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BLOG

California Appeals Court Reverses Dismissal Based on Preemption in Risperdal Case

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A California appeals court recently reversed the dismissal of a failure to warn claim based on preemption in the *Risperdal and Invega Product Liability Cases*, suggesting that in the wake of the Supreme Court's decisions in *Wyeth v. Levine*, 129 S.Ct. 1187 (2009) and *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S.Ct. 1668 (2019), drug manufacturers will continue to face challenges in establishing a preemption defense.

Many state common laws and statutes require drug manufacturers to warn consumers of the risks associated with prescription drugs. But when Congress enacted the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392, it charged the Food and Drug Administration (FDA) with ensuring drugs are "safe for use under the conditions prescribed, recommended, or suggested" in the drug's "labeling." *Id.* at § 355(d). Federal regulations also set out the requirements for the content, format, and order of the safety information on a drug's label. *See* 21 C.F.R. § 201.57(c) (2019). Drug manufacturers have argued it is impossible to comply with both state law duties underlying failure to warn claims and federal law, which authorizes the FDA to approve the exact text in a drug's label. But the Supreme Court has resisted the blanket application of the impossibility preemption doctrine to state law failure to warn claims.

Wyeth and *Merck* explained that while prospective drug manufacturers work with the FDA to develop an appropriate label when they apply for FDA approval of a new drug, FDA regulations also acknowledge that information about drug safety may change over time and that new information may require changes to the drug label. 129 S.Ct. 1197; 139 S.Ct. at 1673. Indeed, the drug manufacturer has a duty to conduct post-market surveillance and revise the label when there is reasonable evidence of an association of a serious hazard with a drug. *See* 21 C.F.R. §§ 201.80(e), 314.80(b); *see also Wyeth*, 129 S.Ct. at 1198. Drug manufacturers are generally required to seek advance permission from the FDA to make substantive labeling changes, but an FDA regulation called the "changes being effected" or "CBE" regulation permits drug manufacturers to change a label without prior FDA approval if the change is designed to "add or strengthen a … warning" where there is "newly acquired information" about the "evidence of a causal association" between the drug and a risk of harm. *See* 21 C.F.R. § 314.70(c)(6)(iii)(A); *see also Wyeth*, 129 S.Ct. at 1197. Notably, manufacturers cannot propose a label change that is not based on newly acquired information and supported by reasonable evidence of a causal association with the drug. *See* 21 C.F.R. § 314.70(c)(6)-(7); *see also Wyeth*, 129 S.Ct. at 1196.

In *Wyeth*, the Supreme Court also observed that while typically a manufacturer may only change a drug label after approval from the FDA, the CBE regulation permits a manufacturer to make certain changes to its label before

receiving FDA approval. *Wyeth*, 129 S.Ct. at 1189. The Supreme Court has held it will not conclude it was impossible to comply with both federal and state requirement absent "clear evidence" the FDA would have rejected a change to a label through the CBE process when a manufacturer acquires new information regarding a risk of harm. *Wyeth*, 129 S.Ct. at 1198; *Merck*, 139 S.Ct. at 1678. It has also defined "clear evidence" to mean "evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include the warning." *Merck*, 139 S.Ct. at 1672.

Though non-binding, the recent California appeals court ruling in *Risperdal & Invega Prod. Liab. Cases*, No. B284002, 2020 WL 2300213 (Cal. Ct. App. May 8, 2020) *("Risperdal")* suggests that following *Wyeth* and *Merck*, some courts will continue to narrowly apply preemption to failure to warn claims based on FDA-approved drug labeling. In *Risperdal*, plaintiffs argued that the manufacturer of the antipsychotic drug risperidone could have used the CBE process to warn of a direct correlation between the drug and gynecomastia, a condition characterized by the enlargement of male breast tissue, and add a recommendation for regular monitoring of prolactin levels associated with the condition. *Id.* at *1, 9. The appellate court agreed, finding that drug manufacturers—not the FDA—bear responsibility for the content of their labels at all times and carry the burden to ensure warnings remain adequate while the drug is on the market. *Id.* at *7.

The *Risperdal* court discounted as "newly acquired information" two studies cited by plaintiffs, because they had been submitted to the FDA as part of the drug's application. *Id.* at *9. But it found that the manufacturer's statistical analysis of pediatric studies, reported as "table 21" in a draft manuscript that was not included in the final article submitted to the FDA, demonstrated a greater risk of side effects than the data provided. *Id*. The defendant argued that the table could not be "newly acquired information" because it did not reveal risks of a different type or greater severity, and in fact "table 21" did not change the overall rate of gynecomastia that was reported on the label. *Id*. While the court agreed that "table 21" did not change the rate of gynecomastia reported on the label, it did provide additional information about elevated prolactin levels during different time periods, and those elevated levels were more likely to lead to side effects, including gynecomastia. *Id.* The court held that "[i]mpossibility preemption requires the drug manufacturer to show that it fully informed the FDA." *Id.* at *10.

The *Risperdal* court also rejected the manufacturer's claim that the FDA would have denied plaintiffs' requested label change, following *Merck's* guidance that "clear evidence is not a typical standard of proof." *Id.* at *8. The manufacturer pointed to the FDA's prior denial of a citizen's petition requesting additional label warnings for risperidone. *Id.* at *10. But the court concluded this did not constitute "clear evidence" that the *Risperdal* plaintiffs' narrower warning would have been rejected and: "[t]he fact that the allegations in the citizens petition were similar and partly based on some of the evidence presented here does not change our conclusion that the claims are distinct. Hypothetical labeling changes and speculative future rejections are not clear evidence of an impossibility preemption defense." *Id*.

This California appeals court decision confirms *Merck's* guidance that preemption must be decided by the trial court as a matter of law, and not a jury. *Id.* at *6. But it highlights the apparent willingness of some courts to broadly interpret the basis for a potential label change via CBE regulation as the grounds for denying the application of a preemption defense. It further highlights the burden on a drug manufacturer to ensure label warnings remain adequate while the drug is on the market, and to revise the label through the CBE process if it identifies any new information not previously submitted to the FDA that may constitute reasonable evidence of an association with a serious risk.

For any questions, please contact Bryce Cooper, Sandra Edwards, or your Winston relationship attorney.

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