

CONSUMER NEWS

SUPPORTERS AND OPPONENTS OF FEDERAL PREEMPTION TAKE SIDES, ANTICIPATE HIGH COURT'S RULING ON THIRD FDA PREEMPTION CASE THIS YEAR

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This fall term, on November 3, the Supreme Court is scheduled to hear oral argument in *Wyeth v. Levine* (No. 07-562).¹ The latest in a trilogy of FDA Preemption cases to make their way to the Court, *Levine* has been dubbed “the most highly anticipated pharmaceutical products liability ruling since the Court’s 1993 decision in *Daubert v. Merrell Dow Pharmaceuticals*.”² “The outcome of this case will affect the fate of hundreds of state tort suits, consumer protection actions of state attorneys general, and the role of the states in our federal government,” says Massachusetts Attorney General Martha

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¹ *High Court Schedules Arguments in Drug Preemption Case*, FDA WEEK (Aug. 1, 2008).

² Jennifer Dukart, *The Last Word on Drug Preemption? Like Colacicco, Levine Ruling May Cut Narrowly*, MONDAQ BUSINESS BRIEFING (July 9, 2008). In *Daubert*, the Court applied the new Federal Rules of Evidence governing expert testimony, holding that the trial judge should be a gatekeeper, allowing evidence in only if it is found to be scientifically valid and relevant, and in so doing supplanted the common-law test of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), under which evidence was admissible if it was generally accepted in the relevant scientific community. *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

Coakley.³ The long list of amicus curiae briefs filed on behalf of both parties by industry groups, government entities, consumer groups and individuals bears this out.

THE TRILOGY

It has been said that all good things, and some bad, come in threes. In February, the Court ruled 8-1 in the first of the three FDA preemption cases, *Riegel v. Medtronic*, that the Medical Device Amendments of 1976 (MDA),⁴ preempt state tort claims.⁵ The decision protects manufacturers from liability for injuries caused by medical devices that have received pre-market approval from the FDA, when the state claims against that manufacturer are found to impose requirements that are “different from, or in addition to,” FDA requirements.⁶

In *Riegel* the Court was asked to interpret an express preemption provision Congress had deliberately written into the MDA.⁷ The FDCA provisions governing pharmaceuticals, however, contain no such provision. In *Warner-Lambert v. Kent*, the second case in the trilogy, the Supreme Court was asked to decide whether state court claims that were preserved by a complicated exception to the Michigan products liability statute were nevertheless impliedly preempted by FDA pre-market drug approval.⁸

³ *Attorney General Coakley Joins Vermont, 45 Other States in Asking Supreme Court to Uphold Vermont Supreme Court Decision Protecting Pharmaceutical Consumers*, US STATE NEWS (Aug. 19, 2008).

⁴ See 21 U.S.C. § 360c *et seq.* The MDA amended the Food Drug and Cosmetics Act (FDCA). 21 U.S.C. § 301 *et seq.*

⁵ *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1011 (2008).

⁶ *Id.*

⁷ See 21 U.S.C.S. § 360k(a) (“State and local requirements respecting devices (a) General rule. Except as provided in subsection (b), 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 Act [21 U.S.C.S. §§ 301 *et seq.*] 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 Act [21 U.S.C.S. §§ 301 *et seq.*].”)

⁸ *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 89 (2d Cir. 2006) *cert. granted*, 128 S. Ct. 31 (2007). Federal law can preempt state law in three ways: (1) Express Preemption: Congress makes its intent to preempt state law explicit in a federal statute; (2) Implied Field Preemption: “State law regulates conduct in a field that Congress intended the federal government to occupy

Although the Michigan statute generally protects a manufacturer from common law liability if its drug has received FDA approval, an exception provides that if the manufacturer withheld or misrepresented information in the approval process that would have affected the FDA's decision to approve the drug, it can still be sued.⁹ The Second Circuit held that common law causes of action surviving this exception were not preempted by federal law.¹⁰ On appeal, the Supreme Court split 4-4 (Chief Justice John Roberts was recused), allowing the Second Circuit's ruling to stand, but providing little guidance for manufacturers and plaintiffs with its one-sentence decision.¹¹

The same issue in *Kent* - preemption of state claims alleging injuries sustained from FDA approved drugs - is again before the Court in *Levine*, this time free from the complicated backdrop of the Michigan products liability statute, and with all nine justices hearing the case. Commentators have predicted that the addition of Chief Justice Roberts, who voted with the majority for preemption in *Riegel* but did not participate in *Kent*, will be enough for the Court to find preemption and issue a binding decision.¹²

The plaintiff in *Levine* was awarded more than \$6 million by a Vermont jury in a suit against the drug manufacturer Wyeth, brought under a failure-to-warn theory.¹³ Levine was administered Wyeth's drug Phenergan at a hospital to treat nausea related to a migraine headache.¹⁴ The hospital administered the drug using the disfavored IV push method, rather than injecting it intramuscularly.¹⁵ The drug was inadvertently injected into an artery, causing Levine to develop gangrene in her arm, which had to be amputated.¹⁶

Although the label for Phenergan warned of the risk of gangrene, the plaintiff argued that the label should have specifically prohibited administration by the IV push method

exclusively"; and (3) Implied Conflict Preemption: "State law actually conflicts with federal law." *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990).

