U.S.S.C. DEVELOPMENTS IN FEDERAL PREEMPTION

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Recent Federal Preemption Decisions and Developments: *Riegel, Altria, and Levine vs. Wyeth*

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Federal preemption is a constitutional doctrine rooted in the Supremacy Clause of the United States Constitution, which provides for the primacy of federal laws over state laws:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const., art. VI, cl. 2. As a practical matter in litigation, the preemption doctrine operates as a defense to an action brought under a state rule of conduct – that is, a state statute, regulation, or common-law duty -- that conflicts with a federal rule on the same subject. Federal preemption may be evident from Congress's *express* statement of its intention to preempt contrary state laws in a formal preemption clause included in statutory text. Alternately, preemption may be *inferred* when there is a practical conflict between federal and state law, such as the impossibility of complying with both, or the state law's frustrating the goals and purposes of the federal laws and regulations. This *implied* form of preemption may be found regardless whether Congress has specifically expressed its intent to preempt in statutory language. (There is no reason to believe that Congress would go to the trouble to enact a federal law while intending that any or all of the states could undo or ignore it; their passage of federal legislation *implies* that they intend the federal law to trump any contrary state law, and not vice versa.) Where preemption exists, the result is that the offending state statute, regulation or civil action is nullified or barred from operation. See, e.g., *Geier vs. American Honda Motor Co.*, 529 U.S. 861 (2000).

Preemption litigation is typically for high stakes and bitterly fought. Supreme Court preemption decisions tend to either kill or sustain not just individual lawsuits, but entire fields of litigation. Because the doctrine lies so close to fundamentally political concepts – the organization of our federal system, and the appropriate ways to resolve tension between federal and state rulemakers – preemption disputes tend to starkly reveal, and outcomes tend to depend upon, the jurisprudential philosophies of the members of an appellate court. Appellate panels are often sharply divided. Circuit splits and conflicting decisions from federal and state appellate courts tend to emerge quickly and find their way to the *certiorari* queue at the Supreme Court. Three recent decisions of the United States Supreme Court illustrate the stakes, the typical tactics and rationales advanced by both pro- and anti-preemption appellate judges, and some of the factors that should be considered in evaluating whether a particular case or body of litigation is a good candidate for the assertion of a preemption defense.

Riegel vs. Medtronic, Inc.

In *Riegel vs. Medtronic, Inc.*, 129 S.Ct. 999 (2008), a cardiac patient and his spouse sued the manufacturer of a balloon catheter used in his angioplasty for personal injuries sustained as a result of the procedure. He asserted state-law claims including strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, sale and manufacture. The subject catheter was a medical device approved and regulated by the federal Food and Drug Administration (FDA) under its regulations promulgated pursuant to the Medical Device Amendments of 1976 (MDA) to the Food, Drug and Cosmetic Act (FDCA). The federal regulatory system for the product had required it to be approved under the most rigorous of several available means, a process called "premarket approval" (PMA). The PMA process requires the manufacturer's submission to FDA of extensive design specifications, clinical testing results, manufacturing process controls, and proposed labeling, and FDA's lengthy review and approval of that material, typically in consultation with a panel of outside expert advisors, and its finding the device "safe and effective" before it may be lawfully marketed. *Id.* at 1004.

The MDA contains an express preemption provision that a State shall not "establish or continue in effect with respect to a device intended for human use any requirement . . . (1) which is different from, or in

addition to, any requirement applicable under [federal law] to the device, and . . . (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under" relevant federal law. 21 U.S.C. § 360k(a). In *Riegel*, the defendant manufacturer asserted a preemption defense on the basis that the plaintiffs' prevailing on their state-law claims would require a state jury to find that the very same design characteristics and labeling that the federal government had found "safe and effective" were, instead, unlawfully negligent and rendered the device defective. Both the district court and the federal court of appeals agreed that the Riegels' claims were preempted, and the Supreme Court granted *certiorari* of their petition seeking reversal and reinstatement of their claims.

The Supreme Court affirmed preemption by a seven-Justice majority, with Justice Stevens concurring in part and concurring in the judgment, and only Justice Ginsburg dissenting. The Court's rationale applied the preemption provision of the MDA in two steps.

