WYETH v. LEVINE: An Unexpected Outcome for "The Business Case of The Century."

J.L. Yranski Nasuti
Iona College, jlnasuti@iona.edu

Follow this and additional works at: http://digitalcommons.fairfield.edu/nealsb

Recommended Citation
Available at: http://digitalcommons.fairfield.edu/nealsb/vol20/iss1/1

This Article is brought to you for free and open access by DigitalCommons@Fairfield. It has been accepted for inclusion in North East Journal of Legal Studies by an authorized administrator of DigitalCommons@Fairfield. For more information, please contact digitalcommons@fairfield.edu.
WYETH v. LEVINE: AN UNEXPECTED OUTCOME FOR "THE BUSINESS CASE OF THE CENTURY."

by

J.L. Yranski Nasuti, JD, LLM*

There was much anticipation in the business world as the U.S. Supreme Court prepared to announce its decision in the case of Wyeth v. Levine.1 During the previous year, the court had ruled that, in most instances, state product liability claims could not be filed against manufacturers of medical devices that had been approved by the Federal Drug Administration (FDA).2 The hope was that the pro-business justices would extend this immunity to pharmaceutical companies who marketed FDA approved drugs. The Chamber of Commerce, which underwrote a multimillion dollar lobbying campaign to push for federal preemption as a protection against state court actions, referred to Wyeth as the “business case of the century.”3 Professor Kathleen M. Sullivan, of Stamford University, noted that “corporate America has discovered that they would much rather be regulated by one government in Washington than by 50 state governments, or by the most aggressive of them.”4 It was, therefore, quite a disappointment to Wall Street when the court ruled that federal law did not preempt state law actions against manufacturers of FDA approved drugs.

*Professor of Legal Studies in Business, Iona College, New Rochelle, NY

I. FEDERAL REGULATION OF PRESCRIPTION DRUGS

The Food and Drugs Act of 19064 was the first important federal legislation in the area of public health regulation to supplement the protection provided through state regulation and common-law liability by prohibiting the manufacture or interstate shipment of adulterated or misbranded drugs and by providing for the creation of the FDA to regulate the food and drug industries. Thirty-two years later, Congress passed the Food, Drug, and Cosmetic Act (FDCA)5 in response to growing concerns about the continued distribution of unsafe drugs and the use of fraudulent marketing. Under the FDCA, a manufacturer could not engage in the interstate marketing of a new drug until the FDA had determined that it was “safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof”.7 The FDCA’s premarket approval process required the manufacturer to submit a “New Drug Application” (NDA) to the FDA for each new drug it sought to market. If the FDA rejected a manufacturer’s application because the drug was deemed to be unsafe for use as labeled, the manufacturer was prohibited from selling that product. If, on the other hand, the FDA approved the application or failed to act within 60 days after the application was filed, the new drug was eligible for sale.8

The FDCA were altered with the passage of the Drug Amendments of 1962 (the 1962 amendments).9 One particularly significant change resulted in the shifting of the burden of proof so that the FDA no longer had to show that a drug would cause harm. The manufacturer now had the burden of establishing that its drug was both “safe and effective” and that its labeling was not “false and misleading.” That meant that the sponsor had to demonstrate that the drug was “safe for the use under the conditions prescribed, recommended, or suggested in the proposed labeling”10 and that there was
"substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling."\(^{11}\)

While the Drug Amendments of 1962 increased the powers of the FDA, they also contained a savings clause that specifically addressed the issue of the federal preemption of state law claims. That provision stated that:

Nothing in the amendments made by this Act to the federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provisions of State law.\(^{12}\)

Prior to 1976,\(^{13}\) the states had the primary responsibility for regulating new medical devices. The passage of the Medical Device Amendments of 1976 (MDA) not only authorized the FDA to regulate medical devices, as well as drugs, it also contained a federal preemption provision that expressly prohibited states and their political subdivisions from establishing, or continuing to give effect to, requirements relating to medical devices intended for human use that were either different from the requirements established under the MDA or which related to the safety or effectiveness of the device.\(^{14}\)

While Congress had never enacted a preemption provision (similar to the one contained in the MDA) for prescription drugs, the FDA attempted to rectify that omission when it inserted a substantive preemption statement into the preamble of a seemingly benign regulation concerning "Requirements on

Content and Format of Labeling for Human Prescription Drug and Biological Products, Supplementary Information (the 2006 Regulation)."\(^{15}\) The wording of the preamble, which preempted state tort claims involving FDA approved drugs, reflected an on-going policy of the Bush administration to insert preemption language into regulations relating to a variety of federally regulated products—including cars, mattresses, motorcycle brakes, and railroad cars.\(^{16}\) The preamble specifically 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 a statement that FDA has considered and found scientifically unsubstantiated . . . [or when State law] purports to preclude a firm from including in labeling or advertising a statement that is included in prescription drug labeling.\(^{17}\)

Congress overhauled the FDCA and attempted to strengthen the resources available to the FDA when it enacted the FDCA Food and Drug Administration Amendments Act of 2007 (FDAAA).\(^{18}\) Under the new amendments, the FDA was authorized, under certain circumstances, to compel label changes in the event that negotiations with the manufacturers have been unsuccessful,\(^{19}\) to require manufacturers to undertake additional safety studies even after a drug has received FDA approval,\(^{20}\) and to require a manufacturer to change its drug label based on safety information that becomes available after the FDA has initially granted approval.\(^{21}\) The FDAAA did not, however, include or endorse the preemption language contained in the preamble of the 2006 regulation.
II. THE FDA APPROVAL PROCESS

A. The Drug Application Process

The FDA’s review of a New Drug Application (NDA) focuses on whether the drug is safe and effective for its intended use. Among the items included in the NDA are “the labeling proposed to be used for such drug” (with “adequate directions for use” as well as “adequate warnings” against unsafe use and methods of administration), “full reports of investigations which have been made to show whether or not such drug [was] safe for use and whether such drug [was] . . . effective in use,” and “a discussion of why the benefits exceed the risks [of the drug] under the conditions stated in the labeling.”

