

1997

# Post-Decision Diagnosis: Medical Device Preemption Alive and Mostly Well after *Medtronic, Inc. v. Lohr*

Scott W. Saylor  
*Shook, Hardy & Bacon L.L.P.*

Steven M. Thomas  
*Shook, Hardy & Bacon L.L.P.*

Follow this and additional works at: <http://lawcommons.luc.edu/annals>

 Part of the [Health Law and Policy Commons](#)

---

### Recommended Citation

Scott W. Saylor & Steven M. Thomas *Post-Decision Diagnosis: Medical Device Preemption Alive and Mostly Well after Medtronic, Inc. v. Lohr*, 6 Annals Health L. 185 (1997).

Available at: <http://lawcommons.luc.edu/annals/vol6/iss1/10>

This Article is brought to you for free and open access by LAW eCommons. It has been accepted for inclusion in Annals of Health Law by an authorized administrator of LAW eCommons. For more information, please contact [law-library@luc.edu](mailto:law-library@luc.edu).

# Post-Decision Diagnosis: Medical Device Preemption Alive and Mostly Well After *Medtronic, Inc. v. Lohr*

Scott W. Sayler  
Steven M. Thomas\*

## INTRODUCTION

As of June 1996, the great majority of courts analyzing the Medical Device Amendments of 1976 had found broad preemption of state common law tort actions. Then came *Medtronic, Inc. v. Lohr*, a case in which the United States Supreme Court addressed the preemption issue in the context of a specific medical device that had been exempted from rigorous premarket approval requirements. In this factually specific context, the Court concluded that each of plaintiffs' common law tort claims survived preemption. *Lohr*, however, does not sound the death knell for medical device preemption. Careful analysis of the four separate opinions and the fractured holding suggests a fact-specific opinion with circumscribed application. In cases involving medical devices distributed pursuant to premarket approval requirements and investigational device exemptions, the express preemption defense arguably should remain viable.

## I. THE MDA AND THE CLASSIFICATION OF MEDICAL DEVICES

Congress enacted the Medical Device Amendments of 1976 ("MDA")<sup>1</sup> to the Food, Drug, and Cosmetic Act of 1938

---

\* Mr. Sayler is a partner in the law firm of Shook, Hardy & Bacon L.L.P., Kansas City, Missouri. He received both his Juris Doctorate and his Bachelor of Science from the University of Kansas. Mr. Thomas is an associate with the same firm. He received both his Juris Doctorate and his Bachelor of Science from the University of Nebraska. Both lawyers practice in the firm's Pharmaceutical and Medical Device Litigation Division.

The views expressed in this article are the authors' and do not necessarily represent the views of Shook, Hardy & Bacon L.L.P.

1. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended at 21 U.S.C. §§ 360c-360k, 379 & 379a (1995), and other scattered sections of 21 U.S.C.).

("FDCA").<sup>2</sup> Some commentators have characterized the MDA as a statute designed "to protect consumers from dangerous medical devices."<sup>3</sup> Legislative history, however, hints that the MDA had an additional purpose—namely, to encourage research and development of medical devices that "hold the promise of improving the health and longevity of the American people."<sup>4</sup> In furtherance of this purpose, the MDA gave the United States Food and Drug Administration ("FDA") jurisdiction over medical devices for the first time.

Under the MDA, medical devices are classified based upon the degree of risk posed to the consumer. Class I devices do not pose an unreasonable risk of injury or illness and, accordingly, are subject to nothing more than "general controls."<sup>5</sup> Examples of Class I devices include tongue depressors, ice bags, and bedpans. Class II devices, while potentially more harmful and distributed without advance approval, are subject only to federal performance standards known as "special controls."<sup>6</sup> Examples of Class II devices include hearing aids and syringes.

Class III devices are those that (1) present a potentially unreasonable risk, or (2) support or sustain human life.<sup>7</sup> Examples of Class III devices include pacemakers and intrauterine devices. A Class III device cannot be marketed unless the manufacturer provides the FDA with a "reasonable assurance" that the device is safe and effective. Specifically, the manufacturer must obtain "premarket approval" ("PMA").<sup>8</sup> The rigorous process requires manufacturers to provide detailed safety and efficacy data.

Under certain circumstances, investigational devices can be distributed without PMA.<sup>9</sup> The manufacturer of an investigational device can file with the FDA an application that, if approved, allows the manufacturer to distribute the device

2. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-395 (1995)).

3. See, e.g., John D. Burnside, *Kennedy v. Collagen Corp.: Falling from the Medical Device Amendments' Federal Preemption Garden*, 28 ARIZ. ST. L.J. 949, 950 (1996).

4. S. REP. NO. 94-33, at 1-2 (1976), quoted in Michael K. Carrier, *Federal Preemption of Common Law Tort Awards by the Federal Food, Drug, and Cosmetic Act*, 51 FOOD & DRUG L.J. 509, 548 (1996).

5. 21 U.S.C. § 360c(a)(1)(A)(i) (1995).

6. *Id.* § 360c(a)(1)(B).

7. *Id.* § 360c(a)(1)(C)(ii)(I) & (II).

8. *Id.* § 360e(a).

9. 21 C.F.R. § 812.1(a) (1996).

pursuant to an investigational device exemption (“IDE”).<sup>10</sup> The overarching purpose of an IDE is to determine, with the help of closely monitored and pre-approved clinical investigations, whether a potentially significant medical device is safe and effective. Intraocular lenses (“IOLs”) are an example of a medical device distributed pursuant to an IDE. Investigational IOLs are subject to pervasive regulation,<sup>11</sup> and courts have recognized that IOL regulations “broadly govern nearly all facets of the investigational program.”<sup>12</sup>

There are two other exceptions to the PMA requirement. First, Congress recognized that medical devices already on the market could not be withdrawn pending PMA analysis by the FDA. Thus, devices marketed before 1976 are beneficiaries of a “grandfather” provision; PMA is not necessary.<sup>13</sup> Second, medical devices that are “substantially equivalent” to devices marketed before 1976 are excepted from the PMA requirement.<sup>14</sup> The latter exemption was intended to (1) prevent makers of “grandfathered” devices from enjoying a commercial advantage while competitors were fighting PMA battles, and (2) assure that improved devices could be marketed without delay.<sup>15</sup> Makers of “substantially equivalent” Class III devices must submit a premarket notification to the FDA. The process of submitting a premarket notification for purposes of obtaining a “substantial equivalence” finding under section 510(k) is referred to as the “section 510(k) process”; medical devices deemed “substantially equivalent” to pre-1976 devices are oftentimes called “510(k) devices.”

