

[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 07-15980

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D. C. Docket No. 05-00926-CV-T-30-TBM

LAURIE A. STUPAK,

Plaintiff-Appellant,

versus

HOFFMAN-LA ROCHE, INC.,
ROCHE LABORATORIES INC.,

Defendants-Appellees.

Appeal from the United States District Court
for the Middle District of Florida

(June 10, 2009)

Before BARKETT, ANDERSON and COX, Circuit Judges.

PER CURIAM:

Plaintiff Laurie A. Stupak appeals the district court's grant of summary judgment to Defendants-Appellees Hoffman-La Roche, Inc. and Roche Laboratories, Inc. (hereinafter collectively "Roche"). Stupak brought a wrongful death claim against Roche in the state of Wisconsin for the suicide death of her son Bartholomew ("B.J.") Stupak in 2000. Specifically, Laurie Stupak claimed that Roche was liable under negligence and strict liability for failing to warn that its prescription acne medication Accutane could cause suicide without premonitory symptoms. Because Stupak has failed to identify any evidence in the record that Roche knew or should have known that Accutane could cause suicide without premonitory symptoms, we affirm the district court's grant of summary judgment.

I. FACTS

B.J. Stupak was prescribed Accutane for his acne condition in December 1999 by his dermatologist. Accutane is a medicine used to treat severe nodular acne which has not responded to other treatments. At the time that B.J. Stupak was prescribed Accutane, the product had the following FDA-approved warnings, which appeared in the 1998 physician package insert, in a 1998 "Dear Doctor Letter," and in the 1999 Physician's Desk Reference:

Psychiatric Disorders: Accutane may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts and suicide. Discontinuation of Accutane therapy may be insufficient; further evaluation may be necessary. No

mechanism of action has been established for these events (see ADVERSE REACTIONS).

...

ADVERSE REACTIONS: . . .

In the post-marketing period, a number of patients treated with Accutane have reported depression, psychosis and, rarely, suicidal ideation, suicide attempts and suicide. Of the patients reporting depression, some reported that the depression subsided with discontinuation of therapy and recurred with reinstatement of therapy (see WARNINGS).

Roche also produced a patient information brochure including the following warning at the time that B.J. Stupak took Accutane:

During your treatment

...

YOU SHOULD BE AWARE THAT ACCUTANE MAY CAUSE SOME LESS COMMON, BUT MORE SERIOUS, SIDE EFFECTS. BE ALERT FOR ANY OF THE FOLLOWING: . . .

...

● CHANGES IN MOOD

...

IF YOU EXPERIENCE ANY OF THESE SYMPTOMS OR ANY OTHER UNUSUAL OR SEVERE PROBLEMS, DISCONTINUE TAKING ACCUTANE AND CHECK WITH YOUR DOCTOR IMMEDIATELY. THEY MAY BE THE EARLY SIGNS OF MORE SERIOUS SIDE EFFECTS WHICH, IF LEFT UNTREATED, COULD POSSIBLY RESULT IN PERMANENT EFFECTS.

The patient information brochure warning set forth above was also printed directly on the blister pack in which B.J. Stupak's Accutane prescription was packaged.

In May 2000, while still taking Accutane, B.J. Stupak committed suicide. He

was seventeen years old. His family asserts that he exhibited no suicidal symptoms or changes in mood prior to his suicide. His mother, Laurie Stupak, initiated this lawsuit against Roche in the Eastern District of Wisconsin in May 2003. Laurie Stupak asserted in her complaint that B.J. Stupak's suicide resulted from his taking Accutane. She asserted that Roche was negligent and strictly liable for failing to adequately warn of the risks of suicide from taking Accutane.

The case was transferred to the Middle District of Florida for discovery as a part of In re Accutane Products Liability Litigation pursuant to a multi-district litigation order. On completion of discovery, Roche moved for summary judgment. The district court granted summary judgment to Roche on Stupak's negligence claim, finding that the warning provided regarding suicide was adequate and that Stupak could not demonstrate proximate cause. The district court later determined that there is no difference under Wisconsin law in the standard of proof required between a negligence failure to warn claim and a strict liability failure to warn claim, and thus the finding that the warning was adequate also disposed of the strict liability failure to warn claim. The district court ordered the case closed. Stupak appealed to this Court.

II. STANDARD OF REVIEW

We review the grant of Roche's motion for summary judgment de novo,

applying the same legal standards as the district court. Pipkins v. City of Temple Terrace, Fla., 267 F.3d 1197, 1199 (11th Cir. 2001). We view all facts in the light most favorable to Stupak, the non-moving party. Id. “Summary judgment is only proper if there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law.” Frederick v. Sprint/United Mgmt. Co., 246 F.3d 1305, 1311 (11th Cir. 2001). We are limited, in our review, to the evidence that was before the district court at summary judgment. Welch v. Celotex Corp., 951 F.2d 1235, 1237 n.3 (11th Cir. 1992).