The wording of the label is of particular concern to the FDA since it is a primary source of information for clinicians in making prescription decisions. A label typically includes a description of the drug’s intended uses as well as its potential risks, contraindications, warnings, precautions and adverse reactions. In the course of reviewing a NDA, the FDA and the manufacturer discuss, in detail, the wording of any proposed warnings. If the FDA approves an NDA, the manufacturer must market the drug with the specific final version of the drug’s label.

As a general rule, a manufacturer may not alter an FDA approved warning label unless the FDA approves the manufacturer’s Supplemental NDA. That having been said, the FDA’s “Changes Being Effected” regulation (CBE regulation) does allow a manufacturer to make some changes to a label after a supplemental application has been filed but prior to its approval by the FDA. The CBE regulation applies in those instances in which the manufacturer seeks 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.”

B. The FDA Approval Process for Phenergan

Promethazine hydrochloride is an antihistamine, which was developed by Wyeth Pharmaceuticals, to treat nausea. The FDA originally approved Wyeth’s NDA for the drug in 1955. Since then, Wyeth has sold the injectable drug under the brand name of Phenergan. Phenergan can be injected either intramuscularly or intravenously. An intravenous injection can be done by an “IV-push” method or an “IV-drip” method. The “IV-push” method allows the clinician to inject the drug directly into the patient’s vein. The “IV-drip” method, on the other hand, requires the clinician to place the drug into a stream of saline solution flowing from a hanging intravenous bag. The solution then slowly drips through a catheter that has been inserted into the patient’s arm.

After receiving its initial approval to market the drug, Wyeth continued to communicate with the FDA concerning issues relating to the text of the warning label for Phenergan. In 1973, 1975, and 1981, the company submitted three supplemental NDAs for the drug. The first two were approved after the FDA proposed a number of labeling changes. A third was submitted in 1981 in response to a new FDA drug labeling rule. Between 1981 and 2004, Wyeth and the FDA continued to communicate intermittently concerning the wording of the warning label. In 1987, the FDA suggested that the label be changed to address the risk of arterial exposure. Although the federal agency received a revised label from Wyeth in 1988, it never responded to Wyeth’s submission—and Wyeth continued to use the previously approved label. In fact, Wyeth
did not hear from the FDA again about the warning label until 1996—when the FDA asked to see a copy of the then in-use label for Phenergan. After Wyeth complied with that request, it was instructed by the FDA “to [r]etain verbiage in current label” as it related to intra-arterial injection and to make a few other changes—not related to intra-arterial injections. In 1998, the FDA finally approved Wyeth’s 1981 application with the provision that the final printed label “must be identical” to the approved package insert.

III. LEVINE V. WYETH—A STATE COURT ACTION

A. Background

Diana Levine, a professional musician who had played the electric bass guitar for bands such as the Re-Bops and Duke and the Detours, suffered from debilitating migraine headaches. On April 7, 2000, Levine went to the Northeast Washington County Community Health, Inc., a local health clinic in Vermont, and asked to be treated for a migraine and nausea. She was given Demerol for the pain and an intramuscular injection of Phenergan for the nausea. Later in the day, she returned to the clinic complaining of “intractable” migraines, “terrible pain,” inability to “bear light or sound,” sleeplessness, hours-long spasms of “retching” and “vomiting,” and the failure of “every possible” alternative treatment.

Jessica Fisch, the physician’s assistant, responded by administering a second dose of Phenergan—this time through a direct intravenous injection into Levine’s arm by means of an “IV push” procedure. Phenergan, a corrosive drug that is meant for infusion into a person’s vein, can cause irreversible gangrene if it inserted into a patient’s artery. Unfortunately the Phenergan given to Levine entered her artery (either because Fisch inserted the needle directly into the artery or because the drug was injected into a vein and then escaped into surrounding tissue where it came into contact with arterial blood.) In the following weeks, Levine developed gangrene—the tissue in her right forearm died, she experienced extreme pain, and her fingers slowly started to turn black. The doctors tried to stop the spread of the gangrene by amputating her right hand. When that did not work, they eventually had to amputate her entire forearm.

B. Vermont Superior Court

Levine originally sued the health center and the physician’s assistant for her pain and suffering, substantial medical expenses, and the loss of her livelihood as a professional musician. Both lawsuits were settled out of court. Levine then filed a complaint against Wyeth Pharmaceutical, the manufacturer of Phenergan, in the Vermont Superior Court, based on state common-law actions of negligence and failure-to-warn product liability. The complaint alleged that the label on the Phenergan product was defective, not because it failed to warn of the danger of gangrene and amputation following an inadvertent intra-arterial injection, but, because it failed to instruct clinicians to use the IV-drip method of intravenous infusion rather than the more dangerous IV-push method. According to Levine, “Phenergan is not reasonably safe for intravenous administration because the foreseeable risks of gangrene and loss of limb are great in relation to the drug’s therapeutic benefits.”

