[PUBLISH]

In the United States Court of Appeals

For the Eleventh Circuit

No. 20-12258

MARK BLACKBURN,

Plaintiff-Appellant,

versus

SHIRE US INC,
SHIRE LLC,

Defendants-Appellees,

SHIRE DEVELOPMENT LLC, et al.,

Defendants.

Appeal from the United States District Court
for the Northern District of Alabama
D.C. Docket No. 2:16-cv-00963-MHH

Before JILL PRYOR, LUCK, and BRASHER, Circuit Judges.

BRASHER, Circuit Judge:

Under Alabama law, the manufacturer of an unreasonably dangerous product has a duty to warn users of the risks presented by the product. When the unreasonably dangerous product is a drug that requires a prescription, a drug manufacturer's duty to warn is usually discharged by warning the prescribing physician of the product's risks.

Mark Blackburn was diagnosed with advanced stage kidney disease after taking LIALDA, a drug manufactured by Shire Pharmaceuticals. Blackburn does not contend that Shire failed to warn of the risk of kidney disease; he and his doctor knew that the drug might impair his kidney function. Instead, Blackburn contends that Shire should have more explicitly warned his doctor about how regularly to monitor his kidney function after prescribing LIALDA. He contends that, if LIALDA's warning label had been better, his physician would have monitored him differently after prescribing LIALDA, discovered the effect on his kidneys sooner, and prevented his injury.

In our view, Blackburn's theory of liability raises two unsettled questions of Alabama law. First, may a pharmaceutical company's duty to warn include a duty to provide instructions about how to mitigate warned-of risks? Second, may a plaintiff establish that an improper warning caused his injuries by showing that his doctor would have adopted a different course of testing or mitigation, even though he would have prescribed the same drug?

Because of how we resolve the federal issues in this appeal, these state-law questions are dispositive. For our part, we believe these questions are important enough—and the resolution uncertain enough—for us to certify them to the Supreme Court of Alabama.

I. BACKGROUND

Blackburn is a professional golf instructor. His training facility is located at a golf club in Birmingham, Alabama, but he frequently travels throughout the world to counsel some of the world's best players and represent one of the game's premium brands. Blackburn suffers from Crohn's disease.

Prior to moving to Birmingham, he lived and worked at a golf course in Guntersville, Alabama. Dr. Craig Young was one of Blackburn's clients and his *de facto* primary care physician. Young ordered routine bloodwork for Blackburn, and his "labs looked good." About eighteen months later, Blackburn reported persistent gastrointestinal issues, and Young referred him to Dr. Dino Ferrante, a gastroenterologist in Huntsville, Alabama. Ferrante

documented Blackburn's primary complaint as urgent diarrhea up to four times daily. Something Young said during his referral led Ferrante to conclude that he did not need to order initial blood-work before treating Blackburn. After several tests and procedures, Ferrante diagnosed Blackburn with Crohn's disease.

Ferrante prescribed LIALDA, and Blackburn began taking the medication on November 6, 2013. LIALDA is the brand name for Shire's mesalamine drug, which is an anti-inflammatory drug specifically aimed at the gut. LIALDA is not approved by the FDA to treat Crohn's, but it is approved to treat ulcerative colitis, Crohn's "sister" disease. The drug is taken orally in pill form unlike other, more invasive Crohn's treatments, and Ferrante considered it the best option for Blackburn due to his travel schedule.

Mesalamine drugs like LIALDA pose a risk of kidney disease. The LIALDA label warns that "[r]enal impairment, including minimal change nephropathy, acute and chronic interstitial nephritis, and, rarely, renal failure, has been reported in patients given products such as LIALDA that contain mesalamine or are converted to mesalamine." Kidney disease is identified by a digression in kidney function over time. LIALDA can cause inflammatory cells to deposit in the kidneys, scarring organ tissue and diminishing kidney function. If a patient experiences this side effect, continuing to take the drug can lead to irreversible damage. To identify potential disease—and thereby prevent severe impairment—the label recommends "that patients have an evaluation of renal function prior to initiation of LIALDA therapy and periodically while on therapy."

