Medtronic v. Lohr: Is There a Future for Preemption in Medical Device Cases?

There's reason to hope that there will be preemption for devices that reach the market via the PMA or IDE channels

By Quentin F. Urquhart Jr. and Robert E. Durgin

LAST JUNE, a sharply divided U.S. Supreme Court handed down its much-awaited decision in *Medtronic Inc. v. Lohr*.[1] The plaintiffs, Lora Lohr and her husband, had filed suit in Florida state court against Medtronic based on the failure of its Model 4011 pacemaker lead. The Lohrs alleged causes of action for defective design, negligent manufacture and failure to warn.

After the action was removed to federal court, the district judge granted Medtronic's motion for summary judgment on the grounds that the Lohrs' claims were preempted by the Medical Device Amendments to the Federal Food Drug and Cosmetic Act of 1938 (MDA).[2] The 11th Circuit reversed in part and affirmed in part, concluding that the Lohrs' negligent design claims were not preempted, but that their claims based on negligent manufacturing and failure to warn were preempted by regulations promulgated by the federal Food and Drug Administration (FDA) pursuant to the MDA.[3]

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The Supreme Court granted both parties' petitions for certiorari because the U.S. courts of appeals were divided over the extent to which state common law tort claims are preempted by the MDA.[4]

In deciding the case, the Supreme Court produced three opinions, which the medi-

1. 116 S.Ct. 2240 (1996)
2. 21 U.S.C. § 360c et seq. (West Supp. 1996).
3. 56 F.3d 1335 (11th Cir. 1995).
4. *See, e.g.,* Talbott v. C.R. Bard Inc., 63 F.3d 25 (1st Cir. 1995) (state common law claims preempted by § 360k(a), Class III device); Becker v. Optical Radiation Corp., 66 F.3d 18 (2d Cir. 1995) (same); English v. Mentor, 67 F.3d 477 (3d Cir. 1995) (§ 510(k) process creates preemptive requirements, Class III device); Duvall v. Bristol-Meyers Squibb, 65 F.3d 392 (4th Cir. 1995) (same); Feldt v. Mentor Corp., 61 F.3d 431 (5th Cir. 1995) (§ 510(k) process does not create preemptive requirements, Class III device); Bingham v. Mentor Corp., 89 F.3d 203 (5th Cir. 1996) (state law not preempted because of insufficient nexus with federal law, Class III device); Michael v. Shiley, 46 F.3d 1316 (3d Cir. 1995) (claim of federal requirement violation not preempted, Class III device); Mitchell v. Collagen Corp., 67 F.3d 1268 (7th Cir. 1995) (all state statutory law and some state common law preempted, Class III device); Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995) (no state common law claims preempted, Class III device); Kealoha v. G.I. Dupont, 82 F.3d 894 (9th Cir. 1996) (state law not preempted, Class III device); Nat'l Bank of Commerce of El Dorado v. Kimberly-Clark Corp., 38 F.3d 988 (state law preempted, Class III device).

cal device industry, its counsel, and plaintiffs' attorneys will debate into the foreseeable future.

First, Justices Ginsberg, Souter and Kennedy joined an opinion authored by Justice Stevens that became the opinion of the Court to the extent that it was joined by Justice Breyer. These five justices found that none of the Lohrs' claims were preempted.

Second, Chief Justice Rehnquist and Justices Scalia and Thomas created a separate four-justice plurality by signing onto an opinion authored by Justice O'Connor. These four justices would have held that the Lohrs' manufacturing and failure to warn claims were preempted by the MDA.

Third, Justice Breyer's separate opinion staked out a middle ground between the opinions authored by Justices Stevens and O'Connor. By siding with Justice O'Connor on one issue and with Justice Stevens on a second, he created shifting 5-4 majorities of the Court.

Lohr raises significant questions whether preemption is still a viable defense in medical device cases. What are some of the possible answers to those questions?

MEDICAL DEVICE AMENDMENTS OF 1976

Medical device regulation in the United States can be traced to the late 1960s and early 1970s when increasing numbers of new medical devices became available to the medical profession. As the public began to rely more and more on these devices, concerns surfaced about the potential for injuries resulting from their failure. Those fears culminated in the 1970s with the introduction of the Dalkon Shield contraceptive device. Although initially touted as a safe and effective contraceptive, its use resulted in an alarmingly high number of injuries.[5] In response to these concerns, the Medical Device Amendments of 1976 were enacted. Through them, Congress sought to establish a comprehensive regulatory framework within which it could "assure the reasonable safety and effectiveness of medical devices intended for human use."[6]

The MDA confers broad powers on the Food and Drug Administration to classify and regulate medical devices. The FDA must assign a medical device to one of three statutorily delineated categories based on the degree of regulation which the FDA deems "sufficient to provide a reasonable assurance of safety and effectiveness."

