No. 04-0412

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

CHARLES RIEGEL and DONNA RIEGEL,
Plaintiffs-Appellants,

v.

MEDTRONIC, INC.,
Defendant-Appellee.

On Appeal from the United States District Court
for the Northern District of New York

REPLY BRIEF OF APPELLANTS
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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES Pages

STATUTORY MATERIALS

REGULATORY MATERIALS

INTRODUCTION

Relying on the majority opinion in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and supported by a long-standing regulation of the Food and Drug Administration ("FDA"), the Riegels' opening brief demonstrated that the preemption provision of the Medical Device Amendments ("MDA"), 21 U.S.C. § 360k(a), does not preempt their damages claims against Medtronic, Inc. In response, Medtronic downplays the *Lohr* opinion, wholly ignoring its two-part approach to preemption under section 360k(a). Instead, Medtronic urges this Court to follow a pre-*Lohr* case, *Becker v. Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995), the reasoning of which is inconsistent with that of the Supreme Court. At the same time, Medtronic exaggerates the significance of the premarket approval ("PMA") process, misrepresents the effect of a jury verdict, and questions the presumption against preemption that the Supreme Court reaffirmed just last month. Medtronic's arguments are meritless, and the decision of the district court holding that the MDA preempts the Riegels' damages claims should be reversed.

ARGUMENT

I. THE RIEGELS' DAMAGES CLAIMS ARE NOT EXPRESSLY PREEMPTED.

Under the Supreme Court's decision in *Lohr* and the FDA's longstanding regulation, 21 C.F.R. § 808.1(d), preemption under section 360k(a) requires a device-

specific FDA requirement and a "counterpart" state-law requirement. Neither the federal nor the state prong of the preemption analysis is satisfied here.

A. Premarket Approval Does Not Impose Device-Specific Requirements That Preempt The Riegels' Claims.

Although the PMA process is demanding, it does not impose device-specific design or labeling requirements, and thus does not preempt the Riegels' design or labeling claims. As the Eleventh Circuit has explained, the PMA process "differs in significant ways from the 510k process at issue" in *Lohr*, but the result regarding preemption is the same: "[B]ecause the [premarket] approval itself neither reveals nor imposes any ascertainable substantive prerequisite for approval that we could compare to a purportedly conflicting state requirement, the approval itself does not fit within section 360k(a)(1)'s demand for a specific federal requirement." *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1374, 1376 (11th Cir. 1999); *see id.* at 1376-77 (FDA's "conditions of approval" are "generic" and thus not preemptive); *Webster v. Pacesetter, Inc*., 171 F. Supp. 2d 1, 11 (D.D.C. 2001) ("[I]t is the specificity of the regulatory mandate, not the length and cost of review, that is relevant under Section 360k."); *Sowell v. Bausch & Lomb, Inc*., 230 A.D.2d 77, 84 (N.Y. App. Div. 1997) ("[W]hile a PMA review is considerably more rigorous and detailed than the

premarket notification at issue in [*Lohr*], it is, in fact, no more 'specific' a requirement.").

1. Medtronic argues that, given the degree of FDA scrutiny of PMA applications, PMA must have preemptive effect. The Riegels agree that PMA has a preemptive effect. The question is, what does PMA preempt? That is, what state requirement is the counterpart to a federal PMA requirement applicable to a particular device? The answer is: a state PMA requirement for that same device. A state requirement that a balloon catheter receive state premarket approval prior to marketing would address the same topic at the same level of specificity as a federal requirement that a balloon catheter receive PMA from the FDA, and would thus be preempted.

For example, in a 1978 Federal Register notice, the FDA explained that state and local PMA requirements are preempted by the FDA's PMA requirements. 43 Fed. Reg. 18661, 18664 (1978). Accordingly, in 1980, the FDA agreed that California could continue to require a state PMA before allowing a particular device to be marketed in California until the FDA established a "counterpart" requirement for that device, that is, until the date on which the FDA either determined that the device did not require PMA at all or the FDA determined that the device could not lawfully be marketed without a federal PMA. 45 Fed. Reg. 67321, 67323 (1980).

The principle that preemption under section 360k(a) turns on device-specific counterparts is expressly stated in both *Lohr*'s majority opinion and the applicable FDA regulation, 21 C.F.R. § 808.1(d). Thus, the existence of one federal device-specific requirement does not preempt all state requirements applicable to that device. Rather, the federal requirement preempts only the counterpart state requirement. To use Justice Breyer's example, a federal regulation that hearing aids must have two-inch wires would preempt a state requirement that hearing aids have a one-inch wire, *Lohr*, 518 U.S. at 505; but that federal regulation would not preempt state rules regarding packaging of hearing aids.

