[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

FILED
U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
JUNE 6, 2007
THOMAS K. KAHN
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No. 05-13834

D. C. Docket No. 02-02838-CV-HS-W

JERRY BODIE,

Plaintiff-Appellant,

versus

PURDUE PHARMA COMPANY, THE,
PURDUE PHARMA, L.P.,
PURDUE PHARMA, INC.,
PURDUE FREDERICK COMPANY,
P.F. LABORATORIES, INC. THE,

Defendants-Appellees.

Appeal from the United States District Court
for the Northern District of Alabama

Before EDMONSON, BIRCH, and ALARCON,[*] Circuit Judges.

BIRCH, Circuit Judge:

Plaintiff-Appellant Jerry Bodie ("Bodie") brought this action against the defendants-appellees, The Purdue Pharma Company, Purdue Pharma, L.P., Purdue Pharma, Inc., Purdue Frederick Co., and The P.F. Laboratories, Inc. (hereinafter, collectively, "Purdue"), who manufacture and market the prescription drug OxyContin. Bodie argued that Purdue distributed OxyContin without providing sufficient warnings about the dangers of the drug, and that it made affirmative misrepresentations about the drug's characteristics. Specifically, Bodie alleged that Purdue understated the addictive nature of OxyContin, and that the company recommended a dosage frequency that would heighten the risk of addiction. After discovery, Purdue moved for summary judgment on all counts, which the district court granted. Bodie now appeals. Upon careful review of the record and the briefs and having heard oral argument, we AFFIRM the judgment of the district court.

I. BACKGROUND

The evidence, which we view in a light most favorable to the nonmoving party -- in this case, Bodie -- is as follows. Bodie first began suffering from

[*] Honorable Arthur L. Alarcon, U.S. Circuit Judge for the Ninth Circuit, sitting by designation.

chronic back and neck problems in 1978, when he was diagnosed with severe spinal and cervical stenosis. Although Bodie tried various methods of treating his condition, he continued to suffer from chronic pain. In March of 1998, he underwent spinal decompression surgery to relieve the pressure on his spinal cord and ameliorate the pain. Although the surgery stabilized the condition of Bodie's spine, he continued to suffer from pain symptoms. After Bodie's neurosurgeon determined that there was little more that could be done to improve Bodie's condition, he referred Bodie to Dr. Eugene Mangieri, a pain specialist, and his associate, Dr. Gabriel Fernandez, a neurologist.

Bodie first visited the pain clinic in November 1998, at which time Dr. Mangieri gave him a prescription for 30 milligrams of OxyContin to help with his back pain.[1] OxyContin is a prescription drug manufactured by Purdue. The drug's sole active ingredient is oxycodone, an opioid -- that is, a synthetic opiate similar to other opium derivatives such as morphine.[2] The drug was approved by the Food

[1] There is some confusion over whether Dr. Mangieri or Dr. Fernandez wrote the initial prescription in 1998. Dr. Mangieri testified–and the medical records admitted into evidence reflect–that it was actually Dr. Fernandez who first saw Bodie and wrote him a prescription for Oxycontin. (Indeed, Dr. Mangieri testified that he never saw Bodie as a patient until May of 1999.) Bodie, however, maintains that he met with Dr. Mangieri in November 1998, that Dr. Mangieri wrote his first prescription, and that the records suggesting that Dr. Fernandez saw him are incorrect. Because we construe the evidence in a light most favorable to Bodie, we will assume that Dr. Mangieri wrote the first OxyContin prescription in November 1998, and that the conversation we describe occurred at the time of that first visit.

[2] For some helpful background on OxyContin, see generally Paul Tough, The Alchemy of OxyContin, N.Y. TIMES, July 29, 2001, § 6 (Magazine) at 32.

and Drug Administration (FDA) in 1995 for the management of moderate to severe pain. Since that time, doctors have prescribed it to treat chronic back and neck pain similar to the kind suffered by Bodie. OxyContin is listed by the FDA as a Schedule II narcotic, which, by law, means that (1) the drug has a high potential for abuse; (2) the drug has a currently accepted medical use, but with severe restrictions; and (3) if abused, the drug may carry a risk of severe psychological and physical dependence. See 21 U.S.C. § 812(b). As such, OxyContin is tightly regulated; no physician can write a prescription for OxyContin without a license from the Drug Enforcement Agency. See 21 U.S.C. § 843(a)(1). In this case, Drs. Mangieri and Fernandez were licensed to prescribe OxyContin to their patients.

When Bodie was first prescribed OxyContin by Dr. Mangieri in November 1998, he testified that the doctor informed him that it was "a miracle drug, that it was not addictive, had very few side effects, constipation being probably the primary thing, and that could be managed by medication or whatever." See R3-88, Exh. 4 at 85; id. at 135 (stating that the doctor told him "basically . . . that . . . it was a miracle drug, very few side effects, wasn't addictive, that type of thing"). Bodie also testified that Dr. Mangieri gave him a pamphlet about OxyContin, and that he later reviewed an internet website (maintained by Purdue) containing additional information about the drug. Bodie claims that both of these sources

reiterated the statements of Dr. Mangieri -- namely, that OxyContin "was safe and non-addictive." Id. at 89.

Bodie took OxyContin from November 1998 until March 2002. He took the drug exactly as prescribed; there is no evidence that he ever abused the medication. Initially, Bodie's condition improved as a result of the medication. Indeed, the record suggests that Bodie's chronic pain was under control after he began taking the medication; that he began playing golf regularly; and that the drug permitted Bodie to "get along with everyday life." Id. at 148.

