

The Dispositive Preemption Question

Monday, Jul 30, 2007 --- In a classic federalism battle pitting the makers of medical devices against the plaintiff's bar deploying state law based tort claims, the U.S. Supreme Court will hear *Riegel v. Medtronic* (No. 06-179) in the fall. In doing so, it will resolve judicial conflict over the preemptive effect of the medical device amendments of 1976 on the Food, Drug and Cosmetic Act. See *Riegel v. Medtronic Inc.*, 2006 WL 2849233 (S. Ct. June 25, 2007)

Defendant manufacturers argue that premarket FDA approval of medical equipment trumps and precludes most state law tort claims. At the same time, a similar issue is percolating through federal and state courts in the context of FDA prescription drug labeling regulations, and recently spawned a certiorari petition that went to conference on May 17, causing the Supreme Court to invite the Solicitor General to present the "the views of the United States" on the subject. See *Wyeth v. Levine* (No. 06-1249), 2007 WL 1461080 (May 21, 2007).

At bottom, these disputes center on the Bush administration's effort to federalize product safety standards (among others) in the interest of uniform regulation nationally.

It has been sixteen years since the Court's seminal preemption ruling in *Cipollone*, which essentially protected tobacco companies from post-1969 failure-to-warn liability based on the terms of the Federal Cigarette Labeling and Advertising Act.

Now, medical device makers are raising similar arguments that the Food, Drug and Cosmetic Act's prohibition against any state law device requirement "which is different from, or in addition to, any requirement" in federal law precludes tort claims under state law.

Recent pro-business decisions from the court—dealing with antitrust law and shareholder class action litigation (by Justice Ginsburg)—may be reason for commercial optimism. Plainly Supreme Court guidance is much needed.

According to *The New York Times* (June 26, 2007 at C3): "[t]he issue has so confounded the courts that three appeals courts reviewing the same medical device made by the same company have reached two different conclusions about whether the patients could bring a lawsuit."

Below we frame the *Riegel* preemption issue.

Background

Plaintiff Charles Riegel underwent an angioplasty, during which his doctor used a balloon catheter manufactured by Medtronic. *Riegel v. Medtronic*, 451 F.3d 104, 107 (2d Cir. 2006). The catheter burst, causing plaintiff to lose consciousness and to be placed on life support. *Id.*

Plaintiff survived emergency bypass surgery, but alleged that he suffered "severe and permanent personal injuries and disabilities" as a result of the defective nature of Medtronic's catheter. *Id.*

Riegel and his wife sued Medtronic alleging multiple New York state common law causes of action challenging the design, testing, manufacturing, distribution, labeling and marketing of Medtronic's "Evergreen Balloon Catheter." *Id.*

Medtronic moved for summary judgment, arguing that plaintiffs' claims were barred by the doctrine of federal preemption. *Id.* The district court granted summary judgment dismissal of all of plaintiffs' claims, except those for negligent manufacturing and breach of express warranty. *Id.* (These surviving claims were subsequently dismissed on other grounds. *Id.* At 108.)

FDA Premarket Device Approval and Preemption

The Second Circuit, in a 2-1 decision, affirmed. After describing the "lengthy and rigorous" process of obtaining pre-market approval ("PMA") from the FDA of certain so-called "Class III" medical devices—like the balloon catheter manufactured by Medtronic—the court concluded that the catheter was "subject to the federal device-specific requirement of complying with the particular standards set forth in its approved PMA application." *Id.* at 119; see also *id.* at 118 (court noting agreement with the "majority of circuits that have held that . . . PMA-approved devices . . . are subject to federal device-specific requirements").

(The Court noted that the "majority of Class III medical devices" do not go through this rigorous PMA process inasmuch as pre-1976 devices and new devices that are "substantially equivalent" to pre-1976 devices can be marketed without FDA approval as long as they comply with "premarket notification," which is a far less rigorous process. *Id.* at 111.)

