

In the
United States Court of Appeals
For the Seventh Circuit

No. 09-3434

MARGARET J. BAUSCH,

Plaintiff-Appellant,

v.

STRYKER CORPORATION, *et al.*,

Defendants-Appellees.

Appeal from the United States District Court
for the Northern District of Illinois, Eastern Division.
No. 08 C 4248—**Samuel Der-Yeghiayan**, *Judge*.

ARGUED OCTOBER 21, 2010—DECIDED DECEMBER 23, 2010

Before EASTERBROOK, *Chief Judge*, and MANION and HAMILTON, *Circuit Judges*.

HAMILTON, *Circuit Judge*. This diversity jurisdiction case presents issues concerning federal preemption and sufficient pleading of a plaintiff's claim that she has been injured by a medical device—a hip replacement—allegedly manufactured in violation of federal law. Plaintiff Margaret J. Bausch appeals the district court's dismissal of her case against defendants Stryker Corpora-

tion, HOC, and Stryker Ireland, Ltd. (collectively “Stryker”), who have manufactured, distributed, and sold the Trident-brand ceramic-on-ceramic hip replacement system (“the Trident”) in the United States since 2003. The Trident is a Class III medical device under federal law, the class of devices that are most critical to human health and subject to the most extensive federal regulation.

Bausch alleged that the defendants violated federal law in manufacturing the Trident. The device was implanted in her body six days after the United States Food and Drug Administration informed the defendants that a component of the Trident hip system was “adulterated” and that the companies’ manufacturing processes failed to comply with federal standards. The Trident implanted in Bausch failed, requiring surgical removal and replacement of the product and leading to a host of serious and painful medical problems. The defendants later recalled a component of the Trident bearing the same catalogue number as the one that had been implanted in Bausch’s body. Bausch brought this suit under Illinois common law for negligence and strict liability for a defective product.

The district court granted defendants’ motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure, holding that Bausch’s common law claims were preempted by federal law. In an unusual step, the district court did not allow plaintiff a requested opportunity to amend her complaint, but immediately entered final judgment dismissing the action with prejudice. The district court then denied Bausch’s motion to

No. 09-3434

3

vacate the judgment and for leave to file an amended complaint.

We conclude that the district court erred. Bausch's claims that she was injured by defendants' alleged violations of federal law are not preempted. Her original complaint should not have been dismissed. Even if the original complaint had been defective, the district court abused its discretion by dismissing the action with prejudice and denying Bausch leave to file an amended complaint. We address first the preemption issue and then the pleading issues.

I. *The Scope of Federal Preemption for Class III Medical Devices*

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. Nevertheless, manufacturers in this case and in others have asserted this theory of defense. As we explain below, the manufacturer's theory tries to stretch the Supreme Court's decisions in this field beyond the boundaries that were made clear in those decisions. Medical device manufacturers who subject their Class III devices to the rigorous premarket approval process are protected by federal

law from civil liability so long as they *comply* with federal law. That protection does not apply where the patient can prove that she was hurt by the manufacturer's *violation* of federal law. We begin by analyzing defendants' asserted defense of express preemption and then their defense of implied preemption.

A. *Express Preemption—The Limited Scope of 21 U.S.C. § 360k*

Defendants' hip implants are so important to patients' health that they are treated as "Class III Medical Devices" under the federal Food, Drug, and Cosmetic Act. Class III medical devices are those used "in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" and those that "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(c). Under the federal act, the Food and Drug Administration (FDA) subjects new Class III medical devices to a rigorous process of federal review for safety and effectiveness called "premarket approval." See 21 U.S.C. § 360e; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-20 (2008) (describing process and requirements).

The Medical Device Amendments of 1976 to the federal Food, Drug, and Cosmetic Act include an express, but limited, preemption provision for product liability claims against manufacturers of Class III medical devices:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a

No. 09-3434

5

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).

The Supreme Court has twice addressed the limited scope of this preemption provision. Its decisions show that plaintiff Bausch has stated a legally viable claim based on alleged violations of federal law. First, in 1996, the Supreme Court held that lawsuits brought under state law against medical device manufacturers who submit “premarket notification” to the FDA—a process described below—are not preempted by 21 U.S.C. § 360k(a) when liability is premised on theories that the device was defective and unreasonably dangerous and that the manufacturer failed to use reasonable care in the device’s design, manufacture, assembly, and sale. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 481, 494-95 (1996). In 2008, the Supreme Court held that lawsuits brought under state law against medical device manufacturers who obtain the full federal “premarket approval” are preempted by section 360k(a) when liability is premised on violations of state law requirements that are in addition to or different from federal requirements regulating the devices. *Riegel*, 552 U.S. at 330. Neither case held that state lawsuits premised on violations of federal law are preempted under section 360k(a). In fact, the

Court's opinions in *Lohr* and *Riegel* expressly left the door open for state law claims based on violations of federal law.

