgically removed the hardware and most of the granuloma, but not in time to prevent the granuloma from rendering Stengel permanently paraplegic.

The Stengels' complaint alleged four generic claims under Arizona law: negligence, breaches of express and implied warranties, and strict liability. The district court granted Medtronic's motion to dismiss the complaint on the ground that federal law expressly preempted these claims.

While the motion to dismiss was pending, the Stengels moved for leave to amend their complaint to re-allege the same four claims under the newly-proffered theory that Stengel's injury was caused by Medtronic's failure to implement procedures to evaluate complaints about the pump and failure to report information to the FDA, as was required by FDA regulations. The Stengels alleged that if Medtronic had complied with the regulations, Medtronic would have warned physicians about the newly-discovered danger that the pump might cause inflammation, which would have allowed a quicker diagnosis of Stengel's symptoms and prevented his paralysis. The Stengels' motion for leave to amend was denied on the ground that this "failure-to-warn" claim was impliedly preempted.

We review *de novo* the district court's holding that all of the Stengels' asserted claims were either expressly or impliedly preempted. *Martinez v. Wells Fargo Home Mortg., Inc.*, 598 F.3d 549, 553 (9th Cir. 2010). We review its denial of leave to amend for abuse of discretion. *Alvarez v. Chevron Corp.*, 656 F.3d 925, 931 (9th Cir. 2011).

II.

[1] In 1976, Congress amended the Food, Drug and Cosmetic Act (FDCA) by enacting the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. § 360c *et seq.*). The MDA added a preemption clause to the FDCA which provides, subject to limited exceptions, that

> no State . . . may establish . . . with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under [the FDCA], 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 [the FDCA].

21 U.S.C. § 360k(a).

The Supreme Court has examined the extent to which this preemption clause "bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the [FDA]." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). The Court reviewed the "rigorous" premarket approval process for Class III medical devices:

> A manufacturer must submit what is typically a multivolume application. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the

> applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling. Before deciding whether to approve the application, the agency may refer it to a panel of outside experts and may request additional data from the manufacturer.
>
> The FDA spends an average of 1,200 hours reviewing each application and grants premarket approval only if it finds there is a reasonable assurance of the device's safety and effectiveness.

Id. at 317-18 (internal citations and quotation marks omitted).

The premarket approval process includes review of the device's proposed labeling to evaluate safety and effectiveness under the conditions of use set forth in the label. *Id.* at 318. After a device is approved, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319. Any changes must be made after FDA approval of an application for supplemental premarket approval, "to be evaluated under largely the same criteria as an initial application." *Id.*

The Court then held that the premarket approval process for Class III devices imposed federal "requirements" applicable to the approved device, that common law tort duties constituted state "requirements," and that the "safety and effectiveness" of the device was the subject of the plaintiff 's common law claims. *Id.* at 322-23. The Court recognized that section "360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regula-

tions" because "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330, *quoting Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). Because the plaintiff asserted that the defendant's device "violated state tort law notwithstanding compliance with the relevant federal requirements," the Court held their claims to be expressly preempted. *Id.*

[2] The Stengels' claims, as they appear in the initial complaint, are expressly preempted under section 360k and *Riegel*. The claims generally challenged the safety and effectiveness of Medtronic's pump without any hint of an allegation that Medtronic's conduct violated FDA regulations. To be successful, the claims would have required the trier of fact, as a matter of state tort law, to conclude that the device should have either been designed differently from what the FDA required through premarket approval, or labeled with warnings different from what the FDA required. Therefore, the district court correctly dismissed the Stengels' initial complaint.

[3] The claims alleged in Stengels' proposed amended complaint are also expressly preempted to the extent they rely on the theory that Medtronic should have sent a medical device correction notice to physicians, whether or not the FDA ordered it, because FDA regulations permitted Medtronic to send the notice without prior FDA approval. *See* 21 C.F.R. § 814.39(d). The Seventh Circuit has addressed this precise question. It held: "Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted." *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005). We agree that such a requirement is expressly preempted.