First, the Court asked whether the federal government, through its application of the PMA process to the subject device, had established *"requirements . . . applicable to the device."* The Court found that FDA had established the requisite "requirements" after reviewing the rigor and specific application of the PMA process and concluding that "FDA <u>requires</u> a device that has received premarket approval to be made with almost <u>no deviations</u> 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 1007 (emphasis added).

Second, the Court examined whether the Riegels' common-law claims relied upon "any requirement" of state law applicable to the catheter that was "different from, or in addition to" federal requirements and that "relate[d] to the safety or effectiveness of the device" and thus came within the ambit of the preemption clause. The Court found that the claims did constitute pertinent and different "requirements" of state law. The majority clarified that tort actions based on state law, and the jury findings of negligence or defect upon which any liability would necessarily rest, constitute state "requirements" that may be subject to preemption.

> Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State's "requirements" includes its common-law duties. As the plurality opinion said in *Cipollone* common-law liability is

> "premised on the existence of a legal duty," and a tort judgment therefore establishes that the defendant has violated a state-law obligation. And 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.' "

Id. at 1008 (citations omitted). The Court concluded that the Riegels' claims were preempted in that the claims, as pled, were "different from, or in addition to" the design and labeling requirements imposed by the federal government pursuant to the PMA process for the device. The Court noted that its decision would not bar "parallel" state-law claims premised on violation of the same federal requirements: a person can sue a device manufacturer for failing to do what FDA told it to do, but *not for its having failed to do something outside the PMA that the plaintiff contends it should have done instead. See id.* at 1011.

The impact of the *Riegel* decision is enormous for medical device manufacturers: in effect, incidents arising from any of their devices approved pursuant to the PMA process, a category that includes many of the most sophisticated and potentially risky modern devices, cannot give rise to liability under most conventional products liability theories. Only claims premised on their violation of or non-conformity with the design, manufacturing, and labeling requirements established in their FDA-approved premarket application should be justiciable. Put differently, state juries cannot re-evaluate the safety and efficacy decisions of the federal agency and hold the manufacturer liable in tort for designing, manufacturing, or labeling their products in conformity with the approved federal requirements.

Altria Group, Inc. vs. Good

In *Altria Group, Inc. vs. Good*, 129 S.Ct. 538 (2008), a group of cigarette smokers sued a tobacco products manufacturer, the maker of Marlboro Light and Cambridge Lights cigarettes, alleging that the manufacturer's claims that the products were "light" and had "lowered tar and nicotine" were misrepresentations under Maine Unfair Trade Practices Act (MUTPA), a typical state consumer protection statute outlawing false and deceptive advertising and trade practices. In short, the plaintiffs argued that the tar- and nicotine-content statements appearing on "light" cigarettes' packages misled consumers into falsely believing that "light" cigarettes would result in less tar and nicotine ingestion, when in fact, they contended, the technology used to measure the "light" tar and nicotine levels failed to account for "compensatory" smoking behaviors, such as smoking more overall, inhaling more deeply, or holding inhaled smoke longer.

The defendant manufacturer asserted that the smokers' claims were preempted under the federal Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA), which required the familiar "Surgeon General" health warnings on cigarette packages. The FCLAA sought to balance health and commercial concerns by imposing a "uniform" cigarette labeling regime. The manufacturer relied on prior Supreme Court decisions that had held that, *inter alia*, state law products-liability claims for failure to warn were preempted by the FCLAA's preemption provision: "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter." 15 U.S.C. 1334(b).

The manufacturer argued that the "light" smokers' claims were similarly preempted. Altria said that liability on the plaintiffs' claims would require them to alter their packaging to include additional language to correct the allegedly misleading tar and nicotine levels, and that such language would constitute federally-barred state "requirements or prohibitions based on smoking and health." The plaintiffs argued around the "health" language of the provision, saying that their claims under the MUTPA were not based on "health," but rather sought only to recover the difference in value between the cigarettes they purchased and the presumably lower prices they would have paid for non-fraudulently labeled cigarettes – only "economic" damages. The district court found the claims preempted, the court of appeals reversed, and the Supreme Court granted review.

