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
September 19, 2012—San Francisco, California

Filed January 10, 2013

Before: Alex Kozinski, Chief Judge; Sidney R. Thomas, Barry G. Silverman, Susan P. Graber, M. Margaret McKeown, William A. Fletcher, Ronald M. Gould, Johnnie B. Rawlinson, Richard R. Clifton, N. Randy Smith, and Paul J. Watford, Circuit Judges.

Opinion by Judge W. Fletcher;
Concurrence by Judge Watford

SUMMARY*

Preemption / Medical Device Amendments

The en banc court reversed the district court's order dismissing appellants' state-law failure-to-warn claim as preempted by the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

The en banc court held that the Amendments do not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the Amendments. Therefore, the en banc court held that the Amendments did not preempt, either expressly or impliedly, appellants' state-law failure-to-warn claim contained in the amended complaint.

Judge Watford concurred. Judge Watford wrote separately to provide additional thoughts as to why the state law failure-to-warn claim alleged in the proposed amended complaint was not preempted.

COUNSEL

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

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OPINION

W. FLETCHER, Circuit Judge:

Plaintiffs Richard and Mary Lou Stengel sued Medtronic under state law when a medical device manufactured by Medtronic rendered Richard permanently paraplegic. Medtronic moved to dismiss the Stengels' complaint, contending that the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") preempted their state-law claims. The Stengels moved to amend their complaint to add a new state-law negligence claim. That claim alleged that Medtronic had violated a state-law duty of care by failing to report known risks associated with use of its medical device to the Food and Drug Administration

("FDA"). The MDA required Medtronic to report those risks to the FDA. Medtronic contended that the MDA also preempted the Stengels' new negligence claim.

The district court held that the MDA preempted all of the Stengels' claims, including the new negligence claim. *Stengel v. Medtronic, Inc.*, No. CV 10-318-TUC-RCC, 2010 WL 4483970, at *3–4 (D. Ariz. Nov. 9, 2010). It denied the Stengels' motion to amend the complaint and dismissed their suit under Federal Rule of Civil Procedure 12(b)(6). *Id.* The Stengels appealed the denial of their motion to amend, as well as denial of an evidentiary ruling. A panel of this court affirmed over a dissent. 676 F.3d 1159 (9th Cir. 2012). We granted rehearing en banc. 686 F.3d 1121 (9th Cir. 2012).

The central question in this appeal is whether the MDA preempts a state-law claim in which the state-law duty of care "parallels" a federal-law duty imposed by the MDA. We conclude that such a state-law claim is not preempted and reverse the district court.

I. Background

Congress enacted the MDA to extend the coverage of the Food, Drug, and Cosmetic Act ("FDCA") to medical devices. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). The MDA divides medical devices into three classes according to user risk. Class I devices pose the least risk; Class III devices pose the most. *See id*. at 316–17; *see also* 21 U.S.C. § 360c(a)(1). Class I devices are subject to "general controls" such as labeling requirements. *Id.* § 360c(a)(1)(A); *Riegel*, 552 U.S. at 316. Class II devices are subject not only to "general controls," but also to "special controls" such as "performance standards, postmarket surveillance, [and]

patient registries." 21 U.S.C. § 360c(a)(1)(B); *Riegel*, 552 U.S. at 316–17. If a device cannot be determined to provide a reasonable assurance of safety and effectiveness under Class I or II controls and is either marketed as a life-supporting device or may cause an unreasonable risk of illness or injury, it is a Class III device. A Class III device is subject to a pre-market approval process of the FDA. 21 U.S.C. § 360c(a)(1)(C); *Riegel*, 552 U.S. at 317. The Medtronic pain pump and catheter that caused Richard Stengel's injury was a Class III device.

The FDA's pre-market approval process of a Class III device is "rigorous." *Riegel*, 552 U.S. at 317. The FDA performs a risk-benefit assessment of the device and determines the adequacy of the manufacturer's proposed label. *Id.* at 318. The FDA then denies, approves, or approves with conditions on distribution, marketing, or sale. *See* 21 U.S.C. § 360e(d); 21 C.F.R. § 814.82; *see also Riegel*, 552 U.S. at 318–19. Once the FDA approves a device, the manufacturer is required to report any information that reasonably suggests that the device (1) "[m]ay have caused or contributed to a death or serious injury" or (2) "[h]as malfunctioned" and that any recurring malfunction "would be likely to cause or contribute to a death or serious injury." 21 C.F.R. § 803.50(a); *see* 21 U.S.C. § 360i(a); *see also Riegel*, 552 U.S. at 319.