Wyeth filed a motion for summary judgment based on the argument that the plaintiff’s failure-to-warn claims were preempted by federal law. The trial court rejected both the defendant’s field preemption and conflict preemption arguments and concluded that the record up until that point “lack[ed] any evidence that the FDA set a ceiling on this matter.” When the case proceeded to trial, the plaintiff
presented expert evidence in support of her assertion that the risk of either intra-arterial injection or perivascular extravasation is almost completely eliminated when the drug is administered by IV-drip rather than IV-push. She also submitted evidence the correspondence between Wyeth and the FDA regarding possible changes to Phenergan’s label. The five day trial ended with the judge giving two key instructions to the jury. The first was that although the jury could consider the evidence that Wyeth had compiled with the FDA requirements, it did not have to conclude that compliance necessarily meant that the warnings had been adequate. The second crucial instruction was that FDA regulations “permit a drug manufacturer to change a product label to add or strengthen a warning about its product without prior FDA approval so long as it later submits the revised warning for review and approval.” The jury, in response to the questions on a special verdict form, found that Wyeth was liable for negligence, that Phenergan was a defective product since its warnings and instructions were inadequate, and that there was no intervening cause to disrupt the causal connection between the defendant’s negligent actions and the plaintiff’s injuries. The jury awarded the plaintiff a final damage award of $7,400,000 (which was reduced by the amount of the previous settlements with the physician’s assistant and the health center).

The defendant then filed a motion for judgment as a matter of law—which was based on preemption arguments. On August 3, 2004, the trial judge rejected the motion on three grounds. The first was that there was no direct conflict between FDA regulations and Levine’s state-law claims. Not only did the FDA regulations permit strengthened warnings without its approval on an interim basis but Wyeth had been aware of at least 20 reported cases of gangrene amputations similar to Levine’s since the 1960’s. The second ground was that Levine’s state tort liability claim did not obstruct the FDA’s work. In fact, the federal agency had not spent much time addressing the question of whether to warn against the I-V push administration of Phenergan. Finally, the court emphasized the compensatory function of the state law action that was absent from the federal regulation.

C. Supreme Court of Vermont

On appeal to the Supreme Court of Vermont, Wyeth claimed that the trial judge erred in allowing the jury to consider the plaintiff’s claims (since they conflicted with the defendant’s obligations under federal law and were therefore preempted) and in failing to properly instruct the jury on the issue of damages. In a 4-1 decision, the appellate court affirmed the lower court decision in its entirety—rejecting the defendant’s preemption arguments on the grounds that Wyeth could have changed the warning concerning the IV-push administration of Phenergan without prior FDA approval and that the “federal labeling requirements create a floor, not a ceiling, for state regulation.”

In order to determine if the doctrine of preemption applied in this case, the majority relied on the following analytical model:

Congress’ intent may be explicitly stated in the statute’s language or implicitly contained in its structure or purpose. In the absence of an express congressional command, state law is preempted 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.
It also noted that the presumption against preemption (absent a clear congressional intention to supersede state law, including state common law duties)43 has "added force" when there is a "long history of tort litigation" in the area of state common law at issue.44 Since Wyeth had conceded that Congress had not expressly preempted state tort actions through the FDCA and did not intend the FDCA to occupy the entire field of prescription drug regulation, the court only considered whether it was "impossible for the private party [Wyeth] to comply with both state and federal requirements" and whether Vermont's common-law "stands as an obstacle to the accomplishment and execution of the full purposed and objectives of Congress."45

The court found no conflict, in general, between federal labeling requirements and state failure-to-warn claims based on the ability of the manufacturer, under the provisions of the CBE regulation, to add to and strengthen its already approved warnings.46 This finding was supported by the nearly unanimous conclusion by other courts that failure-to-warn claims are permissible in state courts.47 Wyeth's attempt to draw a comparison to medical devise cases was unsuccessful since the FDCA's preemption clause only applied to medical devises and not to prescription drugs.48 The majority also rejected the argument that it should follow the conflict preemption precedent established by U.S. Supreme Court in the case of Geier v. American Honda Motor Co.49 In that instance the plaintiff's state tort claim was held to be in direct conflict with Department of Transportation's specific phase-in plan for safety devices and its intent to broaden the range of safety options available to consumers. The key difference between Geier and drug warning label cases was that "the FDA and the state share the purpose of encouraging pharmaceutical companies to alter their drug labels when they are inadequate to protect consumers."50

The court then considered whether the specific facts in the case before it justified a preemption of the state claims based on an impossibility of compliance claim. Wyeth had asserted that it could not comply with state law requirements since the FDA had approved the label in use at the time of Levine's injury. The court noted that the approval of the Phenergan warning label should not preclude a jury from finding that the label was insufficient since the company had the possibility, under the CBE regulation, to strengthen its warning with respect to the IV-push administration of Phenergan.51 It also rejected Wyeth's suggestion that when the FDA approved the label in 1998, with the instruction to "[r]etain the same verbiage" (rather than with the changes suggested by Wyeth in 1988), it was stating its opinion that the stronger warning was unnecessary. The problem with Wyeth's argument was that the label changes that it proposed in 1988 were no more adequate than the original label in warning against the IV-push administration of Phenergan.52