## II. *MEDTRONIC, INC. v. LOHR*: THE FACTS

Medtronic utilized the section 510(k) process in bringing to market its Model 4011 pacemaker lead.<sup>16</sup> In November 1982, the FDA concluded that the product was substantially equivalent to medical devices marketed before the effective date of the MDA.<sup>17</sup> Accordingly, Medtronic’s pacemaker lead—

10. *Id.* §§ 812.20, 812.30 (1996).

11. *See, e.g., id.* § 813.20 (1996).

12. *Becker v. Optical Radiation Corp.*, 66 F.3d 18, 20 (2d Cir. 1995).

13. 21 U.S.C. § 360e(b)(1)(A) (1995).

14. *Id.* § 360e(b)(1)(B).

15. *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2246 (1996).

16. The lead is the portion of a pacemaker that transmits the heartbeat-steadying electrical signal from the pulse generator to the heart itself.

17. 116 S. Ct. at 2248.

while subject to the “general control” provisions of the MDA—was distributed without PMA. In 1987, plaintiff Lora Lohr was implanted with a Medtronic pacemaker that contained a Model 4011 lead. The pacemaker allegedly failed in 1990, resulting in emergency surgery. Ms. Lohr’s physician attributed the pacemaker’s failure to a defect in the lead.<sup>18</sup>

Plaintiffs filed a complaint that included negligence and strict liability counts and challenged the way in which the product had been designed, manufactured, and labeled. The federal district court granted Medtronic’s motion for summary judgment, which contended that plaintiffs’ claims were preempted by section 360k(a) of the MDA. That statute states:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

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

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA].<sup>19</sup>

The Eleventh Circuit—after concluding that state common law actions were “requirements” under section 360k(a)—held that plaintiffs’ failure-to-warn and manufacturing claims were preempted by FDA labeling regulations and “Good Manufacturing Practices” (“GMPs”).<sup>20</sup> Plaintiffs’ design claims, however, survived preemption.<sup>21</sup> The Supreme Court granted certiorari to resolve a split among the circuit courts.<sup>22</sup>

### III. *MEDTRONIC, INC. v. LOHR*: THE COURT’S UNANIMOUS DECISION ON TWO ISSUES

#### A. *Design Claims*

In holding that plaintiffs’ design defect claim was not preempted, the Supreme Court reasoned that the section 510(k) process did not impose a specific, federally enforceable design requirement. In particular, the section 510(k) process did not

18. *Id.*

19. 21 U.S.C. § 360k(a) (1995).

20. *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1350 (11th Cir. 1995), *rev’d in part, aff’d in part*, 116 S. Ct. 2240 (1996).

21. *Id.* at 1347-49.

22. *Medtronic, Inc. v. Lohr*, 116 S. Ct. 806 (1996).

require Medtronic's product "to take any particular form for any particular reason."<sup>23</sup> In the Court's opinion, the section 510(k) process had much to do with "substantial equivalence" and little to do with safety. The Court characterized the section 510(k) process as a "status quo" mechanism intended to give manufacturers the freedom to compete with and on the same terms as makers of pre-1976 medical devices.<sup>24</sup>

### B. Alleged Violations of Federal Requirements

Plaintiffs' claims that Medtronic had violated FDA regulations also survived preemption. The Court explained that nothing in section 360k(a) barred a state from providing a damages remedy for transgressions of state common law duties that were *parallel* to federal requirements.<sup>25</sup> The Court reached this conclusion even though manufacturers would face additional elements under state law. Under the Court's reasoning, the added elements would make such state requirements *narrower*—not broader—than federal counterparts.<sup>26</sup> In such situations, the state requirements would not be "in addition to" federal requirements. The Court dismissed as overly literal the argument that additional elements render the state duties "different from" federal requirements.<sup>27</sup> The Court also determined that a common law damages remedy for violation of federal requirements was not an additional or different requirement.<sup>28</sup> Rather, it was just one more reason to comply with federal law.<sup>29</sup>

---

23. *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2254 (1996).

24. *Id.* at 2255.

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.*

29. In allowing claims based upon the violation of common law duties that mirror federal requirements, the Court found support in the FDA regulations. It quoted 21 C.F.R. § 808.1(d)(2) (1995), which states that section 360k "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." *Lohr*, 116 S. Ct. at 2256. The Court deferred to the FDA regulations for two reasons. First, Congress delegated to the FDA the authority to implement the MDA. That, the Court said, made the FDA "uniquely qualified" to determine whether congressional objectives would be impeded by a particular form of state law. *Id.* at 2255. Second, the Court felt that section 360k(a) was ambiguous. *Id.* at 2255-56. These two factors were said to provide a "sound basis" for giving substantial weight to the FDA's views. *Id.* at 2255. *See also* *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

IV. *MEDTRONIC, INC. V. LOHR*. THE MAJORITY OPINION

A majority of the Court, in the most significant section of the opinion, held that section 360k(a) and the accompanying regulations supported preemption in those instances “where a *particular* state requirement [was] threaten[ing] to interfere with a *specific* federal interest.”<sup>30</sup> In order to be candidates for preemption, *state* requirements will typically be (1) developed “‘with respect to’ medical devices”; (2) specific in terms of applicability, thereby saving from preemption state requirements of “general applicability”; (3) “‘different from or in addition to’ federal requirements”; and (4) concerned with safety, efficacy, or any other matter included in a federal requirement that applies to the device.<sup>31</sup> Similarly, in order to have a preemptive effect, *federal* requirements will typically (1) apply to the device in question, and (2) constitute “specific counterpart regulations” to state law or be specific to a particular device.<sup>32</sup> Thus, in resolving section 360k(a) preemption issues, the Court recommended a “careful comparison between the allegedly preempting federal requirement and the allegedly preempted state requirement.”<sup>33</sup>

At issue in *Lohr* were federal labeling regulations that required manufacturers of nearly every medical device to include in their warning labels “information for use . . . and any relevant hazards, contraindications, side effects, and precautions.”<sup>34</sup> The manufacturing requirements were in the form of GMPs. The Court concluded that these “federal requirements reflect[ed] important but entirely generic concerns about device regulation.”<sup>35</sup> Section 360k(a) and the accompanying regulations, the Court said, “were designed to protect from contradictory state requirements only those federal requirements” evidencing a concern for “a specific device or field of device regulation.”<sup>36</sup> As for the state common law requirements at issue, the Court determined that they were not preempted because they had not

---

30. 116 S. Ct. at 2257.

