

***Riegel v. Medtronic, Inc.:* What Does it Portend for the Broader Pre-Emption of Common Law Claims Against Drug Manufacturers?**

On February 20, 2008, the Supreme Court issued its opinion in *Riegel v. Medtronic, Inc.*, No. 06-179, 2008 WL 440744 (U.S. Feb. 20, 2008). The case, one of a trio issued that day enforcing statutory pre-emption provisions,¹ defines the scope of federal pre-emption with respect to medical devices and may provide an indication of things to come in two further cases that will address pre-emption with respect to prescription drugs.² As few general legal principles have greater financial importance to drug manufacturers than pre-emption, this advisory discusses the *Riegel* decision and what it suggests for the future of drug-based product liability actions.

The *Riegel* Opinion

Riegel involved a claim for damages arising from the unsuccessful surgical use of a balloon catheter marketed by the defendant. The accompanying labeling indicated that use of the catheter was contraindicated in a calcified artery and that the catheter should not be inflated past its burst pressure of eight atmospheres. Despite the heavy calcification in Mr. Riegel's artery, his surgeon inserted the catheter and inflated it five times to a pressure of ten atmospheres. On the fifth inflation, the catheter ruptured. Mr. Riegel suffered a heart block, was placed on life support, and had to undergo emergency bypass surgery.

The Riegels filed suit in federal court in the Northern District of New York. They asserted claims under New York common law on theories of strict liability, breach of implied warranty, and negligence. The district court concluded that the claims (except for claims of negligent manufacture based on an alleged violation of federal law) were pre-empted by the Medical Device Amendments of 1976, 21 U.S.C. § 301c *et seq.* ("MDA"). The Second Circuit affirmed.

The MDA expressly pre-empts state (i) "requirements" that are (ii) "different from, or in addition to, any requirement applicable to the device . . . under federal law." 21 U.S.C. § 360k(a)(1). Justice Scalia, writing for an eight-justice majority, presented the issue as "whether the pre-emption clause . . . in the [MDA] bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by" FDA. *Riegel*, 2008 WL 440744, at * 2.

In an earlier decision, the Court had found that the MDA did not pre-empt common-law claims where the device had been cleared for sale under the "510(k)" process, in which FDA determines that a device may be marketed because it is "substantially equivalent" to a device that had been lawfully sold prior to the MDA's enactment in 1976. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1996). Anticipating its discussion distinguishing *Lohr*, the Court discussed at length FDA's approval and oversight of medical devices under the premarket approval ("PMA") process used for devices not "substantially equivalent" to pre-MDA devices, emphasizing that "the MDA established a rigorous regime of premarket approval for [such] devices." 2008 WL 440744, at *4.

The Court began its analysis by asking whether there are federal "requirements" applicable to the catheter so as to satisfy the first prong of the MDA's pre-emption clause. The starting point for the discussion was *Lohr's* holdings that "federal manufacturing and labeling requirements applicable across the board to almost all medical devices [do] not pre-empt the common-law

claims of negligence and strict liability,” *id.*, and that the “substantial equivalence” review provided for by 21 U.S.C.

§ 510(k) similarly does not impose device-specific “requirements,” *id.* at *6-7. The Court then identified a key difference between the 510(k) process at issue in *Lohr* and the PMA process: Unlike “general labeling duties, premarket approval is specific to individual devices” and is focused on safety, rather than equivalence. *Id.* (noting that devices that have received PMA must be made “with almost no deviations from the specifications in [their] approval application”).