- A Class I device is one that poses little or no threat to public health. Examples of Class I devices include band-aids, crutches, and tongue depressors.[7]
- A Class II device is one that does not pose a direct threat to the public health but they carries a greater risk of injury than a Class I device. Examples of Class II devices include syringes, tampons, and dental x-ray machines.[8]
- A Class III device is one that is "represented to be for use in supporting or sustaining human life or for a use which is a substantial importance in preventing impairment of human health," or which presents an "unreasonable risk of illness or injury," to quote 21 U.S.C. § 360c(a)(1). Examples of Class III devices include heart valves, pacemakers, breast implants, penile prostheses, and replacement joints.[9]

All three classes of devices are subject to "general controls," which include both general labeling and "good manufacturing practices" requirements. Because general controls alone are insufficient to provide the public with an adequate assurance of safety and effectiveness, Class II devices

5. SEN. REP. No. 33, 94th Cong., 1st Sess. 51, reprinted in 1976 U.S. Code & Admin. News 1070, 1071.
6. H. CONF. REP. No. 1090, 94th Cong., 1st Sess. 51, reprinted in 1976 U.S. Code & Admin. News 1070, 1103.
7. 21 C.F.R. §§ 880.5075, 890.3150, 880.6230, respectively.
8. 21 C.F.R. §§ 880.5860, 844.5460, 872.1800, respectively.
9. 21 C.F.R. §§ 870.3925, 870.3600, 878.3530, 876.3350, 888.3150, respectively.

also may be subject to "special controls," such as more stringent performance standards, post-market surveillance, and guidelines for use. Finally, because the safety of Class III devices cannot be adequately assured through the combined use of general and special controls, they also are subject to the most stringent regulation in the form of premarket approval (PMA) from the FDA.

To obtain a PMA under the statutory and regulatory scheme, the manufacturer of a device must submit all available information to establish that the device is safe and effective, a statement of the intended use of the product, a description of expected manufacturing processes, and any other information requested by the FDA. After review by a panel of medical experts, approval is granted if the FDA finds there is a "reasonable assurance" that the device is "safe and effective," "weighing any probable benefit to health from the device against the possible risk of illness or injury from such use."[10] Even after a PMA has been granted, the FDA retains a continuing oversight responsibility over Class III devices.[11]

The MDA provide three important exceptions to the PMA requirement. First, devices that were available publicly before passage of the MDA on May 28, 1976, can remain on the market without FDA approval until such time as the FDA promulgates rules requiring those devices to undergo the PMA process. These devices are referred to as "grandfathered" or "pre-existing" devices. Second, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle and to ensure that improvements to existing devices can be rapidly introduced into the market, the MDA also permits devices that are "substantially equivalent" to pre-existing devices to avoid the PMA requirement. This exemption exists until the FDA issues a regulation requiring a PMA for the device.

A manufacturer that desires to market a product based on "substantial equivalence" must satisfy the requirements of 21 U.S.C. § 360(k), which imposes a limited form of review on every manufacturer by requiring the submission of a "premarket notification" to the FDA. Devices that reach the market in this way are often referred to as "Section 510(k) devices" after the section of the act under which claims for substantial equivalence are made. If the FDA concludes on the basis of the Section 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis.

Although Congress apparently envisioned that the majority of medical devices would make their way to market via the PMA process, this expectation turned out to be unrealistic. As noted by the Court in *Lohr*:

> [B]ecause of the substantial investment of time and energy necessary for the resolution of each PMA application, the ever-increasing numbers of medical devices, and internal administrative and resource difficulties, the FDA simply could not keep up with the rigorous PMA process. As a result, the Section 510(k) premarket notification process became the means by which most new devices—including Class III devices—were approved for the market.[12]

The vast majority of Class III devices on the market today thus have entered via Section 510(k). As noted in one of the leading articles on the subject, the attraction of substantial equivalence is clear because Section 510(k) "notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly."[13]

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10. 21 U.S.C. § 360c(a)(2); 21 C.F.R. §860.7.

11. *See, e.g.*, 21 U.S.C. § 360i (requiring certain reports on device even after PMA is granted); 21 C.F.R. § 803.10 (requiring report of any deaths caused by use of device).

12. 116 S.Ct. at 2247.

13. Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511, 516 (1988).

The third major exception to the PMA requirement is found in Class III devices that obtain an investigational device exemption (IDE) from the FDA. An IDE permits the limited marketing of an unapproved device to allow a further assessment of its risks and benefits. If a device is marketed under an IDE, then the manufacturer is excused from having to meet "good manufacturing practices" requirement, certain labeling requirements, performance standards, and the PMA process during the term of the IDE. At any time, however, the FDA may withdraw the exemption, thus subjecting the exempted device to the formal PMA process.