Renal function is evaluated by measuring the amount of creatinine in a patient's blood. Using the creatinine level, a physician can estimate glomerular filtration rate, which is a marker of how well a patient's kidneys are functioning.

Ferrante set a follow-up appointment for two months after he prescribed LIALDA, but either he or Blackburn canceled it. Even if Blackburn had kept the appointment, it is unlikely Ferrante would have ordered blood work to evaluate kidney function. As a matter of practice, Ferrante periodically tests renal function after "about a year" of treatment. By the time Blackburn had been taking LIALDA for a year, he had moved to Birmingham and requested a referral to a different doctor. Ferrante provided the referral, but Blackburn never followed up. Ferrante's office continued to fill Blackburn's prescriptions for over a year without examining him. Consequently, Blackburn's renal function went unmonitored during that time.

In all, Blackburn took LIALDA for somewhere between 12 and 16 months. He stopped filling the prescriptions in January 2015. Soon after that, Blackburn took himself off the drug because he felt that it wasn't working. He found that changing his diet partially relieved his Crohn's symptoms.

Soon after he stopped taking LIALDA, Blackburn discovered that he was suffering from advanced stage kidney disease. In April 2015, Blackburn underwent a blood test that revealed an excessive amount of creatinine, resulting in a low estimated glomerular filtration rate. His primary care physician referred him to Dr. Agata

Przekwas, a nephrologist. Przekwas diagnosed Blackburn with advanced chronic interstitial nephritis, a type of kidney disease that manifests as irreversible scarring and diminished kidney function. The severity of kidney disease is expressed in six stages, with stage six requiring a patient to undergo dialysis. Blackburn's kidney disease was initially diagnosed as stage four, reflecting the fact that his kidneys were functioning at approximately 20 percent their normal capacity. Blackburn is currently awaiting a kidney transplant.

Przekwas and Dr. Jonathan Winston, a nephrology expert retained by Blackburn, concluded that Blackburn's injuries were preventable. Winston estimated that Blackburn's kidney disease was detectable at least six months before it was diagnosed, and possibly as early as August 2014. If Blackburn had stopped taking LIALDA at that time, Winston opined that his kidney function "would be either normal or near normal." And Winston attributed Blackburn's injury to the LIALDA label. Because of the amorphous "periodic" instruction, Winston reasoned that a physician following the label's warning could fail to detect kidney disease before it "worsen[ed] to a clinically significant level."

Benjamin England, a regulatory expert retained by Blackburn, explained that Shire could have changed the label to include a stronger monitoring instruction. He concurred in Winston's assessment of the label's inadequacies and added that sufficient evidence, including a "a growing body of medical literature," supported a stronger monitoring instruction. England also identified reports of renal impairment that Shire received between the label's

initial approval and Blackburn's injury. He concluded that sufficient evidence would have led to a label change, had Shire sought one.

Blackburn sued Shire in June 2016. Shire initially moved to dismiss for lack of personal jurisdiction and judgment on the pleadings. Blackburn sought leave to amend his complaint, and the district court ordered Shire to show cause why leave should not be granted. Shire responded that the amendments would be futile, but the district court granted Blackburn's motion anyway.

Blackburn originally asserted four claims under Alabama law: strict liability for failure to warn under the Alabama Extended Manufacturers Liability Doctrine, breach of express warranty, and two fraud claims. On Shire's second motion to dismiss, the district court dismissed with prejudice all but the failure-to-warn claim. Blackburn twice moved the district court to revive the dismissed counts. First, Blackburn moved the district court to alter its dismissal to reflect that the counts were dismissed without prejudice, effectively granting him a second opportunity to amend his complaint. The district court denied the motion, concluding that Blackburn had forgone "ample opportunit[ies] to state claims on which relief could be granted." Instead of moving to amend his complaint while Shire's motion to dismiss was pending, Blackburn had "sat idly by" and waited for the district court to tell him whether his allegations were sufficient. Blackburn then moved for reconsideration, but the district court denied that motion as well. It concluded that the amendments would be futile because the LIALDA label

did not create an express warranty for safeness that would support Blackburn's breach of express warranty or fraud-based claims.

