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Medtronic v. Lohr: For Want of a Word, the Patient Was Almost Lost - Fixing the Mischief Caused in Cipollone by Dividing the Preemption Stream

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Medtronic v. Lohr: For Want of a Word, the Patient Was Almost Lost — Fixing the Mischief Caused in *Cipollone* by Dividing the Preemption Stream

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> A little neglect may breed great mischief . . . for want of a nail the shoe was lost; for want of a shoe the horse was lost; and for want of a horse the rider was lost.
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> — *Poor Richard's Almanack*[1]

I. INTRODUCTION

In finding that the statutory language of the Medical Device Amendments of 1976 (MDA)[2] does not preempt the state common law tort claims at issue in *Medtronic v. Lohr*,[3] the U.S. Supreme Court tried to "fix" the mischief caused by its earlier decision in *Cipollone v. Liggett Group, Inc.*[4] In so doing, the Court surprised the federal courts of appeals, the majority of federal trial courts, and the state courts, because virtually every tribunal to consider the issue previously has held, expressly or by implication, that the MDA preempts state common law tort claims.[5]

The lower courts and the medical device manufacturers have relied, almost exclusively, on the meaning attributed to the word "requirement" by the Supreme Court in *Cipollone* to find preemption of state common law claims in the language of the MDA.[6] In *Cipollone*, a woman and her husband brought suit against a cigarette manufacturer under state law after the woman developed terminal lung cancer.[7] Their son, as executor of their estates, continued the suit when his parents died before the court issued a decision.[8] He brought design defect, failure to warn, negligence, express warranty, fraudu-

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[1] BENJAMIN FRANKLIN, POOR RICHARD'S ALMANACK (1758), *quoted in* JOHN BARTLETT, FAMILIAR QUOTATIONS 347 (Emily Morison Beck ed., 15th ed. 1980).

[2] Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections of 21 U.S.C. (1994)).

[3] 518 U.S. 470, 116 S. Ct. 2240 (1996).

[4] 505 U.S. 504 (1992). In *Cipollone*, the Court examined a federal preemptive statute aimed at specific state requirements of smoking and health. The *Cipollone* Court examined the conformity of state smoking and health requirements with federal statutes dealing with the advertising and labeling of cigarettes. *Medtronic*, 116 S. Ct. at 2252 (citing *Cipollone*, 505 U.S. at 524-30). The *Medtronic* Court noted that while the *Cipollone* Court determined that a federal preemption statute preempted specific state requirements and some claims of common law damages, the statute in that case was not nearly as broad as the one in the instant case. Id. (citing *Cipollone*, 505 U.S. at 521-22).

[5] *See, e.g.*, Mark Herrmann & Geoffrey J. Ritts, *Preemption and Medical Devices: A Response to Adler and Mann*, 51 FOOD & DRUG L.J. 1-3 nn.4-6 (1996) (for a comprehensive listing of the courts finding preemption: the nine federal courts of appeals, the majority of federal trial courts, and almost every state court to consider the preemption issue).

[6] *See* Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 916 (1994) (noting that since *Cipollone*, "the courts have been nearly unanimous in finding preemption [under the MDA], in most cases ruling simply that the preemption section in the MDA uses the same word, 'requirement,' that the Supreme Court found preemptive in *Cipollone*.").

[7] 505 U.S. at 508.

[8] *Id.* at 509.

lent misrepresentation, and conspiracy to defraud claims based solely on state law.[9]

The Court held that the Public Health Cigarette Smoking Act of 1969,[10] which required warnings on cigarette packages, preempted the plaintiff's failure to warn claims.[11] Specifically, the Court concluded that the word "requirement" in the Act encompassed common law damages actions. It held that "the phrase 'no requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules."[12]

In *Medtronic*, a woman was injured when a pacemaker implanted in her chest suddenly failed.[13] This failure required immediate surgery.[14] She survived and brought the traditional common law product liability causes of action. The manufacturer of the defective medical device argued that these causes of action — failure to warn, manufacturing defect, and design defect — were preempted by the MDA. The manufacturer relied on the language of section 360(k) of the MDA which, similar to the Cigarette Smoking Act of 1969, contained the word "requirement."[15]

The mischief is clear: in construing the meaning of the word "requirement" in the Public Health Cigarette Smoking Act of 1969 to include state tort claims, the Court opened wide the preemption door. In the words of some commentators, this holding caused the courts to "run amok" in their rulings on preemption, most notably with respect to medical devices.[16]

First, this article provides a synopsis of the facts and holdings of *Medtronic*, and an evaluation of the Court's three separate opinions. Second, it discusses preemption in the wake of the decision and the concomitant division of the preemption stream. Third, the article offers a proposal for resolving the preemption issue left open by the Court, by providing a definition for the word "requirement" in the MDA.

II. MEDTRONIC V. LOHR

In 1987, Lora Lohr was implanted with an Activitrax pacemaker manufactured by Medtronic.[17] The pacemaker failed in 1990 and Ms. Lohr was forced to undergo emergency surgery to replace it.[18] According to her attending physician, the failure was caused

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[9] *Id.* at 509-10.

[10] Pub. L. No. 91-222, 84 Stat. 87 (codified at 15 U.S.C. §§ 1331-1340 (1988)).

[11] 505 U.S. at 530-31.

[12] *Id.* at 521. Section 5(b) of the Public Health Cigarette Smoking Act of 1969 states that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." 15 U.S.C. § 1334(b).

According to the Court, because common law damages arise from tort claims, they "are premised on the existence of a legal duty and it is difficult to say that such actions do not impose requirements or prohibitions." 505 U.S. at 522.

[13] 116 S. Ct. at 2248.

[14] *Id.*

[15] 21 U.S.C. § 360k(a). The preemptive language provides that

> 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 —
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (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.

Id.

[16] Adler & Mann, *supra* note 6, at 898.

[17] *Medtronic*, 116 S. Ct. at 2248.

[18] *Id.*

by a defect in the pacemaker's lead, the wire that carries electrical impulses from the pacemaker to the patient's heart.[19] This component of the Activitrax pacemaker, the Model 4011, was manufactured by Medtronic as part of its pacemaker device.[20]

Lora Lohr and her husband Michael brought suit against Medtronic in a Florida state court seeking damages allegedly sustained as a result of the pacemaker's failure and for Mr. Lohr's alleged loss of consortium.[21] In their complaint, the Lohrs asserted four theories of liability: negligent design, negligent manufacture, negligent failure to warn, and strict liability in tort.[22] A breach of warranty claim contained in the original complaint was dismissed for failure to state a claim under Florida law.[23]

Medtronic moved to remove the case to the U.S. District Court for the Middle District of Florida based on diversity of citizenship.[24] Once the case was in federal court, Medtronic moved for summary judgment, claiming that the Lohrs' claims were preempted by title 21 of the *United States Code* section 360k(a).[25] In December 1993, the district court denied the motion, but later the court reconsidered its decision in view of the Eleventh Circuit's holding in *Duncan v. Iolab Corporation*,[26] which had been decided in the interim. On reconsideration, the court granted Medtronic's motion for summary judgment, interpreting the Eleventh Circuit's decision in *Duncan* as preempting all state law claims for negligence and strict liability in tort.[27]

The Lohrs appealed and the U.S. Court of Appeals for the Eleventh Circuit reversed in part and affirmed in part.[28] This decision to preempt some but not all of the Lohrs' claims pleased no one: Medtronic filed a petition for *certiorari*, seeking review of the court of appeals' decision insofar as it affirmed the district court, and the Lohrs filed a cross-petition seeking review of the judgment insofar as it upheld the preemption defense.[29] The U.S. Supreme Court granted both petitions "because the Courts of Appeals are divided over the extent to which state common-law claims are pre-empted by the MDA."[30]

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[19] *Id.*

[20] *Id.* Because it is responsible for maintaining the natural heartbeat pace in a patient's body, the lead is an integral part of the pacemaker system. Brief for Petitioner at 2, *Medtronic* (Nos. 95-754, 95-886). "The lead is designed to transmit small electrical pulses to the ventricle of the heart from another part of the implanted system — a pacemaker pulse generator — and return signals from the heart to that generator." *Id.* at 2-3.

[21] *Medtronic*, 116 S. Ct. at 2248.

[22] *Id.* The Lohrs' alleged a breach of Medtronic's "duty to use reasonable care in the design, manufacture, assembly, and sale of the subject pacemaker" Complaint at 5, *Lohr* (No. 93-01241 CA)).

[23] *Id.*

[24] Lohr v. Medtronic, Inc., 56 F.3d 1335, 1340 (11th Cir. 1995).

[25] *Medtronic*, 116 S. Ct. at 2248.

[26] *Id.* at 2249 (citing Duncan v. Iolab Corp., 12 F.3d 194 (11th Cir. 1994)). In *Duncan*, the plaintiffs received intraocular lenses manufactured by the defendant. 12 F.3d at 195. The plaintiffs filed state common law strict liability, negligence, and breach of implied warranty claims after suffering injuries. Id. The Eleventh Circuit Court of Appeals held that section 360k(a) of the MDA preempted the plaintiffs' state law claims. Id. The appellate court, however, noted it followed the Seventh Circuit U.S. Court of Appeals' decision in *Slater v. Optical Radiation Corp. Id.* (citing Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992)).

[27] *Medtronic*, 116 S. Ct. at 2249.

[28] *Id.* (citing *Lohr*, 56 F.3d at 1335).

