

Accutane litigation grows

by Correy Stephenson

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After more than a decade, the litigation against Hoffman-LaRoche, the maker of the acne drug Accutane, continues to grow.

More than 7,000 cases are currently on file in multi-district litigation consolidated in New Jersey state court, and both sides continue to vigorously litigate with no settlement negotiations in sight.

To date, 11 trials have been held in the litigation, which alleges that the manufacturer failed to warn Accutane users of the dangers of inflammatory bowel disease. Eight of the cases have been won by plaintiffs, with verdicts ranging from \$2 million to \$25 million. There have also been two defense verdicts and a mistrial.

Most recently, the plaintiffs notched an appellate victory when the New Jersey Supreme Court held that a reasonable person in the plaintiff's situation would not have recognized the connection between Accutane and her IBD, rejecting Roche's argument that her suit was untimely filed.

The decision in [*Kendall v. Hoffman-LaRoche*](#) "was a major victory for pharmaceutical plaintiffs in New Jersey," said David R. Buchanan, a partner at Seeger Weiss in Newark, N.J., who argued the case before the court and has tried several of the Accutane cases.

The defense "invited the court to basically make [Food and Drug Administration] approval of a drug's label dispositive." Had the court agreed with the defendant, "the decision could have had a broad, negative impact," Buchanan said.

The decision also leaves the door open for future Accutane plaintiffs who may not yet have made the connection between their disease and the acne drug, noted Michael Hook, a partner at Hook and Bolton in Pensacola, Fla., who has been involved in the litigation since its inception.

In a statement, Roche spokesperson Chris Vancheri said the company was disappointed in the ruling and "will continue to vigorously defend this case."

A decade of litigation

Hook filed the first Accutane IBD suit in Florida in 2001.

Six years later, the first trial, *McCarrell v. Hoffman-La Roche*, resulted in a [**\\$2.6 million verdict**](#) in May 2007.

That decision was later [**reversed on appeal**](#) when the New Jersey Appellate Division found that the defense was unfairly restricted from presenting evidence to the jury about the number of people who had taken Accutane (Roche wanted to contrast that number with the number who suffered severe side effects).

After a retrial, a second jury awarded McCarrell [**more than \\$25 million**](#).

In the second case to go to trial, a jury awarded Kamie Kendall \$10.5 million. But following the *McCarrell* evidentiary ruling, a New Jersey appellate court [**vacated the award**](#) and remanded the case for a new trial.

However, the court also ruled that Kendall's claim was timely filed.

Roche appealed that ruling, but the New Jersey Supreme Court affirmed, holding that the plaintiff's delay in filing her suit was reasonable under the circumstances.

The plaintiff was 12 years old when she first took Accutane and received six courses of the drug between 1997 and 2003. While the drug's warning label changed over the years, the plaintiff's doctors did not warn her about the possibility of IBD.

Even after Kendall was diagnosed with ulcerative colitis in 1999, her gastroenterologist expressed no objection to her taking Accutane. She argued that the two-year statute of limitations to file her suit wasn't triggered until she saw an advertisement in a magazine listing the risks associated with Accutane in 2004.

Roche contended that updated warning labels in 2003, as well as a worsening of Kendall's disease during her final course of Accutane, put her on notice that there could be a connection between the drug and her condition.

But even though the plaintiff admitted she "skimmed over the book" of updated warnings in 2003, the New Jersey Supreme Court said that Kendall "never received a warning which specifically mentioned IBD or ulcerative colitis."

The 2003 warning "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," the court concluded.

However, despite the court's ruling, Kendall still faces a second trial.

How many more years?

With more than 7,000 pending cases, the Accutane litigation is likely to continue for some time.

The number of trials increased over the years once the litigation was consolidated under Judge Carol Higbee in Atlantic City, N.J. and multiple cases are now tried at once.

Last year, a trio of cases resulted in two defense verdicts and a plaintiffs' verdict for **\$2 million**; another three-plaintiff trial resulted in a **total award of \$13 million**.

Both sides continue to stress the strength of their respective cases.

"The best available science fails to demonstrate a causal relationship between Accutane and IBD," Vancheri argued. "Recent studies have provided evidence that there is no increased risk of developing Crohn's disease (a form of IBD) with Accutane use. Those same studies fail to reach a consensus on whether there is any increased risk of developing ulcerative colitis (also a form of IBD) with Accutane use."

He also emphasized Roche's successful appeals.

The company has "obtained reversals of the only three state court verdicts against it that have received appellate review," he noted – *McCarrell*, *Kendall* and a Florida state court case.

"The most recent trial resulted in [a] mistrial after the jury concluded that [the] plaintiff could not prove her case. The remaining cases that have gone to trial are on appeal or subject to post-trial motions," Vancheri said.

But Hook noted that those other trials occurred after the appellate court decision in *McCarrell*, meaning that the evidentiary problem found by the appellate court was not an issue.

Given the outcome of *McCarrell*'s re-trial, Hook said he felt confident about a re-trial of the *Kendall* case.

Even the two defense verdicts were a partial win for the plaintiffs, Hook asserted.

"Every jury that has addressed the issue of whether Accutane causes IBD has ruled for the plaintiff," he said. "And every jury that has addressed whether the label was inadequate has ruled for the plaintiff."

No settlement talks – yet

Next up: four plaintiffs are scheduled for a joint trial beginning April 19.

Given the plaintiffs' track record, Hook said the lack of settlement discussions is "befuddling."

Roche **pulled the drug from the market** in June 2009, leading to speculation that a settlement was forthcoming. Link:

But Vancheri said the decision to remove the drug from the market was "for business reasons" and was not made for reasons of safety or efficacy.

"Accutane has never been 'recalled' or 'withdrawn,'" he said.

The removal of the drug from the market resulted in the recent uptick in case filings, Buchanan said, and he predicted that more cases will continue to be filed.

Accutane litigation is unique because of its latency, he explained.

"In most cases the plaintiff suffers an injury while they take a drug," he said. "But the problem with Accutane is the delayed recognition that it caused a patient's IBD because the symptoms don't appear until after they have stopped taking the drug."

That makes a logical connection between the symptoms and the drug more challenging for a patient, he argued, resulting in later filing dates.

*Questions or comments can be directed to the writer at:
correy.stephenson@lawyersusaonline.com*

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