As Bodie began to develop a tolerance for the medication,[3] Dr. Mangieri gradually increased Bodie's dosage of 30 milligrams a day. In April 1999, his dosage was raised to 200 milligrams a day. In November 1999, as Bodie's back pain returned in earnest, his dosage was increased again, this time to 400 milligrams a day. Later, in mid-2000, Bodie's dosage was decreased to 320 milligrams, and from mid-2000 to March 2002 Bodie alternated between a daily dosage of 320 and 400 milligrams of OxyContin.

According to Bodie, by early 2002, the OxyContin that he was taking regularly had turned him into a "zombie," and he was not satisfied with the quality

[3] Tolerance, or "the need for increasing doses . . . to maintain a defined effect such as analgesia," is common with opioids such as OxyContin. R3-88, Exh. 1. Purdue recommended frequently assessing the need for an increased dosage to address a patient's tolerance to the drug.

of his life. Id. at 149. Bodie testified that he "pretty much went from the chair to the chair to the bathroom, from the chair to the bedroom, and that was pretty much all [he] did for two or three months." Id. at 149. In one incident the pharmacist at Bodie's local pharmacy warned Bodie that he was "on more OxyContin than any patient [he had] ever had in [the] pharmacy." Id. at 175. That experience -- coupled with the constipation that the drug was causing him[4] -- prompted Bodie to want to cease using the drug. Thus, in February 2002, Bodie visited Dr. Fernandez and told him that he wanted to halt his OxyContin use. Dr. Fernandez advised that he was not familiar with the protocol for ceasing OxyContin, and that Dr. Mangieri, the pain specialist, would have to oversee the process. Dr. Fernandez agreed, however, to start to taper down Bodie's dosages of OxyContin, from 320 milligrams to 240 milligrams a day, in an attempt to gradually wean Bodie off of the drug.[5] Bodie testified that the reduced dosage left him "shaky," "panicky," and "nauseated." Id. at 194.

[4] Constipation is a common side effect of the prolonged use of OxyContin.

[5] Physical dependence is common when patients take high doses of opioids such as OxyContin on a regular basis. As a result, Purdue recommended in its product literature that patients taking OxyContin taper down their dosage of the drug rather than abruptly discontinuing it. The packaging that accompanied OxyContin, provided by Bodie, stated that "[p]hysical dependence is the occurrence of withdrawal symptoms after abrupt discontinuation of a drug. . . . If OxyContin is abruptly discontinued in a physically dependent patient, an abstinence syndrome may occur. . . . If signs and symptoms of withdrawal occur, patients should be treated by reinstitution of opioid therapy followed by a gradual, tapered dose reduction of OxyContin . . . ." See R3-88, Exh. 1. The label also advised that "higher doses should be tapered over several days to prevent signs and symptoms of withdrawal in the physically dependent patient." Id.

Rather than pursuing the gradual tapering off of the drug, in March 2002 Bodie voluntarily admitted himself into the North Harbor Rehabilitation Center in Tuscaloosa, Alabama. Once admitted, Bodie was "lock[ed] . . . up" and began a process of in-patient detoxification. Id. at 198. He was given methadone to aid with the withdrawal symptoms caused by ceasing OxyContin in such an abrupt manner. After approximately two weeks, Bodie was discharged from the Rehabilitation Center. He has not taken OxyContin since that time.

In November 2002 Bodie filed the present action in the Northern District of Alabama, naming as defendants Purdue, Abbott Laboratories, and Abbott Laboratories, Inc.[6] Bodie contended that Purdue had minimized the risks of addiction to OxyContin, and that it had also affirmatively misrepresented these risks in marketing and selling the drug. Specifically, Bodie alleged that Purdue promoted OxyContin as being non-addictive; that it described OxyContin addictions as being "rare" in patients who used it as directed; and that the company's literature made a false distinction between "addiction" to the drug (that is, abusing it for the purpose of getting high) and "dependence" on the drug (where withdrawal symptoms would result if it was discontinued abruptly). Bodie alleged that this false dichotomy between "addiction" and "dependence" was established

[6] Abbott Laboratories and Abbott Laboratories, Inc. were dismissed from the action in September 2004, and are not parties to this appeal.

so that Purdue could publicly understate the number of patients who were, in reality, addicted to the drug.

Bodie also alleged that the 12-hour dosage frequency recommended by Purdue was intentionally designed to lead to addiction in patients. Specifically, he contended that Purdue knew that the 12-hour dosing cycle was not sufficient to mollify a patient's pain, because the drugs's ameliorative effects wore off before the 12-hour period was complete. As a consequence, Bodie alleged that patients would need additional amounts of oxycodone (so called "rescue medication") and larger and larger doses of the drug. He contends that, over time this exacerbated the risk of addiction in patients taking OxyContin.