For purposes of this appeal, we assume that all allegations in the Stengels' proposed amended complaint are true. Medtronic obtained pre-market approval of its SynchroMed Pump & Infusion System in 1988. Medtronic obtained supplemental pre-market approval for its SynchroMed EL Pump and Catheter in 1999.

On October 10, 2000, Richard Stengel had a SynchroMed EL Pump and Catheter surgically implanted in his abdomen to deliver pain relief medication directly into his spine. In February 2005, Stengel collapsed at home. At the hospital, he reported feeling heaviness and decreased sensation in his right leg. He was diagnosed with ascending paralysis in his lower body. A neurosurgeon removed the catheter, but Stengel was left permanently paraplegic. Medtronic's medical device caused the paralysis.

When it received FDA approval of its SynchroMed EL Pump and Catheter, Medtronic was not aware of certain risks associated with the device. Before Stengel was paralyzed, however, Medtronic had become well aware of those risks but had failed to inform the FDA, even though the MDA required Medtronic to do so. The FDA discovered the risks, and discovered that Medtronic already knew about them, when it inspected a Medtronic facility in late 2006 and early 2007. The FDA sent a Warning Letter to Medtronic in July 2007, stating that Medtronic had "misbranded" its Class III device by concealing known risks, in violation of 21 C.F.R. §§ 803.50(a)(1), 806.10(a)(1). In response to the FDA's Warning Letter, Medtronic sent a Medical Device Correction letter to doctors in January 2008. Medtronic recalled the device in March 2008. This advice and recall came too late to help Richard Stengel, who had been paralyzed in 2005.

II. Standards of Review

We review de novo a district court's legal conclusions regarding the sufficiency of a complaint. *Martinez v. Wells Fargo Home Mortg., Inc.*, 598 F.3d 549, 553 (9th Cir. 2010). We ordinarily review for abuse of discretion a denial of a motion to amend a complaint. *Alvarez v. Chevron Corp.*,

656 F.3d 925, 931 (9th Cir. 2011). But here, where the district court denied the motion to amend because of its conclusion that the claim in the proposed complaint was preempted as a matter of law, we review de novo. We have appellate jurisdiction pursuant to 28 U.S.C. § 1291.

III. Discussion

There is a presumption against federal preemption of state laws that operate in traditional state domains. "In all preemption cases, and particularly those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (citations omitted) (omission in original). Parties seeking to invalidate a state law based on preemption "bear the considerable burden of overcoming 'the starting presumption that Congress does not intend to supplant state law.'" *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997) (citation omitted). "[T]he historic police powers of the State include the regulation of health and safety." *Id.* "Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. Because these are 'primarily, and historically, . . . matter[s] of local concern, the 'States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Lohr*, 518 U.S. at 475 (citations omitted) (omission and alteration in original).

The MDA contains an explicit preemption clause that provides as follows:

> 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). Subsection (b) is not relevant to this appeal.

An implementing regulation provides:

> 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. . . . The following are examples of State or local requirements that are not regarded as preempted by [§ 360k]:
>
> . . . .
>
> (2) [Section 360k] does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

21 C.F.R. § 808.1(d).

The Supreme Court has decided three preemption cases under the MDA. 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.

The first case is *Medtronic, Inc. v. Lohr*, decided in 1996. After Lora Lohr's pacemaker failed, the Lohrs sued its manufacturer, Medtronic, under state law for damages. 518 U.S. at 474, 480–81. The Lohrs' complaint included numerous state-law negligence claims, including a claim alleging failure to warn the "plaintiff or her physicians of the tendency of the pacemaker to fail, despite knowledge of other earlier failures." *Id.* at 481. Medtronic moved for summary judgment, contending that all of the Lohrs' state-law claims were preempted. *Id.* The Court held that none of the Lohrs' state-law claims was preempted. *Id.* at 503. It wrote: "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." *Id.* at 495.

Medtronic had argued that because the MDA provides no damages remedy, it preempts states from providing such a remedy, even for violations of parallel state-law duties. *Id.* at 486–87. In Part IV of his opinion, joined by three others, Justice Stevens emphatically rejected Medtronic's argument:

> An examination of the basic purpose of the legislation as well as its history entirely supports our rejection of Medtronic's extreme position. The MDA was enacted "to provide for the safety and effectiveness of medical devices intended for human use." . . . To the extent that Congress was concerned about protecting the industry, that intent was manifested primarily through fewer substantive requirements under the Act, not the pre-emption provision; furthermore, any such concern was far outweighed by concerns about the primary issue motivating the MDA's enactment: the safety of those who use medical devices.