31. *Id.*

32. *Id.* at 2257-58. The Court stopped short of saying that section 360k(a) and accompanying regulations necessarily precluded (1) *general* federal requirements from ever preempting state requirements, or (2) *general* state requirements from ever being preempted. *Id.* at 2257.

33. *Id.* at 2257-58.

34. 21 C.F.R. § 801.109(c) (1996).

35. 116 S. Ct. at 2258.

36. *Id.*

been developed “‘with respect to’ medical devices.”<sup>37</sup> According to the Court, the legal duties that formed the bases of plaintiffs’ manufacturing and failure-to-warn<sup>38</sup> claims were “general obligations” that posed no threat to federal requirements.<sup>39</sup>

In searching for answers to the legal questions before it, the Court went beyond section 360k(a). The Court found within section 360k(a) the intent to preempt *some* state law, but said it would look to other areas to identify the *scope* of the preemptive effect.<sup>40</sup> It began by examining the text, but added that such interpretation could not occur in a “contextual vacuum.”<sup>41</sup> The Court took two principles into account. First, the Court presumed that Congress would “not cavalierly preempt” state common law actions. Absent the clear and manifest purpose of Congress, the presumption against preemption carries the day.<sup>42</sup> Second, the Court said that it would look to congressional intent—something that it views as the “ultimate touchstone” in every preemption case. Specifically, the Court (1) deferred to section 360k(a) *and the surrounding statutory framework*, and (2) attempted to ascertain the way in which Congress expected the statute and the regulatory regime “to affect business, consumers and the law.”<sup>43</sup>

## V. THE PLURALITY OPINION

Justice Stevens led a four-justice plurality that deemed “unpersuasive” and “implausible” Medtronic’s core argument—namely, that *every* state common law action was a requirement preempted by section 360k(a).<sup>44</sup> Ultimately, all nine justices rejected Medtronic’s argument. The plurality opinion, however,

---

37. *Id.*

38. The Court said that “the predicate for the failure-to-warn claim [was] the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use.” *Id.* Actually, in the prescription drug and medical device context, the manufacturer’s duty to warn runs not to the patient but rather to the prescribing physician, whom the law recognizes as a “learned intermediary.”

39. *Id.*

40. *Id.* at 2250.

41. *Id.*

42. *Id.*

43. *Id.* at 2251.

44. *Id.* Medtronic presumably advanced this argument for a number of reasons, not the least of which was its recognition that the company’s exposure might be just as great if plaintiffs were allowed to proceed with one claim instead of 10. Even if liability can be established under all claims asserted, a plaintiff can recover damages only once. In this type of legal setting, the defendant must win every inning to avoid losing the game.



stressed that the statute, if interpreted in such a way, would leave injured persons with no recourse against medical device manufacturers.<sup>45</sup> The foursome maintained that cloaking manufacturers with complete immunity would be improper in the face of ambiguous statutory language and, in addition, would collide with congressional efforts to regulate the industry with increased stringency.<sup>46</sup>

The plurality believed that Congress was concerned with specific state statutes and regulations,<sup>47</sup> not general duties embedded in common law tort actions.<sup>48</sup> In the plurality's view, the medical device industry's aversion was to the creation of *additional* regulations rather than the preservation of *existing* common law duties.<sup>49</sup> Focusing on the word "requirement," the plurality stated that if Congress *did* intend to preempt all state common law actions, it had chosen a "singularly odd" word with which to do it.<sup>50</sup> They said that the oft-scrutinized word, as used in section 360k(a), referred to specific duties imposed by states. In considering how to interpret the word, the plurality's chief concern was not the way in which the same word had been defined four years earlier, but rather the *effect* that a given definition would have. Whereas the effect of defining "requirement" to include state common law claims in *Cipollone v. Liggett Group, Inc.*<sup>51</sup> allowed plaintiff to maintain *some* theories of recovery, the effect of defining "requirement" to include common law actions in *Lohr* was a recipe for "wiping out the possibility of remedy for the Lohrs' alleged injuries."<sup>52</sup> This is the ultimate

---

45. *Id.*

46. *Id.*

47. Two commentators have recognized that inconsistent results may occur if the definition of "requirement" is limited to statutes and regulations. See Mark Herrmann & Geoffrey J. Ritts, *Preemption and Medical Devices: A Response to Adler and Mann*, 51 FOOD & DRUG L.J. 1 (1996). The inconsistency results from the fact that although many states have codified their product liability law, not all have. If "requirement" is limited to statutes and regulations, claims brought under state product liability statutes may be subject to preemption. At the same time, preemption might not apply to claims brought in states with common law product liability standards. *Id.* at 8-9.

48. While Justice Stevens dismissed Medtronic's position as "extreme," 116 S. Ct. at 2253, it should not be forgotten that at the time Medtronic advanced its argument, nearly every circuit that had considered the issue had concluded that Congress intended for the preemptive scope of the MDA to reach common law claims. See Burnside, *supra* note 3, at 950 n.6.

49. 116 S. Ct. at 2253.

50. *Id.* at 2251.

51. 505 U.S. 504 (1992). *Cf. infra* section VI.

52. 116 S. Ct. at 2251-52.

in “results-based” jurisprudence, with the desired results tail wagging the analysis dog.

In a separate section of the plurality opinion, the same four justices declined the plaintiffs’ invitation to rule that state common law actions could never constitute “requirements” under section 360k(a). That, in part, was due to the plurality’s belief that preemption under section 360k(a) would be an uncommon occurrence.

[G]iven the critical importance of device-specificity in our . . . construction of § 360k, it is apparent that few, if any, common law duties have been pre-empted by this statute. It will 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 specific device.”<sup>53</sup>

## VI. JUSTICE BREYER’S CONCURRENCE

Justice Breyer took the position that the MDA would *sometimes* preempt state common law actions. He maintained that the word “requirement” could reasonably be interpreted to include legal requirements that stem from state tort law.<sup>54</sup> Justice Breyer cited *Cipollone*, where a Justice Stevens-led plurality stated:

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. As we noted in another context, “[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief . . . .”<sup>55</sup>

Justice Breyer reasoned that if section 360k(a) preempts a state requirement in the form of “positive” law (for example, statutes, rules, and regulations), then it should also preempt a similar requirement in the form of a standard of care imposed by a state common law action. Distinguishing between different types of state requirements that exert the same effect, he said, would yield anomalous results.<sup>56</sup>

---

53. *Id.* at 2259 (quoting 21 C.F.R. § 808.1(d)(6)(ii) (1995)).

