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Supreme Court Rules That Drug Warning Claims Are Not Preempted

On March 4, 2009, the U.S. Supreme Court dealt what, at first blush, appears to be a blow to the pharmaceutical industry, by holding that federal law does not preempt a claim that labeling for a prescription drug failed to adequately warn about the risks of a particular method of administration. However, the Court's decision leaves open the possibility that implied conflict preemption may apply where the Food and Drug Administration (FDA) has considered a specific risk and made a determination about the way to warn of that risk.

Wyeth v. Levine, no. 06-1249, underscores the importance of performing a case-specific analysis of preemption. The Court held that federal law did not preempt plaintiff's state-law claim that labeling for the prescription drug Phenergan failed to adequately warn about the risks of a particular method of administration. Plaintiff received Phenergan intravenously to treat nausea. She claimed that the drug's label inadequately warned or failed to instruct clinicians to use an IV-drip method, rather than a higher risk IV-push method. Evidence was presented to show that if the drug enters a patient's artery, gangrene may result. Plaintiff developed gangrene which resulted in the amputation of her forearm. Although the labeling contained certain warnings about this risk, the majority of the Court concluded that the labeling could have been strengthened based upon "accumulating data" about the risk of amputation.

Significant to the decision were the so-called "changes being effected" federal regulations which permit manufacturers to enhance warnings without prior FDA approval in certain circumstances. The Court concluded that "absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements."

Importantly, however, the Court held open the possibility that, on a different record, preemption would be upheld. The opinion noted: "Although we recognize that some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case." The dissenting justices observed that this case illustrates the maxim that "tragic facts make bad law." Some legal analysts are concerned that the decision will open the floodgates to other inadequate warnings actions against the pharmaceutical industry. Others see this as affirming the recognition that there is a role for preemption in appropriate cases.

Preemption Does Not Bar State Claim Over Fuel Economy Estimates

In *Paduano v. American Honda Motor Co. Inc.,* 169 Cal.App.4th 1453, a hybrid car buyer sued the manufacturer for breach of state and federal warranty statutes and alleged misrepresentations under state law, arising from the manufacturer's statements about the car's fuel economy. The trial court granted summary judgment to the manufacturer. The California Fourth District Court of Appeal affirmed the car manufacturer's summary judgment motion as to the warranty claims, but reversed summary judgment as to the buyer's state law causes of action for deceptive advertising and remanded the matter to the trial court for further proceedings. The appellate court agreed with the trial court's finding that the federal Environmental Protection Agency mileage estimates for a car do not constitute a warranty. However, the Court of Appeal disagreed with the defense contention that federal law completely preempted the false advertising claims. It held that the federal Energy Policy and Conservation Act of 1975, which regulates fuel economy estimates and labels, does not preempt every lawsuit that challenges statements an automobile manufacturer makes regarding fuel economy.

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The New Wave of Product Claims Involving Overseas Production Practices

The news has been full of product claims based upon overseas manufacturing or production processes, such as those involving contaminated pet food and lead painted toys. These cases have raised some interesting issues:

In Re Mattel Inc. Toy Lead Paint Products Liability Litigation [588 F.Supp.2d 1111 (11/24/08)]

In granting in part and denying in part a motion to dismiss a consumer class action against a number of retailer and manufacturer defendants, the U.S. District Court for the Central District of California ruled that a voluntary product replacement, pursuant to federal Consumer Product Safety Commission regulations, does not bar a state law claim under the California Consumer Legal Remedies Act (CLRA). The court also ruled that out-of-state plaintiffs could state a claim against defendants under California state laws for alleged violations of CLRA and section 17200 of the California Business & Professions Code when they are harmed by wrongful conduct that occurs within the state.

ACE American Insurance Co. v. RC2 Corp., Inc.
[586 F.Supp.2d 946 (6/26/08)]

A recent decision from the U.S. District Court for the Northern District of Illinois provides an overview of insurance coverage issues related to overseas manufacturing cases. The case sought declaratory relief regarding an insurer's duty to defend a toy manufacturer in product liability actions involving allegations of lead paint poisoning where the toys were manufactured in China, but the harm alleged was from use of the products in the United States. The policies at issue provided coverage for any "occurrence" taking place within the policy's "coverage territory." The "coverage territory" under the policy included all parts of the world except the United States. The parties argued whether the terms should be construed to refer to the allegedly improper application of lead paint, which occurred in China, or the alleged injury to plaintiffs, which occurred within the U.S. The court concluded that only the cause of the harm, rather than the harm itself, need occur within the coverage territory for coverage to be triggered. The court granted the manufacturer's summary judgment motion and held that the insurer was obligated to provide a defense under the policy.

No Duty To Warn Of Defects In Another Manufacturer's Product

In *Taylor v. Elliott Turbomachinery Co. Inc.*, 2009 Cal.App. LEXIS 214, decided on February 25, 2009, the California First District Court of Appeal held that component manufacturers and suppliers were properly found not liable for failing to warn of dangers inherent in asbestos-containing products supplied by other manufacturers because they were not part of the chain of distribution of the injury-causing products, and California law recognized no duty to warn of defects in another manufacturer's products. The decedent's injury did not come from defendants' equipment itself, but instead was caused by asbestos released from products made or supplied by other manufacturers and used in conjunction with defendants' equipment. The component parts doctrine also shielded defendant from liability.

In Second Suit Plaintiff Allowed To Present Expert Evidence Of Claim That Had Been Abandoned

In *Gordon v. Nissan Motor Co., Ltd*, 170 Cal. App.4th 1103, decided January 29, 2009, the California Second District Court of Appeal reversed a judgment and remanded a case for a new trial. The plaintiff had sued for strict products liability after he sustained injuries in a rollover accident. He elected not to pursue a roof defect claim at his first trial, which resulted in a mistrial. However prior to the second trial, plaintiff designated experts to testify about that claim. The appellate court found the roof claim was alleged in plaintiff's complaint and the manufacturer was provided fair notice of the claim and an ample opportunity to conduct discovery on that claim. The appellate court found that the trial court had abused its discretion in granting the manufacturer's motion to strike testimony of a new expert regarding a roof defect claim in the second trial, even though the plaintiff had abandoned that claim prior to the first trial and even if the factual basis of his new claim arguably contradicted the facts presented in the first trial.

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