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N.J. SC rules for plaintiff in $10.5M acne-drug lawsuit

by John O'Brien

Long

TRENTON, N.J. (Legal Newsline) - The New Jersey Supreme Court has ruled that the plaintiff in a $10.5 million lawsuit over the acne medication Accutane did not miss the state's two-year statute of limitations when she filed the suit in 2005.

The court ruled Monday that Kamie Kendall had no reason to know that Accutane could cause inflammatory bowel disease before December 2003. Kendall had taken the medication while a teenager and was diagnosed with ulcerative colitis.

Accutane was produced by Hoffman-LaRoche, Inc. After a flood of lawsuits, the company discontinued the product in 2009.

"Although we can conceive of circumstances in which the 2003 warning might have been sufficient to alert a plaintiff of the connection between Accutane and her disease, it was certainly not sufficient, in these circumstances, to cause Kendall to doubt her physicians or to disregard the advice and information that had been imparted to her by them for the prior six years," Justice Virginia Long wrote.

"That is particularly so in light of the lack of a discernible link between Kendall's symptoms and the ingestion of the drug."

The federal Food and Drug Administration approved the use of Accutane in 1982. In the following years, Roche revised the warning label, provided to physicians, to indicate that IBD had been reported in less than 1 percent of patients and may bear no relationship to therapy.

Until 2000, the drug's warning provided that Accutane had been "temporally" associated with IBD in patients without a prior history of intestinal disorders.

In 2003, Roche provided a patient brochure that warned of serious side effects that do not happen in most patients. It said if those side effects, like stomach problems, then the patient should stop taking Accutane.

Kendall was first prescribed the drug in 1997 when she was 12 years old. Two years later, she began having stomach problems, though she continued taking Accutane after being hospitalized. Hospital records show that her grandmother also suffered from ulcerative colitis.

In August 2003, Kendall received the 2003 warnings from Roche, including the brochure. She signed consent forms staking that she read and understood the information.

In January 2004, she saw an advertisement about the side effects of Accutane, and she filed a lawsuit on Dec. 21, 2005, alleging the previous warnings about Accutane were inadequate.

The company said she should have known about the warnings by her August 2003 visit to the doctor, at the latest. A trial judge found that a 2003 booklet devoted 80 pages of its 3,000 pages to gastrointestinal side effects and did not specifically mention ulcerative colitis.

The judge also found that the consent forms focused on pregnancy and suicide and did not mention gastrointestinal side effects, referring only to general warnings made in the booklet.

The court agreed that the information was insufficient.

"Compliance with FDA regulations provides compelling, although not absolute, evidence that a manufacturer satisfied its duty to warn about the dangers of its products," Long wrote.

Marcus Rayner, the executive director of the New Jersey Lawsuit Reform Alliance, said the decision negatively impacts thousands of businesses and adds uncertainty.

"By finding that the Federal Food and Drug Administration's approval is inadequate, Roche and other product manufacturers can now be found liable for damages even if all steps to obtain the proper labeling were taken and approved," Rayner said.

"This adds great uncertainty to the business community and essentially adds enormous overhead costs to the development of critical and life-saving drugs."

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