A divided 5-4 Supreme Court found the light smokers' claims under the MUTPA were <u>not</u> preempted and could go to a jury. Justice Stevens delivered the opinion of the majority. In doing so, he invoked a "presumption" against preemption that, as the dissenters pointed out, had all but disappeared from Supreme Court preemption jurisprudence during the past decade, as well as a rule of statutory construction that "when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption.'" *Id.* at 543. The majority proceeded to read the FCLAA provision very narrowly. They concluded that the smokers' claims were not premised on a preempted state "requirement or prohibition . . . based on smoking and health," but rather on the "general rule that creates a duty not to deceive" embodied in the MUTPA. They reasoned that "the phrase [in the FCLAA's preemption provision] 'based on smoking and health' fairly but narrowly construed does not encompass the more

general duty not to make fraudulent statements." *Id.* at 547. The dissenting Justices (Thomas, Scalia, Roberts, and Alito) sharply criticized the majority's statutory construction as well as its "shifting level of generality," arguing that the products liability laws underlying other smokers' claims in prior cases that the Court had found preempted could likewise be painted as a "general" duty against manufacturing unsafe products, and thus were no more specific to "smoking and health" than the "general" anti-fraud rule embodied in the MUTPA. *Id.* at 563 & n6.

Levine vs. Wyeth

Last month, in Levine vs. Wyeth, 129 S.Ct. 1187 (2009), the Supreme Court found no preemption of a patient's products liability action against Wyeth, the manufacturer of a prescription anti-nausea medication, Phenergan. The plaintiff, a professional guitarist, had suffered serious injuries associated with intravenous administration of Phenergan to treat her migraine symptoms, including onset of gangrene and amputation of her arms. Although risks of the "IV push" method of administration were discussed in detail in the FDA approved labeling for Phenergan, Levine claimed that Wyeth had failed to adequately warn physicians of dangers of administration of the nausea medication directly into patient's vein – in effect, that Wyeth should have given more, different, or more prominent warnings about the risks of the procedure than the language that FDA had approved and required.

Wyeth contended that Levine's claims were impliedly preempted because Phenergan, as a prescription drug, had been extensively regulated by FDA, and bore FDA-approved labeling that discussed risks and recommended precautions associated with intravenous administration. As such, Wyeth argued, allowing a state jury to find the labeling defective and the company liable for dispensing the product with it would conflict with the federal regulatory scheme. Liability on the claims, Wyeth argued, would make it impossible to comply with both federal regulations (which through the FDA approval process had directed it to use FDA-approved labeling) and state law (which would hold it liable for failing to give additional or different warnings about IV push). Further, Wyeth contended, the state claims conflicted with the purposes of the federal scheme, which entrusts risk benefit decisions and judgments about appropriate warnings for prescription drugs to an expert agency, FDA, rather than to myriad juries across the 50 states. FDA approves

prescription drugs and their "labeling," or "package inserts," via its New Drug Application (NDA) process for prescription drugs, which resembles closely the PMA process for medical devices. Unlike the Medical Device Amendments to the FDCA, however, the federal prescription drug laws and regulations contain no express preemption provision.

The Supreme Court held there was no preemption of Levine's claims. Justice Stevens wrote for a four-Justice plurality, with Justices Thomas and Breyer concurring and joining in the judgment, and Justices Roberts, Alito, and Scalia dissenting. The most important reasons for the majority's no-preemption finding were based on interpretation and comparison of the federal statutes and regulations governing prescription drugs.

The majority noted a provision of the federal regulations that permits a manufacturer to modify an existing, FDA-approved product labeling to strengthen a safety warning without prior FDA approval of the new language, provided it submits the change to the agency as a "Changes Being Effected" (CBE) supplement to its existing approved application, and subject to further review and potential rejection of the change by the agency. Justice Stevens wrote that "[t]he CBE regulation permitted Wyeth to unilaterally strengthen its warning, and the mere fact that the FDA [had earlier] approved Phenergan's [allegedly inadequate] label does not establish that it would have prohibited such a change." *Id.* at 1196-99.