Blackburn's remaining failure-to-warn claim alleged that the LIALDA label contained an inadequate warning regarding its potential renal toxicity. Specifically, Blackburn argued that if the label had provided more detailed instructions for safe use, his kidney disease would have been detected earlier. According to Blackburn, the label should have instructed prescribers to "evaluat[e] . . . renal function by a simple serum (blood) test of creatinine levels on a monthly basis for the first three months after initiation of therapy and then on a quarterly basis for at least one year." We refer generally to the label's language as the "periodic" renal function instruction to differentiate it from Blackburn's suggested "monthly" instruction.

Eventually, Shire moved for summary judgment. The district court approved of Blackburn's theory of liability but held that it was not factually supported. Specifically, the district court granted judgment in favor of Shire because it concluded that the label's alleged inadequacies did not actually or proximately cause Blackburn's injuries. The district court concluded that it was undisputed that Ferrante did not rely on or even "look at the LIALDA label before he prescribed the drug." And Blackburn failed to demonstrate that Ferrante would have read and heeded an alternative instruction. Although Ferrante testified that he would have followed a more explicit instruction, the district court dismissed this testimony as "unsubstantiated speculation" and a "self-interested

statement." Thus, Blackburn's claim failed on the facts, and the district court granted summary judgment to Shire.

II. STANDARDS OF REVIEW

We review both the denial of a motion for leave to amend a pleading and a motion for reconsideration for abuse of discretion. *Diaz v. Jaguar Rest. Grp., LLC*, 627 F.3d 1212, 1214 (11th Cir. 2010); *Corwin v. Walt Disney Co.*, 475 F.3d 1239, 1254 (11th Cir. 2007).

A district court's grant of summary judgment is reviewed *de novo*, with all facts and reasonable inferences therefrom viewed in the light most favorable to the nonmoving party. *Carmical v. Bell Helicopter Textron, Inc.*, 117 F.3d 490, 494 (11th Cir. 1997). Summary judgment is warranted only when there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law. *T.W. ex rel. Wilson v. Sch. Bd. of Seminole Cnty.*, 610 F.3d 588, 597–98 (11th Cir. 2010); FED. R. CIV. P. 56(a). We may affirm the district court on any basis supported by the record. *Miller v. Harget*, 458 F.3d 1251, 1256 (11th Cir. 2006).

III. DISCUSSION

We divide our discussion into two main parts. First, we address whether the district court abused its discretion in denying Blackburn further opportunity to amend his complaint. Second, we address whether the district erred in granting summary judgment in favor of Shire.

A. The District Court Did Not Abuse its Discretion in Denying Blackburn Further Opportunities to Amend.

After Blackburn amended his complaint, the district court dismissed his warranty and fraud claims with prejudice. Blackburn moved the court to alter or amend its order to state that the dismissal was without prejudice and to allow him his "one chance" to amend. The court denied that motion, so Blackburn filed a motion for reconsideration, which the court again denied. Blackburn argues that the district court should have allowed him an opportunity to amend his complaint after it dismissed his warranty and fraud claims. Shire contends that Blackburn was not entitled to an additional opportunity to amend, and we agree.

A plaintiff has the right to amend his complaint within 21 days of serving it or 21 days after certain responsive pleadings and motions. FED. R. CIV. P. 15(a)(1). In all other cases, the plaintiff requires leave of court or consent of the opposing party. Ordinarily, a court should "freely give" leave to amend a pleading "when justice so requires." FED. R. CIV. P. 15(a)(2). Whether justice so requires is within the discretion of the district court to determine. *See Burger King Corp. v. Weaver*, 169 F.3d 1310, 1319 (11th Cir. 1999).