[29] *Id.* at 2250. Anticipating this reaction of the parties, the Eleventh Circuit stated in its conclusion that it knew its "decision to preempt some, but not all of Appellants' claims [was] sure to please neither party. Nevertheless, as the Supreme Court noted in a recent preemption decision, '[t]he middle course we adopt seems to us best calculated to carry out the congressional design.' . . . Any displeasure with that design should be directed toward Congress." *Lohr*, 56 F.3d at 1352 (quoting American Airlines v. Wolen, 513 U.S. 219, 234 (1995)).

[30] *Medtronic*, 116 S. Ct. at 2250 n.6 (citing English v. Mentor Corp., 67 F.3d 477, 482 (3d Cir. 1995) (holding that section 510(k) review creates preemption "requirements" under section 360k(a)); Feldt v. Mentor Corp., 61 F.3d 431, 436 (5th Cir. 1995) (finding that the MDA preempted failure to warn claims but did not preempt design defect claims); Michael v. Shiley Inc., 46 F.3d 1316, 1336 (3d Cir. 1995) (holding that section 360k(a) does not preempt a claim alleging a violation of federal requirements); Kennedy v. Collagen Corp., 67 F.3d

In deciding the case, a sharply divided Supreme Court produced three opinions and ultimately failed to provide the guidance necessary to resolve the conflict in the lower courts.

First, Justice Stevens delivered a seven-part opinion that was joined by Justices Ginsberg, Souter, and Kennedy; this became the opinion of the Court to the extent that it was joined by Justice Breyer. These five justices found that the MDA did not preempt any of the Lohrs' state common law tort claims.[31] Second, Justice O'Connor authored an opinion that was joined by Chief Justice Rehnquist and Justices Scalia and Thomas to form a plurality that would have held that the Lohrs' failure to warn and manufacturing claims were preempted by the MDA.[32] Third, Justice Breyer authored a separate opinion, which, because he agreed with Justice O'Connor on one issue and with Justice Stevens on another, created shifting five-to-four majorities of the Court.[33]

The seven-part opinion authored by Justice Stevens reversed in part and affirmed in part the Court of Appeals for the Eleventh Circuit and held that the MDA did not preempt the Lohrs' state common law negligent design, negligent manufacture, failure to warn, and strict liability claims.[34] In not finding preemption in this case, the Court deferred to the historic police powers of the states to protect the health and safety of its citizens.[35] It deferred as well to the purpose, history, and language of the MDA[36] and the authority of the Food and Drug Administration (FDA) to interpret the scope of the statute.

In part I of his opinion, Justice Stevens recognized the police powers of the states to protect the health and safety of their citizens because these were "primarily, and historically" matters of local concern.[37] Despite the prominence of the states in this area, however, Justice Stevens noted that the federal government had come to play an increasingly important role in the protection of public health since the enactment of the Food and Drug Act of 1906.[38] This Act prohibited the manufacture or shipment in interstate commerce of any adulterated or misbranded food or drug.[39] It was not until 1938, however, that federal control was extended over medical devices, and then only after those products were introduced into interstate commerce. While FDA was empowered to enjoin the distribution of devices that were "misbranded" or "adulterated,"[40] it was not until the passage of the MDA in 1976 that FDA had statutory authority to regulate devices' entry to the marketplace.[41]

According to Justice Stevens, Congress enacted the MDA to provide for premarket regulation of medical devices in response to "mounting consumer and regulatory con-

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1453, 1459 (9th Cir. 1995) (holding that section 360k(a) does not cover common law claims at all); Lohr, 56 F.3d at 1352 (concluding that claim alleging a violation of a federal requirement may be preempted by section 360k(a), section 510(k) review process may create preemptive requirements, and section 360k(a) covers common law claims)).

[31] 116 S. Ct. at 2259.

[32] *Id.* at 2264.

[33] *Id.* at 2259-60. Justice Breyer would "basically agree with Justice O'Connor" that the MDA sometimes will preempt a state law tort suit. Regarding the tort claims at issue, however, Justice Breyer concluded that they were not preempted by the MDA.

[34] *Id.* at 2259.

[35] *Id.* at 2245.

[36] *Id.* at 2250-51.

[37] *Id.* at 2245 (citing Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 719 (1985)).

[38] *Id.* at 2246 (citing Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768).

[39] *Id.*

[40] *Id.* (citing Federal Food, Drug, and Cosmetics Act, Pub. L. No. 75-717, ch. 5, 52 Stat. at 1049-51 (1938)).

[41] *Id.* (citing Pub. L. No. 94-295, 90 Stat. 539).

cern" over the growth of sophisticated medical technologies and the "increasingly severe injuries that resulted from the failure of such devices."[42] Justice Stevens pointed specifically to the Dalkon Shield, a contraceptive device, introduced in 1970 as safe and effective, yet responsible for "a disturbingly high percentage of inadvertent pregnancies, serious infections, and even, in a few cases, death."[43] This device, along with artificial heart valves and pacemakers, came to be viewed as possible health risks and spurred congressional action to protect the public from a largely unregulated device industry.

Enacted in 1976, the MDA classified medical devices into three categories based on the risk they posed to the public.[44] In outlining this classification scheme, Justice Stevens focused on FDA's underlying concern with public health and safety. Class I devices pose the least risk and are subject to minimal regulation by only "general controls."[45] Class II devices are "potentially more harmful" and their manufacturers must comply with federal performance regulations known as "special controls."[46] Class III devices present either "a potential unreasonable risk of illness or injury" or are designed for a use "in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health."[47] Class III device manufacturers are required to give "reasonable assurance" to FDA that the device is safe and effective before it can be marketed.[48]

Justice Stevens noted that the Medtronic Model 4011 pacemaker lead entered the marketplace in 1982 through the less stringent premarket notification process, a rather "limited" form of review and "by no means comparable to the [premarket approval application] PMA process."[49] The pacemaker was "grandfathered" into commerce by a finding of substantial equivalence to a pre-existing device, thus enabling it to avoid the more extensive regulatory hurdle of the PMA review. A determination of "substantial equivalence" by FDA does not signify an agency endorsement of the safety and effectiveness of the device but is merely a clearance to market, subject to the general control provisions of the Act.[50]

In part II of his opinion, Justice Stevens set forth the claims of the parties, the procedural path of the dispute, and the section of the MDA at the heart of the controversy. Without commenting, Justice Stevens set out the contradictory and confusing holdings of the court of appeals, and concluded that because the courts of appeals generally were divided over the extent to which state common law claims are preempted by the MDA, the parties' petitions were granted.

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[42] *Id.*

[43] *Id.*

[44] *Id.* at 2246.

[45] *Id.* (citing 21 U.S.C. § 360c(a)(1)(A)).

[46] *Id.* (citing 21 U.S.C. § 360c(a)(1)(B)).

[47] *Id.* (citing 21 U.S.C. § 360c (a)(1)(C)).

[48] *Id.* at 2246-47 (citing 21 U.S.C. § 360e(d)(2)). Congress provided in part that the Secretary can "deny approval of an application for a device if... there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof... [or if] there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 360e(d)(2).

[49] 116 S. Ct. at 2248.

[50] Respondent's Memorandum in Support of Motion for Summary Judgment, exh. A to exh. 1 (declaration of Charles H. Swanson), *Medtronic* (No. 93-482). In its substantial equivalence letter to Medtronic, FDA clearly stated that its letter did "not in any way denote official FDA approval of your device," and that "[a]ny representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding." Letter from Robert G. Britain, Assoc. Dir. for Device Evaluation, Dep't of Health and Human Servs., to Edward W. Numainville, Prod. Reg. Mgr., Medtronic, Inc. (Nov. 30, 1982), *in* Brief for Cross-Petitioners at 10a-11a, *Medtronic* (Nos. 95-754, 95-886).

None of the justices took exception to these two parts of the opinion.

In part III of his opinion, Justice Stevens identified two presumptions about the nature of preemption.[51] As a preliminary matter, the Court noted that the task before it was the same as in *Cipollone*, namely "interpreting a statutory provision that expressly pre-empts state law."[52] Citing *Cipollone*, Justice Stevens observed that "while the pre-emptive language of § 360k(a) means that we need not go beyond that language to determine whether Congress intended the MDA to pre-empt at least some state law, [we must nonetheless] identify the domain expressly pre-empted" by that language.[53] This, however, was the extent of the similarity Justice Stevens drew between the two cases.

Instead, Justice Stevens identified those assumptions that inform the Court's interpretation of statutory language. First, Justice Stevens noted that Congress does not "cavalierly pre-empt state-law causes of action" because the states are independent sovereigns in our federal system.[54] Second, the Court is guided in its inquiry into the scope of preemption by the "oft-repeated comment" that "[t]he purpose of Congress is the ultimate touchstone."[55]

Part IV of Justice Stevens opinion addressed Medtronic's claim that any common law cause of action was a "requirement" that was preempted by the promulgation of FDA regulations pursuant to the MDA.[56] Justice Stevens flatly rejected this argument as "not only unpersuasive, it is implausible."[57] By focusing on the congressional purpose in enacting the statute to protect the public from defective medical devices and on the notable absence from the legislative history of any intent by Congress to protect manufacturers from product liability claims, Justice Stevens concluded that Medtronic's construction of section 360(k) would have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order to "provide for the safety and effectiveness of medical devices intended for human use."[58]

In dismissing Medtronic's construction of the word "requirement," Justice Stevens carefully distinguished the preemptive statute at issue in *Cipollone* from the MDA.[59] While conceding that the *Cipollone* Court found that a federal statute that preempted certain state "requirements" also could preempt common law damages claims, Justice Stevens noted that the preemptive statute in *Cipollone* was "targeted at a limited set of state requirements" and then only at a "limited subset of the possible applications of

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[51] *Medtronic*, 116 S. Ct. at 2250.