Finding that the MDA had established federal requirements applicable to the catheter, the Court then had to determine whether the plaintiffs’ common-law claims were based upon state law requirements “different from, or in addition to” the federal requirements. *Id.* at *7-8 (citing 21 U.S.C. § 360k(a)). Justice Scalia first pieced together statements from two opinions in *Lohr* to conclude that a majority of justices in that case believed that common law duties were “requirements” of law, and hence potentially subject to the statutory pre-emption. *Id.* at *10. The conclusion that these common law “requirements” were “different from, or in addition to” those of federal law followed from the fact that a “state tort law that requires a manufacturer’s catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme.” *Id.* at *8. Indeed, the majority noted that the “benefits” of a device – which is within the scope of FDA’s approval calculus – would not be among the issues considered by a jury.³

Justice Stevens concurred in the judgment and accepted most of the Court’s opinion, including the conclusion that common law rules could constitute “requirements”: “[C]ommon-law rules administered by judges, like statutes and regulations, create and define legal obligations, some of them unquestionably qualify as ‘requirements.’” *Id.* at *11 (citing *Cipollone v. Leggett Group, Inc.*, 505 U.S. 504, 522 (1992)). But he disagreed that the potential actions of a single jury could constitute a “requirement.” *Id.* at *11 & n.1.

Justice Ginsburg dissented, stressing that there is a presumption against pre-emption, *id.* at *12 (Ginsburg, J. dissenting) (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)), even with respect to federal laws that contain express pre-emption clauses, *id.* at *13 (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)). Justice Ginsburg also emphasized that the presumption is heightened where federal law is alleged to bar state action in fields of traditional state regulation, including matters of health and safety. *Id.* (citing *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)). In response to the majority’s argument that FDA is best equipped to regulate medical devices, Justice Ginsburg argued that the Court’s construction of § 360k(a) would have the “‘perverse effect’ of granting broad immunity ‘to an entire industry that, in the judgment of Congress, needed more stringent regulation’ ... not exemption from liability in tort litigation.” *Id.* at *14 (quoting *Lohr*, 518 U.S. at 487).⁴ Justice Ginsburg noted that by the MDA’s design, state premarket regulation of medical devices can, and is supposed to, coexist with federal regulation. *Id.* at *16.

Discussion

It is impossible to take as a coincidence that three decisions interpreting statutory pre-emption provisions all found in favor of pre-emption. The Roberts Court has been mindful that certain types of litigation (like mass torts, antitrust cases, and securities fraud cases) impose tremendous strains on defendants and the federal courts, and has been proactive in finding ways to limit such cases.⁵ Indeed, in none of the three cases decided on February 20 was a conflict among the circuits cited, and in every case the decision of a court of appeals was affirmed.

Elements of the Court’s opinion offer some reason to think that an expansion of implied pre-emption under different portions of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (“FDCA”) may be in the offing. The Court’s reliance on the specificity of FDA’s regulation of Class III medical devices aligns express pre-emption analysis more with conflict pre-emption⁶ analysis than with field pre-emption⁷ analysis, suggesting that the former may be a stronger

ground than previously thought. Indeed, the parallels between the drug approval process and the PMA process at issue in *Riegel* are obvious. Many drug cases, including the *Wyeth v. Levine* case scheduled to be heard next term, ask courts to consider whether FDA labeling requirements are rigorous enough to pre-empt state law. Plaintiffs often contend that FDA labeling requirements set a minimum standard which manufacturers may exceed. But anyone who has ever marketed a drug understands that the labeling regulations are, in the words of FDA, both a “floor and a ceiling” on what may be said. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933-36 (Jan. 24, 2006) (hereinafter, “Preamble”).

As clear a signal as the Court may have intended to send as to the enforcement of statutes with pre-emption provisions, less clear is the future course of pre-emption based upon a conflict between state law and other portions of FDCA that contain no such express pre-emption provision. To be sure, the 8-1 decision itself suggests the absence of an ideological division that might be inclined to limit federal pre-emption in deference to the tort system, but the prominence in the Court’s analysis of the language of the express statutory provision in the MDA is notable. See, e.g., *id.* at *9. Moreover, the Court’s acceptance of jury verdicts as capable of representing state law, and hence creating a basis for pre-emption, leaves at least one key question not definitively answered: Whether a state jury is free notwithstanding express or implied pre-emption to interpret a *federal requirement* on its own, especially in cases (for example, in connection with discretionary enforcement actions) where FDA has not spoken.