In short, the federal requirement that a device cannot be marketed without federal PMA would preempt a state requirement that the device undergo state PMA but would not preempt state rules regarding other aspects of that device. Product liability claims for design defect or failure to warn are not counterpart requirements to a PMA; such claims simply do not address the same topic (marketing approval). They are therefore not preempted by the federal PMA process.

2. The design of Medtronic's balloon catheter originated with Medtronic; it was not mandated by any federal requirement. Medtronic nonetheless argues (at 11, 19, 33) that PMA converts the manufacturer's choice of design into a federally required design. However, the PMA process does not prescribe criteria for the design

of devices. Rather, PMA "represents only the FDA's judgment that a manufacturer has reasonably assured the FDA of the device's safety and effectiveness." *Webster*, 171 F. Supp. 2d at 11. Accordingly, the PMA process contains no rules similar to the hypothetical FDA-required two-inch hearing-aid wire discussed in Justice Breyer's *Lohr* concurrence, 470 U.S. at 504, or to the FDA's device-specific design requirements for certain laser devices, 21 C.F.R. § 886.4392, or absorbency testing requirements for tampons, *id.* § 801.430(f). *See also*, *e.g.*, *id*. § 801.420 (labeling rules specific to hearing aids).[1]

The design specifications of Medtronic's balloon catheter were applicable to the device as a result of the voluntary decision of the manufacturer to introduce the device into the market with a design of the manufacturer's choosing. That federal law attaches a consequence to such private decisions does not convert them into federal "requirements." *See Lohr*, 518 U.S. at 493 (no preemption of Lohrs' design defect claim where FDA did "not 'require' Medtronics' pacemaker to take any particular form for any particular reason"); *cf. Bates v. Dow Agrosciences LLP*, __ U.S. __, 125 S. Ct. 1788, 1799 (2005) ("[A]n event . . . that merely motivates an optional decision

[1]Amicus curiae Product Liability Advisory Council ("PLAC") argues at length that the FDA *can* impose specific design requirements during the PMA process. However, there is no evidence that the FDA did so with respect to the device at issue here.

is not a requirement."); *American Airlines, Inc. v. Wolens*, 513 U.S. 219, 228-29 (1995) (under Airline deregulation Act, no preemption of lawsuit seeking recovery for breach of airline's self-imposed undertakings).

Indeed, Medtronic has changed the design of the balloon catheter since its approval. *See* App. A-120. Although FDA regulations required Medtronic to obtain FDA authorization for those changes, the same was true with respect to the device at issue in *Lohr*. *Compare* 21 C.F.R. § 814.39 (manufacturer must submit PMA supplement before making any change that affects safety or effectiveness of PMA device), *with id*. § 807.81(a)(3)(i) (manufacturer must submit new 510(k) application before making any change that affects safety or effectiveness of 510(k) device); *see also Webster*, 171 F. Supp. 2d at 10 ("Although the approval bars device changes related to safety or effectiveness absent approval, the agency did not identify specific alterations to design or labeling that would or would not be permitted. . . . The determination of what is related to safety and effectiveness is not set forth in the FDA approval letter, but is left to the manufacturer's own determination. Thus, the PMA does not impose any 'identifiable precondition' applicable to the device.").

In fact, much as Medtronic (at 10, 23) relies here on 21 C.F.R. § 814.39, Medtronic relied in the Supreme Court on the corresponding regulation for section 510(k) devices, 21 C.F.R. § 807.81(a)(3)(i). *See* Opening Br. at 29 n.5. Yet the

Supreme Court unanimously rejected the argument that the design-defect claim was preempted. *Lohr*, 518 U.S. at 492-94 (majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). The same result is warranted here.

3. The Riegels' opening brief (at 30) pointed out that, once the products were on the market, both the Medtronic balloon catheter at issue here and the Medtronic pacemaker lead at issue in *Lohr* were subject to the same labeling requirements, embodied in 21 C.F.R. § 801.109. The Supreme Court found that those requirements did not preempt the Lohrs' failure-to-warn claim. They therefore do not preempt the Riegels' failure-to-warn claim. Medtronic offers no response on this point.

Medtronic notes that labeling was one of the items that the FDA reviewed during the PMA process, but labeling was also part of the section 510(k) submission of the pacemaker lead at issue in *Lohr*. *See* 21 C.F.R. § 807(e). Not only has Medtronic failed to distinguish the labeling requirements applicable to its catheter from the labeling requirements applicable to the device at issue in *Lohr*, but Medtronic has not identified a single federal labeling requirement applicable specifically to balloon catheters as a class or to its catheter in particular. Under the analysis of the majority opinion in *Lohr*, the Riegels' labeling claims are not preempted.