54. *Id.*

55. *Cipollone*, 505 U.S. at 521.

56. Justice Breyer used the following example:

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 reg-

Justice Breyer concluded, however, that plaintiffs' particular claims were not preempted. The federal requirements at issue in *Lohr*, he wrote, lacked sufficient specificity. He then injected into the express preemption mix concepts of "conflict" and "field" preemption, both of which are subsumed within the doctrine of "implied preemption."<sup>57</sup> Justice Breyer viewed such basic preemption principles as useful given the "different from, or in addition to" language of section 360k(a).<sup>58</sup> In the end, however, Justice Breyer determined that (1) there was no conflict between the federal requirements and plaintiffs' common law theories of liability; and (2) neither Congress nor the FDA intended for the FDA regulations to entirely occupy any relevant field.<sup>59</sup>

## VII. JUSTICE O'CONNOR'S PARTIAL CONCURRENCE/DISSENT

In their partially concurring and dissenting opinion, Justice O'Connor and three other justices found language within the text of section 360k(a) that specified (1) an intent to preempt state common law actions, and (2) the scope of the intended preemption.<sup>60</sup>

As for the intent to preempt state common law actions, the dissent—like Justice Breyer's concurrence—resurrected favorable language from *Cipollone* and explained that "state common law damages actions operate to require manufacturers to comply with common law duties."<sup>61</sup> As for the *scope* of the intended preemption, the dissent noted that section 360k(a) re-

---

ulation, pre-empts the state "1-inch" agency regulation, why would it not similarly pre-empt a state law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent)?

116 S. Ct. at 2259-60.

57. The plurality opinion also mentions—but does not discuss—the possibility that state common law actions could be preempted under the "conflict preemption" doctrine. *Id.* at 2259.

58. "Conflict preemption" occurs when the state requirement actually conflicts with the federal requirement either because compliance with both is impossible or because the state requirement stands as an obstacle to the full accomplishment of congressional objectives. See *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963); *Hines v. Davidowitz*, 312 U.S. 52 (1941). "Field preemption" occurs when "[t]he scheme of federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

59. 116 S. Ct. at 2259-60.

60. *Id.* at 2262.

61. *Id.*

fers to “any requirement” different from or in addition to a federal requirement.<sup>62</sup> Given the absence of ambiguity in section 360k(a), the dissent refused to delegate statutory interpretation chores to the FDA. The dissent criticized the Court for referring to FDA regulations that narrowed the class of preempting federal requirements to those deemed “device specific,” stating: “The statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction of ‘any requirement’ exists.”<sup>63</sup> Thus, the dissent’s view was that state common law actions were “requirements” that should be preempted if they impose duties different from or in addition to FDCA requirements.

The dissent, however, concluded that plaintiffs’ design claims were not preempted because the section 510(k) process imposed no design requirements.<sup>64</sup> Similarly, Justice O’Connor stated that the claims alleging a violation of federal requirements should survive preemption because any resulting duties were not different from or in addition to federal requirements.<sup>65</sup> The failure-to-warn and defective manufacturing claims, however, were said to be proper targets of preemption. She explained that some or all of plaintiffs’ defective manufacturing and failure-to-warn claims would compel Medtronic to comply with requirements that were different from or in addition to “extensive” federal manufacturing and labeling provisions.<sup>66</sup> For the dissent, it was enough that such federal requirements were “applicable” to Medtronic’s pacemaker lead. “Section 360k(a) requires no more specificity than that for pre-emption of state common law claims.”<sup>67</sup>

#### VIII. ANALYSIS: WHERE THE COURT MISSED THE MARK

In the course of addressing medical device preemption in a specific factual context, the Court issued broad pronouncements that may be misinterpreted and misused in factually dissimilar cases. Improper attempts to exaggerate the reach of *Lohr* and to apply the holding to cases that do not involve section 510(k) devices will be and already have been an unfortunate outgrowth of the opinion. The good news for the medical device industry is

---

62. *Id.*

63. *Id.* at 2263.

64. *Id.*

65. *Id.*

66. *Id.* at 2264.

67. *Id.*

that the amount of attention devoted by the Court to the particulars of the section 510(k) process strongly suggests that the opinion has limited application. In addition, nothing within the four corners of *Lohr* affirmatively states or logically suggests that the opinion has application beyond the section 510(k) context.

The Court's broad pronouncements in *Lohr* stemmed from an unwillingness (1) to view the text of section 360k(a) as unambiguous, (2) to consider the fact that Congress, in the face of years of express preemption, had declined all invitations to amend section 360k(a), and (3) to focus on a principal purpose of the MDA—namely, the use of regulatory uniformity on the federal level to promote innovation and technology.

After recognizing the preemptive language of section 360k(a), the Court should have looked to the statute to identify the *scope* of the intended preemption. The statute clearly defines the type of federal requirement capable of having preemptive effect as “any” requirement “applicable under the [FDCA] to the device.”<sup>68</sup> Section 360k(a) also defines the type of state requirement targeted for preemption, namely “any” requirement that is different from or in addition to any federal requirement and which relates to the safety or efficacy of the device or to any other matter included in a federal requirement applicable to the device under the FDCA.

In identifying the type of *federal* requirement capable of having preemptive effect, the Court strayed unnecessarily from section 360k(a) and, instead, reviewed FDA regulations. Only there did the Court find language supportive of the position that federal requirements, in order to have preemptive effect, must be *specific* counterpart regulations or *specific* to a particular device. The dissent correctly noted that section 360k(a) says nothing about “device specificity.” Rather, under subsections 360k(a)(1) and (2), the federal requirement must merely be “applicable” to the device. How subsections (1) and (2) could be construed as ambiguous so as to invite reference to FDA regulations remains a mystery.

In identifying the type of *state* requirement capable of being preempted, the Court looked to FDA regulations and to section 360k(a). Citing 21 C.F.R. 808.1(d)(1), the Court suggested that state requirements of “general applicability” were not pre-

---

68. 21 U.S.C. § 360k(a) (1995).

empted.<sup>69</sup> In reviewing the preemption statute, the Court found further support for its position that state requirements survive preemption unless *specific* to medical devices. Building upon limitations set forth in subsections 360k(a)(1) and (2),<sup>70</sup> the Court cited language in section 360k(a) and concluded that a state requirement would not be preempted unless established “with respect to” a medical device. Whether the quoted words mean something beyond applicability is doubtful at best. Just as the plurality was unwilling to deny injured persons their day in court on the basis of statutory language viewed as vague,<sup>71</sup> the majority should have refused to subject manufacturers to common law actions on the basis of language that—if not wholly innocuous—is certainly ambiguous.