[52] *Id.*

[53] *Id.* (citing *Cipollone*, 505 U.S. at 517). The Court in *Cipollone* examined the express language of the statute when interpreting congressional intent and the preemptive scope of a statute. 505 U.S. at 517. The *Cipollone* Court held that the Public Health Cigarette Smoking Act of 1969 preempted the plaintiff's claims of "failure to warn and the neutralization of federally mandated warnings to the extent that those claims rely on omissions or inclusions in respondents' advertising or promotions." *Id.* at 530-31. The Court did not preempt the petitioner's claims of express warranty, fraud, and conspiracy. *Id.*

[54] *Id.* (citing Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)). In *Rice*, the Supreme Court began its examination of preemption with "the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." 331 U.S. at 230.

[55] *Medtronic*, 116 S. Ct. at 2250 (quoting Retail Clerks v. Schermerhorn, 375 U.S. 96, 103 (1963)).

[56] *Id.* at 2251.

[57] *Id.*

[58] *Id.* (citing Pub. L. No. 94-295, preamble, 90 Stat. 539). The preamble to the MDA states that its purpose is "[t]o amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes."

[59] *Id.* at 2251-52.

those requirements."[60]

Thus narrowing the reach of "requirements" in *Cipollone*, the Court was ready to look anew at the meaning to be attributed to that word in light of Congress' intention to protect consumers. Justice Stevens noted that section 360(k) referred to "requirement" many times throughout its text, each time linking it with "language suggesting that its focus is device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries."[61] Justice Stevens read this language to mean that Congress was concerned with "specific" state statutes and regulations rather than with general common law damages.[62] When combined with FDA's authority to grant an "exemption from preemption," the Court understood the statute as "not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions."[63]

Instead, the Court concluded that "at least some common-law claims against medical device manufacturers may be maintained after the enactment of the MDA."[64] In reaching this conclusion, it decided that Medtronic's definition of "requirement" was too far-reaching, but nonetheless failed to provide its own definition.[65] This omission by the Court was unfortunate, especially because Justice Stevens had gone so far as to make the connection between "requirement" and device-specificity; it would have been a short step to conclude that a section 360(k) "requirement" means a device "specification."[66] In opting not to make this connection, Justice Stevens lost an oppor-

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[60] *Id.* at 2252. The *Medtronic* Court noted that while the *Cipollone* Court had determined that a federal statute preempted specific state requirements and some claims of common law damages, the statute in that case was not as broad as the one in the instant case. *Id.* (citing 505 U.S. at 521-22).

[61] *Id.*

[62] *Id.*

[63] *Id.* at 2253. The plurality noted that there were no references in the committee reports, the debates, or the hearings to suggest that the purpose of the legislation was to preempt traditional common law remedies. Id. It found that Congress' failure "even to hint" at an intention to preempt common law remedies was "spectacularly odd" because both houses were aware of product liability litigation. Id. FDA's authority to grant an exemption from preemption flows from title 21 *United States Code* section 360k(b), which provides:

> Exempt requirements.
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> Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—
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> (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
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> (2) the requirement—
>
> (A) is required by compelling local conditions, and
>
> (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

Id. at 2249 n.5 (quoting 21 U.S.C. § 360k(b)).

[64] 116 S. Ct. at 2253. Justice Stevens came to this conclusion based on "less-than-precise language of § 360k(a)" and congressional "silence" on the subject of whether the preclusion of common law remedies was intended. *Id.*

[65] *Id.* at 2252.

[66] *Id.* at 2251. The *Medtronic* Court noted that the word "requirement" means the state is imposing a specific duty on the manufacturer of a medical device. *Id.* Then it noted that the word is used many times throughout the text of the section, each time linking it with language suggesting that its focus is "device-specific" enactments of positive law by legislative or administrative bodies." *Id.* at 2252. According to *Webster's Encyclopedic Unabridged Dictionary*, a synonym for "requirement" is "specification." A "specification" is defined as "a detailed description or assessment of requirements, dimensions, materials, etc., as of a proposed building, machine, bridge, etc." A "requirement" is defined as "that which is required; a thing demanded or obligatory; a need or necessity." "A requirement is some quality or performance demanded of a person in accordance with certain fixed regulations: requirements for admission to college." As the dictionary definitions make clear, the

tunity to provide clear guidance to the lower courts. As a result of not conclusively defining a preemptive MDA "requirement," post-*Medtronic* lower courts have continued to grapple with this issue, often with conflicting and potentially harmful results.

Justice Breyer declined to join this part of the opinion. He took exception to the Court's emphasis on the differences between the MDA and the preemption statute in *Cipollone*, finding instead that the differences were not "relevant in this case."[67] Justice Stevens' focus on the differences between the statutes, however, is relevant; it provides a basis for resolution of the preemption issue.[68]

Part V of Justice Stevens' opinion analyzed, on a claim-by-claim basis, the arguments put forth by Medtronic for blanket preemption of all the Lohrs' common law claims.[69] First, Justice Stevens addressed the design claim and focused on the fact that the device in question came to market pursuant to a 510(k) notification regulatory path.[70] The Court noted that the 510(k) process was not an evaluation of device safety and effectiveness but merely a determination of "substantial equivalence" to an earlier device.[71] The dissenting justices and Justice Breyer agreed with Justice Stevens that the Lohrs' design claims were not preempted by the substantial equivalence provision of section 510(k).[72] Moreover, because FDA "did not 'require' the Medtronics' pacemaker to take any particular form for any particular reason," there were no federal requirements that would conflict with any state requirement pertaining to device design.[73]

Next, Justice Stevens addressed the Lohrs' "identity of requirements" claims and concluded that nothing in section 360(k) precluded the recovery of damages under state tort law for violations of FDA regulations or other federal requirements. The Court explained that "[t]he presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law."[74]

Justice Breyer agreed with this holding, as did the dissenting justices. Justice O'Connor reasoned that section 360(k) precludes states from imposing additional or different requirements, not from providing additional or different remedies.[75]

In finding that a claim based on a violation of FDA regulations can be maintained

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imposition of a "requirement" for a machine necessarily would take the form of a "specification." In making the first connection between "requirement" and "specificity" in the statute, Justice Stevens needed only to make the next connection between the nature of a device and a "specification" to find his answer.

[67] *Id.* at 2261.

[68] Justice Stevens' emphasis on the differences between the statute in Cipollone and the MDA can be seen as a basis for a division of the preemption stream.

[69] 116 S. Ct. at 2253.

[70] *Id.* at 2254.

[71] *Id.* (citing *Lohr*, 56 F.3d at 1348). The lower *Lohr* court noted that a finding of substantial equivalence under a 510(k) premarket notification is not a finding of that device's safety and effectiveness. 56 F.3d at 1348.

[72] 116 S. Ct. at 2261-64 (O'Connor, J. concurring in part and dissenting in part). Justice O'Connor reasoned that "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 preempted." *Id.* at 2264.

[73] *Id.* at 2254.

[74] *Id.* at 2255.

[75] *Id.* at 2264 (O'Connor, J. concurring in part and dissenting in part). Justice O'Connor noted that where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is 'different from, or in addition to' requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k

without being preempted by the MDA, the Court deferred to the unique role given by Congress to FDA in determining the preemptive scope of section 360(k).[76] Once again, Justice Stevens noted a difference between the statute in *Cipollone* and the MDA: preemption under the MDA did not arise directly from the enactment of the statute but "only to the extent that the FDA has promulgated a relevant federal 'requirement.'"[77] Because Congress expressly delegated authority to FDA to exempt state regulations from the preemptive effect of the MDA, the agency is required to assess the preemptive effect that the Act and its regulations would have on state laws.[78] Given this congressional grant of authority in combination with the ambiguity in the statute, the Court, relying on,[79] is justified in giving substantial weight to the agency's view of the statute.[80]

Justice Stevens continued in part V with a consideration of the Lohrs' negligent manufacturing and labeling claims. As opposed to defective design claims, there are federal labeling and manufacturing regulations for device manufacturers who seek to bring a device to market.[81] In its "substantial equivalence" letter to Medtronic, FDA referred to these as "general controls provisions of the Federal Food, Drug, and Cosmetic Act."[82] At issue was whether these "general controls" constituted federal requirements that would preempt different or additional state requirements.

In finding that the Lohrs' common law claims were not preempted by the federal labeling and manufacturing requirements, both Justices Stevens and Breyer were guided by FDA regulations. The regulation provides in part that

> [s]tate or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.[83]

Justice Stevens found it "impossible to ignore" the regulation's concern that preemption occur only when a particular state requirement threatened to interfere with a specific federal interest.[84] By focusing on the required link between the requirement and a "specific" device, and then between that requirement and the "safety or effectiveness" of the device, Justice Stevens concluded that the generality of the federal

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does not preclude States from imposing different or additional remedies, but only different or additional requirements.

Id.

[76] *Id.* at 2255.

[77] *Id.*

[78] *Id.* Congress delegated authority to FDA to determine whether state law should be preempted because it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" *Id.* (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

[79] 467 U.S. 837 (1984).

[80] 116 S. Ct. at 2256 (referring to Chevron U.S.A. Inc. v. Natural Resources Defense Council Inc., 467 U.S. 837 (1984)).

[81] *Id.* (quoting 21 C.F.R. § 801.109(b), (c) (1995)).

[82] *Id.* at 2254. In its substantial equivalence letter to Medtronic, FDA advised the manufacturer that it may market its device "subject to the general controls provisions" of the FDCA, which included "good manufacturing practice" and "labeling," among others. *Id.* (quoting Letter from Robert G. Britain, *supra* note 50, at 10a-11a).

[83] 21 C.F.R. § 808.1(d).

