No. 13-6061

IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

PATRICIA CAPLINGER,

Plaintiff-Appellant,

v.

MEDTRONIC, INC., ET AL.,

Defendants-Appellees.

On Appeal from a Final Judgment of the United States District Court for the Western District of Oklahoma, Hon. Judge Miles-LaGrange

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PETITION FOR REHEARING EN BANC OR REHEARING BY THE PANEL

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INTRODUCTION

Pursuant to Federal Rule of Appellate Procedure 35(b), plaintiff-appellant Patricia Caplinger petitions for rehearing en banc or panel rehearing. This case involves a recurring question of exceptional importance: whether a medical device manufacturer is immune from liability for harms caused by its product when it sells that product for a use never approved by the Food and Drug Administration (FDA) and never found to be safe and effective for that use. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Supreme Court held that state-law claims against a device manufacturer were not preempted where the FDA had not given the device premarket approval. Because FDA approval is specific to the uses considered, *Lohr* applies here. Medtronic's wide promotion of the unapproved use of the device at issue has led to a large number of injuries and lawsuits, and the question whether federal law preempts state-law remedies for injuries caused by that unapproved use arises frequently. The panel's erroneous decision—the first federal appellate decision in the many cases involving this dangerous device—significantly undermines state-law protections that federal law, properly understood, does not preempt.

BACKGROUND

1. Federal Medical Device Regulation

In 1976, Congress enacted the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA), giving the FDA authority to regulate med-

ical devices from elastic bandages to artificial hearts. *See Lohr*, 518 U.S. at 475-76. The MDA divides medical devices into three classes. *See id.* at 476-77. Class I devices are basic items such as bandages, and class II includes devices that are more complex and have greater potential to cause harm if defective or misused, such as hearing aids. Class III devices treat serious medical conditions or pose serious risks of injury to patients. 21 U.S.C. § 360c(a)(1)(C). Like new drugs, new class III devices cannot be marketed without premarket approval (PMA) from the FDA. *See Lohr*, 518 U.S. at 477; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318-19 (2008). The PMA process involves detailed review of a device's safety and efficacy for uses specified by the manufacturer in the PMA application. *See Riegel*, 552 U.S. at 318. PMA represents an FDA finding that the device is safe and effective "under the conditions of use included in the proposed labeling." 21 U.S.C. § 360e(d)(1)(A); *see also id*. § 360e(d)(2)(A), (B) (requiring the FDA to deny approval if a device is not safe and effective for the uses specified in the labeling). PMA is also conditioned on the manufacturer's compliance with ongoing regulatory obligations, including reporting adverse incidents involving the device to the FDA. 21 U.S.C. § 360i(a)(1), (3); 21 C.F.R. § 803.50(a); *see Riegel*, 552 U.S. at 319.

Unlike new class III devices subject to the PMA process, class III devices extant when the MDA was enacted are subject to less stringent standards. Such devices and their "substantial equivalents" are grandfathered, and permission to mar-

ket them is obtained through a truncated review process, the "510(k) process." *See Lohr*, 518 U.S. at 477-79. Section 510(k) review focuses on substantial equivalency, not on examination of a device's safety and efficacy. *Riegel*, 551 U.S. at 322.

Whether a device is introduced through PMA or the 510(k) process, it can be marketed only for the use(s) cleared by the FDA and specified in its labeling. In evaluating a PMA application, the FDA "rel[ies] on the conditions of use included in the proposed labeling," 21 U.S.C. § 360e(d)(1)(A), and it determines the safety and effectiveness of a device "with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device," *id.* § 360c(a)(2)(B). Thus, for example, a manufacturer cannot promote a device approved as a knee implant for use as a hip implant. Although doctors, whom the FDA does not regulate, may put approved devices to unapproved uses, *see id.* § 396, a device *intended by the manufacturer* for an unapproved, "off-label" use is adulterated and misbranded. *Id.* §§ 351(f)(1)(B), 352(f).[1] Marketing adulterated or misbranded products is illegal. 21 U.S.C. § 331(a), (b), (c), (g).

The MDA's express preemption provision, 21 U.S.C. § 360k(a), states:

[1] *See* FDA, *Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009), www.fda.gov/oc/op/goodreprint.html.