Wyeth was also unpersuasive in its claim that the Vermont common-law liability in this case would be an obstacle to the purposes and objectives of Congress. The court found that primary goal of the FDCA was to protect consumers from dangerous products53 and the purposes and objectives of Congress in the regulating the marketing of prescription drugs was merely to set the minimum standards under which a manufacturer must comply.54 The fact that the 1962 amendments expressly limited the preemptive effect of the statute unless there is a "direct and positive conflict" between state and federal law enabled the court to conclude that "where it is possible to comply with both state law and the FDCA, the state law is consistent with the purposes and objectives of Congress."55
The discussion of the preemption issue concluded with an analysis of the preemption statement that the FDA had inserted into the preamble to the 2006 regulation. Although the court acknowledged that it is ordinarily required to defer to an agency's interpretation of the statute that it administers, it refused to do so in this case.\textsuperscript{58} Deference is appropriate when a statute is "silent or ambiguous with respect to the specific issue"—it is not appropriate when it contradicts the "unambiguously express intent of Congress."\textsuperscript{59} In this case, Congress had spoken on the issue. The FDCA provided for the express preemption of state laws (in drug regulation matters) only if it was impossible for a manufacturer to comply with both federal and state requirements. Since the CBE regulation already allowed a manufacturer to unilaterally add or strengthen a label warning, the issue of impossibility was not present.

In his dissenting opinion, Chief Justice Reiber argued that Levine’s common-law claims were in conflict with federal law for two reasons. The first was that it would be impossible for Wyeth to comply with both the state and federal requirements. The FDA had approved the administration of Phenergan by the IV method and it had required Wyeth to list the IV administration on its label. If Wyeth altered the label to comply with state law it would have to eliminate an FDA approved use from the label—and that would make it impossible for the company to comply with the state and federal laws.\textsuperscript{60} The second was that allowing the plaintiff’s state law claims to go forward would present an obstacle to federal purposes and objectives. While the goal of the FDA is to ensure that the drugs in the marketplace are safe, it does so knowing that no drug is without risks. When the FDA considers whether to approve a NDA, it engages in a risk-benefit analysis with the intention of maximizing the availability of beneficial treatments. A state court jury, on the other hand, “does not engage in a measured and multi-faceted policy analysis. Rather, a jury views the safety of the drug through the lens of a single patient who has already been catastrophically injured.”\textsuperscript{61} The result is that a jury’s verdict that a drug was unreasonably dangerous can frustrate the FDA’s wider public health assessment that the drug is safe and effective.

IV. \textit{WYETH v. LEVINE}—U.S. SUPREME COURT DECISION

A. Majority Decision

The U.S. Supreme Court, in a six to three decision, with two concurrences and one dissent, affirmed the lower court decisions in favor of the plaintiff.\textsuperscript{62} The issue that Wyeth presented on appeal was “whether prescription drug labeling judgments imposed on manufacturers by the Food and Drug Administration . . . pursuant to FDA’s comprehensive safety and efficacy authority under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., preempt state-law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.”\textsuperscript{63} Justice John Paul Stevens, writing for the majority, addressed the somewhat different issue of whether the FDA’s approval of Phenergan provided Wyeth with a complete defense to Levine’s common-law negligence and strict liability claims—and answered the question in the negative.\textsuperscript{64}

Before discussing the preemption issue, Stevens highlighted two important findings of fact that had been decided at the trial level and identified two legal principles that were essential to his analysis of the case. The first factual finding was that
Levine’s arm would not have developed gangrene if the Phenergan label had adequately warned of the risks of administering the drug by the IV-push method. The fact that the physician assistant’s administered a greater than recommended dose of the drug (which may have inadvertently entered an artery rather than a vein) was a foreseeable intervening force—and the inadequate label was both a but-for and a proximate cause of Levine’s injuries. The second jury finding was that the lack of an adequate warning about the risks of an IV-push administration of Phenergan was the critical defect in its warning label. That the jury found the warning to be insufficient did not, however, mean that it had mandated a particular replacement label nor did it require the contraindicating of IV-push administration.

Stevens then summarized the two legal cornerstones of preemption jurisdiction. The first was the principle that “the purpose of Congress is the ultimate touchstone in every preemption case.” The second was that in those preemption cases in which Congress has legislated in a field traditionally occupied by the States, 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.

Wyeth had argued that Levine’s state tort actions were preempted because of the impossibility of complying with a state-law duty to modify the drug’s label without violating federal law and because a state tort action created an unacceptable “obstacle to the accomplishment and execution of the full purposes and objectives of Congress” since it allowed a jury’s decision about a drug label to trump the expert judgment of the FDA. Stevens found both arguments to be without merit.

1. Impossible to Comply

Wyeth’s impossible to comply argument was based on the premise that, once the FDA has approved a drug warning label, the manufacturer could not change the wording of the label until a supplemental application was filed with, and approved by, the FDA. Wyeth argued that it could not have relied on the CBE regulation to unilaterally change the warning label for Phenergan since the CBE regulation had been amended so that it only applied to cases in which the labels would “reflect newly acquired information.” Since Levine presented no new evidence (which the FDA had not already considered) concerning the risks of the IV-push administration, Wyeth claimed that it would have been impossible to change the label to meet state-law obligations without violating federal law.