⁹ *Desiano*, 467 F.3d at 88.

¹⁰ *Id.* at 98.

¹¹ *Warner-Lambert Co., LLC v. Kent*, 128 S. Ct. 1168 (2008), *aff'g an equally divided Court* 467 F.3d 85 (2d Cir. 2006).

¹² *Dukart*, *supra* note 2.

¹³ *Levine v. Wyeth*, 944 A.2d 179, 182 (Vt. 2006).

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

altogether.¹⁷ The Vermont Supreme Court found Levine's claim was not preempted, emphasizing an FDCA provision that allowed manufacturers, when necessary, to alter a drug's label without first obtaining FDA approval, thereby making the FDA-approved label the minimum, not the mandated, standard.¹⁸ The court noted that the FDCA "does not allow us to interpret FDA approval of a drug label as anything but a first step in the process of warning consumers," and found that the manufacturer could have complied with the FDA's minimum standard and still met state common law requirements for effective warning labels.¹⁹ The court also cited a provision from the 1962 amendment to the FDCA, stating "[n]othing 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 . . . unless there is a direct and positive conflict between such amendments and such provision of State law."²⁰

THOSE IN FAVOR OF FDA PREEMPTION

In the current appeal before the Supreme Court the Pharmaceutical Research and Manufacturers of America (PhRMA), emphasizing the danger of over-warning, have filed a brief in support of Wyeth, arguing that the threat of liability under state law would cause manufacturers to warn of even speculative and unsupported risks, "ultimately dilut[ing] the

¹⁷ *Id.*

¹⁸ *Id.* at 185-86. Note that on August 22, 2008, the FDA published a final rule entitled "Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices," which modifies 21 C.F.R. 314, 601 and 814. The rule addresses the "changes being effected" (CBE) provision cited by the Vermont Supreme Court in *Levine*. It states that a CBE supplement to the label of a drug or device should only be used "to reflect newly acquired information," and must reflect "reasonable evidence of a causal association," before the warning label can be strengthened. Before this rule, plaintiffs like *Levine* could argue that the CBE provision allowed manufacturers to easily comply with stricter state law requirements. The amendment, which the FDA claims is merely a codification of its long-standing interpretation, has been criticized by the American Association for Justice (AAJ) as "irrational and designed to assist the manufacturers." *FDA Issues Final Rule on Controversial Change to Labeling Rules*, FDA WEEK (Aug. 22, 2008).

¹⁹ *Levine*, 944 A.2d. at 188.

²⁰ *Id.* at 190 (citing Drug Amendments of 1962 (Harris Kefauver Act), Pub. L. No. 87-781, § 202, 76 Stat. 780, 793(1962)).

impact of scientifically valid warnings and discourag[ing] physicians and patients from using beneficial drugs.”²¹ The pharmaceutical industry group also recited what has become its common threat, that liability risks would deter the development or marketing of crucial and beneficial drugs.²²

The Bush administration, representing the FDA,²³ also filed a brief in support of Wyeth and in favor of a finding of preemption.²⁴ The government’s brief argues that federal regulation and state tort suits could coexist if the only issue was safety, but “[w]here, however, federal regulation is designed to strike a balance between competing interests, state laws that strike a different balance are impliedly preempted.”²⁵ Briefs supporting a finding of preemption were also filed by the U.S. Chamber of Commerce, the Generic Pharmaceutical Association and the Voice of the Defense Bar.²⁶

THOSE OPPOSED

²¹ *White House, PhRMA Urge High Court to Find Preemption in Drug Case*, FDA WEEK (June 13, 2008) [hereinafter *White House, PhRMA Urge High Court*] (quoting Brief for PhRMA and BIO as Amici Curiae Supporting Petitioner, 2006 U.S. Briefs 1249, *3, *Wyeth v. Levine*, No. 06-1249).

²² *White House, PhRMA Urge High Court*, *supra* note 21.

