Supreme Court Holds That Prior FDA Approval of a Drug Warning Label Does Not Pre-Empt Plaintiff's State Tort Action

On March 4, 2009, the Supreme Court, in a 6-3 decision, issued its Opinion in *Wyeth* v. *Levine,*[1] holding that prior approval by the FDA of the warning label for Wyeth's anti-nausea drug, Phenargan, did not preclude a plaintiff's state tort action against Wyeth for failure-to-warn or strict liability.

I. Facts and Procedural History

After visiting a medical clinic with complaints of a migraine headache and accompanying nausea, plaintiff was administered Phenargan using an "IV push" (rather than "IV drip") method whereby the drug is to be injected directly into a vein. Irreversible gangrene set in, and Plaintiff, a professional musician, was required to have her arm amputated. Plaintiff sued Wyeth in Vermont Superior Court, alleging that Wyeth was negligent in failing to provide an adequate warning of the known danger of administering Phenargan through an IV push, which was known to increase the risk that the drug will enter an artery causing irreversible gangrene.

The trial court instructed the jury that it could consider the FDA's approval of the label used at the time of plaintiff's injury, but that the label's compliance with FDA requirements did not establish the adequacy of the warnings, nor prevent the defendant from adding to or strengthening the warning on the label. The jury found for the plaintiff on both her negligence and products liability claims and awarded her $7.4 million, later reduced to account for a separate settlement with the medical clinic.

Wyeth appealed to the Supreme Court of Vermont.[2] The Supreme Court of Vermont held that: 1) there was no conflict between state and federal law requiring pre-emption of the plaintiff's claim; and 2) that the verdict against the defendant did not conflict with FDA labeling requirements because Wyeth could have further warned against IV push administration without prior FDA approval, as federal labeling requirements create only a floor, not a ceiling, for the state regulation of warning labels.[3]

The Supreme Court of Vermont upheld the Superior Court's decision, Wyeth appealed and the Supreme Court of the United States granted certiorari to address the issue of implied pre-emption.

II. The Decision of the Supreme Court of the United States

The Court rejected both of Wyeth's pre-emption defenses: 1) that it would have been impossible for Wyeth to modify its warning label without violating federal law, and 2) that allowing plaintiff's state law action to proceed creates an unacceptable "obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[4]

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1 *Wyeth* v. *Levine*, 555 U.S. __, No. 06-1249, slip op. (U.S. March 4, 2009).

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

3 *Id.* at 184. In so holding, the Vermont Supreme Court relied on Section 314.70 of the Food, Drug and Cosmetic Act (FDCA), which sets forth procedures permitting drug manufacturers to add to or strengthen their warning labels for previously approved drugs without first obtaining FDA approval. *Id.* at 185-186.

4 *Levine*, No. 06-1249, slip op. at 6-7.

As to Wyeth's first defense, the Court stated that "[i]mpossibility pre-emption is a demanding defense," and disagreed with Wyeth's contention that it would not have been possible for Wyeth to modify its warning label without violating federal law.[5] Relying on the text of the statute, the Court determined that although a manufacturer generally may only change a warning label after first obtaining approval, prior approval is not always required as a result of the FDA's "changes being effected" (CBE) regulation:

> 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; it need not wait for FDA approval.[6]

The Court held Wyeth's reading that the CBE is limited to situations in which only new information not previously considered by the FDA becomes available, was incorrect, and that it remains "a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times."[7]

As to Wyeth's second defense, after reviewing Congress' actions since 1906 in the area of consumer protections, the Court rejected Wyeth's argument that allowing state tort actions based on a warning label approved by the FDA obstructed Congress's purpose and objectives in creating the FDA and enacting the FDCA.[8] Wyeth had pointed to the preamble to a 2006 agency regulation governing the content and format of prescription drug labels, which stated that "the FDCA establishes both a 'floor' and a 'ceiling,' so that 'FDA approval of labeling . . . preempts conflicting or contrary State law.'"[9] While acknowledging that it was appropriate to give "some weight" to an agency's views under the circumstances, the Court largely dismissed the FDA's statements as inconsistent with Congress' stated purposes and objectives and in contravention of the FDA's own longstanding position.[10] Consistent with the Court's view of Congress's intent, it appeared that "the FDA traditionally regarded state law as a complementary form of drug regulation" due to the FDA's limited resources and manufacturers' superior access to information about their own drugs.[11]

