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B&B REVIEW

Product Liability and Casualty Update

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HIGH COURT OPINION ALLOWS STATE COURT JURIES TO SECOND GUESS FDA LABELING DECISIONS

In a 6-3 decision released on March 4, 2009, the Supreme Court of the United States found that state law failure to warn cases against drug companies are not necessarily preempted by federal law. This ruling was made despite the clear language found in the 2006 preamble to FDA drug-labeling regulations, which said that the pertinent statute established "both a 'floor' and a 'ceiling,'" so that "FDA approval of labeling . . . preempts conflicting or contrary State law."

In *Wyeth v. Levine*, Case No. 06-1249, 555 U. S. ___ (Mar. 4, 2009), the Court affirmed a decision allowing a Vermont jury to decide whether the FDA-approved labeling for the long-used anti-nausea drug, Phenergan, was so deficient that it rendered the drug defective.

Diana Levine, a professional musician, suffered from migraine headaches. When she appeared at the local emergency room for treatment for a second time on the same day in April of 2000, complaining of severe headache, sensitivity to light, constant nausea and retching, and inability to sleep, she was prescribed an intravenous injection of Demerol for pain, and Phenergan for nausea. The labeling for Phenergan contained the following language: "INADVERTENT INTRA-ARTERIAL INJECTION CAN RESULT IN GANGRENE OF THE AFFECTED EXTREMITY." The label also contained a lengthy description of the preferred, and far safer, method of administering the drug, along with other statements describing the dire consequences of arterial injection.

The Phenergan was administered to Ms. Levine by way of IV-push. The push (a method which the labeling identified as one which increases the danger of the drug finding its way to an artery) was completed despite Ms. Levine's almost immediate complaints of severe stinging and discomfort at the injection site, symptoms also described in the drug labeling as evidence of arterial injection or perivascular extravasation. She developed gangrene and, eventually, her right arm, in which the Phenergan had been injected, was amputated below the elbow.

Ms. Levine's claims against the doctor, the hospital and the physician's assistant who administered the drug were settled. Her claims against Wyeth, the Phenergan manufacturer, that it had provided an inadequate warning, thereby

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rendering the drug "unsafe," were eventually submitted to a jury, which returned a verdict in her favor in the amount of $7.4 million (later reduced to approximately $6.7 million when the trial judge credited Wyeth with the pro tanto settlements of its codefendants).

Wyeth appealed, losing at every turn, and eventually the case was presented to the Supreme Court of the United States, which granted Wyeth's petition for writ of certiorari.

Wyeth argued that the FDA's labeling rules and regulations, which require drug manufacturers to submit proposed labeling for approval, preempted any state law claims of failure to warn, but the majority found otherwise, giving no weight whatsoever to the FDA's efforts to express a preemptive tone.

Interestingly, the majority consisted of several justices who dissented in the case of *Geier v. American Honda Motor Co.*, 529 U. S. 861 (2000), in which the Court found that state law requirements that all vehicles contain air bags were preempted by federal DOT requirements that were not so inclusive.

Writing for the majority, Justice John Paul Stevens said that the FDA needed the help of product liability suits to adequately protect consumers by increasing the attention given to the labeling required of drug manufacturers. The Court rejected the argument that a drug manufacturer is required to follow the FDA's approved labeling verbatim, instead expressing the view that the FDCA's "changes being effected" (CBE) provisions allow manufacturers to alter labels to account for newly-discovered risks pending later approval of the improved label by the FDA. All this, the Court said, despite the evidence that Wyeth complied with the FDA's instructions regarding the Phenergan label in all respects.

In a lengthy discussion of the various types of preemption, the Court gave no weight to specific efforts made by the FDA to preempt state law effects on the drug labeling world. In fact, the Court commented favorably on the helpful assistance to the FDA provided by failure to warn suits brought by consumers allegedly harmed by drug side effects, stating that these cases constitute "a complimentary form of drug regulation."

The Court seemed to also place emphasis on the fact that the FDA's position regarding preemption of state law had changed over the years.

A very strong dissent written by Justice Samuel Alito pointed out that the label that supposedly did not warn against the administration of this drug by IV-push actually contains at least six (6) separate statements of warning about this specific danger. Justice Alito also recognized that a state court jury finding itself incapable of turning down a plaintiff with a grotesque injury, even though the label clearly warned against the very thing that caused her injury, is proof of the need for preemption in this instance.

The dissent summarized its view as follows: "The FDA told Wyeth that Phenergan's label renders its use 'safe.' But the state of Vermont, through its tort law, said: 'Not so.'"

It is unlikely that this decision will improve the quality of drug warning labels, since the FDA methodology that leads to labeling decisions is, generally speaking, an effective way of analyzing the science relating to U. S. drugs and providing high quality information to medical care providers. The notion that brand drug manufacturers will now have to amend their labels prior to seeking FDA approval to do so, will not only increase significantly the cost of their drugs, but could lead to great inconsistencies in the quality and content of

drug labeling, as each manufacturer struggles to find the right balance between protective disclosure of known and real side effects and accurate information provided to the medical community.

Generic pharmaceutical manufacturers will read the opinion with great interest, but should not reach the conclusion that the opinion necessarily affects their labeling. Indeed, the entire generic pharmaceutical industry was established to allow for low cost drugs to be provided to U. S. consumers by allowing generics to piggyback onto both the science and regulatory work done by brand name drug manufacturers. FDA regulations specifically allow generic manufacturers to avoid conducting their own scientific research and spending money on other things required of brand manufacturers for this very reason: saving costs, so as to allow drugs to be sold at cheaper prices. It is doubtful that the Court meant to include generics in the ambit of this opinion, so, for now, the question of labeling preemption in failure to warn cases remains open in the case of generics.

Balch & Bingham, LLP – Product Liability and Casualty Litigation Practice Group

The attorneys in Balch & Bingham LLP's Product Liability and Casualty Litigation Practice Group have extensive experience in individual, mass, and class action environmental and toxic tort litigation, with specific experience in cases related to children's products or toys. They have litigated personal injury, property damage, and wrongful death claims relating to alleged exposures to and/or releases of lead-based paint, agricultural herbicides and pesticides, asbestos, benzene, boron triflouride (BF3), chlorinated solvents, formaldehyde, industrial waste water, carbon black, carbon dioxide, isocyanate compounds (MDI and TDI), Ilemite dust, maleic anhydryde mercury, mixed-dust, polychlorinated biphenyls (PCBs), particulate matter, perlite, petroleum hydrocarbons, radioactive material and waste, rutile dust, silica, trimelletic anhydryde Tordon, and welding fumes. Balch & Bingham LLP's Product Liability and Casualty Litigation Practice Group also has extensive experience in insurance coverage matters related to such exposures and releases.

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