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Contents

Does FDA Pre-Market Approval Preempt Product Liability Claims Against the Manufacturer of the Device?

by James M. Beck

PREVIEW of United States Supreme Court Cases, pages 113–117. © 2007 American Bar Association.

James M. Beck is "of counsel" in the Product Liability litigation group of Dechert, LLP, in the Philadelphia office. He has represented Medtronic in other preemption matters. Mr. Beck is one of two regular contributors to the blog http://drugandedevicelaw.blogspot.com/. He can be reached at james.beck@dechert.com or at (215) 994-2970.

In *Medtronic, Inc. v. Lohr,* 518 U.S. 470 (1996), the Supreme Court considered express preemption of product liability suits by § 360k(a) of the Medical Device Amendments (MDA) to the Food, Drug & Cosmetic Act (FDCA). The product at issue in that case was a medical device cleared by the FDA for marketing as "substantially equivalent" to a previously marketed device—so-called § 510(k) notification. The court splintered in *Lohr,* producing three opinions, none joined by more than four justices. By a 5-4 majority, the Court held that § 510(k) notification was insufficiently specific to generate preemptive federal requirements within the scope of § 360k(a). In coming to this conclusion, the *Lohr* court explicitly distinguished another form of FDA device approval, so-called Pre-Market Approval (PMA), as being significantly more "rigorous" because it directly considered safety and effectiveness and as a result took much more of the agency's time.

The *Lohr* decision did not decide whether manufacturers of PMA devices could invoke federal preemption, but over the intervening decade most federal and state courts held that the PMA process was sufficiently specific to support preemption under *Lohr*. A significant minority, however, held that the PMA process, like § 510(k) notification, was not sufficiently device specific because it applied equally to an entire category of devices, rather than uniquely to a particular device. The *Riegel* case is expected to resolve this split of authority and perhaps revisit more broadly the question of express preemption of state common-law tort claims.

ISSUE

Does the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempt state-law claims seeking damages for injuries caused by med-

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RIEGEL V. MEDTRONIC, INC.
DOCKET NO. 06-179

ARGUMENT DATE:
DECEMBER 4, 2007
FROM: THE SECOND CIRCUIT

Case at a Glance

Federal law governing medical devices contains an express preemption clause barring state "requirements" that are "different from or in addition to" requirements established by the Food and Drug Administration. Previously, the Supreme Court narrowly found no preemption for medical devices cleared as "substantially equivalent" to already marketed devices. That decision distinguished devices subject to full premarket approval. This case will determine the existence and scope of express preemption of product liability claims involving PMA devices.

ical devices that received premarket approval from the Food and Drug Administration?

Facts

Medtronic, Inc. is probably the largest manufacturer of PMA medical devices in the nation, if not the world. Among the many prescription devices it makes is the Evergreen balloon catheter (EBC), which is used to treat patients with coronary disease. The EBC is used during angioplasty, a surgical procedure, to unclog diseased coronary arteries. It is inserted into the artery, moved to where the clog is located, and inflated like a balloon. Pressure from the inflated EBC squeezes the clog against the arterial wall, reopening the vessel. When the procedure is complete, the EBC is deflated and removed.

The EBC is an innovative device. There was no "substantially equivalent" prior device. Thus the EBC had to undergo premarket approval, the FDA's most rigorous approval process, and the agency had to determine whether the device was safe and effective for its intended use. This occurred on August 30, 1994, after several years of FDA consideration of Medtronic's application. Two PMA supplements altering the EBC's labeling were submitted and later approved, in 1995 and 1996. Because the EBC was essentially a balloon, Medtronic's FDA-approved labeling warned doctors not to overinflate the device, and contraindicated its use on certain types of hard, calcified obstructions.

On May 10, 1996, Charles Riegel underwent an angioplasty in which the EBC was used on an obstruction in his right coronary artery. According to Riegel's medical records, this artery was "diffusely diseased" and "heavily calcified." Thus, Riegel's surgeon used the EBC for a contraindicated purpose. The surgeon also inflated the EBC to a pressure of ten atmospheres, which exceeded the EBC's "rated burst pressure" of eight atmospheres. The EBC burst, causing severe injuries to Riegel that required intubation, advanced life support, and emergency coronary bypass surgery. He survived, but alleges "severe and permanent personal injuries and disabilities."

