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**FEDERAL PREEMPTION OF STATE PRESCRIPTION DRUG
CLAIMS AND ITS POTENTIAL IMPACT ON PRODUCT
LIABILITY CLAIMS AND INSURANCE**

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I. INTRODUCTION

The issue of the day in the United States pharmaceutical arena is federal preemption and exactly how, or even if, preemption will operate to bar state law claims against drug manufacturers, in particular those actions sounding in failure to warn and design defect.

On November 3, 2008, the United States Supreme Court will hear oral argument on this hotly-debated issue in *Wyeth v. Levine*, which will decide whether a state common law “failure to warn” claim is preempted by the United States Food and Drug Administration’s (“FDA”) approval of a drug and the drug’s warning label. Under the federal Food, Drug and Cosmetic Act (“FDCA”), the FDA is charged with determining both the safety and efficacy of drug products sold and marketed in the United States. Pursuant to its mandate under the FDCA, the FDA must also ensure that drug labeling “adequately informs users of the risks and benefits of the products and is truthful and not misleading.” See 71 Fed. Reg. 3935. The question in *Levine* is whether state common law can impose requirements on drug companies that go beyond the requirements imposed by the FDA. In other words, does a lay jury sitting in state court have the power to second-guess the FDA’s drug approval and labeling decisions?

A Supreme Court ruling in favor of preemption could result in sweeping changes in a nation that between 2000 and 2006 saw over 65,000 lawsuits, many involving multiple plaintiffs, filed against drug manufacturers. In 2006 alone, just over 17,000 products liability lawsuits were filed against drug manufacturers.¹ Depending on the scope of a pro-preemption ruling in *Levine*, many of these lawsuits could vanish and the number of future claims could drop precipitously, impacting not only the pharmaceutical manufacturers who have been the targets of mass tort litigation but, indirectly, the insurers of these companies as well. The stakes are undeniably high

¹ By comparison, the industry that was the target of the second highest number of product liability lawsuits in 2006 was the manufacturing sector, whose companies were the targets of over 3,200 lawsuits.

-- to put things in perspective, Merck's 2007 settlement of the Vioxx litigation came at the staggering price of \$4.85 *billion* dollars.

Adding fuel to the preemption fire is the fact that there is an undeniable political aspect to the preemption debate. There are those who argue that the Bush administration is seeking to achieve its goal of tort reform through regulatory agencies such as the FDA, which has spoken out in favor of preemption. The FDA's current position constitutes a 180-degree shift from the position it has traditionally espoused throughout its long history, during which it consistently maintained that its drug approval process and state tort liability claims operated independently, with each providing a significant, yet distinct, level of consumer protection. Indeed, the FDA's current position in favor of preemption did not even emerge until Daniel Troy, a Bush appointee, became chief counsel to the FDA in 2001. It is no wonder that critics of preemption argue that big business, including "big pharma," has insinuated itself into the top levels of government, including those federal agencies charged with protecting consumers. Many are now asking whether business and politics trump science and medicine at the FDA, an agency that has been widely criticized as being underfunded and understaffed.

This paper will explore the potential impact of federal preemption of state common law tort claims against drug manufacturers. Beginning with an overview of the preemption doctrine under United States law, it will then discuss the FDA's changed position on preemption, the deference which courts must give to the agency's position, and how some courts have reacted to the FDA's change in position. Next, this paper will discuss recent and pending United States Supreme Court jurisprudence on preemption, beginning with a significant decision rendered by the high court in early 2008 on the preemption of claims involving FDA-approved medical devices. Finally, this paper will explore the impact that a pro-preemption ruling by the Supreme

Court in *Levine* might have and what could be left of state common law tort claims against drug makers if the high court rules in favor of Wyeth.

II. FEDERAL PREEMPTION

Proponents of greater protection for pharmaceutical manufacturers argue that FDA approval of a drug should preempt state law failure to warn claims. The doctrine of preemption is rooted in the Supremacy Clause of the United States Constitution, which dictates that federal law supersedes state law when the two conflict. Specifically, the Supremacy Clause states that:

This Constitution, and the laws of the Unites 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, § 2 (emphasis added).]

Under the doctrine of preemption, “state law that conflicts with federal law is ‘without effect.’” *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)(quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

In general, there is a presumption *against* the preemption of state law. Recognizing that states are “independent sovereigns,” some courts have been wary of applying the preemption doctrine. *See, e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)(“[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action”). In order for a federal statute to displace state law, congressional intent must be readily apparent in either the statute’s language or its structure and purpose. *Cipollone*, *supra.*, 505 U.S. at 516 (also stating that “[i]n the absence of an express congressional command, state law is pre-empted if that law actually conflicts with federal law, or if federal law so thoroughly occupies a legislative field as to make reasonable the inference that

Congress left no room for the States to supplement it”)(citation omitted). Further, a long history of state law tort litigation serves as evidence of a presumption against preemption, since Congress would presumably express any intent to “deprive injured parties of a long available form of compensation.” *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

There are three recognized forms of preemption. First, Congress may supersede state law by enacting statutory language that explicitly declares that state laws are preempted (“express preemption”). Alternatively, although a federal statute may not incorporate express preemption language, a state law is still preempted to the extent it actually conflicts with federal law (“conflict preemption”). Finally, a federal law may so thoroughly occupy a legislative field as to make reasonable the inference that Congress left no room for the States to legislate (“field preemption”). Under all three scenarios, the federal statute will be deemed to preempt state law to the contrary.