III. DISCUSSION

This case is a tort suit arising under Wisconsin law.¹ Laurie Stupak argues that Roche’s warning regarding suicide associated with Accutane use was not adequate as a matter of law because it did not warn of the risk of suicide without premonitory symptoms at the time that her son B.J. took Accutane.² Stupak also argues that even if the suicide warning were adequate as a matter of law, her strict liability claim is distinct from her negligence claim and would survive summary

¹ Stupak does not challenge the district court’s application of Wisconsin law. Although Roche would have preferred the application of Michigan law, our resolution of the case in its favor under Wisconsin law moots Roche’s arguments. In any event, we see no error in the district court’s decision to apply Wisconsin law to this claim.

² This is the only arguably viable challenge that Stupak makes to the adequacy of the warnings, and thus the only one we discuss.

judgment on the negligence claim.³ Therefore, Stupak argues that the district court erred in granting summary judgment to Roche. Because Stupak has failed to direct this Court to any evidence in the record to satisfy the requirement for a negligence claim that Roche knew or should have known that Accutane could cause suicide without symptoms, and because under Wisconsin law a plaintiff must satisfy that same requirement for a strict liability claim based on failure to warn, we affirm the district court's grant of summary judgment to Roche.

A. Wisconsin Failure to Warn Law

Wisconsin recognizes failure to warn claims arising under both negligence and strict liability. See, e.g., Mohr v. St. Paul Fire & Marine Ins. Co., 674 N.W.2d 576, 583, 588 (Wis. Ct. App. 2003) (analyzing a failure to warn claim arising under both negligence and strict liability). Laurie Stupak has raised her failure to warn claim under both negligence and strict liability theories.

Under Wisconsin law, “[a] negligence action requires the proof of four elements: (1) A duty of care on the part of the defendant; (2) a breach of that duty; (3) a causal connection between the conduct and the injury; and (4) an actual loss or damage as a result of the injury.” Green v. Smith & Nephew AHP, Inc., 629

³ However, it is clear that Stupak's strict liability claim is based on an alleged failure to provide an adequate warning. Stupak has not argued that the product was defective or unreasonably dangerous in any respect other than the inadequacy of the warning.

N.W.2d 727, 745 (Wis. 2001). Wisconsin has adopted the Restatement (Second) of Torts § 388 (1965), which “addresses the duty of a manufacturer to warn in negligence actions.”⁴ Strasser v. Transtech Mobile Fleet Service, Inc., 613 N.W.2d 142, 154 (Wis. 2000). See also Vogt v. S.M. Byrne Construction Co., 115 N.W.2d 485, 486-87 (Wis. 1962), modified, 117 N.W.2d 362 (Wis. 1962) (adopting Restatement (Second) of Torts § 388). The Wisconsin Supreme Court has summarized the connection between foreseeability and the manufacturer’s duty to warn: “The standard of care for a ‘manufacturer’ of a product is to warn of dangers that he or she knows or should know are associated with the proper use of the product. This duty exists whether or not the product was properly designed.” Strasser, 613 N.W.2d at 154. Therefore, any negligence action arising under Wisconsin law premised upon the failure of a manufacturer to adequately warn of a product’s danger must establish that the manufacturer either knew or should have known of the danger.

⁴ The Restatement (Second) of Torts § 388 provides: “One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier (a) knows or has reason to know that the chattel is likely to be dangerous for the use for which it is supplied, and (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.” Mohr, 674 N.W.2d at 583 (emphasis added).

The Wisconsin Supreme Court has also held that a manufacturer may be strictly liable for failure to warn. The Wisconsin Supreme Court first adopted the Restatement (Second) of Torts § 402A,⁵ which provides for the “special liability of seller of product for physical harm to user or consumer,” in Dippel v. Sciano, 155 N.W.2d 55, 63 (Wis. 1967). The Supreme Court of Wisconsin in Dippel read §402A to require the plaintiff to prove:

(1) that the product was in defective condition when it left the possession or control of the seller, (2) that it was unreasonably dangerous to the user or consumer, (3) that the defect was a cause (a substantial factor) of the plaintiff’s injuries or damages, (4) that the seller engaged in the business of selling such product . . . and (5) that the product was one which the seller expected to and did reach the user or consumer without substantial change in the condition it was when he sold it.

