



PREEMPTION IS NOT DEAD

A Fresh Look at Wyeth v. Levine in Context

A White Paper analyzing the state of the preemption doctrine in the wake of the Supreme Court's recent decision in *Wyeth v. Levine* 173 L. E. 2d 51 (Mar. 4, 2009)

COZEN O'CONNOR

Terry M. Henry, Member
Lauren Tulli, Member
Scott Reid, Associate

1900 Market Street
Philadelphia, PA 19103
215-665-2000

The Life Science Litigation Practice Group
therry@cozen.com

TABLE OF CONTENTS

I. INTRODUCTION..... 1

II. FEDERAL PREEMPTION 1

III. THE WYETH V. LEVINE CASE..... 2

 A. BACKGROUND OF THE *LEVINE* CASE 2

 B. KEY FACTUAL ISSUES 3

 C. THE “IMPOSSIBILITY” PREEMPTION..... 4

 D. THE “PURPOSES AND OBJECTIVES” PREEMPTION..... 5

 E. THE CONCURRING JUSTICES 6

 F. THE DISSENT 6

 G. THOUGHTS ON THE LEVINE CASE 7

IV. THE LEGAL LANDSCAPE SINCE *WYETH V. LEVINE*..... 7

 A. *BRADLEY V. FONTAINE TRAILER CO.*, 7

 B. *MCCARRELL V. HOFFMAN-LA ROCHE* 8

 C. *BRUESEWITZ V. WYETH INC.*, 8

 D. *SCHROCK V. WYETH, INC.*,..... 9

 E. *LONGS V. WYETH*,..... 9

 F. *STACEL V. TEVA PHARMACEUTICALS*, 10

 G. *COLACICCO V. APOTEX, INC.*, 10

 H. *PA. EMPLES. BENEFIT TRUST FUND V. ZENECA, INC.*, 11

 I. PROPOSED FEDERAL LEGISLATION..... 11

V. THE FUTURE OF PREEMPTION IN THE WAKE OF *WYETH V. LEVINE* 11

END NOTES..... 12

I. INTRODUCTION

On March 4, 2009, the U.S. Supreme Court issued its decision in the case of *Wyeth v. Levine*. In its opinion, the Court held that the plaintiff's failure to warn claims relating to the prescription drug Phenergan were not preempted by FDA labeling regulations. While product manufacturers and defense attorneys viewed the Court's decision as a major blow, consumer rights activists and the plaintiffs' bar touted it as a "Monumental Victory" for consumers. Much of the hype surrounding the Court's decision is most likely due to the fact that a great number of interested parties were anxiously awaiting the decision, much like the public eagerly awaited the last installment (or what we thought was the last installment) of the Star Wars saga.

When boiled down to its essence, however, the *Levine* decision was not a milestone and it was not a significant departure from previous Court holdings in the area of preemption. The Court merely affirmed its longstanding view that it is the product manufacturer that bears ultimate responsibility for the content of its warnings and instructions. The Court refused to allow the product manufacturer in this case, *Wyeth*, to hide behind labeling regulations and point to the FDA as the entity responsible for the content of its labeling.

With time and viewed in context, the Supreme Court's decision will be seen not as a departure from its previous holdings on the issue of federal preemption, but as a case decided within the bounds of previous Court opinions and which turned on a few key facts. Just as the "final" episode of *Star Wars* was adored by its fandom, but moderately panned by critics, so too the

Wyeth v. Levine decision will not be thought of as a turning point in the doctrine of preemption, but it will become just another road marker on the road of product liability law.

II. FEDERAL PREEMPTION

In the legal system of the United States, preemption generally refers to the displacing effect that federal law can have on a conflicting or inconsistent state law. When there is a conflict between a federal law and a state law, under certain circumstances, the federal law "trumps" the state law.

A fundamental principle of the Constitution is that Congress has the power to preempt state law.¹ Under the Supremacy Clause, any state law that conflicts with the exercise of enumerated federal power is preempted. Courts typically discuss two important concepts when deciding preemption cases. The first is that Congress' purpose is "the ultimate touchstone in every preemption case."² The second is that in all preemption cases, the Court starts with "the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."³

There are two kinds of federal preemption, express and implied, but the Supreme Court has stated that these categories are not rigidly distinct.

Express preemption occurs when Congress explicitly preempts state law.⁴ Express preemption is typically expressed via a "preemption clause" in a statute.⁵ Such a preemption clause might look like this one from the Medical Device Act:

(a) General Rule - 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.⁶

The effect of an express preemption clause is that states are prohibited from adopting conflicting requirements or standards.