A. Express Preemption

Express preemption is the most straight-forward type of federal preemption. “[W]hen Congress has unmistakably ordained that its enactments alone are to regulate a part of commerce, state laws regulating that aspect of commerce must fall.” *Jones v. Rath Racking Co.*, 430 U.S. 519, 525 (1977)(citations and quotations omitted). Therefore, if a federal statute explicitly declares Congress’ intent that the statute trumps all state laws, preemption exists. For example, the Employee Retirement Income Security Act of 1974 (“ERISA”) preempts “any and all State laws insofar as they may now or hereafter relate to any employee benefit plan” 29 U.S.C. §1144(a).

Some analysis is necessary, however, of the federal statute at issue. The exact bounds of the statute’s preemptive effect must be determined based on the words of the statute and

application of normal rules of statutory construction. *See, e.g., Shaw v. Delta Air Lines*, 463 U.S. 85 (1983)(analyzing the ERISA section cited above). If a court concludes that the express preemption provision applies to the situation before it, then any state law on the subject is preempted.

B. Conflict Preemption

In the absence of an express preemption provision, a federal statute may preempt state law if the federal and state laws are in actual conflict. The Supreme Court of the United States has “found implied conflict pre-emption where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)(citation omitted).

Most federal and state statute conflicts are not cut and dry. Often, a court must interpret the specifics of both the federal and state statutes to determine whether one may be followed without violation of the other. Logically, the court will first look to the statutory language to determine whether Congress intended to preempt state law. *See English v. General Electric Co.*, 496 U.S. 72, 88 (1990). Additionally, the court may also examine the statute’s legislative history to fully understand Congress’ intent when enacting the federal law. *See id.* Assuming the court finds a federal requirement that may conflict with state law, the final step is to determine whether such conflict actually exists in the case.

Conflict preemption is at the center of *Wyeth v. Levine*, the preemption case that will be heard by the United States Supreme Court on November 3, 2008. The alleged “conflict” in *Levine* is discussed later in this paper.

C. Field Preemption

Like conflict preemption, field preemption requires a court to ascertain Congress's unspoken but implied intent to exclude state regulation. In fact, courts sometimes refer to field preemption as a form of conflict preemption. *English v. General Elec. Co.*, 496 U.S. 72, 79 n.5 (1990). The difference, however, is that no one law stands as an obstacle to completing a federal objective. Rather, field preemption occurs when federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the states to supplement it.

The Supreme Court has said that Congress implicitly may indicate an intent to occupy a given field to the exclusion of state law in one of three ways. First, the pervasiveness of the federal regulation may preclude supplementation by the states; second, the federal interest in the field may be sufficiently dominant; finally, the object sought to be obtained and the character of obligations may reveal an intent to fully occupy the field. *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 300 (1988).

As an example, in *Abdullah v. American Airlines, Inc.*, 181 F.3d 363 (3rd Cir. 1999), a group of plaintiffs sued an airline after they were injured when severe turbulence disrupted their flight. The plaintiffs argued that the aircraft's crewmembers negligently performed their duties by failing to take reasonable precautions against the turbulent conditions. Following a jury trial in which the plaintiffs were awarded more than two million dollars, lawyers for the airline moved for a new trial. They argued that the jury had improperly considered the wrong standard, the common law standard, and that Congress and the Federal Aviation Administration ("FAA") had established the standard by which the airline employees should be judged. The trial judge agreed and granted a new trial. The plaintiffs appealed.

The Third Circuit Court of Appeals in *Abdullah* found that the FAA was created to establish a single, uniform system for maintaining air safety. Thus, Congress had intended federal law to preempt the entire field of aviation safety. Moreover, the court found that federal regulations had specifically established the standard of aircraft safety: “no person may operate an aircraft in a careless or reckless manner so as to endanger the life or property of another.” 14 C.F.R. 91.13(a). Thus, this was the standard by which the jury was to judge the pilot and flight crew’s conduct, and not by reference to the state law standard of whether their conduct was reasonable.

III. THE FDA’S CURRENT POSITION ON PREEMPTION

Prior to 2002, the FDA had consistently taken the position that its regulatory efforts could comfortably coexist with state law failure to warn litigation brought by consumers allegedly injured by FDA-regulated drugs. *See, e.g.,* David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461 (2008). In the FDA’s view, failure to warn litigation was an important additional tool that provided information to physicians and patients about drug risks. *Id.* In other words, the FDA viewed its drug approval process and state tort liability claims as each providing a significant, yet distinct, layer of consumer protection, particularly due to the fact that certain drug risks might not emerge until after a drug obtains FDA approval. Essentially, while the FDA-approved label was the “floor” as far warnings that were required to be in a drug’s label, the “ceiling” was determined pursuant to state failure to warn law.

In 2002, the FDA took a radical, 180-degree shift in position. Under the leadership of its newly appointed Chief Counsel, Daniel Troy, the FDA began filing *amicus curiae* briefs in lawsuits arguing that its regulation of prescription drug labeling impliedly preempts common law

failure to warn claims. Mr. Troy, a Bush appointee, had previously represented pharmaceutical and other industries in lawsuits *against* the FDA. *See, e.g., S. Schultz, Mr. Outside Moves Inside: Daniel Troy Fought the FDA For Years; Now He's Helping to Run It*, U.S. News & World Report (Aug. 7, 2008). Under Mr. Troy's leadership, the FDA's *amicus curiae* briefs attempted to reverse not only the longstanding judicial presumption that the FDA's labeling decisions impose only "minimum" standards that are open to supplementation by state law, but also the agency's historic position that its drug approval process and state tort liability claims usually operate independently of one another. In 2006, the FDA took another, even stronger, step aimed at thwarting state law tort actions when it attached a "preamble" to its January 24, 2006, Final Rule on labeling (the "Preamble"), which sets forth its current position on preemption.

In the Preamble, the FDA announced that "under existing preemption principles . . . FDA approval of labeling . . . preempts conflicting or contrary State law." *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933 (Jan. 24, 2006)(codified at 21 C.F.R. pts. 201, 314, 601)("Labeling Requirements"). It further stated that the "FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated." *Id.* at 3935.