²³ The FDA has been criticized for aggressively supporting preemption under the Bush administration, an abrupt about-face from the stance it held for decades under previous administrations, that FDA regulations could not only coexist with tort cases under state laws, but that the two actually complemented each other. *With Help from Kessler, Waxman Mounts Assault on FDA Preemption*, FDA WEEK (May 16, 2008) [hereinafter *Waxman Mounts Assault*]. At a hearing of the House Oversight and Government Reform Committee, Rep. Henry Waxman (D-CA) accused the agency of trying to legislate from within the executive branch, telling FDA policy director Randall Lutter, “[y]ou don’t have the power to do it by regulation,” and “[i]f you want a change, come to Congress and make an argument.” *Id.* In July, Rep. Waxman issued a letter to FDA Commissioner Andrew von Eschenback, requesting all of the agency’s preemption-related documents, including some requests related to a 2006 labeling rule in which the FDA included a “preemption preamble” stating that its approval and labeling decisions preempt state tort suits. The preamble is not binding, but courts have considered it a statement of the FDA’s official position on the preemption issue. *Waxman Wants All Preemption Records FDA Has Written Under Bush*, FDA WEEK (July 11, 2008).

²⁴ *White House, PhRMA Urge High Court*, *supra* note 21.

²⁵ *Id.* (quoting Brief for the United States as Amicus Curiae Supporting Petitioner, 2006 U.S. Briefs 1249, *18, *Wyeth v. Levine*, No. 06-1249).

²⁶ *Id.*

On the Plaintiff's side, supporting briefs were filed by members of Congress, medical journal editors, 47 state attorneys general and two former FDA commissioners.²⁷ Although Wyeth has the FDA and the White House on its side, more than twice as many amicus curiae briefs have been filed for the plaintiff.²⁸ The preemption opponents argue that the agency is too underfunded and lacks the information necessary to be the sole arbiter of drug safety.²⁹

Eighteen Congressmen filed a brief arguing that separation of powers principles should be adhered to.³⁰ Their brief claims that "[t]he FDA's attempt to expand the preemptive scope of the regulatory scheme is nothing short of an illegitimate power grab . . . [posing] a threat not merely to injured consumers and the States, but also to the separation of powers and the constitutionally assigned role of Congress in our system of government."³¹

The National Conference of State Legislatures also filed a brief for the plaintiff, arguing for adherence to federalist principles.³² Citing the FDA's abrupt change of heart with respect to preemption, the brief states that "[w]hen an Agency has radically changed its long-standing views, is unable to explain its change in view, and, as here, proceeds in a manner that demonstrates that politics, rather than independent Agency expertise, is the source of the new view, the Agency's arguments for administrative preemption should be rejected out of respect

²⁷ *Lawmakers, NEJM Editors Jump Into Supreme Court Preemption Case*, FDA WEEK, (Aug. 22, 2008).

²⁸ *Id.*

²⁹ *Id.*

³⁰ Brief of Amici Curiae Members of Congress in Support of Respondent, 2006 U.S. Brief 1249, *Wyeth v. Levine*, No. 06-1249. Signers of the brief include Senators Patrick J. Leahy (D-VT), Edward M. Kennedy (D-MA), Sheldon Whitehouse (D-RI), Tom Harkin (D-IA), Dianne Feinstein (D-CA), Richard J. Durbin (D-IL), Bernard Sanders (I-VT), Russell D. Feingold (D-WI) and Representatives Henry A. Waxman (D-CA), John Conyers Jr. (D-MI), John D. Dingell (D-MI), Frank Pallone, Jr. (D-NJ), Bart Stupak (D-MI), Zoe Lofgren (D-CA), Linda Sanchez (D-CA), Debbie Wasserman Schultz (D-FL), Maxine Waters (D-CA), and Peter Welch (D-VT).

³¹ *Id.* at *4.

³² Brief of the National Conference of State Legislatures as Amicus Curiae Supporting Respondents, 2006 U. S. Briefs 1259, *Wyeth v. Levine*, No. 06-1249.

for our shared system of Federalism.”³³

A brief was also filed by the current and former editors of the New England Journal of Medicine [NEJM].³⁴ The doctors’ brief argues that it is good policy to second guess the FDA, citing 23 drugs withdrawn from the market since 1997.³⁵ It claims “the FDA is in no position to ensure the safety of prescription drugs,” in great part because it “is heavily dependent on the drug makers themselves for the information on which [it] bases its decisions.”³⁶ Its authors say “arguments that the \$700 billion pharmaceutical industry, which grows more robust with every passing year, is somehow economically stifled by the products liability system,” are “specious,” and argue that the “theory that the risk of tort liability causes drug manufacturers to ‘over-warn’ of the dangers of their drugs . . . has no empirical support,” while under-warning has unmistakably taken a toll on public health and safety.³⁷ Former NEJM editor Marcia Angell has said that the FDA is not a reliable gatekeeper because it “has been given over to the industry it regulates,” leaving private lawsuits as the only way to deter misbehavior by drug companies.³⁸

Former FDA Commissioner David Kessler also filed a brief urging against preemption. In May he testified before the House Oversight Committee, where he explained that, although the FDA’s approval process for drugs is rigorous, most safety information is not revealed until after the drugs are on the market and being prescribed to a wide range of patients.³⁹ He testified that his “greatest concern with preemption is that it would . . . dramatically reduce the incentives for manufacturers to act quickly and responsibly to detect, analyze, investigate, and take action on potentially serious and life-threatening adverse reactions once a drug is on the market.”⁴⁰

WILL THE COURT PLAY IT SAFE?

