UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

Paul Engelhard, Plaintiff, v. Wyeth Consumer Healthcare Ltd. and R.P. Scherer Corporation, Defendants.	Case No. 11 C 5162 Judge John Robert Blakey

MEMORANDUM OPINION AND ORDER

This products liability action arises from injuries Plaintiff Paul Engelhard purportedly sustained after taking two capsules of Advil Liqui-Gels without food and then laying down. Plaintiff brought failure to warn and defective design claims against the manufacturers of Advil Liquid-Gels, Defendants Wyeth Consumer Healthcare Ltd. and R.P. Scherer Corporation. Compl. [1-2] Counts I-II. Currently, only the failure to warn claim (Count I) remains. Defs.' Statement of Facts ("DSOF") [89] ¶ 44.

Defendants have moved for summary judgment [87]. They argue that Plaintiff has failed to satisfy three of the four elements required to maintain a failure to warn claim at this stage in the proceedings. [88] at 12. For the following reasons, the motion is granted.

I. Legal Standard

Summary judgment is appropriate if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a

matter of law. *Spurling v. C & M Fine Pack, Inc.*, 739 F.3d 1055, 1060 (7th Cir. 2014). A genuine dispute as to any material fact exists if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The party seeking summary judgment has the burden of establishing that there is no genuine dispute as to any material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). In determining whether a genuine issue of material fact exists, this Court must construe all facts and reasonable inferences in the light most favorable to the nonmoving party. *See CTL ex rel. Trebatoski v. Ashland School District*, 743 F.3d 524, 528 (7th Cir. 2014).

II. Background

A. Advil Liqui-Gels

Defendants are the manufacturers of Advil Liqui-Gels. Compl. [1-2] Count I ¶¶ 1-3. Advil Liqui-Gels are a type of non-steroidal anti-inflammatory drug ("NSAID")—a class of medications widely used to alleviate pain and reduce fever. DSOF [89] ¶¶ 5-6. Advil Liqui-Gels consist of a one-piece, soft gelatin capsule containing 200 mg of ibuprofen dissolved in a liquid fill contained in the gelatin capsule. DSOF [89] ¶ 12.

The FDA approved Advil Liqui-Gels for over-the-counter use in adults in 1995. DSOF [89] ¶ 10. A stomach bleeding warning was added to Advil Liqui-Gels (and other Advil products) in 1999. Romano Decl. [90] ¶ 8. The Advil Liqui-Gels that Plaintiff used included the following warning about stomach bleeding:

> **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding.

> The chance is higher if you: ▪ are age 60 or older ▪ have had stomach ulcers or bleeding problems ▪ take a blood thinning (anticoagulant) or steroid drug ▪ take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others) ▪ have 3 or more alcoholic drinks every day while using this product ▪ take more or for a longer time than directed[.]

DSOF [89] ¶ 25.

B. Injury

On Friday, April 14, 2006, Plaintiff, who was then 52 years old and generally healthy, took two Advil Liqui-Gel capsules with water but without food. DSOF [89] ¶¶ 40, 45; Pl.'s Statement of Additional Facts ("PSOAF") [96] ¶¶ 1-2; Discharge Summary [96-1]. He went to bed and slept until Saturday morning. DSOF [89] ¶ 40; PSOAF [96] ¶ 2.

On Saturday night, Plaintiff began to experience symptoms of a stomach bleed and was hospitalized the next day (Sunday). DSOF [89] ¶ 42; PSOAF [96] ¶ 4. Plaintiff was diagnosed with a "bleeding gastric ulcer" in the very upper portion of the stomach. DSOF [89] ¶ 39; PSOAF [96] ¶ 5; Discharge Summary [96-1]. Dr. Mark Blitstein, who treated Plaintiff's ulcer, has opined in this litigation that Plaintiff would not have had an ulcer had he taken the two Advil Liqui-Gel capsules with food and not laid down. PSOAF [96] ¶¶ 7-8, 14.

C. Motion to Strike

Plaintiff moves to strike the Declaration of Nicola Romano [90]. Pl.'s Response [96] to DSOF ¶ 23; [97] ¶ 16.