PREEMPTION UNDER THE MDA

Federal law can preempt state law in one of two ways. Congress either may state its intent to preempt state law explicitly in the language of a statute, or Congress may imply its intent to preempt through the structure and purpose of a statute.[14] Where the intent to preempt is explicit in a statute, the Supreme Court has held that "there is no need to infer congressional intent to preempt state laws from the substantive provisions of the legislation. . . . Congress' enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not preempted."[15]

The preemptive language of the MDA, Section 360k(a), is:

> [N]o State or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Because Congress expressly provided for the preemption of state law in the MDA, the question to be answered is not whether preemption exists at all, but rather the extent of that preemption. That was the question the Supreme Court was called on to resolve in *Lohr*.

THE LOHR DECISION

Justice Stevens delivered a seven-part opinion, which was joined in all respects by Justices Souter, Kennedy and Ginsburg. Justice Breyer joined Parts I, II, III, V and VII. Although the four dissenters—Chief Justice Rehnquist and Justices O'Connor, Scalia and Thomas—did not join any part of the Stevens opinion, they expressly agreed with two of the Court's holdings.

A. Parts I and II

Part I traced the history of medical device regulation in the United States and the enactment of the MDA. Part II reviewed the Section 510(k) process that led to the introduction of the Medtronic Model 4011 pacemaker lead, the factual and procedural background of the Lohrs' case, and the wording of the MDA preemption provision. Neither of these parts provided grounds for debate among the justices.

B. Part III

Part III, which was joined by Justice Breyer, set forth two propositions that served as the foundation for the ultimate disposition of the preemption issue. First, because the states are considered independent sovereigns in a federal system, Justice Stevens noted that the Supreme Court has long presumed that Congress does not "cavalierly" preempt state law causes of action. Second, the Court referenced its oft-repeated rule that the scope of preemption always should be determined with reference to congressional purpose—that is, how Congress "intended the statute and its

14. Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977).

15. Cipollone v. Liggett Group Inc., 505 U.S. 504, 517-518 (1992).

surrounding regulatory scheme to affect business, consumers and the law."

C. Part IV

Part IV, which Justice Breyer declined to join on the ground that it was not relevant to the case, addressed and harshly rejected Medtronic's contention that the promulgation of FDA regulations pursuant to the MDA effected a preemption of *all* common law products liability actions. Justice Stevens focused on the congressional purpose in enacting the MDA to enhance the safety and effectiveness of medical devices, and the purported absence of any intent by Congress to immunize manufacturers from products liability actions:

> Medtronic's construction of Section 360k would therefore 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," 90 Stat. 539 (preamble to act).[16]

Justice Stevens concluded Part IV by noting that there was "nothing in the hearings, the committee reports, or in the debates suggesting that any proponent of the [MDA] intended a sweeping preemption of traditional common law remedies against manufacturers and distributors of defective devices."

D. Part V

Part V analyzed on a claim-by-claim basis whether each of the Lohrs' claims was preempted. With respect to the design claim, Justice Stevens focused on the fact that the Section 510(k) process did not constitute a reasoned evaluation of device safety and effectiveness. Justice Breyer and the dissenting justices agreed with Justice Stevens that the plaintiffs' defective design claim was not preempted by the Section 510k's "substantial equivalence" determination. Further, because the FDA did not "require" the device to take any particular form for any particular reason, there were no federal requirements that would conflict with any state requirement for device design. Thus, claims based on the alleged defective design of a device marketed pursuant to Section 510(k) are not preempted.

Justice Stevens next addressed the Lohrs' "identity of requirements" claims and concluded that Section 360k does not prevent recovery of damages under state tort law for a defendant's alleged violation of FDA regulations or other federal requirements. The Court reasoned:

> The presence of a damages remedy [for violation of FDA regulations] does not amount to the additional or different "requirement" that is necessary under [Section 360k]; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.[17]

The dissenting justices agreed with this holding, accepting the reasoning that Section 360k only precludes states from imposing different or additional requirements, not from providing different or additional remedies. Thus, a complaint that includes an allegation that FDA regulations have been violated cannot be dismissed in its entirety on the basis of a preemption defense.

Part V continued with Justice Stevens's consideration of the Lohrs' negligent manufacturing and labeling claims. Unlike claims based on defective design, there are federal labeling and manufacturing requirements for devices marketed pursuant to Section 510(k). These include regulations requiring manufacturers of every medical device, with a few limited exceptions, to include with the device a label containing "information for use, . . . and any relevant hazards, contraindications, side effects, and precautions."[18] Justice Stevens pointed out that manufacturers also are required to comply with "good manufacturing practices," which are set forth in 32 sections

16. 116 S.Ct. at 2251.
17. *Id.* at 2255.
18. C.F.R. § 801.109(b) and (c).

and less than 10 pages of the Code of Federal Regulations.

