UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

IN RE:

ACCUTANE PRODUCTS LIABILITY **MDL 1626 - IBD TRACK CASES**

Case No: 8:04-MD-2523-T-30TBM
8:11-CV-1621-T-30TBM
(Michelle Colli)

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ORDER

THIS CAUSE comes before the Court upon Defendants' Motion for Summary Judgment Based on the Adequacy of Accutane's Warnings (Dkt. 993), Plaintiff Michelle Colli's Response in opposition (Dkt. 1004), Plaintiffs' Steering Committee's Memorandum in opposition (Dkt. 1005), and Defendants' Reply (Dkt. 1012). The Court, having considered the motion, responses, reply, record evidence, and being otherwise advised of the premises, concludes that the motion should be granted.

BACKGROUND

I. Introduction

This is a product liability case arising from Plaintiff Michelle Colli's use of the pharmaceutical product Accutane. Plaintiff alleges that, as a consequence of taking Accutane, she was diagnosed with inflammatory bowel disease ("IBD"). Defendants move for summary judgment based on the adequacy of Accutane's warnings in place when Plaintiff

first used Accutane in 2004. Defendants also move for summary judgment on Plaintiff's remaining claims, stating that they relate to Plaintiff's failure to warn claim.

The Court concludes that, under New York law, there is no issue of material fact as to the legal adequacy of Accutane's IBD warnings during the relevant time. Accordingly, Defendants are entitled to summary judgment on Plaintiff's warning claims. The Court also concludes that Defendants are entitled to summary judgment on Plaintiff's remaining claims because, under New York law, a prescription drug is not defectively designed when it is accompanied by an adequate warning.

II. Plaintiff's Accutane/Isotretinoin Treatment

Plaintiff first began taking Accutane in March of 2004 at the age of thirteen. On March 3, 2004, Plaintiff visited Dr. Daniel Buchen, a dermatologist. Dr. Buchen diagnosed Plaintiff with cystic scarring acne. His records reflect that he did not prescribe Accutane on this initial visit, but that he counseled Plaintiff about Accutane and provided her with the Accutane consent forms that, at that time, were included within the patient brochures for Accutane.

On March 10, 2004, Plaintiff returned to Dr. Buchen. His records reflect that Plaintiff received thirty minutes of Accutane counseling. The pharmacy records reflect that Plaintiff filled her first prescription for Accutane on March 24, 2004, and received 30 pills of branded Accutane. All of Plaintiff's subsequent prescriptions were filled with a generic version of isotretinoin, Amnesteem, manufactured by Mylan Pharmaceuticals.

Plaintiff used Amnesteem until summer 2005. In May 2006, Plaintiff was diagnosed with Mega Colon, a complication of IBD.

Plaintiff alleges seven causes of action: negligence (Count I), defective design (Count II), failure to warn (Count III), breach of express and implied warranties (Counts IV & V), fraudulent misrepresentations (Count VI), and fraudulent concealment (Count VII).

III. Accutane Labeling

When Plaintiff used Accutane in 2004, warnings and guidance for physicians who prescribed it included the Physician Package Insert, a Medication Guide, and a patient brochure containing two consent forms available to physicians to counsel patients considering Accutane.

The Physician Package Insert in 2004 provided a titled warning in the "Warnings" section of the insert, as well as a cross-reference under the Gastrointestinal system organ class in the Adverse Reactions section:

> **WARNINGS . . .**
> **Inflammatory Bowel Disease**
> Accutane has been associated with inflammatory bowel disease (including regional ileitis) in patients without a prior history of intestinal disorders. In some instances, symptoms have been reported to persist after Accutane treatment has been stopped. Patients experiencing abdominal pain, rectal bleeding or severe diarrhea should discontinue Accutane immediately (see ADVERSE REACTIONS: Gastrointestinal).
>
> . . .

> **ADVERSE REACTIONS . . .**
> Gastrointestinal
> inflammatory bowel disease (see WARNINGS: Inflammatory Bowel Disease), . . . bleeding and inflammation of the gums, colitis, esophagitis/esophageal ulceration, ileitis, nausea, other nonspecific gastrointestinal symptoms

(Dkt. 993 at Ex. E).

