PUBLISH

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 97-5801

D. C. Docket No. 97-6133-CIV

LISA GOODLIN,

Plaintiff-Appellant,

versus

MEDTRONIC, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of Florida

(February 18, 1999)

Before TJOFLAT and EDMONDSON, Circuit Judges, and KRAVITCH, Senior Circuit Judge.

KRAVITCH, Senior Circuit Judge:

This appeal requires us to determine the preemptive effect of the Medical Device Amendments ("MDA"), 21 U.S.C. § 360c et seq., to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq. Lisa Goodlin brought suit against Medtronic, Inc. ("Medtronic"), alleging that her Medtronic cardiac pacemaker lead was defective in a way that gave rise to two causes of action under Florida common law. Medtronic argues that because the United States Food and Drug Administration (the "FDA") approved the device pursuant to the MDA's premarket approval process, section 360k(a) of the MDA preempts Goodlin's state law claims. The district court agreed and granted summary judgment to Medtronic. We reverse.

BACKGROUND

In January 1991, Goodlin received a Medtronic pacemaker and its related components, including Medtronic's 4004/M lead. The pacemaker lead is a wire that transmits the heartbeat-steadying electrical impulse from the pulse generator to the heart. Goodlin depends on the pacemaker to support her life.

The FDA approved Medtronic's 4004/M lead for use in the United States on February 10, 1989. Sometime after Goodlin received her pacemaker, however, an FDA inspection revealed a significant risk that the 4004/M lead would fail due to degradation of the lead's polyurethane insulating material. The FDA, therefore, instructed Medtronic to issue a Health Safety Alert letter to inform

physicians about the risk of defect in the lead. The letter advised physicians to consider prophylactic replacement for pacemaker dependent patients and advised them to replace the lead if the risk of its continued use outweighed the risks associated with its replacement. Upon the advice of her physician, Goodlin underwent open-heart surgery to replace the lead. The lead that the surgeons removed from Goodlin showed no signs of failure.

Goodlin brought suit against Medtronic in 1997. Her amended complaint asserts claims for negligent design and strict product liability, both of which arise under Florida common law. Medtronic moved for summary judgment on the basis of federal preemption, arguing that section 360k(a) of the MDA expressly preempted Goodlin's claims. The district court found that because the FDA had reviewed and approved the safety and effectiveness of the 4004/M device pursuant to its premarket approval process, the MDA preempted Goodlin's claims. The court, therefore, entered summary judgment in Medtronic's favor. We review the district court's decision to grant summary judgment on the issue of preemption de novo and apply the same standards that bound the district court. See Lewis v. Brunswick Corp., 107 F.3d 1494, 1498 (11th Cir.), cert. granted, __ U.S. __, 118 S. Ct. 439 (1997), cert. dismissed, __ U.S. __, 118 S. Ct. 1739 (1998).

DISCUSSION

I. Regulatory Overview

Despite the historical prominence of the states in matters concerning the health and safety of their citizens, the federal government has expanded its role in this field over the past century. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 475, 116 S. Ct. 2240, 2245-56 (1996) (providing a survey of the federal government's legislation in this area). In the 1970s, against the backdrop of several highly publicized events involving defective medical devices, including the tragedies connected to the Dalkon Shield intrauterine device, Congress turned its attention to the regulation of medical devices. Id. at 476, 116 S. Ct. at 2246. In 1976, Congress passed the MDA, the statute at issue here, which categorizes medical devices according to the risk they pose to the public. The MDA classifies devices that either "present a potential unreasonable risk of illness or injury" or that are "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" as Class III devices. Id. at 477, 116 S. Ct. at 2246 (quoting 21 U.S.C. § 360c(a)(1)(C))(internal quotation omitted). Pacemakers, such as the one at issue here, are Class III devices. See 21 C.F.R. § 870.3610(b).

A. The Premarket Approval Process

Before a manufacturer can introduce a new Class III medical device into the marketplace, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. 21 U.S.C. § 360c(a)(1)(C). Manufacturers may furnish this assurance through the FDA's premarket approval process, commonly referred to as the "PMA" process.[1] As the Supreme Court observed in Lohr, and as Medtronic has reminded us in its briefs, the PMA process is rigorous because it permits the FDA to demand the submission of detailed information regarding the safety and effectiveness of the device under review.[2] See 21 U.S.C. §

[1] The MDA permits manufacturers to avoid the PMA process by obtaining approval for devices introduced to the market before May 28, 1976, when the MDA took effect. See 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1). A manufacturer may also seek approval of a new device by showing that the new device is the "substantial equivalent" of such a grandfathered device. See 21 U.S.C. § 360e(b)(1)(B)(ii). The FDA's review for substantial equivalence, dubbed the "510k process" in reference to its section number in the original Act, is limited in scope. Instead of the extensive inquiry into safety and effectiveness contemplated in the PMA process, the FDA completes the average 510k review within 20 hours, and the agency considers only whether the device is indeed the equivalent of a preexisting device—regardless of how unsafe or ineffective the grandfathered device happens to be. See generally Lohr, 518 U.S. at 478-80, 116 S. Ct. at 2247-48 (comparing these two processes). Not surprisingly, the PMA process represents a much more significant financial barrier to the market ($111,000 to $828,000 per device) than the 510k process ($50 to $2,000 per device). See Lohr v. Medtronic, Inc., 56 F.3d 1335, 1345 n.14 (11th Cir. 1995)(citation omitted), aff'd in part & rev'd in part, 518 U.S. 470, 116 S. Ct. 2240 (1996).

[2] The FDA also regulates the testing of these devices by requiring manufacturers to apply for an Investigational Device Exemption ("IDE"). The application for an IDE is itself fairly extensive, and the FDA will not approve an IDE if there is reason

360e(c)(1) (describing the required contents of a PMA application). The FDA then spends substantial time and resources reviewing these applications; indeed, the average submission requires 1,200 hours of review. See Lohr, 518 U.S. at 477, 116 S. Ct. at 2246-47. Ordinarily, the FDA refers the device to an independent panel of experts, which prepares a report and recommendation on whether to approve the device. See 21 U.S.C. § 360e(c)(2). The FDA may also advise an applicant of deficiencies in the PMA application and notify the applicant of any measures necessary to put the application in approvable form. Id. § 360e(d)(2). Once the FDA determines that the manufacturer has provided the required reasonable assurances, the agency issues an order that permits the manufacturer to market the device, exactly as approved. Thereafter, the manufacturer may not change the approved labeling, product design, or manufacturing process in any way that would affect the safety or effectiveness of the device. See 21 C.F.R. § 814.80. The FDA may withdraw its marketing approval if the manufacturer makes any such changes without prior approval. See 21 U.S.C. § 360e(e)(1); 21 C.F.R. § 814.46(a)(2).[3]

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to believe the device will be ineffective or present unreasonable safety risks to patients. See 21 C.F.R. § 812.30(b)(4).