Stevens dismissed Wyeth’s argument as a “misapprehension both of the federal drug regulatory scheme and its burden in establishing a pre-emption defense.” He found no need to consider the merits of Wyeth’s contention that the 2008 amendment of the CBE regulation was consistent with the FDC and the regulation in effect at the time of Levine’s injection since the “newly acquired information” that is referred to in the regulation applies to “new analyses of previously submitted data” and not just to new data. According to the amended CBE regulation:

[If the sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirements for newly acquired information.]
The majority opinion acknowledged that the trial record was “limited concerning what newly acquired information Wyeth had or should have had about the risks of IV-push administration of Phenergan.” There was, however, evidence of at least 20 instances in which a Phenergan injection had resulted in gangrene and amputations. Wyeth had notified the FDA after the first case came to its attention in 1967—and had worked with the FDA to change the label. The court suggested that after it became aware of the additional amputations, Wyeth could have analyzed the accumulating data and added a stronger label warning about the IV-push method of administration.

Stevens presented also two reasons for rejecting Wyeth’s assertion that its unilateral change to the warning label would have constituted an unauthorized distribution and misbranding of the drug. The first was that Wyeth was incorrect when it assumed that a drug would be considered a new drug (without an effective application) if a change had been made to its label. Under the FDCA, the unilateral strengthening of an already approved warning label would not, in fact, change the drug into a new drug. The second problem was Wyeth’s failure to understand that the mislabeling provision of the FDCA did not focus on the alteration of an FDA approved label but rather on the substance of the label—including its failure to include “adequate warnings.” Whether a drug has been misbranded is a matter for a federal jury to ultimately decide. And, neither Wyeth nor the government, in its amicus curiae brief, was able to identify even one instance in which the FDA had initiated an enforcement action against a manufacturer for strengthening a warning label as provided for under the CBE regulation.

The Supreme Court credits “Wyeth’s cramped reading of the CBE regulation and its broad reading of the FDCA misbranding and unauthorized distribution provisions” to the company’s suggestion that the FDA, and not the manufacturer, has the primary responsibility for the content of a drug label. Such a suggestion is in opposition to the central premise of federal drug regulation. Both the amendments to the FDCA and FDA regulations designate the manufacturer as the party responsible for “crafting an adequate label and [for] ensuring that its warnings remain adequate as long as the drug is on the market.” The passage of the FDAAA, in 2007, may have authorized the FDA, under some circumstance, to order manufacturers to revise their labels but it also reaffirmed the manufacturer’s obligations— including those specifically referred to in the CBE regulation. Consequently, Wyeth had an obligation to change its warning label to adequately describe the risk of gangrene from IV-push injections of Phenergan—and was permitted to do so, under the CBE regulation, even before it received FDA approval.

While it is true that the FDA may ultimately reject unilateral labeling changes made pursuant to the CBE regulation, there was no evidence that it would have done so for changes in the Phenergan label. Wyeth did not allege that it was prohibited by the FDA from trying to give the kind of warning that the Vermont jury sought. The Vermont Superior Court found, as a matter of fact, that there was “no evidence in the record that either the FDA or the manufacturer gave more than passing attention to the issue of” the IV-push versus IV-drip administration of Phenergan. The Vermont Supreme Court also concluded that there was no record of the FDA’s intention to either preserve the IV-push method or to prohibit the manufacturer from strengthening the warning with regard to the IV-push method. Finally, Wyeth itself never alleged that it had supplied the FDA with an evaluation or analysis of the specific dangers associated with the IV-push method. Consequently, the U.S. Supreme Court rejected Wyeth’s claim.
that it would have been impossible to comply with the state and federal requirements since there is no evidence that the FDA would have prevented it from adding a stronger warning to the Phenergan label.

2. Obstruction of Purposes and Objectives of Regulation of Congress

Wyeth’s second preemption argument was based on the theory that if it complied with the state-law duty (to provide a stronger warning on the Phenergan label), it would, in fact, obstruct the purposes and objectives of the federal regulatory scheme (including the need for FDA officials to use their expert knowledge to strike a balance between competing objectives of safety and efficiency). Stevens rejected this claim on the grounds that it was faulty in its interpretation of congressional intent and represented an overboard view of the agency’s power to preempt state law.

Congress enacted the Food and Drug Act and the FDCA to supplement, but not replace, the protections already available to consumers under state laws. Neither the acts nor their subsequent amendments provided any federal remedies to injured consumers. Stevens suggested two reasons for this omission. The first was that widely available state remedies already provided appropriate relief. The second was that the possibility of costly state remedies promoted consumer protection by motivating manufacturers to be more vigilant in producing safe products with adequate warning labels.

Another significant matter contributing to the majority’s decision was the fact that Congress had never amended the FDCA to expressly preempt state law suits involving prescription drugs. Congress could have drafted a general preemption clause for the FDCA when it included the specific preemption provision in the Medical Devices Amendments in 1976. The fact that it was silent on the issue at a point in time (when it was certainly aware of the prevalence of state court litigation) convinced Stevens that Congress “did not intend the FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.”

Wyeth had suggested that one of the ways that state lawsuits obstructed the purposes and objections of the federal regulation of drugs was that they did not take into account the balancing of risks and benefits that inform the FDA in its decision making process. The FDA itself had stated in the preamble to the 2006 regulation that the FDCA established “both a floor and a ceiling” for the regulation of drugs. It then proceeded to articulate its conclusion that state laws and state law actions, including failure-to-warn claims, were an obstacle to achievement of the full objectives and purposes of the federal regulatory law since they “threaten FDA’s statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs.”

