Revised March 15, 2002

IN THE UNITED STATES COURT OF APPEALS

FOR THE FIFTH CIRCUIT

No. 00-31440

JOSEPH B. STAHL

Plaintiff-Appellant

v.

NOVARTIS PHARMACEUTICALS CORP.

Defendant-Appellee

Appeal from the United States District Court
for the Eastern District of Louisiana

February 13, 2002

Before KING, Chief Judge, and DUHÉ and BENAVIDES, Circuit Judges.

KING, Chief Judge:

Plaintiff-Appellant Joseph B. Stahl appeals the district court's summary judgment in favor of Defendant-Appellee Novartis Pharmaceuticals Corporation on his claims under the Louisiana Products Liability Act. Stahl also appeals the district court's prior order dismissing his intentional tort claim. For the following reasons, we AFFIRM.

I. FACTUAL AND PROCEDURAL BACKGROUND

Lamisil is a prescription drug manufactured by Defendant-Appellee Novartis Pharmaceuticals Corporation ("Novartis"). The

drug is approved by the FDA for treatment of fungal infections in the toenails and fingernails. The package insert included with Lamisil during the time period relevant to this litigation contained warnings of a number of possible adverse reactions. The "WARNINGS" section of the insert stated: "Rare cases of symptomatic hepatobiliary dysfunction including cholestatic hepatitis have been reported. Treatment with Lamisil . . . Tablets should be discontinued if hepatobiliary dysfunction develops." The "PRECAUTIONS" section of the insert indicated that "[h]epatic function (hepatic enzyme) tests are recommended in patients administered Lamisil for more than six weeks or in those who develop unexplained nausea, anorexia, or fatigue." The "ADVERSE REACTIONS" section of the insert stated that "[r]are adverse events, based on worldwide experience with Lamisil . . . use include symptomatic hepatobiliary dysfunction, including cholestatic hepatitis . . . ."

On April 3, 1998 Plaintiff-Appellant Joseph B. Stahl ("Stahl") was treated by Dr. Martin Claiborne, a dermatologist, for chronic fungal infection of the toenails. Dr. Claiborne prescribed Lamisil to treat Stahl's condition. Dr. Claiborne explained that he planned to treat Stahl's infection with Lamisil for twelve weeks, but prescribed only a six-week supply of the drug. Dr. Claiborne instructed Stahl to return to the doctor's office after the first six weeks of treatment for a liver

(hepatic) function test, due to the risk of liver problems associated with use of Lamisil.

On April 27, 1998, twenty-four days after he began taking Lamisil, Stahl developed cholestatic hepatitis. He did not experience any nausea, anorexia, or fatigue prior to this time. His treating physicians have diagnosed his cholestatic hepatitis as drug-induced.

Stahl commenced the instant action against Novartis in district court on April 5, 1999. Stahl's initial complaint alleged negligent and intentional tort claims under the general tort liability provisions of Louisiana's Civil Code. See La. Civ. Code Ann. art. 2315 (West 1997 & Supp. 2002). In a July 14, 1999 order, the district court dismissed these claims on the ground that the Louisiana Products Liability Act ("LPLA") provides the exclusive remedy for products liability actions against manufacturers under Louisiana law. See La. Rev. Stat. Ann. § 9:2800.52 et seq. (West 1997). In that order, the district court gave Stahl leave to file an amended complaint. Stahl accordingly amended his complaint to allege two claims under the LPLA: that Lamisil is "unreasonably dangerous in composition," see id. § 9:2800.54 (B)(1), and that Lamisil is "unreasonably dangerous because an adequate warning has not been provided," see id. § 9:2800.54(B)(3).

After extensive discovery, Novartis filed a motion for summary judgment. On November 29, 2000 the district court

granted this motion with respect to both of Stahl's LPLA claims, finding: (1) that Stahl had adduced no evidence apart from his own unsubstantiated allegations to support his "unreasonably dangerous in composition" claim, and (2) that the warnings contained in the Lamisil package insert were adequate as a matter of law.

Stahl appeals this summary judgment in favor of Novartis, arguing that the district court's conclusions were erroneous and that the district court improperly considered expert opinion in its summary judgment determination. Stahl further contends on appeal that the district court improperly dismissed the intentional tort claim raised in his original complaint because there is an "intentional acts" exception to the exclusive remedy provision of the LPLA.[1] We will first address the viability of Stahl's intentional tort claim and then discuss the district court's summary judgment on his two claims under the LPLA. Initially, some background information on the LPLA is useful.