The issue in *Lohr* was whether these general regulations constituted federal requirements that would preempt differing state requirements. In addressing this issue, both Justices Stevens and Breyer took guidance from a particular FDA regulation, which provided in relevant part:

> State 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 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.[19]

Because the FDA has not established specific counterpart regulations for devices marketed pursuant to Section 510(k), the Court found that preemption is triggered only if there are "other specific [federal] requirements" that conflict with state requirements applicable to the same device. Both Justice Stevens and Justice Breyer concluded that the general federal regulations for labeling and manufacturing were not specific enough to displace any differing state requirements.

Justice O'Connor and the other dissenting justices disagreed with the reasoning of Justices Stevens and Breyer that the MDA only preempts "specific" federal requirements with respect to particular devices, and in particular their reliance on the language of the regulation set out above. The dissent reasoned that Section 360k(a) of the MDA does not contain language limiting its preemptive effect to "specific" requirements but, instead, states that "any requirement applicable under this chapter to the device" preempts state law "requirements" with respect to the device.

While not necessary for the disposition of the Lohrs' claims, Justice Stevens went on to hold that the "general duties" imposed by state law to use due care in the manufacture and labeling of a product were not specific enough to be preempted by Section 360k. Although Justice Breyer joined Part V of the opinion, it is highly unlikely that he would subscribe to Justice Stevens' analysis of this particular issue, for to do so would be at odds with the reasoning of his own concurring opinion. The degree of state regulatory specificity necessary for preemption promises to be an issue repeatedly litigated in the future.

E. Part VI

Part VI discussed the Lohrs' contention that Section 360k of the MDA never preempts common law tort actions because common law duties are not state "requirements" within the meaning of the statute. While Justice Stevens said "we do not respond directly to this argument," he proceeded to comment that "it will be rare indeed" for a court hearing a common law action to issue a decree that has the effect of establishing a substantive requirement for a specific device.

Relying on *Cipollone v. Liggett Group Inc.*,[20] Justice O'Connor strongly disagreed with Justice Stevens's statement in Part VI that "few, if any, common law duties" will be preempted by the MDA. Adopting a common sense approach, Justice Breyer resolved this issue in Justice O'Connor's favor and concluded that the MDA "will sometimes preempt a state law tort suit."

Employing an analysis that will be useful in future defense efforts, Justice Breyer reasoned:

> Imagine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the "2-inch" MDA regulation, preempts the state "1-inch" agency regulation, why would it not similarly preempt a state law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an

19. C.F.R. § 808.1(d), emphasis supplied.
20. 505 U.S. 504 (1992).

> award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent)? The effects of the state agency regulation and the state tort suit are identical. To distinguish between them for pre-preemption purposes would grant greater power (to set state standards "different from or in addition to" federal standards) to a single state jury than to state officials acting through state administrative or legislative law making processes.[21]

Justice Breyer thus concluded that the MDA would preempt a state law tort action that imposed different requirements on the manufacturer.

F. Part VII

Finally, Part VII of the opinion concisely stated the judgment of the Court.

PREEMPTION POST-LOHR

A. Concerns Unique to Section 510(k) Devices

Lohr involved a product that arrived on the market based on the manufacturer's claim of substantial equivalence pursuant to Section 510(k). Disparate majorities of the Supreme Court held that none of the Lohrs' traditional product liability claims —design defect, manufacturing defect, and failure to warn—were preempted by the MDA. This conclusion was driven by two concerns unique to Section 510(k) devices.

First, it is clear that the *Lohr* Court was troubled by the lack of any meaningful evaluation of device safety. Section 510(k) does not require the FDA to engage in a considered weighing and balancing of the risks and benefits of a medical device before it reaches the market; only device equivalence is at issue. With respect to the Lohrs' design claim, the Court thus found no preemption because the design of the device at issue had not been formally reviewed under the MDA for safety or efficacy. The FDA, according to the Court, had "simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the PMA process." The Court concluded that such a "substantial equivalence" determination provided little protection to the public.

The limited nature of the Section 510(k) process also played a major role in highlighting the second major concern of the Court—the lack of federal regulatory specificity. Section 360k(a) of the MDA mandates preemption only where there is a conflict between a state requirement and a specific federal requirement applicable to the device. Relying on 21 C.F.R. § 808.1(d), the Court held that the Lohrs' manufacturing and warning claims would be preempted only if the FDA had established "specific counterpart regulations" or "other specific requirements" applicable to the device.