*Lohr* should have been decided on the basis of section 360k(a) and *Cipollone*. If the Court truly believed that an examination of congressional intent was necessary, it should have undertaken a less abbreviated inquiry. The Court’s search focused on *affirmative* manifestations of intent, and lost in the inquiry was what Congress did *not* say or do. Despite years of express preemption in the medical device arena, Congress had not modified the express preemption language found in section 360k(a). The Court’s opinion was equally shortsighted in terms of its characterization of the MDA. While repeatedly emphasizing the goal of increased safety and efficacy in the medical device industry, the Court all but ignored legislative history indicating that the MDA was *also* intended to encourage re-

---

69. Given the unambiguous statutory language, the Court’s review of accompanying FDA regulations was unnecessary and improper. But more than that, it was highly selective. The Court’s opinion makes no mention of the FDA regulation that states that

[section 360k(a)] prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

21 C.F.R. § 808.1(b) (1996) (emphasis added). The plurality mentioned this regulation, but determined that the “court decisions” to which it referred were those that construed state statutes or regulations. *Lohr*, 116 S. Ct. at 2258.

70. Subsections 360k(a)(1) and (2) indicate that a state requirement will be preempted only if it is different from or in addition to an FDCA requirement and if it is concerned with the device’s safety, efficacy, or any other matter included in an FDCA requirement.

71. 116 S. Ct. at 2251.

search and development of medical devices by creating, on the federal level, a comprehensive and uniform regulatory environment.

## IX. THE IMPACT OF *LOHR*

### A. *Counting Heads and Opinions*

The collective *Lohr* opinion is a labyrinth. It includes an opinion of the Court (authored by Justice Stevens and joined by Justices Kennedy, Souter, Ginsburg, and Breyer); a plurality opinion (authored by Justice Stevens and joined by Justices Kennedy, Souter, and Ginsburg); a concurring opinion (authored by Justice Breyer); and a partially concurring/partially dissenting opinion (authored by Justice O'Connor and joined by Justices Rehnquist, Scalia, and Thomas). When all heads and opinions are tallied, the numbers add up as follows.

#### 1. Unanimous Opinions Favoring Plaintiffs

All nine justices agreed that, in the section 510(k) context, design claims and "identity of requirements" claims—in other words, claims alleging a failure to satisfy state requirements that *parallel* federal requirements—survived preemption under section 360k(a).

#### 2. Five-to-Four Splits that Favor Defendants

Five justices (Breyer and those who partially concurred and dissented) did not believe that preemption of state common law actions under section 360k(a) would be an uncommon occurrence. Four justices (Stevens and his plurality) believed that section 360k(a) would rarely result in preemption of state common law actions.

Five justices (Breyer and those who partially concurred and dissented) relied heavily upon *Cipollone* and believed that state common law actions were "requirements."<sup>72</sup> Four justices (Stevens and his plurality) distinguished *Cipollone* and took the position that, in section 360k(a), the word "requirement" encompassed positive law enacted by legislative or administrative bodies. However, these four justices stopped short of say-

---

72. The obvious significance of this tally is that the Supreme Court has, for the first time, confirmed that section 360k(a) preempts at least *some* state common law actions.

ing that common law duties could never be “requirements” within the meaning of section 360k(a).

Five justices (Breyer and those who partially concurred and dissented) did not take literally the suggestion that a state common law action must be established “with respect to” a medical device in order to be susceptible to preemption. Justice O’Connor and those who joined her partial concurrence/dissent were clearly in that corner. Justice Breyer embraced the majority’s “with respect to” rule, but affirmatively stated that he did not believe that medical device preemption would be rare. Because common law actions are seldom developed solely “with respect to” a particular type of product, the best inference is that Justice Breyer would apply the “with respect to” rule less stringently than would other members of the majority.

### 3. Five-to-Four Splits that Favor Plaintiffs

Five justices (Stevens and those who joined the majority opinion) believed that federal requirements, in order to have preemptive effect, must be “device specific.” Four justices (O’Connor and those who joined her partial concurrence/dissent) believed that a federal requirement would have preemptive effect if “applicable” to the device in question.

Five justices (Stevens and those who joined the majority opinion) believed that a state requirement, in order to be susceptible to federal preemption, must have something other than “general applicability” and be developed “with respect to” a medical device. Four justices (O’Connor and those who joined her partial concurrence/dissent) believed that “any” state requirement would be preempted if different from or in addition to an FDCA requirement and concerned with safety, efficacy, or any other matter included in an FDCA requirement.

Five justices (Stevens and those who joined the majority opinion) believed that, in the section 510(k) context, failure-to-warn claims and defective manufacturing claims survived preemption.<sup>73</sup> Four justices (O’Connor and those who joined her partial concurrence/dissent) believed that such claims were preempted by section 360k(a).

---

73. In the fall of 1996, the FDA published final regulations revising GMPs for manufacturers of medical devices. See Mary Beth Neraas, *Medical Device Preemption After Medtronic, Inc. v. Lohr*, 51 FOOD & DRUG L.J. 619, 625 n.47 (1996) (opining that the preemption door might be “re-open[ed]” due to new GMPs described as “far more rigorous and specific” than those considered by the *Lohr* Court).



Five justices (Stevens and those who joined the majority opinion) believed that, in order to resolve preemption cases under section 360k(a), there must be an examination of the preemption statute *and* the accompanying FDA regulations. Four justices (O'Connor and those who joined her partial concurrence/dissent) believed that such cases could be decided on the basis of section 360k(a) alone.

### B. *The Future of Medical Device Preemption*

*Lohr* is a narrow opinion that raises more questions than it answers.<sup>74</sup> The Court addressed and ultimately rejected medical device preemption — but it did so in the factually specific, section 510(k) context. At no point did the *Lohr* Court say whether or how its opinion should impact the preemption defense in the context of a medical device distributed pursuant to PMA or an IDE. For manufacturers of medical devices, these are likely to be the battlegrounds of the future. Victories can be expected, in large part because the purpose of the section 510(k) process differs markedly from the objectives of the PMA and IDE processes. Whereas the section 510(k) process has been characterized as a “status quo” mechanism that serves as a marketplace equalizer, the comparatively rigorous, regulation-intensive, and device-specific PMA and IDE processes are safety-oriented mechanisms that — unless disrupted by state common law tort claims — can further an important purpose of the MDA by encouraging research and development of safe medical devices under a uniform system of federal regulation. Thus, unlike in the section 510(k) context, state common law claims concerning PMA and IDE devices are capable of interfering with or impeding implementation of specific federal interests.