II. THE LOUISIANA PRODUCTS LIABILITY ACT

To maintain a successful products liability action under the LPLA, a plaintiff must establish four elements: (1) that the

[1] Stahl purports to raise nine claims of error in his brief. Most of these claims of error are encompassed within our review of the district court's dismissal order and subsequent summary judgment. Stahl's remaining "claims of error" appear to accuse the district court of mischaracterizing testimony in the record and of failing to consider the entirety of the record. Our own review of the record reveals that these claims are without merit.

defendant is a manufacturer of the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product "unreasonably dangerous"; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else. See La. Rev. Stat. Ann. § 9:2800.54(A) (West 1997). A product is "unreasonably dangerous" under the LPLA if the product meets at least one of the following criteria:

> (1) The product is unreasonably dangerous in construction or composition as provided in R.S. 9:2800.55;
> (2) The product is unreasonably dangerous in design as provided in R.S. 9:2800.56;
> (3) The product is unreasonably dangerous because an adequate warning about the product has not been provided as provided in R.S. 9:2800.57; or
> (4) The product is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product as provided in R.S. 9:2800.58.

Id. § 9:2800.54(B). These statutory mechanisms for establishing that a product is unreasonably dangerous "are predicated on principles of strict liability, negligence, or warranty." Jefferson v. Lead Indus. Assoc., 930 F. Supp. 241, 245 (E.D. La. 1996). However, for causes of action arising after the effective date of the LPLA, negligence, strict liability, and breach of express warranty are not available as theories of recovery against a manufacturer, independent from the LPLA. See id.

To maintain a "construction or composition" defect claim under the LPLA, a plaintiff must establish that, at the time the

product left the manufacturer's control, "the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." La. Rev. Stat. Ann. § 9:2800.55 (West 1997). To maintain a failure-to-warn claim, a plaintiff must demonstrate that "the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product." Id. § 9:2800.57 (West 1997). Proving a design defect or a "construction or composition" defect is not a prerequisite to establishing a failure-to-warn claim. Even if a product is not defectively designed or constructed, a manufacturer "may still have a duty to warn consumers about any characteristic of the product that unreasonably may cause damage." Grenier v. Med. Eng'g Corp., 243 F.3d 200, 205 (5th Cir. 2001).

III. STAHL'S INTENTIONAL TORT CLAIM

The district court dismissed the claims in Stahl's original complaint, including his intentional tort claim, because these claims were not based on theories of liability recognized in the LPLA. We review the district court's dismissal of a claim de novo. Proctor & Gamble Co. v. Amway Co., 242 F.3d 539, 564 (5th Cir. 2001).

Because Stahl's cause of action accrued after September 1, 1988, the LPLA governs his claims. See Brown v. R.J. Reynolds

Tobacco Co., 52 F.3d 524, 527 (5th Cir. 1995). As the district court correctly noted, the LPLA contains an exclusive remedy provision, stating that "[a] claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in" the LPLA. La. Rev. Stat. Ann. § 9:2800.52 (West 1997). This provision limits a plaintiff's theories of recovery against a manufacturer of an allegedly defective product to those established by the LPLA. See, e.g., Jefferson, 930 F. Supp. at 244.

Stahl contends that the district court's dismissal of his intentional tort claim was nonetheless improper because there must be an "intentional acts" exception to the exclusive remedy provision of the LPLA. In support of this contention, Stahl cites a number of cases recognizing the existence of an intentional acts exception to the exclusive remedy provision of the Louisiana Workers' Compensation Act (the "LWCA"). See, e.g., White v. Monsanto Co., 585 So.2d 1205, 1208 (La. 1991); Bazley v. Tortorich, 397 So.2d 475, 480 (La. 1981). Stahl reads this provision to suggest that "intentional tort is an exception to every exclusive remedy." We disagree.

Stahl is correct that the exclusive remedy provision of the LWCA contains an express exception for intentional acts. See La. Rev. Stat. Ann. § 23:1032(B) (West 1998) ("Nothing in this Chapter shall affect the . . . liability, civil or criminal, resulting from an intentional act."). However, the fact that the

LWCA contains such a provision does not imply that the LPLA's exclusive remedy provision is subject to a similar exception. There is no language in the LPLA indicating that its exclusive remedy provision does not preclude intentional tort claims, and both federal and Louisiana courts have read the Act's exclusive remedy provision to prevent plaintiffs from bringing intentional tort claims. See, e.g., Grenier, 243 F.3d at 203-06 (affirming the district court's dismissal of a fraud claim and other tort claims not among the exclusive theories of liability in the LPLA); Arabie v. R.J. Reynolds Tobacco Co., 96-0978 (La. App. 5 Cir. 6/30/97), 698 So.2d 423, 424-25 (granting summary judgment to defendants because plaintiffs' battery, fraud, and wrongful death claims were not among the exclusive theories of liability enumerated in the LPLA). Further, there is no reason to read an intentional acts exception into the LPLA, as manufacturers are subject to suit under the Act for both intentional and unintentional acts.[2]

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[2] An "intentional acts" exception, while essential to the remedial scheme established in the LWCA, would be nonsensical in the context of the LPLA. The LWCA provides a remedy only for claims arising out of an "accident." See La. Rev. Stat. Ann. § 23:1031(A) (West 1998). That statute thus extends only to claims based on unintentional acts. Accordingly, the LWCA's exclusive remedy provision contains an exception allowing workers to bring tort claims based on intentional injuries because otherwise workers would have no legal remedy against their employers for such intentional tortious acts.

