Federal Preemption: The Drug and Device Trilogy

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INTRODUCTION:

A trilogy is a set of three "works of art" usually connected by theme and often connected by the same characters or settings. In ancient times, these works were often great literature or Greek dramas. In today's world, these works also include Hollywood blockbusters and video games. What is the benefit or appeal of a trilogy? It can be seen as both a single work and as three separate works and is therefore often used to develop and convey complex ideas over multiple volumes. Perhaps it is fitting then—if not altogether intentional—the law of federal preemption, both express and implied, is being refined by the U.S. Supreme Court this year in a trilogy of drug and medical device cases. Having granted certiorari in three cases, the results thus far have been mixed, with the third decision yet to come.

VOLUME I: *Riegel v. Medtronic, Inc.*[1]—Express preemption bars state law claims involving PMA medical devices

In what is being haled as a victory for the medical device industry, on February 20, 2008, the Court in *Riegel* held by a vote of 8-1 that the express preemption clause of the Medical Device Amendments of 1976 (MDA)[2] preempts state court suits challenging the safety or effectiveness of Class III medical devices that have been approved by the FDA pursuant to its rigorous premarket approval regime (PMA devices). PMA devices are to be distinguished from devices that achieve FDA approval merely by showing, through a much less rigorous process, that they are "substantially equivalent" to a previously approved device (510(k)[3] devices).

Charles Riegel filed suit against Medtronic in federal court in New York after a Medtronic catheter PMA device burst during Riegel's 1996 coronary angioplasty. Although the surgeon admittedly disregarded a number of contraindications regarding the use of the catheter, Riegel nevertheless alleged that the catheter's defective design, labeling and manufacturing caused his injuries. The trial court dismissed Riegel's complaint, holding that the MDA expressly preempted his common law claims for strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter. The trial court further held that Riegel's negligent manufacturing claim was preempted to the extent that it was not predicated on a violation of federal law. The Second Circuit affirmed.

Justice Scalia, writing for the majority, affirmed as well. The Court held that the PMA process, rather than promulgating requirements general to all medical devices, is focused on the safety and effectiveness of the specific device at hand and imposes requirements specific to that device, including that it be made with almost no deviations from the form contained in the approval application. The Court found that state common law tort duties impose requirements on the device pertaining to safety and effectiveness that are different from or in addition to the federal requirements. Thus, they disrupt the federal regulatory scheme and should be preempted under the terms of the express preemption provision of the MDA.

While it is a significant victory, *Riegel* is not likely a death knell for medical device litigation. On its face, *Riegel* does not appear to extend federal preemption to common law claims against 510(k) devices. That review, in the eyes of the Court, is focused on equivalence and not safety. Many currently marketed devices are 510(k) devices rather than PMA devices. Nor does *Riegel* appear to extend preemption to Class I and II devices, which are subject to general controls but not premarket review. Thus, medical device lawsuits will continue to be filed, and only some of them will be eligible for disposal based on preemption.

VOLUME II: *Warner-Lambert v. Kent*[4]—Implied preemption of state law claims left open in cases involving allegations of fraud on the FDA

In *Kent*, the Court, in a one-line per curium opinion, affirmed the Second Circuit's holding that Michigan residents may bring state law tort claims against manufacturers of FDA-approved drugs in circumstances involving allegations of fraud on the FDA. The Michigan "drug shield" statute[5] provides that FDA approval is a bar to state law claims for negligence or product defects. But the statute expressly carves out an exception for cases in which the defendant "intentionally withholds from or misrepresents" to the FDA "information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act and the drug would not have been approved" or such approval would have been withdrawn if an accurate submission had been made.

Kent involved Rezulin[6] lawsuits filed against Warner-Lambert Co., LLC and Pfizer, Inc. Plaintiffs alleged that the manufacturers were not shielded from their product liability claims by the Michigan statute because the company misled the FDA in its New Drug Application (NDA) regarding the seriousness and pervasiveness of liver damage among patients in the company's clinical trials. Like the premarket approval process involved in *Riegel*, the NDA approval process is rigorous. The "FDA will approve an application after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling."[7] At the heart of the dispute was the question of whether the FDA or a jury is better suited to police drug safety.

Defendants asked the Court to extend its holding in *Buckman, Co. v. Plaintiffs' Legal Committee*, because "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives."[8] Thus, defendants asked the Court to hold that the *Kent* plaintiffs' claims were impliedly preempted by federal law. Chief Justice Roberts recused himself, and in a 4-4 decision, the remainder of the Court declined to do so.