With respect to implied preemption, there are two kinds, implied field preemption and implied conflict preemption. Congress' intent to preempt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress "left no room" for supplementary state regulation.⁷ Known as implied field preemption, this is where Congress has occupied the entire field to indicate that there is no room for states to supplement federal regulations.⁸ Implied field preemption can also occur where "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."⁹ We typically see implied field preemption in areas like the Labor Management Relations Act, where the federal government has the exclusive

jurisdiction to resolve disputes between labor unions and employers, as well as the Employee Retirement Income Security Act, where the federal government has exclusive jurisdiction over enforcement of the substantive provisions of employer-sponsored Welfare and Pension Benefit Plans.

Implied conflict preemption can occur when federal and state provisions cover the same subject matter and prevent compliance with both regulations simultaneously. Where Congress has not completely displaced state regulation in a specific area, implied conflict preemption occurs when "compliance with both federal and state regulations is a physical impossibility."¹⁰ Implied conflict preemption can also occur when the state law at issue "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."¹¹

In *Levine*, the Supreme Court took up the issue of implied conflict preemption.

III. THE WYETH V. LEVINE CASE

A. Background of the *Levine* Case

The *Levine* case began in April 2000 when Diana Levine went to her local clinic for treatment of a recurring migraine headache. During her treatment, the physician's assistant gave her an intramuscular injection of Demerol for her headache and Phenergan for her nausea. Because that combination did not provide her relief, she returned to the clinic later that day for further treatment. The second time, the physician assistant administered both drugs by the IV-push method. During administration of the Phenergan, the drug entered Ms. Levin's artery, either because the needle penetrated an artery directly, or because the drug escaped from the vein into surrounding tissue, where it then came into contact with

arterial blood. As a result, Ms. Levine developed gangrene, requiring that doctors amputate first her right hand and then later, her entire forearm.

The drug's label contained upwards of six separate warnings and instructions about the risk of gangrene resulting in possible amputation from the inadvertent intra-arterial injections, but did not specifically contraindicate IV-push injections. A Vermont jury found the manufacturer negligent and Phenergan defective because the label did not give an adequate warning of the risk from IV-push injection. The jury awarded Ms. Levine \$7.4 million, which was subsequently reduced by the court to account for earlier settlements Ms. Levine had reached with the physician assistant and health center where she was treated.

The manufacturer, Wyeth, appealed to the Supreme Court of Vermont, which affirmed the trial court verdict. Wyeth then took its appeal to the U.S. Supreme Court.

At the Supreme Court, Wyeth contended that Ms. Levine's state law tort claims were impliedly preempted by federal law because Congress had empowered the FDA to regulate drug labeling. Wyeth asserted that the FDA had approved the Phenergan label and it was impossible for Wyeth to both comply with the FDA's labeling requirements and the jury-imposed, state-law duty to give a stronger warning against IV-push administration of Phenergan. Wyeth reasoned that by following the jury's direction to give a stronger warning (contraindicating Phenergan for IV-push) Wyeth would violate federal law. Wyeth also argued that the state common law action created an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

The majority opinion of the Supreme Court in *Levine*, written by Justice Stevens and joined by Justices Kennedy, Souter, Ginsburg, and Breyer, rejected both of Wyeth's arguments. Justice Thomas filed an opinion concurring in judgment only. Justice Alito dissented, and was joined by Chief Justice Roberts and Justice Scalia.

B. Key Factual Issues

The majority in *Levine* determined that the trial court settled two key factual issues. The first was that Ms. Levine's injury would not have occurred if Phenergan's label had included an adequate warning about the risks of the IV-push method of administering the drug. The majority saw the lack of an adequate warning about the risks of IV-push administration as a critical determination by the jury, but stopped short of concluding that the jury required a specific warning that IV-push administration should have been contraindicated. In doing so, the majority stated that the jury insisted the warning should have been stronger, but did not require a specific warning.

The other key factual issue was the finding that neither the FDA nor Wyeth "gave more than passing attention to the issue of" IV-push versus IV-drip administration. Having not given much attention to the IV-push method of Phenergan administration, the majority held that Wyeth could not credibly establish that the FDA would not have approved the stronger warning label required by the jury.