III.

[4] However, portions of the claims in the Stengels' proposed amended complaint could be interpreted to survive express preemption. The proposed complaint alleged:

> Under federal law and regulation, [Medtronic] was under a continuing duty to monitor the product after premarket approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.

Substitute Amended Complaint, ¶ 13, ECF No. 22-1 (*citing* 21 U.S.C. § 360i (requirement to maintain and submit information as required by regulation); 21 C.F.R. § 803.50 (requirement to submit reports); 21 C.F.R. § 820.198(a) (requirement to establish procedures for reviewing complaints)). Because of Medtronic's negligent failure to perform these duties, the Stengels alleged, its pump became defective and unfit for its intended purpose. *Id.* ¶ 20. To the extent Medtronic's alleged violations of FDA regulations are actionable under state law, the state obligations parallel the federal requirements, and thus are not expressly preempted.

[5] Nonetheless, this theory in the Stengels' amended complaint which survives express preemption ultimately fails because the claims are impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the plaintiffs alleged that the defendant made fraudulent misrepresentations to the FDA regarding the intended use of its bone screws and that the devices were improperly given market clearance as a result. *Id.* at 346-47. The Supreme Court held that the claims were preempted because, although the defendant had allegedly violated federal requirements, allowing the plaintiffs to bring a state cause of action to remedy the injuries caused by the violations would interfere with the congressional scheme. *Id.* As the Court explained, "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives" which

"can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* at 348.

The Court observed that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Id.* at 349 n.4, *citing* 21 U.S.C. § 337(a) (no private right of action to enforce FDCA). The Court held that "[s]tate-law fraud-on-the FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. The Court distinguished *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), in which the Court previously held certain negligence claims not to be expressly preempted under the FDCA. 531 U.S. at 352-53. It reasoned that "the [*Lohr*] 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," whereas the *Buckman* fraud claims "exist solely by virtue of the FDCA disclosure requirements." 531 U.S. at 352-53.

There is no meaningful distinction between the Stengels' failure-to-warn claims and the "fraud-on-the-FDA" claims held to be preempted in *Buckman*. Therefore, following *Buckman*, we hold that the Stengels' claims are impliedly preempted.[1] The Stengels' theory is that if Medtronic had acted with reasonable care in complying with the regulations that required it to provide information to the FDA, the FDA would have required Medtronic to warn physicians about the danger of inflammation connected to its pump and Stengel could have avoided the injury caused by the pump. *See* 21 U.S.C. § 360h(a). This is precisely the same theory that was rejected in *Buckman*. The only difference is that, in *Buckman*, the

[1]The dissent argues that because the Stengels' claims are not expressly preempted under *Lohr*, they cannot be impliedly preempted under *Buckman*. This is not the law. *Lohr* does not determine the scope of implied preemption because it never considered the issue.

defendant allegedly misinformed the FDA overtly by providing false information, whereas here the defendant allegedly misinformed the FDA tacitly by failing to report information that it had a duty to report. The policing of such conduct in both instances is committed exclusively to the federal government, and recognizing a state cause of action based on such conduct would conflict with the statutory scheme established by Congress. *Cf. Cupek v. Medtronic, Inc.*, 405 F.3d 421, 423-24 (6th Cir. 2005) (negligence per se claim due to "failure to comply with [FDA] conditions of approval" preempted because it was a "disguised fraud on the FDA claim").