In addition to the physician labeling, in January 2001, Defendants Hoffmann-La Roche Inc. and Roche Laboratories Inc. ("Roche"), in consultation with the FDA, adopted one of the first Medication Guides for Accutane.[1] In the version in place in March 2004, the first section entitled "What is the most important information I should know about Accutane?" contained the warning that "Accutane can cause serious side effects." (Dkt. 993 at Ex. F). The Medication Guide listed the "possible serious side effects" of Accutane, including the following paragraph relating to IBD and other gastrointestinal problems:

> **Abdomen (stomach area problems).** Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking Accutane. Stop taking Accutane and call your prescriber if you get severe stomach, chest or bowel pain, trouble swallowing or painful swallowing, new or worsening heartburn, diarrhea, rectal bleeding, yellowing of your skin or eyes, or dark urine.

Id.

[1] A Medication Guide is a relatively new type of risk communication for certain medications, required by federal law to be dispensed at the pharmacy, that explains the risks of a medicine in a patient friendly manner. *See* 21 C.F.R. § 208.24(e) (2011).

Roche instructed medical professionals that the Medication Guide should "be used in all prescriber discussions with patients." (Dkt. 993 at Ex. H). The entire text of the Medication Guide was reproduced in the Physician Package Insert.

In conjunction with the launch of the SMART Risk Management Program in 2001, Roche issued a Guide to Best Practices for use by physicians in prescribing Accutane. In this Guide, Roche instructed that doctors should fully counsel patients about the warnings and precautions in the Physician Package Insert, including specifically "inflammatory bowel disease." (Dkt. 993 at Ex. I).

The SMART Program also expanded the patient brochures; the Ninth and Tenth Edition Patient Brochures were in place and approved by the FDA in November 2002 and November 2003, respectively. (Dkt. 993 at Exs. J & K). Both the Ninth and Tenth Edition Patient Brochures stated in the first section:

> Accutane can cause serious side effects. Before you decide to take Accutane, you must discuss with your prescriber how bad your acne is, the possible benefits of using Accutane, and its possible side effects . . . Your prescriber will ask you to read and sign a form or forms to show that you understand some of the serious risks of Accutane. Please read this brochure carefully and ask your prescriber any questions you may have.

Id. The brochures further stated:

> Do not take Accutane (isotretinoin) unless you completely understand its possible risks and are willing to follow all of the instructions in this brochure. When you pick up your Accutane prescription at the pharmacy, you should receive a copy of the Accutane Medication Guide with your Accutane.

Id. Both brochures also contained the following warning language about gastrointestinal risks derived from the original FDA-authored Medication Guide:

> You should be aware that certain **SERIOUS SIDE EFFECTS** have been reported in patients taking Accutane. Serious problems do not happen in most patients. If you experience any of the following side effects or any other unusual or severe problems, stop taking Accutane right away and call your prescriber because they may result in permanent effects.
>
> * * * * *
>
> • **Abdomen (stomach area) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking Accutane. Stop taking Accutane and call your prescriber if you get severe stomach, chest or bowel pain; have trouble swallowing or painful swallowing; get new or worsening heartburn, diarrhea, rectal bleeding . . .

Id.

In April 2002, the FDA approved a new blister pack that physically affixed the Medication Guide to the Accutane packaging. (Dkt. 993 at Ex. L).

SUMMARY JUDGMENT STANDARD OF REVIEW

Motions for summary judgment should be granted only when the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett,* 477 U.S. 317,

322 (1986). The existence of some factual disputes between the litigants will not defeat an otherwise properly supported summary judgment motion; "the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) (emphasis in original). The substantive law applicable to the claimed causes of action will identify which facts are material. *Id.* Throughout this analysis, the court must examine the evidence in the light most favorable to the non-movant and draw all justifiable inferences in its favor. *Id.* at 255.