In contrast, the applicability of the LPLA does not turn on whether a manufacturer has acted "intentionally" in manufacturing a defective product. A claimant can bring an action under the LPLA based on conduct by a manufacturer that was either intentional or unintentional, presuming that the claim meets the

Because there is no "intentional acts" exception to the exclusive remedy provision of the LPLA, Stahl cannot bring intentional tort claims against Novartis under the Louisiana Civil Code for damages allegedly caused by Lamisil. Accordingly, the district court properly dismissed Stahl's intentional tort claim.

IV. STAHL'S "UNREASONABLY DANGEROUS IN CONSTRUCTION OR COMPOSITION" CLAIM UNDER THE LPLA

The "unreasonably dangerous in construction or composition" provision of the LPLA provides a remedy for damages caused by a product that is defective due to a mistake in the manufacturing process. La. Rev. Stat. Ann. § 9:2800.55 (West 1997). As noted above, to prevail on a claim under this provision, the plaintiff must demonstrate that "at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." Id.

The district court granted summary judgment to Novartis on Stahl's construction or composition defect claim, finding that Stahl's "conclusory and unsubstantiated" assertions that Lamisil is unreasonably dangerous were insufficient to survive summary judgment. We review a district court's grant of summary judgment

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statutory criteria outlined above. Thus, there is no need for a specific exception to the LPLA's exclusive remedy provision for "intentional acts," as intentional acts are encompassed within the LPLA's coverage provisions.

de novo, applying the same standard as the district court. See Rivers v. Cent. & S.W. Corp., 186 F.3d 681, 683 (5th Cir. 1999).

Stahl argues on appeal that the district court's summary judgment determination was erroneous because the district court misinterpreted Celotex Corp. v. Catrett, 477 U.S. 317 (1986). Stahl asserts that the court improperly placed the summary judgment burden on him, the non-moving party, without first requiring Novartis to come forward with documentary proof of the absence of a genuine issue of material fact regarding Stahl's claim. Stahl misreads both Rule 56 and the Celotex decision. Under Rule 56(c), summary judgment is proper "if 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 and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party may meet its burden to demonstrate the absence of a genuine issue of material fact by pointing out that the record contains no support for the non-moving party's claim. In this circumstance, if the non-moving party can point to nothing in the record supporting its claim, summary judgment is appropriate. As the Celotex Court explained, "Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear

the burden of proof at trial." 477 U.S. at 322. In such a situation there can be no genuine issue as to any material fact, since there has been a "complete failure of proof concerning an essential element of the nonmoving party's case." Id. at 323.

In the instant case, Novartis correctly argues that Stahl has provided no evidence raising a genuine issue of material fact as to whether Lamisil is unreasonably dangerous in construction or composition. While Stahl does provide some evidence that Lamisil's active ingredient can be dangerous to the liver, this evidence is not dispositive in a "construction or composition" claim under the LPLA. Therefore, summary judgment is appropriate because Stahl has not provided any evidence suggesting that the particular pills he received deviated in any way from the manufacturer's production standards or from the manufacturer's otherwise identical products.

V. STAHL'S "INADEQUATE WARNING" CLAIMS UNDER THE LPLA

Stahl claims that Novartis failed to provide adequate warnings regarding the dangers associated with Lamisil.[3] Stahl primarily contends that: 1) Novartis should have strengthened the

[3] Stahl also contends at various points in his brief that the limited warnings that Novartis provided were diluted by unfounded assurances of safety offered by its pharmaceutical sales representatives. However, there is no evidence in the record supporting this assertion. The only relevant evidence is Dr. Claiborne's testimony about his conversations with Novartis's drug representatives, and the record reveals that Dr. Claiborne testified unequivocally that the drug representatives informed him of the risks of Lamisil and never told him anything that was inconsistent with the label.

wording of existing warnings to explicitly acknowledge the causal relationship between Lamisil use and liver dysfunction/cholestatic hepatitis; 2) Novartis should have added language to the package insert indicating that use of Lamisil can cause liver failure and death; and 3) Novartis should have recommended or mandated pre-administration blood testing and weekly or biweekly blood testing for all patients taking Lamisil or, at a minimum, should have recommended blood testing for patients who experienced early warning signs of liver damage, including jaundice, dark urine, and pale stools.[4]

To successfully maintain a failure-to-warn claim under the LPLA, a plaintiff must demonstrate that the product in question has a potentially damage-causing characteristic and that the manufacturer failed to use reasonable care to provide an adequate warning about this characteristic. See Grenier, 243 F.3d at 205 ("To prevail on her failure to warn claim, Grenier would need to show only that 'gel bleed' is a potentially damage-causing characteristic of MEC's breast implants and that MEC failed to use reasonable care to provide an adequate warning."); see also La. Rev. Stat. Ann. § 9:2800.57(A) (West 1997). To meet the first prong of this test, we have indicated that a plaintiff must provide evidence about the "cause, frequency, severity, or consequences" of the dangerous characteristic in question.