The Court concluded that the general labeling regulations and good manufacturing practices applicable to all devices were not "specific" enough to preempt differing state requirements:

> The generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing interests should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.[22]

In sum, the *Lohr* court premised its reasoning and analysis on two areas of concern: (1) the lack of any meaningful evaluation of device safety and efficacy by the FDA, and (2) the lack of specificity in the federal requirements applicable to the device. Because these concerns are unique to Section 510(k) devices, this leaves open the question whether claims involving products reaching the market via different channels also will be preempted.

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21. 116 S.Ct. at 2259.
22. *Id.* at 2258.

B. Premarket Approval Devices

In contrast to the superficial nature of the Section 510(k) process, the PMA process was described by Justice Stevens as "rigorous." To obtain a PMA for a Class III medical device, the manufacturer must provide the FDA with a "reasonable assurance" that the device is safe and effective under the conditions of use prescribed in its labeling. "Manufacturers," he wrote, "must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." Thus, the substantial equivalence process is by no means comparable to the PMA process.

An application for premarket approval of a device must include the following detailed information from the manufacturer:

> (1) A summary of the application which includes indications for use, a device description, *a description of alternative practices or procedures,* the marketing history of the device, a summary of the laboratory and clinical studies, and the conclusions drawn from those studies.
>
> (2) A complete description of the device, including *design*, functional components, principles of operation, *the manufacturing method (including facilities and controls)* and quality control procedures.
>
> (3) References to any *performance standards* that are relevant to any aspect of the safety or effectiveness of the device.
>
> (4) *Results of laboratory studies* on the microbiological, toxicological, immunological, biocompatibility, stress and wear characteristics of the device and the results of clinical investigations involving human subjects including clinical protocols and detailed descriptions of the study of methodology.
>
> (5) *A bibliography of all published reports,* adverse or supportive, covering the safety or effectiveness of the device.
>
> (6) Copies of *all proposed labeling for the device, including instructions for use.*[23]

Even after the initial submission of the PMA application, the manufacturer must periodically update its pending application with new safety and effectiveness information learned about the device from ongoing or completed studies.[24] If this new information affects the safety or effectiveness of the device or would require changes in the proposed warnings and contraindications for use of the device, then a formal amendment to the PMA must be submitted to the FDA.[25]

Once the PMA has been submitted, the FDA then decides whether the device is safe and effective. In making that determination, it considers these relevant factors: (1) the person for whose use the device is intended; (2) the conditions of use for the device, including the conditions for use suggested in the labeling; (3) the probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and (4) the reliability of the device.[26] Assuming there is a reasonable assurance that a device is safe and effective, then the FDA issues a formal approval order that permits the sale of the product in the United States.[27] The approval order may impose post-approval requirements as a condition to approval of the device.[28]

The PMA process thus directly addresses both of the concerns that were so troubling to the Court in *Lohr*. Unlike the Section 510(k) process, before approving a PMA application, the FDA does engage in a systematic evaluation of device safety and efficacy. The manufacturer must present detailed evidence that is thoroughly evaluated. Only if the FDA determines that the probable benefits to health from use of the device, when accompanied by adequate directions and warnings, outweigh any probable risks is approval given to market the device.[29]

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23. 21 C.F.R. §§ 814.20(b)(1)-(12), emphasis added.
24. 21 C.F.R. § 814.20(e).
25. C.F.R. § 814.37.
26. C.F.R. § 860.7.
27. 21 C.F.R. § 814.44.
28. 21 C.F.R. § 814.80.
29. 21 C.F.R. § 860.7(d)(1).

In contrast to the Section 510(k) process, the PMA process also results in the imposition of specific "federal requirements" for the design, manufacture, and labeling of that particular device. Once the FDA approves the device for sale, regulations strictly prohibit it from being "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."[30] By approving the PMA application, the FDA implicitly adopts the design, manufacturing, and labeling requirements set forth by the manufacturer, and the FDA must approve any changes to those requirements.[31]

The fact that those "requirements" do not originate from the FDA does not detract from the fact that they are "specific requirements" applicable to a device. This was the conclusion recently reached by the California Second District Court of Appeal in *Armstrong v. Optical Radiation Corp.*:

> [I]n approving [the Class III device] through the PMA process, the FDA imposed federal requirements specific to that product which govern virtually every aspect of its production and sale. . . . Accordingly, in evaluating the effect of Section 360k on [the plaintiff's] claims, we recognize that there are pertinent federal requirements specific to [the device] which dictate its design, manufacture, marketing, labeling, packaging, and distribution.[32]

The availability of preemption as a defense for PMA devices would be consistent with a policy of ensuring that life-saving and life-enhancing products are made available to the public quickly, as long as the risks inherent in such devices have been properly evaluated. If the manufacturer of a medical device were required to remove every conceivable risk from its product before marketing, then it is unlikely that any new device would ever reach the consumer. Instead, in order to allow earlier access to devices and still provide an adequate level of protection to the public, the FDA is charged with making the policy determination of whether the risks inherent in the product are outweighed by its potential benefit. The outcome of that determination is reflected in the issuance or denial of a PMA approval order. A plaintiff should not be able to interfere with that federal policy judgment by imposing different state "requirements" on the manufacturer.