[84] 116 S. Ct. at 2257.

manufacturing and labeling requirements precluded a finding of preemption.[85] They were merely "generic concerns about device regulation generally" and not the sort of concerns regarding a specific device that the MDA or regulations were designed to protect from potentially contradictory state requirements.[86] The "general duties" imposed by state common law to use due care in the manufacture and labeling of a device escape preemption because their "generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices . . . ."[87]

Justice O'Connor and the dissenting justices strongly disagreed with this reasoning that the MDA preempts only "specific" federal requirements with respect to particular devices. The dissent reasoned instead that the language of section 360k(a) of the MDA requires no more specificity than that the requirement be applicable to the device for it to be preempted.[88]

Part VI of Justice Stevens' opinion addressed the Lohrs' argument that section 360(k) never preempts state common law tort actions because common law duties are not "requirements" within the meaning of the statute. Justice Stevens stated that "we do not respond directly to this argument;" because none of the Lohrs' claims were preempted in this case, the Court would not resolve hypothetical cases that might arise in the future. Nevertheless, given "the critical importance of device-specificity in our (and the FDA's) construction of § 360k, it is apparent that few, if any, common-law duties have been pre-empted by this statute."[89] Justice Stevens observed that "it will be rare indeed" for a court hearing a common-law cause of action to issue a decree that effectively establishes a substantive requirement for a specific device.[90]

Relying on the Court's interpretation of "requirement" in *Cipollone*, Justice O'Connor vigorously disagreed with Justice Stevens' finding that "few, if any, common law duties" have been preempted by the MDA.[91] Justice Breyer joined with Justice O'Connor, concluding that the "MDA will sometimes pre-empt a state-law tort suit."[92]

III. IN THE WAKE OF MEDTRONIC

A. *Preemption After Medtronic*

Writing for the Court, Justice Stevens closed a preemption door but left a window open by failing to clearly define a preemptive MDA "requirement" to guide future court decisions. Justice Stevens came very close to holding that common-law duties are never "requirements" within the meaning of the MDA, but coming close to saying

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[85] *Id.* (quoting 21 C.F.R. § 808.1(d)).

[86] *Id.* at 2258. The *Medtronic* Court found that Congress was not concerned with general common law actions but with the potential problem of conflicting state statutes when it enacted section 360k(a). In section 360k(a), each of the references to the word "requirement" in the statute is linked with specific language regulating devices, not with the generalities of common law. *Id.* at 2252.

[87] *Id.*

[88] *Id.* at 2264 (O'Connor, J. concurring in part and dissenting in part).

[89] *Id.* at 2259.

[90] *Id.* (quoting 21 C.F.R. § 808.1(d)(6)(ii)).

[91] *Id.* at 2262 (O'Connor, J. concurring in part and dissenting in part). Justice O'Connor concluded that "state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA." *Id.* Justice O'Connor pointed out that a similar question was addressed by the Court in *Cipollone* and the majority had agreed that state common law claims impose "requirements" *Id.* (citing 505 U.S. at 521-22).

[92] *Id.* at 2259 (Breyer, J. concurring). Justice Breyer refers to *Cipollone* in his concurrence because the similar language in the statute indicates that the MDA can preempt state law tort actions.

so is not the same as actually making that statement. Because a majority of five justices, Chief Justice Rehnquist and Justices O'Connor, Scalia, Thomas, and Breyer, would hold that state common law tort actions do impose "requirements" and therefore would be preempted when they differ from those imposed by the MDA, there remains considerable room for mischief still.

The mischief already has begun, as the first federal court to examine the preemption issue in light of *Medtronic* concluded that the MDA preempts state tort claims within the context of the investigational device exemption (IDE).[93] The U.S. District Court for the Northern District of New York in *Berish v. Richards* held that plaintiff's common law products liability action regarding a device brought to market pursuant to an IDE was preempted by the MDA.[94]

In *Berish*, the plaintiff claimed injury from a manufacturer's prosthetic hip replacement system, which was classified by FDA as an investigational device.[95] The court initially granted the manufacturer's motion for summary judgment, ruling that the plaintiff's state law claims were preempted pursuant to section 360k(a) of the MDA.[96] The plaintiff thereafter challenged the court's decision based on the Supreme Court's decision in *Medtronic*.[97] In reconsidering its previous ruling in light of *Medtronic*, the court found preemption of the plaintiff's state common law claims once again, noting that it "reads nothing in *Lohr* that compels a different result."[98]

In finding preemption, the court carefully distinguished the procedures involved in an IDE from those of a 510(k), the type of device at issue in *Medtronic*.[99] In distinguishing its holding from that in *Medtronic*, the *Berish* court stated that "[u]nlike the § 510(k) devices that so troubled the *Lohr* Court, IDEs are subject to regulations that 'set forth detailed procedures for determining whether [IDEs] are safe and effective.' Moreover, IDEs are subject to specific regulations promulgated for application, not generally to all devices, but to IDEs specifically."[100]

The *Berish* court concluded that "*Lohr* may not apply outside the context of a § 510(k) device, and if it does, an IDE device is subject to specific regulations that, as stated above comport with the *Lohr* standards permitting pre-emption of state common law tort claims."[101]

The flaw in this reasoning is two-fold: first, the *Berish* court read *Medtronic* to mean that the classification of the device in the regulatory scheme was determinative of its preemptive status; and second, even assuming that *Lohr* based its holding on the fact that a 510(k) device does not go through a rigorous review of safety and effectiveness, the *Berish* court failed to consider the difference between a 510(k) and an IDE. An IDE is granted to an investigational device precisely because its safety and effectiveness is unknown and because the manufacturer's clinical trials must be "experiments that involve humans."[102]

FDA provides for the study sponsor to conduct clinical studies of unapproved devices to discover and develop new devices while protecting human subjects from

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[93] Berish v. Richards Med. Co., 937 F. Supp. 181 (N.D.N.Y. 1996).

[94] *Id.* at 185.

[95] *Id.*

[96] *Id.* at 184.

[97] *Id.* at 182.

[98] *Id.* at 185.

[99] *Id.* at 184-85.

[100] *Id.* at 185.

[101] *Id.* at 186.

[102] Susan Alpert, *Current and Future FDA Initiatives in Clinical Trials*, MED. DEVICE & DIAGNOSTIC INDUS., Apr. 1996, at 44. Dr. Alpert was Director of the Office of Device Evaluation at FDA's Center for Devices and Radiological Health.

unreasonable risk.[103] Thus, FDA does not clear the investigational device for marketing, but rather allows it to be used in a clinical setting so the manufacturer can gather safety and effectiveness data.[104] IDE studies often are needed during product development or prior to preparing a PMA or 510(k) submission.[105] Indeed, the "perverse effect" that the *Medtronic* court suggested would exist if it were to grant immunity to an industry that in Congress' judgment needed more stringent regulation to provide for the public's safety, would exist if IDEs were granted such blanket preemption.[106]

Flawed as well is the *Berish* court's reasoning that because an IDE is "subject to the general controls of the MDA and specific regulations promulgated expressly for IDE devices," state common law tort claims would impose additional requirements.[107] This reasoning is problematic because the "specific" regulations the court refers to are, as Justice Stevens noted in *Medtronic*, merely "generic concerns about device regulation generally."[108] In essence, the regulations monitor the procedures for conducting the clinical trial and seek to ensure that the study sponsor effectively has designed the clinical trial so as to "develop valid scientific evidence that demonstrates safe and effective use to support entry of the product into the marketplace."[109] To this extent, FDA prescribes recordkeeping, reporting, and labeling procedures, and monitors the trial design, recognizing that "no single valid clinical trial design is appropriate for all circumstances."[110] Still, "FDA does not dictate the details of clinical trial design because the development of each product is unique."[111]

Thus, the *Berish* court's emphasis on "specific regulations promulgated expressly for IDE devices" was based instead on a flawed understanding of the nature and content of those regulations; the regulations imposed no more specific requirements than would be applicable to a 510(k) device. Congress might have intended more oversight because the health and safety of the public is known to be at risk with IDE devices.[112]

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[103] 21 C.F.R. § 812 (1997). Clinical studies designed to evaluate the safety and effectiveness of a medical device are covered by the IDE regulations at title 21 *Code of Federal Regulations* section 812.

[104] The goal of a clinical trial when conducting research on a new product is "most often to develop valid scientific evidence that demonstrates safe and effective use to support entry of the product into the marketplace. This is true for all health-care products: drugs, biologics, and medical devices." Alpert, *supra* note 102, at 46.

[105] Valid scientific evidence of safety and effectiveness from clinical trials are required to support premarket approval applications since the initiation of the medical device program under the MDA of 1976. 21 U.S.C. §§ 360(a) (1)(C), 360e (1994). The Safe Medical Devices Act of 1990 (SMDA) also requires clinical trials to support a claim of substantial equivalence for some Class II premarket notification 510(k) submissions. 21 U.S.C. § 360c(I). *See* Ellen J. Flannery, *The Safe Medical Devices Act of 1990: An Overview*, 46 FOOD DRUG COSM. L.J. 129, 136 (1991) (describing the changes set forth in the SMDA with respect to Class II devices).

[106] *Medtronic*, 116 S. Ct. at 2251.

[107] 937 F. Supp. at 185.

[108] 116 S. Ct. at 2258. Although the concerns in Berish focused on the regulation of investigational devices, a subset of the general class of medical devices, the concerns remain "generic" to the class of investigational devices.

[109] Alpert, *supra* note 102, at 46.

[110] *Id.* at 44.