[4] Stahl claims to have experienced these symptoms prior to the onset of his cholestatic hepatitis.

Grenier, 243 F.3d at 205; see also Krummel v. Bombardier Corp., 206 F.3d 548, 552 (5th Cir. 2000) (finding that liability for failure-to-warn requires a plaintiff to provide evidence of the probability or risk of injury from the allegedly damaging characteristic of the product). However, in the instant case, neither party contests that Lamisil tablets have a potentially damage-causing characteristic (i.e., hepatoxicity). The parties only dispute whether Novartis used reasonable care to provide adequate warnings regarding this characteristic. Accordingly, we focus our attention on this inquiry.

The district court determined that the warnings contained in the Lamisil package insert were adequate as a matter of law. The court relied primarily on the testimony of Stahl's treating physician, Dr. Claiborne, who indicated that the warnings contained in the Lamisil package insert were clear, unambiguous, and reasonably adequate to inform him of the risk of liver damage associated with the use of the drug. Stahl argues that summary judgment on this issue was inappropriate because the adequacy of a warning is an issue of fact for the jury to decide.

This court has previously rejected the notion that a claim of inadequate warning always presents a jury issue. See Anderson v. McNeilab, Inc., 831 F.2d 92, 93 (5th Cir. 1987). A "mere allegation of inadequacy" is insufficient for a plaintiff to survive summary judgment on a failure-to-warn claim. Id. Stahl must "go beyond the pleadings and designate specific facts in the

record showing that there is a genuine issue for trial" to defeat summary judgment. Wallace v. Texas Tech Univ., 80 F.3d 1042, 1047 (5th Cir. 1996).

Stahl further contends that the district court erred in basing its summary judgment determination on Dr. Claiborne's testimony. Stahl argues that because Dr. Claiborne is an expert in dermatology, not liver disease or the adequacy of drug warnings, the district court should not have considered his "expert" testimony regarding the adequacy of the warning without requiring a hearing under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Stahl further contends that, even if Dr. Claiborne's expertise in liver disease and the adequacy of drug warnings were established, such expert testimony cannot form the basis of a summary judgment determination.

We reject these contentions. When Dr. Claiborne testified as to the adequacy of the warning contained in the Lamisil package insert, he was not providing an expert opinion. While Dr. Claiborne was offered as an expert in the field of dermatology and fielded some questions in his deposition that called upon his expertise as a dermatologist, the portion of his testimony that was relevant to the district court's summary judgment determination involved his own understanding and perception of the warning label as Stahl's treating physician. In that capacity, Dr. Claiborne was testifying as to whether the Lamisil package insert made him aware of the risks involved in

prescribing Lamisil at the time that he treated Stahl. This portion of Dr. Claiborne's testimony does not constitute an expert assessment and is related to matters within the scope of Dr. Claiborne's personal knowledge.[5] It is appropriate for a district court to consider such testimony in evaluating a motion for summary judgment. See Fed. R. Civ. P. 56(e).

We turn now to the substance of Stahl's inadequate warning claims. Louisiana applies the "learned intermediary doctrine" to products liability claims involving prescription drugs. Under

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[5] This court has previously recognized that a treating physician does not necessarily testify in an expert capacity when he or she testifies as to the adequacy of the warning contained in a drug label. Indeed, no expertise outside the treating physician's field is required for such an assessment. See Mauldin v. Upjohn Co., 697 F.2d 644, 648 (5th Cir. 1983). As we reasoned in Mauldin:

> Upjohn insists that only an expert in the preparation or construction of medical product warning statements can testify properly as to the issue of adequacy. We cannot accept this argument, for it belies the essential purpose of the warning. Package inserts and PDR references are not written for medical experts schooled and skilled in the writing of warnings. They are written to inform fully and adequately the medical practitioner who is called upon . . . to prescribe the medication. The understanding and perception of [the prescribing physicians] is entirely relevant, for the sufficiency of the warning is dependent upon their reasonably anticipated comprehension.

Id.; see also Zachary v. Dow Corning Corp., 884 F. Supp. 1061, 1065 (M.D. La. 1995) (noting that in the learned intermediary context, a manufacturer's duty to warn requires adequate warning of inherent dangers not within the knowledge of or obvious to the average learned intermediary).

this doctrine, a drug manufacturer discharges its duty to consumers by reasonably informing prescribing physicians of the dangers of harm from a drug. Anderson, 831 F.2d at 93. This court has acknowledged that there is a two-prong test governing inadequate-warning claims under the LPLA when the learned intermediary doctrine is applicable. First, the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician. Willett v. Baxter Int'l Inc., 929 F.2d 1094, 1098 (5th Cir. 1991). Second, the plaintiff must show that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury. Id. Because we find that Stahl has failed to raise a genuine issue of material fact regarding the adequacy of the warnings contained in the Lamisil package insert, we reach only the first of these questions.