The dissent took the majority to task on the factual assertion that the FDA did not consider specific warnings about the risks of IV-push administration of Phenergan, calling it "demonstrably untrue." The dissent found the record contained ample examples of the FDA considering and reconsidering the strength of Phenergan's

IV-push related warnings in light of continually evolving scientific and medical data. The dissent noted that among the various intra-arterial warnings the FDA mandated, the FDA required Wyeth to label Phenergan with a warning that read: “INADVERTENT INTRA-ARTERIAL INJECTION CAN RESULT IN GANGRENE OF THE AFFECTED EXTREMITY,” and that “[u]nder no circumstances should Phenergan Injection be given by intra-arterial injection.” These warnings about intra-arterial injection were accompanied by an explanation that intra-arterial injection of Phenergan could result in gangrene requiring amputation.

As to the jury’s determination that the Phenergan warnings were inadequate, the dissent determined that given the numerous instructions related to IV-push administration and the warnings against intra-arterial injection, the only message the jury could possibly have been sending Wyeth was that it was required to contraindicate IV administration of Phenergan to make the drug safe for use.

The discrepancies in the factual findings between the majority and dissent in *Levine* are important because the opportunity to distinguish future cases rests in the gap between the two.

C. The “Impossibility” Preemption

One of Wyeth’s central arguments was that it was impossible for it to comply with both the state-law duties underlying Ms. Levine’s state law claims and its federal labeling duties pursuant to the Federal Drug and Cosmetic Act (FDCA). The FDA’s premarket approval of a new drug application includes the approval of the exact text in the proposed label.¹² Wyeth argued that it could only change Phenergan’s label after the FDA approved a

supplemental application with the new language. To do otherwise, would either make Phenergan a new drug, subjecting Wyeth to liability for unauthorized distribution, or result in violation of law for misbranding.¹³

The majority swept away these arguments by pointing out the absurdity of the idea that the FDA might bring an enforcement action against a manufacturer for strengthening a warning. The majority also explained that an FDA regulation permits a manufacturer to make certain changes to its label before receiving the agency’s approval. This “changes being effected” (CBE) regulation provides that if a manufacturer is changing a label to “add or strengthen a contraindication, warning, precaution, or adverse reaction” or to “add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product,” it may make the labeling change upon filing its supplemental application with the FDA and need not wait for FDA approval.¹⁴

The majority pointed out that Wyeth could have complied with both the jury’s requirement for a stronger warning and federal law governing warnings by using the CBE regulation. Wyeth did not believe that the CBE regulation would have provided it the necessary vehicle to change the Phenergan label because FDA policy at the time was that a manufacturer may only change its label “to reflect newly acquired information.”¹⁵ The majority explained that “newly acquired information” did not necessarily mean new data. It could also mean new analysis of previously submitted data, existing data viewed in light of subsequent events or additional adverse events. Any of these could be a basis for a CBE change to a warning based on “newly acquired evidence.”¹⁶ Of course, the majority acknowledged that the FDA retains

authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application. But absent clear evidence that the FDA would not have approved a change to Phenergan's label, the majority could not conclude that it was impossible for Wyeth to comply with both federal and state requirements.

Wyeth's argument suggested that the FDA intended to prohibit it from strengthening the warning about IV-push administration because the agency deemed such a warning inappropriate in light of its review of Phenergan's drug applications. However, the majority found that Wyeth had no evidence that it provided the FDA with an evaluation or analysis concerning the specific dangers posed by the IV-push method. Consequently, the majority gave no credit to Wyeth's contention that the FDA would have prevented it from adding a stronger warning about the IV-push method of intravenous administration.

The majority understood Wyeth to argue that the FDA, as opposed to the manufacturer, bore ultimate responsibility for drug labeling and that Wyeth was using the FDA as a shield to accepting responsibility for making its warning stronger. The majority responded by reiterating that it is the manufacturer that bears responsibility for the content of its label at all times and is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.

On the record before it, the majority held that Wyeth failed to demonstrate that it was impossible for it to comply with both federal and state requirements.

D. The "Purposes and Objectives" Preemption

Wyeth also advanced an argument that requiring it to comply with a state-law duty to provide a stronger warning about IV-push administration of Phenergan would obstruct the purposes and objectives of federal drug labeling regulation. Under this theory, Wyeth argued that Ms. Levine's tort claims were preempted because they interfere with Congress' purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives. Wyeth believed that the Federal Drug and Cosmetic Act establishes both a floor and a ceiling of drug regulation and that once the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue.