In *Lohr*, the Court rejected a preemption defense as applied to another medical device (pacemaker leads) where the plaintiff based her claims on allegations that the manufacturer had violated federal regulations. The Court explained that the federal preemption provision allows claims under a state's common law based on the defendant's violation of federal law:

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 pre-emption 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.

Lohr, 518 U.S. at 495 (reversing dismissal of complaint).

No. 09-3434

7

The pacemaker leads at issue in *Lohr* had not been approved through the FDA's premarket approval process. Instead, the FDA confirmed that the leads were "substantially equivalent" to a device that was already on the market through what is known as a "premarket notification" or "§ 510(k) process." *Id.* at 478-80. The section 510(k) process is less rigorous than the premarket approval process, so much so that *Lohr* held that such generally applicable standards are not "requirements" sufficient even to trigger preemption under section 360k(a). *Id.* at 492-93. The Court went on to explain that section 360k(a) does not preempt state rules that merely duplicate federal requirements. *Id.* at 494-95. Thus, the above quoted language in *Lohr* discussing parallel claims also applies to products that have gone through premarket approval.

Nothing in the more recent *Riegel* case calls into question the ability of a patient to sue a Class III device manufacturer under state law for violations of federal law. In fact, the *Riegel* Court went out of its way to explain that such claims are not preempted. Because the case is so central, we consider it in some detail.

In *Riegel*, the plaintiffs alleged that a medical device that failed was designed, labeled, and manufactured in breach of duties imposed by state common law, and that the defects caused the plaintiffs to suffer severe and permanent injury. *Riegel*, 552 U.S. at 320. The district court held that section 360k preempted the plaintiffs' claims of strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution,

labeling, marketing and sale of the device. *Id.* at 320-21. The district court also held that section 360k preempted the Riegels' negligent manufacturing claim, but only to the extent that the claim was *not* premised on the theory that Medtronic had violated federal law. *Id.* at 321.

But the district court had allowed the Riegels to go forward on claims that Medtronic was negligent in manufacturing by *failing* to comply with federal standards and had breached an express warranty. Those claims were not preempted by section 360k. The district court later granted summary judgment on those claims, apparently on the merits, and those claims, which were essentially identical to plaintiff Bausch's claims for these purposes, were not before the Supreme Court. See *id.* at 321, n.2.

On review, the Supreme Court held that the premarket approval process imposed federal "requirements" that triggered the preemption clause of section 360k. *Id.* at 322-23. The Court further held that the tort duties implicit in a finding of liability under the common law claims brought by the Riegels would also constitute "requirements" under section 360k. *Id.* at 323-25. Ultimately, the Court concluded that, to the extent the state tort law underlying the Riegels' claims would require a manufacturer's device to be safer (but perhaps less effective) than the model device approved by the FDA, those requirements would "disrupt[] the federal scheme no less than state regulatory law to the same effect." *Id.* at 325. Thus, the Court found that the state requirements implicit in the Riegels' common law claims

No. 09-3434

9

were different from or in addition to the federal requirements and were preempted under section 360k.

The *Riegel* Court took care, however, to limit its holding to claims that the device at issue “violated state tort law *notwithstanding compliance with the relevant federal requirements.*” 552 U.S. at 330 (emphasis added). The Court gave lower courts clear instructions to allow claims to proceed when they are based on claimed violations of federal law: “§ 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.” *Id.* That passage in *Riegel* quoted the portion of *Lohr* that we quoted above. See 518 U.S. at 495.

The Supreme Court thus has made clear that section 360k protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law. In other words, where state law is parallel to federal law, section 360k does not preempt the claim.

Consistent with *Lohr*, we held in *McMullen v. Medtronic, Inc.*, 421 F. 3d 482, 489 (7th Cir. 2005), quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005), that state requirements are not expressly preempted under § 360k where the plaintiff can show that the requirements are “genuinely equivalent.” We said that where there are “both state and federal requirements to [the same] effect, then the state requirements will not be different from, or in addition to, the federal requirements.” *Id.* at 488; see also

Chambers v. Osteonics Corp., 109 F.3d 1243, 1248 (7th Cir. 1997) (Medical Device Amendments did not preempt state law claim based on manufacturing defect resulting from violation of FDA requirements); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 n.6 (7th Cir. 1997) (negligence claims not preempted if based on claims that manufacturer did not adhere to FDA standards in the premarket approval process). Nothing in *Riegel* changes our view that state law claims based on violations of federal law are not expressly preempted by section 360k.

In this case, the district court erred by dismissing as preempted plaintiff's common law claims based upon alleged violations of federal law. The district court thought *Riegel* and *Lohr* would leave room for a claim based on "a state regulatory enactment," but that common law claims would be different from or in addition to federal law and thus would be preempted. *Bausch v. Stryker Corp.*, 2008 WL 5157940, at *5 (N.D. Ill. Dec. 9, 2008). That analysis overlooked the Supreme Court's rejection in *Lohr* and *Riegel* of precisely that argument against common law claims. As the passage quoted above begins: "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." 518 U.S. at 495.