Dippel, 155 N.W.2d at 63. Thus, “strict products liability focuses not on the defendant’s conduct, but on the nature of the defendant’s product.” Green, 629 N.W.2d at 745. Because the focus in strict liability claims is upon the defective or unreasonably dangerous nature of the product, and not upon the manufacturer’s

⁵ Section 402(A) of the Restatement (Second) of Torts states: “One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold. (2) The rule stated in subsection (1) applies although (a) the seller has exercised all possible care in the preparation and sale of his product, and (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.” Dippel, 155 N.W.2d at 63.

actions, foreseeability is usually not an element of a strict liability claim. Green, 629 N.W.2d at 746 (“In other words, strict products liability imposes liability without regard to negligence and its attendant factors of duty of care and foreseeability”).

However, the Supreme Court of Wisconsin held in Schuh v. Fox River Tractor Co. that a jury could find that the failure to provide an adequate warning on a product could cause a product to become “unreasonably dangerous and defective in its design.” Schuh v. Fox River Tractor Co., 218 N.W.2d 279, 284 (Wis. 1974). Thus, the failure to adequately warn can lead to strict liability in Wisconsin law. For strict liability claims based on a failure to warn, the Wisconsin courts have premised the manufacturer’s potential liability on a duty to warn. See Schuh, 218 N.W.2d at 285 (“[T]he likelihood of an accident’s taking place and the seriousness of the consequences are always pertinent matters to be considered with respect to the duty to provide a sufficient warning label . . .”); Kozlowski v. John E. Smith’s Sons Co., 275 N.W.2d 915, 921-22 (Wis. 1979) (holding that under strict liability and common law negligence inquiry, whether there was a duty to warn was a jury question because the defect may have been open and obvious). Based on the inclusion of the “duty to warn” requirement in these strict liability cases, the Wisconsin Court of Appeals has held that foreseeability is an element of a strict

liability failure to warn claim. The Wisconsin Court of Appeals has considered the issue of foreseeability in strict liability failure to warn cases, and explained that “[t]he shift in emphasis from the manufacturer’s conduct to the character of the product is true for strict liability based on product design but not for strict liability based on failure to warn. The duty to warn involves foreseeability” Krueger v. Tappan Co., 311 N.W.2d 219, 223 (Wis. Ct. App. 1981). Furthermore, the Krueger court held “a product sold without an adequate warning of danger is in a defective condition. . . . Notwithstanding that apparent merging of defective design and inadequate warning in the ‘condition’ of the product, the duty to warn arises if the seller has, or should have, knowledge of a dangerous use.” Id. (citing Restatement (Second) of Torts § 402A cmts. h & j). See also Tanner v. Shoupe, 596 N.W.2d 805, 812 (Wis. Ct. App. 1999) (“If a product is designed and manufactured to be as safe as possible, but still contains a hidden danger, the manufacturer has a duty to warn the consumer of the hidden danger. . . . The duty to warn arises when the manufacturer has, or should have, knowledge of a dangerous use.”) (internal quotations and citations omitted).

Therefore, under both negligence and strict liability failure to warn claims, the duty to warn arises from the foreseeability of the harm encountered by the user. Hence, in order to maintain an action against a manufacturer for harm arising from

the manufacturer's failure to warn of a danger, whether pursuant to a negligence theory or a strict liability theory, the plaintiff must prove that the manufacturer knew or should have known of the danger which caused the harm at issue.⁶

B) Evidence That Roche Knew or Should Have Known

There is no question that, by the time B.J. Stupak was prescribed Accutane, the warnings issued by Roche included a warning that Accutane “may cause . . . suicidal ideation, suicide attempts and suicide.” B.J. Stupak committed suicide. The district court concluded that the warning regarding suicide issued at the time of B.J.'s prescription was adequate as a matter of law, because the district court noted that suicide often occurs without premonitory symptoms. Therefore, the district court found that the warning that Accutane may cause suicide adequately warned of

⁶ While Laurie Stupak argues that we should certify a question to the Supreme Court of Wisconsin on whether a product could still be rendered defective and unreasonably dangerous even if the manufacturer has provided an adequate warning, based on the Wisconsin court's ruling in Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, we find such certification unnecessary. Laurie Stupak has not argued to this Court that Accutane was defective or unreasonably dangerous in any respect other than the inadequacy of the warning. We agree with the Wisconsin Court of Appeals in Mohr, 674 N.W.2d at 590 n.10, that Green did not overrule the foreseeability requirement of the strict liability failure to warn analysis. Green arose in the context of a claim that a product was defective and unreasonably dangerous because of an excessive amount of a particular substance; Green did not involve a strict liability claim based on a failure to warn. Indeed, the opinion in Green distinguished its context from that of a strict liability failure to warn claim, citing Krueger with apparent approval. Green, 629 N.W.2d at 746 (citing Krueger, 311 N.W.2d 219 (Wis. Ct. App. 1981)). Therefore, under Wisconsin law strict liability failure to warn claims, like negligence failure to warn claims, continue to require the plaintiff to prove that the manufacturer knew or should have known of the danger arising from use of the product that caused the plaintiff's injury.

