

ATLANTIC COUNTY

PRODUCTS LIABILITY

Failure to Warn — Pharmaceutical

Acne drug led to inflammatory bowel disease, said plaintiffs

MIXED VERDICT \$2,125,617

CASE Gillian Gaghan, James Marshall and Kelly Andrews v. Hoffmann-La Roche Inc. and Roche Laboratories Inc.,
No. ATL-L-3361-04-MT

COURT Atlantic County Superior Court

JUDGE Carol E. Higbee

DATE 4/8/2011

PLAINTIFF ATTORNEY(S) Michael D. Hook (lead), Hook & Bolton, P.A., Pensacola, FL
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FACTS & ALLEGATIONS Between 1992 and 1993, plaintiff James Marshall, 20s, an actor, used Accutane, an oral drug that treats severe recalcitrant nodular acne and which does not respond to other treatments, including systemic antibiotics. Between 1997 and 1998, plaintiff Kelly Andrews, a teenager, used Accutane. In 1998, plaintiff Gilliam Gaghan, a 22-year-old medical records clerk, took Accutane.

Accutane was introduced in 1982 after getting approval from the U.S. Food and Drug Administration. The drug is also known by its generic name, isotretinoin. In 2009, Roche discontinued the manufacture and distribution of Accutane. Isotretinoin remains available on the market from generic manufacturers; Accutane has never been "recalled"

or "withdrawn."

Marshall, Andrews and Gaghan sued Accutane's manufacturers and distributors, Hoffmann-La Roche Inc. and Roche Laboratories Inc., for products liability. (The plaintiffs filed separate cases, which were consolidated. Roche is based in Switzerland, but this case was part of a larger, mass action and was transferred to a tort calendar in Atlantic County.)

Plaintiffs' counsel contended that Accutane's warning label, which indicated that the drug was "temporally associated with" inflammatory bowel disease, did not provide adequate warning about possible side effects. Using Roche's documents, counsel alleged that the company was aware of the fact that Accutane had the propensity to cause inflammatory bowel disease, but concealed its risks in order to sell the product. Counsel put on Roche-funded studies documenting the damage Accutane can cause to a user's gastrointestinal tract and intestinal lining, which triggers inflammatory bowel disease. Roche concealed these reports from the medical community, said plaintiffs' counsel.

Plaintiffs' counsel argued that Roche concealed the drug's risks in order to make money.

Roche responded by pointing out that a portion of Accutane labeling, introduced in 1984, did warn about the product's potential link to inflammatory bowel disease.

The defense also contended that the plaintiffs would have taken Accutane regardless of the warning and denied that Accutane caused inflammatory bowel disease in the plaintiffs. Counsel also said there was no reliable scientific evidence that Accutane causes inflammatory bowel disease.

INJURIES/DAMAGES *Crohn's disease; gastrointestinal complications; ulcerative colitis*

Gaghan's initial diagnosis of ulcerative colitis was later changed to Crohn's disease. She reported lupus-like symptoms and nighttime loss of bowel control.

Marshall claimed ulcerative colitis. As he was an actor with a long list of film credits, he claimed that his affliction shortened his acting career. Hollywood luminaries such as actors Martin Sheen and Brian Dennehy and director Rob Reiner testified as to Marshall's acting potential.

Andrews was diagnosed with Crohn's disease.

The plaintiffs asserted unspecified claims for past medical costs and emotional distress.

The defense responded that no reliable scientific evidence proved beyond a doubt that Accutane causes inflammatory bowel disease.

Defense counsel also put on evidence that 300,000 of the approximately 5 million patients that took Accutane between 1982 and 1995 reported getting sick as a result of taking the drug; and of that 300,000, only seven or eight reported symptoms of inflammatory bowel syndrome.

The defense also argued that Marshall had inflammatory bowel syndrome before he started taking Accutane and that the drug did not cause the other alleged damages.