Illinois treats a violation of a statute or ordinance designed to protect human life or property as prima facie evidence of negligence, though the violation may not always be conclusive on the issue of negligence. See, e.g., *Kalata v. Anheuser-Busch Companies, Inc.*, 581 N.E.2d 656,

No. 09-3434

11

661 (Ill. 1991) (violation of public safety ordinance regulating handrails is prima facie evidence of negligence); *Batteast v. Wyeth Laboratories, Inc.*, 560 N.E.2d 315, 323 (Ill. 1990) (violation of safety statute is prima facie evidence of negligence if law designed to (1) protect class to which plaintiff belongs and (2) injury has direct, proximate connection with regulation); *Barthel v. Illinois Central Gulf Railroad Co.*, 384 N.E.2d 323, 326 (Ill. 1978), citing *Davis v. Marathon Oil Co.*, 356 N.E.2d 93 (Ill. 1976) (a defendant's violation of a statute designed to protect human life or property is ordinarily prima facie evidence of negligence); *First National Bank in DeKalb v. City of Aurora*, 373 N.E.2d 1326, 1329-30 (Ill. 1978) (citing violation of ordinances regulating street and sidewalk safety was sufficient to state a cause of action); *Hartje v. Moxley*, 85 N.E. 216, 217 (Ill. 1908) (driving at prohibited rate of speed is prima facie evidence of negligence).

Section 360k provides immunity for manufacturers of new Class III medical devices to the extent that they comply with federal law, but it does not protect them if they have violated federal law. Just as a plaintiff in an auto accident may use the other driver's speeding violation as evidence of negligence, plaintiff Bausch claims that she was injured by Stryker's violations of federal law in manufacturing the device implanted in her hip. It remains to be seen whether she can prove those allegations, including causation and damages. But if she can prove those allegations of harm caused by violations of federal law, her claims under state law would not impose on defendants any requirement "dif-

ferent from, or in addition to, any requirement” imposed by federal law. Her claims are not preempted.

Our conclusion that plaintiff Bausch’s claims for defective manufacture in violation of federal law are not expressly preempted by section 360k is consistent with the Supreme Court’s decisions in *Lohr* and *Riegel*, and also with numerous circuit and district court decisions that have considered similar claims based on alleged violations of federal law. See *McMullen*, 421 F.3d at 488-89; *Chambers*, 109 F.3d at 1248; *Mitchell*, 126 F.3d at 913; *Howard v. Sulzer Orthopedics, Inc.*, 382 Fed. Appx. 436 (6th Cir. 2010) (unpublished opinion); *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 832 (S.D. Ind. 2009); *Prudhel v. Endologix, Inc.*, 2009 WL 2045559 (E.D. Cal. Jul. 9, 2009); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271 (E.D.N.Y. 2009); *Purcel v. Advanced Bionics Corp.*, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008); *Rollins v. St. Jude Medical*, 583 F. Supp. 2d 790 (W.D.La. 2008); *Walker v. Medtronic, Inc.*, 2008 WL 4186854 (S.D. W.Va. Sep. 9, 2008). We have not been directed to any federal decisions, other than the district court in this case, that adopted the broad view of section 360k preemption argued by the defendants.

A few days before oral argument in this case, the Eighth Circuit decided *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 (8th Cir. 2010) (“*Medtronic Leads*”), one of only two circuit court cases to have applied *Riegel* to medical device preemption (the other is *Howard v. Sulzer Orthopedics, Inc.*). A divided panel of the Eighth Circuit affirmed dismissal of the plaintiffs’ manufacturing defect claims on the basis of

No. 09-3434

13

express preemption. The majority properly left open some possibility for parallel claims not preempted by section 360k. The court noted, for instance, that there is a “narrow gap through which a plaintiff’s state-law claim must fit if it is to escape express or implied preemption.” *Medtronic Leads*, 623 F.3d at 1204, quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009). The majority affirmed dismissal of the manufacturing defect claims, however, because “as pleaded and argued” to the district court, plaintiffs had failed to identify specific violations of federal law but had mounted instead a “frontal assault” on the FDA’s decision to approve the device. *Id.* at 1207. While the case might well be distinguishable from our case based on the *Medtronic Leads*’ plaintiffs’ deliberate decision not to seek discovery and to assert claims for patients whose devices had not failed, we essentially agree with Judge Melloy’s dissent in *Medtronic Leads*. Judge Melloy argued that the plaintiffs could not be expected to plead their claims with greater specificity without discovery to obtain access to confidential government and company documents. 623 F.3d at 1209-14 (Melloy, J., dissenting).

Defendants argue in the alternative that if a common law claim can survive their preemption defense, the plaintiff must allege and prove a violation of a “concrete, device-specific” federal regulation. The issue is important because manufacturers of Class III medical devices are required by federal law to comply with Quality System Regulations established by the FDA.