B. The Riegels' State-Law Claims Would Not Impose Requirements That Have Any Specific Federal Counterpart.

As discussed in the Riegels' opening brief, *Lohr* requires that, before preemption may occur, both the allegedly preemptive federal requirement and the allegedly preempted state-law requirement must be "specific" within the meaning of section 360k(a) and regulations promulgated thereunder. 518 U.S. at 501-02; *see* 21 C.F.R. § 808.1(d). Medtronic's brief pays little attention to the state-law side of the preemption analysis.

First, Medtronic (at 25-28) spends several pages defending the proposition that state-law damages claims can constitute "requirements." On this point, Medtronic relies heavily on this Court's pre-*Lohr* decision in *Becker v. Optical Radiation Corp*., 66 F.3d 18. There, in the context of an experimental device that later received PMA, the Court stated that "requirements" may include state common law. *Id*. at 20 n.2; *see also* Opening Br. at 16 n.2 (discussing *Becker*). To begin with, insofar as *Becker* considered the device at issue to be a PMA device, the opinion premised preemption on "the general requirements of the MDA" and on general state-law duties not specific to devices. 66 F.3d at 20. The Supreme Court has since rejected the notion that "general requirements" can serve as the basis for preemption of damages claims. *Lohr*, 518 U.S. at 501, 502. Because the Supreme Court's decision casts doubt on

this Court's prior decision, *Becker* is not binding here. *Union of Needletrades, Industrial & Textile Employees v. INS*, 336 F.3d 200, 201 (2d Cir. 2003) (overruling Circuit precedent in light of intervening Supreme Court decision). Moreover, courts that considered the issue pre-*Lohr* have agreed that the Supreme Court's decision required them to reconsider the matter. *See*, *e.g.*, *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) (re-examining circuit precedent in light of *Medtronic*, ultimately upholding prior decision); *Goodlin v. Medtronic, Inc.*, 167 F.3d at 1376 n.16 (re-examining circuit precedent in light of *Medtronic*, ultimately reversing prior decision); *Haidak v. Collagen Corp.*, 67 F. Supp. 2d 21, 23-24 (D. Mass. 1999) (rejecting as inconsistent with *Lohr* prior First Circuit precedent finding PMA preempts damages claims); *see also Mitchell v. Collagen Corp.*, 518 U.S. 1030 (1996) (vacating and remanding decision involving PMA device in light of *Medtronic*).

In any event, the primary question here is not whether damages claims can ever impose "requirements" within the meaning of section 360k(a). The question is whether the Riegels' damages claims would do so. *Lohr*'s majority opinion makes clear that the answer is no, because the Riegels' claims are based on state-law duties of general applicability. 518 U.S. at 502; *see Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997) (failure to warn claim not preempted because it "is predicated upon a general duty applicable to every manufacturer 'to inform users and purchasers of

potentially dangerous items of the risks involved in their use.'" (citing *Lohr*)); *State ex rel. Miller v. New Womyn, Inc.*, 679 N.W.2d 593, 596 (Iowa 2004) (no preemption of claim against device manufacturer brought under state consumer fraud statute because statute not limited to devices); *Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997) (no preemption because "Kentucky's strict liability case law and statutes [on which plaintiff relies] are laws of general applicability to all products and fall beyond the scope of the federal preemption under § 360k"); *see also* Opening Br. at 32 (citing cases).

Medtronic (at 29-30) tries to convert damages claims based on generally applicable state-law tort duties into device-specific requirements by asserting that a jury verdict would somehow require Medtronic to change the design of its device. The Supreme Court has firmly rejected this argument:

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common-law duty at issue, see *Cipollone* [*v. Liggett Group*], 505 U.S., [504] at 524 [1992]; it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action (a question, in any event, that will depend on a variety of cost/benefit calculations best left to the manufacturer's accountants).

Bates, 125 S. Ct. at 1799. Thus, here, a jury verdict in favor of the Riegels would require Medtronic only to pay damages; it would not require Medtronic to take any other action, much less action inconsistent with federal requirements.