Id. at 490–491 (citation omitted). Justice Breyer did not concur in Part IV, but specifically stated his reason for not joining: "I do not join Part IV, which emphasizes the differences between the MDA and the pre-emption statute at issue in *Cipollone* [*v. Liggett Group, Inc.*, 505 U.S. 504 (1992)], because those differences are not, in my view, relevant in this action." *Id.* at 508 (Breyer, J., concurring in part and concurring in the judgment). Justice Breyer's stated

reason for not joining Part IV did not include disagreement with the passage quoted above.

The Court held that the MDA did not preempt the Lohrs' state-law claim alleging that Medtronic negligently had failed to warn "plaintiff or her physicians" of the known dangers of its pacemaker. The generality of the state-law duty to warn was important to the Court's analysis. The Court wrote:

> [T]he predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. Th[is] general obligation[] [is] no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force.

Id. at 501–02. The state-law duties upon which the Lohrs relied escape preemption "because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers." *Id.* at 502.

The second case is *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). The plaintiffs in *Buckman* brought a state-law negligence suit for damages alleging injuries resulting from orthopedic bone screws, a Class III medical device. *Id.* at 343–44. Defendant Buckman was not the manufacturer of the screws. Instead, it was a consulting company that plaintiffs alleged had made fraudulent misrepresentations to the FDA in the course of obtaining pre-

market approval for its client, the manufacturer. *Id.* at 343. The Court characterized the plaintiffs' state-law claims against Buckman as "fraud-on-the-FDA claims." *Id.* at 348. It wrote that such claims

> conflict with, and are therefore impliedly pre-empted by, [the MDA]. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.

Id. (footnote omitted).

The Court in *Buckman* distinguished *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 241, 258 (1984), in which it had held that a state-law negligence cause of action allowing punitive damages was not preempted by the Atomic Energy Act. The Court wrote, "Silkwood's claim was not based on any sort of fraud-on-the-agency theory, but on traditional state tort law principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant." *Buckman*, 531 U.S. at 352. The Court also distinguished *Medtronic v. Lohr*, in which the Lohrs' "claims arose from the manufacturer's alleged failure to use reasonable care" and had not been concerned with wrongdoing during the FDA's pre-market approval process. *Id.* In contrast to the plaintiffs in *Medtronic v. Lohr*, the plaintiffs in *Buckman* alleged no state-law claim and were concerned exclusively with alleged fraud on the FDA that had

occurred as part of that approval process. The Court found that the pre-market approval process of a Class III device is wholly federal—it "originates from, is governed by, and terminates according to federal law." *Id.* at 347–48. It continued:

> In the present case, . . . the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* [*v. Lohr*] can be read to allow certain state-law causes of action that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.
>
> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law . . . .

Id. at 352–53.

The final case is *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). Plaintiffs sued Medtronic for damages under state law after an FDA-approved Class III catheter in the lead plaintiff's coronary artery ruptured. *Id.* at 320. The catheter had been inflated to a higher pressure than recommended on the FDA-approved label. *Id.* Plaintiffs alleged that the catheter was defective under state law. *Id.* The Court held that plaintiffs' claims were expressly preempted by the MDA because state law imposed a more stringent safety requirement than federal law. *Id.* at 325. However, the Court was careful to state that *Medtronic v. Lohr* remained good law. It wrote:

> State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. § 360k(a)(1). Thus, § 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. *Lohr*, 518 U.S., at 495[.]

Riegel, 552 U.S. at 330.

There are three categories of preemption: express, field, and conflict. *See Indus. Truck Ass'n v. Henry*, 125 F.3d 1305, 1309 (9th Cir. 1997). Field and conflict preemption are subcategories of implied preemption. Though the Court did not say so explicitly, it is clear that its decision in *Lohr* was an across-the-board holding that there was no preemption under any of the three categories. The Court framed the issue without any qualification as to category of preemption: "The question presented is whether [the MDA] pre-empts a state common-law negligence action against the manufacturer of an allegedly defective medical device." *Lohr*, 518 U.S. at 474.