The Quality System Regulations also set forth Current Good Manufacturing Practices. 21 C.F.R. § 820.1(a)(1). (Many writers refer to these as QSRs and CGMPs. In this already acronym-rich environment, we prefer not to use the short versions.)

Defendants contend that the Quality System Regulations and Current Good Manufacturing Practices are too general to allow juries to enforce them. Some federal courts have adopted this approach in the wake of *Riegel*. See, e.g., *Horowitz*, 613 F. Supp. 2d at 284, quoting *In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litig.*, 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009), (plaintiff's claims were "simply too generic, standing alone" to serve as basis for manufacturing-defect claim), *aff'd*, 623 F.3d 1200 (8th Cir. 2010); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009) (the "intentionally vague and open-ended nature of the regulations relied upon is the precise reason why they cannot serve as the basis for a parallel claim"). The Sixth Circuit has rejected this approach. See *Howard*, 382 Fed. Appx. at 440 (reversing summary judgment on preemption grounds, concluding that the Current Good Manufacturing Practices are "not so vague as to be incapable of enforcement.").¹

¹ The Eighth Circuit panel majority opinion in *Medtronic Leads* appears to have agreed that a plaintiff must allege and prove violation of a device-specific requirement to avoid the preemption defense for a manufacturing defect claim. 623 F.3d at 1207 ("Plaintiffs simply failed to adequately plead that Medtronic violated a federal requirement specific to the FDA's PMA (continued...)

No. 09-3434

15

Like the Sixth Circuit in *Howard*, we do not see a sound legal basis for defendants' proposal to distinguish between general requirements and "concrete, device-specific" requirements. Section 360k makes preemption a defense if a state seeks to impose on a manufacturer "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). We emphasize the phrase "any requirement." And federal law is clear: for manufacturers of Class III medical devices, the

¹ (...continued)

approval of this Class III device."). The *Medtronic Leads* opinion did not explain its apparent rejection of claims based on violations of the Quality System Regulations or Current Good Manufacturing Practices. In *Howard v. Sulzer Orthopedics*, by contrast, all members of the Sixth Circuit panel appeared to agree that a claim based on violations of the Quality System Regulations or Current Good Manufacturing Practices could avoid preemption, so that it was not necessary to show violation of a device-specific requirement. The point of disagreement in *Howard* was in the interpretation of 21 C.F.R. § 820.70(h): whether it required actual removal of manufacturing materials (like lubricants) from the device, or whether only a procedure to remove manufacturing materials was sufficient, whether the procedure was successful or not. Compare 382 Fed. Appx. at 440-41 (majority concluding that actual removal was required), with *id.* at 442-43 (Guy, J., dissenting) (having a removal procedure is sufficient to comply with regulation, whether successful or not).

Quality System Regulations and Current Good Manufacturing Practices adopted by the FDA under its delegated regulatory authority are legally binding requirements “under this chapter.” 21 C.F.R. § 820.1. “The failure to comply with any applicable provision in this part [of the regulations] renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.” 21 C.F.R. § 820.1(c).

Defendants’ proposed distinction between concrete, product-specific requirements and more general requirements would also leave injured patients without any remedy for a wide range of harmful violations of federal law. The FDA regulations contain many requirements that are not concrete or product-specific, yet which are obviously vital to producing safe and effective medical devices. For example, the regulations require each manufacturer to “establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality,” 21 C.F.R. § 820.70(e), and to “establish and maintain procedures for the use and removal” of manufacturing material (such as lubricants or abrasives, or cleaning and disinfectant agents) “to ensure that it is removed or limited to an amount that does not adversely affect the device’s quality.” 21 C.F.R. § 820.70(h). If a patient were harmed by an implanted hip replacement system that was contaminated, for example, by a production worker’s blood or mucus or by a lubricant or abrasive that caused an infection after implantation, that contamination would

No. 09-3434

17

present a substantial claim for violating requirements that are not “concrete” and “product-specific,” yet which surely are essential for the manufacture of safe and effective medical devices for implantation in the human body. See *Howard*, 382 Fed. Appx. at 442 (reversing summary judgment for manufacturer when lubricant used in manufacturing had been left on knee replacement implanted in plaintiff).

We also assume that manufacturing processes are not perfect, despite what may be the best human efforts to achieve perfection. Perhaps more to the point, the FDA makes the same assumption, as is evident from its Quality System Regulations and Current Good Manufacturing Process requirements. The FDA regulations require each manufacturer to put in place processes to test products for compliance with product specifications, to check and document compliance with product specifications before products are accepted for sale and use, and to identify and control nonconforming products. 21 C.F.R. §§ 820.72 to 820.90. Plaintiff Bausch’s amended complaint alleges that the FDA found that the defendants had failed to comply with section 820.90 regarding nonconforming products, and that the product implanted in plaintiff Bausch failed to comply with product specifications as approved by the FDA through the premarket approval process.