The Adequacy of the Warnings Addressing Liver Dysfunction and Cholestatic Hepatitis

Stahl's first inadequate warning claim is that the Lamisil package insert inadequately informed his treating physician of the risk of liver dysfunction and hepatitis associated with Lamisil use. While Stahl acknowledges that the "WARNINGS" section of the 1997 package insert specifically indicated that "[r]are cases of symptomatic hepatobiliary dysfunction including cholestatic hepatitis have been reported" and that "treatment with Lamisil . . . Tablets should be discontinued if

hepatobiliary dysfunction develops," he contends that the wording of these warnings was not strong enough. According to Stahl, the warnings provided in the package insert were inadequate because they did not acknowledge the causal relationship between Lamisil use and liver dysfunction or cholestatic hepatitis.

Novartis maintains that the Lamisil insert fulfilled the company's duty to warn. Novartis points to a line of cases decided under Louisiana law finding that a drug warning is adequate as a matter of law if it clearly and unambiguously notifies the prescribing physician of the particular adverse reaction that forms the basis of the plaintiff's complaint. See Bealer v. Hoffman-La Roche, Inc., 729 F. Supp. 43, 44-45 (E.D. La. 1990); Calhoun v. Hoffman-La Roche, Inc., 98-2770, (La. App. 1 Cir. 2/18/00), 768 So.2d 57, 61-62. Indeed, one of those courts concluded that, if a warning label clearly and unambiguously states the particular ailment suffered by the plaintiff, summary judgment on a failure-to-warn claim is appropriate despite the prescribing physician's testimony that the warning did not adequately inform him of the risk involved. See Calhoun, 768 So.2d at 62 ("The Calhouns have not cited to us, nor have we found, any jurisprudential support for their contention that the test of whether a warning is adequate is subjective, based solely on the opinion of the prescribing physician."). Based on this line of authority, Novartis contends that the language in the insert indicating that "[r]are cases of

symptomatic hepatobiliary dysfunction including cholestatic hepatitis have been reported" and that treatment "should be discontinued if hepatobiliary dysfunction develops," constitutes an adequate warning about the danger of liver dysfunction or cholestatic hepatitis as a matter of law because these portions of the warning mention Stahl's particular ailments.

Novartis is correct that in Calhoun and similar cases courts apparently interpreted Louisiana law to require summary judgment in favor of a drug manufacturer whenever the particular ailment suffered by the plaintiff is mentioned in the warnings section of the package insert, regardless of the prescribing physician's testimony about his or her actual awareness and understanding of the risks involved. However, this suggestion that any clear and unambiguous reference to a particular adverse effect is sufficient to satisfy the manufacturer's duty to warn is inconsistent with this court's jurisprudence interpreting the LPLA. In applying the learned intermediary doctrine to an inadequate warning claim under the LPLA in Anderson, for example, we noted that "[u]nder Louisiana law, a drug manufacturer has discharged its duty to consumers of its prescription drugs when it has reasonably informed prescribing physicians of the dangers of harm from such a drug." Anderson, 831 F.2d at 93 (emphasis added). Thus, as our language in Anderson indicates, a mere reference to an adverse effect is not necessarily an "adequate warning" under the LPLA. The warning must contain language that

is adequate to reasonably inform the recipient (i.e., the doctor in a learned intermediary case) about the nature of the danger involved. See also Restatement(Third) of Torts: Products Liability § 6(d) (1997) (noting that a prescription drug or medical device "is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided") (emphasis added).

An alternate line of Louisiana authority suggests that a warning regarding a particular adverse drug reaction is adequate as a matter of law if the package insert clearly and unambiguously mentions the specific ailment suffered by the plaintiff AND the plaintiff's prescribing physician unequivocally testifies that the information provided in the warning was adequate to provide that physician with a reasonable understanding of the risks involved. Compare White v. Slidell Mem'l Hosp. & Med. Ctr., No. 89-2691, 1990 WL 111447 (E.D. La. July 26, 1990) (finding summary judgment appropriate when the particular ailment suffered by the plaintiff was mentioned in the warning and the plaintiff's physicians testified that they considered the manufacturer's warnings adequate); Mikell v. Hoffman-LaRoche, Inc., 94-0242, (La. App. 1 Cir. 12/22/94), 649 So.2d 75, 80 (affirming the trial court's summary judgment in favor of the defendant manufacturer when the particular ailment suffered by the plaintiff was specifically mentioned in the

warning and the plaintiff's physicians testified that they considered the manufacturer's warnings adequate); and Cobb v. Syntex Labs., Inc., 444 So.2d 203, 205-06 (La. Ct. App. 1984) (same) with Timm v. Upjohn Co., 624 F.2d 536, 539 (5th Cir. 1980) (finding that when a prescribing physician's testimony that a warning was adequate was not unequivocal, a jury is "entitled to weigh the conflicting statements made by [the prescribing physician] . . . along with all the other evidence presented in the case").