The majority held that because the Riegels' state-law claims "would, if successful, impose state requirements that differed from, or added to, PMA-approved standards," those claims were preempted by federal law. *Id.* At 121-22.

The dissent argued that while the PMA process did "focus[] on safety and effectiveness," it did not impose "specific" requirements on the device seeking pre-market approval. *Id.* at 131-32 (emphasis added). It reasoned that "although the PMA process involves a rigorous and intensive review of a device, neither that review nor eventual approval imposes any ascertainable requirement upon the device that could be compared to any state requirement" to determine whether the state requirement is in fact

preempted. *Id.* at 132.

Put differently, the PMA approval process merely establishes that a product "has met the FDA's minimum requirements" (setting basically a floor)—it "does not represent a reasoned consideration and rejection by the agency of possible alternative, safer designs." *Id.*

On this basis, the dissent held that the PMA approval process, without more, does not preempt state law tort claims like those asserted by the Riegels: because PMA does not itself mandate "device-specific requirements."

Certiorari Briefs Paint Starkly Different Pictures of the Current State of Law

The Riegels' petition highlighted the purported: "division among the federal and state appellate courts [on the issue of] whether the FDA's grant of PMA for a medical device triggers preemption of state-law damages claims alleging that a manufacturer did not properly design the device and failed to warn of the device's risks." Petitioner's Brief, 2006 WL 2252499, at *14 (Aug. 3, 2006). As one example of this alleged split of authority, petitioner noted that in states such as Illinois, Kentucky and Iowa, federal courts find preemption of such claims, while state courts do not. *Id.*

In opposition, by contrast, Medtronic downplayed the magnitude of any circuit split, emphasizing instead a "clear and growing consensus" of courts throughout the country that premarket approval of medical devices preempts conflicting state law claims based on the design, manufacture and labeling of these FDA-approved products. Respondent's Brief, 2006 WL 2849233, at *1 (Oct. 5, 2006).

Medtronic maintained that: "[e]very court of appeals to have considered the issue in the past seven years has concluded, as did the Second Circuit below, that the FDA's vigorous PMA process established device-specific federal requirements that . . . preempt state common law damages claims that would effectively create state requirements 'different from' or 'in addition to' the federal requirements." *Id.*

It characterized the few aberrant decisions finding no preemption as mere "vestigial inconsistenc[ies]" rooted in an earlier misinterpretation of a landmark Supreme Court decision on federal preemption, *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996). According to Medtronic, these early outlier decisions are inconsistent with subsequent Supreme Court case law that clarified and crystallized the holding in *Lohr*, and were therefore "unlikely to survive even absent [the Supreme] Court's intervention" in the instant case. *Id.* at *14.

Finally, the United States Government filed an amicus brief arguing against certiorari. In its brief, the Government argued that the Second Circuit had "correctly held. . . that the FDA's premarket approval of a Class III medical device imposes federal 'requirements' that preclude the imposition of state-law tort liability based on a respondent's alleged failure to satisfy

inconsistent or additional state-law requirements." Government Amicus Brief, 2007 WL 1511526, at *7-8 (May 23, 2007).

The Government also observed that the only federal circuit decisions (from the Eleventh Circuit) and state supreme court decision (from the Kentucky supreme court) to the contrary "predate most of the other cases addressing the question, and were issued without the FDA's current judgment" on the issue. *Id.* at *8.

After recognizing that the Government's position in a 1998 amicus brief filed with the Court was that PMA "did not itself establish" federal requirements that would be preemptive, the Government conceded that it "has since reexamined the issue and determined that the position it announced" in 1998 "was erroneous." *Id.* at *16.

Having previously denied several certiorari petitions raising this exact issue, the U.S. Supreme Court has set the stage for clarification. (See Respondent's Brief, 2006 WL 2849233, at *1 (listing five denials of certiorari review by the Court on this precise issue).

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