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SUPERIOR COURT OF NEW JERSEY
COUNTIES OF
ATLANTIC AND CAPE MAY

CAROL E. HIGBEE, P.J.Cv.

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MEMORANDUM OF DECISION ON MOTION
Pursuant to Rule 1:6-2(f)

CASE:	**In re Accutane Litigation**
DOCKET #:	**Case No. 271**
DATE:	**December 10, 2008**
MOTION:	**Omnibus Motion for Summary Judgment on the Adequacy of Accutane Warnings following the adoption of the Medication Guide in January 2001**
ATTORNEYS:	**Michelle M. Bufano, Esq. – Defendants** **David R. Buchanan, Esq. - Plaintiffs**

Having carefully reviewed the papers submitted and oral arguments presented, I have ruled on the above Motion as follows:

BACKGROUND

Defendants Hoffman-La Roche Inc. and Roche Laboratories Inc. (hereinafter "defendants") filed the instant Motion for Summary Judgment against eighty-four (84) plaintiffs who reside or resided outside of New Jersey at the relevant periods in time, but who have brought an action under the New Jersey Products Liability Act ("NJPLA"). N.J.S.A. § 2A:58C-1 to -11. All plaintiffs allege that their ingestion of Accutane after January 2001 caused them to develop inflammatory bowel disease ("IBD"). The Accutane warnings in existence after January

2001 (hereinafter "the January 2001 warnings") include the post-May 2000 package insert, which this Court previously declined to find adequate as a matter of law. In Re: Accutane Litigation, No. 271 (Law Div. March 20, 2008) (slip op.). In addition, the January 2001 warnings include a Medication Guide, the "Dear Healthcare Provider" letter, and the Informed Consent/Patient Agreement. Defendant urges this Court to find that the addition of these documents made the January 2001 warning adequate as a matter of law.

The post-May 2000 warning states:

> **WARNINGS:** ...
>
> *Inflammatory Bowel Disease*: Accutane has been associated with inflammatory bowel disease (including regional iletis) 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*), hepatitis (see WARNINGS: *Hepatotoxicity*), pancreatitis (see WARNINGS: *Lipids*), bleeding and inflammation of the gums, colitis, ileitis, nausea, other nonspecific gastrointestinal symptoms.
>
> [Accutane Physician Package Insert (May 2000 ed.)].

The Medication Guide states in the relevant portion:

> **Accutane has possible serious side effects** ...
>
> **Abdomen (stomach area) problems**. Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, and bowel (intestines). If your organs are damaged, they may not get better even after you stop taking Accutane. Stop taking Accutane and call your provider if you get severe stomach or bowel pain, diarrhea, rectal bleeding, yellowing of your skin or eyes, or dark urine.
>
> . . . .
>
> Serious permanent problems do not happen often. However, because the symptoms listed above may be signs of serious problems, if you get them, stop taking Accutane and call your provider. If not treated, they could lead to serious

> health problems. Even if these problems are treated, they may not clear up after you stop taking Accutane.
>
> [Accutane Medication Guide (Jan. 2001 ed.)].

The January 22, 2001 "Dear Health Care Provider" letter states primarily that the Medication Guide summarizes "key safety issues" and was intended "to be available for every patient." Accutane Dear Health Care Provider Letter (Jan. 22, 2001 ed.). It also states that "[p]atient education materials are intended to be used in all prescriber discussions with patients to assure the safe and effective use of Accutane." Accutane Dear Health Care Provider Letter, supra. It contains no additional, independent warnings.

The Informed Consent form is described in the Medication Guide. It states:

> The Informed Consent for Accutane is also a new document that is to be completed and signed by each Accutane patient before receiving Accutane. After the prescriber has determined that a patient may be a candidate for Accutane, and has explained the proper use of this medication and the possible side effects the patient may experience, the patient must initial each of the 12 items and sign and date the entire informed consent. The prescriber is also to sign this document.
>
> [Accutane Dear Health Care Provider Letter (Jan. 22, 2001 ed.)].

SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law." R. 4:46-2(c). A "genuine" issue is one that, with "all legitimate inferences therefrom favoring the non-moving party, would require submission of the issue to the trier of fact." Id. A genuine issue is *not* one which is "immaterial or of an insubstantial nature, a mere scintilla." Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 530

(1995) (quoting Judson v. Peoples Bank & Trust Co. of Westfield, 17 N.J. 67, 75 (1954)). The court should deny a motion for summary judgment only if the non-moving party raises a genuine issue of material fact. It is not sufficient to name merely "any fact in a dispute." Brill, supra, 142 N.J. at 529.

Furthermore, "[t]he judge's function is not himself [or herself] to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Id. at 540 (internal quotations omitted). Ultimately, "[c]redibility determinations" must be made by a jury, and not a judge. Ibid.

DISCUSSION

Defendant contends that the issue of whether the warnings are adequate can be resolved as a matter of law in this instance. The plaintiffs allege in response that the issue of adequacy is typically left to a jury, and cannot be appropriately resolved by summary judgment. Viewing all the evidence in favor of the plaintiff, the Court must deny this motion for summary judgment because it cannot find that the January 2001 warnings are adequate as a matter of law.

The eighty-four plaintiffs at issue here brought claims under the NJPLA. N.J.S.A. § 2A:58C-1 to -11. The NJPLA indicates that no liability will be imposed if the product contains an adequate warning. N.J.S.A. § 2A:58C-4. NJPLA states in the relevant part:

> An adequate product warning ... is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, ... [and] in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.
>
> [N.J.S.A. § 2A:58C-4].

Adequacy of the Warnings

"[Q]uestions of reasonableness in determining the adequacy of warnings are ordinarily left for the jury to resolve." Grier v. Cochran Western, 308 N.J. Super. 308, 317 (App. Div. 1998). Therefore, a warning may be found to be adequate as a matter of law *only* if the warning is "accurate, clear, and unambiguous". Banner v. Hoffman La-Roche, 383 N.J. Super. 364, 379-380 (App. Div. 2006), certif.. denied, 190 N.J. 393 (2007).

The test utilized by the New York courts and relied on in Banner v. Hoffman La-Roche is of particular assistance in determining whether the warning is adequate as a matter of law. First, the Court must examine "the seriousness of the involved risk." Id. at 380. The Court must evaluate "the language 'for its accuracy, clarity and relative consistency ... [and require] that the language of the warning is direct, unequivocal and sufficiently forceful to convey the risk." Ibid. Finally, the Court must determine "if, when read as a whole, the warning conveys a meaning as to the consequences that is unmistakable." Ibid.

This Court has previously ruled that the warning post 2000 could be found by a reasonable jury to be adequate or inadequate, but it is not so clear that the issue shall be taken from the jury. The Medication Guide primarily at issue here was intended to be distributed directly to the patient by the physician or pharmacist and to be utilized in physician-patient discussions about the risks of Accutane. Although the Medication Guide was intended to be directly distributed to the consumer, the defendants argue that the learned intermediary doctrine does apply. That doctrine, applicable in the vast majority of states, indicates that a "pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying *physicians* with information about the drug's dangerous propensities." Niemiera v. Schneider, 114 N.J. 550, 559 (1989) (emphasis added). The NJPLA also confirms that an adequate warning is owed to the physician. N.J.S.A. 2A:58C-4.

In evaluating the adequacy of the warnings, the NJPLA requires the drug manufacturer to consider the "characteristics of, and the ordinary knowledge common to, the prescribing physician."[1] N.J.S.A. § 2A:58C-4. This Court must then expressly consider what the warning "convey[s] to a reasonable physician." In Re: Accutane Litigation, supra, No. 271, slip. op. at 4. Here, the prescribing physicians are dermatologists; this Court will, therefore, consider the ordinary knowledge of a reasonable dermatologist in examining the adequacy of the warnings.