the harm suffered. In other words, the district court apparently held that because suicide frequently occurs without premonitory symptoms, doctors would know from the simple suicide warning that a risk of suicide without premonitory symptoms was an encompassed risk. We need not either accept or reject the district court's statement that suicide often occurs without premonitory symptoms.⁷ Instead, we analyze Laurie Stupak's claim while assuming arguendo that suicide without premonitory symptoms is materially distinct from "normal" suicide, and therefore that Roche could have a duty to separately warn of this danger.

As explained above, Roche can only be negligent or strictly liable for a failure to warn if it had a duty to warn, and Roche only had a duty to warn of dangers of which it knew or should have known. While Stupak has asserted that Roche knew or should have known that Accutane could cause suicide without premonitory symptoms, to survive a motion for summary judgment, a party must do

⁷ One matter on which the parties were directed to file supplemental briefs was whether or not the medical literature indicated that suicide does occur with frequency without premonitory symptoms, and if so why the simple suicide warning actually given would not have encompassed the thus included risk of suicide without premonitory symptoms. Stupak's supplemental brief failed to address the issue. However, Roche's supplemental brief provides considerable citations to information in the public domain and available to doctors indicating that doctors would have known that suicides in general do occur with frequency without premonitory symptoms. Thus, although we need not (and do not) so decide, it appears that there may well have been considerable evidence in the public domain to support the district court's belief that doctors would know from a simple suicide warning that a risk of suicide without premonitory symptoms was encompassed. There is no evidence in this record that persons who have taken Accutane are subject to any different risk (i.e. different from the general public) with respect to suicide without premonitory symptoms.

more than make conclusory allegations. “This court has consistently held that conclusory allegations without specific supporting facts have no probative value One who resists summary judgment must meet the movant’s affidavits with opposing affidavits setting forth specific facts to show why there is an issue for trial.” Leigh v. Warner Bros., Inc., 212 F.3d 1210, 1217 (11th Cir. 2000) (internal citation omitted). Furthermore, as noted above, we are limited in our review to the evidence that was before the district court at summary judgment. Welch v. Celotex Corp., 951 F.2d at 1237 n.3. In her response to Roche’s motion for summary judgment on the issue of warning adequacy, Stupak did not provide the district court with any indication that there was evidence in the record to support an inference that Roche knew or should have known that Accutane could cause suicide without premonitory symptoms. The only mention of evidence that Stupak provided to the district court in response to Roche’s motion for summary judgment was an oblique reference to “case reports” of patients who committed suicide without premonitory signs of depression while taking Accutane. Stupak did not provide these case reports to the district court, nor did she indicate where in the record they could be located.⁸

⁸ After the district court granted Roche’s motion for summary judgment on warning adequacy, Stupak filed a motion for reconsideration of summary judgment. In that motion, Stupak referred to “at least 17 reports of accomplished suicides in Accutane patients who

In an abundance of caution, this Court directed Stupak to file a supplemental letter brief pointing to any evidence in the record and indicating where in the record it could be found that Roche knew or should have known that Accutane may cause suicide without overt premonitory signs or symptoms. Stupak's supplemental brief refers to three items, and attaches a copy of each as an exhibit to the supplemental brief. However, notwithstanding our clear direction to indicate where in the record such evidence could be found, Stupak failed to do so. Roche argues that the three items are not in the underlying record. "Neither the district court nor this court has an obligation to parse a summary judgment record to search out facts or evidence not brought to the court's attention." Atlanta Gas Light Co. v. UGI Utilities, Inc., 463 F.3d 1201, 1208 n.11 (11th Cir. 2006). Accordingly, for this reason alone, we can conclude that Stupak has failed to adduce evidence that Roche knew or should have known that Accutane could cause suicide without premonitory symptoms, and that the district court's judgment granting summary judgment to Roche should be affirmed.

exhibited no signs of depression prior to their suicides" located in "a December 21, 1999 Psychiatric Disorder Work-up." Stupak did not provide the "work-up" or the "17 reports" to the district court, nor did she indicate where the reports could be located in the record. As discussed in the text of this opinion, Roche argues that this "work-up" is not in the record. Therefore, we cannot say that these reports were before the district court at summary judgment. Nonetheless, as discussed fully in the text, we have considered these reports and have found that they would not be sufficient to defeat summary judgment.

