In the

United States Court of Appeals

For the Seventh Circuit

No. 04-3678

JACK MCMULLEN and BARBARA MCMULLEN,

Plaintiffs-Appellants,

v.

MEDTRONIC, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of Indiana, Terre Haute Division.
No. 03 C 5—**Larry J. McKinney**, *Chief Judge.*

ARGUED JUNE 10, 2005—DECIDED AUGUST 26, 2005

Before FLAUM, *Chief Judge*, and POSNER and KANNE, *Circuit Judges.*

FLAUM, *Chief Judge.* Plaintiffs-appellants Jack and Barbara McMullen filed suit against defendant-appellee Medtronic, Inc., alleging state-law claims arising out of the implantation of two of Medtronic's Activa Tremor Control Systems ("Activas") in Jack McMullen's brain. The district court granted summary judgment in favor of Medtronic on the ground that the McMullens' claims are preempted by federal requirements imposed by the Food and Drug Administration ("FDA") pursuant to the Medical Device Amendments ("MDA"), 90 Stat. 539, to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*

The McMullens appeal, and for the reasons stated herein, we affirm.

I. Background

The Medtronic Activa is classified under the MDA as a Class III medical device, which means that it "is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or . . . presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii). Before a Class III device may be introduced into the market, the manufacturer must provide the FDA with a "'reasonable assurance' that the device is both safe and effective." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996) (quoting § 360e(d)(2)). The process by which the FDA decides whether a manufacturer has provided a "reasonable assurance," known as the "premarket approval" or "PMA" process, is a rigorous one. *Id.* Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA thoroughly reviews. *Id.* Approval by the FDA may constitute acceptance of such things as the product's design, testing, intended use, manufacturing methods, performance standards, and labeling. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997).

In 1997, following a full PMA review, the FDA approved Medtronic's Activa for use in the suppression of tremors in patients diagnosed with Parkinson's Disease. The Activa is composed of three parts: the implantable pulse generator ("IPG"), which is the power source; the lead, which is a thin insulated wire with a series of tiny electrodes at one end; and the extension, which connects the IPG to the lead. Electrical impulses are conveyed through the device, electrically stimulating areas of the brain that control

movement and muscle function.

Pursuant to its approval, the FDA required Medtronic to track the name and contact information of patients implanted with the Activa. The FDA also required Medtronic to list specific warnings regarding "electrocautery" and "diathermy"[1] in its manuals for physicians and patients. The patient manual was required to state:

> Tell your dentist where your IPG is implanted, so he or she can take precautions with dental drills and ultrasonic probes used to clean your teeth. These devices should not be used directly over the implant site.
>
> Therapeutic ultrasound, electrolysis, radiation therapy, and electrocautery also should not be used directly over the implant site.
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> * * *
>
> Diathermy treatments that are sometimes used for muscle relaxation may affect the neurostimulator output and/or damage its electronics.

In May 2000, Jack McMullen, who has been experiencing the symptoms of Parkinson's Disease since 1985, was implanted with two Activas, one on each side of his brain.[2]

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[1] While neither party provided precise definitions of these terms, it appears that "electrocautery" is the burning or searing of tissue by means of an electrically heated instrument, and "diathermy" is therapeutic local heating by means of passing electric currents through tissue. The distinction between the two procedures is not important for the purposes of this case.

[2] Before the district court, McMullen argued that he was not implanted with an Activa, but instead with a different Medtronic (continued...)

As a result of the bilateral stimulation, McMullen experienced an excellent remediation of his Parkinson's symptoms.

In January 2001, Medtronic learned of an anecdotal report involving a 70-year-old Parkinson's patient who had been implanted with an Activa. According to the report, a dentist treated the patient with diathermy following oral surgery. During the procedure, the patient was found unresponsive and it was determined that he was in a coma. The suspected cause was damage to brain tissue surrounding his Activa leads, induced by the diathermy.

About two months later, in March 2001, Jack McMullen underwent a dental procedure, which possibly involved diathermy or electrocautery. Thereafter, McMullen experienced a decline in the control of his Parkinson's symptoms. Despite further surgeries to replace components of the implanted Activas, the reduced symptom control continues to this day. McMullen suspects the cause to be damage to brain tissue surrounding the leads of his Activas.