The majority found that all of the evidence before it was that Congress' purpose in enacting the FDCA was to the contrary. It reasoned that Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs, recognizing that state-law rights of action provided appropriate relief for injured consumers. The majority also pointed out that in 1976, when Congress provided an express exemption for medical devices, it did not enact such a provision for prescription drugs.¹⁷

Wyeth, however, also relied upon the FDA's preamble to a 2006 regulation governing the content and format of prescription drug labels.¹⁸ The preamble expressly stated that the FDCA establishes "both a 'floor' and a 'ceiling,'" such that "FDA approval of labeling . . . preempts conflicting or contradictory State law."¹⁹ Because the majority viewed the preamble as "an agency's mere assertion that state law is an

obstacle to achieving its statutory objective”, it did not give the FDA’s statement the force of law which permitted the majority to perform its own conflict determination.²⁰

The majority saw the preamble in conflict with the other evidence of Congressional intent and a reversal of the FDA’s longstanding position without any reasoned explanation. The majority also was troubled by the fact that the preamble was added only in the final version of the regulation, meaning that the States or other interested parties were not put on notice of the change and given an opportunity to comment. Because the FDA did not allow such notice and comment, the majority concluded that the preamble was “inherently suspect” and did not deserve any deference.

Consequently, the majority held that the Vermont jury verdict did not conflict with the purposes and objectives of the statutory scheme envisioned by Congress.

E. The Concurring Justices

Justice Breyer, who also joined in the majority opinion, wrote separately on the potential preemptive effect of FDA regulations. He suggested that there were some specific areas in which the FDA could regulate that could result in a direct conflict with state tort claims, but that such a regulation was not at issue.

Justice Thomas did not join in the majority opinion but he concurred with the judgment. He explained his narrow, texted-based view of preemption and that the circumstances under which implied preemption occurs are very few. Justice Thomas stated that when the Court entertains a “purposes and objectives” analysis, it facilitates free-wheeling, extra-textual, and broad evaluations of the purposes and objectives embodied in federal law. This free-wheeling, he stated, leads to decisions

giving improperly broad pre-emptive effect to judicially manufactured policies, rather than to the statutory text enacted by Congress pursuant to the Constitution and the agency actions authorized by Congress.

F. The Dissent

The dissent began its criticism of the majority by stating the majority identified the wrong issue to be resolved. The dissent stated that it was not whether the Phenergan’s label should bear a “stronger” warning, but whether a state tort jury can countermand the FDA’s considered judgment that Phenergan’s FDA-mandated warning label renders its intravenous use “safe.” The dissent then followed with a detailed analysis of the FDA’s multi-year review of evidence related to intra-arterial administration of Phenergan, administration of Phenergan by way of IV-push, the numerous warnings and instructions included with the drug, and the failure of the physician’s assistant to follow even one of those warnings and instructions. The conclusion that the dissent reached was that the FDA had studied the data and risks associated with IV-push and required the Phenergan label to warn against them. Thus, Wyeth could not comply with both the federal labeling requirements and the state-law requirements stemming from the jury’s verdict, and the dissent would have determined that the FDCA pre-empted Ms. Levine’s claims.

The dissent next took on the majority’s opinion that Vermont’s jury verdict did not interfere with Congress’ objectives and purposes in developing the regulatory scheme for labeling under the FCDA. Although the majority sought to distinguish its holding in *Geier v. Honda, supra*, the dissent went to great lengths to demonstrate how the analysis and holding in *Geier* was very similar to the facts in the case before it

and that drug labeling by a jury, such as in *Levine*, undermines both the broader pre-emption doctrine and the workability of the federal drug-labeling regime.

In the end, the dissent expressed the opinion that the FDA had appropriately performed the cost-benefit balancing function in reviewing the warnings for the IV-push administration of Phenergan. The dissent stated that juries are ill-equipped to perform this function, because juries tend to focus on the limited facts of the injured plaintiff before them and are unable (perhaps unwilling) to take the longer view that the FDA must take.

G. Thoughts on the *Levine* Case

Reading over the majority and dissenting opinions, one wonders whether the various justices were looking at the same case. The *Levine* decision, however, is a good example of how the Court, on occasion, approaches cases from completely divergent perspectives. The majority attacked the issue from the perspective of the manufacturer's obligation to ensure its warnings and instructions included all information to make the product safe. Absent evidence that it did everything possible to get the FDA to adopt a stronger warning, as suggested by the jury, the majority would not relieve Wyeth of its responsibility.