Following *Riegel*, another area of uncertainty is how the Court will treat the Preamble, where FDA set forth its view that its approval of labeling under the FDCA pre-empts any contrary state law. See Preamble, 71 Fed. Reg. at 3933-36. Some have argued that the Preamble represents a change in the FDA’s view, and *Riegel* contains an ambiguous discussion of the deference to be paid to a changed agency position. Whether this will make any difference in *Wyeth v. Levine* remains to be seen, but we tend to think that, whichever way the Court goes, it will decide that case based on general pre-emption principles, and not the Preamble.

We also note that Justice Stevens once again has used a concurrence to make express some of the implicit assumptions of a majority opinion. Here, he observes that the majority has dissociated construction of the MDA from its legislative history, because the statute’s “text and general objective cover territory not actually envisioned by its authors.” *Riegel*, 2008 WL 440744, at *11 (Stevens, J. concurring). That observation, if applied more broadly to other provisions of the FDCA, may have lasting significance. Many important issues under both the MDA and the FDCA – including questions of generic drug approval and prescription drug advertising – generally can be described in that way, and to suggest that plain language so easily trumps presumed statutory intent could embolden a court inclined to change the law.

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1. The other cases were *Preston v. Ferrer*, No. 06-1463, 2008 WL 440670, at *1 (2008) (pre-empting state law requirement that dispute subject to arbitration first be subject to state administrative proceeding) and *Rowe v. New Hampshire Motor Transp. Ass’n*, No. 06-457, 2008 WL 440686, at *1 (2008) (pre-empting state law regulating the delivery of tobacco into the state by common carriers).
 2. The Court will take up the issue of the pre-emptive effect of FDA regulation of drugs in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *cert. granted sub nom. Warner-Lambert Co., LLC v. Kent*, 128 S. Ct. 31 (2007), and *Levine v. Wyeth*, No. 2004-384, 2006 WL 3041078 (Vt. Oct. 27, 2006), *cert. granted*, 552 U.S. ___ (2008). *Warner-Lambert Co.*, which was argued on February 25, involves the question whether a Michigan statute that bars personal injury suits against drug manufacturers unless the plaintiff proves that the manufacturer deliberately withheld information from FDA, is pre-empted in whole or in part. The *Wyeth* case involves the pre-emptive effect more generally of FDA’s labeling provisions.
 3. This summary and dismissive statement of the obligation of juries to conduct cost-benefit analyses in deciding product liability cases is, to say the least, debatable. See, e.g., John S. Allee, Theodore V.H. Mayer & Robb W. Patryk, *Product Liability* § 2.05(2)(b) (2008) (discussing the use of cost-benefit analysis in design defect cases).
 4. Concurring in part and in the judgment, Justice Stevens also emphasized that “the overriding purpose of the [MDA] was to provide an additional protection to consumers, not to withdraw existing protections.” *Id.* at *11 (Stevens, J. concurring). He believed, however, that the plain language of the pre-emption provision could not be so limited on grounds of policy and legislative history. *Id.*
 5. See *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955 (2007) (antitrust); *Credit Suisse Sec. (USA) LLC v. Billing*, 127

- S. Ct. 2383 (2007) (antitrust); *Tellabs Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499 (2007) (securities fraud).
6. Conflict pre-emption exists where a state law conflicts with or compromises the applicability of federal law. See *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65, (2002) (“[I]f a state common-law claim directly conflicted with a federal regulation..., or if it were impossible to comply with any such regulation without incurring liability under state common law, [conflict] pre-emption would occur.”).
 7. Field pre-emption exists where Congress is deemed to have occupied an entire field of regulation, leaving no room for state legislation of any kind. See *Louisiana Public Service Comm’n v. F.C.C.*, 476 U.S. 355, 368 (1986) (Field pre-emption arises when “Congress has legislated comprehensively, thus occupying an entire field of regulation and leaving no room for the States to supplement federal law.”).

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