The federal regulations that Medtronic is alleged to have violated impose detailed reporting requirements with respect to a broad category of information. For example, a manufacturer must report to the FDA information the manufacturer becomes aware of, from any source, that reasonably suggests that its device may have caused or contributed to a serious injury. 21 C.F.R. § 803.50. This report must be made no later than 30 days after the day the manufacturer receives or becomes aware of the information. Section 803.50(a). The FDA considers information that is reasonably known to the manufacturer to include any information that the manufacturer can obtain by contacting the initial reporter or by testing the device. Section 803.50(b). A manufacturer must investigate each adverse event and evaluate the cause of the event. Section 803.50(b)(3). If the manufacturer cannot submit complete information in a report, it must provide a statement explaining why the information was incomplete and the steps taken to obtain the information. *Id.* Regulations also require a manufacturer to maintain complaint files and establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. 21 C.F.R. § 820.198. These procedures must ensure that all complaints are processed in a uniform and timely manner, and that oral complaints are documented upon receipt. Section 820.198(a). A manufacturer must review and evaluate all complaints to determine whether an investigation is necessary, and if it chooses not to investi-

gate, must record its reasons and the name of the individual responsible for a decision not to investigate. Section 820.198(b). When a complaint describes an event that must be reported to the FDA, the records of the investigation must contain enumerated categories of information and must be maintained in a separate portion of the complaint files or otherwise clearly identified. Section 820.198(d), (e). If the FDA determines that a notification to physicians is necessary to eliminate an unreasonable risk of substantial harm to the public health, the FDA can order the manufacturer to issue the notification after consulting with the manufacturer. 21 U.S.C. § 360h(a).

In contrast, Arizona common law imposes liability on a manufacturer that fails to exercise reasonable care to inform a consumer of its product's dangerous condition or of the facts that make the product likely to be dangerous, if the manufacturer knows or has reason to know that the product is likely to be dangerous and has no reason to believe that the consumer will realize its dangerous condition. *Anguiano v. E.I. Du Pont De Nemours & Co., Inc.*, 44 F.3d 806, 811-12 (9th Cir. 1995). The federal regulations that Medtronic is alleged to have violated, which require investigation and disclosure to the FDA in a particular manner so that the FDA can make a decision whether notification of consumers is necessary, are not tied to this general duty to warn consumers under Arizona law. Thus, the Stengels' failure-to-warn claims, to the extent they survive express preemption, exist solely by virtue of the FDCA disclosure requirements and are, therefore, impliedly preempted.

[6] Nothing in our holding requires preemption of all state claims challenging the safety of a medical device that has received premarket approval. But as another court aptly put it, it is "a narrow gap through which a plaintiff 's state-law claim must fit if it is to escape express or implied preemption." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010), *quoting Riley v. Cordis*

Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009). At least some claims have proven capable of passing through that gap. For instance, in *Bausch v. Stryker Corp.*, the Seventh Circuit held that state claims based on manufacturing defects were not preempted under *Buckman* because, "[w]hile there may not be a 'traditional state tort law' claim for an 'adulterated' product in so many words, the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law." 630 F.3d 546, 557 (7th Cir. 2010). We offer no opinion as to whether a particular state claim that is tied directly to compliance with federal law would be preempted under *Buckman*. In this case, the duty of manufacturers under federal law to report to the FDA information regarding their devices is not tied directly to the duty of manufacturers under state law to warn consumers of a device's dangerous condition. On the contrary, the enforcement of the duty to report is an element of the federal scheme that is committed solely to the federal government.

The Stengels contend that *Buckman* is distinguishable because it only requires preemption of fraud-on-the-FDA-type claims where the FDA has not previously determined that the manufacturer violated federal reporting requirements. A warning letter from the FDA to Medtronic was attached to the proposed amended complaint, and shows that the FDA had already determined that Medtronic violated its federal disclosure obligations. Thus, the Stengels contend, they could prove their claims without second-guessing the FDA's decision making.

We are not convinced by the Stengels' attempt to distinguish *Buckman* because it is based on the concurrence in *Buckman*, which disagreed with the majority specifically because the majority did not take the position now advocated by the Stengels. *See* 531 U.S. at 354 (Stevens, J., concurring in the judgment). The *Buckman* majority's rationale, unlike the concurrence's, was not solely based on a desire to avoid

jurors second-guessing the FDA's decision making; it was also based on the idea that state fraud-on-the-FDA claims would "exert an extraneous pull on the scheme established by Congress," in which the FDA was supposed to enforce the FDCA's disclosure requirements. *Id.* at 353 (majority opinion). The majority's rationale remains relevant in this case, even where the FDA has issued a warning letter describing Medtronic's regulatory violations.