The dissent took the view that process of developing the warnings and instructions is a heavily regulated process that not only governs the content of the warnings and instructions, but also dictates the interactions of the FDA and manufacturer. The dissent saw the FDA as the entity empowered by Congress to determine the safety of drugs and that any encroachment by state juries on this power undermines the FDA and upsets the delicate balance the FDA must perform

when weighing the costs and benefits of each drug it evaluates.

When boiled down to its essence, however, the *Levine* decision was not a milestone and it was not a significant departure from previous Court holdings in the area of preemption. The Court merely affirmed its longstanding view that product manufacturers bear ultimate responsibility for the content of their warnings and instructions.

In the short time since *Levine* was decided, it has already had an impact in a number of cases. A brief discussion of those cases follows.

IV. THE LEGAL LANDSCAPE SINCE *WYETH V. LEVINE*

A. *Bradley v. Fontaine Trailer Co.*,²¹

In *Bradley*, plaintiffs brought a product liability action under the Connecticut Product Liability Act (CPLA) following a fatal traffic collision between plaintiffs' automobile and a flatbed truck owned by defendant. The tractor trailer crashed into and over a concrete median on Interstate 95 near Fairfield, Connecticut. The tractor became separated from the trailer and the trailer was left protruding onto the opposite lanes of traffic. Due to weather conditions, visibility was low and plaintiffs did not see the trailer as they traveled toward it from the opposite direction. Of the eight passengers in the SUV, four were killed and four were seriously injured.

In response to plaintiffs' product liability claims, defendant asserted twelve affirmative defenses, including express preemption by federal law. The defendant argued that it complied with Federal Motor Vehicle Safety Standard 108, promulgated by the National Highway Safety

Administration under the National Traffic and Motor Safety Act of 1966 (“Safety Act”).

The Safety Act provides a saving clause stating that compliance with a motor vehicle safety standard does not exempt a person from liability at common law. The CPLA permits a cause of action for damages for product defect.

With respect to defendants’ affirmative defense relating to Safety Standard 108, the court determined that Congress has allowed the states to set safety standards stricter than those set by Congress, and therefore no express preemption was found. However, with regard to the CPLA, the court acknowledged that conflict preemption may apply if defendant could not meet both the federal requirements and remedy whatever defect plaintiffs suggest the tractor trailer possessed.

Quoting from *Levine*, the court held it may be possible for the defendant to demonstrate that plaintiffs’ claims are preempted by Standard 108, but determined that inquiry to be fact intensive and therefore premature at an early stage of litigation. Although the court found *Levine* to be instructive, it was not dispositive because the dispute it was deciding arose before the parties completed discovery.

B. *McCarrell v. Hoffman-La Roche*²²

The New Jersey Superior Court, Appellate Division, remanded *McCarrell* for a new trial on the basis of reversible and harmful error because the trial court precluded defendants from presenting certain evidence to the jury and to consider defendant’s contention that plaintiff’s failure to warn claims are preempted by federal law, in light of the recent decision in *Levine*. The court reasoned that under *Levine*, plaintiff’s state

law products liability claims for failure to provide an adequate warning would not be preempted unless defendant could show that the FDA would not have approved a change to the drug’s label. However, the appellate court determined that the record was incomplete as to the FDA’s review of the drug’s labeling. Therefore, the appellate court directed the trial court to further develop the record in that regard so that the case could be properly evaluated in light of *Levine*, prior to a new trial.

C. *Bruesewitz v. Wyeth Inc.*²³

On appeal from the District Court for the Eastern District of Pennsylvania, the Third Circuit affirmed the lower court’s holding that the National Childhood Vaccine Injury Act expressly preempted all design defect claims against the manufacturer of a vaccine.

Although the Third Circuit recognized that the Supreme Court recently concluded in *Levine* that state tort law claims were not preempted, the Third Circuit found *Levine* “readily distinguishable on several grounds.” First, the Court explicitly noted the absence of an express preemption provision and found Congress’s silence, “coupled with its certain awareness of the prevalence of state tort litigation, [] powerful evidence” (*citing Levine*). In *Bruesewitz*, however, Congress included an express preemption provision that was prompted, as evidenced by the Committee Report, by the prevalence of state tort litigation. Second, *Levine* recognized that, under federal law, a drug manufacturer could strengthen a drug’s label without pre-approval from the FDA. The Third Circuit held this to stand in contrast to the FDA’s far-more extensive control and oversight of the approval of a drug’s design and alteration.

