



# In re Accutane Litigation, 234 N.J. 340 (N.J. 2018)

Topics Covered: Abusive Litigation Against Physicians

## Outcome: Very Favorable

### Issue

The issue in this case was whether the plaintiffs' expert witnesses should be allowed to testify that Accutane, a medication commonly prescribed for severe acne, causes Crohn's disease.

### AMA Interest

The AMA supports efforts of state medical societies to deter abusive lawsuits.

### Case Summary

Accutane, a Vitamin A derivative, was formerly manufactured by Hoffman LaRoche, Inc. and its subsidiary, Roche Laboratories Inc. (collectively HLR) as a treatment for severe, scarring acne. While effective, the drug engendered several side effects.

Since 1984, there have been suggestions that Accutane might be linked to various forms of inflammatory bowel disease, including Crohn's disease. Despite numerous studies on the subject, no such linkage has been found – at least not with substantial reliability. In fact, some studies have even suggested that Accutane may decrease the likelihood of developing Crohn's disease.

Nearly 8,000 plaintiffs from around the country have sued HLR in the New Jersey state courts, claiming that Accutane caused them to develop Crohn's disease. Many of these suits were consolidated into the present case, which was brought against HLR.

At a pre-trial stage of the proceedings, the plaintiffs proffered two expert witnesses, who were prepared to testify that Accutane caused Crohn's disease – a necessary element of the plaintiffs' case. HLR sought and received a hearing on the validity of this expert testimony. The plaintiffs' experts acknowledged that the scientific community did not generally accept a causative link between Accutane usage and Crohn's disease. Nevertheless, the experts claimed there was a causal link, based on such factors as personal observations, animal studies, anecdotal case reports, biological plausibility, and studies of analogous medications.

After a two-week hearing, the trial court found the proffered testimony of the plaintiffs' experts to be scientifically unsound and ordered their testimony barred. It then entered summary judgment on and dismissed 2076 lawsuits that had been brought against HLR.

The plaintiffs appealed. The Appellate Division found that the conclusions of the plaintiffs' experts, while not based on generally accepted theories of causation, were nevertheless

founded on scientific methodologies. Those conclusions therefore satisfied the standards for admissibility in mass tort suits. Accordingly, the Appellate Division held that the trial court had abused its discretion in excluding the plaintiffs' expert testimony. The 2076 summary judgments and dismissals were reversed, and the cases were remanded.

HLR appealed to the New Jersey Supreme Court. On August 1, 2018, the Supreme Court reversed the Appellate Division, holding that the trial court had correctly excluded the plaintiffs' experts. The Court said that when a proponent of expert testimony fails to demonstrate the soundness of the methodology used to develop that testimony from the perspective of the relevant scientific community, the testimony should be excluded. The Supreme Court cited the Litigation Center brief.

### **Litigation Center Involvement**

The Litigation Center, along with the Medical Society of New Jersey, the American Academy of Dermatology, and other medical societies, filed an amicus brief with the New Jersey Supreme Court, supporting the HLR petition. The brief confirmed that the causation issue has been adequately tested to draw a reasonable medical conclusion: Accutane does not cause Crohn's disease. In addition, the brief pointed out the dilemmas physicians will face if causation is determined by non-mainstream testimony which runs contrary to accepted medical standards. Physicians are legally and ethically required to formulate their treatment recommendations based on the consensus findings of medical science and not on outlier opinions which courts may choose to adopt. Similarly, physicians should advise their patients of the reasonably probable side effects of medications and obtain informed consent based on the medical literature, rather than on judicial developments.

New Jersey Supreme Court brief