

[Mixed Signals About The Safety Of Acne Medication Accutane \(Isotretinoin\) Continue To Emerge In Summer 2010](#)

FDA Says Accutane Was Not Withdrawn Because Unsafe Drug, While Medical Journal Article Finds Link Between Isotretinoin Therapy And Ulcerative Colitis

(Posted by Tom Lamb at www.DrugInjuryWatch.com on August 6, 2010; see <http://bit.ly/9slHVu>)

When we last wrote about the acne medication Accutane (isotretinoin), it seemed that there was some momentum growing as regards the idea that Accutane was an unsafe drug, as can be seen by this headline:

[April 2010 Accutane Update: More Medical Evidence Follows A Large Trial Verdict For Drug Injury Victim](#) -- New Study Finds Increased Risk Of Developing Ulcerative Colitis; New Jersey Jury Decides Accutane Caused Man's Inflammatory Bowel Disease

In the few months which followed, however, the safety debate about Accutane -- which actually is no longer available; [in June 2009 the drug company Roche Holding AG announced that Accutane will no longer be available to American patients](#) -- and isotretinoin, its generic equivalent -- which is still available by prescription in the U.S. -- continues, and the tide may be turning.

First, we learn from this August 6, 2010 article by *Bloomberg* reporter Jef Feeley, "[Roche Wins Reversal of \\$10.5 Million Accutane Verdict in New Jersey Case](#)", that in early August 2010 a New Jersey appellate court reversed on legal grounds the [2008 verdict in favor of Kamie Kendall, a Utah woman who developed inflammatory bowel disease \(IBD\) after using Accutane.](#)

Next, in early July 2007 the FDA published this Notice (the title of which speaks for itself) in *The Federal Register*:

[Determination That ACCUTANE \(Isotretinoin\) Capsules, 10 Milligrams, 20 Milligrams, and 40 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness](#)

But a relatively recent medical journal article found an apparent association between Accutane and ulcerative colitis (UC), one type of inflammatory bowel disease (IBD). From the Abstract for "[Isotretinoin Use and the Risk of Inflammatory Bowel Disease: A Case-Control Study](#)", which was initially published online by *The American Journal of Gastroenterology* back in late March 2010:

OBJECTIVES: Isotretinoin is commonly prescribed for the treatment of severe acne. Although cases of inflammatory bowel disease (IBD) have been reported in isotretinoin users, a causal association remains unproven....

RESULTS: ... [Ulcerative colitis (UC)] was strongly associated with previous isotretinoin exposure (odds ratio (OR) 4.36, 95% confidence interval (CI): 1.97, 9.66). However, there was no apparent association between isotretinoin and [Crohn disease (CD)] (OR 0.68, 95% CI: 0.28, 1.68).

CONCLUSIONS: UC but not CD is associated with previous isotretinoin exposure. Higher dose of isotretinoin seems to augment this risk. Although the absolute risk of developing UC after taking isotretinoin is likely quite small, clinicians prescribing isotretinoin as well as prospective patients should be aware of this possible association.

We will continue to monitor the legal realm, the regulatory realm, and the medical realm for further developments as regards the issue of whether Accutane and isotretinoin are safe to use, or not.

Our readers can engage in this Accutane safety debate by leaving a Comment below.

Attorney [Tom Lamb](#) 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>