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Client Alert Product Liability Law

In re Accutane Litigation: A Victory for Pharmaceutical Companies on Choice of Law and Label Warnings

On October 3, 2018, the New Jersey Supreme Court granted pharmaceutical companies two significant legal victories in the Accutane multi-county litigation ("MCL"), which consolidated 532 product-liability from plaintiffs in forty-five jurisdictions. *In re Accutane Litig.* 2018 N.J. LEXIS 1187 (N.J. Oct. 3, 2018). First, the Court held in its choice-of-law analysis that New Jersey's relationship to the claims was more significant than those of the other 44 jurisdictions, and New Jersey's Product Liability Act's ("PLA") provisions on the adequacy of warning labels should, therefore, apply. Second, the Court held plaintiffs who seek to overcome the presumption of adequacy attached to a FDA-approved drug label must present clear and convincing evidence that the manufacturer knew or should have known of a causal association between the drug and "a clinically significant hazard."

Introduction

Accutane, the brand name for isotretinoin, was developed and marketed by Hoffmann-LaRoche Inc. and Roche Laboratories, Inc. (collectively "Roche") to treat severe acne. The FDA approved Accutane in 1982, and one year later, Roche learned that six to eight of the 300,000 patients who had taken Accutane had developed inflammatory bowel disease ("IBD"). In 1984, Roche issued label warnings to prescribing physicians stating that Accutane "has been temporally associated with [IBD] (including regional ileitis) in patients without a prior history of intestinal disorders." In 1999, the FDA asked

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Roche whether data demonstrated the "reversibility" of Accutane-associated IBD. By then, Roche was aware of approximately 300 patients whose IBD was associated with Accutane. Of that group, 188 recovered after they stopped using Accutane. Roche informed the FDA there was not sufficient information to determine whether the label should be updated. Nevertheless, the FDA asked Roche to remove the word "temporally" from the warning label and add that IBD symptoms "have been reported to persist after Accutane treatment has stopped." Roche complied.

By April 10, 2002, Roche developed several FDA-approved warning labels for physicians, pharmacists, and patients. The Court noted that the physician information is particularly significant because New Jersey has adopted the "learned intermediary" doctrine, which recognizes that the prescribing physician has the primary responsibility of advising a patient of a drug's risks and benefits. *See* N.J.S.A. 2A:58C-4. The warnings included: (1) a physician label, or package insert, which warned medical professionals of Accutane's risks, including IBD; (2) a Best Practices Guide for physicians, which advised them to counsel their patients on the risks detailed in the package insert; (3) a Patient Safety Packet, which physicians were to provide to patients and which advised patients to stop taking Accutane if they experienced abdominal pain; (4) a Medication Guide for pharmacists, which was developed in conjunction with the FDA and which warned of "possible serious side effects" including damage to digestive organs; and (5) "blister packaging" that warned patients of serious gastrointestinal side effects. Roche discontinued marketing Accutane in the United States in 2009, and one year later, the FDA issued an official Notice in which the agency stated it found no evidence to suggest Accutane was "was withdrawn from sale for reasons of safety or effectiveness."

The Long Form Complaint filed on behalf of all plaintiffs alleged: (1) Roche knew or should have known that taking Accutane "was causally related" to IBD; and (2) Roche "did not adequately inform physicians or consumers of [Accutane's] propensity to induce, aggravate or cause IBD." Plaintiffs sought compensatory and punitive damages. Roche moved for summary judgment on the grounds that its 2002 warnings were adequate. The trial court conducted a choice-of-law analysis and determined New Jersey law should apply to all of the claims. The determination was significant because the PLA provides a "rebuttable presumption" of adequacy for FDA-approved label warnings. *See* N.J.S.A. 2A:58C-4. The presumption affords pharmaceutical companies greater protection than they would receive in many other jurisdictions. The trial court found that plaintiffs failed to overcome the presumption of adequacy and granted Roche's motion.