[3] For a detailed description of the PMA process, see Worthy v. Collagen Corp., 967 S.W.2d 360, 363-64 (Tex.), cert. denied, __ U.S. __, 118 S.Ct. 2372 (1998).

B. The PMA Process for the 4004/M Lead

The PMA process preceding the FDA's approval of Medtronic's 4004/M pacemaker lead was an extensive one. In 1982, the FDA approved Medtronic's application for an IDE to conduct clinical tests on a predecessor lead, the Model 4003 lead; Medtronic submitted the results of those trials to the FDA when it filed a PMA application for the Model 4003. During that process, the FDA asked Medtronic to submit information that addressed the effect of long-term degradation of the insulating materials on the Model 4003 lead. In February 1984, Medtronic responded with studies and reports that revealed that some of the leads experienced environmental stress cracking failures but supported Medtronic's view that Pellethane 80-A polyurethane, the Model 4003 lead's insulating material, was biostable and suitable for long-term implants. The FDA requested still further tests involving the performance of similar leads with identical insulation materials and referred the Model 4003 application to an outside panel of experts, which concluded that Medtronic had provided the requisite reasonable assurances of safety and effectiveness. The FDA approved the Model 4003 PMA application on July 29, 1986.

On July 15, 1988, Medtronic filed a PMA application for the 4004/M as a supplement to the Model 4003 PMA application. The supplemental PMA application relied on the information that Medtronic already had submitted to the FDA and identified the

lead's insulating material as Pellethane 80-A. The supplemental PMA application also described Medtronic's research and testing on environmental stress cracking and metal-induced oxidation, both known as potential causes of defects in leads that used polyurethane insulating material. On February 10, 1989, the FDA approved the supplemental application for the 4004/M with an order that included a list of "Conditions of Approval." Medtronic now seeks to use the FDA's approval to preempt Goodlin's claims concerning the 4004/M lead.

II. Preemption Under the MDA

By virtue of the Constitution's Supremacy Clause,[4] it long has been settled that "state law that conflicts with federal law is 'without effect.'" Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516, 112 S. Ct. 2608, 2617 (1992) (quoting Maryland v. Louisiana, 451 U.S. 725, 746, 101 S. Ct. 2114, 2128 (1981) and citing M'Culloch v. Maryland, 17 U.S. (4 Wheat.) 316, 427 (1819)). A federal statute may preempt state law either expressly, by the statute's language, or implicitly, by the statute's structure and purpose. Id., 112 S. Ct. at 2617. In the absence of an express command, federal law will preempt state law if that law actually conflicts with federal law or if the federal law "so thoroughly

[4] The Supremacy Clause provides that: "the Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const., art. VI, cl. 2.

occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it." Id., 112 S. Ct. at 2617 (internal quotations and citations omitted).[5]

The MDA contains an express provision that governs the extent to which the federal statute preempts state law:

> (a) General rule
>
> Except as provided in subsection (b) of this section,[6] no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The Supreme Court attempted to elucidate the extent to which section 360k(a) preempts product liability suits arising under state law in Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S. Ct. 2240 (1996), which involved a different allegedly defective Medtronic pacemaker lead. Despite the striking superficial similarity of the cases, the Supreme Court's

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[5] This latter form falls under the general heading of implied preemption. See generally Irving v. Mazda Motor Corp., 136 F.3d 764 (11th Cir.), cert. denied, __ U.S. __, 119 S. Ct. 544 (1998) (describing and applying the different forms of preemption). Although Medtronic has raised an implied preemption argument, we find it to be without merit.

[6] Subsection (b) provides a means for a state or political subdivision thereof to apply for an exemption to preemption when compelling local conditions require a more stringent requirement. See 21 U.S.C. § 360k(b).

disposition of Lohr provides little more than a rudimentary analytical framework to guide our resolution of Medtronic's preemption claims in this case because Lohr involved the 510k process rather than the PMA process, and because the Court fractured in an all but irreconcilable manner over the extent to which section 360k(a) would ever preempt a general state common law tort claim. See Mitchell v. Collagen Corp., 126 F.3d 902, 910 (7th Cir. 1997), cert. denied, __ U.S. __, 118 S. Ct. 1300 (1998).[7]

Nevertheless, the Lohr Court instructed that two broad "presumptions about the nature of pre-emption" inform the interpretation of section 360k(a). Lohr, 518 U.S. at 485, 116 S. Ct. at 2250. First, the Court explained that deference to state sovereignty, particularly in fields that the state governments

[7] The Lohr Court split 4-4 over whether a jury's imposition of liability in a product liability suit pursuant to state common law tort duties would ever amount to a conflicting state requirement subject to federal preemption. Justice Breyer provided the fifth vote necessary to support the Court's holding that none of the Lohrs' claims were preempted but asserted that he agreed with Justice O'Connor's dissenting opinion on the extent to which more appropriate FDA requirements might preempt state law claims. See Lohr, 518 U.S. at 503, 116 S. Ct. at 2259 (Breyer, J., concurring). A number of courts have parsed these opinions and the actual votes only to arrive at conflicting positions. Compare Mitchell, 126 F.3d at 912 (noting that it would have made little sense for Justice Breyer to write separately if he agreed that most state tort claims were not preempted) with Oja v. Howmedica, Inc., 111 F.3d 782, 789 (10th Cir. 1997) (finding no preemption of a general state common law tort claim by relying on Justice Breyer's vote to concur in the judgment and ignoring the reasoning of his concurring opinion). Fortunately, we need not enter that particular fray because we can resolve this case on the basis of the federal requirement alone.

traditionally have occupied, requires an assumption that Congress will not supersede "the historic police powers" of the states by federal statute without making that purpose "clear and manifest." Id., 116 S. Ct. at 2250 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230, 67 S. Ct. 1146, 1152 (1947)). Second, the Court cautioned that "'[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case." Id., 116 S. Ct. at 2250 (quoting Retail Clerks Int'l Ass'n Local 1625 v. Schermerhorn, 375 U.S. 96, 103, 84 S. Ct. 219, 223 (1963)). The MDA's preemption provision and its surrounding statutory framework, therefore, provide our primary guide for discerning Congressional intent regarding the scope of preemption, but we must also examine the "structure and purpose of the statute as a whole" by reviewing the "way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." Id. at 486, 116 S. Ct. at 2251 (internal quotation omitted).