Bodie's complaint lodged five counts against Purdue, for strict product liability (Count 1); breach of implied warranty (Count 2); negligent failure to warn (Count 3); malicious conduct (Count 4);[7] and fraud (Count 5). Bodie sought damages for the cost of rehabilitation from his addiction to OxyContin; for his lost

[7] There is no independently cognizable cause of action for "malicious conduct" under Alabama law. Presumably Bodie included this count, Count 4, in order to support his request for punitive damages. See Ala. Code § 6-11-20 (1975) (stating that punitive damages may not be awarded in a tort action unless "it is proven by clear and convincing evidence that the defendant consciously or deliberately engaged in oppression, fraud, wantonness, or malice with regard to the plaintiff"). Essentially, Count 4 is a reiteration of the negligent failure to warn claim alleged in Count 3 of the complaint. See R1-1 at 24 (stating, in connection with Count 4 for "malicious conduct," that "the Pharmaceutical Defendants *breached their duty*" towards the plaintiff, thereby causing him injury) (emphasis added). Thus, for purposes of this appeal, we construe Count 4 as identical to the negligent failure to warn claim asserted in Count 3.

wages brought about by the effects of that addiction; compensatory damages for his pain and suffering; and punitive damages. Following discovery, Purdue moved for summary judgment. After a hearing, the district court granted Purdue's motion as to all counts.

The district court's order granting summary judgment in favor of Purdue was predicated on a number of separate conclusions. First, and most important, the district court concluded that Bodie's claims failed because he failed to show that Purdue's allegedly inadequate warnings had proximately caused his injuries. Applying Alabama's "learned intermediary doctrine," which imposes on a pharmaceutical company a duty to provide warnings solely to the prescribing physician, rather than to the patient directly, see Stone v. Smith, Kline & French Labs., 447 So. 2d 1301, 1304-05 (Ala. 1984), the court concluded that there was no evidence that Purdue's allegedly inadequate warnings proximately caused Dr. Mangieri's decision to prescribe OxyContin to Bodie. In fact, because Dr. Mangieri -- the learned intermediary -- testified in his deposition that he was well aware of the potential for addiction to OxyContin in patients, and because he stated that he had chosen to prescribe the drug to Bodie independent of the adequacy or inadequacy of Purdue's warning, the court concluded that there was no showing that the allegedly inadequate warnings had proximately caused Bodie's addiction.

In light of the court's conclusion that Bodie had failed to establish proximate cause, the court concluded that summary judgment was proper as to the counts for negligence (Count 3); breach of implied warranty (Count 2); and malicious conduct (Count 4).[8]

As to the remaining count, Count 5, for fraud, the district court again applied the "learned intermediary" doctrine. The court first concluded that under Alabama law a pharmaceutical company could not be liable in a fraud action brought directly by a consumer for misrepresentations allegedly made in its product literature, because permitting such an action would eviscerate the purpose of the learned intermediary doctrine, which limits a pharmaceutical company's duty to the obligation to adequately warn the *doctor* -- who makes an independent assessment of the drug -- not the patient. Accordingly, the court concluded that permitting a fraud action brought directly by a consumer against a pharmaceutical company -- for allegedly misleading information that the consumer read and relied upon in taking a prescription drug -- would undermine the viability of the learned intermediary doctrine.

Moreover, in reviewing the fraud count the court concluded that Bodie had

[8] The district court did not address the merits of Count 1 of Bodie's complaint, the so-called "strict liability" count, based on the court's determination that a product liability action grounded in strict liability was not viable under Alabama law.

failed to present substantial evidence as to what specific misrepresentations were made by Purdue about OxyContin. Observing that Bodie had failed to produce *any* Purdue documentation about OxyContin from the time period in which Bodie alleged that the misrepresentations were made (that is, November 1998), the court concluded that Bodie's fraud claim was not specific enough to withstand summary judgment. Therefore it granted summary judgment on the fraud count (Count 5).

After granting Purdue summary judgment on all of Bodie's claims, the court entered final judgment in favor of Purdue. This appeal followed.

II. DISCUSSION

Bodie argues that the district court erred in granting summary judgment in favor of Purdue. We review a district court's grant of summary judgment de novo, applying the same legal standard used by the district court. See Johnson v. Bd. of Regents, 263 F.3d 1234, 1242 (11th Cir. 2001). Under that standard, summary judgment is appropriate where "there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). We view the evidence and all factual inferences in a light most favorable to the non-moving party -- in this case, Bodie -- and all reasonable doubts about the facts are resolved in favor of the non-movant. Johnson, 263 F.3d at 1243. "[T]he plain language of Rule 56(c) mandates the entry of summary judgment . . .

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.'" Johnson, 263 F.3d at 1243 (quotations and citation omitted).

In reviewing Bodie's case on appeal, we discuss together Bodie's claims based upon the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD") (Count 1)[9] and Purdue's negligent failure to warn (Counts 3 and 4). We then turn to Bodie's claim for breach of implied warranty (Count 4). Finally, we address Bodie's claim for fraud (Count 5).

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[9] Count 1 of Bodie's complaint was framed as a count for "strict product liability." As the district court noted, Alabama does not adhere to a system of strict product liability, but instead follows a modified version of strict liability known as the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD"). See Sears, Roebuck & Co., Inc. v. Haven Hills Farm, 395 So. 2d 991, 994 (Ala. 1981) (per curiam). This cause of action, which has been described as a "fault based defective product theory," is comparable to a defective product action grounded in strict liability. Atkins v. Am. Motors Corp., 335 So. 2d 134, 140 (Ala. 1976). Alabama's AEMLD action, however, retains the negligence-based notion of "fault" on the part of the manufacturer, supplier or retailer, rather than adhering to the "no-fault" system posited in a traditional strict liability jurisdiction. Id. at 139-140.