In addition, the majority compared the federal prescription drug laws with the analogous medical device regime. It noted that, unlike the preemption clause enacted in the device provisions (MDA) of the FDCA (the same provision upon which preemption was based in *Riegel)*, the drug provisions contained no express preemption provision. The majority inferred that the absence of an express provision in the prescription drug laws indicated that Congress intended no preemption for drugs, and that Congress instead intended state tort actions to be "complementary" to the federal drug safety system, rather than for the federal system to operate as an "exclusive" safety regime. *Id.* at 1200. The majority refused to accord any deference to FDA's statement in the preamble to a 2006 regulation that its drug-labeling regulations operated as "both a floor and a ceiling" (i.e., that additional or different state-required labeling language would conflict with and frustrate the agency's judgments), rejecting the agency's statement based on its administrative

procedural history (the preamble was not vetted for public comment and hearing or adopted as an official regulation) and apparent conflict with Congress's intent not to preempt (inferred from its failure to include an express preemption provision). *Id.* at 1200-01.

The likely impact of the *Levine* decision will be to limit the circumstances in which preemptive effect will be given to FDA's approval and mandating of prescription-drug labeling. In many and perhaps most cases, lay juries across the country will be free to conclude that a manufacturer could or should have changed or added to labeling that FDA directed it to issue with its product. If the product is instead a medical device, approved by a virtually identical process at the same agency, the same claims will be preempted under *Riegel*.

Takeaway Points

The Court's recent decisions in *Riegel, Altria,* and *Levine* suggest several considerations for litigants pursuing preemption defenses or considering the prospects for successful preemption arguments in particular cases.

- Applicable federal statutes with express preemption provisions are likely to be the strongest predicates. The presence of an express preemption provision, like those in the Medical Device Amendments at issue in *Riegel* or the FCLAA at issue in *Altria*, deny the opposing party the easy argument that courts should infer from the absence of a preemption provision that Congress did not intend preemptive effect to be given to the federal requirements it enacted (the rationale in *Levine*).

- State laws are more likely to be preempted the more specifically they relate to the subject matter of the analogous and conflicting federal requirement. (Cf. *Altria*) Where the state law, regulation, or action is tied closely to the same concern as the federal law (e.g., to "smoking and health"), the opponent will be unable to make the type of "shifting level of generality" argument made in *Altria* -- for example, that the state law or tort action sought to be preempted is merely a "general duty" that Congress would not have intended to preempt by regulating the conduct, product, or safety information at issue.

- Federal agencies' interpretation of the preemptive effect of their regulations probably will be given deference only if it is implemented as a formal regulation pursuant to normal administrative procedural requirements (notice and comment, public hearing, and so forth). Informal agency interpretations suggesting that its regulations are intended to operate preemptively against contrary state laws or regulations are likely to be accorded little or no deference if they are evident only in guidance documents, policy statements, longstanding practices, or similar sources. Formal regulations espousing preemptive force, on the other hand, may be given deference, particularly if there is bolstering evidence of express of inferable Congressional intent that the federal regulation prevail in the form of an express preemption provision or a direct and manifest conflict.

- In implied preemption cases involving putative conflicts between compliance with both state and federal requirements (conflicting product-safety warning requirements, for example), cases in which the conflict between the state law or potential state-law tort judgment is truly impossible will offer the strongest factual basis for preemption. Where the federally-prescribed warning language is or can be construed as merely a "floor" to which the defendant can add additional warnings, *Levine* suggests that a conflict with preemptive effect is less likely to be found.

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Cases

McNellis v. Pfizer
Taylor v. Solvay Pharmaceutical
Miller v. Pfizer Inc
Motus v. Pfizer Inc
Tebbetts v. Ford Motor Co.

Legal Memberships, Activities, and Honors

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Colorado Bar Association
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Articles and Presentations

Punitive Damages, presented at 27th Annual Conference of Colorado Defense Lawyers Association (Aug. 20, 2004)

Court-Appointed Experts, presented at The Network of Trial Law Firms (Mar. 14, 2002)
The Future of Preemption, presented at Defense Research Institute (May 3, 2001)

Daubert and Differential Diagnosis, presented at The Network of Trial Law Firms (Jan. 4, 2001)

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