Because it is evenly split, the *Kent* decision has no precedential value. Unfortunately, that means there still exists a split between the Second Circuit (Connecticut, New York, and Vermont)[9] and the Sixth Circuit (Kentucky, Michigan, Ohio, and Tennessee)[10] as to whether claims excepted from a state's drug shield law are nonetheless still preempted by federal law. This uncertainty in the law creates at least two readily identifiable problems. First, it encourages forum shopping. A plaintiff who wants to keep his claims alive will look long and hard at how to file his claims in the Second Circuit where those claims can go forward, rather than in the Sixth Circuit where they may be preempted. Second, in a multidistrict litigation, it makes the choice of transferee court (the court that issues pretrial rulings in all of the federal cases nationwide), which would ordinarily be a mostly administrative decision, a significant substantive decision since the transferee court usually applies its federal circuit precedent to pretrial rulings.

If the decision in the third and final case, *Wyeth v. Levine*, discussed below, is in favor of preemption, it could resolve this split. But even then, much would depend on the precise scope of the decision.

VOLUME III: *Wyeth v. Levine*[11] —Implied preemption of all state law claims involving prescription drugs to be decided

The last in the trilogy of drug and device preemption cases is *Wyeth v. Levine*. In *Levine,* plaintiff lost her arm to gangrene, then amputation, after an inadvertent arterial injection of intravenous Phenergan. Plaintiff filed suit in state court in Vermont alleging that Wyeth was negligent in failing to adequately warn of the known dangers associated with the drug's intravenous administration and the risk of inadvertent arterial injection. The jury returned a multi-million dollar verdict, and the Vermont Supreme Court affirmed.

In its petition for certiorari, Wyeth framed the issue as whether state law product liability claims premised on the adequacy of a prescription drug's labeling are preempted by the authority given to the FDA under federal law. Wyeth had already sought direction from the FDA as to changes to certain of the warnings at issue in the *Levine,* but that direction was not forthcoming from the FDA. Nevertheless, the state court verdict effectively held the company liable for not changing the warning.

The broad issue raised by *Levine* is whether federal law displaces state law product liability claims against prescription drug manufacturers. This is essentially the same question for drugs that the Court decided as to medical devices in *Riegel*. *Riegel*, however, involved a question of express preemption, whereas *Levine*, like *Kent*, will ask the Court to hold that the FDA's regulatory authority impliedly preempts any state court requirements different from or in addition to the federal regulatory scheme. Given the Court's split in *Kent*, it is difficult to predict where the Court will come down on the broader question. If decided in Wyeth's favor, the case could bar most, if not all, state law product liability claims against drug manufacturers.

It was originally thought that *Levine* would be heard by the Court this term, but the briefing schedule for the case was recently extended through the summer making it more likely that the case will be heard in the next term of court. Although no change in the composition of the Court is expected before that time, any such change could affect the outcome of this case since the Court seems to be divided on implied preemption issues.

CONCLUSION:

Although preemption has been raised as a defense in all drug and device cases for years, in the past, it has not had much chance of success. The cases discussed above change that. The potential viability of a preemption defense is stronger now than it has been in years, and preemption should be considered in every case. If the circumstances of the case are right, a company may be able to dispose of certain claims, and if fortunate, certain lawsuits in their entirety.

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[1] 128 S.Ct. 999 (2008).

[2] These are amendments to the Federal Food, Drug, and Cosmetic Act found at 21 U.S.C. § 301 *et seq.* (the Act), which as enacted, are scattered throughout the Act. The preemption clause is found at 21 U.S.C. §360k(a).

[3] "510(k)" is a reference to the section of the MDA describing this less stringent review process.

[4] No. 06-1498, 2008 WL 552875 (Mar. 3, 2008).

[5] Mich. Comp. Laws § 600.2946(5).

[6] Rezulin, a diabetes drug, has since been withdrawn from the market.

[7] 21 C.F.R. § 314.1059(c).

[8] 531 U.S. 341, 350 (2001).

[9] *See Desiano v. Warner-Lambert,* 467 F.3d 85 (2d Cir. 2007).

[10] *See Garcia v. Wyeth-Ayerst Labs*., 385 F.3d 961 (6th Cir. 2004).

[11] 2006 Vt.107 (Vt. 2006), *cert. granted,* 128 S.Ct. 1118 (Jan. 18, 2008) (No. 06-1249).