IN THE DISTRICT COURT OF APPEAL
FIRST DISTRICT, STATE OF FLORIDA

HOFFMANN-LA ROCHE INC. and ROCHE LABORATORIES INC.,

Appellants,

v.

ADAM W. MASON ,

Appellee.
_____/

NOT FINAL UNTIL TIME EXPIRES TO FILE MOTION FOR REHEARING AND DISPOSITION THEREOF IF FILED

CASE NO. 1D08-2032

Opinion filed October 27, 2009.

An appeal from the Circuit Court for Escambia County.
Michael G. Allen, Judge.

Michael X. Imbroscio and Paul W. Schmidt of Covington & Burling LLP, Washington, D.C., Barry Richard and Arthur J. England, Jr., of Greenberg Traurig, Tallahassee, Charles F. Beall, Jr., of Moore, Hill & Westmoreland, PA, Pensacola, and Edward Moss of Shook, Hardy & Bacon LLP, Miami, for Appellants.

Michael D. Hook and Stephen F. Bolton of Hook & Bolton, P.A., Pensacola, Timothy M. O'Brien of Levin, Papantonio, Pensacola, Louis K. Rosenbloum of Louis K. Rosenbloum, P. A., Pensacola, Mary Jane Bass, of Beggs & Lane RLLP, Pensacola, and Michael J. Ryan of Krupnick, Campbell, Ft. Lauderdale, for Appellee.

PER CURIAM.

Appellants, Hoffman-La Roche Inc. and Roche Laboratories Inc., challenge a final money judgment in favor of Appellee, Adam W. Mason, awarding Appellee

compensatory damages after a jury found that Appellants placed Accutane on the market with an inadequate warning to Appellee's physicians about the risk of developing inflammatory bowel disease ("IBD"), and that the failure to provide an adequate warning was a substantial contributing cause of Appellee's development of IBD. Because Appellee presented no evidence from either treating physician that a differently worded warning would have resulted in either physician not prescribing Accutane for his extreme acne, Appellee failed to establish that the allegedly deficient warning was the proximate cause of his injury; therefore, we reverse.

Appellee developed severe acne while in middle school, which caused him to seek treatment from Dr. George Fisher, a dermatologist. After Appellee's acne failed to respond to topical agents and antibiotics, Dr. Fisher prescribed Accutane, a drug manufactured and marketed by Appellants. Because Appellee's acne returned when he discontinued use of Accutane, he continued taking Accutane as prescribed by his family practitioner, Dr. Kenneth Counselman, until November 2000, at which time he was diagnosed with Crohn's Disease, a form of IBD. Appellee filed suit against Appellants under theories of strict liability and negligent failure to warn alleging that Accutane's warning label was inadequate to warn his physicians about the risk of developing IBD.

When Dr. Fisher first prescribed Accutane for Appellee, the label contained the following warning:

> *Inflammatory Bowel Disease*: Accutane has been temporally associated with inflammatory bowel disease (including regional ileitis) in patients without a prior history of intestinal disorders. Patients experiencing abdominal pain, rectal bleeding or severe diarrhea should discontinue Accutane immediately.

Appellee presented an expert witness who testified that the warning was insufficient because "temporal" did not adequately describe the relationship between Accutane and IBD. Dr. Fisher testified that he understood the phrase "temporally associated" to mean that there was at least a possibility of a causal relationship between Accutane and IBD. He also testified that he would have prescribed Accutane for Appellant even if the label warned that Accutane could cause IBD. Dr. Counselman admitted that he did not consult a prescribing reference manual before prescribing the drug for Appellee. At the close of Appellee's case, Appellants' counsel moved for a directed verdict, arguing that Appellee failed to establish that his injury was proximately caused by any inadequacies in the warning. The trial court denied the motion after the jury returned its verdict in favor of Appellee.

The trial court's denial of the motion for a directed verdict is reviewed de novo. Weinstein Design Group, Inc. v. Fielder, 884 So. 2d 990, 997 (Fla. 4th DCA 2004). In order to prevail at trial on either of his claims, Appellee was required to

prove that the warning label was inadequate, that the inadequacy of the warning proximately caused his injury, and that he suffered an injury from using Accutane. Colville v. Pharmacia & Upjohn Co. LLC, 565 F.Supp. 2d 1314, 1321 (N.D. Fla. 2008). As to the causation element, Appellee was required to prove by a preponderance of the evidence, with reasonable medical probability, that Appellants' alleged negligent failure to warn was the proximate cause of his injury. Id. at 1322 (holding that a plaintiff must show that a defendant's act was more likely than not a substantial cause of a plaintiff's injury). Appellee failed to meet this burden.

As a general rule, drug companies have the duty to warn of a drug's dangerous side effects; however, the duty to warn is directed to physicians rather than patients under the "learned intermediary" doctrine. Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989); Buckner v. Allergan Pharm., Inc., 400 So. 2d 820, 822 (Fla. 5th DCA 1981) (explaining that a physician acts as a learned intermediary between the manufacturer and the consumer because the physician, as a medical expert, can make an informed choice based on the propensities of the drug and the susceptibilities of the patient). "[I]f the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the

informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient." Buckner, 400 So. 2d at 823 (quoting Terhune v. A.H. Robbins Co., 577 P.2d 975, 978 (Wash. 1978)). Thus, the duty of a drug manufacturer to warn of the dangers involved in the use of a drug is satisfied if it gives an adequate warning to the physician who prescribes the drug. Buckner, 400 So. 2d at 823.

While Appellee presented testimony that the warning label was inadequate to warn physicians that Accutane use could lead to IBD, Dr. Fisher, the prescribing physician, testified that he understood the warning label to mean that there was at least a possibility of a causal relationship between Accutane and IBD. He testified that he would still be willing to prescribe Accutane to his patients even if there was evidence showing that it could cause IBD in rare cases. He also testified that even if the warning label contained all of the information suggested by Appellee's expert, he would still have prescribed the medication for Appellee. Thus, any inadequacies in Accutane's warning label could not have been the proximate cause of Appellee's injury because Dr. Fisher understood that there was a possibility that use of the drug could lead to Appellee developing IBD and he made an informed decision to prescribe the drug for Appellee despite this risk. Because Appellee presented no evidence to establish proximate cause, the trial court erred in denying Appellants' motion for a directed verdict. Accordingly, we reverse the final

judgment entered in Appellee's favor. In light of our disposition of this issue on appeal, we do not need to address the other issues raised on appeal.

REVERSED.

WEBSTER, DAVIS, and LEWIS, JJ., CONCUR.