We recognize the possibility that there may be some room for interpretation of the applicable federal requirements, and it is at least conceivable that a jury deciding a common law claim might apply those requirements

more stringently than the FDA intended. That danger is defendants' best argument in favor of their distinction between general requirements and concrete, product-specific requirements. We are not persuaded. First, the meaning of the FDA's requirements will present questions of law for the court to decide, not questions of fact for a jury to decide. Second, those questions of law will be questions of federal law, subject to the usual processes for reconciling conflicting views. Third, the proposed distinction between general requirements and concrete, product-specific requirements seems to us more slippery and less workable than its proponents acknowledge. And fourth, for the reasons we have explained above, we believe the proposed distinction cannot be derived from the language of the statutory preemption provision or from its purpose, to provide preemption for medical device manufacturers to the extent they actually comply with stringent requirements of federal law. Plaintiff Bausch's claims are not expressly preempted by federal law to the extent they are based on defendants' violations of federal law.

B. *Implied Preemption*

We turn now to the defendants' argument on appeal that Bausch's amended complaint is not only expressly preempted but impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). The defendants argue specifically that implied preemption is necessary to maintain the "statutory and regulatory framework under which the FDA pursues difficult (and

No. 09-3434

19

often competing) objectives” for medical devices, such as ensuring the safety and efficacy of the devices while ensuring that the devices are available to those who need them, and that Bausch’s claims are impliedly preempted because they conflict with the FDA’s regulatory regime. *Id.* at 349. They extract language from *Buckman* to conclude that Congress clearly provided that the Food, Drug, and Cosmetic Act and the Medical Device Amendments should be “enforced exclusively by the Federal Government” and that only the FDA can enforce the regulations on which Bausch’s claims are based. See *id.* at 352. This argument is not convincing.

In *Buckman*, patients claimed to have suffered injuries from implantation of orthopedic bone screws into their spines. The patients brought suit alleging that a regulatory consultant to the manufacturer made fraudulent representations to the FDA in the course of obtaining approval to market the screws. The Supreme Court held that the Food, Drug, and Cosmetic Act as amended by the Medical Devices Amendments impliedly preempted the patients’ state law fraud claims because the claims conflicted with federal law. The Court concluded that the federal statute empowers the FDA to deter and punish fraud and that the “balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.” *Id.* at 348. But the *Buckman* court specifically distinguished such “fraud-on-the-agency” claims, *i.e.*, claims not related to a field of law that states had traditionally occupied, from claims based on state law tort principles such as in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984),

and *Lohr* itself. “In contrast to situations implicating ‘federalism concerns and the historic primacy of state regulation of matters of health and safety,’ as in *Lohr*, 518 U.S. at 485, no presumption against pre-emption obtains in this case.” *Id.*

Bausch’s claims, like those in *Lohr*, and unlike those in *Buckman*, are tort law claims based on manufacturing defects, not fraud on a federal agency. For these claims, as both *Buckman* and *Lohr* make clear, 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.” *Lohr*, 518 U.S. at 485, quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Here we look to the express preemption provision, and we find no indication that Congress intended preemption of state claims based on violations of federal law, beyond the limitations set forth in the express preemption clause as discussed above. An express preemption provision does not “bar the ordinary working of conflict preemption principles,” *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000), but we see no way in which Bausch’s claims conflict with the federal regulations, and thus no reason for them to be impliedly preempted.

The defendants argue that Bausch’s claim that the medical device was “adulterated” must be impliedly preempted because there is simply no state tort duty to manufacture a product that is not adulterated. We disagree. The MDA defines an “adulterated” device as a device “not in conformity with applicable requirements

No. 09-3434

21

or conditions.” 21 U.S.C. § 351(h). While 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. The evidence showing a violation of federal law shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law toward the patient.

Finally, the defendants point to the Eighth Circuit’s opinion in *Medtronic Leads*, one of two cases from other circuits that address the application of *Riegel* to claims that medical device manufacturers violated federal law. There the court upheld the district court’s dismissal of all claims related to a Class III medical device on the basis of express and implied preemption. The court concluded that there is only a “narrow gap” through which a plaintiff’s state law claim may fit to “escape express or implied preemption.” *Medtronic Leads*, 623 F.3d at 1204, quoting *Riley*, 625 F. Supp. 2d at 777. “The plaintiff must be suing for conduct that *violates* the [Food, Drug, and Cosmetic Act] (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the [Food, Drug, and Cosmetic Act] (such a claim would be impliedly preempted under *Buckman*).” *Id.* Regardless of how wide or narrow the gap may seem, the Eighth Circuit’s comment was reflecting the limits of both *Buckman* and *Lohr*. The plaintiffs in *Buckman* who claimed that the manufac-

turer had defrauded the federal agency did not have an implied right of action under federal law, and they were not claiming the breach of a recognized state-law duty for their benefit. Here, as in *Lohr* and as recognized in *Riegel*, the plaintiff claims breach of a well-recognized duty owed to her under state law—the duty of a manufacturer to use due care in manufacturing a medical device. She may do so as long as she can show that she was harmed by a violation of applicable federal law. Her claim is not impliedly preempted by federal law.