We find this second line of authority, represented by White, Mikell, and Cobb, to be a more persuasive reading of Louisiana law. Contrary to the holding of the Calhoun court, a prescription drug warning is not adequate as a matter of law simply because the warning label contains a clear and unambiguous reference to the adverse reaction suffered by the plaintiff. For summary adjudication of an inadequate warning claim to be appropriate, the plaintiff's prescribing physician must also unequivocally testify that the warning was adequate to inform him or her of the risks involved in prescribing the drug. The doctor's testimony provides added assurance that the language in the package insert was worded strongly enough to adequately inform him or her of the actual level of risk involved.

This reading of Louisiana law is consistent with the principles underlying the learned intermediary doctrine. Under Louisiana law, "[t]he obligation to the consumer is fulfilled

when the prescribing or treating physician is informed of any potential side effects or risks from the drug's use so that they may intelligently decide on its use and advise the patient." McCarthy v. Danek Med., Inc., 65 F. Supp. 2d 410, 413 (E.D. La. 1999) (citing Mikell, 649 So.2d at 80). The premise underlying a failure-to-warn claim in the learned intermediary context is that the patient is claiming that the manufacturer failed to adequately warn the treating physician. The treating physician's knowledge is thus the focus of the inquiry. Accordingly, when a particular adverse effect is clearly and unambiguously mentioned in a warning label and the prescribing physician unequivocally states that he or she was adequately informed of that risk by the warning, the manufacturer has satisfied its duty to warn under the learned intermediary doctrine.

In the instant case, we agree with the district court that Dr. Claiborne unequivocally testified that the Lamisil package insert's warning was clear, unambiguous, and adequate to inform him of the risks of cholestatic hepatitis associated with prescribing Lamisil. Accordingly, the district court correctly determined that under Louisiana law, this warning is adequate as a matter of law. Summary judgment is appropriate on this claim.

The Failure to Warn of Liver Failure and Death

Stahl's second contention is that the Lamisil package insert was inadequate because it failed to warn prescribing physicians

that liver failure and death could result from Lamisil use.[6] In considering this claim, the district court found that because Stahl had not yet suffered liver failure or death, he could not bring a failure-to-warn claim based on these dangers.[7] This logic is questionable. Because liver failure and death are widely recognized to be possible outcomes in a serious case of hepatitis (a condition that Stahl unquestionably suffered), it makes little sense to suggest that the plaintiff must wait until he dies to complain that the company failed to warn him of the risk of hepatitis-induced death. However, in the same vein, because liver failure and resulting death are widely recognized to be possible outcomes in a severe case of hepatitis, those risks are adequately addressed by the warnings already provided in the Lamisil insert.

Under Louisiana law, there is no duty to warn of obvious risks. See La. Rev. Stat. Ann. § 9:2800.57(B). In the context of warnings addressed to a physician acting as learned intermediary, this court has interpreted this "obvious risk" exception to exclude any duty to warn of risks that are "within

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[6] The two-part test described above, governing when a warning can be deemed "adequate as a matter of law" under the LPLA, is not applicable to this claim because the adverse effects that are the subject of this claim were not specifically mentioned in the warning label.

[7] In reaching this holding, the district court relied on Grenier v. Med. Eng'g Corp., 99 F. Supp. 2d 759, 766 (W.D. La. 2000), aff'd, 243 F.3d 200 (5th Cir. 2001), which held that a claimant cannot seek to impose a duty to warn on a product manufacturer with respect to a damage not sustained.

the knowledge of or obvious to the average learned intermediate." Willett, 929 F.2d at 1098 n.16. Consequently, because any prescribing physician who is forewarned of a risk of systematic liver dysfunction and cholestatic hepatitis would find it obvious that there is an attendant possibility of liver failure and death, Novartis fulfilled its duty under the LPLA to warn physicians specifically of that possible outcome. Summary judgment is therefore appropriate.[8]

The Adequacy of the Medical Monitoring Instructions

Stahl's final failure-to-warn claim is that Novartis's recommended medical testing regime, indicating that "[h]epatic function (hepatic enzyme) tests are recommended in patients administered Lamisil for more than six weeks or in those who develop unexplained nausea, anorexia, or fatigue," was inadequate.[9] According to Stahl, Novartis should have

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[8] This court has determined that "obviousness" can be appropriately evaluated as a matter of law in a summary judgment proceeding. See, e.g., Scallan v. Duriron, 11 F.3d 1249, 1252 (5th Cir. 1994) (determining that because "[t]he danger inherent in pumping chlorine through a hydraulic pump is obvious to an ordinary user of hydraulic pumps . . . . no genuine issue of material fact exist[ed] as to whether [the defendant] had a duty to warn"); see also Grenier, 99 F. Supp. 2d at 766 (determining in a summary judgment proceeding that "Defendants had no duty to warn against additional scarring that would result from additional surgery as scarring to some degree is an obvious consequence of surgery").

