Wyeth v. Levine: No Federal Preemption for Drug Labeling

March 5, 2009

LIFE SCIENCES ALERT - MARCH 5, 2009

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The Supreme Court yesterday decided *Wyeth v. Levine*, the long-awaited decision on preemption of state court product liability claims against the pharmaceutical manufacturers. In a 6 to 3 decision, the Supreme Court determined that the foundation of federal regulation for pharmaceuticals is that the drug manufacturer has the responsibility for the adequacy of its warnings. The decision by Justice Stevens, joined by Kennedy, Souter, Ginsburg and Breyer, rejected Wyeth's argument that it was impossible to comply both with FDA regulations on warnings and with a state law duty, imposed by jury verdict, that a stronger warning against a particular method of administration of the drug was required. The Supreme Court also rejected, over a rigorous dissent, the proposition that state court product liability claims obstructed the purposes and objectives of the federal drug labeling regulations.

The drug involved, Phenergan, was medication that has been on the market for many years. The drug was administered intramuscularly but could also be administered intravenously, by IV drip or directly into the veins by IV-push. Administration of any drug by IV-push carries the risk that the healthcare professional may inadvertently inject the drug into an artery, causing gangrene. The manufacturer, Wyeth, became aware of that risk and proposed certain warnings for FDA approval signaling that danger. The FDA approved those warnings and the drug's labeling was revised to include them at several prominent places in the drug labeling.

While these warnings were in place, Diana Levine received an IV-push injection of Phenergan that, unfortunately, reached her arterial blood and caused irreversible gangrene and subsequent amputation of her arm. A jury and a state court in Vermont awarded her $6.7 million dollars in damages against Wyeth.

The Supreme Court's majority opinion today finds that the primary responsibility for the adequacy of warnings rests on the manufacturer. On the specific preemption arguments raised by Wyeth, the majority opinion rejects the proposition that FDA-approved labeling and warnings are the ceiling as well as the floor of warnings that may be carried on a drug label. In particular, the majority rejected the argument that it was impossible for Wyeth to comply with FDA-approved warnings and with the finding of inadequate warnings by the jury in Vermont. The majority noted that Wyeth could have availed itself of FDA's "Changes Being Effected" regulations that allow a manufacturer to unilaterally strengthen its warnings without first seeking agency approval. The Court said there was no indication that the FDA would have rejected that course and said it was improbable that the FDA would take action against a manufacturer who chose to strengthen its warnings through this CBE route.

The majority also rejected the proposition that state court claims, such as this one in Vermont, obstruct the purpose of federal regulation of pharmaceutical products. In this regard, this Supreme Court dismissed FDA's position, articulated in preamble language in a 2006 rulemaking, that FDA-approved warnings must preempt state court claims. The majority saw the 2006 FDA position as contrary to Congressional intent, inconsistent with prior FDA positions, and promulgated in a procedurally inadequate fashion.

Justice Breyer wrote a brief concurring opinion stressing that the decision in *Wyeth* did not address a federal regulation entitled to the power of law and noting that a future lawful and specific regulation may have preemptive effect. Justice Thomas concurred in the judgment, noting specifically that Wyeth had the opportunity to alter its warnings unilaterally, had it chosen to do so. Justice Thomas, however, disagreed with the implicit endorsement of implied preemption that informed the majority opinion.

Justice Alito, joined by the Chief Justice and Justice Scalia, dissented on the grounds that public policy ought to be made by expert agencies and not by juries. The dissent, further, took issue with the majority opinion's view that the FDA had paid only passing attention to the issue of IV-push administration of Phenergan. Because, in the dissent's view, the FDA had determined that the IV-push administration was safe when done according to the approved warnings, the Vermont jury's finding of liability for failure to warn should have been preempted.