In considering whether the MDA accords a federal obligation preemptive effect, the Lohr Court read section 360k(a) to demand three things: (1) the imposition of a specific federal requirement that (2) applied to a particular device and (3) focused on the safety and effectiveness of the device. The Court held that the 510k process did not satisfy the preemption provision, in large part, because the FDA's review addressed substantial equivalence rather than safety and effectiveness. Id. at 492-94, 116 S. Ct. at

2254-55. The PMA process at issue in the case before us addresses safety and effectiveness; indeed, the entire purpose of the PMA process is for the FDA to obtain a "reasonable assurance" that the device is safe and effective. See 21 U.S.C. § 360c(a)(1)(C). Accordingly, we now turn to the question of whether the PMA process satisfies section 360k(a)'s two other conditions by imposing any specific federal requirement on a particular device.

In addressing the federal requirement condition of section 360k(a)(1), the Lohr Court sought guidance from an FDA regulation interpreting the preemption provision. The Court noted that the language of section 360k(a) was unclear and that Congress expressly had given the FDA authority to assess the preemptive effect of its own requirements on state laws. Id. at 495-96, 116 S. Ct. at 2255-56 (relying on 21 U.S.C. §§ 371(a) & 360k(b)). Although the Court may have avoided the question of whether the FDA's regulations were due any deference under Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 104 S. Ct. 2778 (1984), cf. Lohr, 518 U.S. at 511-12, 116 S. Ct. at 2263 (O'Connor, J., concurring in part and dissenting in part), five Justices agreed that the FDA's "view of the statute" was entitled to "substantial weight." Id. at 496, 116 S. Ct. at 2256; see id. at 505-07, 116 S. Ct. at 2260-61 (Breyer, J., concurring). The FDA's regulation interpreting section 360k, issued in 1978, advises that:

> State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or

> there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.

21 C.F.R. § 808.1(d).

Considered together, section 360k(a)(1) grants preemptive effect to any federal "requirement applicable under this chapter to the device," and the FDA regulation reads that language to include only "specific counterpart regulations" or "specific requirements" that apply to "a particular device." 21 C.F.R. § 808.1(d). Accordingly, to prevail on its preemption argument in this case, Medtronic must identify a specific federal requirement imposed on its particular device that would preempt any conflicting or additional state requirement inherent in a jury verdict in Goodlin's favor. Medtronic argues that the FDA's approval of its 4004/M lead, which required the FDA to find that Medtronic had provided a reasonable assurance of the device's safety and effectiveness, amounts to the imposition of such a requirement. Medtronic also cites the FDA's letter of approval and the attached "Conditions of Approval," as well as the FDA's demand that Medtronic not alter the device in any way affecting the safety or effectiveness of the 4004/M lead, as preempting requirements.[8] We

[8] Medtronic also points out that in addition to compelling manufacturers to submit to the PMA process, the MDA and the FDA's regulations specifically require manufacturers to provide substantial relevant information and disclosures. We would have to consider the MDA's provisions calling for PMA review of the

address each argument in turn.

A. PMA Approval

In this court's own review of Lohr, before the Supreme Court considered the case, we voiced substantial doubt that the FDA's 510k approval process, which permits a successful applicant to market its device, imposed a specific requirement upon the device. See Lohr v. Medtronic, Inc., 56 F.3d 1335 (11th Cir. 1995), aff'd in part & rev'd in part, 518 U.S. 470, 116 S. Ct. 2240 (1996). The majority of our discussion in support of our decision to deny the 510k process preemptive effect addressed our primary concern that the process confines the FDA's consideration to substantial equivalence rather than safety and effectiveness. Id. at 1348-49. Nevertheless, we also expressed reservations about whether any finding pursuant to the 510k process would constitute a specific federal requirement,[9] and we made those misgivings part of our

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type of medical device at issue in this case "specific requirements," although it is not obvious that these requirements are device-specific, see infra Part II(B). These requirements need not detain us, however, because the state of Florida has passed no provisions that would conflict with the general PMA requirement by permitting Medtronic to market the device in Florida without receiving FDA approval. We presume that such efforts necessarily would have no effect in view of § 360k(a).

[9] We wrote, "*[e]ven assuming* that a safety and effectiveness finding would constitute a specific design requirement under the MDA, we are not convinced that 510(k) approval constitutes a finding of safety and effectiveness." Id. at 1348 (emphasis added).

decision by holding that the FDA's 510k approval, standing alone, "does not impose specific requirements on a device for preemption purposes." Id. at 1349.[10]

Similarly, when the Supreme Court considered the preemptive effect of a device's progress through the 510k process, the Court focused its attention on the scope and focus of the 510k inquiry, which are limited to substantial equivalence rather than safety and effectiveness. See Lohr, 518 U.S. at 492-94, 116 S. Ct. at 2254-55. The Court's opinion,[11] however, also refers to the panel's concern that the 510k process "imposes no 'requirement'" on the design of the pacemaker and the panel's conclusion that "the requirements with which the company had to comply [as a consequence

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[10] In another section of our Lohr opinion, in which we rejected the plaintiff's assertion that § 360k and the FDA's interpreting regulation contemplated a device-specific federal requirement, we suggested that the PMA process was a much better candidate for preemption than the 510k process because of its heightened rigor. Id. at 1345-46 & nn.14 & 15. Given our subsequent misgivings about converting the FDA's 510k approval into a specific requirement, however, we cannot read this portion of our opinion to suggest that the PMA process is itself preemptive. Instead, the Lohr panel used the PMA process as an example to support its view that the federal requirement in § 360k(a)(1) need not be device-specific. Based on this understanding, the Lohr panel held that the MDA's good manufacturing practices ("GMPs"), which apply generally to almost all manufacturers of medical devices, were specific requirements and thus entitled to preemptive effect. Id. at 1350. The Supreme Court, however, held that § 360k(a)(1) does demand device-specificity and reversed the panel on this point. See Lohr, 518 U.S. at 500-01, 116 S. Ct. at 2257-58.