II. Pleading “Parallel” Medical Device Claims

Beginning from the premise that federal law does not preempt parallel claims under state law based on a medical device manufacturer’s violation of federal law, we turn to the problem of how difficult it is to plead such a claim sufficiently to survive a motion to dismiss for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure. There are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular. The federal standard of notice pleading applies, so long as the plaintiff alleges facts sufficient to meet the new “plausibility” standard applied in *Iqbal* and *Twombly*. See *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (to survive a motion to dismiss, the complaint “must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face’ A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the

No. 09-3434

23

reasonable inference that the defendant is liable for the misconduct alleged.”), quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556, 570 (2007).

In applying that standard to claims for defective manufacture of a medical device in violation of federal law, moreover, district courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim. Accordingly, the district court erred in this case by dismissing plaintiff’s original complaint and by denying her leave to amend her complaint.

A. The Original Complaint

Bausch’s original complaint asserted claims under Illinois law for strict product liability and negligence. Because the appeal is from the grant of a motion to dismiss under Rule 12(b)(6), we must accept as true Bausch’s allegations. See, e.g., *Bonte v. U.S. Bank, N.A.*, 624 F.3d 461, 462 (7th Cir. 2010).

According to the original complaint, the defendants manufacture the Trident brand ceramic-on-ceramic hip replacement system. It is a Class III medical device subject to the authority of the FDA. Plaintiff had right total hip replacement surgery on March 21, 2007, in which a Trident device was implanted. The original complaint alleged that the Trident product was unreasonably dangerous, causing plaintiff to suffer an

unstable right hip, pain, suffering, disability, and what is euphemistically called “revision” surgery—in Bausch’s case a second major operation in which the Trident product was removed and replaced with a different product.

The original complaint also alleged facts indicating that defendants knew, or at least should have known, before plaintiff’s original surgery that the Trident implanted in her was defective. According to the original complaint, by early 2005, the defendants received complaints that the Trident was failing after it was implanted. Defendants recalled a batch of Trident components in March 2006 because of “dimensional anomalies.” The FDA conducted an inspection at the defendants’ Ireland manufacturing facility from October 31 to November 3, 2006, and, following the inspection, informed the defendants of “numerous deficiencies [in the Trident] manufacturing and inspection processes.” Six days before plaintiff Bausch’s surgery, “after several months of inadequate response to the FDA findings by the defendants,” the FDA issued a letter to defendants on March 15, 2007 warning that the Trident was “adulterated due to manufacturing methods . . . not in conformity with industry and regulatory standards.” A device, bearing the same catalogue number as the device allegedly not in compliance with regulations, was then implanted in Bausch’s body the next week. The device in Bausch’s body failed and the same device was later recalled.

The original complaint served the purposes of Rule 8 of giving the defendants fair notice of the nature of the

No. 09-3434

25

claim against them and of stating a claim for relief that was “plausible on its face” as required by *Iqbal* and *Twombly*. In deciding whether a complaint can survive a motion to dismiss, we have consistently said: “As a general rule . . . notice pleading remains the standard.” *Windy City Metal Fabricators & Supply, Inc. v. CIT Tech. Financial Services*, 536 F.3d 663, 667 (7th Cir. 2008). Pursuant to Rule 8, pleading is meant to “‘focus litigation on the merits of a claim’ rather than on technicalities that might keep plaintiffs out of court.” *Brooks v. Ross*, 578 F.3d 574, 580 (7th Cir. 2009), quoting *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 514 (2002). We give the plaintiff “the benefit of imagination, so long as the hypotheses are consistent with the complaint.” *Bissessur v. Indiana Univ. Bd. of Trs.*, 581 F.3d 599, 603 (7th Cir. 2009), quoting *Sanjuan v. American Bd. of Psychiatry and Neurology, Inc.*, 40 F.3d 247, 251 (7th Cir. 1994). “Together, these rules ensure that claims are determined on their merits rather than on pleading technicalities.” *Christensen v. County of Boone*, 483 F.3d 454, 458 (7th Cir. 2007).

We do not see a fatal defect in the original complaint that would have justified its dismissal, let alone entry of a final judgment dismissing the action with prejudice. The only significant issue we see with the original complaint is that it alleges not only violations of “regulatory” standards, but also violations of “industry” standards. To the extent that the claims are based upon violations of “industry standards” that are different from or in addition to the federal regulatory standards (which have the force of law), those claims would be preempted under section 360k. Yet complaints that combine legally

valid and invalid claims are common. When a complaint asserts claims that are legally valid and those that are not, the correct judicial response is not to dismiss the complaint, let alone with prejudice. It's not even necessary to require a plaintiff to file a "cleaner" amended complaint. The case may proceed under the original complaint, with the understanding, provided by the court if necessary, as to the proper scope of claims that can survive the legal challenge.