Congress' decision not to include an express provision for prescription drugs following a long history of state tort claims was, in the Court's view, evidence that Congress had not intended to pre-empt state failure-to-warn actions when it enacted the FDCA to "bolster consumer protection against harmful products."[12] Furthermore, over the years Congress' "silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence" that FDA oversight was not intended to pre-empt state tort actions relating to prescription drugs.[13] This is in contrast to Congressional enactment of an express pre-emption provision for medical devices in the FDCA, which led to the Court's ruling during the previous term that a

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5 *Id.* at 16.

6 *Id*. at 11 (citing 21 C.F.R. §314.70(c)(6)(iii)(A), (C)).

7 *Id.* at 14.

8 *Id.* at 17 ("The most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary.").

9 *Id*. at 19.

10 *Id.* at 20.

11 *Id*. at 22.

12 *Id.* at 17.

13 *Id.* at 18.

products liability action brought by a plaintiff who was injured by a balloon catheter previously approved by the FDA that burst during an angioplasty procedure was pre-empted.[14]

Both Justice Breyer and Justice Thomas wrote concurrences to the Court's decision. Justice Breyer wrote to emphasize that unlike in *Geier* v. *American Honda Motor Co.*,[15] "we have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law."[16] In *Geier* the Department of Transportation had promulgated a rule that provided car manufacturers with a range of choices among passive restraint devices that must be installed but did not mandate that manufacturers choose to install airbags.[17] In that case the Court held that plaintiff's claim that manufacturers had a duty to install airbags "presented an obstacle to achieving 'the variety and mix of devices that the federal regulation sought.'"[18] Justice Breyer agreed with the majority's opinion that under the circumstances there had been no interference with the FDA's ability to regulate drug labels, but he noted that there could be instances where state tort law could "interfere with the FDA's desire to create a drug label containing a specific set of cautions and instructions." [19] Justice Thomas agreed with the majority's result, but wrote separately to voice his concern that he has "become increasingly skeptical of this Court's 'purposes and objectives' pre-emption jurisprudence."[20] In his view, the "purposes and objectives" line of cases improperly rely on legislative history, broad notions of congressional purpose, or even congressional inaction, and thus is not rooted in the text of federal law.

In their dissent, Justices Alito, Roberts, and Scalia found the majority's result at odds with the Court's holding in *Geier*, and general principles of conflict pre-emption.[21] The dissent also emphasized that there were six separate warnings on the Phenargan label regarding the method of "IV push," and questioned if a seventh would have really prevented Ms. Levine's injuries.[22]

III. Significance of the Decision

While each case of implied pre-emption must be addressed in context, the Court's ruling may make it more difficult for defendants in state failure-to-warn tort actions to assert a defense of implied pre-emption.

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14 *Riegel* v. *Medtronic, Inc.*, 552 U.S. __, No. 06-179, slip op. at 14 (U.S. 2008).

15 529 U.S. 861 (2000).

16 *Levine*, No. 06-1249, slip op. at 1 (Breyer, J., concurring).

17 529 U.S. at 875.

18 *Levine*, No. 06-1249, slip op. at 23 (citing *Geier*, 529 U.S. at 881).

19 *Levine*, No. 06-1249, slip op. at 1 (Breyer, J., concurring).

20 *Levine*, No. 06-1249, slip op. at 2 (Thomas, J., concurring).

21 *Levine*, No. 06-1249, slip op. at 1 (Alito, J., dissenting).

22 *Id*. at 1-2.

If you have any questions about the issues addressed in this memorandum or if you would like a copy of any of the materials mentioned, please do not hesitate to call or email Charles A. Gilman at 212.701.3403 or cgilman@cahill.com; Jon Mark at 212.701.3100 or jmark@cahill.com; John Schuster at 212.701.3323 or jschuster@cahill.com; Justin Lubeley at 212.701.3369 or jlubeley@cahill.com; or Hilary Wolkoff at hwolkoff@cahill.com.