---

74. Lars Noah, a University of Florida law professor who specializes in product liability law, noted:

Breyer's concurrence means this opinion only applies to cases brought against devices approved under 510(k). . . . The opinion does not indicate what would happen with devices approved under the more rigid premarket approval procedure, so not all medical devices are covered. This was a very fractured opinion, which in some ways created more of a mess than you had before. . . . It leaves you to speculate on how the Court would rule on the broader questions of federal preemption, and how this opinion related back to *Cipollone*. . . . The holding gives the lower courts no clear guidance on how to resolve common law claims involving preemption issues except for the 510(k) claims. . . . In that sense, it's clearly not going to help.”

James Cahoy, *U.S. Supreme Court: Medical Device Patients Can Sue in State Courts*, WEST'S LEGAL NEWS 6272, 1996 WL 354146, June 27, 1996.

## 1. Section 510(k) Devices

The *Lohr* Court concluded that the section 510(k) process was bereft of “requirements” within the meaning of section 360k(a).<sup>75</sup> Accordingly, the Court determined that the section 510(k) process lacked preemptive effect.<sup>76</sup> Post-*Lohr* opinions involving section 510(k) devices have similarly rejected preemption.<sup>77</sup> The viability of the preemption defense in future section 510(k) cases may turn upon the interpretation given to newly promulgated GMPs—or, for that matter, any other relevant federal or state requirements—and be limited to those instances in which the FDA has played a more active role in assessing the product safety aspects of the section 510(k) device.

## 2. Medical Devices Distributed Pursuant to Premarket Approval (“PMA”)

A careful reading of *Lohr* suggests that there is substantial protection for manufacturers of medical devices that have received PMA.<sup>78</sup>

The *Lohr* Court devoted tremendous attention to the way in which Medtronic’s pacemaker lead reached the marketplace. By drawing sharp distinctions between devices deemed “sub-

75. *Lohr*, 116 S. Ct. at 2254.

76. Design defect claims are the most clearly impacted. All nine justices agreed that the section 510(k) “substantial equivalency” process failed to impose upon manufacturers any design requirements. While only five of the nine justices took the position that manufacturing and failure-to-warn claims survive preemption in the section 510(k) context, it is unlikely that the Court will revisit this issue—much less reverse its position—in the near future.

77. See, e.g., *Reeves v. Acromed Corp.*, 103 F.3d 442 (5th Cir. 1997) (holding that plaintiff’s “unreasonably dangerous per se” claim against a metal bone implant manufacturer was not preempted); *Duval v. Bristol-Myers Squibb Co.*, 103 F.3d 324 (4th Cir. 1996) (holding that plaintiffs’ claims against a penile prosthesis manufacturer were not preempted by section 360k(a)); *Dutton v. Acromed Corp.*, Nos. 69332, 69333, & 69358, 1997 WL 15248 (Ohio App. Jan. 16, 1997) (holding that failure-to-warn and fraud claims in a case involving bone plates and screws were not preempted); *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) (holding that plaintiff’s negligent failure-to-warn claim for a prosthetic hip replacement was not preempted); *Shea v. Oscor Med. Corp.*, 950 F. Supp. 246 (N.D. Ill. 1996) (holding plaintiff’s strict liability claims for alleged design defect involving sensing and pacing lead were not preempted).

78. Prior to *Lohr*, several circuit courts had determined that the PMA requirements had preemptive effect because they were specific to particular devices. See, e.g., *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), cert. denied, 116 S. Ct. 67 (1995); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), cert. denied, 115 S. Ct. 2614 (1995); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), cert. denied, 510 U.S. 824 (1993); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 (5th Cir.), cert. denied, 510 U.S. 824 (1993).

stantially equivalent” under the section 510(k) process and devices marketed pursuant to the PMA process, the Court did everything but affirmatively state that its holding was limited to section 510(k) devices. Section 510(k) products—subject to nothing more than “general control” provisions—are reviewed for “substantial equivalence” rather than safety.<sup>79</sup> At the conclusion of the section 510(k) process, manufacturers are admonished by the FDA that “substantial equivalence” determinations are *not* akin to product safety endorsements.<sup>80</sup> Recognizing that the average “substantial equivalence” assessment is a twenty-hour undertaking, the Court concluded that the section 510(k) process was “by no means” comparable to the PMA process.<sup>81</sup>

In stark contrast to the section 510(k) process,<sup>82</sup> the PMA process is “extensive.”<sup>83</sup> The *Lohr* Court referred to the PMA process as “rigorous” on more than one occasion.<sup>84</sup> The adjectives are accurate. In the PMA setting, manufacturers must provide detailed safety and efficacy data to FDA officials. On average, the FDA needs approximately 1200 hours to review a PMA submission.<sup>85</sup> During the PMA process, the FDA reviews reams of information about a *particular* device—all in an effort to determine whether that *particular* device is safe and effective. The FDA implements requirements applicable to PMA devices by sending specific approval letters to manufacturers. Device specificity is an inherent aspect of the PMA process. As one commentator noted:

---

79. *Lohr*, 116 S. Ct. at 2254.

80. *Id.* at 2248.

81. *Id.*; see also Michael K. Carrier, *Federal Preemption of Common Law Tort Awards by the Federal, Food, Drug, and Cosmetic Act*, 51 FOOD & DRUG L.J. 509, 550 (1996) (“The simplest route to market is through the provisions found in subsection 510(k) of the MDA.”).

82. The FDA’s section 510(k) process was made more demanding through the passage of the Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990) (codified as amended at scattered sections of 21 U.S.C.). Section 510(k) devices now receive more active review and are cleared through an FDA order. See 21 U.S.C. § 360c(i)(1)(A) (1995). In addition to providing information comparing the proposed device with devices marketed prior to 1976, manufacturers must provide any available data concerning safety or efficacy. See Neraas, *supra* note 73, at 625 n.46 (concluding, however, that courts are unlikely to deem the new section 510(k) procedures preemptive of state common law claims); see also *Lohr*, 116 S. Ct. at 2248 n.4 (“In 1990, Congress enacted amendments to the MDA which were designed to reduce the FDA’s reliance on the section 510(k) process while continuing to ensure that particularly risky devices received full PMA review.”).

83. See Burnside, *supra* note 3, at 951.

84. See, e.g., 116 S. Ct. at 2246, 2248.

85. *Id.* at 2246-47.