As an initial matter, we reject Blackburn's argument that his complaint was first amended as a matter of right, such that his second request for leave to amend was his first such request. Before he filed his first amended complaint, Blackburn expressly sought

leave to amend under Rule 15(a)(2)'s "freely given" standard, and he acknowledged that Shire's motion for judgment on the pleadings "cut off [his] ability to amend . . . as a matter of right." *See* FED. R. CIV. P. 15(a)(1). The district court then granted Blackburn leave to amend after considering Shire's opposing arguments. Thus, the district court afforded Blackburn an opportunity to amend his complaint that he was not entitled to as of right.

Nor can we say that the district court abused its discretion in denying the second motion to amend. When deciding whether to grant leave to amend, a court considers five factors: (1) undue delay, (2) bad faith or dilatory motive, (3) repeated failure to cure deficiencies by amendment, (4) undue prejudice to the opposing party by virtue of allowance of the amendment, and (5) futility. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Burger King Corp.*, 169 F.3d at 1319. Here, the district court based its decision to deny the motion on the undue delay and futility factors. The district court noted that Blackburn had "ample opportunity" and "sat idly by" as he awaited determination of Shire's second motion to dismiss. By the time the district court considered Blackburn's second request to amend, the parties and the court had spent significant time preparing and reviewing the initial complaint, Shire's motion for judgment on the pleadings, Blackburn's response to that motion, Blackburn's first motion to amend, Shire's memorandum in response, and Blackburn's first amended complaint. The parties then again briefed the sufficiency of Blackburn's allegations, and the district court held that they were insufficient.

We find no abuse in the district court's conclusion that permitting such a late amendment "would be contrary to promoting judicial efficiency." A district court is not required to grant a counseled plaintiff leave to amend his complaint *sua sponte* before ruling on a dispositive motion. *Wagner v. Daewoo Heavy Indus. Am. Corp.*, 314 F.3d 541, 542 (11th Cir. 2002) (en banc). Accordingly, a plaintiff may not "sit idly by as he await[s] the district court's determination with respect to a Rule 12(b)(6) motion to dismiss." *Id.* at 543.

Relying on our decision in *Bryant v. Dupree*, 252 F.3d 1161, 1163 (11th Cir. 2001), Blackburn argues that, after the district court dismissed his first amended complaint, he was still entitled to one more chance to amend. But *Bryant* is distinguishable. The plaintiffs in *Bryant* amended their complaint once as a matter of course; then, in response to the defendant's motion to dismiss, the plaintiffs sought leave to amend a second time—while the motion to dismiss was still pending. *Id.* at 1163–64. Here, Blackburn did not first amend as a matter of course. And Blackburn did not seek leave to amend (a second time) until *after* the district court granted Shire's second dispositive motion. Blackburn's reliance on *Bryant* is therefore misplaced.

B. Summary Judgment on Failure to Warn

We now turn to the main issue—the district court's summary judgment on Blackburn's failure-to-warn claim. A prescription drug manufacturer has a duty to provide a warning that

adequately apprises of the product's risks. *Stone v. Smith, Kline & French Lab'ys*, 447 So.2d 1301, 1304 (Ala. 1984). Because a prescription drug can be obtained only through an intermediary, such as a doctor, Alabama law assesses the adequacy of the warning by asking whether the warning label adequately warned that intermediary. *Wyeth, Inc. v. Weeks*, 159 So.3d 649, 673 (Ala. 2014), *superseded by statute on other grounds*, ALA. CODE § 6-5-530, *as recognized in Forest Lab'ys, LLC v. Feheley*, 296 So.3d 302 (Ala. 2019). To succeed on a failure-to-adequately-warn claim, a plaintiff must show that the label's inadequacies actually and proximately caused his injury. *Gurley v. Am. Honda Motor Co.*, 505 So.2d 358, 361 (Ala. 1987). That is, the plaintiff must show that curing the label's inadequacies would have altered the prescribing physician's conduct in a way that would have prevented the plaintiff's injury. *See Weeks*, 159 So.3d at 673; *E.R. Squibb & Sons, Inc. v. Cox*, 477 So.2d 963, 970 (Ala. 1985).