³³ *Id.* at *15-16.

³⁴ Alicia Mundy, *NEJM Editors Enter Supreme Court Fray Over Drug Risks*, WALL ST. J. (Aug. 1, 2008).

³⁵ *Id.*

³⁶ Brief of New England Journal of Medicine Editors and Authors as Amici Curiae in Support of Respondent, 2006 U.S. Briefs 1249, *4, *Wyeth v. Levine*, No. 06-1249.

³⁷ *Id.* at *4-5.

³⁸ Mundy, *supra* note 34.

³⁹ *Waxman Mounts Assault*, *supra* note 23.

⁴⁰ *Id.*

Although most of those who have filed amicus briefs in *Levine* are either strongly in favor of or strongly against preemption, some commentators predict the Court is likely to take a narrow middle ground that may dissatisfy both sides. Rather than creating a sweeping rule for or against preemption, the Court could instead issue a ruling applicable only to the specific circumstances of the case, leaving for another day the issue of whether claims involving different drugs with different labels approved under different circumstances may be preempted.⁴¹

This is what the Third Circuit recently did in *Colacicco v. Apotex*, when it rejected the manufacturer's argument that tort cases based on a failure-to-warn theory are preempted by the mere fact of FDA approval.⁴² There the court found preemption under the special circumstances of the case before it, including its determination that the FDA had actively monitored the specific safety concern that was at issue for 20 years and had publicly rejected the need to include it on the drug's warning label, finding it would be "false and misleading."⁴³

Similarly, in *Levine*, the Court could rule that the long history of FDA regulation of the drug Phenergan might warrant preemption, while still leaving the door open for an alternative finding in cases involving newly approved drugs, or older drugs whose risks have only recently been discovered.⁴⁴

IS THE FDA UP TO THE CHALLENGE?

Many are skeptical of the FDA's ability to adequately protect the public from unsafe drugs and ineffective warning labels. In July, the Government Accountability Office (GAO) released a report in which it found the FDA is able to review only a small fraction of the marketing materials and activities it is charged with regulating.⁴⁵ For example, between 2003 and 2007, 277,000 submissions of final promotional materials were

⁴¹ *Dukart, supra* note 2.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ U.S. GOV'T ACCOUNTABILITY OFFICE, DRUG SAFETY: FDA'S OVERSIGHT OF THE PROMOTION OF DRUGS FOR OFF-LABEL USES (July 2008), available at <http://www.gao.gov/new.items/do8835.pdf>.

submitted for review to determine if inappropriate marketing for off-label uses was occurring.⁴⁶ The FDA could not, however, provide any data on what percentage of the materials had actually been reviewed, how many violations had been identified, or how long the average review took, because the agency does not keep track of such things. Because the agency does not have the resources to review all the materials submitted, it must prioritize, though the GAO reported that it “does not prioritize its reviews in a systematic manner but rather relies on its staff to sort through large volumes of material” selecting only a fraction for actual review.⁴⁷

In fact, in November 2007, the FDA’s own science board questioned whether the agency was capable of fulfilling its mandate.⁴⁸ The board “concluded that science at the FDA is in a precarious position,” and the agency “is not positioned to meet current or emerging regulatory responsibilities.”⁴⁹ It cited two sources for this deficiency: 1) demands on the FDA have soared, and 2) resources allocated to the agency have not increased in proportion to those demands.⁵⁰

No matter what the Court’s decision this term in *Levine*, Congress may ultimately agree that the FDA is not up to the challenge and decide to amend the Food Drug and Cosmetics Act to either reverse the Court’s decision or to clarify it. At least some members of Congress seem willing to take on the task. After the *Riegel* decision in February, outraged Congressional Democrats led by Sen. Edward Kennedy (D-MA) called for Congress to “correct the Court’s decision,” because “Congress never intended that FDA approval would give blank immunity to manufacturers from liability for injuries caused by [their products].”⁵¹

⁴⁶ *Id.* at 16.

⁴⁷ *Id.* at “Highlights” page preceding full report.

⁴⁸ FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY, (Nov. 2007), available at http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_index.html.

⁴⁹ *Id.* at 2.

⁵⁰ *Id.*

⁵¹ *Kennedy, Pallone Eye Legislation to Undo Preemption Ruling*, FDA WEEK (Feb. 29, 2008).