[111] *Id.* at 46. While FDA does not dictate the details of clinical trials, it does offer the device sponsor detailed guidance as to the form of the submission and the types of data it is seeking for the particular device. Alpert refers to the Office of Device Evaluation's (ODE's) more than 200 guidance documents available to provide such information relevant to clinical trials. Alpert notes that these guidance documents are "one way ODE consistently communicates regulatory requirements. Product-specific guidances address clinical trial needs for given product types and outline preclinical requirements as well as the format of marketing submissions." *Id.* at 47. Guidance documents do not have the authority of FDA regulations but are the means whereby FDA "informally" communicates its requirements to industry. *See* Jonathan S. Kahan, *Revolution by Phases: FDA's Regulation of Investigational Device Exemptions*, MED. DEVICE & DIAGNOSTIC INDUS., Jan. 1996, at 121, 123. Kahan advises study sponsors to make incorporate as much of the study and protocol design contained in a relevant guidance document. He notes that "sponsors should be aware that some ODE divisions treat these guidances as if they were regulations, and thus should deviate from them only where there is a valid scientific or medical justification." *Id.*

[112] In regulating investigational devices, FDA differentiates between "significant" and "nonsignificant"

Similarly flawed is the *Berish* court's finding of significance in the exemption of IDE devices from such regulatory provisions as misbranding under section 502, registration and listing under section 510, premarket notification under section 510(k), performance standards under section 514, and good manufacturing practices under section 520(f), among others.[113] Such devices are exempt from these provisions precisely because there are no performance standards relating to the device, no information pertaining to the device's safety or effectiveness on which to base its premarket approval, no production of the device on which to monitor its manufacturing practices, and no actual device for which to require its registration and listing. When and if the device completes clinical trials and the product sponsor chooses to bring it to market, it will be subject to these regulations. Thus, the IDE process is not necessarily an exception to the PMA requirement that "manufacturers may utilize to avoid the rigorous PMA process," but one that may be preliminary or ancillary to either a PMA or 510(k), depending on the particular objectives of the device sponsor.[114]

Even with these flaws in the court's reasoning, the real mischief in the case lies in its interpretation of *Medtronic* as distinguishing among device classifications when determining the applicability of preemption. Unfortunately, the *Berish* court is not alone in this reading of *Medtronic*.[115]

The U.S. Court of Appeals for the Sixth Circuit in *Martin v. Telectronics Pacing Systems, Inc.* found that "the Medtronic device's exemption from the PMA process by way of the § 510(k) notification process was central to the outcome of *Medtronic*."[116] The *Martin* court distinguished between regulatory paths in deciding whether the MDA preempted the state law product liability claims brought against a manufacturer of an allegedly defective pacemaker.[117] Rather than addressing the question of whether the state imposed additional or different requirements applicable to the device and relative to the safety and effectiveness of the device as required by the statute, the court identified as "imperative" the need to determine "whether the device at issue was approved as an investigational device or through the § 510(k) process."[118]

The *Martin* court's subsequent analysis of the medical device at issue in the plaintiff's injury is critical to an appreciation of how damaging this interpretation of *Medtronic* will be to current and future products liability cases under the MDA. By

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risk devices. Only sponsors for significant risk devices must submit an IDE application for approval by FDA prior to the initiation of the clinical trial. For nonsignificant risk devices, the sponsor is still required to follow the IDE regulations at title 21 *Code of Federal Regulations* section 812, but no IDE application need be made to FDA. *See* Kahan, *supra* note 111, at 21 (describing the IDE process, including the differences in reporting obligations between a significant and nonsignificant risk device).

[113] 937 F. Supp. at 185. Conceivably, the device developer is preempted from state tort law liability for an IDE based on compliance with title 21 *Code of Federal Regulations* part 50 (Protection of Human Subjects; the informed consent regulation). This provision requires each investigator to obtain informed consent from each patient prior to participation in the trial. At this point, the patient can choose to opt out of the study and not be exposed to the medical device.

[114] Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090,1095 (6th Cir. 1997). *See* Kahan, *supra* note 111, at 121. Clinical data to demonstrate safety and efficacy is "essential for the ultimate premarket approval of all Class III devices" and has come to be increasingly requested by FDA for Class II devices as well. *Id.*

[115] The mischief exists even if courts find that state tort actions are not preempted but insist on reading *Medtronic* to have found preemption because a 510(k) device was at issue. *See* Reeves v. Acromed Corp., 103 F.3d 442, 447 (5th Cir. 1997) (concluding that the "substantial equivalence" provision did not preempt plaintiff's unreasonably dangerous *per se* claim); Lewis v. American Cyanamid Co., 682 A.2d 724 (N.J. App. Div. 1996) (stating that *Medtronic* "suggests another reason for its holding which may be the most important reason" is that the majority of devices escape any form of meaningful review under the substantial equivalence process).

[116] 105 F.3d at 1095.

[117] *Id.* at 1098-1101.

[118] *Id.* at 1097.

viewing *Medtronic*'s finding of preemption as based on device classification, the *Martin* court effectively took the device apart, component by component.[119] While the manufacturer's Model 4210 system at issue was approved by FDA as an investigational device under an IDE, component elements had in fact received clearance to market pursuant to a 510(k).[120] Although the court ultimately chose to ignore the component-based argument put forth by the plaintiff, deciding instead to "view the device as a whole, approved as an investigational device,"[121] the possibility for finding an exemption under the MDA on a "component" basis remains entirely possible.[122]

The court in *Martin* held that the manufacturing defect, design defect, and inadequate warning claims were preempted by the MDA.[123] It based its holding on the theory that the state requirement, while not developed specifically with "respect to" medical devices, would nonetheless "impede the implementation and enforcement of specific federal requirements."[124] The court found that the IDE regulations regarding manufacturing and design were applicable specifically to investigational devices and that to allow the state cause of action would "thwart the goals of the IDE exemption 'to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use.'"[125]

In examining the design defect claim, the court noted that, because the device at issue was approved as an investigational device, its "risks and benefits [had been] specifically reviewed and balanced" in accordance with federal regulations.[126] Because FDA had determined that the benefits of the device outweighed its risks, for a jury in a state court action to conclude that the risks outweigh the benefits would constitute the imposition of a state requirement different from the federal require-

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[119] *Id.*

[120] *Id.*

[121] *Id.* at 1098.

[122] For other possibilities, see *Oja v. Howmedica, Inc.*, 111 F.3d 782, 787 (10th Cir. 1997). The court noted that its case was distinguishable from *Martin* and *Berish* because the device at issue in *Oja* had not received an IDE at the time the plaintiff was injured. Interestingly, after noting this fact, the court ignored it, choosing instead to trace the entire FDA history of the device at issue, from April 25, 1983 through January 8, 1993. This exercise, however, was unnecessary because the concern of the court should have been the device at the time of the injury, whether there was a federal requirement applicable to the device, and, if so, whether the state requirement reached a medical device and was different from or in addition to the federal requirement. Ultimately, the court did narrow its focus to the device in 1983, and held that the failure to warn claim was not preempted under the MDA.

Although not crucial to the court's ultimate holding, what makes this decision particularly relevant was the court's initial concern with the classification of the device. At first, the court appeared to make much of the fact that the manufacturer had not yet received an IDE for the particular use of the device at issue. Because the court failed to make a decision based on this fact, it seemed that the court believed it should take account of the classification, but did not know what to conclude on the issue. This most likely would be the result of interpreting *Medtronic* to read that device classification is critical, but then finding that the distinction fails to survive scrutiny under the language of the statute itself.

Duvall v. Bristol-Myers Squibb Co., 103 F.3d 324 (4th Cir. 1996), presents another variation on this theme. Here the manufacturer claimed that *Medtronic* did not control the outcome of the dispute because the device at issue was tested under an IDE prior to the submission of a 510(k). It argued that this distinction was critical because the controls applicable to an IDE are sufficiently specific to give rise to preemption. The court, however, was not persuaded, and dismissed the manufacturer's argument, stating that whether regulations for an IDE were specific was not the issue; at the time the device was implanted in the patient, it had been marketed as a 510(k). The *Duvall* court further noted that it had found no support for the "proposition that the controls applicable to IDE devices remain in effect after the IDE has expired." *Id.* at 330.

[123] 105 F.3d at 1099-1100.

[124] *Id.* at 1100.

[125] *Id.* at 1099 (citing 21 U.S.C. § 360j(g)).

[126] *Id.*

ment. The court held that to allow "a cause of action for design defect where the FDA has specifically approved of the design of the device for investigational purposes would thwart the goals of safety and innovation."[127]

This argument, too, is flawed because FDA does not approve the design of an investigational device; rather it approves the clinical protocol as part of the IDE application.[128] Thus, for the *Martin* court to use such a distinction between an IDE and a 510(k) as a basis for preemption of an IDE under the MDA is without merit.

Just as Justice Stevens admonished Medtronic's counsel that its defense "exaggerates the importance of the § 510(k) process," so too do these decisions, which read the *Medtronic* decision as narrowing the scope of preemption under the MDA to 510(k) devices.[129] Other courts have not made this error, finding instead that "the Supreme Court was well aware of the distinction between a PMA-approved device and a § 510(k)-approved device . . . [and] failed to limit . . . [its] holding to the latter."[130]

The U.S. District Court for the District of Columbia in *Lakie v. Smithkline Beecham* dismissed the defendant manufacturer's claim that *Medtronic* applied only to a product that received market clearance through the 510(k) process and that a product that undergoes the PMA process is subject to a specific federal requirement.[131] Instead, the court stated that "the fact that the PMA process requires certain information and mandates certain procedures from manufacturers does not transform the PMA process itself into a specific federal requirement which triggers preemption and protects a manufacturer from suit."[132] In finding that this was not a case in which the federal government had weighed the competing interests relevant to the particular requirement and implemented its conclusion by a specific mandate on the manufacturer, the *Lakie* court distinguished it from a recent Ninth Circuit decision that held that state law claims against tampon manufacturers were preempted because FDA regulations mandated the "specific substantive content" of warnings regarding toxic shock syndrome.[133]

This distinction is critical because the Ninth Circuit in *Papike v. Tambrands, Inc.* identified the federal regulation mandating the substantive content of the toxic shock warning as a specific requirement applicable to the device.[134] In so finding, the court returned MDA preemption analysis to a consideration of the device and not to its number in the classification scheme.