Once a party properly makes a summary judgment motion by demonstrating the absence of a genuine issue of material fact, whether or not accompanied by affidavits, the nonmoving party must go beyond the pleadings through the use of affidavits, depositions, answers to interrogatories and admissions on file, and designate specific facts showing that there is a genuine issue for trial. *Celotex,* 477 U.S. at 324. The evidence must be significantly probative to support the claims. *Anderson,* 477 U.S. at 248-49 (1986).

This Court may not decide a genuine factual dispute at the summary judgment stage. *Fernandez v. Bankers Nat'l Life Ins. Co.*, 906 F.2d 559, 564 (11th Cir. 1990). "[I]f factual issues are present, the Court must deny the motion and proceed to trial." *Warrior Tombigbee Transp. Co. v. M/V Nan Fung,* 695 F.2d 1294, 1296 (11th Cir. 1983). A dispute about a material fact is genuine and summary judgment is inappropriate if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Anderson,* 477 U.S. at 248; *Hoffman v. Allied Corp.,* 912 F.2d 1379 (11th Cir. 1990). However, there must exist a

conflict in substantial evidence to pose a jury question. *Verbraeken v. Westinghouse Elec. Corp.*, 881 F.2d 1041, 1045 (11th Cir. 1989).

DISCUSSION

I. Plaintiff's Failure to Warn Claims

The Court must determine whether Defendants' warnings were adequate as a matter of law under New York law, which is where Plaintiff resided and was prescribed Accutane.[2] Under New York law, a prescription drug manufacturer may avoid liability for injuries that would ordinarily render the manufacturer strictly liable by distributing proper directions and warnings with the drug. *See generally Martin v. Hacker*, 628 N.E.2d 1308 (N.Y. 1993). To avoid liability, a manufacturer must warn of "all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist." *Id.* at 1311.

New York courts apply the "learned intermediary" doctrine. *Id.* Under this doctrine, physicians act as "informed intermediaries" between manufacturers and patients regarding warnings for prescription drugs. *Id.* Thus, a "manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient." *Id.* The warning "must provide sufficient information to that category of prescribing physicians who may be expected to have the least knowledge and experience with the drug." *Id.* Also, the warning must be "sufficient to convey to any

[2] The Court previously addressed adequacy under New York law in *Snyder v. Hoffmann-La Roche, Inc.*, No. 8:07-cv-1282-T-30TBM, 2008 WL 4790666 (M.D. Fla. Oct. 30 2008), with respect to Accutane's psychiatric warnings.

reasonably prudent physician an unambiguous and consistent message" about the alleged risk. *Id.* at 1315.

A court may hold a prescription drug warning to be adequate as a matter of law "if it provides specific and detailed information on the risks of the drug." *Id.* at 1312. In considering the adequacy of a warning, a court "must examine not only the meaning and informational content but also the form and manner of expression." *Id.* The factors a court should consider include "whether the warning is accurate, clear, consistent on its face, and whether it portrays with sufficient intensity the risk involved in taking the drug." *Id.* A warning is accurate if it is "correct, fully descriptive and complete" and conveys "updated information as to all of the drug's known side effects." *Id.* at 1313. A warning is clear if it is "direct, unequivocal and sufficiently forceful to convey the risk." *Id.* An otherwise clear warning may be obscured by inconsistencies in other sections of a package insert that contradict or dilute the warning. *Id.* However, "a court should consider the warning as a whole," and any vagueness "may be overcome if, when read as a whole, the warning conveys a meaning as to the consequences that is unmistakable." *Id.*

Importantly:

> It has long been the law in New York that prescription medicine warnings are adequate when, as here, information regarding "the precise malady incurred" was communicated in the prescribing information. *Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 96–97 (N.Y. App. Div. 1979), aff'd, 417 N.E.2d 1002 (N.Y. 1980); *Fane v. Zimmer,* 927 F.2d 124, 129 (2d Cir.1991). In such instances, when a plaintiff claims to be injured in a manner that is addressed by warnings provided to his physician, summary judgment is granted on failure to warn claims. *See, e.g., Sita v. Danek Medical, Inc.,* 43 F. Supp. 2d 245, 260

> (E.D.N.Y. 1999) (summary judgment granted because defendant warned physician "against the precise usage and injuries in question").