The Appellate Division reversed the trial court's choice-of-law determination and found that the laws of the various jurisdictions in which the alleged harms occurred should apply. The court conducted a state-by-state analysis and determined that the trial court erred in granting summary judgment as to all claims except those governed by the laws of California, Colorado, Indiana, Maryland, Mississippi, New York, Texas, and Virginia. The court found there were issues of material fact as to warnings' adequacy in the remaining thirty-seven jurisdictions, including under New Jersey's PLA.

Discussion

The Court reversed the Appellate Division's choice-of-law determination, as well as the its partial denial of summary judgment on the warnings' adequacy. The Court observed that New Jersey's choice-of-law rules require an initial determination as to whether the laws of the states with interests in the litigation are in conflict. The Court found the PLA's presumption of adequacy conflicted with the laws of most, if not all, of the other jurisdictions. The Court then applied the *Restatement (Second) of Conflict of Laws*' ("Restatement") most-significant-relationship test, which it adopted in *P.V. ex rel. T.V. v. Camp Jaycee*, 197 N.J. 132, 135-36 (2008). Under the most-significant-relationship test, courts first look to Restatement § 146, which states there is a presumption in favor of applying the law of the state where the injury occurred. That presumption can be overcome, however, if another state has a more significant relationship as determined by the factors in Restatement §§ 145 and 6. Section 145 of the Restatement, which applies specifically to tort actions, instructs courts to consider four factors when making a choice-of-law determination: (1) the place where the injury occurred; (2) the place where the conduct that caused the injury occurred; (3) the parties' domicile, residence, place of incorporation, and place of business; and (4) the place where the relationship, if any, between the parties is centered. Section 6, which sets forth overarching choice-of-law principles, includes seven factors: (1) the needs of the interstate and international systems; (2) the relevant policies of the forum; (3) the relevant policies of other interested states and the states' relative interests in the determination of the issue in question; (4) the protection of justified expectations; (5) the basic policies that underlie the particular field of law; (6) certainty, predictability, and uniformity of result; and (7) ease in determination and application of the law to be applied.

The Court determined that there was sufficient justification to overcome the presumption in favor of the states in which plaintiffs' injuries occurred. In particular, the Court found the last two factors of Restatement § 6—the certainty, predictability and uniformity of result, and the ease in determination and application of the law to be

applied—were the most significant considerations in the Accutane MCL. The Court reasoned that applying a single state's standard to evaluate the warnings' adequacy served both purposes. The results of the various plaintiffs' claims would be more certain, predictable, and uniform under a single standard, and the courts could most easily determine and apply one legal standard. The Court stated the application of New Jersey's PLA also removed the element of fortuity, in which a plaintiff's state of residence could prove determinative. While plaintiffs argued New Jersey law favored Roche, the Court pointed out that, as a general principle, plaintiffs control their fate and may elect to bring suit in their states of residence.

Having decided the PLA applied to all 532 claims, the Court addressed what standard is required to overcome the PLA's presumptions of adequacy for FDA-approved warnings during the post-marketing phase of a prescription medication. The Court reviewed two prior decisions that set forth the bases for overcoming the PLA's presumption of adequacy: the Court's own decision in *Perez v. Wyeth Labs., Inc.*, 161 N.J. 1 (1999), and the Appellate Division's decision in *McDarby v. Merck & Co.*, 401 N.J. Super. 10, 63 (App. Div. 2008). In *Perez*, the Court addressed for the first time the relationship between the FDA's regulatory process and the PLA's presumption of adequacy. The Court stated that "FDA regulations are pertinent in determining the nature and extent of any duty of care that should be imposed on pharmaceutical manufacturers" and that "FDA regulations serve as compelling evidence that a manufacturer satisfied its duty to warn the physician about potentially harmful side effects of its product." *Perez*, 161 N.J. at 24. In view of those findings, the Court held that "absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of [product-liability and failure-to-warn] claims." *Id.* at 25.