[11] The relevant discussion appears in section V of the plurality opinion, in which Justice Breyer concurred. Id. at 508, 116 S. Ct. at 2261-62 (Breyer, J., concurring).

of 510k review] were not sufficiently concrete to constitute a pre-empting federal requirement." Id. at 492, 116 S. Ct. at 2254. Moreover, the Court's analysis of the 510k process explains that the FDA's finding of substantial equivalence "*did not 'require'* Medtronics' pacemaker to take any *particular form* for any particular reason." Id. at 493, 116 S. Ct. at 2254 (emphases added). Finally, the partial dissenters, who would have found preemption elsewhere in the case far more readily than the majority, concurred in this part of the opinion and rejected preemption as a consequence of surviving the 510k process for both reasons: "Because the § 510(k) process seeks merely to establish whether a pre-1976 device and a post-1976 device are equivalent, and *places no 'requirements' on a device*, the Lohrs' defective design claim is not pre-empted."[12] Id. at 513, 116 S. Ct. at 2264 (emphases added); cf. id. at 507, 116 S. Ct. at 2261 (Breyer, J., concurring) ("Insofar as there are any applicable FDA requirements

[12] Of these two bases for deciding that the 510k process has no preemptive effect, the latter finds far more support in the language of § 360k(a). That section provides that no state may establish a requirement that (1) is different from a federal requirement and (2) relates to safety and effectiveness. Section 360k(a)(1) contemplates a federal requirement, which the FDA reads to mean a specific requirement. See 21 C.F.R. § 808.1(d). Section 360k(a)(2) demands that the requirement relate to safety and effectiveness, but it is at least ambiguous whether § 360k(a)(2) modifies the state or federal requirement at issue. The Supreme Court plainly read the provision to apply to the federal requirement, but an argument could be made that the more natural reading of the provision is as a limitation on the state requirement.

here, those requirements . . . are not 'specific' in any relevant sense."). See also In re Orthopedic Bone Screw Prods. Liab. Litig., 159 F.3d 817, 823 (3d Cir. 1998) (stating that the Lohr Court gave the 510k process no preemptive effect because it imposed no requirement).

Accordingly, although the Lohr case had little to do with the PMA process, which differs in significant ways from the 510k process at issue there, at least eight, and probably all nine, of the otherwise divided Justices expressed reservations as to whether the FDA's 510k review process and approval, standing alone, imposed any "requirement" on a device. See Worthy v. Collagen Corp., 967 S.W.2d 360, 369-70 (Tex.), cert. denied, __ U.S. __, 118 S. Ct. 2372 (1998)(explaining that the Supreme Court's decision that the 510k process was "too general to have preemptive effect" was unanimous). As noted above, because the PMA process before us focuses on safety and effectiveness, we must examine these misgivings further to determine whether the FDA's PMA process, which produces a finding that the manufacturer has provided the reasonable assurances of safety and effectiveness necessary to market the device, translates into the necessary imposition of a "specific requirement."

Our initial concern with this question is a conceptual one. Absent a more specific statutory definition, we must accord the language at issue its ordinary meaning. See, e.g., Park 'N Fly,

Inc. v. Dollar Park and Fly, Inc., 469 U.S. 189, 194, 105 S. Ct. 658, 661 (1985)("Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose."). We also may consider Congress's use of a particular term elsewhere in the statute to determine its proper meaning within the context of the statutory scheme. See, e.g., Estate of Cowart v. Nicklos Drilling Co., 505 U.S. 469, 479, 112 S. Ct. 2589, 2596 (1992). In ordinary usage, a requirement refers to "*something* that is wanted or needed" or "*something* called for or demanded: a requisite or essential *condition*." Webster's Third New Int'l Dictionary 1929 (1986) (emphases added). Similarly, within section 360k, Congress referred to a requirement as something a state or political subdivision could "establish," which appears to contemplate the state's creation of and, thus, identification of some thing. 21 U.S.C. § 360k(a). Finally, the FDA's interpretive regulation, which describes the federal requirement as "specific counterpart regulations" that the FDA "has established," or "specific requirements" that apply to the device under the MDA, 21 C.F.R. § 808.1(d), also indicates that a section 360k(a) preempting federal requirement must be some ascertainable condition.[13] The

[13] The FDA's interpretive regulation also speaks of the conflicting state regulation in terms that contemplate an ascertainable condition that the state must establish in one manner or another. See 21 C.F.R. § 808.1(b) (explaining that federal law preempts requirements "having the force and effect of

ordinary construction of the language of section 360k, as well as the use of the term "requirement" in the broader statutory context and its interpretation in the FDA's regulation, therefore, all contemplate the imposition of some identifiable precondition that applies to the device in question. Indeed, the statute, the FDA's regulation, and the Supreme Court's analysis in Lohr instruct us to conduct a "careful comparison" between the state and federal requirements at issue. Lohr, 518 U.S. at 500, 116 S. Ct. at 2257-58. Such a comparison is impossible if we cannot identify or ascertain the precise federal requirement at issue. Our conceptual difficulty with Medtronic's argument stems from our inability to ascertain any such identifiable requirement from the FDA's approval of Medtronic's 4004/M lead.

Medtronic points out that even a cursory review of the statutory framework reveals that the MDA imposes a legion of readily identifiable requirements upon the PMA applicant. See generally supra Part I(A); Worthy, 967 S.W.2d at 363-64 (providing an overview). Despite the specificity and considerable rigor of these conditions, see supra note 8, however, neither the FDA's actual review of a device and its supporting information nor the agency's eventual approval of the device imposes any ascertainable

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law (whether established by statute, ordinance, regulation or court decision)."). Furthermore, the FDA's description of state requirements in the remainder of the interpretive regulation refers only to concrete and identifiable rules and regulations. Id. at § 808.1(d)(1-10).

requirement upon the device. In the typical PMA review and approval and, more particularly, in the context of the 4004/M PMA, the FDA issues no regulation, order, or any other statement of its substantive benchmark. Cf. Papike v. Tambrands Inc., 107 F.3d 737, 740-41 (9th Cir.), cert. denied, __ U.S. __, 118 S. Ct. 166 (1997) (finding preemption based on an ascertainable requirement in an express FDA regulation requiring specific warnings on a device's packaging); Lohr, 518 U.S. at 489 n.9, 116 S. Ct. at 2252 n.9 (plurality opinion) ("In the MDA, no . . . specifics exist until the FDA provides them."). The approval represents only a finding that the manufacturer's proposal to market a device has reasonably assured the FDA of the device's safety and effectiveness. Nor does the FDA's willingness to notify an applicant of deficiencies and to propose modifications to the PMA application add any further force to Medtronic's argument for preemption, because an applicant who corrects or modifies a deficient PMA application before receiving the FDA's approval stands in no better position than an applicant whose initial PMA application was flawless.[14] In either case, the

[14] In this vein, Medtronic argues that the FDA imposed a number of specific requirements on the 4004/M during the process of reviewing the PMA application. Our review of the record, however, reveals that these requirements amounted to nothing more than requests for further information and explanations of data already before the FDA. These requests for information may shed light upon the issues the FDA examined but do not impose any specific requirement upon the device. We also note that the Lohr Court did not consider the FDA's power to make similar requests for additional information during the 510k review, see 21 C.F.R. § 807.87(l), as a factor that would support according that

FDA enters a finding that the applicant has furnished the relevant assurances and therefore may begin to market its device. In neither case, however, does the approval provide any indication of what (if any) specific substantive requirements the FDA may have applied to reach that result.[15] Compare Hurley v. Lederle Lab. Div. of Am. Cyanamid Co., 863 F.2d 1173, 1177 (5th Cir. 1988) (explaining that the FDA's approval of a certain form of vaccine provides "no basis for finding a federal interest in" that form) with Lohr, 518 U.S. at 500, 116 S. Ct. at 2257 ("[P]re-emption [must] occur only where a particular state requirement threatens to

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process preemptive effect.