Already, the Preamble has been cited by parties arguing in favor of preemption. Under federal law, contents of the *Federal Register* are entitled to judicial notice. *See* 44 U.S.C. § 1507 (stating that "the contents of the *Federal Register* shall be judicially noticed"). Accordingly,

defense attorneys no longer need to rely on case-specific *amicus curiae* briefs from the FDA to ensure that judge's take notice of the FDA's position on preemption.

Whether the United States Supreme Court will defer to the FDA's position on preemption as set forth in the Preamble is an open question at this time.

On the one hand, an argument exists that because the Preamble does not have the force of law it should not be entitled to deference by the courts. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 863-64 (1984). Under *Chevron*, a government agency's statutory interpretation is entitled to deference if: (1) the statute is ambiguous, and (2) the agency's interpretation is reasonable. *Id.* at 842-43. However, in *United States v. Mead Corporation*, 533 U.S. 218 (2001), the United States Supreme Court added what some commentators have referred to as "Step Zero," a preliminary inquiry as to whether the *Chevron* framework even applies in a given situation. *See* Cass Sunstein, *Chevron Step Zero*, 92 VA. L.R. 187 (2006). Under *Mead*, judicial deference is warranted only if: (1) Congress has delegated to the agency the authority to make rules with the force of law and (2) the agency promulgated its interpretation in exercise of that authority. *Mead*, *supra.*, 533 U.S. at 226-27. Consequently, "interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law . . . do not warrant *Chevron*-style deference" but are instead entitled only to so-called *Skidmore* deference, which is proportional to their "power to persuade." *Christensen v. Harris County*, 529 U.S. 576, 587 (2000); *see also Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)(holding that agency interpretations contained in statements that "lack the force of law" are "entitled to respect" only to the extent they have the "power to persuade"). Since the 2006 Preamble does not have the force of law, it should not be entitled to deference by the courts under *Chevron*.

On the other hand, another line of cases suggests that the Preamble is entitled to judicial deference. In particular, two cases, *Bowles v. Seminole Rock Sand & Co.*, 325 U.S. 410 (1945), and *Auer v. Robbins*, 519 U.S. 452 (1997), hold that even an agency's *informal* interpretation of its own regulations is entitled to *Chevron*-level deference. In *Seminole Rock*, *supra*, 325 U.S. at 414, the United States Supreme Court held that an agency's interpretation of its own regulations has "controlling weight unless it is plainly erroneous or inconsistent with the regulation." Thirteen years after *Chevron*, the Supreme Court unanimously held in *Auer*, *supra*, 519 U.S. at 461, that an agency interpretation of a regulation contained in an *amicus curiae* brief "easily met" *Seminole Rock*'s deferential standard. Conservative Justice Antonin Scalia, who still sits on the Court, rejected the notion that an *amicus* brief was unworthy of deference since he found "no reason to suspect that the interpretation does not reflect the agency's fair and considered judgment on the matter in question." *Id.* at 462.

Significantly, if the FDA's current position on preemption is followed, it has the potential to effectively ban all state failure to warn claims against drug manufacturers. *See* Labeling Requirements at 3936 (describing the types of claims preempted, including where a company "breached an obligation to warn," but providing an exception where the FDA finds that the company "withheld material information relating to the proposed warning"). Further, judicial deference to the FDA's position could usher in an era of federal preemption of other claims against drug manufacturers, such as design defect claims. For example, the Preamble stated that the FDA intended to "at least" preempt failure to warn claims. *Id.* at 3935-36. This leaves room for the Preamble to be invoked as support for preempting other products liability claims against drug manufacturers as well.

IV. COURTS' RESPONSES TO THE FDA'S POSITION ON PREEMPTION

Since 2006, courts have varied in the degree of deference they have given to the Preamble and the FDA's recent interpretation stated therein. Some have deferred to the Preamble and precluded recovery against FDA-compliant drug companies for failure to warn. In *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 271-72 (3d Cir. 2008), for example, a federal appellate court held that a state law failure to warn claim was preempted under circumstances where the FDA previously rejected the need for the warning that plaintiffs argued was required under state law.² *Colacicco* involved a claim by a widower brought against the manufacturer of the anti-depressant Paxil, as well as its generic equivalent, alleging that his wife's suicide resulted from defendant's failure to warn of the increased risk of suicidal behavior linked to the drug. Relying extensively on an *amicus curiae* brief filed by the FDA, the district court sitting below dismissed the claim in deference to the Preamble. *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 526-28 (E.D. Pa. 2006). The district court noted the FDA's inconsistency in its preemption policy, but minimized the FDA's "flip-flop" by noting that in recent years the FDA has been consistent in its construction of the preemption doctrine's applicability. *Id.* at 531-32. On appeal, the Third Circuit affirmed the district court's judgment, and agreed with the lower court that the FDA's view was entitled to some degree of deference. *Colacicco*, supra, 521 F.3d at 275. It specifically concluded that: (1) an agency's position concerning preemption need not be contained in a formal regulation in order to be considered, and (2) such a position is subject to a level of deference approximating that set forth in *Skidmore*, supra., 323 U.S. at 134 ("power to persuade"). *Colacicco*, supra, 521 F.3d at 274-75.

² The Court expressly stated that it did not decide whether the FDA's mere approval of drug labeling is sufficient to preempt state law claims alleging that the labeling failed to warn of a given danger, or whether FDA approval of drug labeling constitutes minimum standards in the absence of the FDA's express rejection of a specific warning. *Id.* at 271.

