Legal Backgrounder

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RIEGEL V. MEDTRONIC: WHAT DOES IT PORTEND FOR DEVICE & DRUG SUIT PREEMPTION?

by

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On February 20, 2008, the United States Supreme Court issued an 8-1 opinion holding that the Medical Device Act expressly preempts most common law personal injury claims against the manufacturers of Class III medical devices. *Riegel v. Medtronic, Inc.*, No. 06-179, 2008 WL 440744 (U.S. Feb. 20, 2008). *Riegel* was the first of three FDA preemption cases before the Court this year. On March 3, 2008, the Court issued a 4-4 *per curiam* opinion (with Roberts abstaining) in *Warner-Lambert Co. v. Kent*, No. 06-1498, 522 U.S. ___ (2008), thus allowing to stand a U.S. Court of Appeals for the Second Circuit opinion (conflicting with that of the Sixth Circuit) that a fraud-on-the-FDA exception to a Michigan statute precluding product liability claims involving FDA safety-approved products was not impliedly preempted. In the fall of 2008, the Court will hear oral argument in *Wyeth v. Levine* on the question whether and to what extent common law personal injury claims against prescription drug manufacturers are impliedly preempted.

The first part of this LEGAL BACKGROUNDER reviews the Court's reasoning in *Riegel* in finding claims against Class III medical device manufacturers to be preempted. The second part analyzes the *Riegel* opinion and the *Kent* oral argument for clues as to where the Court may be headed on the issue of preemption in cases involving prescription drugs.

The Status of Medical Device Products Litigation Following Riegel

Following *Riegel*, common law products liability claims involving Class III medical devices will be preempted with one or possibly two exceptions: (1) the Court held that claims based on alleged violation of FDA regulations would not be preempted, 2008 WL 440744, at *11, and (2) the Court did not reach the question whether express warranty claims would be preempted, because that claim was dismissed below on other grounds. *Id.* at *5 n.2. In her dissenting opinion, Justice Ginsburg also argues that "[t]he Court's holding does not reach an important issue outside the bounds of this case: the preemptive effect of §360k(a) where evidence of a medical device's defect comes to light only *after* the

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device receives premarket approval." *Id,* at *12 n.1 (Ginsburg, J., dissenting). The majority opinion, however, makes no such distinction and, to the contrary, notes that "[o]nce a device has received pre-market approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at *5.[1] In support of this assertion, the Court cites to the general regulation governing PMA supplements, 21 C.F.R. 814.39(c). *Id*. Notably, the Court makes no mention of the "changes being effected" ("CBE") regulatory provision at 21 C.F.R. 814.39(d)(2)(1), which allows device manufacturers to change device labels pending subsequent FDA review to "add or strengthen" warning language. The petitioners had specifically relied on the CBE provision in opposing preemption and the provision has been a key weapon in plaintiffs' arguments against preemption both in cases involving medical devices and those involving prescription drugs (which are subject to a similar CBE regulation).

While there has been significant attention given to FDA's position in support of preemption, both the *Riegel* majority and Justice Ginsburg in dissent agreed that FDA is entitled to only limited deference in its interpretation of the MDA statutory language, particularly given its change in position on preemption from that taken by the Agency in an *amicus* brief in the late 1990s. *See* 2008 WL 440744, at *8; *id.* at *14 n. 8 (Ginsburg, J., dissenting). The majority held, however, that it was "unnecessary to rely upon that agency view because we think the statute itself speaks clearly to the point at issue." *Id.* at *8. The majority also gave greater deference to FDA with regard to its interpretation of its own *regulations*. *Id.* at *9 ("The agency's reading of its own rule is entitled to substantial deference.")

Riegel speaks only in passing about other types of medical devices (e.g., Class II devices), but the Court's reasoning suggests that there will continue to be only limited preemption defenses available in litigation involving such devices. The key issue will be whether FDA regulation of these devices constitutes a "specific requirement applicable to a particular device" in question. 2008 WL 440744, at 6. There are a handful of Class II devices that may meet this threshold. For example, courts have held preempted common law claims involving Class II tampons and Class II contact lens solutions because of specific FDA regulations regarding the labeling of such products. *See Papike v. Tambrands Inc.*, 107 F.3d 737 (9th Cir. 1997); *Tuttle v. CIBA Vision Corp.*, No. 2:05CV340, 2007 WL 677134 (D. Utah March 1, 2007). However, FDA regulation of most non-Class III medical devices is less detailed, and *Riegel* does not provide any obvious hooks to expand the scope of preemption to encompass such devices.

That being said, *Riegel* includes a number of passages that reflect a more receptive view of preemption than is reflected in the Court's 2005 FIFRA preemption decision, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005). For example, while *Bates* spoke favorably about common law juries complementing and improving upon regulatory safety schemes, *Riegel* focuses on the fact that juries have only a limited view of the cost-benefit analysis underlying the FDA approval of medical devices: "A jury … sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court." 2008 WL 440744, at *8. Likewise, *Riegel* dismisses the argument cited with favor in *Bates* that it is "difficult to believe that Congress would, without comment, remove all means of judicial recourse" for consumers injured by FDA-approved devices, holding that "this is exactly what a pre-emption clause for medical devices does by its terms." *Id*. The Court notes: "the only indication available – the text of the statute – suggests that the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was

[1]The Court also notes that "[t]he FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." *Id.*

overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." *Id*. *Riegel* also reverted back to the Court's earlier holdings in *Cippolone v. Liggett Group, Inc*., 505 U.S. 504 (1992) and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), that state common law obligations constitute "requirements" for purposes of an express preemption provision. 2008 WL 440744, at *7. While *Bates* had continued to adhere to this position in principle, it had rejected the argument that jury verdicts constitute preemptive requirements because they only "motivate an optional decision" and "induce [but do not require] a pesticide manufacturer to change its label." *Bates*, 544 U.S. at 443. Without mentioning this reasoning in *Bates*, *Riegel* puts forth a more preemption-friendly argument, noting that "while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy." 2008 WL 440744, at *7 (quotations omitted).[2] Finally, again unlike *Bates*, the *Riegel* majority makes no mention of a presumption against preemption.

