BLACKBURN V. SHIRE US INC.: ELEVENTH CIRCUIT CERTIFIES QUESTIONS TO THE SUPREME COURT OF ALABAMA OF WHETHER A FAILURE-TO-WARN PLAINTIFF MAY ESTABLISH LIABILITY UNDER ALABAMA LAW BASED ON A PHARMACEUTICAL COMPANY'S FAILURE TO PROVIDE INSTRUCTIONS FOR MITIGATING RISKS ASSOCIATED WITH A PRESCRIPTION DRUG

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In *Blackburn v. Shire US Inc.*, the United States Court of Appeals for the Eleventh Circuit sought guidance from the Supreme Court of Alabama on two questions concerning the duty of a pharmaceutical company to warn of the potential risks associated with prescription medications.[1] The Plaintiff premised his failure-to-warn claim on a pharmaceutical company's failure to provide adequate instructions to mitigate risks associated with a medication that is used to treat ulcerative colitis, which is similar to Crohn's disease.[2] The Eleventh Circuit held that the district court did not abuse its discretion in denying the Plaintiff's motion to amend his complaint.[3] Additionally, the court declined to determine whether the Plaintiff's theory gives rise to liability under Alabama law, instead certifying the question to the Supreme Court of Alabama.[4]

The Plaintiff, Mark Blackburn, was prescribed LIALDA by Dr. Dino Ferrante after being diagnosed with Crohn's disease.[5] LIALDA is a prescription drug made by the Defendant, Shire Pharmaceuticals ("Shire").[6] Because taking LIALDA "pose[s] a risk of kidney disease," the drug's label provides a warning to that effect.[7] The label also recommends "that patients have an evaluation of renal function prior to initiation of LIALDA therapy and periodically while on therapy."[8] Both before prescribing LIALDA and during the twelve to sixteen months that Blackburn took LIALDA, Ferrante did not perform an examination of Blackburn's renal function as the label recommended.[9] Although an appointment was scheduled two months after Ferrante prescribed LIALDA, the appointment was cancelled either by him

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[1] Blackburn v. Shire US Inc., 18 F.4th 1310, 1322 (11th Cir. 2021).

[2] *Id.* at 1318–19.

[3] *Id.* at 1317–18.

[4] *Id.* at 1322.

[5] *Id.* at 1314. "LIALDA is not approved by the FDA to treat Crohn's, but it is approved to treat ulcerative colitis, Crohn's 'sister' disease." *Id.*

[6] *Blackburn*, 18 F.4th at 1313.

[7] *Id.* at 1314.

[8] *Id.* at 1314–15.

[9] *Id.* at 1315.

or Blackburn.[10] However, Ferrante likely would not have evaluated Blackburn's kidney function at the follow-up appointment.[11] Ferrante's common practice was to evaluate a patient's kidney function after a year of treatment, by which time Blackburn had been referred to a different doctor.[12]

After taking LIALDA for a period of approximately twelve to sixteen months, Blackburn "took himself off the drug because he felt that it wasn't working."[13] A few months after he stopped taking LIALDA, Blackburn was diagnosed with stage four kidney disease.[14] Two doctors, including the diagnosing doctor and Blackburn's nephrology expert, determined that Blackburn's disease was "detectable at least six months before it was diagnosed[,]" and that, had he been taken off LIALDA at that time, the extent of his disease could have been prevented as his kidney function "would be either normal or near normal."[15] Blackburn's expert also determined that the ambiguity in the term "periodic" on the LIALDA warning label could cause a physician to "fail to detect kidney disease before it worsen[ed] to a clinically significant level."[16]

Blackburn brought suit against Shire in June 2016 in the United States District Court for the Northern District of Alabama asserting four claims under Alabama law, including a failure-to-warn claim, two fraud claims, and breach of express warranty.[17] Following Shire's second motion to dismiss, only Blackburn's failure-to-warn claim survived dismissal.[18] Blackburn's specific argument was that had the LIALDA warning label provided sufficiently detailed instructions for safe use, as opposed to recommending "periodic" kidney examinations, "his kidney disease would have been detected earlier."[19] The district court, although finding Blackburn's theory of liability viable, granted summary judgment in favor of Shire because "Blackburn failed to demonstrate that Ferrante would have read and heeded an alternative instruction."[20] Additionally, the district court denied Blackburn's motion to amend his complaint and his subsequent

