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
8:14-CV-157-T-30TBM
(Karly Greenshields)

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ORDER

THIS CAUSE comes before the Court upon Defendants' Corrected Dispositive Motion for Summary Judgment Based on the Adequacy of Accutane's Warnings (Dkt. 1361). The Court, having considered the motion, 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 Karly Greenshields' use of the pharmaceutical product isotretinoin. Plaintiff alleges that, as a consequence of taking isotretinoin, she was diagnosed with inflammatory bowel disease ("IBD"). Defendants move for summary judgment based on the adequacy of isotretinoin's warnings in place when Plaintiff first used isotretinoin in 2007. 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 California law, there is no issue of material fact as to the legal adequacy of isotretinoin'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 they are based on the adequacy of Defendants' warnings.

II. Plaintiff's Isotretinoin Treatment

Plaintiff first began taking isotretinoin in 2007 at the age of eighteen. Plaintiff initially consulted her pediatrician for treatment of facial and back acne in December 2005. For the next six months, Plaintiff tried several acne medications, however, none were successful. On July 13, 2006, Plaintiff visited a dermatologist, Dr. Emily Jong and inquired about using isotretinoin. Her records reflect that Dr. Jong and Plaintiff reviewed an isotretinoin pamphlet, discussed side effects, and Dr. Jong answered Plaintiff's questions. Dr. Jong provided Plaintiff with materials for a mandatory patient registry program called iPLEDGE that, at that time, were included within the patient brochures for isotretinoin. The materials included two consent forms, which Plaintiff signed. Dr. Jong instructed Plaintiff to report any "persistent symptom which is unusual."

Plaintiff did not begin taking isotretinoin, but instead elected to try a different acne medication. This medication did not work and Plaintiff reconsidered isotretinoin. On October 22, 2007, Plaintiff again visited Dr. Jong, reviewed side effects information and

signed consent forms for a second time. Plaintiff was prescribed 40 mg daily isotretinoin. The pharmacy records reflect that Plaintiff filled her first prescription for isotretinoin on October 26, 2007. Plaintiff used isotretinoin until May 2008.

In January 2012, Plaintiff visited a gastroenterologist. Her records reflect that she complained of an "altered bowel pattern", "intermittent abdominal pain", and "intermittent blood-streaked diarrhea."

On November 1, 2012, Plaintiff brought a complaint in California state court alleging causes of action for strict product liability, product liability due to manufacturing and design defect, failure to warn, and negligence. The action was later removed to federal court and transferred to this Court.

III. Isotretinoin Labeling

When Plaintiff first discussed using in 2006, 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 isotretinoin.

The Physician Package Insert in 2006 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**
> [isotretinoin] 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 [isotretinoin] 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. 1361 at Ex. A).

Plaintiff received similar materials from Dr. Jong again in 2007, which contained the same warnings regarding gastrointestinal symptoms. 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 isotretinoin.[1] The version in place in 2006 and 2007, contained the warning that isotretinoin "can cause serious side effects." (Dkt. 1361 at Exs. A, B). The Medication Guide listed the "possible serious side effects" of isotretinoin, including the following paragraph relating to IBD and other gastrointestinal problems:

> **stomach area (abdomen) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection

[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).

> between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking [isotretinoin]. Stop taking [isotretinoin] 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
> - dark urine.

Id.

Roche instructed medical professionals that the Medication Guide should "be used in all prescriber discussions with patients." (Dkt. 1361 at Ex. D). The entire text of the Medication Guide was reproduced in the both of the iPLEDGE informational brochures. The brochures further cautioned patients that "[i]sotretinoin can cause serious side effects, including birth defects" and that patients should "learn about the iPLEDGE program and the isotretinoin side effects and risks" and talk to their doctors "about how isotretinoin can help your skin and about the side effects." (Dkt. 1361 at Ex. F). Patients were required to sign informed consent forms confirming that they had "read the *iPLEDGE Program Patient Introductory Brochure*, and other materials [their] provider gave [them] containing important safety information about isotretinoin" and confirming that the patient "underst[ood] all the material [she] received." (Dkt. 1361 at Exs. A, B). The form also required the prescribing physician to attest that she had "fully explained to the patient…the nature and purpose of isotretinoin treatment, including its benefits and risks." *Id.*

Additionally, in April 2002, the FDA approved a new blister pack that physically affixed the Medication Guide to the isotretinoin packaging. (Dkt. 1361 at Ex. G).