Other courts have not been so willing to defer to the FDA. In *Perry v. Novartis Pharmaceuticals Corporation*, 456 F.Supp.2d 678 (E.D. Pa. 2006), another district court judge in the Eastern District of Pennsylvania, in a decision that preceded the Third Circuit's opinion in *Colacicco*, minimized the impact of the Preamble and refused to dismiss a failure to warn claim. *Perry* involved an infant who developed lymphoma six months after commencing use of Elidel, a drug prescribed for the treatment of eczema. In refusing to dismiss the failure to warn claim, the Court reasoned that the Preamble had little, if any, authority, on the basis that it is merely an advisory opinion that is not entitled to any judicial deference. *Id.* at 683. Moreover, the Court noted that the inconsistencies in the FDA's interpretation of its own regulations further limited the Preamble's influence. *Id.* ("To be sure, because of its expertise in the area, the FDA's construction of its own regulations is likely to carry great weight. But where an interpretation has changed frequently in significant respects, the persuasive force of the argument diminishes."). In addressing the issue of preemption, the Court's most important consideration was that the Preamble "deals chiefly with 'specific warnings that FDA had specifically considered and rejected as scientifically unsubstantiated.'" *Id.* at 684. The Court stated that, in order for preemption to be even considered, the proposed warning must have been considered and subsequently rejected by the FDA. *Id.* at 685-86. That was not the case in *Perry*.

The Supreme Court of Vermont discussed the Preamble's effect in *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006), *cert. granted*, 128 S. Ct. 1118 (2008), discussed in more detail below. Rather than question the validity of the Preamble, the Vermont Supreme Court stated that the preemptive direction of the Preamble simply did not apply as authoritative or persuasive since it did not perceive there to be a conflict between federal and state law. The Court rested this

judgment on a provision in the FDCA that allows drug manufacturers to add or strengthen a warning to increase the safe use of the drug product without prior FDA approval.

Colacicco, Perry and the Vermont Supreme Court decision in *Levine* demonstrate varied judicial reactions to the Preamble, leaving open the question of what, if any, level of judicial deference the United States Supreme Court will give to the Preamble when it hears Wyeth's appeal of the Vermont Supreme Court's decision in *Levine*.

V. MEDICAL DEVICE PREEMPTION: DOES THE UNITED STATES SUPREME COURT'S RULING IN *RIEGEL* FORESHADOW THE PREEMPTION OF PHARMACEUTICAL CLAIMS?

Wyeth v. Levine is not the first preemption case to appear on the United States Supreme Court's docket this year. In a preemption case decided in February, 2008, the Supreme Court held that the FDA's approval of a medical device preempted state common law products liability claims. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008). Although the laws governing the FDA's approval of medical devices differ from those governing pharmaceuticals, the Supreme Court's ruling in *Riegel* is noteworthy and may provide insight on how the Court may rule in *Wyeth v. Levine*. The opinion of the Court in *Riegel* was delivered by Justice Antonin Scalia. Justice Ruth Bader Ginsburg was the only justice who filed a dissenting opinion.

The facts of *Riegel* are as follows. In 1996, Charles Riegel ("Riegel") underwent coronary angioplasty after suffering a heart attack. Because his right coronary artery was diffusely diseased and heavily calcified, his doctor inserted an Evergreen Balloon Catheter ("the Catheter"), manufactured by Medtronic, Inc. ("Medtronic"). The Catheter was approved by the FDA in 1994 and its label was approved for changes in 1995 and 1996. The 1996 label contraindicated use of the Catheter in patients with diffuse or calcified stenoses and warned that it should not be inflated to greater than eight atmospheres. Regardless of the warnings contained

on the Catheter’s label, Riegel’s doctor inflated the Catheter five times to a pressure of ten atmospheres. On the fifth inflation, the Catheter burst, causing Riegel to develop a heart block. Riegel was placed on life support and underwent emergency coronary bypass surgery. Riegel and his wife sued Medtronic in April 1999, alleging that the design, labeling and manufacturing of the Catheter, which caused Riegel to suffer the heart block, violated New York common law.

The District Court dismissed Riegels’ action against Medtronic, finding that the Medical Device Amendments of 1976, 21 U.S.C. §360k (“MDA”), preempted the Riegels’ state common law claims. The United States Court of Appeals for the Second Circuit affirmed the dismissal, concluding that the Riegels’ claims, “‘would, if successful, impose state requirements that differed from, or added to’ the device-specific federal requirements.” *Riegel*, supra, 128 S. Ct. at 1006 (quoting *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 121 (2nd Cir. 2006)). The Riegels appealed this decision to the United States Supreme Court.

A. MDA Preempts State Tort Common Law Claims That Impose Additional Requirements on Medical Device Manufacturers

The Supreme Court agreed with the lower court holding that the MDA expressly preempts state common law. The Court began its analysis by looking to the *express* preemption provision of the MDA, which states that:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may 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 this chapter 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 this chapter.

[21 U.S.C. §360k(a).]

Based on this statutory language, the Supreme Court undertook a two-step analysis of the issue of preemption. First, the Supreme Court determined whether the federal government had established requirements applicable to the Catheter. Next, it decided whether the Riegels' New York common law claims were different from such requirements.

As to the first question, the Supreme Court determined that “[p]remarket approval . . . imposes ‘requirements’ under the MDA . . .” *Riegel*, supra, 128 S. Ct. at 1007. Indeed, the Supreme Court spent significant time in *Riegel* discussing the “rigorous” premarket approval process involved in approving medical devices. *Id.* at 1004-05. As part of the approval process, the FDA also considers the device’s proposed labeling, and once a device has received premarket approval its manufacturer is forbidden to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness. *Id.* at 1005 (citations omitted). In other words, an FDA approved medical device is required to be made with no deviations from its approved specifications. *Id.*

Satisfied that the federal government had established requirements applicable to the Catheter, the Court turned to the second question, namely, whether the New York common law claims involved requirements that differed from those established by the federal government. *Id.* The Supreme Court concluded that New York common law causes of action were “requirements” that were preempted by the MDA. Even though “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). In discussing this second question, the Court also explained that:

[s]tate tort law that requires a manufacturer’s catheter to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by

juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, 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.