Defendants object that the original complaint does not specify the precise defect or the specific federal regulatory requirements that were allegedly violated. Although the complaint would be stronger with such detail, we do not believe the absence of those details shows a failure to comply with Rule 8 of the Federal Rules of Civil Procedure or can support a dismissal under Rule 12(b)(6). First, Rule 9(b) does not impose any special requirement that such a claim be pled with particularity, as it does for fraud claims, for example.

Second, the victim of a genuinely defective product—for example, an air bag that fails to inflate in a serious automobile collision, or an implantable cardiac defibrillator that delivers powerful electric shocks to a heart that is functioning normally—may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem. It is common, for example, for injured plaintiffs to plead both defective manufacture and defective design and to pursue discovery on both theories, as occurred in *Riegel* itself, for example. 552 U.S. at 320-21; accord, *e.g.*,

No. 09-3434

27

Gardner v. Tristar Sporting Arms, Ltd., 2010 WL 3724190 (S.D. Ind. Sept. 15, 2010) (granting summary judgment for defendant on design defect claim but denying summary judgment on manufacturing defect claim); *Show v. Ford Motor Co.*, 697 F. Supp. 2d 975 (N.D. Ill. 2010) (granting summary judgment for defendant on both design defect and manufacturing defect claims); *Gaskin v. Sharp Electronics Corp.*, 2007 WL 2819660 (N.D. Ind. Sept. 26, 2007) (granting summary judgment for defendant on design defect claim but denying summary judgment on manufacturing defect claim); *In re Air Crash Disaster at Sioux City, Iowa*, 781 F. Supp. 1307 (N.D. Ill. 1991) (in airliner crash case, denying motions for summary judgment for defendants on plaintiffs' claims of manufacturing and design defects against different defendants); see generally, e.g., *Bennett v. Schmidt*, 153 F.3d 516, 519 (7th Cir. 1998) ("Litigants are entitled to discovery before being put to their proof").

Third, in the context of Class III medical devices, much of the critical information is kept confidential as a matter of federal law. The specifications of the FDA's premarket approval documents, for example, are confidential, and there is no public access to complete versions of these documents. An injured patient cannot gain access to that information without discovery. See 21 C.F.R. § 814.9; *Medtronic Leads*, 623 F.3d at 1211, n. 7 (Melloy, J., dissenting). If the problem turns out to be a design feature that the FDA approved, section 360k will protect the manufacturer. *Riegel*, 552 U.S. at 330. But if the problem turns out to be a failure to comply with the FDA's legally enforceable conditions for approval

of the device, section 360k will not protect the manufacturer.

As noted earlier, one of the only two other circuits to examine the application of *Riegel* to medical device preemption is the Eighth Circuit in *Medtronic Leads*, where the majority concluded that the plaintiffs had waived discovery early in the proceedings. The majority upheld the district court's refusal to grant the plaintiffs discovery to respond to the motion to dismiss. There the court acknowledged the plaintiffs' argument that the district court held them to an "impossible pleading standard" because the FDA's premarket approval application was accessible only to the FDA and the manufacturer. The court found that "this argument—which focuses on the timing of the preemption ruling—would have considerable force in a case where a specific defective Class III device injured a consumer, and the plaintiff did not have access to the specific federal requirements in the [premarket approval application] prior to commencing the lawsuit." *Medtronic Leads*, 623 F.3d at 1206. That is exactly the situation in this case. Here, there has not yet been an opportunity for discovery, and Bausch never waived discovery. For her to plead with any more detail that her claims were "based entirely on a specific defect in the Trident that existed outside the knowledge and regulations of the FDA," she would need access to the confidential materials in the premarket approval application setting forth the medical device's specifications. This is simply not possible without discovery. It is also unreasonable to expect that Bausch could have pled more specifically without access to the

No. 09-3434

29

failed Trident itself, but accessing the Trident outside of a discovery process would risk charges of spoliation of evidence, as Bausch's counsel acknowledged at oral argument. As Judge Melloy noted in *Medtronic Leads*: "If plaintiffs must allege that the defendant violated a particular FDA-approved specification before discovery, then it is difficult to appreciate how any plaintiff will ever be able to defeat a Rule 12(b)(6) motion." *Id.* at 1212 (Melloy, J., dissenting). We think Judge Melloy said it well in suggesting that, in analyzing the sufficiency of pleadings, "a plaintiff's pleading burden should be commensurate with the amount of information available to them." *Id.* Here, Bausch pled sufficiently given the amount of information to which she had access.

