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NJ Justices Say Garden State Law Topples Accutane Cases

By **Lauren Berg**

Law360 (October 3, 2018, 6:23 PM EDT) -- The New Jersey Supreme Court handed a victory to F. Hoffmann-LaRoche Inc. in multidistrict litigation alleging its acne drug Accutane labels didn't adequately warn users of possible gastrointestinal side effects, ruling Wednesday that the labels were adequate under New Jersey law and that only Garden State law applies.

Reversing in part and affirming in part a lower court's finding, the ruling, penned by Justice Barry T. Albin, found that after the 532 cases from 45 jurisdictions were consolidated, New Jersey had the most significant interests and that the plaintiffs did not overcome the state's Products Liability Act's presumption of adequacy for medication warnings approved by the FDA.

"[W]e do not find that Roche withheld from the FDA material information that would have altered the nature of the warnings or engaged in economically driven manipulation of the regulatory process," Albin wrote. "We also find that plaintiffs did not present clear and convincing evidence that Roche knew or should have known that the label warnings were inadequate."

In April 2002, Accutane included physician label advising doctors that inflammatory bowel disease had been associated with taking the acne medication and that symptoms had been reported to persist even after treatment had been stopped. The patient safety packet that came with the medication also mentioned the connection to IBD.

The FDA approved the warning tools that came with Accutane, according to court filings.

The plaintiffs in the case, however, took issue with language in the warning and said it should have said Accutane "causes" IBD, instead of "has been associated with." But in their ruling Wednesday, the panel found that the plaintiffs failed to present clear evidence that Roche's use of the word "associated" was inadequate.

The panel also found that the plaintiffs failed to establish that Roche engaged in the deliberate concealment of the alleged knowledge that Accutane causes IBD.

A trial court had concluded in 2015 that the New Jersey Products Liability Act governed all of the claims and dismissed all of the actions, finding that the plaintiffs failed to overcome the presumption of adequacy that attached to the label warnings approved by the FDA.

In 2017, however, an appellate court reversed the trial court's decision and found that each individual case had to be judged under the law of the jurisdictions where each plaintiff took Accutane. The panel affirmed the summary judgment in favor of Roche in cases in seven states where referencing IBD on the warning label was enough, but reversed the remaining 37 states, finding that the adequacy of the label was a question for a jury.

Wednesday's panel found that applying a single standard to govern the adequacy of label warnings in the 532 individual cases would ensure predictable and uniform results. Following this ruling, the 37 cases remaining under the 2017 appellate court's decision were dismissed.

In a statement from Roche Wednesday, the company said it was pleased with the court's decision.

"Because Accutane has for decades been such an important medicine for patients, Roche is gratified that New Jersey's highest court has confirmed that Roche provided complete and accurate information about the medicine's risks and benefits," the statement said.

Christopher Placitella, representing the New Jersey Association for Justice, which had submitted an amicus brief in the case, said Wednesday that the court's decision to apply New Jersey law was not surprising.

"In its decision the court clearly sought to set bright-line rules to govern the administration of justice in New Jersey," Placitella said. "The facts here were very difficult for the plaintiffs to overcome given the law as applied by the court."

Edward Fanning, who represented the Healthcare Institute of New Jersey and the New Jersey Business and Industry Association, also amici, told Law360 that the decision reinforces the strength of the super-presumption of the adequacy of FDA-approved warnings.

"The decision is consistent with what we advocated and it's consistent with prior New Jersey law," Fanning said. "It confirms that plaintiffs who have flocked to New Jersey from other states to sue our pharmaceutical companies are going to be subject to that heightened protection that is afforded to companies in New Jersey."

Counsel for the plaintiffs did not immediately respond to a request for comment Wednesday.

Chief Justice Stuart Rabner and Justices Jaynee LaVecchia, Faustino J. Fernandez-Vina, Lee A. Solomon, Walter F. Timpone and Barry T. Albin sat on the panel that reached Wednesday's decision.

The plaintiffs are represented by Bruce D. Greenberg of Lite DePalma Greenberg LLC, David R. Buchanan of Seeger Weiss LLP and Peter Samberg of Weitz & Luxenberg PC.

Roche is represented by Paul W. Schmidt and Michael X. Imbroscio of Covington & Burling LLP, Natalie H. Mantell of Gibbons PC, Russell L. Hewit of Dughi Hewit & Domalewski PC, and Edward J. Dauber of Greenberg Dauber Epstein & Tucker PC.

Amicus curiae Healthcare Institute of New Jersey and the New Jersey Business and Industry Association is represented by Edward Fanning Jr. of McCarter & English LLP.

Amicus curiae New Jersey Association for Justice is represented by Christopher M. Placitella of Cohen Placitella & Roth PC and Adam M. Slater of Mazie Slater Katz & Freeman.

The case is In re: Accutane Litigation, case number 079933, in the New Jersey Supreme Court.

--Additional reporting by Jeannie O'Sullivan. Editing by Pamela Wilkinson.