We acknowledge that there is a division among the circuits whether state failure-to-warn claims are preempted by *Buckman*. On one hand, the Eighth Circuit has held that federal law impliedly preempts a state failure-to-warn claim to the extent the claim is based on the defendant's failure to provide the FDA with sufficient information and failure to file adverse event reports timely. *See In re Medtronic*, 623 F.3d at 1205-06. On the other hand, the Fifth Circuit has held that a state failure-to-warn claim is not preempted. *See Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 775-76 (5th Cir. 2011).

Hughes is not persuasive. First, it erroneously distinguished *Buckman* on the ground that the plaintiffs in *Buckman* "were attempting to assert a freestanding federal cause of action," *Hughes*, 631 F.3d at 775, notwithstanding that *Buckman* described the claims at issue as seeking damages "under state tort law," *Buckman*, 531 U.S. at 343. *Buckman*'s preemptive reach clearly extends to state law causes of action. *See Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1206 (9th Cir. 2002) (interference with prospective economic advantage claim preempted); *see also PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010) ("The Supreme Court made clear in *Buckman* that [21 U.S.C. § 337(a)] also limits the ability of a private plaintiff to pursue claims under state law theories where such claims collide with the exclusive enforcement power of the federal government").

Second, *Hughes* distinguished *Buckman* because the claims "[did] not depend on speculation that the FDA would have

taken any particular regulatory action in response to violation of the regulations at issue, as in *Buckman*." *Hughes*, 631 F.3d at 775. But this reasoning follows the rationale adopted by Justice Stevens in his concurrence. *See* 531 U.S. at 354 (Stevens, J., concurring in the judgment). The *Buckman* majority never adopted this limitation on its holding.

[7] Third, *Hughes* argued that allowing preemption would be inconsistent with *Riegel*'s recognition that "parallel" claims are not preempted. 631 F.3d at 775. But *Riegel* established only that such claims would not be *expressly* preempted by section 360k. 552 U.S. at 330. Since the claims before the Court in *Riegel* failed under express preemption, the Court had no reason to discuss implied preemption at all. *See id*. We join the Eighth Circuit in holding that a failure-to-warn claim based on failure to provide disclosures to the FDA is impliedly preempted.

IV.

Finally, we turn to the additional grounds for reversal offered by the Stengels. They argue that the district court should have allowed them to amend their complaint after removal to conform to the federal pleading standard set forth in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). However, the district court did not dismiss the Stengels' complaint on the ground that it did not conform to the *Twombly* standard, but instead on the ground that the Stengels' claims were preempted.

[8] Next, the Stengels contend that the district court erred by failing to convert Medtronic's motion to dismiss into a motion for summary judgment and then refusing to grant a continuance for discovery under Federal Rule of Civil Procedure 56(f).[2] This contention fails as well. The district court

[2]In the 2010 amendments to the Federal Rules of Civil Procedure, the provisions of Rule 56(f) were moved to Rule 56(d) without substantial change.

took judicial notice of the fact that Medtronic's pain pump received premarket approval as demonstrated by FDA records. A court may consider facts extraneous to a complaint on a motion to dismiss, without converting the motion into one for summary judgment, if such facts are judicially noticeable under Federal Rule of Evidence 201. *Lee v. City of Los Angeles*, 250 F.3d 668, 688-89 (9th Cir. 2001). A court may take judicial notice of a fact that "is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Because the accuracy of FDA records cannot reasonably be questioned, the premarket approval status of Medtronic's pump is a fact subject to judicial notice. *See Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (affirming judicial notice of FDA letter granting premarket approval). The district court thus did not abuse its discretion in considering this fact in connection with the motions to dismiss.