During the course of its opinion, the Court addressed the three categories. First, the Court held that there was no express preemption. It wrote:

> [A]ny understanding of the scope of a pre-emption statute must rest primarily on "a fair understanding of *congressional purpose*." . . . Congress' intent, of course, primarily is

> discerned from the language of the pre-emption statute and the "statutory framework" surrounding it.

Id. at 485–86 (citation omitted) (emphasis in original).

Second, the Court held there was no field preemption. Justice Stevens wrote in Part IV:

> [Medtronic] argues that the plain language of the statute pre-empts any and all common-law claims brought by an injured plaintiff against a manufacturer of medical devices.
>
> Medtronic's argument is not only unpersuasive, it is implausible. . . .
>
> . . . Given the ambiguities in the statute and the scope of the preclusion that would occur otherwise, we cannot accept Medtronic's argument that by using the term "requirement," Congress clearly signaled its intent to deprive the States of any role in protecting consumers from the dangers inherent in many medical devices.

Id. at 486–87, 489. Justice Breyer concurred on this point. He wrote, "[I cannot] find any indication that either Congress or the FDA intended the relevant FDA regulations to occupy entirely any relevant field." *Id.* at 508 (Breyer, J., concurring in part and concurring in the judgment).

Third, the Court held that there was no conflict preemption. Conflict preemption exists when a state

requirement actually conflicts with a federal requirement, making impossible compliance with both requirements, *see Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963), or when a state requirement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). The MDA's implementing regulation provides that state requirements are not preempted if they "are equal to, or substantially identical to, requirements imposed by or under the act." 21 C.F.R. § 808.1(d)(2). Justice Stevens wrote in Part IV of *Lohr* that state requirements that fall within the regulatory definition do not conflict with the MDA:

> 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. . . . 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.

518 U.S. at 495. Justice Breyer again concurred, writing, "I can find no actual conflict between any federal requirement and any of the liability-creating premises of the plaintiffs' state-law tort suit[.]" *Id.* at 508 (Breyer, J., concurring in part and concurring in the judgment).

Our sister circuits have uniformly held that, in cases dealing with violations of the MDA outside the pre-market

approval process, the MDA does not preempt state-law causes of action for damages in which the state-law duty "parallels" the federal-law duty under the MDA. Two cases are directly on point.

First, in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 765 (5th Cir. 2011), Jan Hughes suffered severe burns when hot liquid leaked from a Class III medical device manufactured by Boston Scientific. Hughes brought suit under Mississippi law, alleging a violation of a state-law duty to warn. *Id.* The Fifth Circuit held that Hughes's state-law failure-to-warn claim was not preempted "to the extent that this claim is predicated on Boston Scientific's failure to comply with the applicable federal statutes and regulations." *Id.* at 764. The court stated explicitly that its holding extended to both express and implied preemption: "We conclude that Hughes's failure to warn claim is neither expressly nor impliedly preempted by the MDA to the extent that this claim is premised on Boston Scientific's violation of FDA regulations with respect to reporting burns caused by the [device]." *Id.* at 776.

Second, in *Bausch v. Stryker Corp*., 630 F.3d 546, 549 (7th Cir. 2010), *cert. denied*, 132 S. Ct. 498 (2011), Margaret Bausch was injured by a Class III ceramic hip replacement. Bausch brought suit against the manufacturer under Illinois tort law, alleging a violation of state-law duties, premised upon a violation of parallel federal-law duties under the MDA. *Id.* at 549. The Seventh Circuit wrote:

> The central issue in this appeal is whether federal law preempts product liability claims against manufacturers of Class III medical devices where a patient claims that she was

> harmed by the manufacturer's violation of federal law. That statement of the issue may be a little startling. The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive.

Id. The court concluded that Bausch's state-law claims were neither expressly nor impliedly preempted, writing that "federal law does not preempt parallel claims under state law based on a medical device manufacturer's violation of federal law . . . ." *Id.* at 558.

The Eighth Circuit has also addressed preemption under the MDA. In *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1203 (8th Cir. 2010), plaintiffs in multidistrict litigation alleged that a Class III cardiac defibrillator wire manufactured by Medtronic was defective. Plaintiffs alleged various torts under state laws, including failure to warn. The Eighth Circuit held that the MDA preempted both of the plaintiffs' failure-to-warn claims. First, 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 1205 (quoting *Riegel*, 552 U.S. at 330). Second, the plaintiffs sought to bring actions based solely on the MDA rather than on state law, which the court found foreclosed by *Buckman*. *Id.* at 1205–06. At no point did the court address a state-law claim based on a state-law duty that paralleled a federal-law duty, and thus *Sprint Fidelis* is not inconsistent with *Hughes* and *Bausch*.