[*Id.*]

Therefore, the Supreme Court concluded that the MDA preempts State requirements “to the extent that they are different from, or in addition to the requirements imposed by federal law.”

Id. at 1011.

B. Justice Ginsburg’s Dissent in *Riegel*

Justice Ginsburg dissented from the majority’s decision that the MDA preempts state common law claims against a manufacturer alleging that a medical device was defectively designed, labeled and manufactured. *Id.* at 1013-20. According to Justice Ginsburg, “preemption analysis starts with the assumption that the historic police powers of the States are not to be superseded unless that was the clear and manifest purpose of Congress.” *Id.* at 1013 (citations omitted). She argued that there is a “presumption against preemption,” which exists even when there is an express preemption provision in a federal statute. When Congress is not exact in its preemption language and the statute is open to more than one possible reading, the Court must read the statute to disfavor preemption. *Id.* at 1014. Because the MDA did not expressly preempt all state common law claims against medical device manufacturers, it must be read to allow such claims.

Additionally, Justice Ginsburg was persuaded by the fact that the MDA does not create a federal compensatory remedy for patients injured by medical devices. In her opinion, “[i]t is

difficult to believe that Congress would, without comment, remove all means of judicial recourse for large numbers of consumers injured by defective medical devices.” *Id.* at 1015 (citations omitted). Justice Ginsburg further opined that the fact that the FDA engages in a “rigorous” approval process does not necessitate a rule favoring preemption. In her opinion, the fact that drugs are also subject to a rigorous FDA approval process but are not subject to express preemption under the FDCA persuaded her that medical devices should be treated in the same manner as drugs for preemption purposes. The majority responded, however, that if Congress wanted to treat medical devices and drugs in the same manner it would not have included an express preemption provision in the MDA but leave one out of the FDCA.

VI. *WYETH V. LEVINE* – WILL THE SUPREME COURT PREEMPT STATE LAW TORT CLAIMS AGAINST DRUG MANUFACTURERS WHOSE PRODUCTS HAVE RECEIVED FDA APPROVAL?

The issue of preemption is once again front and center at the United States Supreme Court, which will hear oral argument in *Wyeth v. Levine* on November 3, 2008. The specific question presented to the Supreme Court is:

Whether the prescription drug labeling judgments imposed on manufacturers by the FDA pursuant to the FDA’s comprehensive safety and efficacy authority under the FDCA preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.

The deference question, as applied to FDA approved drugs, will remain unresolved until the Supreme Court issues its ruling in *Levine*.

Diana Levine (“Levine”), a professional musician, went to a medical clinic on April 7, 2000 after suffering from a severe migraine headache. During that visit, Levine received intramuscular injections of Demerol (to alleviate the headache) and Phenergan (for nausea that is commonly associated with a migraine as well as a potential side effect of Demerol). Levine’s

migraine returned later that day so she returned to the medical clinic for more treatment. During her second visit, Levine received another Demerol-Phenergan treatment. This second injection of Phenergan was administered using the “IV-push” method, whereby the medication is injected directly into the patient’s vein. The nurse administering the Phenergan penetrated one of Levine’s arteries, severely damaging it and causing gangrene. In the next few weeks, Levine’s tissue died and her hand and forearm were amputated.

The FDA-approved Phenergan label expressly warned of the risks associated with using the IV-push method of administration, specifically mentioning the risk associated with accidentally injecting the drug into an artery and explaining that injection into an artery would likely lead to gangrene and amputation. Levine sued Wyeth, Phenergan’s manufacturer, in Vermont state court, alleging that the Phenergan label warning was insufficient. Levine claimed that IV-push is an improper method of administering Phenergan because the severe risk of gangrene and amputation is not outweighed by the limited benefit of alleviating nausea symptoms through a method that is only slightly faster than other methods of administration.

A. Vermont Court Decisions

At the trial in Vermont state court, Levine presented experts who testified that IV-push should not have been used as a method of administration due to the availability of other, safer methods. Specifically, Phenergan could be administered via an intramuscular injection or through the tubing of a hanging IV bag. Wyeth responded by presenting expert evidence that allowing the drug to be injected via IV-push, while including warnings about the risks of arterial injection, was sufficient. The jury was instructed that, while it could consider FDA-approval in its deliberations, “compliance with FDA requirements did not establish the adequacy of the warning or prevent defendant from adding to or strengthening the warning on the label.” *Levine*,

supra, 944 A.2d at 182. The jury found in favor of Levine on both her negligence and product-liability claims, awarding her \$2.4 million in economic damages and \$5 million in noneconomic damages. This amount was reduced to \$6,774,000 pursuant a stipulation between the parties.

Wyeth appealed the verdict, arguing, as it had in summary judgment motions at the trial court level, that the FDCA preempts state tort failure to warn claims when the label is approved by the FDA. Specifically, Wyeth argued that any state common law requirement to strengthen the warning about the IV-push method of administration directly conflicts with the FDA-approved label. Wyeth conceded on appeal that there is no express preemption of state tort actions in the FDCA and that Congress did not intend that the FDCA occupy the entire field of prescription drug regulation. *Levine*, supra, 944 A.2d at 184. Instead, Wyeth argued that plaintiff's claims actually conflict with the FDCA and are therefore preempted.

In a 4-1 decision, the Vermont Supreme Court upheld the jury verdict, agreeing with the trial court that the state tort claims were not preempted by federal law. The majority explained that the jury verdict did not conflict with the FDA's labeling requirements for Phenergan because: (1) Wyeth could have changed its warning without prior FDA approval, and (2) federal labeling requirements create only a *minimum* standard requirement for state regulation, not a maximum.

