## <u>April 2010 Accutane Update: More Medical Evidence Follows A Large</u> <u>Trial Verdict For Drug Injury Victim</u>

## New Study Finds Increased Risk Of Developing Ulcerative Colitis; New Jersey Jury Decides Accutane Caused Man's Inflammatory Bowel Disease

(Posted by Tom Lamb at <a href="http://bit.ly/av3abq">www.DruglnjuryWatch.com</a> on April 7, 2010; see <a href="http://bit.ly/av3abq">http://bit.ly/av3abq</a>)

In the first quarter of 2010 there were two significant developments concerning the acme medication Accutane (isotretinoin).

As general background, in June 2009 the drug company Roche Holding AG announced that Accutane will no longer be available to American patients. The apparent reasons for this June 2009 Accutane recall are loss of market share and mounting personal injury lawsuits.

As regards what has been happening with Accutane in 2010, we start with the legal realm.

In mid-February 2010 a New Jersey state court jury decided that Roche must pay \$25.16 million in damages to Andrew McCarrell, a former user of its Accutane drug who blamed the acne medicine for his inflammatory bowel disease (IBD). Mr. McCarrell developed his IBD after taking Accutane for acne in 1995; he needed five surgeries, including one to remove his colon.

As some may recall, in May 2007 a New Jersey state court jury handed down a \$2.619 million verdict in favor of Mr. McCarrell. A New Jersey appeals court subsequently overturned that verdict and ordered a retrial. It was this retrial, or second trial, in February 2010 that resulted in the \$25.16 million award to McCarrell.

We move, next, to the medical developments regarding Accutane and its active ingredient, isotretinoin.

By means of an April 6, 2010 article, "More evidence ties acne drug to bowel disease", we learned about a recent medical journal report about a study which found that patients on Accutane or isotretinoin were four times more likely than non-users to develop ulcerative colitis within a year. From this April 6 *Reuters Health* article we get this summary:

Reporting in the American Journal of Gastroenterology, researchers say that the risk of any one isotretinoin user developing ulcerative colitis is "likely quite small."

However, the findings do strengthen the evidence of a cause-and-effect relationship between the acne drug and inflammatory bowel disease (IBD) -- a group of digestive disorders that includes ulcerative colitis and Crohn's disease....

[Roche] has maintained that there is no strong evidence that the acne drug triggers IBD. Between 1997 and 2002, 83 cases of IBD among isotretinoin users were reported to the U.S. Food and Drug Administration, but that does not prove that the drug itself is to blame.

For the new study, Dr. Seth D. Crockett and colleagues at the University of North Carolina Chapel Hill tried to test the cause-and-effect relationship.

Using a database of information from 87 U.S. health insurance plans, the researchers identified 8,189 people -- mostly adults -- who'd been diagnosed with IBD. They then compared each of those individuals with up to three other health plan members the same age and sex with no history of IBD.

Of the nearly 8,200 IBD patients, Crockett's team found, 24 had used isotretinoin in the year before diagnosis; and of the nearly 22,000 controls, 36 had used the acne drug over a one-year period.

Overall, the researchers found, isotretinoin users were roughly four times more likely than nonusers to have ulcerative colitis. There was no association, however, between isotretinoin use and Crohn's disease.

The report about this study regarding Accutane-related ulcerative colitis cases, "Isotretinoin Use and the Risk of Inflammatory Bowel Disease: A Case—Control Study", was published online March 30, 2010 by the American Journal of Gastroenterology.

We will continue to watch for legal and medical developments regarding serious side effects associated with the acne drug Accutane.

Attorney <u>Tom Lamb</u> represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.

http://www.DrugInjuryWatch.com