Following further investigation of the January 2001 anecdotal report, Medtronic sent letters by mail to both physicians and patients in May 2001. Medtronic's patient letter stated:

> CONTRAINDICATION: Inform anyone treating you that you CANNOT have any

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[2] (...continued)
device called the Activa Parkinson's Control Therapy, which had not yet received FDA approval. The district court concluded that the record could not support this assertion. On appeal, McMullen still hints that he was not implanted with an Activa, but does not challenge the district court's conclusion directly. Accordingly, any arguments based on this factual assertion have been forfeited. *See Tyler v. Runyon*, 70 F.3d 458, 464-65 (7th Cir. 1995).

> shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) anywhere on your body because you have an implanted neurostimulation system. Energy from diathermy can be transferred through your implanted system, can cause tissue damage and can result in severe injury or death.
>
> Diathermy can also damage parts of your neurostimulation system. This can result in loss of therapy from your neurostimulation system, and may require additional surgery to remove or replace parts of your implanted device. Injury or damage can occur during diathermy treatment whether your neurostimulation system is turned "on" or "off."

To make changes affecting the safety or effectiveness of a device that has gone through the PMA process, a manufacturer must submit a PMA Supplement for review and approval by the FDA. *See* 21 C.F.R. § 814.39(a). Medtronic submitted a PMA Supplement, seeking FDA approval to market the Activa with a new, stronger warning, like that which was provided in the May 2001 patient letter. In June 2001, three months after McMullen's injury, the FDA approved the use of the new warning.

Thereafter, Jack McMullen and his wife, Barbara McMullen, filed a complaint in the Vermillion County Indiana Circuit Court alleging that Medtronic breached its post-sale duty to warn of dangers arising from the use of diathermy or electrocautery on a patient implanted with a Medtronic Activa. Specifically, plaintiffs assert that the January 2001 report about the 70-year-old Parkinson's patient triggered Medtronic's duty to immediately issue a new warning directly to patients about the increased risks

of diathermy and electrocautery. The McMullens' complaint alleges that, as a result of the use of the electrical surgical instrument during his dental procedure, Jack McMullen suffered severe brain damage. In addition, Barbara McMullen alleges a derivative claim for loss of consortium.

Medtronic removed the case to the United States District Court for the Southern District of Indiana based on diversity jurisdiction, after which the parties filed cross-motions for summary judgment. Medtronic argued that plaintiffs' claims were preempted under the express preemption clause of the MDA and, in the alternative, that it was entitled to judgment as a matter of law on the merits of the McMullens' claims. The McMullens disputed Medtronic's claim of preemption and argued that the uncontroverted facts demonstrated that they were entitled to judgment as a matter of law on both of their claims.

The district court granted Medtronic's motion, holding that the post-sale failure to warn claim is preempted and that the derivative loss of consortium claim falls with it. The McMullens appeal, asking us to reverse the district court and direct it to enter summary judgment in their favor.

II. Discussion

We review the district court's grant of summary judgment de novo, viewing all facts and drawing all reasonable inferences in the non-moving party's favor. *Eisencorp, Inc. v. Rocky Mountain Radar, Inc.*, 398 F.3d 962, 965 (7th Cir. 2005). Summary judgment is appropriate if the evidence presented by the parties "show[s] that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 569(c).

At issue in this case is whether Jack McMullen's common-

law claim against Medtronic for post-sale failure to warn is preempted by federal law. The principle of preemption arises from the Supremacy Clause of the Constitution which states that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI. "Pursuant to this authority, Congress may preempt state law." *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1246 (7th Cir. 1997). "A federal law may preempt a state law expressly, impliedly through the doctrine of conflict preemption, or through the doctrine of field (also known as complete) preemption." *Boomer v. AT&T Corp.*, 309 F.3d 404, 417 (7th Cir. 2002); *see also Hoagland v. Town of Clear Lake, Ind.*, 415 F.3d 693 (7th Cir. 2005). The MDA contains an express preemption provision, under which, as we explain below, the state law that is the basis for McMullen's claim is expressly preempted. Accordingly, we do not address the doctrines of conflict and field preemption.