Finally, the Stengels contend that the district court erred by not ruling on their request to take judicial notice of Medtronic's correction letter and a document showing that the pump was ultimately recalled in 2008. But the district court did not need to take judicial notice of the correction letter because that document was included as an exhibit to the proposed amended complaint and, therefore, was part of the pleadings. Moreover, regardless of whether judicial notice would have been proper, it was not necessary because the facts that Medtronic sent a correction letter and that the FDA issued a recall on the pump do not affect the preemption analysis. Any error in the district court's failure to rule on the request for judicial notice was harmless and, therefore, is not reversible. *See Sanchez v. Aerovias De Mexico, S.A. De C.V.*, 590 F.3d 1027, 1029 (9th Cir. 2010).

V.

We recognize that it may seem harsh to deny compensation to a person who alleges serious injury from a medical device.

But such is the direction from the Supreme Court for cases like the one before us. We are required to follow the Court.

To the extent the Stengels' claims are based on the theory that state law required Medtronic to warn consumers about the dangerous condition of its pain pumps without first receiving an order to do so from the FDA, the state law establishes a requirement different from the requirements of the FDCA. *See* 21 U.S.C. § 360k; *Riegel*, 552 U.S. at 325. To the extent the Stengels' claims are based on a theory that Medtronic caused them injury by failing to comply with its duty to report information to the FDA, their claims threaten to skew the delicate balance of statutory objectives sought to be achieved by the FDCA. *See Buckman*, 531 U.S. at 348. Congress has established the premarket approval process as an important balance between getting help to patients who need it as soon as possible and protecting patients who will use the newly proposed help. Those who have benefitted from this congressional balancing are not before us, but they reap the benefit of Congress's insights. It is a balance we must observe. Any change must be made by Congress itself.

Therefore, we hold that even if some of the Stengels' claims can be interpreted to escape express preemption, they cannot be interpreted to escape implied preemption. The district court correctly held that the Stengels' proposed amendment was futile, and therefore did not abuse its discretion in denying leave to amend. *See Alvarez*, 656 F.3d at 935.

AFFIRMED.

NOONAN, Circuit Judge, dissenting:

The issue that this court must address is serious and the magnitude of its potential implications is great:

> From 2000 through 2011, more than 150 new high-risk medical devices were approved by the Food and Drug Administration (FDA) through the premarket approval known as PMA) process, and an additional 600 devices were cleared through the less demanding 510(k) process, in four medical specialty areas (cardiovascular care, neurology, obstetrics and gynecology, and orthopedics; see graph Numbers of High-Risk (Class III) Medical Devices Approved or Cleared by the FDA in Cardiovascular Care, Neurology, Obstetrics and Gynecology, and Orthopedics, 2000-2011.).

"Postmarketing Surveillance of Medical Devices – Filling in the Gaps," Frederic S. Resnic, M.D., and Sharon-Lise T. Normand, Ph.D., February 14, 2012 (10.1056/NEJMp1114865).

Has Congress or the Supreme Court created such freedom from liability for the manufacturers of such sensitive devices that only in nonexistent cases are the manufacturers subject to suit for damages? Are individuals injured by the malfunction of such devices without remedy against the manufacturers of them? That appears to be the conclusion of this court today with its holding that the MDA explicitly preempts and implicitly preempts any state remedy of damages for violation of a state requirement paralleling the MDA.

This conclusion, astonishing in its comprehensiveness, is equally astonishing in the light of binding federal law as determined by the United States Supreme Court.

The law. In a case involving the defendant in our case, the Court held:

> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a

> matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding preemption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996).

As the Supreme Court puts it, "common law duties" not pre-empted by the express terms of the MDA may "parallel" the MDA. Such "common law duties" cannot amount to zero because the states may provide a remedy for their breach. *See id.* Literally, as the Supreme Court also points out, the state may add an element to the state cause of action without destroying the parallel with the federal requirement. *Id.*

This magisterial exposition of the statute by the Supreme Court sets out what the Supreme Court has consistently held and what is necessary for the correct decision of our case. *Nothing* in the statute prevents provision by a state of "a traditional damages remedy" for violation of "state duties" that parallel the federal requirements.