Blackburn's theory of liability is that Shire provided his doctor inadequate instructions to mitigate the risk of impaired kidney function. Blackburn argues that the district court erred in concluding that, as a matter of undisputed fact, his doctor would have pursued the same course of treatment no matter the warning. For its part, Shire argues that Alabama tort law does not recognize a cause of action based on a pharmaceutical company's failure to give mitigation instructions.

We agree with Blackburn that the district court erred in the way it viewed the record. We certify the question of whether

Alabama law recognizes this cause of action to the Supreme Court of Alabama.[1]

1. The district court overlooked disputes of material fact.

The district court considered three undisputed facts fatal to Blackburn's failure-to-warn claim: first, Ferrante did not read the LIALDA label before prescribing the drug to Blackburn; second, Ferrante never tested Blackburn's renal function; and third, Blackburn did not attend the follow-up appointment. From these three facts, the district concluded that the label's alleged inadequacies did not cause Blackburn's injuries as a matter of law. Blackburn argues that, despite these facts, genuine issues of material fact exist concerning causation because Ferrante testified that he would have read the label and treated Blackburn differently if the label carried a different warning. We agree with Blackburn.

As to the first issue, we believe the district court misunderstood Ferrante's testimony about reading the label. Although Ferrante testified that he did not actually look at the LIALDA label before prescribing it to Blackburn, he also testified that he had

[1] Shire also argues that federal law would preempt a state law cause of action if it existed. The district court rejected this preemption defense. *See generally Wyeth v. Levine*, 555 U.S. 555, 581 (2009). We will address it, if necessary, after we know the contours of state law. *See Blue Cross & Blue Shield of Ala., Inc. v. Nielsen*, 116 F.3d 1406, 1412 (11th Cir. 1997) (certifying a question because "the state law issues must be decided before we can dispose of" the preemption question), *certified question answered*, 714 So.2d 293 (Ala. 1998).

prescribed the medication before, he was familiar with its existing label, and he knew that renal function should be monitored periodically. He explained that he complied with his interpretation of the label's instructions. And he said he would have followed a different label. In other words, this is not a case where the label's warning did not matter to the physician. It is instead a case where the existing label's warning was so well known to the physician that he did not read it before each new prescription.

The district court dismissed Ferrante's testimony about whether he would have read and incorporated a different label into his practices as "unsubstantiated speculation" and "self-interested" testimony. We disagree. Shire argues that Blackburn cannot create a genuine issue of material fact by speculating about whether he and Ferrante would have complied with a monthly monitoring instruction. We agree that a party may not avoid summary judgment by offering only his own speculation about a material fact. *See, e.g.*, *Cordoba v. Dillard's, Inc.*, 419 F.3d 1169, 1181 (11th Cir. 2005). But that is not what Blackburn has done.

As an initial matter, Ferrante's testimony is no more self-serving than any other kind of evidence that must be considered at summary judgment. We have held that "a litigant's self-serving statements based on personal knowledge or observation can defeat summary judgment." *United States v. Stein*, 881 F.3d 853, 857 (11th Cir. 2018); *see also* FED. R. CIV. P. 56. Here, of course, Blackburn is relying on Ferrante's testimony, not his own. It may be, as Shire argues, that Ferrante has some self interest in minimizing his role

in causing Blackburn's adverse side effects. But this argument goes to credibility, not the usefulness of the testimony at summary judgment. *See Stein*, 881 F.3d at 857.

Ferrante's testimony is also not speculative, at least as we have used that term in addressing the usefulness of summary judgment evidence. The question under Blackburn's causation theory is whether a different label would have led to a different outcome for Blackburn, which turns on the factual question of what Ferrante would have done if the label had been different. As Blackburn's treating physician, Ferrante may testify on that issue. *See United States v. Henderson*, 409 F.3d 1293, 1300 (11th Cir. 2005) (citing FED. R. EVID. 701); *see also* FED. R. EVID. 704. And his testimony here is no more speculative than testimony we have considered when answering whether a change in label would have affected a doctor's treatment in other cases. *Toole v. McClintock*, 999 F.2d 1430, 1433 n.6 (11th Cir. 1993) (holding that a doctor's similar testimony supported sending a failure-to-warn claim to the jury).