The Court reasoned that, under federal law, drug manufacturers submit a new drug application ("NDA") to the FDA prior to drug approval. The labels of all approved drugs, which must conform to FDA regulations regarding content, are also approved by the FDA. Normally, changes to a drug's approved label require submission of a supplemental NDA for approval by the FDA. The Vermont Supreme Court noted that, "[i]f the NDA process and the submission of changes for FDA approval were the exclusive means of creating and altering prescription drug

labels, this might be a very different case.” *Id.* at 185. However, the court found that a particular provision in the FDCA, 21 C.F.R. §314.70(c), allows a drug manufacturer to change an FDA approved label that insufficiently protects consumers. This option allows the manufacturer to strengthen warnings as the need arises. As a result, the Court believed that an FDA-approved label creates the minimum acceptable warning level and that section 314.70(c) allows manufacturers to avoid state failure to warn claims without violating federal law. Therefore, the Court concluded that the FDCA does not preempt Vermont common law because Wyeth could have complied with both state and federal law. *Id.* at 194.

Chief Justice Paul Reiber, one of two members of the Vermont Supreme Court appointed by Republican Governor Jim Douglas, dissented from the Court’s majority opinion. *Id.* at 197. Justice Reiber argued that state law “actually” conflicts with federal law on the grounds that compliance by Wyeth with Vermont law was impossible and that state law conflicts with the objectives of the FDCA. According to Chief Justice Reiber, “[t]he crux of plaintiff’s claim was not based on the label warnings per se, but on the approved uses listed there.” *Id.* at 198. Therefore, even if section 314.70(c) allows a drug manufacturer to strengthen a warning, plaintiff did not seek a stronger warning but was instead seeking elimination of an approved use, namely, the IV-push method of administration. Further, Justice Reiber explained that while section 314.70(c) allows a manufacturer to warn of risks that were previously unknown and unanalyzed, it “does not allow manufacturers to simply reassess and draw different conclusions regarding the *same* risks and benefits already balanced by the FDA.” *Id.* at 199 (emphasis added).

Additionally, Chief Justice Reiber argued that the majority failed to consider the fact that plaintiff’s state-law failure to warn claim poses an obstacle to federal purposes and objectives. The FDA’s goal is to balance risks and benefits associated with prescription drugs in order to

maximize the availability of beneficial drugs to the public. The FDA, therefore, considers the greater good to the public at large balanced against the possibility of severe, even life-threatening risks. A jury, on the other hand, looks only at the injury to a specific plaintiff and does not consider the public health and the associated risk-benefit analysis. Therefore, in Chief Justice Reiber's opinion, the jury's verdict conflicts squarely with the FDA's assessment of Phenergan's risks and benefits. *Id.* at 202.

B. Appeal to United States Supreme Court

Wyeth found in *Levine* a good "test case" on preemption to appeal to the United States Supreme Court. The fact that the case involves a risk that the FDA knew of and expressly warned about makes *Levine* ripe for a ruling on preemption, as opposed to a case involving a newly-discovered risk that was never evaluated by the FDA.

In its brief to the United States Supreme Court, Wyeth argues that the FDCA preempts state tort actions on two grounds. First, the FDCA does not allow a drug manufacturer to unilaterally change an approved label without violating federal law. Second, Congress' objective of having an expert agency balance a drug's risks and benefits, and the FDA's implementation of that objective, is frustrated by state laws requiring strengthening of FDA-approved labels.

According to Wyeth, a manufacturer may not change an FDA-approved drug label without first obtaining approval of the change from the FDA. The narrow exception to this rule found in 21 C.F.R. §314.70(c) permits a manufacturer who has filed a supplemental NDA to implement a labeling change before the FDA acts on the application, but only if the change is intended "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction," or "[t]o add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." *See* 21 C.F.R. §314.70(c)(6)(iii)(A), (C) (known as the

changes being effected, or “CBE”). However, a CBE is allowed only if the drug manufacturer discovers “new evidence” about a given risk. According to Wyeth, Levine did not offer any evidence at trial that Wyeth discovered “new evidence” about the risks associated with IV-push administration. As a result, Wyeth argues that it was unable to amend the FDA-approved label of Phenergan without first obtaining FDA approval and that any amendment without FDA approval would have violated federal law. Accordingly, it asserts that Levine’s state law claims are preempted by the FDCA.

Additionally, Wyeth argues that complying with the Vermont state verdict would defeat the objective of the carefully-crafted regulatory scheme of Congress. The FDA was created to strike a balance between protecting the public from dangerous drugs and to advance the public health by ensuring that beneficial treatments are available to patients who need them. When the FDA approves a drug, which includes approving the drug’s label, it strikes an appropriate balance between the benefits and risks associated with that drug. Therefore, according to Wyeth, FDA approval constitutes both a “floor” and a “ceiling” as to what should and should not be included in an approved drug’s label and federal law is frustrated when lay juries are given the power to second-guess the FDA’s informed expert opinion.

In her brief to the Supreme Court, Levine counters Wyeth by arguing that the FDCA does not preempt state tort actions. Specifically, Levine contends that if Congress had intended to preempt state tort lawsuits it would have explicitly done, as it did in the MDA. Additionally, Levine claims that Wyeth’s analysis of the CBE rule is flawed and that drug companies may strengthen warnings to protect the public without violating federal law. Therefore, Levine contends that federal law does not preempt state tort actions and the jury verdict should be affirmed. Levine’s argument stresses the fact that Congress never enacted a prescription drug

preemption provision in the FDCA, despite numerous opportunities to do so. According to Levine, the fact that Congress has acted before to preempt state tort actions, as it did in the MDA, demonstrates that it knows how to effect preemption when it chooses to do so.