The exception to pre-emption stated by the Court in *Lohr* was restated by the Court in yet another case involving the present defendant: "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation

of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel v. Medronic*, 552 U.S. 312, 330 (2008) (citing and quoting *Lohr*, 518 U.S. at 495).

Pellucidly, the Supreme Court has twice interpreted the MDA and held states may provide a damages remedy. In the language of *Lohr*, it would be "strange" if the Court expressly preserved state remedies from preemption but believed such remedies were implicitly rejected by the statute.

Our court in our present case comes to this strange conclusion by its reading of *Buckman*, 531 U.S. at 353, where the Supreme Court disparaged the notion of an "extraneous pull" on the MDA. This reference to "extraneous pull" was surely a make-weight. A dictum, it does not conform with *Lohr* or stand after *Riegel*. State damages do exert an additional pull for compliance with the MDA.

Buckman, 531 U.S. 341, relied on in our case by the majority, predated *Riegel* and carefully distinguished *Lohr*. The plaintiffs in *Buckman* alleged that Medtronic had committed fraud on the FDA. *Buckman*, 531 U.S. at 347. That charge did not allege a state cause of action. Fraud on a federal agency was not a tort that the states had traditionally penalized. *Id.* "To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character . . . ." *Id*. "Accordingly — and in contrast the situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,' . . . — no presumption against pre-emption obtains in this case." *Buckman*, 531 U.S. at 348 (quoting *Lohr*, 518 U.S. at 485). The Court went on to stamp the state claims in the case as "conflict[ing] with" the MDA and "therefore impliedly pre-empted[ ] by federal law." *Id*. (footnote omitted).

The fraud-on-the-FDA claims in *Buckman* "exist[ed] solely by virtue of the FDCA disclosure requirements" and did not

"rely[ ] on traditional state tort law which had predated the federal enactments in question." *Id.* at 353; *see also id.* at 352-53 (contrasting *Buckman*'s preempted fraud-on-the-FDA claims with the claims in *Lohr*, 518 U.S. at 481, which "arose from the manufacturer's alleged failure to use reasonable care in the production of the product"). The claims in the present case are traditional, free-standing tort claims, analogous to those in *Lohr*.

Not a word in *Buckman* limits *Lohr*. The majority invoke it but do not show that it has application here. *Riegel* demonstrates that *Lohr* is still binding law determined by the United States Supreme Court.

The federal requirements. The federal statutory scheme imposes on manufacturers of medical devices a continuous reporting obligation that applies after a device goes to market. 21 U.S.C. § 360i. In its 2008 Warning Letter, detailing the regulatory history, the FDA noted that Medtronic's Educational Brief of July 2003 was "a reportable correction under CFR 806.10(a)(1)." Whatever information Medtronic gave its physician customers, it had not reported its action to the FDA as a correction. The FDA Warning Letter told Medtronic the incidents of formation of an inflammatory mass at the catheter tip between November 2000 and July 2006 "had not yet been communicated to customers," that is, the physicians. The FDA letter told Medtronic that the FDA "disagrees with your conclusion that the July 2003 Educational Brief was not a correction or removal." The new labeling in 2003, the FDA told Medtronic, had not been communicated to physicians "whose patients already had a SynchroMed pump implanted within them." Stengel's doctor was in this category of physicians uninformed of the new information.

These failures of Medtronic to report are identified in the FDA letter as acts in violation of the federal statute and the regulations applying it. Under the FDA's assessment of its conduct, Medtronic was in violation of federal law as early as

2003 because it failed to adequately respond to events indicating that its device posed a specific danger.