B. *The Proposed Amended Complaint*

We turn to a final procedural problem with the district court's handling of this case. Plaintiff Bausch, in her brief opposing dismissal of her original complaint, asked the district court for an opportunity to file an amended complaint in the event the court found a deficiency in the original complaint. The district court granted the defendants' motion to dismiss under Rule 12(b)(6), dismissed the original complaint with prejudice, and entered a final judgment in favor of defendants. The district court did not address the plaintiff's request for leave to file an amended complaint. Plaintiff then filed a motion to alter the judgment under Rule 59 and submitted with the motion a proposed amended complaint. The proposed amended complaint clarified (unneces-

sarily) that the plaintiff sought relief solely on a theory that the defendants had violated federal law. The proposed amended complaint also included additional factual detail, particularly about the FDA's notice to defendants that their Trident products were adulterated as a result of problems in the manufacturing process. We review the district court's denial of a request to vacate the judgment and for leave to file an amended complaint under an abuse of discretion standard. *Foster v. DeLuca*, 545 F.3d 582, 583 (7th Cir. 2008).

The defendants led the district court into a procedural sidetrack that began with defendants' decision to move for dismissal under Rule 12(b)(6) rather than filing an answer to plead preemption as an affirmative defense and moving for judgment on the pleadings under Rule 12(c). Preemption is an affirmative defense, *e.g.*, *Fifth Third Bank v. CSX Corp.*, 415 F.3d 741, 745 (7th Cir. 2005), and pleadings need not anticipate or attempt to circumvent affirmative defenses. *Gomez v. Toledo*, 446 U.S. 635, 640 (1980) (concluding that there was no basis for imposing on plaintiff the burden to anticipate an affirmative defense); *Doe v. GTE Corp.*, 347 F.3d 655, 657 (7th Cir. 2003) ("Affirmative defenses do not justify dismissal under 12(b)(6)"); Fed. R. Civ. P. 8(c) ("in responding to a pleading, a party must affirmatively state any avoidance or affirmative defense"). If the defense had been properly presented under Rule 12(c), and if the district court had adhered to its erroneous view of preemption, then the proposed amended complaint would have seemed futile, but, having been presented with an affirmative defense, the plaintiff was entitled to try to cure the problem through an amended complaint.

No. 09-3434

31

As the case was briefed, in any event, we find that the denial of leave to amend the complaint was an abuse of discretion for three reasons. First, for reasons explained above, the judge erred when he concluded that the amended complaint was futile on the merits because its claims would still be preempted. Second, the judge concluded that Bausch had earlier failed to file a formal motion for leave to amend, when she requested leave to file an amended complaint in her response to the defendants' motion to dismiss. But a formal motion for leave to amend was not necessary at the Rule 12(b)(6) stage, and the plaintiff was entitled to wait and see if any pleading problems the court might find could be corrected. Finally, the judge concluded that Bausch's request was unduly delayed. We find no merit in the undue-delay rationale. There was no new theory of relief, but only a clarification that Bausch's claims were focused only on violations of federal law, and a showing of additional factual details, especially related to the FDA warning letter.

As a general matter, Rule 15 ordinarily requires that leave to amend be granted at least once when there is a potentially curable problem with the complaint or other pleading. A plaintiff is entitled to amend the complaint once as a matter of right, Fed. R. Civ. P. 15(a), and a court should "freely give leave [for a party to file an amended complaint] when justice so requires." Fed. R. Civ. P. 15(a)(2). A district court may deny leave to file an amended complaint in the case of "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments

previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment." *Airborn Beepers & Video, Inc. v. AT&T Mobility LLC*, 499 F.3d 663, 666 (7th Cir. 2007), quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962). However, while a court may deny a motion for leave to file an amended complaint, such denials are disfavored. As we said in *Foster*, "[d]istrict courts routinely do not terminate a case at the same time that they grant a defendant's motion to dismiss; rather, they generally dismiss the plaintiff's complaint without prejudice and give the plaintiff at least one opportunity to amend her complaint." 545 F.3d at 584. Even if the Bausch court was correct in dismissing with prejudice under *James Cape & Sons Co. v. PCC Const. Co.*, 453 F.3d 396, 400-01 (7th Cir. 2006) (affirming dismissal with prejudice where the losing plaintiff failed to request leave to amend until it was too late, and the district court had no way of knowing what the proposed amended complaint entailed), it was not correct in later refusing to vacate the judgment to provide Bausch leave to amend when, in the absence of undue delay or other fault on her part, Bausch submitted a revised complaint that was not futile.

One objective of Rule 8 is to decide cases fairly on their merits, not to debate finer points of pleading where opponents have fair notice of the claim or defense. See Fed. R. Civ. P. 8(e) ("Pleadings must be construed so as to do justice."). Generally, if a district court dismisses for failure to state a claim, the court should give the party one opportunity to try to cure the problem, even

No. 09-3434

33

if the court is skeptical about the prospects for success. See *Foster*, 545 F.3d at 584.

Conclusion

For the foregoing reasons, we REVERSE the judgment of the district court dismissing Bausch's suit and denying her the opportunity to file an amended complaint, and we REMAND for further proceedings consistent with this opinion.