[15] In 1997, the FDA promulgated a proposed rule on the preemption of state product liability claims under the MDA. See 62 Fed. Reg. 65,384 (1997). In that proposed rule, the FDA's analysis of its general approval processes (the 510k, the IDE, and the PMA) echoed our concern regarding the imposition of an ascertainable "specific requirement" as contemplated in § 360k(a)(1). Id. at 65,387. As a result of irregularities in the timing and circumstances of the FDA's action and in response to Congressional criticism of those circumstances, however, the FDA withdrew the proposed rule in July 1998. See 63 Fed. Reg. 39,789 (1998). Accordingly, we have given the FDA's expression of its views in this proposed rule no authoritative weight or deference. Nor do we defer to any position the FDA may have taken as an amicus curiae in cases involving issues of preemption. See McKee v. Sullivan, 903 F.2d 1436, 1439 n.3 (11th Cir. 1990) ("[E]vidence of a litigating position is insufficient to establish an agency's interpretation.").

Nevertheless, we find the analysis of the PMA process presented in the FDA's proposed rule interesting for two reasons. First, we are convinced that the proposed rule's analysis is faithful to the language of § 360k(a)(1), the broader statutory framework, and Congress's purpose in passing the MDA. Second, we find it unsettling that the agency charged with conducting PMA review has doubts regarding whether an approval pursuant to that process should preclude subsequent state tort liability.

interfere with a *specific federal interest*.") (emphasis added).

Medtronic seeks to convert the FDA's finding and the accompanying permission to market its device into the federal government's implied validation of the safety of its device and every step of its manufacture and, then, to use that validation as a shield against liability in tort. The FDA's approval is clearly specific to the device under review, but because the approval itself neither reveals nor imposes any ascertainable substantive prerequisite for approval that we could compare to a purportedly conflicting state requirement, the approval itself does not fit within section 360k(a)(1)'s demand for a specific federal requirement. As the New York Appellate Division persuasively explained, "while a PMA review is considerably more rigorous and detailed than the premarket notification [510k] process at issue in [Lohr v.] Medtronic, it is, in fact, no more 'specific' a requirement." Sowell v. Bausch & Lomb, Inc., 646 N.Y.S.2d 16, 20 (N.Y. App. Div. 1997).[16]

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[16] Medtronic argues that our adoption of Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir. 1992) in Duncan v. Iolab Corp., 12 F.3d 194, 195 (11th Cir. 1994) precludes our analysis and conclusions here. Slater, however, involved the preemptive effect of the IDE process, not the PMA process, and therefore does not control our disposition of this case. Moreover, Slater explicitly relied on the experimental nature of the device undergoing IDE review. See Slater, 961 F.2d at 1333.

Nevertheless, we acknowledge that part of the reasoning in Slater is at odds with our analysis today because the Slater court implied a specific federal requirement from the FDA's determination that the device was sufficiently safe and effective to permit experimental use. Id. Given our analysis, in section

B. The FDA's Conditions of Approval

Medtronic also points to the "Conditions of Approval" that accompanied the FDA's approval of the PMA application for the 4004/M lead, as well as the agency's demand that Medtronic make no changes to the device without first seeking FDA approval, as possible sources for a preempting federal requirement. Although we agree that these conditions constitute specific federal requirements, as discussed in part II(A) above, we are not convinced that these requirements satisfy section 360k(a)(1)'s further admonition that a preempting requirement be "applicable under this chapter to the device." 21 U.S.C. § 360k(a)(1).

The MDA permits the FDA to impose similar conditions on devices it approves pursuant to the 510k process. See, e.g., 21 U.S.C. § 360j(e) (giving the FDA the authority to impose conditions on the sale of any device); cf. id. § 396 (referring to the FDA's

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II(A), of the manner in which the Supreme Court addressed section 360k(a)(1)'s demand for a specific federal requirement in its intervening Lohr decision, however, we do not believe that Slater's reasoning on this point has survived. See Niehoff v. Surgidev Corp., 950 S.W.2d 816, 819-20 (Ky. 1997), cert. denied, __ U.S. __, 118 S. Ct. 1187 (1998) (rejecting Slater in light of the Supreme Court's demand for a specific federal requirement). On this point, we part company with the Seventh Circuit, which continues to apply the relevant portion of Slater despite Lohr. See Mitchell v. Collagen Corp., 126 F.3d 902, 911 (7th Cir. 1997) (applying Slater's approach without citing the case); Chambers v. Osteonics Corp., 109 F.3d 1243, 1246-47 (7th Cir. 1997)(relying on the case explicitly). In any event, to the extent Slater is at odds with our decision today, we believe the Supreme Court's reasoning in Lohr calls that case, and thus our adoption of it in Duncan, into question.

existing authority to enforce restrictions on the sale or distribution "of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations"). Moreover, the Supreme Court in Lohr took note of these conditions and the FDA's "continuing authority to exclude the device from the market if its design is changed" and recited Medtronic's arguments in favor of construing these factors as preemptive requirements. Lohr, 518 U.S. at 492, 116 S. Ct. at 2254; see also 21 C.F.R. § 807.81(a)(3) (requiring premarket notification for the reintroduction into commercial distribution of any device that is about to be significantly changed or modified). Nevertheless, the Court found these arguments insufficient to fit the 510k approval process within the confines of section 360k(a)(1) and declined to grant the 510k process preemptive effect. See Part II(A), supra.