Stevens found Wyeth’s reliance on the FDA’s preamble to the 2006 regulation to be less than convincing. While it is true that a federal regulation may preempt conflicting state laws, preemption is not guaranteed if the agency acts without congressional authorization. An agency’s mere assertion that state law has been preempted because it is an obstacle to statutory objectives cannot survive a judicial determination to the contrary. One of the problems with the FDA’s preamble statement was that it directly contradicted the FDA’s notice of proposed rulemaking for the 2006 regulation. That notice specifically stated that the rule “would not contain policies that have federalism implications or preempt State Law.” Consequently, when the FDA finalized the rule with its new articulation of the FDCA’s preemptive effect in the preamble,
it did so without giving the states or other interested parties notice of the proposed change or opportunity to comment it.93

The preamble was also suspect since it reversed two of the FDA’s longstanding positions (that the federal labeling standards were a floor upon which the states could build and that the FDA would not attempt to preempt failure-to-warn claims) without providing a reasoned explanation for the change.94 Prior to 2006, both Congress and the FDA have treated state law as a complementary form of drug regulation and had traditionally relied on state tort suits to “uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly.”95

The court also rejected Wyeth’s claim that the alleged conflict between federal and state law in the present case was analogous to the one that supported the car manufacturer’s preemption claim in the Geier v. American Honda Motor, Co.36 In that case, the Department of Transportation had formulated the regulatory scheme (which allowed car manufacturers to satisfy a safety requirement by choosing from a range of passive restraint devices) after it had conducted a formal rulemaking and then adopted a phase-in plan. Unlike the FDA’s nonexistent record to explain the basis for the changes announced in the 2006 preamble, the Department of Transportation’s contemporaneous record “revealed the factors the agency had weighed and the balance it had struck.”97

For all of the above reasons, Stevens concluded that preamble of the 2006 regulation did not merit deference, that it was plausible for Wyeth to comply with the state and federal laws, and that Wyeth’s obstruction of purposes and objectives claims were insufficient to preempt Levine’s common law claims.

B. Concurring Opinions

1. Justice Breyer

The Justice Stephen Breyer’s concurring opinion was very brief. His primary concern was to emphasize that the reason the majority arrived at its opinion was because there was “no occasion in this case to consider the preemptive effect of a specific agency regulation bearing the force of law.”98 As such, this decision would not preclude the court from deciding in the future that FDA had sought to determine whether and when state law acts had become a hindrance to achieving the congressional goal of safe drug-related medical care and had embodied those determinations in lawful regulations that had a preemptive effect.

2. Justice Thomas

Justice Clarence Thomas filed an opinion that concurred in the judgment but did not join the majority’s implicit endorsement of a far-reaching implied preemption doctrine that “routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are embodied within the text of federal law.”99 His approach was based on his more traditionally conservative view of the “delicate balance of power mandated by the Constitution.”100

The recurring theme in Thomas’ concurring opinion was his conviction that the question of preemption had to turn on whether state law conflicted with the text of the relevant federal statute or with the federal regulations authorized by that text. Since the texts of the statutory and regulatory scheme did not guarantee that a company was insulated from liability under state law once it received an FDA-approval for a
particular drug label, there was no “direct conflict” between the federal law and state law and a judgment based on the state law could not be preempted.101

C. Dissenting Opinion

In his dissenting opinion, Justice Samuel Alito characterized the Wyeth case as an illustration of the proposition “that tragic facts make bad law.”102 Alito found it incomprehensible that the majority would allow a state tort jury, rather than the FDA, to have the ultimate responsibility for regulating the warning labels for prescription drugs. Such a result was possible only because the Court had ignored its own precedent in the case of Geier103 and had disregarded the general principles of conflict preemption.

The minority was convinced that the proper framing of the issue in this case should have been “whether a state tort jury can countermand the FDA’s considered judgment that Phenergan’s FDA-mandated warning renders its intravenous (IV) use “safe.”104 Alito emphasized the importance of a drug’s warning label. Not only is it “the standard under which the FDA determines whether a product is safe and effective,”105 it is also the “ centerpiece of risk management” . . . “as it communicates to health care practitioners the agency’s formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively.”106 When the FDA follows its statutory mandate and determines that a drug is on the balance “safe,” its judgment should not be countermanded by a conflicting determination under state common-law. The conflict itself is the basis for federal preemption—even in those instances where Congress has not enacted an express preemption.107

Alito then went on to demonstrate how the court, in Geier, was able to apply the conflict preemption doctrine to a situation where the regulatory statute contained a savings clause.108 A key factor in that case was the view of the Secretary that the Department of Transportation’s decision to allow the auto makers to choose from a number of safety options was the best way to promote safety. “Because the Secretary determined that the menu of alternative technologies was “safe,” the doctrine of conflict preemption barred [the plaintiff’s] efforts to deem some of those federally approved alternatives “unsafe” under state tort law.”109 The minority thought the court should have applied its rationale in Geier to the present case—in which the FDA had deemed the methods of alternative administration provided in the menu on the Phenergan label to be “safe” and “effective.”