D. *Schrock v. Wyeth, Inc.*,²⁴

In *Schrock*, plaintiff was prescribed Reglan to treat reflux. The active ingredient, MCP, was available in brand or generic form. Plaintiff ingested the generic form from March 2000 to June 2006, and ultimately developed tardive dyskinesia, a neurological movement disorder.

In her complaint, plaintiff alleged that defendants failed to adequately warn about the association between long term use of MCP and movement disorders. Defendants allegedly failed to submit a request for a labeling revision to the FDA and failed to report safety information to the medical community. Pliva and the other generic defendants filed a motion to dismiss based on federal preemption.

Citing directly to *Levine*, the court found plaintiff's state law action did not obstruct the purposes and objectives of Congress. Quoting *Levine*, the court held, "...failure to warn actions, in particular, lend force to the premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." Denying the defendants' motion to dismiss based on preemption, the court relied on *Levine* and held the Supreme Court has clearly concluded that Congress did not intend to the preempt state law failure to warn actions.

E. *Long v. Wyeth*,²⁵

In *Long*, plaintiff brought product liability claims against Wyeth relating to the diet pill Redux. In February 2008, the court granted summary judgment in favor of Wyeth on all of plaintiff's claims, finding the strict liability and negligence claims relating to pre-FDA approval were preempted by federal law as directly conflicting with the FDA's authority to determine which drugs are sufficiently safe and effective to be

marketed, "...all claims relating to the pre-FDA approval are preempted by the FDA." Additionally, the court preempted any claim which may have alleged fraud-on-the-FDA or that defendants concealed or misrepresented information to the FDA. However, the court found that plaintiff's *post*-FDA approval design defect claims were not preempted under strict liability and negligence.

Thereafter, on March 10, 2009, the plaintiff filed a motion to vacate the order and judgment that had been entered, basing the motion on both *Riegel v. Medtronic* and *Wyeth v. Levine*. Plaintiff asserted that both cases bore on the preemption issues in her case. The court disagreed and denied both motions, finding both cases distinguishable from the facts before it. With respect to *Riegel*, the court pointed out that the question of whether plaintiff's pre-FDA approval claims were preempted by the FDCA was not an issue before that court. Instead, the *Riegel* court only addressed the effect of the MDA on claims premised on violations of the FDA regulations, not the extent to which claims are preempted by the FDCA.

The court also found *Levine* did not apply. Characterizing the issue before the Supreme Court in *Levine* as "narrow," the court held the case was distinguishable from the plaintiff's claims because the plaintiff did not assert a failure to warn claim, which was the basis for the determination in *Levine*. Additionally, the court pointed out that *Levine* drew a distinction between the *post*-FDA approval duty and a manufacturer's duty prior to approval by the FDA. Specifically, *Levine* held that *post*-FDA approval claims are not preempted, but did not address *pre*-FDA approval claims.

F. *Stacel v. Teva Pharmaceuticals*,²⁶

In *Stacel*, plaintiff alleged that she was afflicted with drug induced lupus as a result of ingesting a drug called minocycline, a generic of the brand name Minocin, which is manufactured by defendant Teva. She brought a product liability suit alleging failure to warn, fraud and misrepresentation, among other allegations. Teva filed a motion to dismiss, arguing, *inter alia*, that the state law causes of action are preempted by the FDCA.

The court's opinion included a discussion on the types of federal preemption and the differences in the processes by which a new drug manufacturer and a generic drug manufacturer must comply to obtain FDA approval for a drug. Citing to *Levine*, the court pointed out that in the context of new drugs, the Supreme Court recently held state law claims are not preempted, but found *Levine* not directly controlling, since the case at bar involved a generic drug manufacturer. Ultimately, however, the court reasoned there was no basis to conclude that Congress felt differently about generic drugs and extended *Levine* to apply to the generic drugs as well, stating, "Given the sweeping language and overall conclusions of the Supreme Court in [*Wyeth v. Levine*], this court concludes that such claims [as to generic drugs] should not be preempted as a matter of law."

G. *Colacicco v. Apotex, Inc.*,²⁷

On petition for writ of certiorari to the United States of Appeals for the Third Circuit. The Supreme Court initially granted the petition for writ of certiorari, but recently vacated judgment and remanded the case back to the United States Court of Appeals for the Third Circuit for further consideration in light of *Levine*. Despite the remand there are aspects of the Third

Circuit's April 8, 2008 opinion which warrant discussion.

