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A legal update from Dechert's Mass Torts and Product Liability Group

Riegel v. Medtronic: A Win for Federal Preemption and Medical Device Makers

Background

For the first time in over a decade, since *Medtronic v. Lohr*, 518 U.S. 470 (1996), the U.S. Supreme Court has revisited express preemption of product liability claims involving medical devices. Last week, the Court issued its eagerly awaited opinion in *Riegel v. Medtronic, Inc.*, Opinion No. 06-179, Feb. 20, 2008. The 8-1 decision, which significantly limits state tort liability for makers of medical devices given premarket approval (PMA) by the FDA, is a major victory for the industry.

In *Riegel*, the plaintiffs sued Medtronic for injuries Charles Riegel sustained after a catheter used during Mr. Riegel's coronary angioplasty ruptured. The plaintiffs asserted that the catheter was "designed, labeled and manufactured in a manner that violated New York common law, and that these defects caused Riegel to suffer severe and permanent injuries." Medtronic argued that these claims were preempted. The district court agreed, dismissing most of the plaintiffs' claims, and the U.S. Court of Appeals for the Second Circuit affirmed. *Id.* at 6-7.

The Decision

The Supreme Court held that the preemption provision in the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360k, bars most state tort claims challenging the safety and efficacy of medical devices that receive PMA.[1] Section 360k prohibits states from "establish[ing] or continu[ing] in effect with respect to a device . . . any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device" and (2) that "relates to the safety or effectiveness of the device." *Id.* at 2 (quoting § 360k).

The Court opened its opinion with a detailed examination of the MDA and PMA requirements. Of the three levels of FDA oversight, Class III devices, including Medtronic's catheter, receive the greatest scrutiny—"rigorous premarket approval." *Id.* The FDA grants PMA only if it determines there is "reasonable assurance" of the device's "safety and effectiveness." *Id.* (quoting § 360e(d)). PMA obligates the FDA to weigh the probable benefits of the device against any potential health risks. *Id.* Once the FDA grants PMA, the statute prohibits a manufacturer from making changes in design, labeling, manufacturing, or attributes that may affect safety or efficacy without another round of FDA approval. *Id.* at 5.

PMA stands in contrast to the less rigorous § 510(k) "substantial equivalence" review, addressed in *Lohr*, under which most medical devices are marketed. *Id.* at 3. Devices sold before the MDA was enacted are exempt from PMA, and new devices that are "substantially equivalent" pre-MDA exempt devices share that exemption. *Id.* at 3-4.

Beginning with statutory interpretation, the Court determined that the FDA had established "requirements applicable to" Medtronic's catheter under the PMA process. *Id.* at 8-10. In reaching this conclusion, the Court relied on FDA regulation, 21 CFR § 808.1(d), which

[1] Due to the plaintiffs' failure to raise the issue below, the Supreme Court did not review their arguments that state law claims paralleling federal requirements, rather than supplementing them, were not preempted.

provides that state requirements are preempted "only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device." *Id.* at 8 (internal quotations omitted). Here, the Court distinguished *Lohr* as involving "an exemption from federal safety review." Pre-market approval, by contrast, "*is* federal safety review." *Id.* at 9 (emphasis in original). Put simply:

> [W]hile the FDA does not 'require' that a device allowed to enter the market as a substantial equivalent 'take any particular form for any particular reason,' the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.

Id. at 9-10.

The Court next determined that the plaintiffs' state law claims amounted to requirements that were different from, or in addition to, the FDA's PMA requirements relating to safety and efficacy. *Id.* at 11. "Requirements" preempted by § 360k(a) include common-law duties within the normal meaning of the term. *Id.* Excluding "common-law duties from the scope of pre-emption would make little sense." *Id.* Indeed, the Court regarded state tort law as "less deserving" than state administrative action of protection from preemption—because common-law juries "see[] only the cost of a more dangerous design, and [are] not concerned with its benefits; the patients who reaped those benefits are not represented in court." *Id*.

The Court next turned to the plaintiffs' argument that their claims escape preemption because New York's "general" tort duties are not maintained "with respect to devices." The Court readily rejected this contention, finding nothing in the statute suggesting that the "pre-empted state requirement must apply *only* to the relevant device, or only to medical devices and not to all products and all actions in general." *Id.* at 15 (emphasis in original).

Finally, responding to the dissent's argument that it is "difficult to believe that Congress would, without comment, remove all means of judicial recourse" for injured consumers, the Court declared that this is precisely what a "pre-emption clause for medical devices does by its terms."[2] *Id.* at 12. Plainly stated, "[t]he operation of a law enacted by Congress need not be seconded by a committee report on pain of judicial nullification." *Id.*

Implications Of *Riegel*

The *Riegel* decision should eliminate many product liability claims against manufacturers of PMA devices. So long as manufacturers comply with federal regulations, the Court has made it clear that state law requirements differing from, or supplementing, federal standards will be preempted, whenever those requirements relate to "safety and effectiveness."

After *Riegel*, courts will be grappling with what exactly constitutes a tort claim that "parallels" PMA regulations so as to escape preemption. While not reaching this issue in *Riegel*, the Court may yet offer further guidance in the pending *Warner-Lambert v. Kent* matter, which involves "fraud on the FDA" violation claims. On a more fundamental level, *Riegel* provides manufacturers a powerful policy argument against all future attempts to shield product liability claims from preemption—that litigation is far less appropriate than administrative action as a forum in which to decide whether *overall* product risks outweigh its benefits, as juries do not hear from the persons who have benefited from the product.

While the landscape for device manufacturers has improved with the *Riegel* decision, both medical device and pharmaceutical manufacturers must remain vigilant. Within 48 hours of the Court's decision, the *New York Times* editorialized that Congress should "move quickly to pass corrective legislation." *See* "No Recourse for the Injured," *NYT*, Feb. 22, 2008. Thus, while device manufacturers can celebrate this most recent victory, they also must remain on guard against legislative action that seeks to reverse their gains.

One Last Word For Pharmaceutical Companies

Riegel also has implications for *Wyeth v. Levine*, the pharmaceutical preemption decision that the Court will hear next term. Responding to the dissent's assertion that there is no preemption of product liability claim involving prescription drugs, the majority stated, "[i]t

[2] Justice Ginsburg dissented because of an absence of evidence that Congress intended "a radical curtailment of state common-law suits." (opinion of Ginsburg, J. at 1).

has not been established (as the dissent assumes) that no tort lawsuits are pre-empted by drug or additive approval under the FDCA." *Riegel*, slip op. at 14. Nor does the majority so much as mention the "presumption against preemption," relied upon by Justice Ginsberg in dissent, which is essential to so much of the *Levine* plaintiffs' arguments. Although prognosticating in the arena of Supreme Court decision-making is, at best, a hazardous sport, it is clearly worth noticing these comments relating to the much-anticipated *Levine* decision.

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