To use Justice Breyer's hypothetical, assume that the manufacturer of a hearing aid is faced with the decision of whether to use a 1-inch or a 2-inch wire in its product. Based on testing it has conducted, the manufacturer determines that although the 1-inch wire lasts longer, the 2-inch wire provides better hearing reception with only a slightly shorter life expectancy. After weighing those risks and benefits, the manufacturer decides that the use of the 2-inch wire is most prudent under the circumstances. The manufacturer fully discloses the data on which it based its decision to use the 2-inch wire in its PMA application. The FDA reviews the PMA application and requests no change in the design for the product. The hearing aid is then marketed with the 2-inch wire. A claim is later brought by a plaintiff whose expert contends the design of the product was defective because the manufacturer should have used a 1-inch wire instead of the 2-inch wire.

This scenario demonstrates why Section 360k(a) of the MDA should be interpreted to preempt state law tort claims for medical devices that have reached the market through the PMA process. The decision to

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30. 21 C.F.R. § 814.80.

31. A manufacturer of a PMA device may make a change that "enhances the safety of the device or the safety in the use of the device" without FDA approval under limited circumstances. 21 C.F.R. §§ 814.39(d)(1).

32. 57 Cal.Rptr.2d 763, 771 (Cal.App. 1996). Despite reaching this conclusion, the court in *Armstrong* later went on to find no preemption because it concluded that there was no "state law requirement" specifically developed for medical devices. This issue is discussed in greater detail at footnote 49, *infra*.

use the 2-inch wire would have been thoroughly evaluated by both the manufacturer and the FDA. Although that decision carried with it some risk, the over-all benefit to the public from the use of the design was found by the federal agency charged with protecting the public health to outweigh that risk. A manufacturer should not have to defend repeatedly the decisions it makes in the design, manufacturing, and labeling of a medical device once a PMA has been obtained. To permit a plaintiff in a state tort action or a federal diversity action to challenge the FDA's determination that the device should be made available to the public creates a direct conflict between the federal regulations and state law, thus making preemption appropriate.

C. IDE Approval[33]

Manufacturers of new medical devices that cannot be marketed pursuant to Section 510(k) are faced with a difficult dilemma. For approval to market their device, they must obtain a PMA, but in order to do that they must submit data sufficient to demonstrate that the device is safe and effective when utilized by human beings. These data usually are collected from clinical trials involving selected patients. The MDA provides a mechanism to conduct such clinical trials in the form of an investigational device exemption (IDE).

To obtain an IDE, the manufacturer must submit detailed information on its device to the FDA for evaluation. The IDE application must include, among other items, a summary of the investigational plan proposed by the manufacturer, a description of the methods, facilities and controls used for the manufacture of the device, copies of labeling for the device and the proposed materials to obtain informed consent.[34]

The investigational plan submitted by the manufacturer must include:

> (1) The name and *intended purpose of the device.*
>
> (2) A written protocol and an analysis demonstrating why that protocol is *scientifically sound.*
>
> (3) An *analysis of the increased risks* to which the subjects will be exposed and a justification for the investigation.
>
> (4) A *description of each important component, ingredient, property and principle of operation of the device.*
>
> (5) Copies of all *labeling* for the device.[35]

After submission of the IDE application, the FDA determines whether the device warrants further human investigation. In making that determination, the agency must be satisfied that "the anticipated benefits to the subjects and the importance of the knowledge to be gained" outweigh "the risks to the subjects."[36] The FDA will not grant an IDE if the informed consent is inadequate, or the investigation is scientifically unsound, or "there is reason to believe that the device as used is ineffective."[37] After IDE approval, the manufacturer may not, without the FDA's consent, modify the investigational plan, including the design, manufacture, and labeling.[38]

Like the PMA process, the IDE process appears to satisfy both of the concerns that drove the Court in *Lohr* to conclude that claims for Section 510(k) devices were not preempted. An IDE approval represents a reasoned evaluation by the FDA that the anticipated benefits and the importance of the knowledge to be gained in conducting the investigation outweigh the risks to the patients participating in the clinical trial. Hence, unlike the "substantial equivalence" determination for Section 510(k) devices, the *Lohr* Court remarked, "the federal government has weighed the competing interests relevant to the particular requirement in question, reached an unam-

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33. The authors wish to acknowledge the valuable input from Steven Glickstein and Maris Veidemanis of Kaye, Scholer, Fierman, Hays & Handler, L.L.P., New York City, to this section of the article.