The Third Circuit was the first federal appellate court to hold that federal law preempts state product liability claims against manufacturers of prescription drugs, concluding that such claims are preempted when they seek to hold a manufacturer liable for not including a warning that the FDA previously determined was not supported by the scientific evidence. From the court's perspective, this would be asking juries to impede upon the FDA approval and monitoring process, so preemption is appropriate.

In *Colacicco*, plaintiff alleged the defendant manufacturer was responsible for failing to warn that the anti-depressant drug it manufactured increased the risk of suicide. The FDA approved the manufacturer's labeling, finding that the scientific evidence did not support additional warnings to the label. The court determined that "[it] need not speculate on the rationale of the FDA for its failure to require the adult suicidality warnings. [The FDA has] repeatedly rejected the scientific basis for the warnings that [the plaintiffs] argue should have been included in the labeling."

In its opinion, the Third Circuit acknowledged that *Levine* was pending before the Supreme Court the following term, but apparently determined the issues in *Levine* to be factually distinguishable enough from those presented in *Colacicco* to warrant a ruling without waiting for the Supreme Court to decide *Levine*. The Third Circuit specifically addressed the scenario in which the FDA rejects the scientific basis or necessity for a warning urged by the plaintiff, which is different than the facts presented in *Levine* or the issue upon which certiorari was granted in *Levine*.

Nevertheless, the Supreme Court remanded *Colacicco* to the Third Circuit for further review in light of *Levine*, so it is unclear whether the Third Circuit will persevere in its opinion that preemption was appropriate under the facts as presented in *Colacicco* (i.e. juries should not be permitted to second-guess the FDA's scientific determination) or whether it will change course and find there to be no preemption consistent with the conclusion in *Levine*. Based on the factual differences between the two cases, which the Third Circuit considered in rendering its pre-*Levine* opinion, it appears that the Third Circuit has room to maintain its holding that preemption is appropriate under the facts presented.

H. *Pa. Emples. Benefit Trust Fund v. Zeneca, Inc.*,²⁸

Zeneca is a conflict preemption case involving state consumer fraud claims stemming from advertisements for the drug Nexium. The Third Circuit held that the state false advertising claims were preempted by federal law based on the FDA's exclusive authority to regulate prescription drug advertisements.

In both *Colacicco* and *Zeneca*, the Third Circuit relied on the case *Medtronic, Inc. v. Lohr*²⁹ for the principle that "state laws are preempted when they frustrate regulations that have been promulgated following a specific inquiry into a particular area of agency authority." Although somewhat factually dissimilar from *Colacicco*, the Third Circuit reached the same conclusion in *Zeneca*, finding preemption to be appropriate. The Supreme Court has also vacated the order in *Zeneca* and remanded the case back to the Third Circuit for consideration in light of *Levine*.

I. Proposed Federal Legislation

Following the Supreme Court's decision last year in *Riegel v. Medtronic, Inc.*, legislation was introduced in both the House and Senate.³⁰ Both bills were identical and sought to roll back the express preemption provision of the Medical Device Act. The pertinent section read:

Section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360k) is amended by adding at the end of the statute the following:

(c) NO EFFECT ON LIABILITY UNDER STATE LAW. – Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.

Neither bill came up for a hearing or a vote and they both died with the end of the congressional term. Rep. Henry A. Waxman, D-Calif., and Rep. Frank Pallone Jr. D-N.J., along with Senator Kennedy reintroduced the legislation following the Court's decision in *Levine*. The legislation is backed by several advocacy groups, including Consumers Union and Public Citizen.

V. THE FUTURE OF PREEMPTION IN THE WAKE OF WYETH V. LEVINE

It is too early to tell precisely what effect the Supreme Court's ruling in *Levine* will have on the multi-faceted issue of federal preemption generally, or in the pharmaceutical arena specifically. It appears from the handful of decisions over the past few weeks that the *Levine* holding may have limited applicability under a

precise set of facts, rather than changing the landscape of federal preemption. As evidenced by the discussions regarding *Levine* in these recent cases, courts have easily been able to draw distinctions between *Levine* and the facts in their individual cases.