Riegel and his wife timely filed a product liability complaint against Medtronic in the U.S. District Court for the Northern District of New York, alleging state-law claims for negligent design, testing, inspection, manufacture, distribution, labeling, marketing, and sale concerning the EBC, as well as strict liability; and breach of express and implied warranty. Medtronic sought summary judgment on grounds of express preemption under the MDA. The district court granted Medtronic's motion on March 14, 2002, as to all claims except negligent manufacturing and express warranty. Discovery failed to substantiate the remaining claims. After final judgment was entered, Riegel appealed the preemption ruling to the U.S. Court of Appeals for the Second Circuit, which affirmed 2-1. *Riegel v. Medtronic, Inc.,* 451 F.3d 104 (2d Cir. 2006). Riegel sought *certiorari* from the Supreme Court, which was granted on June 25, 2007.

Case Analysis

Plaintiffs-petitioners contend that the Second Circuit—as well as the majority of other circuits to address the express preemption issue in the context of PMA devices (the Third, Fifth, Sixth, Seventh, Eight, and Ninth)—erred in finding that the PMA process generated preemptive requirements that barred common-law tort suits. Petitioners argue, first, that § 360k(a) should be construed narrowly. They assert language of the preemption clause does not logically include state-law damages claims within its preemptive scope at all. This is evident, petitioners claim, because when Congress enacted the MDA, the legislative history did not mention preemption of common-law damages claims. Because such preemption would be controversial, such legislative silence, petitioners argue, cannot provide the requisite intent to preempt.

In support of their proffered construction, petitioners offer two other provisions in the MDA as indicative of lack of congressional preemptive intent. The first of these is the section of the express preemption clause, § 360k(b), which provides for FDA preemption exemption for particular state "requirements." Petitioners argue that the exemption procedures cannot workably apply to damages claims. Petitioners also rely upon § 360h(d), concerning the "Effect on Other Liability" of FDA recall orders. This section, petitioners assert, demonstrates that Congress provided for continued state-law litigation of claims against device manufacturers. Preemption, petitioners argue, contradicts these other sections of the MDA and should be rejected.

Petitioners also rely upon a presumption against preemption. Any express preemption of historic state police powers, they claim, requires a "clear and manifest" statement of congressional intent that is absent from § 360k(a). Petitioners also point to the device industry's failure to argue preemption for quite some time after the adoption of the MDA in 1976.

Petitioners also rely upon *Lohr,* despite the distinction *Lohr* drew between § 510(k) notification and PMA. They point out that *Lohr,* like *Riegel,* involved tort liability allegedly arising from the use of a defective class III medical device. According

to petitioners, *Lohr* held that for the MDA to preempt any state-law claim, that claim must relate to a device-specific federal requirement. Further, the state legal requirement must have been created "with respect to" medical devices specifically. Petitioners find neither of these prerequisites satisfied by the PMA process. That process, they contend, does not impose device-specific design or labeling requirements. Conversely, petitioners argue that damages verdicts and common-law tort duties do not represent device-specific state-law requirements because they extend to all products, not just medical devices.

In addition, petitioners assert that their claims are "substantially identical" to the requirements that the FDA imposed upon the EBC. Because the tort duties petitioners advance are "equivalent" to the federal standards applicable to the device, those tort duties should not be preempted.

Finally, petitioners argue that the effect of PMA preemption upon state-law tort remedies would not be as "limited" as the Court of Appeals surmised. Instead, petitioners contend, PMA devices are the "riskiest" type of device, and thus injure many more patients than their relatively small numbers might suggest. Petitioners therefore argue that, instead of being "quite limited," the effect of applying preemption to damages claims for injuries caused by PMA devices would be broad. That effect would be particularly profound, petitioners claim, on those persons injured by PMA devices because federal law provides no alternative remedy.

Defendant-respondent Medtronic responds, first, by arguing that preemption is appropriate because petitioners' state claims would impose "requirements" "with respect to" the design, manufacturing, and labeling of the EBC that are "different from" and in "addition to" the FDA's device-specific federal requirements established by FDA premarket approval. Respondent argues that, under the express terms of § 360k(a), those claims are preempted.