Although AEMLD liability is described as a "fault-based" system, in actuality the defendant's "fault" in an AEMLD action -- or the required scienter -- "is supplied by [his] selling a product in a defective condition." Sears, 395 So. 2d at 994. That is, "[t]he fault of the manufacturer, or retailer, is that he has conducted himself unreasonably in placing a product on the market which will cause harm"; the existence of a "dangerously unsafe chattel is negligence within itself." Atkins, 335 So. 2d at 140. Thus, in practice, an AELMD claim is similar to a traditional strict product liability claim.

Because Alabama's analogous cause of action for strict product liability is an AELMD claim, for purposes Bodie's appeal we will construe Count 1 as being based upon the AEMLD.

A. Bodie's Claims Based on the AEMLD and Negligent Failure to Warn

Bodie's complaint alleged claims based on the AEMLD (Count 1) and negligent failure to warn (Counts 3 and 4). To establish liability under the AEMLD, a plaintiff must show:

> (1) he suffered injury or damages to himself or his property by one who [sold] a product in a defective condition unreasonably dangerous to the plaintiff, as the ultimate user or consumer, if
>
> (a) the seller [was] engaged in the business of selling such a product, and
>
> (b) it [was] expected to and [did], reach the user or consumer without substantial change in the condition in which it [was] sold.

Morguson v. 3M Co., 857 So. 2d 796, 800 (Ala. 2003) (citations and quotations omitted). In connection with this *prima facie* case, the burden is also on the plaintiff to show that "that which rendered the product in such an unfit condition in fact caused the injury." Sears, 395 So. 2d at 995. In addition, the Alabama Supreme Court has stated that, for AEMLD cases involving prescription drugs, which are inherently unsafe, "the adequacy of [a drug's] accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous." Stone, 447 So. 2d at 1304 (citation omitted). In other words, "the adequacy of the warning issued by a drug manufacturer bears on whether a plaintiff has proved a prima facie case under the [AEMLD]." Id. (citation omitted).

As to the negligent failure to warn claims, Counts 3 and 4, the plaintiff must establish the same elements as a standard negligence action under Alabama law. See E.R. Squibb & Sons, Inc. v. Cox, 477 So. 2d 963, 969, n.3 (Ala. 1985) (per curiam). Thus, a plaintiff bringing such an action must establish: (1) that the defendant had a duty; (2) that the defendant failed to provide adequate warnings of the hazards of a particular product, thereby breaching that duty; (3) that the breach was the proximate cause of the plaintiff's harm; (4) that the plaintiff suffered injury as a result. See Toole v. Baxter Healthcare Corp., 235 F.3d 1307, 1314 (11th Cir. 2000) (affirming comparable jury charge on negligent failure to warn under Alabama law).

As with an AELMD claim, "[t]he element of proximate cause is essential to the plaintiff's prima facie case of negligent failure to adequately warn." Gurley v. Am. Honda Motor Co., Inc., 505 So. 2d 358, 361 (Ala. 1987). Thus, "[u]nder both the AEMLD and the negligence theory, *[the plaintiff] has the burden of proving proximate causation*." Clarke Indus., Inc. v. Home Indem. Co., 591 So. 2d 458, 461 (Ala. 1991) (emphasis added).

As the district court noted, Bodie's claims must also be viewed through the lens of Alabama's "learned intermediary" doctrine, which applies both to actions brought pursuant to the AEMLD, see Morguson, 857 So. 2d at 802-03, and to

those based on a negligent failure to warn theory. See Stone, 447 So. 2d at 1304-05. The "learned intermediary" doctrine creates an exception to the general rule that one who markets goods must warn foreseeable ultimate users about the inherent risks of his products. Walls v. Alpharma USPD, Inc., 887 So. 2d 881, 883 (Ala. 2004). The doctrine, which applies in all cases involving prescription drugs, Toole, 235 F.3d at 1313, provides that a drug manufacturer's duty is limited to the obligation to advise the *prescribing physician* of any potential dangers that may result from the use of the drug. That is, because the pharmaceutical company's duty extends only to the prescribing physician, rather than to the patient, "a manufacturer of prescription drugs discharges its duty by providing the physician with information about risks associated with these products." Christopher v. Cutter Labs., 53 F.3d 1184, 1192 (11th Cir. 1995) (citation omitted).

While the "learned intermediary" doctrine does not create an automatic bar to recovery for a plaintiff alleging claims under the AEMLD or the negligent failure to warn, application of the doctrine will often temper the viability of these actions. Specifically, application of the "learned intermediary doctrine" may have the effect of destroying the causal link between the allegedly defective product, and the plaintiff's claimed injury. As we stated in Christopher:

> [T]he failure of the manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is not the

> proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated. Thus, the causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had "substantially the same" knowledge as an adequate warning from the manufacturer should have communicated to him.

53 F.3d at 1192 (internal citations omitted).

Bodie maintains that Purdue's warnings about the drug were inadequate and deceptive, in that they both underscored the risk of addiction to the drug and sought to characterize OxyContin as being non-addictive, when Purdue knew that was not the case. Even were we to assume that Purdue's warnings and accompanying literature about OxyContin were, in fact, inadequate and deceptive,[10] we would nevertheless conclude that Bodie's claims based on the

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[10] We will assume, without deciding, that Purdue's literature about OxyContin was inadequate and misleading for purposes of Counts 1, 3, and 4. This is an assumption we would not otherwise be willing to concede, based on the product literature that was introduced into evidence. First, in addition to the heading "Warning: May Be Habit Forming," which appeared at the top of each page of the product packaging, Purdue's packaging made clear that "OxyContin is a mu-agonist opioid with an abuse liability similar to morphine and is a Schedule II controlled substance." See R3-88, Exh. 1; see also 21 U.S.C. § 812 (defining a Schedule II narcotic as one that "has a high potential for abuse" and "may lead to severe psychological and physical dependence"). The OxyContin label further warned that "[o]xycodone products are common targets for both drug abusers and drug addicts." R3-88, Exh. 1.