More significantly, the Lohr Court construed section 360k(a)(1)'s description of a federal requirement "applicable under this chapter to the device" as an instruction to limit preemption to device-specific requirements. To interpret the relevant language, the Court again relied on the FDA's interpreting regulation, which reads section 360k(a)(1) to demand a specific federal requirement "applicable to a particular device." 21 C.F.R. § 808.1(d) (emphasis added), quoted in Lohr, 518 U.S. at 498, 116 S. Ct. at 2257. The Court then noted the FDA's "overarching

concern" regarding a broader construction of preemption and determined that the FDA's general labeling requirements and its Good Manufacturing Practices ("GMPs") were too general to merit preemptive effect under the statute and regulation. See Lohr, 518 U.S. at 497-501, 116 S. Ct. at 2256-58. A similar concern animates the Court's discussion of the general nature of the conditions the FDA imposed in its letter notifying Medtronic of its approval of the device pursuant to the 510k process. Id. at 493, 116 S. Ct. at 2254 ("That letter only required Medtronic to comply with 'general standards'—the lowest level of protection 'applicable to all medical devices' . . . .").

Analogously, the restrictions Medtronic proffers in this case are entirely general in nature, and the FDA has not promulgated them with respect to the "particular device" before us, the 4004/M, or even with respect to the class of specific devices at issue, pacemaker leads. The "Conditions of Approval" document enclosed with the letter that noted the FDA's approval of the 4004/M PMA application sets forth rules and regulations generally applicable to all devices approved through the PMA process. For example, the "Conditions of Approval" remind Medtronic of its obligation to provide post-approval reports, to refrain from changing the device without FDA approval, and to report adverse reactions and device defects.[17] The document, dated almost two years before Medtronic

[17] See R1-24, Ex. E-3.

submitted its supplemental PMA application, is cast in the most generic of terms and mentions neither the 4004/M nor even pacemaker leads as a class of devices.[18] As the Supreme Court explained:

> [T]he federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements.

Lohr, 518 U.S. at 501, 116 S. Ct. at 2258. We do not believe that requirements applicable to all devices that receive the FDA's approval via the PMA process satisfy the Court's demand for a specific requirement that applies to a particular device. See Kennedy v. Collagen Corp., 67 F.3d 1453, 1458-59 (9th Cir. 1995) (pre-Lohr case expressing doubt that Class III devices collectively constitute a "particular device" within the meaning of section 360k(a)(1) and the FDA's interpreting regulation), overruled in part on other grounds by Lohr, 518 U.S. 470, 116 S. Ct. 2240.

C. The "Ultimate Touchstone" of Congressional Intent

We recognize that our conclusions on these questions, although not without precedent,[19] are at odds with the results reached in a

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[18] Id. at 1, 3.

[19] See Kennedy, 67 F.3d at 1458-59 (pre-Lohr case finding that the PMA process imposes no specific federal requirement), overruled in part on other grounds by Lohr, 518 U.S. 470, 116 S. Ct. 2240; Lakie v. SmithKline Beecham, 965 F. Supp. 49, 54 (D.D.C. 1997) ("The fact that the PMA process requires certain information and mandates certain procedures from manufacturers

number of cases both before and after the Supreme Court's decision in Lohr. See Mitchell v. Collagen Corp., 126 F.3d 902, 911 & n.2 (7th Cir. 1997) (finding that PMA approval constitutes a specific federal regulation and examining cases both in support and to the contrary); Worthy, 967 S.W.2d at 372-74 (surveying cases before and after Lohr). Nevertheless, we remain convinced that our conceptual difficulty with Medtronic's attempts to divine a specific federal requirement from the FDA's approval of its PMA application reflects the real difference between the questions at stake during the PMA process and the discrete issues presented in a product liability suit.[20] The PMA process permits the FDA to regulate the

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does not transform the PMA process itself into a specific federal requirement which triggers preemption and protects a manufacturer from suit."); accord Sowell, 656 N.Y.S.2d at 20; Walker v. Johnson & Johnson Vision Prods., Inc., 552 N.W.2d 679 (Mich. App. 1996).

[20] We recognize that our decision may have implications beyond the preemption of state tort suits. Our analysis of the PMA review process and our decision that the FDA's approval imposes no preemptive requirement might preclude the express preemption of any conflicting state requirement, no matter how the state asserts it. Although we find it difficult to conceive of any such hypothetical state requirement that actually would conflict with the FDA's approval rather than the federal laws preventing the sale of unapproved devices, see supra note 8, we note the Supreme Court's recent teaching that the presence of an express preemption provision in a federal statute does not preclude field or conflict preemption. See Freightliner Corp. v. Myrick, 514 U.S. 280, 115 S. Ct. 1483 (1995), cited in Lohr, 518 U.S. at 503, 116 S. Ct. at 2259 (plurality opinion). To the extent, therefore, that a state's law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress'" as embodied in the PMA approval process, the state's efforts still may fall to preemption. Freightliner Corp., 514 U.S. at 287, 115 S. Ct. at 1487 (quoting Hines v.

introduction and sale of medical devices to assure their minimal safety for public consumption—it does not appear to address the appropriate standards of liability once the product enters the marketplace. Our inability to discern a specific requirement that fits the demands of section 360k(a) in the FDA's approval process, therefore, finds broader support in the language and structure of the MDA and is consistent with the factual backdrop that prompted Congress to enact the MDA.

Neither the MDA itself nor the FDA's interpretive regulations directly addresses the question of liability arising in connection with defective medical devices. Instead, the preamble to the MDA states that the amendments are for the purpose of "provid[ing] for the safety and effectiveness of medical devices intended for human use." Pub. L. No. 94-295, 90 Stat. 539, 539 (1976) (preamble). Similarly, the legislative history of the MDA fails to address issues of liability for defective devices. See Lohr, 518 U.S. at 491, 116 S. Ct. at 2253 (plurality opinion). Instead, the legislative history recounts the difficulty the FDA experienced in its earlier attempts to keep dangerous medical devices out of the marketplace. See S. Rep. No. 94-33 at 2-7 (1976), reprinted in 1976 U.S.C.C.A.N. 1070, 1071-76. This attention to the regulation of medical devices before they reach the marketplace is consistent with the events that prompted Congress to consider the MDA. As the

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Davidowitz, 312 U.S. 52, 67, 61 S. Ct. 399, 404 (1941)).

Supreme Court observed in Lohr, several highly publicized incidents involving defective medical devices, particularly the Dalkon Shield intrauterine device, gave rise to Congress's legislation in this area. See Lohr, 518 U.S. at 475-77, 116 S. Ct. at 2246. It would have been inconsistent for the same Congress that enacted these sweeping reforms, intending to make a potentially dangerous industry safer for patients by blocking the admission of defective devices to the market, then to preempt product liability suits when those devices caused injury. Moreover, we find no support for Medtronic's assertions that a concern for preserving innovation prompted Congress even to consider, let alone enact, preemption of tort liability in all cases involving devices that survived the PMA process. Id. at 490-91, 116 S. Ct. at 2253 (plurality opinion). Instead it appears that the members of Congress who sought to foster continued innovation in the field focused their efforts on reducing the regulatory burden that manufacturers would have to bear before they could market their products. Id.; 116 S. Ct. at 2253 (plurality opinion). Again, these efforts are consistent with our observation that Congress intended to regulate medical devices before they reached consumers, rather than address their consequences once on the market.

