

**UNITED STATES DISTRICT  
COURT MIDDLE DISTRICT OF  
FLORIDA TAMPA DIVISION**

**Case No: 8:04-md-2523-T-30TBM**

**IN RE: MDL: 1626**

**AC CUTANE PRODUCTS LIABILITY**

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**ORDER**

THIS CAUSE is before the Court on the Motion of Hoffmann-LaRoche Inc. and Roche Laboratories Inc. to Exclude the Re-Asserted General Causation Testimony of Ronald Fogel (Dkt. #678) and the Plaintiffs' Response thereto (Dkt. #685). The Court held an evidentiary hearing on July 16, 2009, in which Dr. Fogel testified concerning his opinion and the basis therefor. Upon consideration of the pleadings, memoranda in support, and the testimony of Dr. Fogel, the Court concludes that the Motion to Exclude Dr. Fogel's testimony should be granted.

The individual cases in this MDL are divided into two groups: one for inflammatory

bowel disease (IBD) and one for psychiatric problems. Dr. Fogel's opinion, concerning general causation of the IBD group, is that Accutane causes IBD. Two years ago this Court

struck Dr. Fogel's testimony because his opinion overreached the underlying scientific data.

The Court entered a detailed Order reviewing each basis upon which Dr. Fogel relied. See Order of June 15, 2007, at Dkt. #580. The Court will not repeat that discussion but notes that

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it applies equally well to Dr. Fogel's present opinion because he relies upon the same scientific bases.

Dr. Fogel is certainly qualified to render an opinion on inflammatory bowel disease

("IBD"). He is the head of the Division of Gastroenterology at Henry Ford Hospital in

Detroit, Michigan, a member of the Gastrointestinal Drug Advisory Committee for the

United States Food and Drug Administration, a member of peer review panels, a lecturer, an

author of several articles and book chapters on gastroenterology, and a practicing board

certified gastroenterologist for over twenty five years. The difficulty with Dr. Fogel's opinion is not with his qualifications, but whether reliable scientific data exists to support an opinion of general causation.

Dr. Fogel's second report, which is now before the Court and the subject of Defendants' Motion, includes more detail and explanation than his first report, but relies upon the same scientific tests and data. As additional support at the hearing, he relied heavily upon an article (Isotretinoin and Intestinal Inflammation: What Gastroenterologists Need to Know) which was published a few weeks before the hearing (about six months after his second report was rendered). *Gut*, June 2009, Shale, M., et al., 58:737-41, Dkt. #708-3.

Dr. Fogel contends that since Dr. Shale used the same methodology as he, it demonstrates that his (Dr. Fogel's) methodology is scientifically sound and therefore his opinion is admissible because the issue is not whether he is correct but whether the opinion is based on a sound methodology.

Dr. Shale reviewed existing case reports, the earlier case report article by Dr. Reddy,

et al. (see this Court's earlier opinion at Dkt. #580), and discussed biological plausibility for

causation. In essence, Dr. Shale repeated the steps taken by Dr. Reddy and arrived at a

similar conclusion: there is a "potential association of IBD with the use of the vitamin A

analogue isotretinoin . . . which is widely prescribed in the treatment of severe acne."

First

paragraph, Shale, et al., supra. Dr. Reddy had previously concluded that Accutane was

"perhaps acting as a trigger for IBD in properly predisposed individuals, or unmasking

symptoms in those with pre-existing but sub-clinical disease." Reddy, et al., at 1571, exhibit

F to Defendants' First Motion to Strike, document #411-10. But a conclusion that there is

a "potential association" or that something is "perhaps acting as a trigger" is not an opinion

of causation, but rather an hypothesis. A scientist tests an hypothesis to determine its validity

and reliability, and then, depending on the results, may form an opinion.

To demonstrate that Dr. Shale's hypothesis is just that, a theory, one only needs to look to his calculation of the expected incidents of IBD in patients treated with Accutane.

Dr. Fogel acknowledges that IBD occurs in the general population, without regard to Accutane, at a rate of 16-20 out of 100,000 persons. This number would be higher in a younger population, those who most frequently use Accutane, because IBD occurs most frequently in teenagers and young adults. So, where one would expect more than 20 out of a population of 100,000 persons using Accutane (a younger population) to develop IBD even if Accutane had no causal effect (the background rate), Dr. Shale calculates there would be

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less than ten.

Available data are inadequate to allow the calculation of the incidence of the IBD in patients treated with Isotretinoin; however, it is likely to be very low (< 1:10,000).

Shale, et al., supra., Dkt. #708-3, p. 4. Less than one in ten thousand is the equivalent of less

than ten in one hundred thousand.

The Court has not given any weight to Dr. Shale's calculation as to whether Accutane

does, or does not, cause IBD because Dr. Shale does not explain the basis for his calculation.

If, for example, Hoffmann-LaRoche used this calculation in an attempt to prove that

Accutane does not cause IBD, it would be of little use unless the basis for the calculation was

demonstrated to be reliable. But, since it is Dr. Shale's calculation, it does emphasize that his conclusions are only at the hypothetical stage.

While Dr. Shale's methodology may be sufficient to support an hypothesis, that does

not mean it is sufficient to support an opinion of causation. As this Court said in its earlier opinion, when an expert relies on the studies of others, he must not exceed the limitations the

authors themselves place on the study. That is, he must not draw overreaching conclusions.

McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1245-1247 (11<sup>th</sup> Cir. 2005). Both Dr. Shale

and Dr. Reddy, in their review of the existing literature, case reports and scientific data, only

formed hypotheses, not opinions of causation. Without some scientific data to close the gap

between hypothesis and opinion, Dr. Fogel cannot do more.

It is therefore ORDERED AND ADJUDGED that the Motion of Hoffmann-LaRoche

Inc. and Roche Laboratories Inc. to Exclude the Re-Asserted General Causation Testimony

of Ronald Fogel (Dkt. #678) is GRANTED.

**DONE and ORDERED** in Tampa, Florida on August 11, 2009.

**Copies furnished to:**  
Counsel/Parties of  
Record