Romano is the Director of Regulatory Affairs at Pfizer Consumer Healthcare, which now owns the Advil brand. Romano Decl. [90] ¶¶ 2-3. Romano has certified

that she is personally knowledgeable about the regulatory background of the Advil product line based on her job duties. Romano Decl. [90] ¶ 4. In her Declaration, Romano describes the regulatory history of Advil Liqui-Gels, including two clinical studies conducted by Defendants involving the drug.

As shown below, this Court only considers the factual information offered by Romano, which is proper under Rule 56(c)(1)(A), and thus denies the motion to strike.

In the event this Court decides to consider the Romano Declaration, Plaintiff has alternatively moved to have this Court reconsider the earlier decision [79] barring one of his experts, David Wingate. Pl.'s Response [96] to DSOF ¶ 23; [97] ¶ 16. This request is denied, however, because Romano is not offering expert testimony (and thus she is not an undisclosed expert), and because Plaintiff has not otherwise shown any manifest error of law or fact or newly discovered evidence warranting reconsideration of the prior decision to bar Wingate. *Oto v. Metropolitan Life Insurance Co.*, 224 F.3d 601, 606 (7th Cir. 2000).

II. Analysis

Plaintiff argues that Defendants failed to warn him that taking Advil Liqui-Gels without food or before laying down increases the risk of stomach bleeding. DSOF [89] ¶ 44; Engelhard Dep. Tr. [90-9] at 185:6-12, 195:8-196:2; [97] ¶¶ 3, 6, 11, 17.

The parties agree that Illinois law applies in this case. Status Report [105] § I.C. To establish that drug manufacturers failed to adequately warn under Illinois

law, Plaintiff must show that (1) Defendants had a duty to warn; (2) Defendants knew or should have known of the danger but failed to warn Plaintiff of the fact; (3) the omission of such information made the warning inadequate and the drug defective; and (4) this defect proximately caused Plaintiff's injuries. *Northern Trust Co. v. Upjohn Co.*, 572 N.E.2d 1030, 1037 (Ill. App. Ct. 1991); *see also Begley v. Bristol-Myers Squibb Co.*, No. 06 C 6051, 2013 WL 144177, at *4 (D.N.J. Jan. 11, 2013) (applying Illinois law); *Langer v. Dista Products Co.*, No. 90 C 4598, 1996 WL 526763, at *2 (N.D. Ill. Sept. 12, 1996). Defendants admit they have a duty to warn (element 1) but argue that Plaintiff has failed to satisfy the other three elements at this stage in the proceedings. [88] at 12. Failure to satisfy any element essential to a claim warrants summary judgment. *Bombard v. Fort Wayne Newspapers, Inc.*, 92 F.3d 560, 562 (7th Cir. 1996).

A. Knowledge (Element 2)

Plaintiff must prove that Defendants knew or should have known of the danger that caused his injury. *Woodill v. Parke Davis & Co.*, 402 N.E.2d 194, 198-200 (Ill. 1980); *Schultz v. Hennessy Industries, Inc.*, 584 N.E.2d 235, 242 (Ill. App. Ct. 1991); *Giles v. Wyeth, Inc.*, 556 F.3d 596, 600, 602 (7th Cir. 2009); *Crisostomo v. Stanley*, 857 F.2d 1146, 1152 (7th Cir. 1988). That knowledge must exist in the industry. *Woodill*, 402 N.E.2d at 198. The rationale for imposing a knowledge requirement is to avoid turning manufacturers into virtual insurers of their products by holding them liable for failing to warn about dangers unknown to them. *Woodill*, 402 N.E.2d at 199-200; *see Giles*, 556 F.3d at 602.

The Seventh Circuit has provided guidance about the type of evidence that is insufficient to establish a drug manufacturer's knowledge. In *Crisostomo*, the drug manufacturer prevailed on its argument that it lacked knowledge that the combination of penicillin and a drug it manufactured (Zyloprim) exacerbated the appearance of Stevens-Johnson Syndrome (a serious skin disorder). 857 F.2d at 1152-53. As a matter of law, the district court granted a directed verdict for the drug manufacturer at the close of the plaintiff's case-in-chief, and the Seventh Circuit affirmed. *Id.* at 1147.