The issue before the *Levine* Court has been characterized as “narrow,” specifically questioning whether the FDA’s drug labeling regulations (in some cases limited to post-approval activities) preempt state law product liability claims. Since the decision, courts have been quick to point out how *Levine* can be distinguished: it specifically involved a failure to warn claim; it related to the actions of the manufacturer post-FDA approval (as opposed to the manufacturer’s duty prior to FDA approval); it relates to a drug and not a medical device (for which the MDA has provided express preemption); and it directly addressed a primary drug manufacturer instead of a generic drug manufacturer.

Although the *Levine* decision will directly impact some aspects of federal preemption, at this point it appears there will be ample opportunity for litigants to argue that *Levine* does not apply to the facts of their case. In fact, the Supreme Court has not precluded manufacturers from asserting federal preemption and the majority acknowledged that on a different record implied conflict preemption might apply. There are complex questions to be resolved by lower courts regarding the nature and amount of evidence needed to establish the defense. Because *Levine* only involved preemption of inadequate warning claims, the ruling did not address design defect or other non-warning allegations.

It is important to remember that *Levine* does not address or change other implied preemption theories that manufacturers

commonly assert in product liability litigation, such implied field preemption. Similarly, consistent with the Supreme Court’s decision last year in *Riegel v. Medtronic, Inc.*, express preemption theories are still available and remain unchanged by *Levine*.

End Notes

¹ See U.S. Const. art. VI, cl. 2; *Gibbons v. Ogden*, 22 U.S. 1, 9 Wheat. 1, 211, 6 L.Ed. 23 (1824).

² *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996).

³ See *id.* at 485.

⁴ *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985).

⁵ *Jonathan V. O’Steen and Van O’Steen, The FDA Defense: Vioxx and the Argument Against Federal Preemption of State Claims for Injuries*, 48 Ariz. L. Rev. 67 (2006).

⁶ See, 21 U.S.C. §360k(a).

⁷ *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

⁸ *Jonathan V. O’Steen and Van O’Steen, The FDA Defense: Vioxx and the Argument Against Federal Preemption of State Claims for Injuries*, 48 Ariz. L. Rev. 67 (2006).

⁹ *Hines v. Davidowitz*, 312 U.S. 52 (1941).

¹⁰ *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963)

¹¹ *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) and *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000)

¹² *See*, 21 U.S.C. §355; 21 CFR §314.105(b) (2008).

¹³ For “new drug,” *see*, 21 U.S.C. §321(p)(1) and 21 CFR §310.3(h). For misbranding, *see*, 21 U.S.C. §352(f); 21 U.S.C. §§331, 332, 334 (a)-(b).

¹⁴ *See*, 21 CFR §§ 314.70(c)(6)(iii) (A),(C).

¹⁵ A 2008 amendment codifies the FDA’s prior policy on CBE regulation concerning “newly acquired information.” 73 Fed. Reg. 49603 - 49609.

¹⁶ *See*, 21 C.F.R. § 314.70(c)(6)(iii)(A), (C).

¹⁷ For the preemption provision applying to medical devices, *see*, 21 U.S.C. §360k(a) and *Riegel v. Medtronic, Inc.*, 552 U.S. ___, 128 S. Ct. 999, 1009, 169 L. Ed. 2d 892, 905 (“Congress could have applied the preemption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.”)

¹⁸ *See*, 71 Fed. Reg. 3922 (2006).

¹⁹ *Id.* at 3934-35.

²⁰ *But see*, *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000), where the Court did consider the regulatory scheme developed by the Department of Transportation with regard to phase-in of a mix of passive restraints designed to spur development and win consumer acceptance.

²¹ 2009 U.S. Dist. LEXIS 22598 (D. Conn. Mar. 20, 2009)

²² 2009 WL 614484 (N.J. Super. A.D. Mar. 12, 2009).

²³ 2009 U.S. App. LEXIS 6410 (3d Cir. Pa. Mar. 27, 2009).

²⁴ 2009 WL 635415 (W.D. Okla. Mar. 11, 2009)

²⁵ 2009 U.S. Dist. LEXIS 27112 (N.D. Ohio, Mar. 20, 2009).

²⁶ 2009 U.S. Dist. LEXIS 21079 (N.D. Ill. Mar. 16, 2009).

²⁷ 77 U.S.L.W. 3504 (U.S. Mar. 9, 2009)

²⁸ 77 U.S.L.W. 3504 (U.S. Mar. 9, 2009)

²⁹ 518 U.S. 470 (1996)

³⁰ *See*, Senate bill S. 540 and House bill H.R. 1346.