Other provisions of the statutory scheme also indicate that Congress expected some state tort liability to survive the MDA. For example, the statute contains a savings clause that

specifically addresses the MDA's effect on other liabilities arising from defective medical devices: "Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law." 21 U.S.C. § 360h(d). The effect of this savings clause is somewhat ambiguous because it appears in a section that addresses the FDA's powers to provide notification and other remedies when the agency discovers that a medical device (presumably including one that received PMA approval) presents an "unreasonable risk of substantial harm to the public health." Id. § 360h(a). As a matter of careful statutory construction, therefore, we would have to read section 360h(d) to refer only to compliance with FDA orders regarding notification, repair, replacement, refund, or reimbursement—and not to include compliance with the PMA process, which arises under a different section of the MDA. This limitation on section 360h(d)'s technical application, however, need not compel us to ignore the provision's broader implications because product liability in tort is the most immediately obvious source of state law liability that ordinarily would arise in a situation implicating the FDA's section 360h authority. Moreover, although the Lohr panel refused to read section 360h(d) as a vehicle to reject all preemption under the MDA because that section does not speak to the type of state liability contemplated and because a general savings clause cannot supersede a more specific preemption provision, see Lohr, 56 F.3d at 1342-43,

rev'd in part and aff'd in part, 518 U.S. 470, 116 S. Ct. 2240, the Supreme Court never addressed the impact of section 360h(d) on its preemption analysis. Despite these lingering concerns, we would misread neither the plain language of section 360h(d) nor the Lohr panel's interpretation of the law by concluding that the savings clause casts real doubt on the idea that Congress intended to preempt state tort liability for all PMA approved devices. Cf. Irving v. Mazda Motor Corp., 136 F.3d 764, 767-68 (11th Cir. 1998) (holding that a federal regulatory statute that includes a preemption clause and a savings clause is ambiguous on the preemption of state common law claims).

Finally, and as the Lohr plurality observed, the MDA provides no federal means by which injured plaintiffs can pursue legal remedies against the manufacturers of defective medical devices. See Lohr, 518 U.S. at 487, 116 S. Ct. at 2251 (plurality opinion)("[T]here is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action . . . ."). Reading the PMA process to impose specific federal requirements that enjoy preemptive effect under section 360k, therefore, would deprive all persons suffering injury as a result of a defective device—the very class of persons that Congress intended to protect by enacting the MDA—of "most, if not all relief." Id. at 487, 116 S. Ct. at 2251 (plurality opinion). The Supreme Court considered an analogous

situation in Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 104 S. Ct. 615 (1984). In that case, Congress had enacted the Atomic Energy Act (the "AEA") "to prohibit the States from regulating the safety aspects of nuclear development," on the premise that the federal government's commission was more qualified to define the safety standards that should control the industry. Id. at 250, 104 S. Ct. at 622. To support its conclusion that the statute did not preempt state tort remedies and punitive damage awards against the nuclear power industry, the Court observed that Congress had provided no indication that it even had considered preempting state tort law liability. Id. at 251, 104 S. Ct. at 623. Moreover, the Court refused to attribute any intent to preempt state tort claims after observing that preemption would leave the public—the target of Congress's safety concerns—without a remedy, because Congress had not enacted a federal private cause of action for injured plaintiffs: "It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." Id., 104 S. Ct. at 623, quoted in Lohr, 518 U.S. at 487, 116 S. Ct. at 2251 (plurality opinion). We too are reluctant to conclude that Congress sought to remove all remedies available to the very class of persons that it sought to protect when it enacted the MDA.

In its attempts to discern Congress's intentions regarding the preemption of tort liability, the Silkwood Court also looked to

Congress's subsequent legislation in the field. The Court observed that Congress had passed the Price-Anderson Act to provide a federal indemnification regime to encourage private companies to enter the nuclear power industry despite the risk of significant state tort liability. See Silkwood, 464 U.S. at 251, 104 S. Ct. at 623. Although the indemnification provisions had no application to the case at hand, the Court explained that their very existence demonstrated that Congress never intended to preempt state tort remedies when it passed the AEA. Id. at 251-56, 104 S. Ct. at 623-25. We find similar evidence of Congress's intent with regard to the MDA in its 1994 attempt, albeit failed, to enact the Product Liability Fairness Act ("PLFA"). The proposed act, which sought to create federal standards of product liability,[21] would have prevented private litigants from recovering punitive damages from the manufacturers of medical devices in cases where the "drug or device" that caused a plaintiff's harm "was subject to pre-market approval by the [FDA] with respect to the safety of the formulation or performance of the aspect of such drug or device which caused the claimant's harm . . . ." S. 687, 103d Cong. § 203 (1994).

[21] The PLFA would not have created a new federal cause of action but rather would have imposed uniform standards of liability for product manufacturers and sellers. See S. 687, 103d Cong. § 202. The proposed law would have permitted plaintiffs to bring causes of action pursuant to applicable state law, to the extent not in conflict with the PFLA's provisions. Id. § 201. Similarly, a plaintiff could also pursue punitive damages under "applicable law" to the extent not in conflict with the PFLA. Id. § 203.

Although the bill never became law, section 203's attempt to prevent plaintiffs suing the manufacturers of PMA devices under state tort law (to the extent not inconsistent with the proposed federal standard) from recovering punitive damages is significant because, if the 1976 Congress truly had intended section 360k(a) of the MDA to preempt all or most state law claims involving PMA approved devices, then there would have been no need for the 1994 Congress to include those devices in its proposed solution to the more general travails of product liability law.

These factors indicate beyond any doubt that, at least with respect to the FDA's PMA authority, Congress was deeply concerned with assuring the minimal safety of medical devices that enter the marketplace but gave no appreciable thought to the effect such regulation should have on any liability that might result from the sale and use of such medical devices. As a result, the PMA process is proactive rather than reactive; it concerns the manufacturers' ability to market minimally safe devices but makes no attempt to announce substantive safety standards that might determine the outcome of a product liability suit. See S. Rep. No. 94-33 at 2 (1976), reprinted in 1976 U.S.C.C.A.N. 1070, 1071 ("Medical device legislation is intended to assure that medical devices . . . meet the requirements of safety and effectiveness before they are put in widespread use throughout the United States.")(emphasis added). This view of the statutory scheme and the purposes behind the MDA

is in harmony with our reading of section 360k(a)(1)'s limitation on the type of specific federal requirements to which Congress intended to grant preemptive effect and with our conceptual objection to conjuring such specific federal requirements from the FDA's approval of particular devices.