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[10] *Id.*
[11] *Blackburn*, 18 F.4th at 1315.
[12] *Id.*
[13] *Id.*
[14] *Id.* "The severity of kidney disease is expressed in six stages, with stage six requiring a patient to undergo dialysis." *Id.*
[15] *Id.* at 1315.
[16] *Blackburn*, 18 F.4th at 1315 (alteration in original) (internal quotation marks omitted).
[17] *Id.* at 1315–16.
[18] *Id.* at 1316.
[19] *Id.*
[20] *Id.*

motion for reconsideration.[21] Blackburn appealed the district court's denial of his motion to amend and its grant of summary judgment.[22]

The Eleventh Circuit first addressed the district court's denial of Blackburn's motion to amend.[23] After Blackburn's first amendment in this case, "the district court dismissed his warranty and fraud claims with prejudice."[24] Blackburn asked the district court to alter its order to instead dismiss his claims without prejudice and to permit him to amend his complaint.[25] Blackburn contends that his request for leave to amend his complaint was his first such request because he filed his first amended complaint "as a matter of right."[26] The Eleventh Circuit rejected this argument, finding that "the district court [had already] afforded Blackburn an opportunity to amend his complaint that he was not entitled to as of right" since Shire filed a motion for judgment on the pleadings after Blackburn filed his original complaint.[27]

Based on this conclusion, the Eleventh Circuit declined to find that the district court abused its discretion in denying Blackburn's motion to amend on the grounds of undue delay and futility.[28] Rather, the court accepted the district court's finding that "the parties and the court had spent significant time preparing and reviewing the initial complaint," and that allowing Blackburn to amend his complaint again "'would be contrary to promoting judicial efficiency.'"[29] Finally, the court disagreed with Blackburn's argument that *Bryant v. Dupree* governed in this case.[30] In *Bryant*, the plaintiff was permitted to amend his complaint for a second time because his first amendment came "as a matter of course[,]" and his motion to amend for a second time was filed before the court decided the defendant's motion to dismiss.[31] However, the court here already determined that Blackburn's first amended complaint was not as a matter of course.[32] Additionally, Blackburn's second motion to amend was filed after the district court awarded Shire's second motion to dismiss.[33] Therefore, the court

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[21] *Id.*
[22] *Blackburn*, 18 F.4th at 1313.
[23] *Id.* at 1317.
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.; see also* FED. R. CIV. P. 15(a)(1).
[28] *Blackburn*, 18 F.4th at 1317–18.
[29] *Id.* at 1318.
[30] *Id; see* Bryant v. Dupree, 252 F.3d 1161 (11th Cir. 2001).
[31] *Blackburn*, 18 F.4th at 1318 (citing *Bryant*, 252 F.3d at 1163–64).
[32] *Id.*
[33] *Id.*

concluded that *Bryant* did not control in this case and that the district court did not abuse its discretion in denying Blackburn's second motion to amend.[34]

The Eleventh Circuit then moved to the issue of whether the district court erred in granting summary judgment on Blackburn's failure-to-warn claim.[35] As a prescription drug manufacturer, Shire "has a duty to provide a warning that adequately apprises of [its] product's risks."[36] Under Alabama law, a failure-to-warn claim rests on whether a prescription drug's warning label adequately warned a prescribing doctor of those risks.[37] A plaintiff bringing a failure-to-warn claim 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."[38] In this case, Blackburn argued that LIALDA's warning label was inadequate in that it failed to provide doctors with adequate instructions to "mitigate the risk of impaired kidney function."[39] Shire's rebuttal argument was that a failure to give mitigating instructions is not sufficient to give rise to failure-to-warn liability under Alabama law.[40]

In reviewing the district court's grant of summary judgment, the Eleventh Circuit determined the district court erred in concluding that there was no genuine dispute of material facts.[41] First, the court addressed Dr. Ferrante's failure to read the warning label before he prescribed LIALDA.[42] The court held that a reasonable jury could have found that, although Dr. Ferrante did not read the LIALDA label because he had prescribed the drug before, "he would have followed a different warning label."[43] Next, the court discussed the fact that Dr. Ferrante failed to test Blackburn's kidney and that Blackburn failed to "attend the follow-up appointment."[44] The Eleventh Circuit agreed with the district court's reasoning that the failure to attend the follow-up appointment would break the causal chain "only if a doctor would have tested [Blackburn's] renal function at the appointment."[45] However, "the record [did] not indicate that any doctor would have" tested for renal function, and instead suggested that the purpose of the appointment would