Reading the Riegel *and* Kent *Argument Tea Leaves for Preemption in Prescription Drug Litigation*

Aside from the generally pro-preemption slant of its opinion, the Court's analysis of preemption in *Riegel* focuses fairly closely on the express preemption provision of the MDA and, thus, provides only limited authority for preemption arguments in prescription drug litigation. Unlike some federal circuit courts which previously considered Class III medical device preemption, the Supreme Court did not explicitly rely on the type of conflict between state tort law and FDA-approval that would also inform the prescription drug implied preemption analysis. And while the 8-1 alignment of the justices in *Riegel* is obviously promising, the inclusion of an express preemption provision in the MDA provides Class III medical device manufacturers with a much cleaner preemption argument than that being made by prescription drug manufacturers. That being said, both Justice Scalia for the majority and Justice Ginsburg in dissent clearly had an eye on the Court's upcoming debate over prescription drug preemption, and their opinions provide some hints at where the Court may be headed.

Justice Scalia specifically addresses the issue of prescription drug preemption in response to Justice Ginsburg's reliance in dissent on the rejection (until recently) of preemption arguments in prescription drug litigation. Justice Scalia's provides two counter-arguments, one that suggests that the Court may extend preemption to prescription drug litigation but the other that cautions against any expectation of a broad preemption ruling.

> The dissent also describes at great length the experience under the FDCA with respect to drugs and food and color additives. Two points render the conclusion the dissent seeks to draw from that experience – that the [MDA] pre-emption clause permits tort suits – unreliable. (1) It has not been established (as the dissent assumes) that no tort lawsuits are pre-empted by drug or additive approval under the FDCA. (2) If, as the dissent believes, the pre-emption clause permits tort lawsuits for medical devices just as they are (by hypothesis) permitted for drugs and additives; and if, as the dissent believes, Congress wanted the two regimes to be alike; Congress could have applied the pre-emption clause to the entire

[2]Justice Stevens takes issue with this reasoning in his concurring opinion. While agreeing that common law rules administered by judges can constitute preemptive requirements, Justice Stevens argues that "[t]he verdicts of juries who obey the rules ... are not 'requirements.'" *Id.* at *11 n.1 (Stevens, J., concurring).

> FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.

2008 WL 440744, at *9 (internal citation omitted).

In her dissent, Justice Ginsburg cites repeatedly to the similarities between the FDA approval process for Class III medical devices and that for prescription drugs. *See*, *e.g. id.* at *15 (Ginsburg, J., dissenting) ("Congress' experience regulating drugs and additives informed, and in part provided the model for, its regulation of medical devices. I therefore turn to an examination of that experience."); *id.* at *16 ("the process for approving new drugs is at least as rigorous as the premarket approval process for medical devices"). Despite opposing express preemption in *Riegel*, however, Justice Ginsburg arguably provides a foundation for a preemption defense that would also apply to some prescription drug cases. Following up on an argument raised by the Washington Legal Foundation in an *amicus* brief to the Court, Justice Ginsburg suggests that the question of preemption should be addressed under the doctrine of implied conflict preemption: "a 'pre-emptive provision, by itself, does not foreclose (through negative implication) any possibility of implied conflict preemption. … Accordingly, a medical device manufacturer may have a dispositive defense if it can identify an actual conflict between the plaintiff's theory of the case and the FDA's premarket approval of the device in question." *Id*. (Citations omitted). Given Justice Ginsburg's argument as to the similarities between the prescription drug and medical device regulatory approval process, her conflict preemption argument would seem to apply equally to prescription drugs.

While the *per curiam* opinion in *Warner-Lambert Co. v. Kent* offers no reasoning and limited predictive value given Chief Justice Roberts' abstention, the February 25, 2008 oral argument may have provided another clue of where the Court may be heading in *Levine* in the questioning by Justice Breyer, who will be a potential swing vote on prescription drug preemption. As indicated by his concurring opinions in *Bates*, 544 U.S. at 454-55, and *Medtronic v. Lohr*, 518 U.S. 470, 506 (1996), Justice Breyer has been particularly sensitive in his preemption analysis to concerns raised by the federal regulatory agencies as to how state tort claims might interfere with federal regulatory oversight. During the *Kent* oral argument, Justice Breyer repeatedly questioned plaintiff's counsel about the fact that a common law jury is not in a position to make the balanced risk-benefit analysis necessary in considering the approval of prescription drugs. Justice Breyer stated that Congress had decided that FDA should be the party to make those decisions, and noted the serious adverse health consequences that could arise from jury determinations on such issues if patients are thus deprived of beneficial drug treatment.

Conclusion

The Scalia and Ginsburg opinions in *Riegel* and the Breyer line of questioning at the *Kent* oral argument suggests that the Court may be moving toward a middle ground on prescription drug preemption, allowing the defense only in cases of an actual conflict between FDA's approval of the drug labeling and the plaintiff's state tort theories. Of course, the significance of such a ruling would depend upon the definition, if any, the Court provides for the term "actual conflict." *Riegel* provides no direct guidance on this question.

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