PMA approval is a specific determination by the FDA regarding a particular device. The FDA reviews detailed design, labeling, and manufacturing data specific to the device, granting approval only when there is “reasonable assurance” that the device is both safe and effective. The FDA’s approval must be based on “valid scientific evidence,” which includes animal studies and human clinical investigations where appropriate. . . . Thus when the FDA finally gives PMA approval, it has found that the specific design, manufacturing, and labeling of a particular device are reasonably safe and effective. The PMA supplemental regulations underscore the specificity of this finding, requiring FDA approval for any changes in those features of the device that affect safety or effectiveness. PMA approval, therefore, is an authorization under federal law to distribute a particular device manufactured under a specific process with a specific approved design and labeling.<sup>86</sup>

Because of the “device specific” nature of the PMA process, the pivotal issue in post-*Lohr* PMA cases is likely to be whether the state common law action has *specific* applicability and was established “with respect to” medical devices. In tackling this issue, manufacturers must focus on language that helps explain the apparent need to demonstrate *specificity* on the part of the state common law action. There are two helpful passages in *Lohr*. First, the Court stated that preemption should occur “only where a particular state requirement threatens to interfere with a specific federal interest.”<sup>87</sup> More importantly, the Court wrote that state common law requirements that are not developed “with respect to” medical devices are “not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements.”<sup>88</sup> The necessary corollary is that a common law requirement *is* developed “with respect to” medical devices if, in fact, it would impede implementation and enforcement of specific federal requirements. The first passage similarly focuses upon the threat that the common law requirement poses to the specific federal requirement. Again, the comprehensive nature of the PMA process should enable manufacturers to demonstrate that state common law actions are capable of interfering with and impeding the implementa-

---

86. Daniel G. Jarcho, *Premarket Approval and Federal Preemption of Product Liability Claims in the Wake of Medtronic, Inc. v. Lohr*, 51 FOOD & DRUG L.J. 613, 617 (1996).

87. 116 S. Ct. at 2240, 2257.

88. *Id.* at 2258.

tion of specific federal interests and requirements. The courts, however, have reached differing results in post-*Lohr* PMA cases.<sup>89</sup>

### 3. Devices Distributed Pursuant to an Investigational Device Exemption ("IDE")

*Lohr* should also bode well for manufacturers of medical devices distributed pursuant to an IDE. An IDE is intended "to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use . . . ."<sup>90</sup> A detailed regulatory regime specifies how an IDE "may be applied for, how the application is reviewed and approved by the FDA, and how clinical investigations . . . are to be monitored."<sup>91</sup> Manufacturers seeking an IDE for a particular medical device must (1) submit to the FDA an application containing an investigational plan, (2) maintain records of the investigation, and (3) report investigations to the FDA.<sup>92</sup> Manufacturers applying for an IDE must justify the commencement of testing in humans and assure that the rights and safety of humans are adequately protected. Investigations must be re-

---

89. *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. App. 1996) (holding plaintiff's negligence, strict liability, and breach of warranty claims against a surgical aid fluid manufacturer were not preempted); *Kernats v. Smith Indus. Med. Sys., Inc.*, 669 N.E.2d 1300 (Ill. App. 1996) (holding that design defect, manufacture, and warranty claims against a catheter manufacturer were not preempted); *Walker v. Johnson & Johnson Vision Prod., Inc.*, 552 N.W.2d 679 (Mich. App. 1996) (holding plaintiff's claims against a disposable contact lens manufacturer were not preempted); *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996) (in a case involving Zyderm Collagen Implant, the court held (a) that plaintiff's strict liability claim was preempted by section 360k(a), (b) that negligence claims involving product labeling and product development were preempted because the FDA had "preempted the field of regulation," and (c) that several other negligence claims were not preempted because they would have imposed duties that mirrored federal requirements); *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16 (1997) (in case involving extended-wear contact lenses, the court found no preemption with respect to claims based upon negligence, breach of warranty, and strict liability).

90. 21 U.S.C. § 360j(g) (1995); see also Stephen D. Harris, *Preemption of State Tort Claims Under the Medical Device Amendments*, 24 COLO. LAW. 2217, 2217 (1995) ("The IDE process is designed to encourage innovation and experimentation in the development of medical devices.").

91. See *Carrier*, *supra* note 81, at 550.

92. See 21 U.S.C. § 360j(g)(2)(B); see also 21 C.F.R. § 812.20(b)(3) (1996) (manufacturer must provide a "description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device").

viewed by a qualified Institutional Review Board established pursuant to FDA regulations.<sup>93</sup> Investigators<sup>94</sup> must agree that the patient will provide an informed consent and execute an FDA-approved informed consent form.<sup>95</sup>

Investigational devices, which can be distributed without PMA, are excepted from most safety, efficacy, and performance standards.<sup>96</sup> However, pervasive and device-specific regulations nevertheless apply. In a pre-*Lohr* opinion, the Seventh Circuit accurately explained that during the investigational stages, the FDA cannot “be expected to specify the safe and effective design of a device.”<sup>97</sup> If there were a design known to be safe and effective, the medical device would cease to be experimental. The circuit court noted that the entire aim of such an investigation is to determine whether the medical device is safe and effective.<sup>98</sup> FDA regulations that concern medical devices distributed pursuant to an IDE “do not specify the safe and effective design; they specify the *procedures* for determining whether the experimental design is safe and effective. These are requirements relating to safety and effectiveness and they can therefore have preemptive effect.”<sup>99</sup> Even in the wake of *Lohr*, the specificity of the IDE procedures should empower them with preemptive effect.

The other hurdle constructed by *Lohr* involves the need to demonstrate specificity with regard to the state requirement. In determining whether the state common law action was developed “with respect to” medical devices, the focus should rest on whether the state common law action interferes with or impedes implementation of specific federal interests. In the IDE context, there clearly is a specific federal interest in creating a protective environment in which the safety and efficacy of certain medical devices can be thoroughly investigated. Allowing liability to attach through state common law actions would interfere with that

---

93. 21 U.S.C. § 360j(g)(3)(A)(i).

94. An investigator is the physician “who actually conducts an investigational study” (in other words, the person “under whose immediate direction an investigational device is” implanted). 21 C.F.R. § 813.3(e).

95. 21 U.S.C. § 360j(g)(3).

96. 21 C.F.R. § 812.1(a).

97. *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992).