IV. The Proposed Amended Complaint

The new claim in the Stengels' proposed amended complaint alleges that, under federal law, Medtronic had a "continuing duty to monitor the product after pre-market 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." It further alleges that Medtronic failed to perform its duty under federal law to warn the FDA. Finally, the complaint alleges that, because Medtronic failed to comply with its duty under federal law, it breached its "duty to use reasonable care" under Arizona negligence law.

The Stengels' proposed new claim under Arizona law, insofar as the state-law duty parallels a federal-law duty under the MDA, is not preempted. Arizona state law has long been concerned with the protection of consumers from harm caused by manufacturers' unreasonable behavior. Plaintiffs' claim is brought under settled Arizona law that protects the safety and health of Arizona citizens by imposing a general duty of reasonable care on product manufacturers. "'The whole modern law of negligence, with its many developments, enforces the duty of fellow-citizens to observe in varying circumstances an appropriate measure of prudence to avoid causing harm to one another.'" *Crouse v. Wilbur-Ellis Co.*, 272 P.2d 352, 365 (Ariz. 1954) (quoting Pollock, *Law of Torts* 17 (15th ed. 1951)). Arizona tort law includes a cause of action for failure to warn. Under Arizona law, "negligence standards impose a duty to produce products with appropriate warning instructions." *Wilson v. U.S. Elevator Corp.*, 972 P.2d 235, 237 (Ariz. Ct. App. 1998) (internal quotation marks omitted). "A product may be unreasonably

dangerous in the absence of adequate warnings." *Dole Food Co. v. N.C. Foam Indus., Inc.*, 935 P.2d 876, 880 (Ariz. Ct. App. 1996). "The manufacturer of a product must warn of dangers which he knows or should know are inherent in its use. This duty may be a continuing one applying to dangers the manufacturer discovers after sale." *Rodriguez v. Besser Co.*, 565 P.2d 1315, 1320 (Ariz. Ct. App. 1977) (citations omitted), *abrogated on other grounds as recognized by Piper v. Bear Med. Sys.*, 883 P.2d 407, 414 (Ariz. Ct. App. 1993).

If a more precise parallel were necessary, the Stengels have alleged it and Arizona law provides it. The Stengels' new claim specifically alleges, as a violation of Arizona law, a failure to warn the FDA. Arizona law contemplates a warning to a third party such as the FDA. Under Arizona law, a warning to a third party satisfies a manufacturer's duty if, given the nature of the warning and the relationship of the third party, there is "reasonable assurance that the information will reach those whose safety depends on their having it." *Anguiano v. E.I. DuPont de Nemours & Co.*, 808 F. Supp. 719, 723 (D. Ariz. 1992), *aff'd* 44 F.3d 806 (9th Cir. 1995).

We do not decide whether plaintiffs can prevail on their state-law failure-to-warn claim. That question is not before us. But we do hold, under *Lohr, Buckman*, and *Riegel*, that this claim is not preempted, either expressly or impliedly, by the MDA. It is a state-law claim that is independent of the FDA's pre-market approval process that was at issue in *Buckman*. The claim rests on a state-law duty that parallels a federal-law duty under the MDA, as in *Lohr*. In holding that the Stengels' failure-to-warn claim is not preempted, we join the Fifth and Seventh Circuits, which reached the same

conclusion with respect to comparable state-law claims in *Hughes* and *Bausch*.

In light of our decision on the merits of the state-law claim in the Stengels' proposed amended complaint, it is not necessary to address their appeal of the district court's evidentiary ruling.

The Stengels have not appealed the dismissal of the state-law claims in their original complaint. We agree with the district court that those claims are preempted as they are currently pled. The Stengels have not specified in those claims a state-law duty that parallels a federal-law duty under the MDA. Now that we have clarified preemption law under the MDA, it is possible that the Stengels could plead non-preempted versions of these claims. We leave it to the sound discretion of the district court to determine whether, in light of this opinion, the Stengels should be permitted to file a further amended complaint if they wish to do so.

Conclusion

For the foregoing reasons, we conclude that the MDA does not preempt the Stengels' state-law failure-to-warn claim contained in their proposed amended complaint. We therefore reverse the decision of the district court and remand for further proceedings consistent with this opinion.