> 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.

2. Medtronic's Infuse Bone Graft Device

Infuse is a bio-engineered bone-filling material used in spinal fusion surgery as an alternative to grafting a patient's own bone, typically from the patient's hip. It uses a genetically engineered protein called rhBMP-2 to help fuse vertebrae in the lower (lumbar) spine to treat degenerative disc disease. Appx. 9, ¶ 18.

As a class III medical device, Infuse required PMA, which Medtronic obtained in 2002. *Id*. 10, ¶ 26. The FDA approved Infuse only for surgery in which the surgeon approaches *from the front* (anterior) of the patient, to treat degenerative disc disease in the lower, or lumbar, spine. *Id*. 75, 80. Infuse is not approved for spinal surgery in which the surgeon proceeds through the patient's *back* (posterior). The unapproved use of Infuse for posterior lumbar fusion surgery creates an undue risk of unwanted bone growth, intractable pain, weakness, and foot drop, among other things. *Id*. 6, ¶ 9; 11, ¶ 31.

Medtronic aggressively promoted Infuse for unapproved use in posterior-approach surgeries. As the Department of Justice, the Senate, and a leading journal

of spinal medicine documented, Medtronic's illegal promotion included paying kickbacks and other incentives to physicians to influence clinical studies, prevent publication of adverse events, and encourage the unapproved use. *See generally id.* 12-20, ¶¶ 35-63. Medtronic was a defendant in two lawsuits alleging that it violated the False Claims Act, 31 U.S.C. § 3729, by paying illegal kickbacks to physicians to promote the unapproved use of Infuse, resulting in submission of fraudulent claims to federal healthcare programs. Appx. 13, ¶ 39. In July 2006, Medtronic agreed to pay $40 million to the United States to settle these lawsuits. *Id*. 14, ¶ 42.

Despite the settlement, Medtronic continued to illegally market Infuse for unapproved use in posterior spinal surgery. In 2008, following a Wall Street Journal article about Medtronic's practices (*see* Armstrong & Burton, *Medtronic linked to surgery problems*, Wall St. J., Sept 4. 2008), U.S. Senators expressed concerns about wrongdoing by Medtronic. Appx. 15-17, ¶¶ 48-54. In 2011, the Senate Committee on Finance began a probe into whether Medtronic was misrepresenting adverse events resulting from Infuse and rhBMP-2, as well as whether Medtronic improperly influenced clinical trials and reporting regarding rhBMP-2 by payments to physicians. *Id*. 17, ¶ 55.

In June 2011, The Spine Journal, a leading medical journal, published a special edition addressing serious patient safety and ethical concerns related to the use of Infuse. *Id*. 18, ¶ 58. In an editorial summarizing the journal's findings, five

prominent physicians wrote that Medtronic-sponsored trials and reports were "remarkable for the complete absence of reported rhBMP-2- related clinical adverse events," including adverse back and leg pain events, radiculitis, bone resorption, and implant displacement. *Id*. 19, ¶ 60. They concluded that the trials and reports suffered from idiosyncratic trial design, reporting bias, and peer-review and publication shortfalls. *Id*. According to the journal, industry-sponsored articles reported only successful fusions and low rates of complications, "which led to the 'off-label' use of Infuse" and "may have promoted widespread poorly considered on- and off-label use, eventual life-threatening complications and deaths." *Id*. 19, ¶ 61.

3. Patricia Caplinger's Injuries, the Lawsuit, the District Court's Decision, and the Panel Decision

On August 25, 2010, Patricia Caplinger had surgery to correct a degenerative disc condition. The surgeon used the off-label posterior approach to place the Medtronic Infuse bone graft into the lumbar region of Ms. Caplinger's spine. A Medtronic representative was present and actively involved during the surgery, providing information about the application of Infuse to Ms. Caplinger's surgery. *Id*. 20-21, ¶¶ 64-66. In late 2010, Ms. Caplinger's symptoms returned and worsened. She experienced foot drop in her right leg resulting from exuberant bone growth. In December 2010, the foot drop condition caused a tear of the anterior cruciate ligament in her right knee, requiring surgery in February 2011. Imaging of Ms. Caplinger's lumbar spine confirmed exuberant bone growth caused by the use

of Infuse and requiring revision surgery on September 9, 2011. *Id*. 21, ¶¶ 67-69. Ms. Caplinger continues to suffer exuberant bone growth and resulting pain, weakness, and foot drop, and she will likely require additional surgery. *Id*. 21, ¶ 70.