While the label did draw a distinction between physical dependence and addiction -- stating that "tolerance and physical dependence in pain patients are *not* signs of psychological dependence" and that "iatrogenic 'addiction' to opioids legitimately used in the management of pain is very rare" -- the label also made quite clear that the drug carried a high potential for abuse and could be habit-forming. Id. Thus we are not persuaded that Purdue's labeling of OxyContin was misleading or false. For purposes of this section of the opinion, however, we assume, without deciding, that Purdue's warnings were inadequate and that more thorough warnings should have been given in connection with the drug.

AEMLD and negligent failure to warn must fail, because Bodie has failed to satisfy his burden of proving proximate causation between these allegedly flawed warnings and his injury of addiction. We conclude that the application of the "learned intermediary" doctrine to the facts of Bodie's case severs the causal chain between Purdue's allegedly flawed drug warnings and Bodie's resulting injury.

In Bodie's case, the prescribing physician, Dr. Mangieri, testified that he was well aware of the risks of Schedule II narcotics such as OxyContin, specifically the risk that such drugs "ha[ve] the potential to cause addiction in patients." R3-88, Exh. 9 at 26, 49; see also id. at 51 (agreeing that OxyContin has a "high potential for abuse and addiction"). Dr. Mangieri testified that he took the prospect of prescribing a Schedule II narcotic to a patient very seriously. Dr. Mangieri also agreed in his deposition that he was aware of the contents of OxyContin.

Moreover, Dr. Mangieri's testimony established that his decision to prescribe OxyContin to Bodie was made independent of Purdue's accompanying literature about the drug. That is, Dr. Mangieri testified that his decision to prescribe OxyContin was based upon his role as the prescribing physician and his familiarity with the particular needs of his patient, Bodie; Dr. Mangieri's choice to prescribe OxyContin was not driven by Purdue's product literature about the drug.

After expressly stating that his decision to prescribe OxyContin to Bodie was not based any marketing materials about the drug provided to him by Purdue, Dr. Mangieri testified at length, as follows:

> I think promotional materials are valuable, and I think they serve as educational tools by pharmaceutical firms to physicians in at least making them aware that certain products are available and that they exist . . . .But then it's incumbent upon the physician through the literature and through actually understanding the drug, what the drug is intended to do, how the drug was studied, and then go into the issue as to whether or not he or she feels comfortable in prescribing that medication for whatever the condition might be. So though it's nice to have the pharmaceutical rep come and give you the introduction to it, but then one doesn't go and prescribe a medication simply on the basis of what somebody comes into your front door and tells you, especially not a Class II drug. Not in this office.
>
> [W]ith any drug that I'm going to write for a patient, I want to know exactly what's in there, what it's supposed to do, how did we find out what it does do, what's the side effect profile like, how many patients really benefitted from it, what are the things I need to be looking for in terms of, you know, long-term toxicity, and how do I monitor the patient to find out that they're getting into trouble before it happens. Those are things that are incumbent upon a physician who's responsible for taking care of a person . . . .

R3-88, Exh. 9 at 68-70.

Put simply, Dr. Mangieri made clear that his decision to prescribe OxyContin to Bodie was based upon his understanding of the drug and his evaluation of this particular patient, and that his decision did not hinge upon the product literature (be it adequate or inadequate) that was provided to him by

Purdue. Under application of Alabama's "learned intermediary" doctrine, when a prescribing physician such as Dr. Mangieri "had independent knowledge of the risk[s] that the adequate warning should have communicated," and chose to prescribe the drug based on that independent knowledge, then, by law, the allegedly inadequate warning of the drug company is not the proximate cause of the plaintiff's injury. See Christopher, 53 F.3d at 1192 (citations omitted). Because Bodie has failed to satisfy his burden of proving causation, his claims under both the AEMLD and the negligent failure to warn must fail. See Clarke Indus., Inc., 591 So. 2d at 461.

Specifically, with respect to the AEMLD action (Count 1), the Alabama Supreme Court has indicated that a drug that carries inadequate warnings will be deemed defective or unreasonably dangerous for purposes of the AEMLD. Stone, 447 So. 2d at 1304. The burden remains on a plaintiff bringing an AEMLD action, however, to prove that "that which rendered the product [dangerous] in fact *caused* the injury." Sears, 395 So. 2d at 995 (emphasis added). Here, even if we assume that OxyContin failed to carry adequate warnings -- such that it was an unreasonably dangerous product -- we cannot conclude it was this defect that caused Bodie's injury. The "learned intermediary" doctrine applies to claims brought under the AEMLD. See Morguson, 857 So. 2d at 802-03; Toole, 235 F.3d

at 1314. Because the evidence suggests that the learned intermediary, Dr. Mangieri, prescribed OxyContin based on his independent knowledge of the drug and its high potential for addiction, we cannot conclude that the allegedly inadequate warning (that is, the claimed defect) proximately caused Bodie's injury of addiction.

