Supreme Court Issues Decision In Accutane Litigation

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If you ever pondered why drug companies continue to maintain their corporate headquarters in New Jersey, perhaps the Supreme Court's recent "Accutane" decision may shed some light. On October 3, the New Jersey Supreme Court (Justice Albin authoring the Opinion) issued a 70-page Opinion that involved 532 plaintiffs who used the well-known drug, Accutane. *See In re: Accutane Litigation*, No. A-26/27-17 (October 3, 2018). The case presented two main issues: (1) what states' law or laws governed whether Hoffmann-La Roche Inc./Roche Laboratories Inc.'s ("Roche") label warnings were adequate; and (2) the adequacy of the label warnings for the period after April 2002.

Background

The plaintiffs in this matter were 532 individuals from 45 jurisdictions, including New Jersey, who were prescribed Accutane by their treating physicians for their respective acne conditions. In a nutshell, the plaintiffs' claimed that they suffered Irritable Bowel Syndrome (IBS) as a result of their Accutane use. The thrust of the plaintiffs' legal arguments was their contention that Accutane caused their IBS and that Roche "failed to adequately warn" of that risk. Although I will spare you the history of Roche's Accutane-based interactions with the Food and Drug Administration (FDA) (which date back to 1982), it is important to note that by April 10, 2002, Roche had generated a variety of FDA-approved warning labels and materials for prescribing physicians, pharmacists, and patients. The information provided to physicians is of particular importance because New Jersey has adopted the "learned intermediary" doctrine, which recognizes that a prescribing doctor has the primary responsibility of advising the patient of the risks and benefits of taking a particular medication. Roche had generated a variety of FDA-approved warning labels and materials for a target audience of prescribing physicians, pharmacists, and patients.

The trial court held that New Jersey's Product Liability Act, N.J.S.A. 2A:58C-4 (the "PLA") applied, concluded that the plaintiffs failed to overcome the PLA's "presumption of adequacy" that attached to

Roche's Accutane warnings, and granted summary judgment to Roche. The Appellate Division reversed, applied the laws of the states of each of the individual plaintiffs, and reinstated the claims of the plaintiffs except for those from the following states: California, Colorado, Indiana, Maryland, Mississippi, New York, Texas, and Virginia. The Supreme Court granted Certification. *Spoiler alert*: in the movie the "Sixth Sense" the little boy… Just kidding, but at page 70 of the Opinion, Justice Albin summarized the result of the Court's Opinion: "the 532 failure-to-warn cases brought by plaintiffs against Roche are dismissed." But, as with any published decision, the "why" matters.

Choice of Law Issue

All three courts – trial, appellate, and Supreme – relied on the Restatement (Second) of Conflict of Laws. The Appellate Division reversed the trial court and held that because the PLA provides broader protection to New Jersey-based pharmaceutical companies than the laws of other states, an application of sections 145 and 6 of the Restatement that resulted in application of New Jersey law to all plaintiffs "might frustrate the other states' policies in deterring a broader scope of inadequate warnings[.]" The Appellate Division based its holding on section 146 of the Restatement, which provides that the law of the state where the *injury occurred* is presumed to govern unless another state has "a more significant relationship." On appeal to the Supreme Court, Roche argued that the appropriate choice-of-law analysis required the Court to recognize New Jersey's strong interest in protecting this State's pharmaceutical companies from unmeritorious product-liability litigation from out-of-state residents. The plaintiffs argued that the Court should adopt the Appellate Division's approach, which required the application of the law of the jurisdiction where each plaintiff was prescribed, and took, Accutane. The Supreme Court, citing to its prior decision in *P.V. ex rel. T.V. v. Camp Jaycee*, 197 N.J. 132, 143 (2008), provided an in-depth discussion of New Jersey choice-of-law principles (it is recommended that you read that discussion). The Court highlighted that in *Camp Jaycee* it adopted the Restatement's "most significant-relationship test" as set forth in sections 146, 145, and 6 as the rubric through which New Jersey choice-of-law issues would be decided. The Court concluded that under section 6 of the Restatement, New Jersey had the most significant relationship to the occurrence and the parties. In turn, the section 146 presumption – that the law of the place of injury governs – had been overcome. Accordingly, the Court applied the PLA to the 532 cases on appeal.

As to the Adequacy of the Warnings

The Court relied on N.J.S.A. 2A:58C-4, which provides that:

[i]f the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under [federal laws], a rebuttable presumption shall arise that the warning or instruction is adequate.

Stated more simply, the PLA provides for a presumption of adequacy if the FDA approved of the product's label warnings. Of course, the presumption can be overcome. *See Feldman v. Lederle Laboratories*, 125 N.J. 117, 157 (1991). I will not provide a recitation of Justice Albin's detailed discussion of: FDA regulations, the "problems" associated with the FDA's post-marketing oversight of drug label warnings, or the case law in this sphere; it suffices to say that the Court's Opinion in this matter (*In re: Accutane Litigation* (A-26/27-17) (079933)) provides a near-law review level of discussion of the subject – and you should read *Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009), in which the United States Supreme Court concluded that state-law failure-to-warn lawsuits against manufacturers provide "a complementary form of drug regulation" in the post-marketing phase.

After a thorough review of the PLA and FDA regulations, the Court discussed and analyzed the three avenues by which a plaintiff can overcome the PLA presumption: (1) if a plaintiff can establish deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects; (2) if a plaintiff can demonstrate economically driven manipulation of the post-market regulatory process; and (3) if a plaintiff can prove by clear and convincing evidence that a manufacturer knew or should have known in the post-marketing phase that the drug warnings were inadequate. The Court analyzed the plaintiffs' claims, noting that the chief claim is that the physician label and other warning materials should have used the language "causes" instead of "has been associated with" (i.e. the plaintiffs argue that the following language should have been used "Accutane causes IBS"). In broader terms, the Court determined that the plaintiffs failed to establish any of the above-enumerated exceptions.