REVERSED and REMANDED.

WATFORD, Circuit Judge, joined by KOZINSKI, Chief Judge, and THOMAS, SILVERMAN, GRABER, McKEOWN, and GOULD, Circuit Judges, concurring:

While I join Judge Fletcher's opinion, I write separately to provide a few additional thoughts as to why the state law failure-to-warn claim alleged in the proposed amended complaint is not preempted.

Given the Supreme Court's preemption decisions in this area, the Stengels faced a dilemma in framing their failure-to-warn claim. The most direct way to state the claim would be to allege that under Arizona law Medtronic owed a post-sale duty to warn doctors when it learned of adverse events in which the medical device at issue here caused a death or serious injury. Regulations issued by the Food and Drug Administration (FDA) permitted Medtronic to issue such post-sale warnings, even without receiving prior approval from the FDA, but those regulations did not require such warnings. *See* 21 C.F.R. § 814.39(d). As a result, any attempt to predicate the Stengels' claim on an alleged state law duty to warn doctors directly would have been expressly preempted under 21 U.S.C. § 360k, which forbids state-imposed requirements that are "different from, or in addition to" the requirements imposed by federal law. *See McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) ("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.").

But the Stengels have not predicated their failure-to-warn claim on a duty to warn doctors directly. They have instead alleged that Medtronic breached its duty of reasonable care under Arizona negligence law by failing to report adverse

events *to the FDA*. That requirement is not "different from, or in addition to" the requirements imposed by federal law, because FDA regulations required Medtronic to file an adverse event report with the FDA if it learned of information "reasonably suggest[ing]" that one of its devices "[m]ay have caused or contributed to a death or serious injury," as the Stengels have alleged here. 21 C.F.R. § 803.50(a). Framed in this fashion, the Stengels' negligence claim is not expressly preempted because it seeks to hold Medtronic accountable only for failing to do what federal law mandated — nothing more. The state law duty, as alleged by the Stengels, is precisely parallel to the duties imposed by federal law. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996).

Because they predicate their claim on Medtronic's reporting duty to the FDA, as they must to avoid express preemption, the Stengels face a causation hurdle that would not otherwise exist. To prevail, they will ultimately have to prove that if Medtronic had properly reported the adverse events to the FDA as required under federal law, that information would have reached Mr. Stengel's doctors in time to prevent his injuries. *See Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 770 n.5, 776 (5th Cir. 2011). But at this juncture — a request for leave to amend their complaint — the Stengels' allegations of causation are adequate.

Medtronic argues that the Stengels' choice to predicate their claim on a reporting duty to the FDA renders the claim impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In that case, the plaintiffs asserted a state law fraud claim based on purported misrepresentations made to the FDA during the premarket approval process for the medical device at issue. *Id.* at 343. The Supreme Court held that this claim was impliedly

preempted because it sought to enforce an exclusively federal requirement and was not grounded in traditional state tort law. *Id.* at 352–53. Likewise here, Medtronic argues, the Stengels' failure-to-warn claim seeks to enforce an exclusively federal requirement and is not based on traditional state tort law because Arizona law has never required adverse events to be reported to the FDA.

In my view, accepting that argument would require an unwarranted expansion of *Buckman*'s rationale. Central to the Court's reasoning in *Buckman* was that the state law claim asserted there "exist[ed] *solely* by virtue" of the federal enactments, *id.* at 353 (emphasis added), because state law traditionally had no role to play in policing "the relationship between a federal agency and the entity it regulates," *id.* at 347. But *Buckman* left intact claims "relying on traditional state tort law which had predated the federal enactments" in question. *Id.* at 353.

In this case, Medtronic's failure to report was more than a mere misrepresentation to the FDA because it simultaneously misled the device's current and potential users, to whom Medtronic owed an independent duty under state law. There is no question that state law has an important and legitimate role to play in regulating the adequacy of post-sale warnings for products already on the market. That Arizona law did not previously address reporting duties to the FDA specifically is irrelevant; nothing in *Buckman* suggests that the preexisting state law needs to mirror the federal requirement at that level of specificity to avoid preemption. It is sufficient here that, in contrast to *Buckman*, the Stengels' claim is grounded in a traditional category of state law failure-to-warn claims that predated the federal enactments in

question, and that the claim therefore does not exist solely by virtue of those enactments.