Respondent asserts that the PMA process imposes device-specific federal requirements on medical devices. In contrast to the abbreviated § 510(k) notification process at issue in *Lohr,* respondent contends the much more rigorous PMA procedure requires substantive evaluation of a device's safety and effectiveness.

This is because, respondent argues, the FDA grants PMA approval only if the device is "safe and effective" according to MDA standards that require the devices to be designed, manufactured, and labeled in accordance with the specifications set forth in the corresponding PMA application. According to respondent's interpretation of the regulations, a manufacturer is prohibited from changing the design, manufacturing, or labeling of a PMA device in a manner that could impact its safety or effectiveness. Thus, respondent contends, the design, manufacturing, and labeling specifications contained in the PMA application become device-specific requirements imposed by the FDA when the FDA approves the application and mandates that the device conform to the Agency's conditions of approval. This, they argue, is what happened when the FDA approved the EBC's PMA application.

Lohr fully supports PMA preemption, respondent argues. In *Lohr,* the manufacturing and labeling requirements applicable to the § 510(k)-cleared device were entirely generic—the manufacturing and labeling regulations applicable to all medical devices. Respondent contrasts the requirements imposed in that case with the PMA requirements imposed on the EBC, describing those as going far beyond generic and encompassing the device-unique manufacturing, design, and labeling requirements set forth in the FDA-approved PMA application and incorporated by the FDA's approval letter.

Respondent argues, as well, that the FDA regulation (21 C.F.R. § 808.1) governing preemption does not indicate that preemption is limited solely to FDA regulations. Rather, both § 360k(a) and the FDA's interpretive regulation extend preemption beyond "specific counterpart regulations" to other kinds of "specific requirements," such as those generated by the PMA approval of an individual device. All of these "requirements," whether in the form of regulations, approvals, or other FDA action, give rise to preemption under respondent's view of the FDA's regulatory scheme.

Respondent argues in addition that state tort claims impose specific state-law "requirements" on the PMA devices such as the EBC. This result was affirmed, respondent contends, by a majority of the Court in *Lohr* and in the Court's other tort preemption precedent. Respondent cites several holdings in which the Court held that state common-law claims constitute "requirements" within the meaning of similar statutory language. *E.g., Bates v. Dow Agrosciences LLC,* 544 U.S. 431, 443 (2005); *Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 521 (1992) (plurality). In light of these cases, respondent argues that any argument that state common-law claims cannot be preempted under § 360k(a) is foreclosed by prior precedent.

(Continued on Page 116)

Respondent goes on to argue that nothing in the language or legislative history of the MDA warrants any more limited reading of the term "requirement," as used specifically in § 360k(a). To the contrary, respondent claims, § 360k(a) uses "requirement" in its broadest sense, since that section refers to "any requirement" established by a state. That contrasts, respondent asserts, to the more limited context in which the term is used elsewhere in the MDA.

Petitioners are incorrect, respondent contends, to resort to the legislative history of the MDA in an attempt to displace the unambiguous meaning of "any requirement." Respondent also disputes petitioners' assertion that it is "unprecedented" that Congress would preempt state-law claims without providing an alternate federal remedy. Respondent provides examples where this type of preemption took place because it was essential to some important federal objective, chiefly promoting the public health by means of comprehensive federal regulation.

Respondent also meets petitioners' arguments about device-specific state "requirements" with a discussion of Justice Breyer's concurrence in *Lohr,* in which Breyer assertedly recognized that there is no difference for preemption purposes between a medical device requirement imposed by state regulation and one imposed by state common law. While common-law tort duties are expressed in general terms, respondent argues that they become device specific when a jury is empowered to decide whether a particular liability theory applies to a state design, manufacturing, and labeling requirement with which the device did not comply. In that way, respondent argues, a verdict for petitioners would have the same practical effect as a state regulation mandating design, manufacture, or labeling standards that differ from those approved by the FDA with respect to the EBC. For that reason, respondent argues, both types of state-imposed standards are equally preempted by § 360k(a).