Similarly, with respect to Purdue's alleged failure to warn about the risks of the drug (Counts 3 and 4), we cannot conclude that the allegedly flawed warnings that accompanied OxyContin were the proximate cause of Bodie's injury. Because Dr. Mangieri, as the learned intermediary, testified that his decision to prescribe OxyContin was reached independent of the allegedly insufficient information on OxyContin's label or its accompanying literature, Bodie has failed to establish that the inadequate warning proximately caused his injury. See Christopher, 53 F.3d at 1192; Anderson v. Sandoz Pharma. Corp., 77 F. Supp. 2d 804, 808 (S.D. Tex. 1999) ("If [the doctor] was aware of the possible risks involved in the use of the drug, yet chose to use it regardless of the adequacy of the warning, then, as a matter of law, the adequacy of the warning was not a producing cause of the plaintiff's injury.") (internal quotations and citations omitted). See also Timmons v. Purdue Pharma. Co., No. 8:04-CV-1479-T-26MAP, 2006 WL 263602 (M.D. Fla. Feb. 2., 2006) (unpublished) (where doctor's decision to prescribe OxyContin

was made independent of any alleged misrepresentations by Purdue, stating that "the learned intermediary doctrine precludes a finding of causation" between the faulty warnings and the injury of addiction).[11]

In conclusion, because Dr. Mangieri's testimony–viewed in conjunction with Alabama's "learned intermediary" doctrine–precludes a finding of proximate causation,[12] Bodie's claims based upon the AEMLD (Count 1) and negligent

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[11] Although it is an unpublished district court decision in our circuit, we note that the facts of Timmons are strikingly similar to the facts of Bodie's case. There, as here, the plaintiff sued Purdue, alleging that the company had downplayed the risks of addiction to OxyContin and had affirmatively misrepresented the drug as being non-addictive, when those representations were not true. The district court observed that the "learned intermediary" doctrine applied to the case. In light of record evidence that none of the plaintiff's physicians had relied on Purdue's statements that addiction was "rare," as well as testimony that the doctors had been independently aware of the addictive nature of the drug, the Timmons court concluded that the plaintiff had failed to establish proximate cause, and granted summary judgment to Purdue.

[12] Bodie attempts to circumvent Dr. Mangieri's testimony -- and the damaging effect that it has on his ability to establish causation -- by citing to Bodie's testimony in rebuttal that Dr. Mangieri expressly told him that OxyContin was "not addictive." See R3-88, Exh. 4 at 85. Bodie argues that the credibility of Dr. Mangieri's testimony is undermined by Bodie's own conflicting testimony on this issue. He contends that this creates an issue of fact as to what Dr. Mangieri told him about OxyContin, and that therefore summary judgment was inappropriate. On appeal, Bodie argues that the district court erred in essentially "crediting" Dr. Mangieri's testimony and in discounting his own testimony.

This line of argument misses the point, however. The question, for purposes of Bodie's negligent failure to warn action, is whether Dr. Mangieri's decision to prescribe OxyContin to Bodie ultimately hinged on the information (accurate or inaccurate) that he obtained from Purdue. Dr. Mangieri testified it quite clearly was not. See R3-88, Exh. 9 at 67-68 (stating that he had independent knowledge of the risks of the drug, including its addictiveness, and that he chose to prescribe OxyContin regardless of the adequacy of the warning). Bodie presented no evidence to refute this testimony.

Nor does Bodie's testimony that Dr. Mangieri may have told his patient that the drug was non-addictive establish that Dr. Mangieri chose to prescribe the drug based on Purdue's alleged misrepresentations. To the extent that Bodie encourages us to infer that Dr. Mangieri relied on Purdue's alleged misrepresentations -- based on the fact that Dr. Mangieri's statements were similar to those allegedly made by Purdue -- we find that this fact inference is too tenuous to

failure to warn (Count 3 and 4) must fail as a matter of law. The district court acted properly in granting summary judgment in favor of Purdue on these counts.

B. Bodie's Claim Based on Breach of Implied Warranty

In Count 2 of his complaint, Bodie lodged a claim against Purdue for breach of the implied warranty of merchantability. Under Alabama law, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Ala. Code § 7-2-314 (1975). "Merchantability" refers to a product's being, in part, "fit for the ordinary purpose for which such goods are used." Id. These provisions in the Alabama Code mirror the Uniform Commercial Code ("U.C.C.")'s provisions on the implied warranty of merchantability. See U.C.C. § 2-314. To establish a *prima facie* case for breach of the implied warranty of merchantability, the plaintiff must prove: (1) the existence of the warranty; (2) a breach of that warranty; and (3) and damages proximately resulting from that breach. Barrington Corp. v. Patrick Lumber Co., Inc., 447 So. 2d 785, 787 (Ala. 1984) (citation omitted).

Where the goods appear to be otherwise fit for the purpose for which they

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withstand a motion for summary judgment, especially in light of Dr. Mangieri's express testimony that no representative of Purdue ever told him "that OxyContin was less addictive than other opioids." Id. at 72. See, e.g., Bald Mountain Park v. Oliver, 863 F.2d 1560, 1564 (11th Cir. 1989) ("In passing upon a motion for summary judgment, a finding of fact which may be inferred but not demanded by circumstantial evidence has no probative value against positive and uncontradicted evidence that no such fact exists.") (quotation omitted).

are used, however, the Alabama Supreme Court has declined to permit claims based on the use of allegedly unreasonably dangerous products to be redressed under the mechanism of the U.C.C., instead limiting the parties to remedies under products liability law. For example, in Shell v. Union Oil Co., 489 So. 2d 569, 570-71 (Ala. 1986), the plaintiff alleged a claim for breach of the implied warranty of merchantability because a product, purchased by his employer from the defendants and provided to him, contained benzene, a cancer causing agent. The plaintiff alleged that the benzene was not "fit for the ordinary purposes for which such goods are used," Ala. Code 1975 § 7-2-314(2), because it was a cancer-causing substance that was unreasonably dangerous.