[9] Stahl and Novartis dispute the exact meaning of this language. Novartis contends that this warning recommends that physicians perform blood testing on the subset of Lamisil patients that will be taking the drug for more than six weeks (i.e., those patients who take a twelve-week course of Lamisil to treat fungal infections of the toenails, rather than a six-week

recommended or mandated pre-administration blood testing and weekly or biweekly blood testing for all patients taking Lamisil or, at a minimum, should have recommended blood testing for patients who experienced early warning signs of liver damage, including jaundice, dark urine, and pale stools. Novartis contends that that this claim is not appropriately classified as a failure-to-warn claim because the blood testing recommendations contained in the package insert do not actually constitute "warnings." Novartis's position is that it is inappropriate to consider recommended medical monitoring schedules contained in a drug insert when evaluating the adequacy of a manufacturer's warnings. According to Novartis, such monitoring recommendations are mere suggestions — the actual determination of when and how to monitor the patient is left to the discretion of the treating physician.

We find Novartis's characterization of the recommended medical monitoring scheme unpersuasive. An inadequate warning claim under the LPLA can appropriately be based on alleged inadequacies in a recommended medical monitoring or testing

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course to treat fungal infection of the fingernails). Novartis maintains that this language does not purport to provide any particular instruction regarding the appropriate timing of this blood testing. Stahl, however, reads this recommendation to suggest that no blood testing is necessary until and unless a patient has been taking Lamisil for more than six weeks. To the extent that this distinction makes any difference as a practical matter, for the purposes of reviewing Novartis's motion for summary judgment we shall construe the warning consistent with Stahl's interpretation.

regime. The LPLA provision defining an "adequate warning" encompasses "instructions" as well as "warnings." See La. Rev. Stat. Ann. § 9:2800.53(9) (West 1997) (defining an "adequate warning" as a "warning or instruction that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product and either to decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made"); see also Restatement(Third) of Torts: Products Liability § 6(b) (1997) (noting that a prescription drug or medical device is defective if it "is not reasonably safe due to inadequate instructions or warnings") (emphasis added). Indeed, it is an accepted tenet of Louisiana products liability law that a manufacturer's duty to warn includes a duty to provide adequate instructions for safe use of a product. See Hines v. Remington Arms Co., Inc., 648 So. 2d 331, 337 (La. 1994). There appears to be no compelling reason to exempt recommended medical monitoring schemes — which are, in essence, instructions for safe use of prescription drugs — from a drug manufacturer's duty to warn. Louisiana courts have not specifically addressed whether a recommended medical monitoring program constitutes a "warning." However, many courts applying the law of other states have implicitly assumed that medical monitoring recommendations contained in package inserts are "warnings" by evaluating such recommendations (or the absence of such recommendations) in

determining whether a drug manufacturer has fulfilled its duty to warn. See, e.g., Salmon v. Parke, Davis & Co., 520 F.2d 1359, 1362 (4th Cir. 1975) (applying North Carolina law) (finding that the plaintiff established a jury question precluding summary judgment by providing evidence that the blood studies recommended in a drug's warning label were inadequate); Fornoff v. Parke, Davis & Co., 434 N.E.2d 793, 802 (Ill. App. 1982)(applying Illinois law) (indicating that the plaintiff's inadequate warning claim created a jury issue as to whether a drug "was so unpredictable in its rate of absorption so as to require monitoring, and therefore a warning" to that effect); Formella v. Ciba-Geigy Corp., 300 N.W.2d 356, 359 (Mich. App. 1980) (applying Michigan law) (citing medical monitoring language in a warning label in support of the court's finding that a warning was adequate); Cooper v. Bowser, 610 S.W.2d 825, 831-32 (Tex. Civ. App. 1980) (applying Texas law) (same).

In support of his inadequate warning claim, Stahl relies primarily on an expert report from Dr. William George, the Director of the Toxicology Center at the Tulane University School of Medicine.[10] In this report, Dr. George opines (based on a

[10] Stahl points to two other sources of support for his inadequate instruction claim. Initially, Stahl argues that Novartis's alteration of the Lamisil package insert in the years following his injury provides evidence that the 1997 version of the insert was inadequate. Specifically, he points out that the current version of the Lamisil package insert includes a warning that patients should undergo liver testing if they develop jaundice, dark urine, or pale stools. Such evidence of subsequent remedial measures cannot be considered in evaluating

literature review and review of Stahl's medical records) that Lamisil can cause symptomatic hepatobiliary dysfunction as early as two to three weeks following initiation of treatment. Dr. George concludes that hepatic function testing would be more likely to identify the onset of hepatoxicity in a more timely way if such testing was performed on patients taking Lamisil within three weeks of initial dosing.