C. The Purpose And History Of The MDA Underscore That PMA Does Not Preempt State-Law Damages Actions.

Medtronic (at 35) makes the absurd argument that, under the reasoning of cases such as *Goodlin* in which courts have found that PMA does not preempt damages claims, section 360k(a) would be "surplusage." In fact, the Eleventh Circuit's reasoning leaves section 360k(a) with the same reach as the FDA, manufacturers, and patients all understood it to have for at least the first 15 years after its enactment, for not until 1992 did an appellate court hold that the MDA preempts damages claims. *See Slater v. Optical Radiation Corp*., 961 F.2d 1330 (7th Cir. 1992); *see also Goodlin*, 167 F.3d at 1381 ("[I]t seems unlikely that the industry would have ignored its immunity under the MDA for so long after the statute's enactment if Congress, in fact, had intended to provide immunity in 1976."). Until then, the FDA, the states, and manufacturers understood preemption to extend only to state medical device statutes and regulations. *See*, *e.g.*, 45 Fed. Reg. 67321, 67321-38 (1980). And case law construing section 360k(a) addressed the preemptive effect on positive law, with most courts holding that even state regulatory efforts were not preempted in the

absence of specific federal regulations on the same topic as the state regulation. *See*, *e.g.*, *Smith v. Pingree*, 651 F.2d 1021 (5th Cir. Unit B 1981); *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795 (N.J. 1978).

Moreover, the purposes and history of the MDA confirm that section 360k(a) was crafted with positive state enactments, not lawsuits, in mind. The MDA was enacted in the wake of the Dalkon Shield disaster, in which thousands of women were injured or killed by a hazardous medical device. *See* S. Rep. 33, 94th Cong., 1st Sess. 1-2, *reprinted in* 1976 U.S.C.C.A.N. 1070-72. Although a great many lawsuits were filed against the manufacturer of the Dalkon Shield, the legislative history expresses no concern about damages lawsuits. *See also Lohr*, 518 U.S. at 487 (plurality opinion) ("It is, to say the least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct,' *Silkwood v. Kerr-McGee Corp*., 464 U.S. 238, 251 (1984), and it would take language much plainer than the text of § 360k to convince us that Congress intended that result."). Rather, the House Committee that sponsored the legislation cited the lawsuits only as evidence of the enormity of the public health tragedy that could have been avoided if effective federal regulation had been in place. H.R. Rep. 853, 94th Cong., 2d Sess. 8 (1976) ("House Report"); *see also Haudrich v. Howmedica*, 642 N.E.2d 206, 211 (Ill. App. 1994) ("[T]he debate and Congressional record are barren

of any indication that Congress intended to preempt court decisions by passing the [MDA].").

Although it does not mention preemption of damages claims, the legislative history does address the types of state laws that are preempted. The House Report states that, after a particular MDA requirement is in place, corresponding statutory provisions "governing regulation of devices by States and localities" would be preempted, and the Report specifically mentions a California premarket approval statute. House Report at 45. Therefore, although section 360k(a) does not preempt product liability actions, it is not "surplusage."

Finally, Medtronic's suggestion (at 30-31) that subjecting device manufacturers to common-law liability puts them in a "Catch-22" situation is belied by the fact that damages actions for personal injuries caused by medical devices and FDA regulation have co-existed since 1976. *See also Bates*, 125 S. Ct. at 1802-03 (recognizing that tort law can complement regulation and help to improve product safety). Medtronic offers no evidence that manufacturers faced difficulty marketing their PMA devices in the years before any court held damages claims preempted, or that manufacturers face difficulty today in the states of the Tenth or Eleventh Circuits, for example, or

in Illinois, Kentucky, or Missouri, where the courts have held that section 360k(a) does not preempt common-law claims in cases such as this one.[2]

Amicus curiae PLAC cites (at 21-26) amicus briefs filed by the FDA in other cases to argue that preemption of damages claims supports the regulatory scheme. However, as the Riegels' explained in their opening brief, the FDA's views on the scope of section 360k(a) have not been consistent. Until a few years ago, the FDA's view had been that section 360k(a) did not preempt damages actions, and the FDA argued that position to the Supreme Court both in *Lohr* and in a case involving a PMA device, *Smith Medical Industries v. Kernats*. *See* Opening Br. at 21 n.3. Given the FDA's about face on this issue, the positions stated in the amicus briefs cited by PLAC deserve no weight. *See Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 (2000); *see also Bates*, 125 S. Ct. at 1801 (noting agency's change in view and giving no weight to agency brief). In contrast, the agency's interpretation of section 360k(a) as set forth in its long-standing regulation, 21 C.F.R. § 808.1(d), is entitled to deference. *Lohr*, 518 U.S. at 496-97, 498-99; *id*. at 505-06 (Breyer, J., concurring). PLAC's view, which casts aside both the need for counterpart state and federal

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[2]*See Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999); *Oja v. Howmedica*, 111 F.3d 782 (10th Cir. 1997); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999); *Niehoff v. Surgidev*, 950 S.W.2d 816 (Ky. 1997); *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc).

requirements and the need for device-specific requirements, is inconsistent with that regulation.[3]

D. The Presumption Against Preemption Supports Reversal.

Last month, the Supreme Court issued its decision in *Bates*, 125 S. Ct. 1788, a case concerning the scope of the express preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act. In the course of an opinion that cut back significantly on the broad preemption holdings of most federal and state appellate courts, the Supreme Court reaffirmed the presumption against preemption. Citing *Lohr*, the Court reiterated that, where the reach of an express preemption provision is not clear, the Court has "a duty to accept the reading that disfavors preemption." *Id*. at 1801.