98. *Id.*

99. *Id.*

important federal objective.<sup>100</sup> While the courts have reached differing results in post-*Lohr* IDE cases,<sup>101</sup> one Sixth Circuit opinion is particularly helpful for manufacturers of IDE devices.<sup>102</sup>

#### 4. Preemption in the Event of Actual Conflict

The majority opinion indicates that one of the ways in which preemption will occur is through the existence of an *actual conflict* between a device-specific federal requirement and a state requirement that has specific applicability. Preemption should undoubtedly lie in those instances in which the state and federal requirements actually conflict. However, it does not necessarily

---

100. One commentator makes a strong argument in support of the position that, in post-*Lohr* IDE cases, preemption under section 360k(a) will be particularly appropriate with respect to design defect claims. Neraas, *supra* note 73, at 628. ("If plaintiffs are permitted to bring tort suits claiming defective design of experimental devices, in effect they would be imposing design requirements on devices that are affirmatively exempt under federal . . . requirements 'different from, . . . or in addition to,' the federal standard, which in this case is the lack of a requirement.")

101. See, e.g., *Sanders v. Optical Radiation Corp.*, 92 F.3d 1181 (4th Cir. 1996) (holding that a claim alleging noncompliance with federal regulations against an intraocular lens manufacturer was not preempted; the court did not address claims based upon strict liability, negligence, and breach of warranty); *Shea v. Oscor Med. Corp.*, 950 F. Supp. 246 (N.D. Ill. 1996) (holding that plaintiff's claims against a cardiac defibrillator manufacturer were not preempted because the state law claims would have imposed duties equal or substantially identical to federal requirements); *Berish v. Richards Med. Co.*, 937 F. Supp. 181 (N.D.N.Y. 1996) (holding that plaintiff's claims against the manufacturer of a prosthetic hip replacement system were preempted because the IDE regulations were specific counterparts to state requirements that would be imposed by tort liability); *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc) (holding plaintiff's tort claims against an intraocular lens manufacturer were not preempted because the IDE regulations did not conflict with the state requirements that plaintiff's lawsuit would have imposed); *Chambers v. Osteonics Corp.*, 109 F.3d 1243 (7th Cir. 1997) (holding plaintiff's strict liability and implied warranty claims for an artificial hip were preempted, but plaintiff's claim based upon failure to comply with FDA requirements could proceed).

102. In *Martin v. Teletronics Pacing Sys., Inc.*, 105 F.3d 1090 (6th Cir. 1997), *petition for cert. filed*, No. 96-1749 (May 1, 1997), the court found plaintiff's tort claims preempted in a case involving an allegedly defective pacemaker. In determining whether the federal requirements at issue were "device specific" and therefore capable of preemptive effect, the Sixth Circuit acknowledged the absence of regulations governing pacemakers like the one at issue. However, the court concluded that the federal requirements nevertheless had preemptive effect due to the "device specific" nature of the IDE application and approval process. *Id.* at 1097. As for the state requirements, the court acknowledged that it was "questionable" whether they were "with respect to" a medical device and not merely of "general applicability." The court stated: "[T]he state requirement appears not specifically applicable solely to medical devices. However, the state statute is the kind of requirement that would impede the implementation and enforcement of specific federal requirements." *Id.* at 1099.

follow that preemption *only* occurs in the event of an actual conflict between the state and federal requirement. While plaintiffs advanced such a position in *Lohr*, the Court stopped short of articulating an “actual conflict” requirement. In fact, the only hint that “actual conflict” may be a preemption prerequisite is the dissent’s interpretation of the majority opinion.<sup>103</sup> However, given the possible ambiguity, the medical device industry should be on the lookout for attempts by plaintiffs to characterize federal requirements as *minimum* standards that are not in actual conflict with different or additional duties imposed by state common law actions.

Consider, for instance, a device-specific federal provision that requires a pacemaker warning label to contain information about A. Further assume that plaintiff asserts a failure-to-warn claim, contending that the pacemaker warning label should have contained information about A and B. Plaintiff might argue that there is no actual conflict in a strict sense. In other words, it may be possible for the manufacturer to (1) comply with the federal requirement by warning about A, and (2) comply with the state requirement by warning about A and B. In such a situation, requiring an “actual conflict” in a strict sense strays much too far from the text of section 360k(a). The plain language of the statute indicates that the state requirement is preempted if different from or in addition to the federal requirement. Without question, a common law duty to warn about A and B would be different from *and* in addition to a federal provision that requires the manufacturer to warn about A.

### C. Different Approaches in the Wake of *Lohr*

*Lohr*’s bark is worse than its bite. While the opinion’s *holding* is adverse to defendants, its *reach* is suspect. The amount of attention devoted to the lenient nature of the section 510(k) process suggests that the holding warrants narrow application. Thus, the medical device industry must be wary of adversaries’ attempts to exaggerate the impact of the opinion. Unfortunately, efforts to confine the holding to the section 510(k) context may not always be successful. Accordingly, the industry must develop litigation strategies designed to combat the possibility of increased exposure.

---

103. *Id.* at 2263.



Because federal requirements are less likely to dictate product design than manufacturing processes or product labeling, design defect claims may be the most likely to survive preemption. Thus, manufacturers should consider fighting design defect claims with weaponry other than section 360k(a). The American Law Institute is in the process of completing its work on the Restatement (Third) of Torts: Products Liability. The section of the proposed restatement devoted to prescription drugs and medical devices provides that design defect liability will attach *only* in those instances where the medical device's foreseeable risks of harm outweigh the therapeutic benefits to such an extent that no reasonable health care provider would prescribe the device for *any* class of patients. A comment to the proposed section explains that "[g]iven this very demanding standard, liability is likely to be imposed only under unusual circumstances."<sup>104</sup>

#### CONCLUSION

The most that can be said of *Medtronic, Inc. v. Lohr* is that it definitively answered one question—whether the MDA, given the federal and state requirements applicable at the time of the decision, preempted the state common law actions asserted by the plaintiffs in a case that involved a medical device that had been distributed pursuant to the section 510(k) process. The Court did not say how its holding should be applied, if at all, in cases involving PMA and IDE devices. While not all “precincts” are reporting, early returns hint of confusion and inconsistency in the lower courts. It remains possible and appropriate that the Supreme Court will settle the issue by agreeing to review a PMA or IDE case. In the meantime, medical device manufacturers can and should view *Lohr* as an open door. The purpose and specific nature of PMA and IDE provisions—coupled with the fact that common law requirements pertaining to such devices are capable of disrupting these important federal interests—indicate that the preemption defense remains viable beyond the section 510(k) context.

---

104. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 8 cmt. f (Proposed Final Draft Oct. 18, 1996).