The remainder of the dissenting opinion was devoted to a discussion of the three categories of reasons why the majority of the court failed follow its own precedent in Geier. The first was factual. The minority suggested that the court had willfully disregarded the fact that the FDA had considered (and struck a balance between) the costs and benefits attached to the IV push method.110 The second was legal. The court had denied the existence of a federal-state conflict in this case;111 it dismissed the FDA’s articulation of its preemptive intent in the preamble to the 2006 regulation on the grounds that the interested parties were not afforded notice or an opportunity for comment;112 it determined that the FDA’s preamble, unlike the Department of Transportation’s regulation, did not “bear the force of law;”113 it “sandwiched” its discussion of Geier between its discussion of the “presumption against preemption” and its lengthy consideration of the traditional coexistence of state and federal law in the area of drug regulation;114 and it appeared to completely disregard the FDA’s explanation, in its amicus brief, with regard to the
conflict between state tort cases and the federal labeling regime. And, the third reason was judgmental. The court had decided to recklessly allow ill-equipped juries to perform the FDA's cost-benefit balancing functions.

V. CONCLUSIONS

The Supreme Court's decision in Wyeth v. Levine was certainly disappointing to many in the business community. This was particularly true for companies producing commodities that are regulated by the federal government. If the court had preempted the state product liability actions against drug companies, there was hope that it would eventually extend that same preemption protection to product liability cases involving manufacturers of products as diverse as antifreeze, fireworks, popcorn, cigarettes, and light bulbs. It would also have allowed companies to concentrate on complying with only one set of regulatory laws.

In recent years, business has found many sympathetic allies in Washington, D.C. The Bush administration "encouraged federal agencies to issue rules preempting state laws and declared that a single federal standard held sway." The court used theories of express and implied preemption to limit the ability of injured parties to sue manufacturers in state court. There has, however, been some shifting of sympathies under the Obama administration. On January 20, 2009, a memorandum was sent to federal agency heads instructing them to stay pending or recently completed rules. On March 4, 2009, the Supreme Court rejected the preemption arguments of Wyeth (and the Bush administration's amicus brief in support of Wyeth). A week later, the Office of Budget and Management issued a statement that it had taken note of the principles in Wyeth and intended to provide adequate notice and comment periods for federal regulations and to instruct federal agencies to preempt state tort laws only when Congress intends it to do so. Finally, on May 20, 2009, President Obama issued a revised Executive Order 13132 instructing federal agency heads to roll-back the prior administration's attempts to issue regulations that were designed to protect companies from state court lawsuits and that were not justified.

ENDNOTES

1 129 S. Ct. 1187 (2009).
7 Id. at § 505(a), (d), 52 Stat. 1052.
8 Id. at § 505(c), 52 Stat. 1052.
10 Id. at § 102(d), 104(b), 76 Stat. 781, 784.
11 Id. at § 102(d), 76 Stat. 781.
12 Id. at § 202, 76 Stat. 793.
14 21 U.S.C. § 360k(a). "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.
also attempted to preempt state tort law actions for the following products regulated by the FDA: skin bleaching products, OTC drugs in trial sample packages, OTC analgesics, sunscreen products, fatty acids, pregnancy and lactation labeling, noncarcinogenic sweeteners, OTC dandruff products, OTC laxatives, dietary sweeteners, OTC contraceptives, skin protectant drug products, soluble fiber (used for coronary heart disease.)


Supra, n. 15, at 3935.

Id. at Tit. IX, § 901(a), § 505(o)(4), 121 Stat. at 924-26. This can only be done if the FDA promptly notifies the manufacturer that it has become aware of new safety information that the FDA has determined needs to be included on the label. The manufacturer then has 30 days to either submit a supplement with proposed labeling changes that reflect the new safety information or to notify the FDA that it does not think that a new label is necessary. If the FDA either rejects the manufacturer's proposed wording or if the manufacturer claims that no change is needed, the FDA must attempt to work out some kind of agreement with the manufacturer. Should that fail, the FDA may then issue an order requiring the manufacturer to make the changes that the FDA has recommended. Although there is an agency appeal process, the FDA clearly has the ability to make the final determination with regard to the wording of the label.

Id. at Tit. I, § 104, § 736A, 121 Stat. 823, 832-40.

Id. at Tit. IX, § 901(a), id. at 924-926.

Supra, n. 6, at § 505(b), 52 Stat. at 1052; (codified at 21 U.S.C. § 355(b)(1)); see 21 C.F.R. 314.50(c)(2)(i) and (e)(2)(i).

Id. at §§ 201(p), 301(a), 502, 505(a), (d), 52 Stat. at 1041-1042, 1050-1052 (codified as amended at 21 U.S.C. §§ 321(p), 331 (a), 352, 355(a), (d)).

Id. at 21 U.S.C. 355(b)(1)(A).

21 C.F.R. 314.50(d)(viii); see 21 C.F.R. 314.50(c)(2)(ix).


21 C.F.R. § 314.70 (c)(6).

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

Wyeth’s proposal for a revised warning label read in relevant part:

INADVERTENT INTRA-ARTERIAL INJECTION: There are reports of necrosis leading to gangrene, requiring amputation, following injection of

[Phenergan], usually in conjunction with other drugs; the intravenous route was intended in these cases, but arterial or partial arterial placement of the needle is now suspect.

There is no established treatment other than prevention:

1. Be aware of close proximity of arteries and veins at commonly used injection sites and consider the possibility of aberrant arteries.

2. When used intravenously, [Phenergan] should be given in a concentration no greater than 25 mg/ml and at a rate not to exceed 25 mg/minute. Injection through a properly running intravenous infusion may enhance the possibility of detecting arterial placement. In addition, this results in delivery of a lower concentration of any arteriolar irritant.

3. Supra, n. 1, at 1192, citing App. at 395.

Id. at 1192, citing App. at 382.