In *McDarby*, the Appellative Division set forth the second method of overcoming the PLA's presumption of adequacy. The *McDarby* court considered the issue of whether *Perez*'s dictum concerning the weight of FDA approval should apply to drugs in the post-marketing phase. 401 N.J. Super. at 63-66. The court reasoned that the FDA's oversight of post-market drugs was far less thorough than the pre-market scrutiny that the *Perez* decision stated is evidence a manufacture has satisfied its duty to warn consumers. *Id.* at 64. In view of the limits on the FDA's post-marketing oversight, the Appellate Division ruled that plaintiffs can overcome the PLA's presumption of adequacy by offering evidence of "economically-driven manipulation of the post-market regulatory process." *Id.* at 63-64.

In *In re Accutane*, the Court recognized a third method through which plaintiffs can overcome the PLA's presumption of adequacy. In view of *McDarby*'s distinction between pre- and post-approval warnings, the Court stated "[p]rior FDA approval of a label's warning is not a license for a manufacturer to withhold updating and revising that warning in accordance with federal regulations." *In re Accutane Litig.*, 2018 N.J. LEXIS 1187 at *74. The Court cited *N.J. Model Civil Jury Charges* 5.40C (Model Civil Jury Charges Comm. 2017), which states "[a] duty to warn arises if [a manufacturer] actually knew or should have known of the need to issue a particular warning." *Id.* The Court, relying on the FDA's regulatory scheme and legal precedent, held that to overcome the PLA's rebuttable presumption for a FDA-approved drug label plaintiffs can "present clear and convincing evidence that a manufacturer knew or should have known, based on newly acquired information, of a causal association between the use of the drug and 'a clinically significant hazard' and that the manufacturer failed to update the label accordingly." *Id.* at *75 (citing 21 C.F.R. § 201.57(c); 21 C.F.R. § 314.70(c)). The Court added the caveat that a manufacturer will receive the protection of the rebuttable presumption when it "acts in a reasonable and timely way to update its label warnings with the FDA in accordance with its federal regulatory responsibilities." *Id.* A manufacturer that does not timely update its label warnings, however, "cannot seek shelter behind [the rebuttable presumption]." *Id.*

The Court found the plaintiffs' evidence could not meet the clear and convincing standard and Roche was, therefore, entitled to the rebuttable presumption. Among the documents plaintiffs cited as evidence of Roche's deliberate noncompliance were a 1994 memorandum in which a Roche physician stated Accutane "may induce or aggravate a preexisting colitis," and a 2000 regulatory report in which a Roche physician stated Accutane "has been found to be causally associated with [IBD], including colitis." The Court rejected plaintiffs' citation of "isolated examples . . . exhumed from the volumes of evidence." The Court further noted there was "no evidence that Roche deliberately concealed or withheld any material information from the FDA or engaged in economically driven manipulation of the regulatory process."

In summation, the Court noted that there are three "pathways" to overcome the PLA's presumption of adequacy. First, plaintiffs can establish "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects." *Perez*, 161 N.J. at 25. Second, plaintiffs can demonstrate "economically-driven manipulation of the post-market regulatory process." *McDarby*, 401 N.J. Super. at 63. Third, plaintiffs can show by clear and convincing evidence that the manufacturer knew or should have known that a drug's post-marketing warnings were inadequate based on federal label warning requirements.

Conclusion

The Court's decision in *In re Accutane* represents a significant victory not only for Roche, but for the pharmaceutical industry as a whole. While the Court's choice-of-law analysis was specific to the Accutane MCL, the principles upon which it based its decision would likely apply to any multi-county or multi-district litigation in which the plaintiffs' injuries occurred in several jurisdictions. Three weeks after the Court's decision, Superior Court Judge Rachelle L. Harz cited *In re Accutane* as the basis for ruling that New Jersey law would govern the "substantive issues" of the 132 cases in the C.R. Bard pelvic mesh MCL in Bergen County. Judge Harz's decision indicates courts will likely apply the PLA in mass tort litigation venued in New Jersey involving New Jersey manufacturers, due to the certainty, predictability, and uniformity of result, as well as the court's ease in applying the law.

Whether a party has presented "clear and convincing evidence" required to rebut the presumption of adequacy is, of course, case specific, but the Court provided some helpful guidance in this regard. It will be interesting to see how the case law develops on this point.

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