Alston v. Caraco Pharmaceutical, Inc., 670 F. Supp. 2d 279, 284-85 (S.D.N.Y. 2009).

Here, Defendants argue that Roche's extensive IBD warnings in place during the time Plaintiff used Accutane (in 2004) were adequate as a matter of law. The Court agrees. The Physician Package Insert plainly and prominently identified inflammatory bowel disease by name as a *possible consequence of taking Accutane*. This risk information appeared in the "WARNINGS" and "ADVERSE REACTIONS" sections of the insert. It also identified the common symptoms of IBD and instructed what should be done if those symptoms appeared. Likewise, the Medication Guide warned that Accutane may result in *permanent damage to the bowels*. The Medication Guide and patient brochures also broadly communicated that Accutane "can cause" serious side effects and proceeded to list *permanent damage to various organs, including the bowels*, among such potential serious side effects. This language tracked the WARNINGS section of the Physician Package Insert, which notified physicians that Accutane "has been associated with" IBD. Both independently and taken together, these formulations communicated the same essential message to prescribing physicians: IBD is a potential risk of Accutane.

Plaintiff's arguments against summary judgment are unpersuasive. For example, Plaintiff's argument that summary judgment is premature fails because, as Defendants point out, no further discovery is necessary to establish the *objective* adequacy of the warnings.[3]

[3] Notably, the Court initially denied Defendants' summary judgment motion as premature (continued...)

Also, the law is clear that Defendants' duty runs to the medical community, not to the patients. Roche had no duty to warn Plaintiff directly or otherwise ensure that her prescribing physician conveyed appropriate warnings to her. Finally, the Court disagrees that this issue should be left to a jury. As stated above, the warnings are direct, unequivocal and sufficiently forceful to convey the risk of IBD. Indeed, they warned of the "precise malady" Plaintiff incurred. Under New York law, summary judgment is appropriate as a matter of law under these circumstances. Thus, Defendants' motion is granted on this issue.

II. Plaintiff's Remaining Claims

Defendants argue that they are entitled to summary judgment on Plaintiffs' remaining claims because these claims are predicated on a failure to warn. The Court agrees that, under New York law, the adequacy of the warnings, as a matter of law, precludes any related claims for negligence, strict liability, breach of warranties, or fraud. *See Martin*, 628 N.E.2d at 1311, n.1 ("[w]here liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent").

Finally, Plaintiff's argument in her response that the design defect claims "are separate and distinct" from the "inadequacy of warnings claims" is without merit because, under New York law, an adequate warning bars design defect liability against the manufacturer. Specifically, in *Martin*, the Court of Appeals wrote:

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[3](...continued)
in *Snyder* (*see* n.2 above) because, like *Stupak v. Hoffman-La Roche, Inc.*, 2007 WL 2350561 (M.D. Fla. Aug. 17, 2007), proximate cause was at issue. Here, only adequacy is at issue.

> Although a prescription drug is by its nature an inherently unsafe product and would in the usual case impute strict liability to its manufacturer, a defense is provided against such liability when the drug is properly prepared, and accompanied by proper directions and warning. Therefore, even though its side effects may cause injury, *a prescribed drug, accompanied by adequate warnings, is not defective, nor is it unreasonably dangerous*.

628 N.E.2d at 1311 (internal citations and quotations omitted) (emphasis added); *see also Gensler v. Sanolfi-Aventis*, 2009 WL 857991, at *6 (E.D.N.Y. Mar. 30, 2009).

Accordingly, Defendants' motion is granted with respect to Plaintiff's remaining claims.

It is therefore **ORDERED AND ADJUDGED** that, for the reasons stated herein:

1. Defendants' Motion for Summary Judgment Based on the Adequacy of Accutane's Warnings (Dkt. 993) is **GRANTED**.
2. The Clerk of Court is directed to enter **FINAL JUDGMENT** in favor of Defendants and against Plaintiff.
3. The Clerk of Court is directed to close case: **8:11-CV-1621-T-30TBM**.

DONE and **ORDERED** in Tampa, Florida on July 24, 2012.

JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel/Parties of Record

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