Ms. Caplinger filed this lawsuit on June 4, 2012. Her amended complaint asserts state-law products-liability claims for failure to warn, design defect, breach of express and implied warranty, negligence, negligent misrepresentation, fraudulent misrepresentation, fraud in the inducement, and constructive fraud. Medtronic moved to dismiss, principally on the ground that Ms. Caplinger's claims are preempted by section 360k(a) of the MDA, which, as explained above, prohibits state laws imposing "requirements" on devices that are "different from, or in addition to" requirements imposed under the MDA. The district court granted the motion to dismiss. Appx. 70. Ms. Caplinger moved for reconsideration or leave to file a second amended complaint. *Id*. 4. The district court denied the motion. Appx. 74.

In a 2-1 decision, a panel of this Court affirmed. The majority held that all of the claims are expressly preempted by the MDA. The majority made clear its confusion about how to apply the Supreme Court's MDA preemption precedents: "How are we to apply all these competing instructions?" (Slip Op. 11); "laying out the rules governing our review is a real struggle in this area" (*id*. (internal quotation marks omitted)). Nonetheless, the majority held that the underlying state-law duties would impose different or additional requirements on the Infuse device in

violation of § 360k(a). Ms. Caplinger had explained that the FDA does not approve devices in a general sense, but for specific uses, and that the FDA had not approved Infuse for posterior-approach surgery. Accordingly, she had explained, the FDA had imposed *no* requirements on Infuse for posterior use, and thus, as in *Lohr*, § 360k(a) did not preempt state-law claims. The majority held, however, that the MDA preempted the claims because the FDA had approved the device for one use, even if not for the use for which Medtronic had marketed it.

Judge Lucero dissented. As he explained, Ms. Caplinger alleged conduct that was both tortious under state law and violative of federal laws that forbid the marketing of misbranded or adulterated medical devices. The majority decision that her claims are preempted thus "is compelled neither by binding precedent nor by the plain text and clear purpose of" the MDA. Slip Op., Dissent at 1.

ARGUMENT

The panel decided an important, recurring legal question inconsistently with Supreme Court case law, the FDA's views, and decisions of other federal appellate courts. The panel's avowed confusion about Supreme Court case law on MDA preemption, Slip Op. 11, shows the need for en banc review to ensure proper application of the law. The result reached by the panel distorts the MDA's preemption provision, § 360k(a), "beyond recognition by transforming its protection for FDA-approved devices that comply with federal law into a grant of civil immunity for

FDA-approved devices that violate federal law." *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 832 (S.D. Ind. 2009).

1. As the United States told the Supreme Court last year, several courts of appeals have erred in addressing preemption in cases involving PMA devices by assuming "that the existence of any device-specific federal requirement has across-the-board preemptive effect, even on a state requirement addressed to a different subject." U.S. Br., *Medtronic, Inc. v. Stengel*, No. 12-1351, at 15 (filed May 2014), available at www.justice.gov/sites/default/files/osg/briefs/2013/01/01/2012-1351.pet.ami.inv.pdf (U.S. Br.). That approach, the government explained, "would be contrary to *Lohr*'s reasoning and FDA's consistent interpretation in its regulations and briefs." *Id*. Yet the majority here took precisely that approach. It focused on the fact that the PMA for Infuse imposed requirements (applicable to the design and disclosures required to market a device for anterior lumbar surgery) and relied on the existence of those requirements as the basis for preemption of state-law claims addressed to a different subject (whether the device was designed defectively for posterior lumbar surgery and whether Medtronic's warnings and representations concerning that different use were tortious under state law). *See* Slip Op. 19 ("[B]y its terms, the statute preempts any effort to use state law to impose a new requirement on a federally approved medical device."). The decision reflects "a mistaken belief that the act of [PMA] itself establishes device-specific require-

ments on all possible subjects, thus preempting additional or different state requirements whatever their subject." U.S. Br. 16.