Id. at 1226, citing App. 40 (testimony of Dr. John Matthew; id., at 103, 106, 109 (testimony of physician’s assistant, Jessica Fisch).

Through the process of perivascular extravasation.

Failure-to-warn cases, brought by consumers who have been injured by dangerous drugs, have their roots in common-law cases that established a high degree of responsibility for those businesses that sold food for human consumption. Restatement (Second) of Torts § 402A cmt. b. (1965).

The 2002 warning on the Phenergan label read in relevant part:

“INADVERTENT INTRA-ARTERIAL INJECTION: Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of [Phenergan], usually in conjunction with other drugs intended for intravenous use, suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances. Intravenous injection was intended in all the cases reported but perivascular extravasation or arterial placement of the needle is now suspect. There is no proven successful management of this condition after it occurs . . .

When used intravenously [Phenergan] should be given in a concentration no greater than 25 mg per ml and at a rate not to exceed 25 mg per minute. When administering any irritant drug intravenously it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily.”
38 Supra, n. 1, at 1192, citing App. 14-15.
39 Id., at 1192.
40 This is in part because the IV drip begins with a saline drip that will only flow if the catheter is in a vein and will not work if the saline fluid is attempting to enter an artery or surrounding tissue.
41 Supra, n. 1, at 1193, citing App. at 228.
42. Id. at 1193, citing App. at 249-252.
48 Id. at 87.
50 Id. at 89-90.
51 529 U.S. 861; 120 S. Ct. 1913 (2000). In Geier, the Court preempted state tort claims based on manufacturer’s failure to provide airbags in its cars since the Department of Transportation had specifically designated a range of permissible safety options, including those that did not involve the use of an airbag, as a way of gradually phasing in auto safety requirements.
52 Supra, n. 43, at 90.
53 Id. at 91.
54 Id. at 93. See n. 31 and n. 37.
56 Id. at 93, citing McNellis, supra, n. 49.
57 Id. at 95.
59 Id. at 97, quoting id., Chemova, at 842-843.
60 Id. at 104.
61 Id. at 112.
62 The majority decision was delivered by Justice John Paul Stevens and joined by Justices Anthony Kennedy, David Souter, Ruth Bader Ginsburg, and Stephen Breyer. Justice Breyer filed a concurring opinion and Justice Clarence Thomas filed an opinion concurring in judgment. The dissenting opinion was filed by Justice Samuel Alito and joined by Chief Justice John Roberts and Justice Antonin Scalia.
63 Pet. For Cert. at i.
64 Supra, n. 1, at 1191.
65 Id. at 1194.
66 Id. at 1194.
67 The importance of this clarification by Stevens is to remove from the discussion the question of whether a state rule precluding intravenous administration is preempted.
68 Supra, n. 1, at 1194, citing Metronic, supra, n. 45, at 485.
69 Id. at 1194-1195, citing Metronic, supra, n. 45, at 485 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 239, 67 S. Ct. 1146 (1947)).
70 Id. at 1193, citing Hines v. Davidowitz, 312 U.S. 52, 67, 61 S. Ct. 399 (1941).
71 73 Fed. Reg. 49603, 49609. Even though the regulation was not changed until 2008, Wyeth contended that it simply reaffirmed the interpretation of the regulation that was in effect when the present case was tried in Vermont.
72 Supra, n. 1, at 1196.
73 Id., at 1197.
74 Id. at 1197.
75 Id. at 1197. (During the course of the trial, Wyeth had not argued that such information was required for a CBE labeling change.)
77 Id. at 1197. See 21 U.S.C. § 352(f).
78 Id. at 1197. See 21 U.S.C. §§ 331, 332, 334 (a)-(b).
79 Id. at 1197.
80 Id. at 1198, citing 21 CFR §201.80(e) (requiring the manufacturer to revise a label “to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug”); 21 U.S.C. 314.80(b)
(placing responsibility for postmarketing surveillance on the manufacturer); 73 Fed. Reg. 49605 ("Manufacturers continue to have a responsibility under Federal law . . . to maintain their labeling and update the labeling with new safety information.") 81 The FDAAA specifically states that the manufacturer retains the responsibility "to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of Title 21, Code of Federal Regulations (or any successor regulations.)" 121 Stat. 925-926.

82 Supra, n. 1, at 1198.
83 Id. at 1199, citing App. 249.
84 Id. at 1199, citing supra, n. 43, at 93.
85 Id. at 1199.
86 Id. at 1199, citing Kordel v. United States, 335 U.S. 345, 349; 69 S. Ct. 106 (1948); Sullivan, supra, n. 55, at 696.
87 Id. at 1199-1200.
88 Id. at 1200.
89 Supra, n. 15, at 3934-3935.
90 Id. at 3935.
93 Supra, n. 1, at 1201.
94 Id. at 1201-1202.
95 Id. at 1202.
96 Supra, n. 51.
97 Supra, n. 1, at 1203.
98 Id. at 1204.
99 Id. at 1204.
100 Id. at 1206.
101 Id. at 1211.
102 Id. at 1217.
103 Supra, n. 51.
104 Supra, n. 1, at 1217.
107 Supra, n. 1, at 1220.
108 Id. at 1221.
109 Id. at 1221.
110 Id. at 1222.

111 Id. at 1227.
112 Id. at 1227.
113 Id. at 1228.
114 Id. at 1228.
115 Id. at 1229.
116 Id. at 1229.