The record in *Crisostomo* contained no evidence from which the drug manufacturer knew or should have known that combining penicillin and Zyloprim would exacerbate the appearance of Stevens-Johnson Syndrome. *Id.* at 1153. The plaintiff had propounded medical expert testimony favorable to his case, but the medical reports underlying that testimony showed that combining ampicillin (a drug chemically distinct from penicillin) and Zyloprim may lead to an increased incidence of a rash generally, not the more serious Stevens-Johnson Syndrome specifically. *Id.* Despite the Plaintiff's attempt to extrapolate the effects from ampicillion to penicillin, the Court found the evidence legally inadequate to establish the knowledge element.

Moreover, the Seventh Circuit held in *Giles* that the district court correctly granted the drug manufacturer's motion to exclude evidence of its subsequent suicide warnings on depression medication where the record did not contain any evidence that the data underlying the subsequent warnings was available (and thus

potentially known) to the drug manufacturer at the time the injury in that case occurred. 556 F.3d at 598.

Consistent with *Crisostomo* and *Giles,* courts grant summary judgment in favor of the manufacturer where the record contains insufficient evidence from which to reasonably infer knowledge. *E.g.*, *Vhora v. Michelin North America, Inc.*, No. 98 C 2657, 1999 WL 63682, at *1 (N.D. Ill. Feb. 4, 1999); *Schultz*, 584 N.E.2d at 242. The plaintiff in *Vhora*, for example, had propounded expert testimony about what an appropriate warning should have included but, as in this case, that testimony did not address the defendant's *knowledge* of the dangerous propensity of the tires that it manufactured. 1999 WL 63682, at *3.

In light of the holdings in *Crisostomo* and *Giles*, summary judgment is warranted here because Plaintiff has failed to make a sufficient showing at this stage of the proceedings that Defendants knew or should have known about the alleged product defect. Indeed, the record contains virtually no evidence that there is, in fact, any increased risk of stomach bleeding from taking Advil Liqui-Gels without food or before laying down. Plaintiff has not identified any medical or scientific evidence to support the existence of these purported dangers other than the expert testimony of a single doctor, Dr. Blitstein. Yet Dr. Blitstein has admitted that he has not seen any medical or scientific literature or other evidence suggesting that taking a NSAID, without food or just before laying down, increases the risk of stomach bleeding. DSOF [89] ¶¶ 48-50. By his own sworn testimony, Dr. Blitstein has based his opinion not on any literature or study, but rather on his

own personal extrapolation from the possibility that pill ulcers can occur in the esophagus when an individual lays down after taking a NSAID. DSOF [89] ¶ 51; Blitstein Dep. Tr. [90-11] at 201:6-202:9, 211:17-22. Such extrapolation, however, fails to create a genuine issue of disputed fact regarding the knowledge element.

Far from establishing Defendants' knowledge, the record here shows the opposite, that is, Defendants investigated the risks but found no causal link between stomach bleeding and taking of Advil Liqui-Gels without food or before laying down. DSOF [89] ¶¶ 26-38 (based on the Romano Declaration). In fact, Defendants conducted two relevant clinical studies prior to April 2006 when the injury in this case occurred. DSOF [89] ¶¶ 26-36.

The first study was conducted in 1996 and found no increased risk of stomach bleeding from subjects who took the maximum dose of Advil Liqui-Gels in a fasted state. DSOF [89] ¶¶ 26-29. Subjects were instructed to take Advil Liqui-Gels every 4 to 6 hours for 10 consecutive days and were required not to eat for an hour before and after taking each dose. DSOF [89] ¶ 27. As a result, in 1998, the FDA removed the "take with food" warning from Advil Liqui-Gels. DSOF [89] ¶ 30; 2/23/1998 FDA Letter [90-5].

The second study was conducted during 2000 and 2001 and found no clinically relevant safety concerns with the night time formulation of Advil Liqui-Gels (called Advil PM Liqui-Gels). DSOF [89] ¶¶ 31-36. With the addition of a nighttime sleep-aid, Advil PM Liqui-Gels contain the very same amount and formulation of ibuprofen in each capsule as Advil Liqui-Gels. DSOF [89] ¶ 32.