The parallel state claims. The Stengels sought to amend their original complaint to allege that Medtronic negligently failed "to provide adequate warnings, information, or both, of the risks and hazards of the pain pump[.]" The Arizona Supreme Court has recognized a cause of action based on a manufacturer's failure to remedy or give notice of an unreasonably dangerous condition discovered post-market. *See Readenour v. Marion Power Shovel*, 149 Ariz. 442, 448 (1986) (plaintiff could argue that manufacturer, upon discovering "an unreasonably dangerous condition at any time during the product's history[,]" should have either retrofitted "each of the models already sold or warn[ed] each of the buyers of the existence of the latent danger"). That Medtronic discovered the danger of granuloma formation after the pain pump went to market does not defeat the Stengels' cause of action under Arizona law. *See id.*

Whether the state law claim has elements that further *restrict* its application is of no import. *See Lohr*, 518 U.S. at 495. The Stengels have alleged a valid parallel state law cause of action. Arizona law imposes requirements that parallel the requirements under federal law, and Arizona law provides a remedy in damages for the violation of the state requirement.

The state claim for damages. In their proposed amendment, the Stengels sought the state remedy of damages for the injuries suffered by Richard Stengel as a consequence of Medtronic's failure to warn of the danger posed by its pump.

To sum up, the Stengels seek to amend their complaint to assert Arizona requirements that parallel federal requirements under the MDA and for which Arizona provides a remedy in damages. The amendments should be allowed.

Appendix

The FDA Warning Letter, addressed to the CEO of Medtronic, July 3, 2008, setting out the history of reports of the inflammatory mass, states:

> **A correction or removal conducted to reduce a risk to health posed by a device was not reported in writing to FDA, as required by 21 CFR 806.10(a)(1).**
>
> In July 2003 your establishment sent a letter with an enclosed "EDUCATIONAL BRIEF," entitled "Information about Inflammatory Mass," to SynchroMed customers (physicians). Also enclosed were reprints of two articles published in the December 2002 issue of Pain Medicine and revised labeling for the SynchroMed Technical Manual. FDA defines a "correction" in 21 CFR 806.2(d) as " . . .the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location." FDA believes that the July 2003 Educational Brief, which was sent to all customers using SynchroMed pumps, meets the definition of "correction" in that the letter provided updated labeling to customers for devices that were already in distribution.
>
> The FDA also believes that the July 2003 Educational Brief is a reportable correction under 21 CFR 806.10(a)(1) in that the letter contained specific information intended to reduce the risk to health posed by the device. For example, the July 2003 Educational Brief specifically states that "[i]f an inflammatory mass is detected in its clinical course, prompt discontinuation of opioid delivery into the mass may cause it to shrink or disappear without the

need for surgical removal." The letter also specifically recommends catheter replacement, repositioning, and other interventional procedures, depending on the patient's clinical condition. These recommendations were neither included in the pump's original labeling, nor conveyed to customers in a January 2001 communication regarding inflammatory masses.

Additionally, the July 2003 Educational Brief contained new "Post implant" warnings that suggest that clinicians should routinely monitor patients for prodromal clinical signs or symptoms of inflammatory mass such as change in character, quality or intensity of pain; reports of new radicular pain, especially at or near the dermatomal level of the catheter tip; frequent or large escalations of daily drug does to maintain the analgesic effect; and dose escalations that may only temporarily alleviate the patient's increasing pain. These new warnings were not included in the January 2001 letter or the pump's original technical manual.

Furthermore, the journal articles included with the July 2003 Educational Brief stated with regard to adverse event reporting that 41 adverse events regarding inflammatory mass were identified as of November 2000 (conveyed to customers in the January 2001 letter). The articles also state that an additional 51 events were identified after the 2001 letter had been distributed to customers. The articles suggest that the number of new adverse events has more than doubled in one year of reporting. It is noteworthy that during the most recent inspection of your facility, your firm calculated the current rate of inflammatory masses to be approximately [**redacted**] events per **[redacted**] implants. This figure, which has not yet been communicated to your

customers, suggests that the risk of inflammatory masses occurring at or near the tip of intrathecal catheters used with SynchroMed pumps is **[redacted**] greater than the **[redacted**] rate indicated in the January 2001 letter.