The Alabama Supreme Court determined that the plaintiff's sole basis for claiming that the product was not "merchantable" was because it was cancer-causing and thus unreasonably dangerous. Id. at 571. The court stated: "[s]uch an argument ignores the clear distinction between causes of action arising under tort law and those arising under the U.C.C. as adopted in Alabama." Id. The court held that "[w]hether this product was unreasonably dangerous . . . is not a question properly addressed in an action brought under the provisions of the U.C.C. That question could be properly raised in an action under [the AEMLD], but not in this U.C.C. action for breach of warranty." Id. Noting that the product at issue

performed as it was supposed to, and that the warnings accompanying the product adequately described the inherent dangers of the product, the court questioned whether there was an "implied warranty of merchantability in the sense that these two manufacturers promised the employee that he would not be injured by his use or contact with their product." Id. at 571-72. The court determined that a manufacturer or supplier's implied warranty was limited to "*commercial* fitness and suitability," not "the broader obligation to warrant against health hazards inherent in the use of the product" when it was otherwise commercially fit for its intended use. Id. at 572. Thus the court granted judgment as a matter of law to the defendants on the breach of warranty claim.

Similarly, in Yarborough v. Sears, Roebuck & Co.. 628 So. 2d 478 (Ala. 1993), the plaintiffs sued the manufacturers of a kerosene heater that caught fire, causing damage to the plaintiffs' home and personal injuries. The evidence established that the warnings that accompanied the heater had been "specific, comprehensive, and detailed" in warning users of the dangers of using the item improperly, and that the plaintiff had not heeded these warnings. Id. at 482-83. The Alabama Supreme Court, in reviewing the claim for breach of implied warranty, found that the gravamen of the plaintiffs' claim was that "the kerosene heater was unreasonably dangerous and therefore could not be merchantable." Id.

at 483. The court, however, held that "[w]hether the kerosene heater was unreasonably dangerous is not a question properly addressed in a claim alleging breach of warranty under the U.C.C. but it could be . . . properly raised in a claim under the AEMLD." Id. Where the evidence suggested that the item was fit for its intended use, the court was unwilling to permit a breach of implied warranty of merchantability claim based solely on the allegation that the product was inherently dangerous.

In light of these cases, courts applying Alabama law have seen fit to subsume U.C.C.-based breach of implied warranty claims into tort and product liability claims, where the product is fit for its intended use and there is no evidence of "non-merchantability" other than a general allegation that the product contains inherent dangers. See Emody v. Medtronic, Inc., 238 F. Supp. 2d 1291, 1296 (N.D. Ala. 2003); Brock v. Baxter Healthcare Corp., 96 F. Supp. 2d 1352, 1356 n.2 (S.D. Ala. 2000). Cf. Spain v. Brown & Williamson Tobacco Corp., 872 So. 2d 101, 108 (Ala. 2003) (en banc) (per curiam) (permitting a breach of warranty claim in a product liability case where there was insufficient evidence that the products were in fact fit for their intended use).

Here, Bodie alleged that Purdue breached the implied warranty of merchantability because OxyContin was "not of merchantable quality," was

"unsafe" and was "unreasonably dangerous [,] thereby causing injury to plaintiff." R1-1 at 22. The evidence suggests, however, that OxyContin was, in fact, fit for its intended use as an analgesic treatment for chronic pain; indeed, as Bodie himself conceded, use of the drug managed his pain and improved his quality of life. Bodie has offered scant evidence as to how OxyContin was not fit for its intended use; in effect, his U.C.C. breach of warranty claim -- based on the general allegation that the drug was "unsafe" and "dangerous" -- is akin to the type of claim that the Alabama Supreme Court refused to recognize in Shell. As in Shell, there was no "implied warranty of merchantability in the sense that [Purdue] promised [Bodie] that he would not be injured by his use or contact with their product." See 489 So. 2d at 571-72. In fact, Purdue provided warnings with respect to OxyContin's addictive qualities,[13] and the product was fit for its intended pharmacological purpose of treating pain. We conclude that Bodie does not have a viable cause of action under Alabama law for breach of the implied warranty of merchantability. See Yarborough, 628 So. 2d at 483; Shell, 489 So. 2d at 571-72. Accordingly, the district court acted properly in granting summary judgment on Count 2 of Bodie's complaint.

[13] As noted previously, Purdue's OxyContin label stated that the drug could be "habit forming," and warned that it was an "opioid with an abuse liability similar to morphine and [was] a Schedule II controlled substance." See R3-88, Exh. 1.

C. Bodie's Claim Based on Fraud and Misrepresentation

In Count 5 of his complaint, Bodie alleged a claim for fraud. Under Alabama law, in order to establish a prima facie case for fraud, the plaintiff must show: (1) a false representation, that is, proof that the defendant made an untrue statement; (2) of an existing material fact; (3) that is reasonably relied upon; and (4) that plaintiff was damaged as a proximate result of the reliance. See Prestwood v. City of Andalucia, 709 So. 2d 1173, 1175 (Ala. 1997). For fraud claims brought in federal court–such as Bodie's–a higher threshold of specificity is required; under Federal Rule of Civil Procedure 9(b), "the circumstances constituting fraud or mistake shall be stated with particularity." We have construed this rule as requiring that a plaintiff alleging a fraud count alert the defendant to the precise misconduct with which he is charged. See Clausen v. Lab Corp. of America, Inc., 290 F.3d 1301, 1310 (11th Cir. 2002). That is, the plaintiff alleging fraud or misrepresentation must set forth "(1) precisely what statements were made in what documents or oral representations or what omissions were made, and (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) same; and (3) the content of such statements and the manner in which they misled the plaintiff, and (4) what the defendants obtained as a consequence of the fraud." Id.