The district court reasoned that Ferrante's "conduct" contradicted his testimony, but we fail to see how it reached that conclusion if it viewed the facts in Blackburn's favor, as it was required to do. Although Ferrante did not initially or periodically test Blackburn's renal function, he explained why: first, he relied on Young's indication that Blackburn's blood work "checked out" prior to the referral; and second, Blackburn requested a referral to a new doctor before Ferrante would have ordered periodic bloodwork. Given his explanation for why he did not test Blackburn, a reasonable jury

could find that Ferrante would have followed a different warning label.

Finally, the district court made an improper inference concerning the missed follow-up appointment. Blackburn's failure to attend the appointment would "sever[] the causal chain," as the district court concluded, only if a doctor would have tested his renal function at the appointment. But the record does not indicate that any doctor would have. Ferrante testified that the appointment was primarily to address any side-effects of the medication, that he did not typically assess renal function until much later, and that either he or Blackburn canceled the appointment. The district court was also persuaded that Blackburn would not have attended an appointment for a blood test, even if Ferrante ordered one. However, drawing inferences in Blackburn's favor, his failure to attend the follow-up appointment to assess medication side-effects was based on matters completely unrelated to whether he would have attended a testing appointment, such as not noticing any side effects from the medication. There is no other evidence that Blackburn would not have submitted to more frequent testing if his doctor had recommended it based on a different warning label.

Considering Ferrante's testimony, and drawing all inferences in Blackburn's favor, a reasonable jury could find that Ferrante would have read and heeded a different LIALDA label that warned of a need for more frequent testing. These genuine disputes of material fact preclude us from affirming based on the district court's reasoning.

2. We certify two state law questions to the Supreme Court of Alabama.

As an alternative basis to affirm the district court's summary judgment, Shire argues that the district court erred in recognizing Blackburn's theory of liability as a matter of Alabama law. There are two parts to this argument, as we see it. First, citing the learned intermediary doctrine, Shire contends that it satisfied its duty as a matter of law by warning of the risk of renal impairment and that, once a drug manufacturer warns of a risk, it is up to the prescribing doctor to assess and mitigate that risk. Second, Shire argues that Blackburn's theory of proximate cause is "not in accord with Alabama law." Specifically, Shire argues that a failure-to-warn plaintiff may establish that his injury was caused by a prescription drug only by showing that the physician would not have prescribed the drug if the warning had been adequate. Shire's arguments present the following state-law questions:

> 1. Consistent with the learned intermediary doctrine, may a pharmaceutical company's duty to warn include a duty to provide instructions about how to mitigate warned-of risks?
>
> 2. May a plaintiff establish that a failure to warn caused his injuries by showing that his doctor would have adopted a different course of testing or mitigation, even though he would have prescribed the same drug?

We believe these questions are dispositive, but we confront a dearth of clear authority to resolve them.

We have not expressly addressed Shire's first argument. Some federal district courts have arguably accepted the argument. *See In re Chantix (Varenicline) Prods. Liab. Litig.*, 881 F. Supp. 2d 1333, 1342 n.12 (N.D. Ala. 2012) (dismissing the claim that a drug's label should have included prescribing instructions where the label "clearly set[] forth" the experienced side effect); *Dye v. Covidien LP*, 470 F. Supp. 3d 1329, 1341 (S.D. Fla. 2020) (holding that a drug manufacturer "need only warn of complications stemming from the use of the Product—not the subsequent measures medical professionals may employ to treat those complications"). On the other hand, the Fifth Circuit has concluded (applying Louisiana law) that "recommended medical monitoring schemes . . . are, in essence, instructions for safe use of prescription drugs" that must be included to satisfy a manufacturer's duty to warn. *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 269–70 (5th Cir. 2002) (citing 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 omitted))); *see also PLIVA, Inc. v. Mensing*, 564 U.S. 611 (2011) ("a manufacturer's duty to warn includes a duty to provide adequate instructions for safe use of a product"). No decision of the Supreme Court of Alabama directly adopts either position. Although the court has at times used the terms "instructions" and "warnings" interchangeably, *Yarbrough v. Sears, Roebuck & Co.*, 628 So.2d 478,

483 (Ala. 1993), it has also said that a drug manufacturer's duty is "limited to an obligation to advise the prescribing physician of any potential dangers that may result from the use of its product," *Weeks*, 159 So.3d at 673 (quoting *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313–14 (11th Cir. 2000)).