34. 21 C.F.R. §§ 812.20(b).

35. C.F.R. § 812.25(a-j), emphasis added.

36. 21 U.S.C. § 360j(g)(4)(B); 21 C.F.R. § 812.30(b)(4).

37. 21 C.F.R. § 812.30(b)(4).

38. 21 C.F.R. § 812.35(a).

biguous conclusion about how those competing considerations should be resolved . . . and implemented that conclusion via a specific mandate."[39]

The IDE process also addresses the second concern of the *Lohr* Court—the lack of federal regulatory specificity. The approval of an IDE means that the FDA has granted permission for use of the specific design, manufacturing procedure, and labeling submitted in the IDE application, which may not be modified without FDA permission. Unlike the Section 510(k) process, the FDA's approval of the IDE therefore imposes specific "requirements" on that device.

However, even if the IDE process did not satisfy the dual concerns of the *Lohr* court, there is an additional important policy reason why preemption should be available for such devices. The stated purpose of the IDE process, according to 21 U.S.C. § 360j(g)(1), is to "encourage . . . the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose." The MDA's preemption provision allows manufacturers the freedom to undertake clinical trials with the knowledge that they are protected from liability under different state tort law requirements.

If preemption is not a viable defense to such claims, then manufacturers may become more hesitant to undertake clinical trials. As the Seventh Circuit explained in *Slater v. Optical Radiation Corp.*, if "experimental procedures are subject to hindsight evaluation by juries, so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatment, and patients will suffer."[40] Similarly, the Third Circuit concluded that state tort claims regarding IDE devices "run counter to the important public policy, recognized by Congress, of promoting scientific inventions."[41]

The chilling on clinical trials would be contrary to the congressional intent, expressly stated in the MDA, that "scientific investigators" should have "optimum freedom" to experiment in order to develop innovative new medical devices. In order to preserve that freedom, Section 360k(a) should be interpreted to allow preemption for IDE devices.

Notably, the first federal court to decide the MDA preemption issue in the IDE context since *Lohr* concluded that IDE requirements preempt state tort claims. In *Berish v. Richards Medical Co.*,[42] the U.S. District Court for the Northern District of New York held that the plaintiff's common law claims regarding a device marketed under an IDE were preempted by the MDA. The court distinguished the stringent IDE procedures from those at issue in *Lohr*:

> Unlike the Section 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.[43]

The Berish court therefore concluded that "*Lohr* may not apply outside the context of a Section 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 preemption of state common law claims."[44]

D. Specificity of State Requirements

Even if the manufacturer of a PMA or IDE device is able to convince a court that

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39. 116 S.Ct. at 2258.
40. 961 F.2d 1330, 1334 (7th Cir. 1992), *cert. denied*, 506 U.S. 917 (1992).
41. Gile v. Optical Radiation Corp., 22 F.3d 540, 546 (3d Cir. 1994), *cert. denied*, 115 S.Ct. 429 (1994).
42. 937 F.Supp. 181 (N.D. N.Y. 1996).
43. *Id.* at 185, quoting Becker v. Optical Radiation Corp., 66 F.3d 18, 21 (2d Cir. 1995).
44. *Id.* at 186. However, some post-*Lohr* state court decisions have found that the IDE process does not preempt state law tort actions. *See, e.g.*, Walker v. Johnson & Johnson Vision Prods. Inc., 552 N.W.2d 679 (Mich.App. 1996); Connelly v. Iolab Corp., 927 S.W.2d 848 (Mo. 1996).

the PMA and IDE processes do impose "specific" federal requirements, there may be still another hurdle for the manufacturer to clear before preemption will exist. Section 360k of the MDA mandates preemption only when the state requirement sought to be preempted was established "with respect to" a device. This wording raises two issues. First, is an action for damages under state tort law a state "requirement"? Second, if so, how specific must those state tort law requirements be before they are subject to preemption? While *Lohr* provides a clear answer to the first question, there is considerable ambiguity in resolving the second.

In Part VI of the Supreme Court's *Lohr* opinion, Justice Stevens addressed the issue of whether state common law duties are ever "requirements" within the meaning of Section 360k. Although the Court declined to consider this issue directly, it noted that because of the "critical importance" of device specificity, it would be "rare indeed for a court hearing a common law cause of action to issue a decree that has the effect of establishing a substantive requirement for a particular device."[45]

A majority of five justices expressly disagreed with this conclusion. Justice O'Connor, joined by Chief Justice Rehnquist and Justices Scalia and Thomas, held that state common law damages actions "do" impose "requirements" and therefore are preempted when they would differ from those imposed by the MDA.