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 California law, which is where Plaintiff resided and was prescribed isotretinoin. Under California 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 Brown v. Superior Court*, 44 Cal. 3d 1049, 1058, 751 P.2d 470, 475 (1988). To avoid liability, a manufacturer must warn of "warn of dangers inherent in the use of its product that were either known

or knowable." *Id.* at 1059. California courts apply the "learned intermediary" doctrine. *See Carlin v. Superior Court*, 13 Cal. 4th 1104, 1126, 920 P.2d 1347, 1360-61 (1996). This doctrine provides that in the case of prescription drugs, the duty to warn "runs to the physician, not to the patient." *Id.* at 1116 (citations omitted). Thus, "a prescription drug manufacturer may avoid liability for injuries that would ordinarily render the manufacturer strictly liable by providing adequate warnings to physicians about any known or reasonably knowable dangerous side effects, regardless of whether the warning reaches the patient." *Stanley v. Novartis Pharm. Corp.*, CV 11-03191-JGB OPX, 2014 WL 1316217, at *11 (C.D. Cal. Apr. 2, 2014) (applying California law). The warning must include any "particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." *Carlin*, 13 Cal. 4th 1104 at 1112.

A court may hold a prescription drug warning to be adequate as a matter of law "if it directly warns in plain and explicit terms of the specific risk that has caused injury to plaintiff. *Dash v. Roche Labs.*, 74 F.3d 1245 (9th Cir. 1996) (citing *Kearl v. Lederle Laboratories*, 218 Cal. Rptr. 453, 467 (1985) (applying California law). Here, Defendants argue that Roche's extensive IBD warnings in place during the time Plaintiff used isotretinoin (in 2006-2007) 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 isotretinoin*. 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 isotretinoin may result in *permanent damage to the bowels*. The Medication Guide and patient brochures also broadly communicated that isotretinoin "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 isotretinoin "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 isotretinoin. Accordingly, under California 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 negligence and manufacturing and design defect claims because these claims are predicated on a failure to warn and because California law does not recognize separate design defect claims sounding either in strict liability or negligence for prescription pharmaceuticals. The Court agrees that, under California law, where warnings are adequate, as a matter of law, any related claims for manufacturing or design defect are precluded. *See Brown*, 751 P.2d at 475 ("The producer of a properly

manufactured prescription drug may be held liable for injuries cause by the product only if it was not accompanied by a warning of dangers the manufacturer knew or should have known about"; *see also Garrett v. Howmedica Osteonics Corp.*, 153 Cal. Rptr. 3d 693, 699 (Cal. 2013) ("Under the negligence standard…adopted in *Brown*, a manufacturer is liable for a design defect only if it failed to warn of a defect that it either knew or should have known existed). Accordingly, Plaintiff's manufacturing and design defect claim cannot survive summary judgment.

Defendants argue that Plaintiff's negligence claim is similarly premised on the failure to warn. Plaintiff alleges that isotretinoin was "unsafe for the use and purpose for which [it was] intended when used as recommended by Defendants" and that Defendant did not make this "known" to Plaintiff. The Court concludes that Plaintiff's negligence claim is encompassed by its warnings claims. California courts have recognized that the duties imposed in strict liability inquiries based on failure to warn are greater than those imposed under negligence standard. *See Valentine v. Baxter Healthcare Corp.*, 81 Cal. Rptr. 2d 252, 263 (Cal Ct. App. 1999). Because Defendants have satisfied the greater strict liability showing to prove its warnings were adequate, Plaintiff's negligence claims must also fail. 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' Corrected Dispositive Motion for Summary Judgment Based on the Adequacy of Accutane's Warnings (Dkt. 1361) is **GRANTED**.

2. The Clerk of Court is directed to enter **FINAL JUDGMENT** in favor of Defendants and against Plaintiff.

3. The case shall remain open.

DONE and **ORDERED** in Tampa, Florida on September 23, 2014.

JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel/Parties of Record

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