Further, Levine argues that Wyeth is able to comply with both a damages judgment in Vermont state court and its obligations dictated by the FDCA. She contends that Wyeth could have changed the Phenergan label without violating the FDCA and points out that the FDA, in its *amicus curiae* brief filed in *Levine*, does not even contend that it would have brought a misbranding action against Wyeth if Wyeth had changed the Phenergan label to prevent the use of IV-push as a valid method of administration. Levine also argues that Wyeth's understanding of CBEs is flawed. She points out that drug companies may withdraw an approved drug from the market for any reason. In her opinion, it logically follows that a drug company may withdraw a specific method of administering that drug as well. Further, Levine argues that a drug company does not need "new information" to make a CBE.

Significantly, Levine argues that a pro-preemption ruling in *Levine* would preclude all state tort actions, dealing a devastating blow to public safety. She argues that tort suits encourage drug companies to continue to study their drugs in an effort to stay abreast of all possible injuries that may result from their use and that, oftentimes, risks associated with a drug are not learned until that drug has been on the market for many years. Another point raised by Levine is that the FDA is too underfunded and understaffed to stay abreast of *every* study of *every* drug that has *ever* been approved.

C. Predicting the Outcome of *Levine*

It is difficult to predict with any degree of certainty how the United States Supreme Court will rule on the preemption issue in *Levine*. In recent years, the increasingly-conservative high

court has sided with Bush administration policy on numerous occasions. Whether it will agree with the position of the FDA on drug preemption remains to be seen. Several observations are worth noting, however.

First, in *Riegel*, the Supreme Court majority went out of its way to stress that its decision -- that the express preemption provision of the MDA bars tort claims challenging FDA approved medical devices -- does not bear on the drug provisions of the FDCA, which contain no preemption provision. *See Riegel*, supra., 128 S. Ct. at 1009-10. There, the Supreme Court specifically noted that “[i]t has not been established . . . that no tort lawsuits are pre-empted by drug or additive approval under the FDCA.” *Id.* at 1009. It also stated that if Congress wanted drugs and medical devices to be treated alike it “could have applied the pre-emption clause to the entire FDCA,” instead of writing a preemption clause that applies to medical devices only. *Id.* at 1009-10. This language may indicate that a majority of the Court will decide against preemption in *Levine*.

Conversely, the Supreme Court may give the FDA’s current position on preemption more weight in *Levine* than it did in *Riegel*. In *Riegel*, the majority noted that because the MDA “spoke clearly” on preemption, it found it unnecessary to rely on the FDA’s position. *Id.* In other words, because the MDA contains an express preemption provision, the Supreme Court did not look to the FDA’s position for any guidance and did not need to accord it any deference. The majority in *Riegel* stated, however, that if the statute were ambiguous it would have considered the FDA position. *Id.* According to the Court, “*Skidmore* deference would seemingly be at issue.” *Id.* As discussed above, that level of judicial deference does not hold an agency’s position to have the force of law; however, it does look to it as being persuasive. *See Skidmore*, supra., 323 U.S. at 134. The majority in *Riegel* also noted that it found the FDA’s pre-2002

position on preemption to be “compromised, indeed deprived of all claim to deference,” in light of the FDA’s current position, as set forth in the Preamble. *Riegel*, 128 S. Ct. at 1009. Thus, the Supreme Court may find persuasive guidance in the Preamble.

Finally, as recognized by at least one commentator, an analysis of Supreme Court products liability preemption decisions beginning in the early 1990s indicates that in every case save one, the Supreme Court’s decision, whether pro-preemption or anti-preemption, aligned with the position urged by the relevant federal agency. *See* The Federalist Society for Law and Public Policy Presents: Panel: Agency Preemption: Speak Softly, but Carry a Big Stick?, 11 Chap. L.R. 363, 373 (Winter, 2008)(hereinafter, “Agency Preemption”). *See also Cipollone*, supra., 505 U.S. at 504 (federal cigarette labeling and advertising statutes held to preempt some, but not all, state law claims); *Buckman Company v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001)(state law “fraud on the FDA” claims regarding bone screw devices held to be preempted by FDCA, as amended by the MDA); *Medtronic*, supra., 518 U.S. 470 (1996)(state common-law negligence claims involving allegedly defective pacemaker held not pre-empted by FDCA); *Geier v. American Honda Motor Company, Inc.*, 529 U.S. 861 (2000)(National Traffic and Motor Safety Act held to preempt state common law tort claim that car manufacturer ought to have equipped car with airbags); *Freightliner*, supra., 514 U.S. 280 (1995)(state common law claims against tractor-trailer manufacturers held not preempted by National Traffic and Motor Vehicle Safety Act); *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002)(state-common law tort action seeking damages from manufacturer of allegedly unsafe outboard motor held not preempted by Federal Boat Safety Act); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005)(Federal Insecticide, Fungicide and Rodenticide Act held not to preempt at least some

state law claims by farmers for damages from particular pesticides allegedly injuring crops).

This commentator noted that:

Thus, the FDA had argued in favor of preemption in *Buckman*, and the Court went that way; it argued against preemption in *Medtronic*, and the Court went that way. NHTSA [National Highway Traffic Safety Administration] argued in favor of preemption in *Geier* and against preemption in *Freightliner*, and the Court followed suit. The Court's anti-preemption holding in *Sprietsma* likewise follows the agency's [the Coast Guard's] position.

[See Agency Preemption, *supra.*, 11 Chap. L.R. at 373.]

The only exception was the Supreme Court's decision in *Bates*, *supra.*, 544 U.S. at 431, where the Court did not adopt the position urged by the Environmental Protection Agency. *Id.* This is an interesting observation that is worthy of consideration when attempting to predict the outcome of *Levine*.