According to the Ninth Circuit in *Kennedy v. Collagen Corporation*, because "distinctions between Class II and Class III devices make little sense," there is "no reason for a court's preemption analysis to change depending on the class of device in issue."[135] The *Kennedy* court noted that just because the

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[127] *Id. See* Alpert, *supra* note 102, at 46.

[128] 21 C.F.R. § 812. The IDE application includes the investigational plan for the study. *Id.* §§ 812.25(a)-(e). The investigational plan should include the purpose of the investigation and the study protocol. It is the study protocol that receives the closest scrutiny from FDA. Still, FDA approval of an IDE application is approval of the proposed clinical trial design, not the proposed device.

[129] *Medtronic*, 116 S. Ct. at 2254.

[130] Comeau v. Heller, 945 F. Supp. 7, 12 (D. Mass. 996). *See also* Lakie v. Smithkline Beecham, 965 F. Supp. 49 (D.D.C. 1997).

[131] 965 F. Supp. at 53.

[132] *Id.* at 54 (citing Kennedy v. Collagen Corp., 67 F.3d 1453, 1459 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996)).

[133] Papike v. Tambrands, Inc., 107 F.3d 737, 741 (9th Cir. 1997).

[134] *Id.*

[135] 67 F.3d at 1458-59. The *Kennedy* court concluded that "distinctions between Class II and Class III devices make little sense" in determining whether a device is preempted under the MDA from state common law

> premarket approval process involves specific requirements . . . [this fact] must not be confused with the premarket approval requirement itself acting as a specific requirement. The result of holding that the premarket approval process is a 'specific requirement applicable to a particular device' is the preemption of claims which, if barred, leave injured plaintiffs without any remedy in state or federal law.[136]

Thus, while the premarket approval process as a requirement for entrance into the marketplace would not in itself qualify as a "requirement" within the meaning of the MDA for preemption purposes, if compliance with the process required a manufacturer to meet a device-specific requirement, that "specification" imposed under the auspices of a PMA would qualify as a "requirement."

So, device classification is not a crucial distinction in a finding of preemption, but one that mistakenly has been seized upon by some courts. The problem with focusing on device classification rather than the device itself is three-fold. First, it fails to recognize that the *Medtronic* Court, while noting the difference in FDA scrutiny afforded the PMA versus the 510(k) device, did not construe the statute's reference to "device" to mean "device classification." Second, the plain language of the statute refers to "device," not "device classification." Third, even if the language of the statute were interpreted to mean device classification, this interpretation would render the statute completely meaningless.

Despite the Court's recognition of the difference in scrutiny afforded a Class II device as opposed to a Class III device, Justice Stevens focused the analysis on the specific language of the statute and noted that each time the word "requirement" was used, it was "linked with language suggesting that its focus is device-specific."[137] Justice Stevens also referred to FDA regulations that provide that state requirements are preempted only when the FDA has established "specific counterpart regulations or . . . other specific requirements applicable to a particular device."[138]

Second, despite the difference of opinion between the Justices as to whether the meaning of the statute was ambiguous, the language of the statute is quite specific: it refers only to "device" and not to "device classification."[139] To hold otherwise would be to substitute the language of the court for that of Congress.

Third, an interpretation of the statute that emphasizes the classification of the device and not the device itself would render the statute essentially meaningless. Since passage of the Safe Medical Devices Act of 1990, the distinction in regulatory oversight between PMA and 510(k) submissions has blurred significantly. Section 510(k)

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claims because "while it is true that Class II devices are subject to specific performance standards only if the FDA deems them a sufficient health hazard whereas all Class III devices are subjected to a stringent 'premarket approval process,' *this distinction in no way changes the fact that the MDA does not preempt claims based upon state common law of general applicability.*" *Id.* at 1459, n.2 (emphasis added). The *Kennedy* court pointed out that, for preemption purposes under the MDA, the classification of the device was irrelevant. The "requirement" of premarket approval prior to a product's introduction into the marketplace was not a "requirement" within the meaning of the statute because reading the statute in this manner would "result in consumers of Class III devices being left without recourse for any harm suffered. Such a result flies in the face of the congressional intent behind the MDA legislation: consumer protection." *Id.* at 1459.

[136] *Id.*

[137] *Medtronic*, 116 S. Ct. at 2252.

[138] *Id.* at 2257 (citing 21 C.F.R. § 808.1(d) (1995)).

[139] Justice Stevens found "ambiguities in the statute." *Id.* at 2252. Justice O'Connor found that "the language of the statute is clear" so as to preclude resort to the agency's interpretation. *Id.* at 2263 (O'Connor, J. concurring in part and dissenting in part).

notices are now "often laden with performance data (including mechanical, animal, and often clinical test data) as well as biocompatibility or electromagnetic compatibility information, depending upon the nature of the technology."[140] They have become what has been termed a "hybrid 510(k) or mini-PMA" and in some cases, such notices "walk, talk, and squawk like PMA applications."[141] In recent years, the number of 510(k) submissions supported by clinical data has increased from two-to-four percent to ten percent or more.[142]

Courts as well as commentators have noted this change in the substantive content of 510(k) submissions. In discussing the difference between the scrutiny afforded PMA submissions in comparison to 510(k) notices, the *Lakie* court noted that "Congress has toughened [510(k)] requirements in 1990, mandating that companies seeking market access through [this] section . . . submit information about the safety and effectiveness of the device, including clinical data in some instances."[143] Thus, the courts' justification for finding preemption on the basis of device classification would be misplaced given this substantial change in the nature and content of 510(k) submissions.[144]

Another basis for rejecting this interpretation of the statute is that it would preclude finding preemption for any device other than a PMA device, even when the basis for preemption may exist. For example, a diagnostic x-ray high voltage generator, recently reclassified as a Class I device from a Class II device, must comply with performance standards for ionizing radiation-emitting products under part 1020 of subchapter J.[145] One such requirement pertains to a warning label on the control panel of the x-ray device. The text of section 1020.30(j) requires that the control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."[146] Because this is a Class I device, a court that relied on "device classification" as dispositive of preemption would be unable to find preemption in this instance. Yet there exists a federal "requirement" applicable to the device. In *Papike*, the Ninth Circuit found a similar warning requirement for packages of tampons to be "device-specific" and therefore required a finding of preemption.[147]

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[140] Jonathan S. Kahan, *FDA Regulatory Programs: Cooperation and Common Sense Typify a Record of Success*, MED. DEVICE & DIAGNOSTIC INDUS., May 1996, at 88, 89.

[141] *Id.*

[142] *Id.* 510(k) notices are now highly structured documents, often with performance data and clinical data. In recognition of the growing complexity and specificity of submissions, ODE has issued many device-specific guidance documents regarding testing and other information to be included in 510(k)s, including guidance on when to submit a 510(k). *See* Arthur C. Kohler, *A 510(k) Primer FDA's Premarket Notification Process*, MED. DEVICE & DIAGNOSTIC INDUS., Jan. 1996, at 127, 134 (describing the 510(k) submission process and the format of the submission).

[143] 965 F. Supp. at 52. In footnote 3 of that opinion, the court cited title 21 *United States Code* section 360(c)(I).

[144] More mischief still: if *Medtronic* is read to find preemption under the MDA according to the classification of the device and the rigor and scrutiny afforded the submission by FDA, then in light of the change in the content and nature of 510(k)s under the SMDA, the courts should extend their analysis to differentiate between pre- and post- SMDA submissions. The courts then would be creating another classification of device based on the date of the 510(k) submission, thus according a different legal status to a pre-SMDA 510(k) submission versus a post-SMDA submission. This could not have been Congress' intent.

[145] 21 C.F.R. § 892.1700. This device is now exempt from premarket notification procedures. Even when devices have been reclassified, making them exempt from 510(k) requirements, the device still must comply with relevant performance standards. *Id.* § 1010.3.

[146] *Id.* § 1020.30(j).

[147] 107 F.3d at 740.

There would appear to be no substantive difference between the warning at issue in *Papike* and the warning required for an x-ray control. A similar result necessarily should follow: a finding of preemption for the control. If the language of the statute is controlling, then the requirement pertains to the "device" and the classification of the device as either Class I, II, or III is irrelevant. In this case, therefore, a finding of preemption would be likely for this Class I device.[148]

B. *Dividing the Preemption Stream*

While Justice Stevens may have failed to close the preemption door, he nonetheless divided the preemption stream to provide for a result in *Medtronic* different from that in *Cipollone*. At least this is how some courts have come to interpret his decision.