Justice Breyer, writing separately, similarly held:

> [I]nsofar as the MDA preempts a state requirement embodied in a state rule, regulation, or other administrative action, it would also preempt a similar requirement that takes the form of a standard of care or behavior imposed by a state law tort action.[46]

Having established that actions for damages under state tort law are subject to preemption by federal requirements, the remaining question becomes how "specific" must the standards imposed by the state tort action be before they will be preempted. Justice Stevens focused on this question in the last paragraph of Part V of the opinion:

> The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce. These state requirements therefore escape preemption, not because the source of the duty is a judge-made common law rule, but rather because their generality leaves them outside the category of requirements that Section 360k envisioned to be "with respect to" specific devices such as pacemakers.[47]

Under this view, an action for damages based on the breach of a "general duty" applicable to all manufacturers would not be preempted because that duty was not created "with respect to" a particular device. This would be true even though the plaintiff in a "general" state law tort action might (through his expert) impugn a specific aspect of the device's design, manufacture or labeling that was the subject of prior FDA approval.

Although Justice Breyer joined Part V of the Court's opinion, it is doubtful that he would agree with the degree of state law specificity apparently required by Justice Stevens. In his concurring opinion, Justice Breyer did not consider it relevant whether the state requirement originated from a "general duty" to make a safe product or not; his focus was on the specific obligation imposed on the manufacturer irrespec-

45. 116 S.Ct. at 2259, citing 21 C.F.R. § 808.1(d)(6)(ii).
46. *Id.* at 2260.
47. *Id.* at 2258.

tive of its source. This was made clear through his example involving the hearing aid in which the plaintiff's expert attempted to impose a standard of care on the manufacturer different from that embodied in the "2-inch" MDA regulation. If Justice Breyer agreed with Justice Stevens that the "general duty" to design a product in a safe manner did not create a "state requirement," then there would have been no need for his hypothetical.

Although the *Lohr* opinion is less than clear on this point, it is suggested that there is at least a five-justice majority who would hold that the imposition of a specific state requirement on a device manufacturer through a general common law tort action would be preempted by Section 360k of the MDA.

Unfortunately, the first reported cases to address this issue explicitly have reached a contrary result.

In *Kernats v. Smith Industries Medical Systems Inc.*, suit was brought for injuries allegedly caused by a catheter used in prenatal tissue sampling. The catheter had received premarket approval from the FDA. The Illinois Appellate Court initially accepted the manufacturer's argument that the PMA requirements were sufficiently device-specific to have preemptive effect, but the court concluded that there was no preemption because the "second prong" of Lohr had not been satisfied:

> Here, the plaintiffs' common law claims based on the manufacture of the [catherter] are also "general obligations" applicable to all manufacturers and, under the holding in [Lohr] are not requirements specifically established for medical devices. Therefore, they are not preempted under the MDA.[48]

A similar result was reached in *Armstrong*. An action was brought against the manufacturer of a surgical aid (Orcolon) alleged to have caused damage to the plaintiff's eye. Orcolon is a Class III medical device that had received a PMA from the FDA. After concluding that the PMA process did result in the imposition of "specific" federal requirements on the manufacturer, the California Court of Appeal addressed the issue of whether there were any state law requirements specifically developed for medical devices.

After reviewing the origin of the plaintiff's claims, the court concluded:

> As with [the plaintiff's] negligence claim, her theory of strict liability as to a manufacturing defect is based on general principles of state tort law which were not specifically developed with respect to medical devices. Thus, it is not preempted.[49]

In order to avoid similar results, counsel for device manufacturers will need to demonstrate that the requirement of state regulatory specificity set forth in Justice Stevens's opinion likely does not command a majority of the Supreme Court and should not be considered controlling when preemption is sought pursuant to Section 360k.

CONCLUSION

Although *Lohr* has made the assertion of a preemption defense more difficult for medical device manufacturers, all hope is not lost. Preemption should continue to be available to manufacturers whose products have reached the market via the PMA or IDE channels. Counsel representing those manufacturers should be prepared to demonstrate that state law tort actions do result in the imposition of device specific requirements under Section 360k of the MDA and thus are preempted.

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48. 669 N.E.2d 1300 (Ill.App. 1996).

49. 57 Cal.Rptr.2d at 772. *See also* Comm. of Dental Amalgam Mfgrs. & Distribs. v. Stratton, 92 F.3d 807 (9th Cir. 1996) (state statute of general applicability was not enacted "with respect to" medical devices and thus was not preempted by the MDA).