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whether the 1997 warning was adequate. See Fed. R. Evid. 407 (indicating that evidence of subsequent remedial measures is not admissible to show a defect in a warning or instruction).

Stahl also attached to his memorandum opposing summary judgment a collection of lists of medical journal articles, paragraph-long summaries of medical journal articles (apparently obtained from an unidentified computerized database), and photocopied passages from medical journal articles purportedly discussing the relationship between terbinafine (the active ingredient in Lamisil) and liver problems. Stahl argues that these written materials demonstrate that Novartis had notice that earlier blood testing of Lamisil patients was necessary. While the district court does not appear to have addressed the admissibility of this evidence, we shall undertake this inquiry pursuant to our de novo review.

With the exception of two photocopied passages from medical journals where the title and date of the journal are identified in the photocopy, Stahl has presented insufficient indicia as to the authenticity of these resources to satisfy the requirements of Rule 901 of the Federal Rules of Evidence. See Fed. R. Evid. 901(a) ("The requirement of authentication or identification as a condition precedent to admissibility is satisfied by evidence sufficient to support a finding that the matter in question is what its proponent claims."). With respect to the two photocopied passages of medical journal articles, we find that the portions excerpted by Stahl are insufficient to create a genuine issue of material fact regarding the adequacy of the monitoring regime recommended in the Lamisil package insert, particularly in light of the fact that the excerpted passages present in full only the factual circumstances of the adverse incident(s) discussed in the articles. The portions of these articles analyzing and drawing implications from these adverse incidents are not included in full in the photocopies that Stahl has submitted.

At oral argument, Novartis argued that Dr. George's testimony was insufficient to create a genuine issue of material fact with respect to the adequacy of the medical monitoring instruction. Novartis also questioned the relevancy of Dr. George's testimony, pointing out that he is not an expert in the adequacy of warnings. We disagree with Novartis's suggestion that Dr. George's testimony is irrelevant because he is a toxicologist rather than an expert on warning labels. However, we agree with Novartis that Dr. George's testimony is insufficient to create a genuine issue of material fact with respect to the adequacy of the medical monitoring instructions.

The statutory definition of an "adequate warning" provides insight into the appropriate standard to govern inadequate instruction claims. As one commentator has aptly noted, the LPLA definition of an adequate warning contains two components, one component apparently addressing warnings, and one component apparently addressing instructions: "the warning must both lead the ordinary user or handler to contemplate the danger in using the product (the warning component) and to either use it safely (the instruction component) or decline to use it." See Thomas C. Galligan, Jr., The Louisiana Products Liability Act: Making Sense of it All, 49 La. L. Rev. 629, 677 (1989). Interpreting the statute in this manner, in order to prevail on an inadequate instruction claim for a prescription drug, a plaintiff must demonstrate that the instructions provided did not enable the

treating physician to "use or handle the [drug] . . . in such a manner as to avoid the damage for which the claim is made." La. Rev. Stat. Ann. § 9:2800.53(9) (West 1997).

Dr. George's vague suggestion that "a number of reports in the literature indicate that hepatoxicity associated with terbinafine has occurred as early as weeks following initiation of treatment," coupled with his tenuous conclusion that testing "would be expected to be more effective" if conducted around two to three weeks following initiation of dosing, is inadequate to create a genuine issue of material fact as to whether the instructional language in the Lamisil package insert enabled treating physicians to use the drug safely. This assessment of Dr. George's testimony is bolstered by the fact that many of the reports upon which Dr. George relies were published after Stahl's injury in 1998.[11] Indeed, within the text of his report Dr. George specifically cites only one pre-1998 study, which details only one reported case where symptoms of liver dysfunction

[11] While a manufacturer has a duty to update warnings as new information about the risks of a product is discovered, see La. Rev. Stat. Ann. § 9:2800.57(C) (1997), a manufacturer's duty to warn a particular plaintiff is measured by the state of scientific and/or technical knowledge at the time the product left the manufacturer's control. See La. Rev. Stat. Ann. § 9:2800.59(B) (1997) ("[A] manufacturer of a product shall not be liable for damage proximately caused by a characteristic of the product if the manufacturer proves that, at the time the product left his control, he did not know and, in light of then-existing reasonably available scientific and technological knowledge, could not have known of the characteristic that caused the damage or the danger of such characteristic.").

occurred as early as two to three weeks following initiation of treatment with terbinafine. Such equivocal and ill-supported testimony is simply insufficient to preclude summary judgment on this inadequate warning claim.

VI. CONCLUSION

For the foregoing reasons, we AFFIRM both the district court's summary judgment in favor of Novartis on Stahl's LPLA claims and that court's prior order dismissing Stahl's intentional tort claim.