In a recent line of cases regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[149] the courts have had occasion to reexamine preemption under *Cipollone* in light of *Medtronic*. Because the preemption clause in FIFRA relating to labeling is so similar to that at issue in *Cipollone*, "numerous federal appellate courts have relied on *Cipollone* in holding that FIFRA preempts state law failure to warn claims. The Courts of Appeals for the First, Fourth, Fifth, Seventh, Eighth, Tenth, and Eleventh Circuits have all held that state law claims based on labels are preempted."[150]

Since *Medtronic,* however, plaintiffs previously denied recovery under state tort law causes of action have claimed that the Supreme Court has

> effectively overturn[ed] all of the cases which made the facile leap from the *Cipollone* plurality's opinion to a conclusion that common law claims were requirements different or in addition to federal regulations [and t]his Court should follow its lead and hold that none of plaintiffs' claims is preempted under FIFRA.[151]

Plaintiffs' argument in *Hawkins* failed to carry the day; the court dismissed their claim and instead concluded that the *Medtronic* Court "took pains to distinguish the MDA from the statute at issue in *Cipollone*" and did not alter the law on FIFRA preemption.[152] The *Hawkins* court relied on two cases decided after *Medtronic*: *Grenier v. Vermont Log Buildings, Inc.*[153] and *Lewis v. American Cyanamid Company*.[154]

In *Grenier*, the plaintiffs claimed that the defendants should have warned them that a wood preservative was not suitable for residences.[155] The Court of Appeals for the First Circuit held that the claim, whether sounding in negligence or breach of

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[148] Another basis for finding that the classification of the device is irrelevant to a finding of preemption is the ability of FDA to change the classification of a device. Under title 21 *United States Code* section 360(c)(e), "[b]ased on new information respecting a device, the Secretary [of Health, Education, and Welfare] may, upon his own initiative or upon petition of an interested person, by regulation . . . change such device's classification . . . ." 21 U.S.C. § 360(c)(e). If the language of section 360k(a) is read to mean "device classification" instead of "device," then by "reclassifying" a device, one could effectively "lose" the "requirement." The Secretary of Health, Education, and Welfare (now Health and Human Services) was invested with authority for implementing the MDA by Congress; the Secretary delegated that responsibility to FDA.

[149] Pub. L. No. 100-532, § 24, 102 Stat. 2654 (1988) (codified at 7 U.S.C. §136v (1994)).

[150] Hawkins v. Leslie's Poolmart, 965 F. Supp. 566, 569 (D.N.J. 1997).

[151] *Id.* at 570.

[152] *Id.* at 571.

[153] 96 F.3d 559 (1st Cir. 1996).

[154] 682 A.2d 724.

[155] 96 F.3d at 559.

implied warranty, was preempted by FIFRA.[156] In its analysis, the court never considered that *Medtronic* might have overruled impliedly the appellate decision's holding that FIFRA preempts claims based on labeling. Instead, the court cited a pre-*Medtronic* case to support its holding and noted that that case, unlike *Medtronic,* "involved FIFRA itself."[157]

In *Lewis*, a New Jersey Appellate Division Court explicitly distinguished *Medtronic* from *Cipollone*.[158] In this case, the plaintiff was injured while using an aerosol insecticide. The trial court held that plaintiff's claims based on inadequate product labeling were preempted by FIFRA.[159] While the plaintiff's appeal was pending before the Appellate Division, *Medtronic* was decided. The Appellate Division concluded that "the holding of the plurality opinion in *Medtronic* is not inconsistent with *Cipollone*, and [held] that the Law Division's ruling that plaintiff's claims based on inadequate labeling are preempted by FIFRA remains an accurate statement of the applicable law."[160]

The *Lewis* court found that *Cipollone* and *Medtronic* reached different results based on the different legislative intent reflected in the statutes at issue.[161] It noted that unlike the cigarette acts at issue in *Cipollone*, the MDA and its implementing regulations "do not prescribe any specific language for labels and its preemptive provision does not contain any express statement of an intent to preempt state labeling requirements."[162] The Appellate Division opined that the "driving force" of *Medtronic* was "the plurality's determination not to infer that Congress intended to have whatever consumer protection might be afforded by common-law tort actions preempted in favor of a regulatory scheme that was largely toothless because of the MDA's 'grandfathering' and 'substantially equivalent' provisions."[163] Continuing, the court reasoned that

> [l]ike the preemption clause at issue in *Cipollone* and unlike that in *Medtronic*, the preemption provision of FIFRA is precise and explicit; i.e., a State "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." Furthermore, FIFRA, like the *Cipollone* statutes, leaves unconstrained all state common law causes of actions for defective products except those based on inadequate labels. Finally, FIFRA has no escape clauses like the "grandfathering" and "substantially equivalent" provisions of MDA.[164]

The *Lewis* decision makes it clear that *Medtronic* and *Cipollone* achieved different results because of differing legislative intent. Similar to the *Lewis* court, the U.S. District Court in *Koch v. Shell Oil Company*[165] attributed the outcome in *Medtronic* to be the result of an interpretation of congressional intent.

In *Medtronic*, the Court held that the court's interpretation of whether pre-

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[156] *Id.* at 563.
[157] *Id.*
[158] 682 A.2d at 724.
[159] *Id.* at 727.
[160] *Id.* at 729.
[161] *Id.* at 730.
[162] *Id.*
[163] *Id.* at 731.
[164] *Id.*
[165] 173 F.R.D. 288 (D. Kan. 1997).

> emption is applicable is determined by consideration of two presumptions: first, Congress does not "cavalierly pre-empt state-law causes of action" due to our system of federalism and second, "fair understanding of congressional purpose." The issue becomes congressional intent.[166]

Hence, *Medtronic* has divided the preemption stream when public policy so demands, providing protection for injured consumers from the dangers inherent in medical devices.

C. *The Role of FDA*

While the *Medtronic* Court may have neglected to "fix the mischief" regarding preemption by failing to hold that state common law tort actions do not impose "requirements" within the meaning of the MDA, it nonetheless provided the means to do so by affirming the role and authority of FDA.

Justice Stevens deferred to the "unique role" of FDA in "determining the scope of § 360k's pre-emptive effect."[167] Moreover, because FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, it is "uniquely qualified" to determine whether a particular state rule should be preempted.[168]

In his concurring opinion, Justice Breyer agreed with Justice Stevens on this point and went even further in his submission to the authority and judgment of FDA in administering the MDA.[169] Justice Breyer noted that FDA's responsibility for administering the MDA provides "informed agency involvement" and therefore a "special understanding" of state and federal requirements.[170] Moreover, FDA "can translate these understandings into particularized pre-emptive intentions accompanying its various rules and regulations."[171] In what may read as a call to action, Justice Breyer further stated that "it [the FDA] can communicate those intentions, for example, through statements in 'regulations, preambles, interpretive statements, and responses to comments,' as well as through the exercise of its explicitly designated power to exempt state requirements from pre-emption."[172]

Justice Breyer also pointed to the specific regulation that FDA has promulgated in reference to the MDA, noting, however, that the regulation's language failed to completely "fill all the statutory gaps."[173] He stated that the regulation's addition of the word "divergent" was not adequate to provide guidance for finding when "different device-related federal and state requirements are closely enough related to trigger pre-emption analysis."[174]

IV. WHAT REMAINS TO BE DONE

FDA should pay heed to Justice Breyer's call to "fill all the statutory gaps" and define the term requirement to make clear when preemption is triggered. While Con-

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[166] *Id.* at 289.
[167] 116 S. Ct. at 2255.
[168] *Id.*
[169] *Id.* at 2260 (Breyer, J. concurring).
[170] *Id.*
[171] *Id.*
[172] *Id.*
[173] *Id.* at 2261 (Breyer, J. concurring).
[174] *Id.*

gress could pass clarifying legislation to resolve the dilemma faced by the courts in deciding preemption issues under the MDA, action by FDA is preferable. The agency is the body most qualified to speak to the issue by virtue of its authority from Congress and its experience in implementing the provisions of the FDCA.

This author would suggest that FDA replace "requirement" with "requirement specification" where appropriate in the *Code of Federal Regulations*, and then add this term and its definition to title 21 *Code of Federal Regulations* section 808.3 to appear immediately before the definition of "substantially identical to" in that section. This change is critical, especially in light of the definition of "substantially identical to": "substantially identical to refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement."[175] An agency-provided definition of "requirement" will give meaning to this phrase as well.

By qualifying "requirement" with "specification," FDA would narrow the "universe of federal requirements" to technical product specifications.[176] In addition, this definition would give meaning to current language in the regulations that provides that state requirements of "general applicability" are not preempted except when they have "the effect of establishing a substantive requirement for a specific device."[177] Justice Stevens noted that the statutory and regulatory language focused on "specificity," but he did not make the connection to "specification" and the precise technical meaning of this word. Perhaps this task rightly belongs to FDA.

A plurality of the Court clearly deferred to the authority of FDA to regulate in this area, so FDA's definition of "requirement specification" would be accorded considerable weight by the courts in deciding preemption issues under the MDA. Furthermore, by emphasizing the importance of device specificity in its understanding of the preemption scheme, and by carefully distinguishing between the "requirement" at issue in *Cipollone* and the "requirement" in the MDA, Justice Stevens prepared a foundation for a new or different definition of that term.[178] Finally, in defining "requirement" in terms of a technical product specification, FDA would be faithful to precedent, the needs of the medical device industry, and the basic intent of Congress in promulgating the statute.

There is precedent for defining "requirement" as a product specification. In *Bibb v. Navajo Freight Lines, Inc.*,[179] the Supreme Court invalidated an Illinois safety measure that specified contour mudguards for trucks operated within its jurisdiction.[180] The statute's unique variation on mudguard design made the use of straight mudguards illegal in Illinois, although the design was legal in at least forty-five states.[181] In addition, the Illinois design was itself illegal in Arkansas, a state that required straight mudguards.[182] This variation in standards unnecessarily retarded the free flow of interstate trucking, and the statute was held to be invalid as an undue burden on interstate commerce.[183]

The *Bibb* Court referred to the state's specification of a particular kind of mud-

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[175] 21 C.F.R. § 808.3(f).