Under the Supreme Court's decisions in *Lohr* and *Riegel*, the general duties imposed on all manufacturers by the MDA are not preemptive because they are not device-specific. PMA, by contrast, does impose device-specific requirements with respect to design, labeling, and manufacturing, *see Riegel*, 552 U.S. at 323, but only with respect to the authorization PMA grants the manufacturer to market the product for the approved use(s). *See supra* page 3. PMA does not involve a determination as to the device's safety and effectiveness for other uses, and a manufacturer of a PMA device is not permitted to promote the product for other uses. *See* 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A). For that reason, after obtaining PMA for one use of Infuse, Medtronic sought and obtained additional FDA approval to market the product for two other uses—use in specific dental surgeries and tibial fracture repairs. *See* Appx. 11, ¶¶ 27-28. Although the PMA process is demanding—as Medtronic emphasized in its brief (at 5)—Medtronic sought the additional approvals because it could not otherwise legally market Infuse for those uses. And until Medtronic received PMA for them, the FDA had imposed no requirements on Infuse with respect to those uses.

Likewise, because the FDA has not approved Infuse for use in posterior-approach spinal surgery, it has not imposed any requirements on Infuse for that

use. As in *Lohr*, where the FDA had reviewed a pacemaker's substantial equivalence to another device but had *not* reviewed the pacemaker's safety and effectiveness, 518 U.S. at 493, here, the FDA reviewed the safety and effectiveness of Infuse for anterior use but *not* its safety and effectiveness for posterior use. And as *Lohr* holds, the MDA has no preemptive effect as to matters that the FDA did not consider and approve. *See* 518 U.S. at 493-94.

The panel erred by looking to the general holding of *Riegel*—that PMA may form the basis for preemption—without appreciating its factual premise: that PMA is based on the FDA's determination, based on the information set forth in the PMA application for the stated "conditions of use," that the product "provides a reasonable assurance of safety and effectiveness."[2] *Riegel*, 552 U.S. at 322. The MDA does not preempt state requirements "absent a specific federal requirement that reflects the FDA's weighing of competing considerations on the same subject and specific to the device." U.S. Br. 11. Here, Medtronic marketed its product for a non-PMA use, never evaluated by the FDA for safety and effectiveness, and never determined by the FDA to provide a reasonable assurance of safety and effective-

[2] The panel suggests that the facts here are analogous to those in *Riegel* because the doctor in that case used the device off-label. Slip Op. 22. The *Riegel* plaintiffs, however, never claimed that Medtronic *promoted* that unapproved use, and *Riegel* did not address the consequences of such promotion.

ness. *Riegel* no more applies to this situation than to the non-PMA device at issue in *Lohr* or to a device marketed with no approval at all.

2. In addition, the Supreme Court has repeatedly stated that § 360k(a)'s preemption of state requirements that are "different from, or in addition to," federal requirements does not extend to claims seeking to enforce state-law duties that are "equal to, or substantially identical to," or "parallel" to federal requirements. *Lohr*, 518 U.S. at 496-97. The archetype of such a non-preempted claim is one "premised on the violation of FDA regulations." *Riegel*, 552 U.S. at 330. Here, the panel majority again erred, with potentially important impact on future cases.

Because a class III device marketed for an unapproved use is adulterated and misbranded, 21 U.S.C. §§ 351(f)(1)(B), 352(f); *see* FDA, *Guidance for Industry*, *supra* page 3, such marketing is prohibited by federal law, 21 U.S.C. § 331(a), (b), (c), (g). Ms. Caplinger's claims parallel these federal prohibitions. Her claims are not premised on the notion that Medtronic owed her a duty that required something *more* than compliance with the FDA's requirements and restrictions regarding adverse event reporting, off-label marketing, and misbranding. Rather, she claims that exactly the same conduct that violated federal device requirements violated Medtronic's state-law duties—namely, duties not to market a device for a use for which it is unsafe and for which proper warnings have not been provided, and not to conceal information about the risks posed by that use. *See Riegel*, 552 U.S. at

330; *Lohr*, 518 U.S. at 496-97. Although the panel stated that Ms. Caplinger had failed to identify parallel federal and state requirements, Slip. Op. 12-13, her brief did so at length. *See* Opening Br. 32-38 & nn. 9-11. The panel also held that her claims were broader than the federal requirements to the extent that they challenged Medtronic's advertising and representations made to her physician and others. Slip. Op. 13. But the federal prohibition on such off-label promotion parallels the state-law claims that Medtronic's representations were tortious, as the earlier briefing explained in describing the restrictions that the statutory scheme places on promotion for unapproved uses. *See* Opening Br. 8. In any event, state requirements that address matters *not* addressed by federal requirements are not preempted, as the United States has emphasized. *See* U.S. Br. 10.