Attempting to avoid the presumption, Medtronic argues (at 36-37) that section 360k(a) unambiguously preempts damages claims such as those asserted here. If

[3]In any event, the amicus briefs in *In re Paxil Litigation*, *Motus v. Pfizer*, and *Bernhardt v. Pfizer* are irrelevant here. Those briefs do not purport to construe section 360k(a); they address implied preemption in cases involving prescription drugs. Moreover, PLAC obscures the fact that the court in *In re Paxil* rejected the FDA's preemption argument, saying that the FDA's position "vitiates, rather than advances, the [statute's] purpose of protecting the public" and calling it "contrary to common sense." 2002 WL 31375497, *1 (C.D. Cal. Oct. 18, 2002). In *Motus*, the district court had found no preemption, and the court of appeals did not reach the issue. *See* 358 F.3d 659 (9th Cir. 2004). Likewise, in *Bernhardt*, which was not a damages case, the court did not reach the preemption issue. *See* 2000 WL 1738645, *1 (S.D.N.Y. 2000).

Medtronic were correct, surely device manufacturers would not have waited nearly 15 years after enactment of section 360k(a) to argue for preemption of damages claims. *See Goodlin*, 167 F.3d at 1381. And, if Medtronic were correct, surely the profusion of cases on both sides of the question that has existed since the mid-1990s would never have developed. Likewise, the Supreme Court would not have needed to address the scope of the provision in *Lohr*, a decision that effectively reversed the preemption holdings of the majority of the courts that had considered the issue in the context of a "substantially equivalent" device.

Medtronic also seeks help from *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In that implied preemption case, however, the Court did not apply the presumption because the case did not arise in an area of historic state concern. *Id*. at 347 ("Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied' . . . ." [citation omitted]). In contrast, the state interest at issue in this case is the same as the interest at issue in *Lohr* and *Bates*—protection of the health and safety of the states' citizens. *See Bates*, 125 S. Ct. at 1801; *Lohr*, 518 U.S. at 485. That interest is a matter of historic state concern. *Lohr*, 518 U.S. at 486; *Hillsborough County v. Automated Med. Labs*., 471 U.S. 707, 716, 719 (1985).

II. SUMMARY JUDGMENT SHOULD BE REVERSED WITH RESPECT TO THE MANUFACTURING DEFECT CLAIM.

The Riegels' opening brief explained that the district court erred in granting summary judgment on their negligent manufacturing claim because genuine issues of material fact are in dispute as to that claim. In response, Medtronic argues the facts and, in the process, makes the Riegels' point: The facts are disputed. The Riegels should have been given the opportunity to present the disputed facts to a jury.

The parties agree that, because the balloon was discarded and could not be used as direct evidence, the Riegels bear the burden of excluding causes of the product's failure other than product defect. However, the Riegels presented expert testimony that the balloon burst *radially*. *See* App. A-635, A-637-38. If the jury credits that testimony, then all causes of the failure not attributable to Medtronic would be excluded because Medtronic's theories all assume a *longitudinal* failure. To be sure, Medtronic disputed the expert testimony. That dispute, however, does not mean that the Riegels failed to meet their burden. It means that a disputed issue of material fact exists, and thus that the decision to grant summary judgment to Medtronic on this claim should be reversed.

CONCLUSION

For the foregoing reasons and the reasons stated in the Riegels' opening brief, the decisions of the district court holding that the Riegels' design and labeling claims are preempted and that the factual disputes regarding the Riegels' negligent manufacturing claim should not be submitted to a jury should be reversed.

Respectfully submitted,

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RULE 32(a)(7)(C) CERTIFICATION

Using the word count provided on our word processing system, I hereby certify that the above brief contains 4,019 words.

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May 24, 2005

CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of May, 2005, I served the foregoing REPLY BRIEF OF APPELLANTS CHARLES AND DONNA RIEGEL on appellee Medtronic, Inc. by causing two true and correct copies thereof to be placed in the United States mail, first-class postage prepaid, addressed as follows:

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