As to Shire's second argument, the district court reasoned that "proof of proximate cause could also take the form of evidence that, although the physician still would have prescribed the drug, the physician would have changed her behavior or treatment in some way that would have resulted in a different outcome for the plaintiff." We have arguably approved of this theory under Alabama law. *See Toole*, 999 F.2d at 1433. And several district court decisions also endorse this position. *See Barnhill v. Teva Pharms. USA, Inc.*, 819 F. Supp. 2d 1254, 1261 (S.D. Ala. 2011); *Fields v. Eli Lilly & Co.*, 116 F. Supp. 3d 1295, 1306 (M.D. Ala. 2015). But Shire argues with some force that this theory is in tension with the Supreme Court of Alabama's latest statements on causation in the pharmaceutical failure-to-warn context. *See Weeks*, 159 So.3d at 673–74 ("In short, the patient must show that, but for the false representation made in the warning, the prescribing physician would not have prescribed the medication to his patient.").

Thankfully, the Supreme Court of Alabama permits federal courts to certify questions when faced with "determinative" issues of state law upon which "there are no clear controlling precedents in the decisions of the Supreme Court [of Alabama]." ALA. R. APP. P. 18(a). The "most important" factors in deciding to certify are

"the closeness of the question and the existence of sufficient sources of state law . . . to allow a principled rather than conjectural conclusion." *Florida ex rel. Shevin v. Exxon Corp.*, 526 F.2d 266, 274–75 (5th Cir. 1976). Thus, certification is generally appropriate where we face "substantial doubt on a dispositive state law issue." *WM Mobile Bay Env't Ctr., Inc. v. City of Mobile Solid Waste Auth.*, 972 F.3d 1240, 1251 (11th Cir. 2020). Unsurprisingly, we have sought guidance from the Supreme Court of Alabama on similar issues of tort liability before. *See Farsian v. Pfizer, Inc.*, 52 F.3d 932, 934 (11th Cir. 1995), *certified question answered*, 682 So.2d 405 (Ala. 1996); *Campbell v. Cutler Hammer, Inc.*, 996 F.2d 1164, 1166 (11th Cir. 1993), *certified question answered*, 646 So.2d 573 (Ala. 1994). We believe it is the best course to seek the Supreme Court of Alabama's guidance again.

IV. CONCLUSION

Before we can decide whether to affirm or reverse the district court, we must determine whether Blackburn's theory of liability is consistent with Alabama law. We therefore certify to the Supreme Court of Alabama the following questions:

> 1. Consistent with the learned intermediary doctrine, may a pharmaceutical company's duty to warn include a duty to provide instructions about how to mitigate warned-of risks?
>
> 2. May a plaintiff establish that a failure to warn caused his injuries by showing that his doctor would

> have adopted a different course of testing or mitigation, even though he would have prescribed the same drug?

We defer our decision in this case until the Supreme Court of Alabama has considered our certified questions. We note that our phrasing of the certified questions is not intended "to restrict the Supreme Court's consideration of the problems involved and the issues as the Supreme Court perceives them to be in its analysis of the record certified in this case." *Martinez v. Rodriquez*, 394 F.2d 156, 159 n.6 (5th Cir. 1968). To that end, "if we have overlooked or mischaracterized any state law issues or inartfully stated [the] questions we have posed, we hope the Alabama Supreme Court will feel free to make the necessary corrections." *Spain v. Brown & Williamson Tobacco Corp.*, 230 F.3d 1300, 1312 (11th Cir. 2000). The entire record of this case, including the parties' briefs, is transmitted to the Supreme Court of Alabama.

QUESTIONS CERTIFIED.