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[34] *Blackburn*, 18 F.4th at 1317–18.
[35] *Id.* at 1318.
[36] *Id.* (citing Stone v. Smith, Kline & French Lab'ys, 447 So. 2d 1301, 1304 (Ala. 1984)).
[37] *Id.* (citing Wyeth, Inc. v. Weeks, 159 So. 3d 649, 673 (Ala. 2014)).
[38] *Id.* (citing *Weeks*, 159 So. 3d at 673).
[39] *Id.* at 1318–19.
[40] *Blackburn*, 18 F.4th at 1319.
[41] *Id.* at 1319–21.
[42] *Id.* at 1319.
[43] *Id.* at 1319–20.
[44] *Id.* at 1320.
[45] *Id.*

have been to test Blackburn's blood levels.[46] Additionally, viewing the facts in the light most favorable to Blackburn, his failure to attend the follow-up appointment could be found to be "completely unrelated to whether he would have attended a testing appointment."[47] The court suggested that Blackburn may have simply not noticed any side effects from taking LIALDA and that he may have agreed to more renal function testing if Dr. Ferrante had required it based upon the suggestion of a different LIALDA label.[48] In light of these findings, the court refused to affirm the district court's conclusion that no genuine dispute of material facts existed.[49]

Following this factual analysis, the court discussed whether Blackburn's theory that Shire failed to provide adequate instructions to mitigate the risk of kidney disease is recognized under Alabama law.[50] The court separated its discussion by analyzing Shire's arguments that (1) "it satisfied its duty as a matter of law by warning of the risk of renal impairment and that . . . it is up to the prescribing doctor to assess and mitigate that risk" and (2) 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."[51]

Concerning Shire's first argument, the court noted that the Eleventh Circuit has not addressed whether pharmaceutical companies have "a duty to provide instructions about how to mitigate warned-of risks."[52] The court also found that the Alabama Supreme Court "has at times used the terms 'instructions' and 'warnings' interchangeably" and thus has not "directly adopt[ed] either proposition."[53] As for Shire's second argument, the court stated that it has endorsed the theory that proximate cause could be established by "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 of the plaintiff."[54] However, while the Eleventh Circuit and various district courts

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[46] *Blackburn*, 18 F.4th at 1320.
[47] *Id.*
[48] *Id.*
[49] *Id.* at 1320–21. "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." *Id.* at 1320.
[50] *Id.* at 1321.
[51] *Blackburn*, 18 F.4th at 1231.
[52] *Id.*
[53] *Id.* (first citing Yarbrough v. Sears, Roebuck & Co., 628 So.2d 478, 438 (Ala. 1993); and then citing *Weeks*, 150 So.3d at 673).
[54] *Id.* at 1322.

have suggested that this theory is viable under Alabama law,[55] the Alabama Supreme Court's opinion in *Weeks* is at odds with the theory.[56]

In light of the uncertainty surrounding these issues, the Eleventh Circuit certified the following two questions to the Supreme Court of Alabama related to Blackburn's theory of liability:

> 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?[57]

Undoubtedly, pharmaceutical companies such as Shire anxiously anticipate the Supreme Court of Alabama's decision regarding a potentially heightened standard for prescription drug warning labels under Alabama law. Perhaps more importantly, Blackburn awaits a kidney transplant[58] and a decision from Alabama's highest court that could make or break his ability to recover from his suffering.[59]

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[55] *Id.* (first citing Toole v. McClintock, 999 F.2d 1430, 1433 (11th Cir. 1993); then citing Barnhill v. Teva Pharms. USA, Inc., 819 F. Supp. 2d 1254, 1261 (S.D. Ala. 2011); and then citing Fields v. Eli Lilly & Co., 116 F. Supp. 3d 1295, 1306 (M.D. Ala. 2015)).

[56] *Id.* (citing *Weeks*, 159 So. 3d at 673–74) ("[T]he 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.").

[57] *Blackburn*, 18 F.4th at 1321 (citing Florida *ex rel.* Shevin v. Exxon Corp., 526 F.2d 266, 274–75 (5th Cir. 1976)) (holding that certification is proper where the court faces "substantial doubt on a dispositive state law issue.").

[58] *Id.* at 1315.

[59] *Id.* at 1322.