The MDA's preemption clause provides in relevant part:

> [N]o 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). This provision sets three conditions for preemption: (1) there must be a "requirement" that a state "establish[es] or continue[s] in effect, with respect to a device intended for human use"; (2) there must be a rele-

vant federal requirement under the FDCA applicable to the device at issue; and (3) the state "requirement" must be "different from, or in addition to," the federal requirement. *See id.*

Here, the parties agree that the first condition is satisfied. McMullen states that his post-sale failure-to-warn claim arises either under the law of Indiana, where the injury occurred, or under the law of Minnesota, where Medtronic's headquarters are located. We need not decide which law governs or the scope of the applicable common-law duty. It is enough to note that any state requirement that would provide a basis for McMullen's claim must have imposed on Medtronic a duty to provide an additional warning between January 2001, when Medtronic learned of the anecdotal report, and March 2001, when McMullen underwent the dental procedure and was injured. For the purposes of our preemption inquiry, we may assume that there is such a state-law duty and that McMullen's claim would be viable if not preempted. To the extent this duty exists and could be a basis for a verdict in favor of McMullen, it establishes a "requirement" with respect to the Medtronic Activa, a device intended for human use, and thus satisfies the first condition of preemption. *See Mitchell*, 126 F.3d at 910 (common-law causes of action may be "requirements" as the term is used in § 360k(a)); *see also Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 867 (2000) (noting that a majority of the Supreme Court in *Lohr* agreed that common-law tort actions may be preempted under the MDA's preemption clause); *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1798 (2005) (holding that the term "requirements" in the preemption clause of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") "reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties").

There also is no dispute as to the second condition. To have preemptive effect under § 360k(a), a federal require-

ment must be specific to a particular device and relevant to the conduct that is the subject of the state requirement at issue. *Mitchell*, 126 F.3d at 910 (citing *Lohr*, 518 U.S. at 500-01). We have held that federal requirements specific to individual products are imposed through the PMA process. *Id*. at 911. Here, there were specific federal requirements as to the warnings given both before and after implantation of the Medtronic Activa. For example, the FDA approved and required the precise language of the diathermy/electrocautery warning given to McMullen, and, in its PMA approval letter, the FDA directed Medtronic to track all Activa recipients. Medtronic also had a continuing obligation to report to the FDA any adverse events which would reasonably suggest that the device caused or contributed to a death or serious injury. *See* 21 U.S.C. § 360i; 21 C.F.R. §§ 803.10(c), 803.50. If Medtronic believed that a warning different from the one approved by the FDA was appropriate in light of an adverse event, it was required to seek FDA approval of any proposed changes. *See* 21 C.F.R. § 814.39(a). These are relevant federal requirements limiting Medtronic's conduct as to the warnings it issued to Activa recipients. The second condition of § 360k(a) preemption is satisfied.

As to the third condition, the only one contested in this case, we must ask whether the state common-law duty underlying McMullen's claim would impose a requirement that is "different from, or in addition to," the relevant federal requirements. A claim that a manufacturer failed to provide an adequate warning at the time of sale would be based on the assertion that the manufacturer should have provided a different warning than the one approved by the FDA. Such a state-law claim would impose a requirement that was different from, or in addition to, the applicable federal requirements and would be preempted. *Cf. Mitchell*, 126 F.3d at 913-14 (time-of-sale mislabeling claim preempted); *accord Horn v. Thoratec Corp.*, 376 F.3d 163, 177

(3d Cir. 2004) (time-of-sale failure-to-warn claim pre-empted); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 796-98 (8th Cir. 2001) (en banc) (same); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir. 2001) (same); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir. 2000) (same); *Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997) (same); *but see Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1374-78 (11th Cir. 1999) (no preemption of common-law claims involving PMA-approved devices); *Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997) (no preemption of common-law claims where device undergoes the less rigorous "Investigational Device Exception" process).