Nevertheless, we can conceive of a situation in which Congress may have intended to establish an exemption from state tort liability as a trade-off for imposing the PMA system upon new medical devices. Congress would have been aware of such litigation given the backdrop of high profile cases involving defective medical devices, and that experience could have led Congress to substitute regulation for litigation by preempting all claims involving devices that received PMA approval. Indeed, Congress recently attempted an ambitious, but more limited, attempt to make such a trade-off by enacting the proposed Universal Tobacco Settlement Act and thereby bring a negotiated resolution to years of tobacco litigation. See S. 1415, 105th Cong. (May 14, 1998). Congress's controversial and ultimately unsuccessful experience with this particular attempt to provide even limited immunity from suits arising under state product liability laws, however, only bolsters our conviction that the 1976 Congress contemplated no such consequences under the MDA.[22] It is difficult to believe that

[22] We note that the 1998 Congress that considered granting a number of domestic tobacco companies immunity against state-initiated litigation and class actions (but not private,

Congress struck a similar bargain—regulation in exchange for immunity from state tort suits—in the area of medical devices without mentioning its aspirations in the statute or its legislative history and with nary a comment in the FDA's interpretive regulations or in the contemporary reviews of industry observers. See Lohr, 518 U.S. at 490-91 & n.13, 116 S. Ct. at 2253 & n.13 (plurality opinion).

Finally, we are loath to infer a tacit trade-off between regulation and liability when it appears that even the regulated industry was unaware of the purported bargain until relatively late in the day. Our research reveals that the first reported decisions on the industry's attempts to assert federal preemption of state product liability claims for devices subject to the FDA's approval regimes did not appear until 1991, fifteen years after Congress passed the MDA. See Slater v. Optical Radiation Corp., 756 F. Supp. 370 (N.D. Ill. 1991), aff'd, 961 F.2d 1330, 1331 (7th Cir. 1992) (recognizing that the preemptive effect of an FDA issued IDE

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individual lawsuits) did so directly and unambiguously. See S. 1415, 105th Cong. §§ 701-703. We further observe that Congress rigorously defined this immunity in the proposed statute, id., even though it also planned to subject new tobacco products to FDA regulation and review through a process akin to the MDA's PMA process, id. §§ 901-910. Finally, we observe that the debate over granting even this limited immunity to tobacco manufacturers, and the price Congress properly should have demanded for it, were matters of extreme and extended controversy. Moreover, the FDA's concurrent attempts to regulate nicotine as a drug prompted a blizzard of commentary from the legal academy and industry observers.

presented a matter of first impression at the appellate level). We recognize that the costs and delays associated with the PMA process have led the industry to avoid it when possible. See Lohr, 518 U.S. at 479, 116 S. Ct at 2248 (noting that in 1990 eighty percent of new medical devices had entered the market without undergoing PMA review). Even so, it seems unlikely that the industry would have ignored its immunity under the MDA for so long after the statute's enactment if Congress, in fact, had intended to provide immunity in 1976.

Just beneath the surface of Medtronic's arguments in support of preemption lies a relatively appealing policy argument in favor of immunity for devices that receive the FDA's most extensive review and approval. It seems presumptuous, to say the least, to permit a jury composed of ordinary citizens, none of whom we can expect to have significant medical training, to second-guess a decision, already extensively and rigorously considered by some of the most qualified minds in the relevant medical and scientific fields, regarding the rather complicated question of the safety of a particular medical device. As Medtronic described the PMA process for the 4004/M lead, a number of government and independent experts, as well as Medtronic's own scientists, examined, over several years, the performance of the Pellethane 80-A polyurethane insulating material at issue in Goodlin's complaint and came to the conclusion that Medtronic had reasonably assured its safety.

Goodlin's complaint, however, demands that a jury—a much less scientifically qualified body—decide whether the 4004/M lead was unreasonably dangerous because it used the Pellethane 80-A insulating material and, if so, to award damages.

No matter how compelling we might find Medtronic's policy objections as citizens, as judges, bound to apply the law rather than create it, we may not act on those objections here. The jury system, although imperfect, is the method by which we resolve an ever-increasing number of disputes, many of which might more appropriately be resolved by experts. We cannot accept that Congress intended to exempt the manufacturers of medical devices from tort liability for all devices subject to the PMA process on the scant evidence presented here. We also read the Supreme Court's most recent admonition that "[t]he purpose of Congress is the ultimate touchstone in every pre-emption case," Lohr, 518 U.S. at 485, 116 S. Ct. at 2250 (internal quotation omitted), and the Court's instruction that deference to state sovereignty requires us to assume that Congress does not preempt the states' "historic police powers" without making its purpose "clear and manifest," id., 116 S. Ct. at 2250 (internal quotation and citations omitted), as unmistakable directions that lead us to today's decision. Accordingly, we may not bend the language of section 360k(a)(1) to permit the manufacturers of medical devices to infer from the FDA's approval of a PMA application specific federal requirements that

remain unstated and unascertainable until an injured consumer brings a lawsuit alleging a defect.

Our decision does not mean that Medtronic's efforts to provide the FDA with reasonable assurances regarding the 4004/M lead's safety and effectiveness have no bearing on the question of its liability on Goodlin's claims. To the contrary, to prevail at trial, Goodlin must show either that Medtronic designed the lead negligently or that the lead was inherently dangerous because the risks it imposed outweighed its benefits.[23] Medtronic's efforts to improve its product and the information it collected in support of its safety will be relevant to these questions. The FDA's approval of the device, particularly after an independent panel of experts recommended that approval, should impress the jury that must evaluate the reasonableness of Medtronic's actions at the time it manufactured and marketed the 4004/M lead. Although the task of presenting this information in a manner that a jury can understand may make for a lengthy and complicated trial—and may even demand a better solution—section 360k(a) of the MDA provides no means to avoid it.

CONCLUSION

We conclude that the FDA's approval of a medical device

[23] Goodlin also will have to prove that Medtronic's negligence or the device's inherent danger caused her harm. As the district court observed, but did not decide, Goodlin's case faces some serious causation problems under Florida law.

pursuant to the PMA process, standing alone, imposes no specific federal requirement applicable to a particular device and, therefore, has no preemptive effect under section 360k(a) of the MDA. Accordingly, we REVERSE the district court's entry of summary judgment in Medtronic's favor and REMAND the case for further proceedings consistent with this opinion.