In holding such parallel claims preempted, the panel decision is inconsistent with decisions of the other federal courts of appeals that have considered MDA preemption since *Riegel*. Those courts have recognized that § 360k(a) does not preempt a state-law duty that parallels a federal duty imposed on PMA products, including duties comparable to the misbranding provisions and marketing restrictions on which Ms. Caplinger relies. *See Stengel v. Medtronic*, 704 F.3d 1224, 1233 (9th Cir. 2013) (no preemption of state-law duty to warn that parallels FDA requirement to report adverse events); *Bass v. Stryker Corp*., 669 F.3d 501, 510 (5th Cir. 2012) (no preemption of state-law duty that parallels FDA good manufac-

turing practices regulations); *Hughes v. Boston Scientific Corp*., 631 F.3d 672, 770-71 (5th Cir. 2011) (no preemption of state-law duty to warn that parallels FDA medical device reporting regulations); *Bausch v. Stryker Corp.*, 630 F.3d 546, 555 (7th Cir. 2010) (no preemption of state-law duty that parallels FDA good manufacturing practices regulations); *Howard v. Sulzer Orthopedics, Inc*., 382 Fed. App'x 436, 441 (6th Cir. 2010) (same).

By contrast, in cases where other courts of appeals have held state-law claims concerning PMA devices preempted, the plaintiffs failed to "set forth any specific problem or failure to comply with any FDA regulation that [could] be linked to the injury alleged." *Wolicki-Gables v. Arrow Int'l, Inc*., 634 F.3d 1296, 1301-02 (11th Cir. 2011). In *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 (8th Cir. 2010), the plaintiffs alleged that the devices at issue were defectively manufactured because Medtronic used a process called spot welding, but they "conceded" that the PMA authorized spot welding. *Id*. at 1207. Thus, "*as pleaded and argued*, the manufacturing defect claims are not parallel, they are a frontal assault on the FDA's decision" to approve the product and authorize use of spot welding. *Id*. Similarly, in *Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. 2012), the plaintiff did not allege a state-law duty that paralleled a federal requirement but instead "contend[ed] that the device should have been designed differently" for the approved use. *Id*. at 580. The device, however, "was

undisputedly designed, manufactured, and distributed in compliance with its FDA premarket approval." *Id*. at 581.

As the Seventh Circuit has explained, "[s]ection 360k(a) 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." *Bausch*, 630 F.3d at 553 (emphasis added). Here, where Medtronic's violations of state-law duties also constitute violations of federal law, § 360k(a) does not preempt Ms. Caplinger's claims. The panel's contrary decision is incorrect.

* * *

The panel's decision reflects acknowledged confusion about the Supreme Court decisions in *Lohr* and *Riegel*, is inconsistent with those decisions and with the decisions of numerous other federal courts of appeals, and addresses an issue raised in a large number of pending cases (because of the large number of patients injured by Infuse). Rehearing en banc is needed to correct the panel's error, resolve the conflict with other appellate decisions, and bring the Court in line with the Supreme Court's decisions and the views of the FDA.

CONCLUSION

For the foregoing reasons, the Court should grant the petition for rehearing en banc or rehearing by the panel.

Respectfully submitted,

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CERTIFICATE OF DIGITAL SUBMISSION

I hereby certify that with respect to the foregoing:

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(2) if required to file additional hard copies, that the ECF submission is an exact copy of those documents;

(3) the digital submission has been scanned for viruses with the current version of VIPRE Business virus scanning program and, according to the program, is free of viruses.

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CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2014, I electronically filed the foregoing Petition for Rehearing En Banc Or Rehearing By the Panel using the CM/ECF system, which will send notification of such filing to counsel for appellee as follows:

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ADDENDUM