In any event, the three items to which Stupak’s supplemental brief refers are insufficient to create a genuine issue of fact that Roche knew or should have known that Accutane could cause suicide without premonitory symptoms. Only the third item – Roche’s internal Psychiatric Disorder Issue Work-up dated December 21, 1999 and authored by Robert Nelson – deserves discussion.⁹ This work-up or report contains a chart from which Stupak extracts information and asserts that the chart “identified at least 17 reports of accomplished suicides in Accutane patients who exhibited no signs of depression before their suicides.” These are apparently the case reports to which Stupak made reference in the district court. Even if we considered these case reports, they provide no more than a “scintilla of evidence” to support Stupak’s claim that Roche knew or should have known that Accutane

⁹ The first of the items to which Stupak’s supplemental brief refers is a February 23, 1998, internal FDA memorandum. This memorandum was not brought to the district court’s attention, nor is there any evidence that (or even any assertion by Stupak that) Roche would have had a copy of this memorandum before B.J. Stupak’s suicide. Moreover, the portion of the memorandum on which Stupak relies is an unanalyzed comment that of twelve case studies reviewed a majority had “no antecedent history of depression and the patients were not noted or known to be depressed in the time period prior to their suicide.” Even if Roche had access to this internal FDA memorandum, and even if the twelve case reports are different from the seventeen discussed in the text, they are insufficient for the same reasons discussed in the text with respect to the seventeen case reports. The second item to which Stupak’s supplemental brief refers is a November 24, 1997, FDA letter to Roche suggesting a labeling change to the effect that: “These adverse reactions have been reported for patients with and without previous psychiatric symptoms. It is not known whether a history of psychiatric disorder or pre-existing depression increases the risk associated with Accutane.” This suggested statement in no way addresses whether those individuals committed suicide without displaying premonitory symptoms. Rather, the suggested statement refers to whether a person had a history of psychiatric disorder or depression prior to taking Accutane.

could cause suicide without premonitory symptoms. Therefore, they are insufficient to defeat a motion for summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252, 106 S. Ct. 2505, 2512 (1986). After reviewing the case reports, it is clear that they are anecdotal, and do not establish whether the seventeen suicides reported were in fact asymptomatic, or whether the symptoms were simply not recorded in some of the case reports. Indeed, the Nelson work-up or report (from which Stupak extracted the seventeen case reports) expressly discounts the case reports: “The reports of completed suicides were among the most poorly documented cases reviewed. In the typical case, very little detail was presented and nothing close to a psychological autopsy was performed on any case.” Seventeen such inconclusive case reports (out of millions of Accutane prescriptions) is simply insufficient to support an allegation that Roche knew or should have known that Accutane could cause suicide without premonitory symptoms. See McClain v. Metabolife Int’l, Inc., 401 F.3d 1233, 1254 (11th Cir. 2005) (“Simply stated, case reports raise questions; they do not answer them”); Rider v. Sandoz Pharmaceuticals Corp., 295 F.3d 1194, 1199 (11th Cir. 2002) (“[W]hile they may support other proof of causation, case reports alone ordinarily cannot prove causation”). Therefore, even if these case reports were in the record, the reports are insufficient to establish that Roche knew or should have known that

Accutane could cause suicide without symptoms.

Stupak has simply not provided any evidence from the record that Roche knew or should have known that Accutane could cause suicide without premonitory symptoms. Without any evidence that Roche knew or should have known that Accutane could cause suicide without premonitory symptoms, Stupak cannot maintain a claim that Roche had a duty to provide a separate warning of that danger. Because the duty to warn is a necessary element of both negligence and strict liability failure to warn claims under Wisconsin law, Stupak's failure to meet that element requires that we uphold the district court's grant of summary judgment. Earley v. Champion Int'l Corp., 907 F.2d 1077, 1080 (11th Cir. 1990) (“[T]he non-moving party still bears the burden of coming forward with sufficient evidence on each element that must be proved. . . . If on any part of the prima facie case there would be insufficient evidence to require submission of the case to a jury, we must affirm the grant of summary judgment for the defendant”) (internal punctuation and citations omitted). Accordingly,¹⁰ the judgment of the district court is AFFIRMED.

¹⁰ Stupak's other arguments on appeal are rejected without need for further discussion, either because our conclusions above moot the argument or because Stupak failed to provide factual support or legal support for the argument.