[176] *Medtronic*, 116 S. Ct. at 2261 (Breyer, J. concurring).

[177] 21 C.F.R. § 808.1(d)(6)(ii).

[178] 116 S. Ct. at 2259. Justice O'Connor did not "subscribe to the Court's reading into § 360k the additional requisite of 'specificity.'" *Id.* at 2264 (O'Connor, J. concurring in part and dissenting in part).

[179] 359 U.S. 520 (1959).

[180] The Illinois statute, cited in relevant part by the *Bibb* Court in footnote 1, provided detailed "specifications" for the rear fender splash guards, setting precise measurements and tolerances. *Id.* at 520.

[181] *Id.* at 523.

[182] *Id.* at 526.

[183] *Id.* at 528.

guard as a "requirement."

> A State which insists on a design out of line with the *requirements* of almost all the other States may sometimes place a great burden of delay and inconvenience on those interstate motor carriers entering or crossing its territory. Such a new safety device — out of line with the *requirements* of the other States — may be so compelling that the innovating State need not be the one to give way.[184]

The Court noted the district court's findings that the effect of the contour mudguard possessed no safety advantages over the conventional flap or straight mudguard design permitted in all other states, and indeed created safety hazards by accumulating heat in the brake drum.[185] The Court concluded that the special mudguard design, because of the different and conflicting design requirements of other states, placed an undue burden on interstate commerce.[186] The Court also noted that if the only issue were the cost of adjusting an interstate operation to local safety regulations, then the measure would have to be sustained.[187]

In *Bibb*, the Court engaged in a balancing test between a state's legitimate interest in the health and safety of its citizens and the national interest in free trade as reflected in the Commerce Clause. This balancing test is not unlike that engaged in by FDA, wherein it "weigh[s] the competing interests relevant to the particular requirement in question, reach[es] an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implement[s] that conclusion via a specific mandate on manufacturers or producers."[188]

As Justice Stevens noted, Congress has given the agency a unique role in the interpretation of the MDA and its preemptive scope. At once concerned with the protection of the public's health and safety and the federal interest in preventing unnecessary restrictions on trade, FDA must weigh these often competing interests when promulgating regulations. In addition, FDA must consider similar interests of the states in regulating health and commerce issues. In recognition of this task and the likelihood of competing interests and concerns, Congress explicitly delegated to FDA the authority to exempt state regulations from the preemptive effect of the MDA, an authority that required FDA "to assess the pre-emptive effect that the Act and its own regulations will have on state laws."[189]

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[184] *Id.* at 529-30 (emphasis added).

[185] *Id.* at 524.

[186] *Id.* at 529.

[187] *Id.* at 526.

[188] *Medtronic*, 116 S. Ct. at 2258.

[189] *Id.* at 2255-56. FDA shares this view. In a recent article in the *Food and Drug Law Journal*, Margaret Jane Porter, Chief Counsel for FDA, summarized FDA's position on the *Medtronic* decision. "The agency's position was adopted by the Supreme Court in *Lohr*. . . . [The] agency's position in *Lohr* and the Court's decision are the logical extensions of the agency's long-standing presumption against preemption in implementing section 521 of the Federal Food, Drug, and Cosmetic Act (FDCA)." Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 10 (1997).

With *Medtronic*, the Court adopted the agency's view that the scope of preemption under section 521 is to be interpreted narrowly. FDA's narrow construction of the preemptive effect of the statute is "reflected in the multiple rulemakings under that section, including part 808, the regulation interpreting section 521 that was issued in 1978, and several regulations granting or denying exemptions from preemption for various state and local requirements. Various portions of these regulations were cited by the Court in *Lohr*." *Id.* at 7.

In addition to discussing FDA's narrow view of the scope of preemption, Porter addressed the agency's position on the issue of whether state tort remedies were requirements with respect to a device so as to be pre-

In assessing a state regulation for "exemption from preemption," FDA necessarily must consider whether there is a conflict between the requirements of the state and federal regulations. Here the similarity to the use of the word "requirement" in the mudguard dilemma becomes apparent: states cannot impose additional or different "requirement specifications" when they create an undue burden on commerce because manufacturers cannot design a device to competing specifications. Just as the trucks could not comply with the conflicting design specifications of mudguards between Illinois and Arkansas, the medical device manufacturer cannot design a product to meet either conflicting state specifications or conflicting federal and state specifications.

In defining "requirement" as a technical product specification, FDA would be meeting the needs of the medical device industry for clarity and precision in federal regulations and guidelines; it also would be using the language appropriate to the industry and technology it regulates. Quite simply, the medical device industry "deals" in technical specifications in the design and development of the products it brings to market. It is the language the industry knows, understands, and uses to communicate with other manufacturers and FDA.[190]

The medical device industry uses the words "requirements" and "specifications" interchangeably. Still, there is a subtle difference between the terms: a "requirement" is what the product is required to do and the "specification" is the means by which it will do it.[191] For most purposes relating to design and development, however, there is

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empted by section 521. Porter noted that

> although the agency had not formally expressed its position on this precise issue, it was clear from the views it expressed in many other contexts that it did not believe that state tort claims were preempted under section 521. Indeed, this was the prevailing view in the legal community until the early 1990s; no arguments were put forward that there should be preemption of these claims.

Id. at 8.

Porter, like the Supreme Court, sought evidence of the intent of Congress to support FDA's position. First, the legislative history of section 521 contained no indication that the section was intended to preempt state tort claims. Second, and perhaps the most important evidence of Congress' failure to consider a "requirement" to be a tort claim, were the specific procedures Congress created in the statute for states to apply for exemption from preemption. Such a mechanism does not readily encompass state tort claims. According to Porter, "the exemption procedure is designed to accommodate state and local legislative and regulatory provisions; it does not logically accommodate judicial rulings in private tort suits." *Id.*

Finally, Porter concluded her article with two powerful observations. The first relates to the regulatory strength of FDA but recognizes its limitations, while the second, frequently overlooked by courts and commentators alike, considers two other areas subject to FDA regulatory authority: drugs and biologics.

> FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection. FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time. Preemption of all such claims would result in the loss of a significant layer of consumer protection, leaving consumers without a remedy for injuries caused by defective medical devices. Moreover, FDA's regulation of devices would have been accorded an entirely different weight in private tort litigation than its counterpart regulation of drugs and biologics. This disparity is neither justified nor appropriate, nor does the agency believe it was intended by Congress when section 521 was enacted.

Id. at 11.

[190] FDA's preproduction quality assurance guidelines provide clear insight into requirements management and the language used within the industry to discuss design activities. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMIN., PREPRODUCTION QUALITY ASSURANCE PLANNING: RECOMMENDATIONS FOR MEDICAL DEVICE MANUFACTURERS (1989) (HHS Pub. No. FDA 90-4236).

[191] Alan Davis & Dean Leffingwell, *Requirements Management in Medical Device Development*, MED.

essentially no difference between a "requirement" and a "specification."[192]

Finally, in defining "requirement specification," FDA would give effect to the intent of Congress in enacting the statute — to regulate an increasingly sophisticated technology without placing unduly restrictive burdens on the manufacturer.[193] This mission can be understood only by recognizing that it would be an undue burden to impose substantive, conflicting, or redundant requirements that go to the actual design and production of the device rather than requiring procedural safeguards that ensure public safety.

V. CONCLUSION

By providing a definition for "requirement" as "requirement specification" in its regulations, FDA would be fulfilling its role as intended by Congress. This definition, based on the technological nature and circumstances surrounding the adoption of the MDA, very likely encompasses the meaning intended by the Ninety-fourth Congress in 1976. Even assuming arguendo that such was not Congress' intended meaning, this definition nonetheless would resolve the preemption issue left open by the *Medtronic* Court.

Moreover, this definition should be incorporated into the language of section 360(a) of the MDA, for only by incorporating this language into the statute itself will the health and safety benefits be passed directly to consumers and patients.

DEV. & DIAGNOSTIC INDUS., Mar. 1996, at 100, 107.

[192] *Id.* at 101. The need for "requirements management" has arisen because the design process itself has come under closer scrutiny both on the part of the manufacturer, interested in reducing the cost of product development, and FDA, interested in ensuring that the design of the device meets its revised good manufacturing processes regulations. *Id.* "Requirements management" is defined as "a systematic approach to eliciting, organizing, documenting, and managing both the initial and the changing requirements of a system. A primary result of this effort is the development of one or more requirements specifications that define and document the complete external behavior of the system to be built." *Id.* at 100. The authors subsequently define requirements by starting as an abstraction, outlining the needs for the device, and gradually becoming more specific, as they emerge as a set of detailed requirements such as "the pump will weigh less than 12 ounces" or "the pump will operate for up to 24 hours on a 9V battery." *Id.* at 107. They add that good requirements specifications have the following attributes in common: clarity, completeness, consistency, and traceability. In discussing consistency, the authors note that "a system that satisfies all requirements cannot be built if two requirements conflict." *Id.* The need for consistency in requirements specifications is further discussed as part of the process of device development, in which the last step in the gathering and eliciting of requirements for a new device is the removal of "conflicting or redundant requirements." *Id.*

[193] H.R. REP. NO. 94-853, 94th Cong., 2d Sess. 45 (1976). Congress explained that "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the federal government, interstate commerce will be unduly burdened." *Id.*

In enacting the MDA, Congress sought to promote the public health by encouraging the development of new medical devices: "As medicine progresses, as research makes new breakthroughs, an increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of the American people. The Committee wants to encourage their research and development." S. REP. NO. 94-33, 94th Cong., 2d Sess. 2 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071.