McMullen, however, does not take issue with Medtronic's original warning. Rather, he claims that Medtronic violated a *post-sale* duty to warn, under which it was required to provide an additional warning in light of the January 2001 anecdotal report. Medtronic distributed just such an additional warning in May 2001, but McMullen contends that this was too late. He argues that Medtronic was obligated, under parallel state and federal laws, to send a "timely" additional warning, which he defines as one delivered sometime before his dental appointment in March 2001. If he is correct that there are both state and federal requirements to this effect, then the state requirements will not be different from, or in addition to, the federal requirements and McMullen's claim will not be preempted pursuant to § 360k(a). *See Mitchell*, 126 F.3d at 909 ("[T]o the extent a common law action mirrors the FDA regulations, it would not be preempted."); *Lohr*, 518 U.S. at 495 ("Nothing in § 360k denies [states] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."); *see also Bates*, 125 S. Ct. at 1800-01 (relying on *Lohr* in holding that the phrase "in addition to or different from" in the FIFRA's preemption clause does not preclude states from providing

remedies for violations of FIFRA's requirements). In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are "*genuinely* equivalent." *Bates*, 125 S. Ct. at 1804 (emphasis in original). State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law. *See id.*

McMullen points to two federal regulations as the basis for his contention that federal law creates a duty that is equivalent to the state-law duty underlying his claim: 21 C.F.R. § 821.1, which requires manufacturers to track recipients of devices; and § 814.39, which permits manufacturers to enhance warnings pending approval of a proposed change to an earlier-approved warning. Contrary to McMullen's contention, however, neither of these regulations, considered alone or together, imposed upon Medtronic a duty to issue an additional warning between January and March 2001.

Section 821.1 states that "[e]ffective tracking of devices from the manufacturing facility . . . to the patient is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act) or device recall (section 518(e) of the act)." Sections 518(a) and (e) of the MDA, codified at 21 U.S.C. §§ 360h(a) and (e), give the Secretary of Health and Human Services the discretion to issue or withhold warnings concerning medical devices based on the Secretary's assessment of the risks, and to issue recall orders "[i]f the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death." Thus, the required tracking enables warnings to be issued and devices to be recalled if the Secretary decides that it is appropriate to do so. It does not impose on the manufacturer the obligation to make warning or recall decisions unilaterally, nor does it authorize the manufacturer to do

so.

Section 814.39 permits a manufacturer to temporarily amend a warning pending FDA approval of the proposed changes. Once a temporarily amended warning has been approved, modified, or denied, the manufacturer must comply with the FDA's decision. *See Brooks*, 273 F.3d at 796. McMullen discusses at length the fact that Medtronic was "allowed" and "permitted" to issue an interim safety alert while awaiting approval of its amended warning. He argues that state common law requiring a post-sale warning merely "complements" the federal policy of allowing such warnings, and thus is not preempted. Recall, however, that the MDA's preemption clause provides that state requirements that are "in addition to" federal requirements are preempted. 21 U.S.C. § 360k(a). 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. Because § 814.39 permits, but does not require, a manufacturer to provide interim supplemental warnings pending approval by the FDA, a common-law duty to provide such a warning imposes an additional obligation.[3] Neither § 821.1 nor § 814.39 imposed on Medtronic a duty "genuinely equivalent" to the state common-law duty to provide an additional warning to McMullen between January and March 2001.

Because McMullen's claim based on the common-law post-sale duty to warn would impose on Medtronic a requirement that is in addition to federal requirements, we hold that the claim is preempted pursuant to 21 U.S.C.

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[3] McMullen cites to an FDA letter of opinion stating that manufacturers are "urge[d]. . . to initiate a voluntary removal or correction of marketed violative products." An agency's urging, however, does not change a permissive provision into a mandatory one.

§ 360k(a), and that the district court correctly granted summary judgment in favor of Medtronic. *Accord Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424-25 (6th Cir. 2005) (holding that common-law post-sale duty to warn claim was preempted by requirements imposed through the PMA process). Accordingly, it also was proper for the district court to grant summary judgment in favor of Medtronic on Barbara McMullen's derivative claim for loss of consortium. *See Chambers*, 109 F.3d at 1244-45; *Mitchell*, 126 F.3d at 906; *accord Kemp*, 231 F.3d at 237. We need not reach the parties' arguments regarding possible alternative grounds for summary judgment.

III. Conclusion

The district court's entry of summary judgment in favor of Medtronic is AFFIRMED.

A true Copy:

Teste:

Clerk of the United States Court of Appeals for the Seventh Circuit