Respondent responds to petitioners' "substantially identical requirements" argument, first, with a waiver argument: that petitioners never argued that theory in the lower courts. Should the Court nevertheless entertain the position that only state requirements "paralleling" the FDA's requirements are involved, respondent argues that petitioners are still wrong because a state-law product liability claim necessarily rests on the premise that a device, designed, manufactured, and labeled in conformity with its PMA specifications, is somehow defective under state law. Such a finding of defect, respondent posits, would be directly at odds with applicable PMA requirements and could not possibly "parallel" them.

Next, the respondent argues that preemption of petitioners' state-law claims furthers the policy and objectives of the MDA. Respondent asserts that Congress extended FDA regulation to medical devices in order to promote the public health by ensuring that safe and effective devices would be widely available. To achieve that objective, respondent contends, Congress intended that the FDA would maintain a careful balance between twin goals of safety and technological innovation. Preemption of state-law claims involving FDA-approved design, manufacturing techniques, and labeling is essential, respondent believes, to achieving these congressionally set public-health objectives. Absent preemption, medical device manufacturers would allegedly be subject to overlapping and often irreconcilable state and federal regulatory requirements. Such widespread conflict, respondent argues, would on one hand significantly complicate the process of introducing new medical devices. On the other hand, without preemption, respondent asserts, lay juries would be free to second-guess expert FDA regulatory determinations regarding the safety and effectiveness of PMA-approved devices. This is why, respondent argues, the Second Circuit decided that it supports preemption.

Lastly, respondent points out that the universe of petitioners left without a common-law remedy by preemption in the context of PMA medical devices is relatively small. This is because, respondent states, the vast majority—over 99 percent—of medical devices reach the market through the § 510(k) notification process, which the Court held in *Lohr* did not preempt state-law claims. Even with respect to PMA-approved devices, there are still viable remedies for breach-of-express-warranty and negligent manufacturing, which respondent concedes are not "different from" or "in addition to" mandatory federal requirements for PMA-approved devices. According to the respondent, the petitioners were afforded full discovery and could not establish a viable, unpreempted state-law claim.

Significance

The outcome of this case is extremely significant for the most technologically sophisticated medical device companies, such as Medtronic, which are heavily invested in cutting-edge devices that do not qualify for the easier and cheaper § 510(k) notification means of approval. For the vast majority of medical devices that come to market under the § 510(k) process, however, it is unlikely that *Riegel*

will change the legal landscape in any relevant respect.

A decision in favor of preemption would have considerable significance going forward with respect to other PMA products. For example, a decision unambiguously requiring broad preemption of the claims at issue in *Riegel* would likely have prevented any significant mass tort from arising out of the problems some manufacturers (including Medtronic) encountered with implantable defibrillators. A relative reduction in the product liability burden for the most sophisticated products could, in the long run, cause more risk capital to flow into the development of this type of medical device, possibly to the detriment of similar research in prescription drugs, assuming no decrease in the litigation burden faced by drug manufacturers.

There are a number of issues being argued that could have much broader implications. Chief among these is the petitioners' contention that, by their nature, state common-law tort claims are incapable of being state "requirements" subject to express federal preemption. This is the same "positive enactments" argument that petitioners have lost since *Cipollone*. While it is unlikely that the Court would reverse itself on this issue, if that were to happen, then the viability of express preemption under a variety of other statutes, such as the Cigarette Labeling Act, FIFRA (insecticides), and even ERISA could be undermined.

On a more general level, *Riegel* will be of interest as an indicator of whether there is likely to be any greater unanimity in the Roberts Court on preemption issues involving common-law torts. *Lohr,* in particular, was a badly fractured decision in which most of the major issues were decided 5-4 with no majority opinion. Other major preemption cases, such as *Bates* and *Geier v. American Honda Motor Co.,* 529 U.S. 861 (2000), have been decided by similarly narrow votes. At the moment, that appears doubtful, as the changes in personnel that have occurred since *Lohr* have involved replacing justices who tended to look favorably upon preemption (Rehnquist, O'Connor) with other justices (Roberts, Alito) whom many speculate will share similar views.

Finally, *certiorari* was granted in *Riegel* despite an amicus brief filed by the Solicitor General recommending against that action. The Solicitor General can be expected to maintain the same substantive position in the brief that the government will be filing on the merits. In light of the recent problems that have wracked the Justice Department, *Riegel* might well be a test of how much credibility the legal positions taken by the Bush Administration remains with the Court.

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