Subjects in that study were instructed to take Advil PM Liqui-Gels prior to bedtime. DSOF [89] ¶ 31. Based on this study, the FDA approved Advil PM Liqui-Gels for over-the-counter use and a label indicating the drug's intended use as a sleep aid. DSOF [89] ¶ 36. Plaintiff has presented no evidence to properly rebut these two studies.

Instead, Plaintiff responds by simply generalizing his failure to warn claim. [97] ¶¶ 9-11. Plaintiff cannot, however, create a genuine issue of material fact by (1) taking the original alleged dangers; (2) generalizing those dangers; and (3) then arguing that Defendants must have had knowledge of the generalized dangers. *See Woodill*, 402 N.E.2d at 199-200 (manufacturers are not virtual insurers of their products). Plaintiff has done just that here. Ignoring the relevant inquiry into what Defendants' knew or should have known about the specific dangers posed by taking Advil Liqui-Gels without food or before laying down, Plaintiff shifts his focus to Defendants' general knowledge that ibuprofen (the active ingredient in Advil Liqui-Gels) may cause ulcers in portions of the stomach where there are little to no protective secretions, namely, the upper portion of the stomach. DSOF [89] ¶ 5; PSOAF [96] ¶¶ 15-24; [97] ¶¶ 10-11. Such generalized knowledge is sufficient, Plaintiff claims, because just a single dose of Advil Liqui-Gels might cause an ulcer when the drug physically comes into contact with the stomach lining (referred to as the "topical effect"). [97] ¶¶ 2, 10; [103] at 6-9. Plaintiff's efforts are unavailing.

There is no dispute that Advil Liqui-Gels can cause stomach bleeding. DSOF [89] ¶¶ 19-20. That proposition is firmly established in the medical community.

Blitstein *Daubert* Tr. [90-12] at 144:6-10, 157:16-159:5. Likewise, there is no dispute that Advil Liqui-Gels contain a warning for stomach bleeding. DSOF [89] ¶ 25; [97] ¶ 17. Plaintiff accordingly could not prevail by attacking the stomach bleeding warning generally. *See Kelso v. Bayer Corp.*, 398 F.3d 640, 642-43 (7th Cir. 2005) (holding that an over-the-counter drug warning is adequate where it is "plain, clear and unambiguous").

In sum, Plaintiff has not identified any evidence in the record which shows that prior to April 2006 Defendants knew or should have known of the two relevant risks presented here, that is, taking Advil Liqui-Gels creates a risk of bleeding in the upper portion of the stomach when taken without food or before laying down. As Plaintiff has repeatedly asserted, Advil Liqui-Gels should have included a warning advising Plaintiff of the risks of taking Advil Liqui-Gels without food or before laying down. *E.g.*, Compl. [1-2] Count I ¶ 6; DSOF [89] ¶ 44; Engelhard Dep. Tr. [90-9] at 185:6-12, 195:8-196:2; [97] ¶¶ 3, 6, 11, 17; Status Report [105] § I.C. In his testimony, Plaintiff has conceded that the warning was not deficient in any other way:

> Q. Okay. Now, you're saying that the label was deficient with respect to Liqui-Gel capsules. In which ways -- in what ways are you alleging that they were deficient?
>
> A. They don't warn to take with, you know, food or -- or drink; and they don't tell you not to lie down --
>
> Q. Anything else?
>
> A. -- after taking.
>
> Q. Anything else?
>
> A. No.

> Q. So only those two things? Those are the two ways in which you believe that the label should have been modified?
>
> A. Correct.

Engelhard Dep. Tr. [90-9] at 195:8-22. Nevertheless, Plaintiff has offered no medical or scientific literature, nor any internal company document, identifying the existence of these two specific risks. To the contrary, the record shows that Defendants investigated the relevant dangers through clinical studies but found no cause for concern. Summary judgment therefore is warranted.

B. Adequate Warning and Proximate Cause (Elements 3 and 4)

Having concluded that there is no genuine issue of material fact as to the requisite knowledge element, this Court need not, and does not, consider the two alternate grounds for summary judgment advanced by Defendants. *See Bombard*, 92 F.3d at 562.

III. Conclusion

Defendants' motion for summary judgment [87] is granted.

Dated: March 11, 2015

Entered:

John Robert Blakey
United States District Judge