VII. THE END OF PHARMACEUTICAL PRODUCTS LIABILITY LITIGATION?

A Supreme Court ruling in *Levine* in favor of preemption may not spell the end of state common law tort claims against drug manufacturers, especially if certain Democratic members of the United States Congress get their way.

On May 14, 2008, in response to the Supreme Court's decision in *Riegel*, the United States House of Representatives' Committee on Oversight and Government ("COG") Reform held a hearing to explore whether Congress should enact legislation specifically overruling *Riegel* and providing that the FDCA does not preempt state tort lawsuits. The hearing was convened by the COG committee chairman, Representative Henry A. Waxman, a Democrat. In his opening comments, Representative Waxman noted the FDA's recent change in position and expressed his concern that an under-funded FDA alone is not in a position to protect the public health if preemption is allowed under the MDA and FDCA. Additionally, Representative

Waxman claimed that certain drug and medical device companies manipulate, or even hide, data provided to the FDA in an effort to continue selling dangerous products. He also asserted that the data relied upon by the FDA is often too limited to detect serious, long-term problems. As a result, it is Representative Waxman's opinion that the FDA should not be the sole "gatekeeper" in protecting the American public from dangerous drugs and that state tort law claims serve a vital public good.

Certain panelists supported Representative Waxman's call for a federal law barring preemption. Primarily, these panelists argued that Congress never intended to allow companies that jeopardize public safety to escape legal liability. They believe that constant drug safety monitoring is necessary in an effort to discover all of the risks associated with a particular product, even if it is FDA approved. These panelists also argued that information on drugs and medical devices evolves as the products are on the market and that new risks, and the severity of previously known risks, are often discovered years after FDA approval. In their opinion, manufacturers need more than just a sense of doing what is "right" to incentivize them to report the facts without misrepresenting findings or minimizing potential risks. That incentive is present in the potential liability they face in state common law tort actions.

On the other side of the aisle, certain members of the COG, including Representative Thomas M. Davis, a Republican, argued that allowing state judges and juries to second-guess the "expert" analysis of the FDA and their scientific advisory panels adds instability, not protection, to a system the nation relies upon for vital medical advances. Likewise, another Republican, Representative Mark E. Souder, agreed that while the public needs to be protected from dangerous drugs entering the marketplace, there is also a need to get important drugs to the public as soon as medically and scientifically possible. The question that Representative Davis

posed to the COG was, is it preferable to have an expert agency or a jury of twelve randomly-selected lay people balance the risks and benefits of a new drug?

Even if Congress does not act to effectively overrule a pro-preemption decision in *Levine*, it is possible that some state common law tort claims against drug manufacturers may survive preemption. Recall that in the statement contained in the Preamble, the FDA itself stated that it intended to “at least” preempt failure to warn claims. *Id.* at 3935-36. Even if deference is given to the FDA’s position, this statement may serve as an indication that the FDA believes that the preemption doctrine might not eliminate *all* products liability claims against drug manufacturers. A drug manufacturer may still be liable under a “failure to warn” theory for failing to warn about *newly-discovered* risks that it failed to bring to the FDA’s or to the public’s attention. Furthermore, a drug maker who promotes its drug for “off-label” uses not officially approved by the FDA may also be open to liability. While physicians may prescribe a drug for an off-label use, it is illegal for a drug manufacturer to promote unapproved uses. It is possible, but unlikely, that design defect claims may also escape preemption. The vast majority of products liability claims against drug manufacturers are based on failure to warn and not design defect, which is much more difficult to establish and is thus not frequently asserted by plaintiffs. In all likelihood, however, preemption would also likely encompass design defect claims involving drugs whose formulations were approved by the FDA and whose manufacturers did not deviate from those formulations in production.

A likely scenario is that the Supreme Court may try to achieve some middle ground between full preemption and a more narrowly-construed form of preemption, along the lines of the Third Circuit’s ruling in *Colacicco*, *supra.*, 521 F.3d at 253, where the Court held that a failure to warn claim was preempted where the FDA previously studied and rejected the very

same warning that plaintiffs argued was required under state law. However, the Court in *Colacicco* expressly stated that its decision did not constitute a holding that the FDA's mere approval of drug labeling is sufficient to preempt all state law failure to warn claims. *Id.* at 271. It is possible that the Supreme Court will decide in favor of preemption in *Levine* on the basis that the FDA expressly considered and approved the IV-push method of administration, the very same method which Levine believes should not have been approved.

In any event, even if the Supreme Court decides in favor of a more broad-based form of preemption, it appears that the Democrat-controlled Congress would be prepared to undue that decision by enacting an anti-preemption statute.

VIII. CONCLUSION

Preemption is one of the hot-button issues in American law today, and for good reason. The United States Supreme Court will soon decide whether, and if so, to what extent, the FDA's administrative decisions on drug approval and drug labeling preempt state common law tort claims against pharmaceutical manufacturers. What makes the preemption debate even more noteworthy is that what contributed to bringing this issue to forefront was the FDA's radical, 180-degree shift of a position it held for the better part of a century. That change has many people asking whether a government agency ostensibly dedicated to truth and science has become politicized by an administration eager to push an agenda of tort reform and protect big business. It is fair to say that the FDA's shift in position has also emboldened the pharmaceutical industry which, in all fairness, has found itself on the receiving end of an inordinate number of lawsuits, including many which may not have much merit to them. The drug companies appear to have reached their boiling point with the plaintiffs' bar, and they found themselves a strong test case to take the Supreme Court in *Levine*.

For all of the critics of the FDA, the Bush administration and “big pharma,” there is also another point of view which holds that a lay jury, unversed in medicine and science, should not supplant the judgment of the government agency charged with protecting the public health.

Where things go from here will soon be in the hands of the nine justices of the United States Supreme Court, who will render their decision in *Levine* before this year’s Supreme Court term is over.