Here, the district court determined that the "learned intermediary" doctrine applied to Bodie's count for fraud, such that Purdue's "duty" extended only to the obligation to provide truthful and accurate information to Dr. Mangieri, not to Bodie directly. In other words, the district court concluded that the "learned intermediary" doctrine barred a plaintiff from bring an action directly against a pharmaceutical company for allegedly deceptive statements made to consumers in its drug literature. Applying the learned intermediary doctrine, and determining that there was no evidence that *Dr. Mangieri* had "reasonably relied upon" the allegedly false statements Purdue made to him in prescribing OxyContin, the court concluded that Bodie's fraud count failed.

On appeal, Bodie argues that the district court erred in applying the "learned intermediary" doctrine to his fraud claim. He contends that the Alabama Supreme Court has not held that the "learned intermediary" doctrine applies to claims based on fraud and misrepresentation. Moreover, Bodie argues that consumers *should* be permitted to bring a claim for fraud directly against a pharmaceutical company, where the company makes false statements about a drug in its advertising and product literature, and the consumer relies upon those false statements in deciding to take the drug.

Alabama courts have not directly addressed whether the "learned

intermediary" doctrine applies in cases alleging fraud by a pharmaceutical company.[14] We need not reach whether the "learned intermediary" doctrine precludes a plaintiff from bringing an action directly against a pharmaceutical company, however, because even if we were to assume that the doctrine did not apply, Bodie's action would fail, due to a lack of any specific evidence as to what misrepresentations were made by Purdue about OxyContin. That is, even assuming that Alabama were to permit a direct fraud action against a pharmaceutical company (independent of the "learned intermediary" doctrine) for false statements made in promoting and marketing a prescription drug, Bodie's claim would fail, because he has not presented specific evidence of what materially false statements -- if any -- Purdue made.

A plaintiff alleging fraud must describe "precisely what statements were made in what documents," "the time and place of each such statement and the person responsible for making . . . same," and "the content of such statements." Clauson, 290 F.3d at 1310. Bodie failed to present any documentation to support his allegation that Purdue's literature and website contained false information

[14] Other circuits, such as the Fourth Circuit and Fifth Circuit, have broadly construed the doctrine, holding that it applies to all claims involving prescription drugs. See Talley v. Danek, 179 F.3d 154, 163 (4th Cir. 1999); In re Norplant Contraceptive Prod. Liab. Litig., 165 F.3d 374, 379 (5th Cir. 1999). Courts applying Georgia law in our circuit have reached a similar conclusion. See, e.g., Catlett v. Wyeth, 379 F. Supp. 2d 1374, 1381 (N.D. Ga. 2004) (stating that the doctrine encompasses any cause of action related to prescription drugs, including fraud claims directly against a pharmaceutical company).

about OxyContin. The Purdue documentation that Bodie admitted into evidence to support his fraud claim had been written years after Bodie alleges that the purportedly false statements were in fact made to him (in November 1998). As the district court pointedly observed, "*[n]o pre-1999 Purdue documentation regarding OxyContin has been offered into evidence*." R4-110 at 3 (emphasis added).

In addition, Bodie failed to present specific evidence of the content of the alleged misstatements. In his deposition, when asked about the content of the allegedly deceptive pamphlet and website about OxyContin, Bodie stated: "I'd just have to give you generalities, I can't give you specifics." R3-88, Exh. 4 at 85. Asked about the pamphlet, Bodie stated that he got "some sort of pamphlet," and that he could not remember whether he received it at the pharmacy or in the doctor's office, but that "generally speaking, it was kind of saying it was safe and the best thing, you know, for pain . . . that type of thing." Id. at 82-83, 86. As to the website, Bodie stated that the website reinforced the pamphlet's general message that OxyContin was "safe and non-addictive." Id. at 89.

Upon review, we agree with the district court that Bodie failed to present specific evidence of Purdue's representations about OxyContin and how, if at all, they were false. Bodie not only failed to offer into evidence documentary evidence to establish "precisely what statements were made in what documents," see

Clausen, 290 F.3d at 1310, but his testimony on these questions in his deposition was highly vague and general in nature. Bodie also failed to demonstrate with adequate specificity "the time and place of each such statement and the person responsible for making . . . same." Id. Finally, Bodie failed to establish with particularity "content of such statements," id., other than his highly general testimony that Purdue stated (in an unavailable document and on an unavailable website) that OxyContin was safe and non-addictive. This evidence was not sufficient to support a direct claim for fraud against Purdue, even if such a cause of action were available. Accordingly, the district court acted properly in granting summary judgment to Purdue on the fraud count (Count 5).

III. CONCLUSION

Bodie appealed the district court's decision to grant summary judgment in favor of Purdue, contending that this decision was in error. Having reviewed the record, we conclude that summary judgment was appropriate as to all of Bodie's counts. Accordingly, we **AFFIRM** the judgment of the district court.