This Court, as noted above, previously declined to find the post-May 2000 package insert alone adequate as a matter of law. The Court stated that "[a] warning can be adequate without using the word 'causes,' but it can also be inadequate depending on all the facts," and left the issue to a jury. In Re: Accutane Litigation, supra, No. 271, slip. op. at 6. Therefore, I will not re-address questions of whether the "associated with" language, or any other language in the package insert, is sufficiently clear and unambiguous to merit summary judgment. Rather, this Court will focus on the addition of the Medication Guide to the package insert, and whether this addition renders the warnings sufficiently clear and unambiguous to a reasonable dermatologist with ordinary knowledge to take the issue away from the jury.

For the purpose of this decision, this Court must examine the facts in a light most favorable to the plaintiff. Therefore, we accept the plaintiff's allegations that Accutane causes IBD. The parties have previously acknowledged that IBD is a permanent condition. In Re: Accutane Litigation, supra, No. 271, slip. op. at 5. While, in some cases, some gastrointestinal symptoms may subside after a patient stops taking the drug, if Accutane has damaged the intestine and triggered IBD, that is a permanent condition. Plaintiffs also point out that IBD symptoms may not present themselves while the patient is on the drug, and IBD can require

[1]Although the NJPLA refers only to physicians, this term has been extended to include other health care providers. Perez v. Wyeth Lab., 313 N.J. Super. 511, 517 (Law Div. 1997), rev'd on other grounds, 161 N.J. 1 (1999).

surgery and other invasive medical treatments. It can have a very terrible effect on a person's life.

The Court must evaluate the "accuracy, clarity, and relative consistency" of the language. To find the warning adequate as a matter of law, the warning's language must convey in a direct and sufficiently forceful way the risk of developing IBD. The question now is does the language in the patient guide strengthen the 2000 warning and make it so clear that the issue of adequacy of the label should be taken from the jury. As the plaintiffs point out, **the new language itself does not mention IBD**. In fact, the new language refers generally to "the liver, pancreas, and bowel (intestines)." It is so general it could be found to weaken the information in the label, not strengthen it. There is no direct reference to IBD.

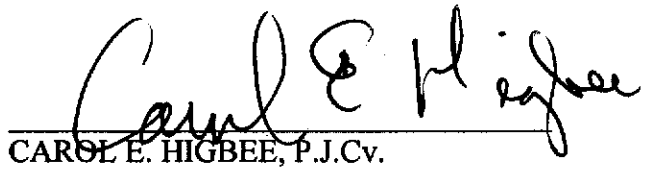
The Medication Guide also states "[the symptoms] **may not** get better even after you stop taking Accutane." (emphasis added). It is not disputed that if you have IBD, you will not get "better," in the sense you will ever be cured.

Additionally, the plaintiffs point out (and the defendants ignore) additional language in the Medication Guide in a paragraph at the bottom of the "serious side effects" listings. The language states that "[i]f [the symptoms are] not treated, they **could lead** to serious health problems. Even if these problems are treated, they **may not** clear up after you stop taking Accutane." (emphasis added). The "could lead" and "may not" language are ambiguous. The ambiguity of the warnings reflects the defendants position that there is no proof of causation. Since the Court must accept all facts in favor of the plaintiff, including causation, which four juries have found does exist, "could lead" and "may not" are just not direct enough to render the warning adequate as a matter of law even if they directly discussed IBD which they do not. Again, it may be adequate, but it clearly is a jury question.

The defendants point out that the language in the Medication Guide was intended to be read by patients, is appropriate language for a layperson, and it is "coupled with" the express language of the package insert. Since this Court declined to grant summary judgment on the package insert which does refer directly to IBD, the Court cannot find the generalized language of the Medication Guide, which doesn't mention IBD, sufficiently forceful to render the warning adequate as a matter of law.

As a whole, the warning includes both the post-May 2000 package insert and the January 2001 Medication Guide. The language in the package insert specifically refers to IBD and notes that symptoms "have been reported to" continue after Accutane is stopped. The Medication Guide does not refer to IBD and states that symptoms "may" continue. There is an apparent and wide difference in language between these two documents. Again, a jury may be satisfied that these communications conveyed to a reasonable physician the nature of the risk involved. This Court will not take this issue from the jury and find the warnings adequate or inadequate as a matter of law.

The motion for summary judgment on all the cases pending on Schedule A involving Accutane use when this warning was in effect is denied.



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XXXX Order is attached.