UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

MARK BLACKBURN,	}	
	}	
Plaintiff,	}	
	}	
v.	}	**Case No.: 2:16-cv-00963-MHH**
	}	
SHIRE U.S., INC., et al.,	}	
	}	
Defendants.	}	

MEMORADUM OPINION[1]

In this prescription drug products liability case, plaintiff Mark Blackburn contends that defendants Shire U.S., Inc. and Shire, LLC, the makers of the prescription drug LIALDA, breached their obligation to provide adequate instructions for the safe use of the drug, and the breach proximately caused his chronic, irreversible kidney injury. According to Mr. Blackburn, if Shire had included in its written warning information that instructed prescribing physicians to perform renal assessments at specific intervals, his prescribing physician would have detected his kidney injury and altered the treatment he prescribed for Mr.

[1] [1] The Court is issuing this opinion during a declared national emergency concerning COVID-19. To enable parties to pursue their rights during this emergency, the Court is continuing its work. For information about the timing of appeals, please review the information provided in the conclusion of this opinion. The Court is including this procedural information in each opinion that it issues during the national emergency.

Blackburn's Crohn's disease. The Shire defendants have asked the Court to enter judgment in their favor. (Doc. 194). For the reasons stated below, the Court will grant the defendants' motion for summary judgment.

STANDARD OF REVIEW

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). To demonstrate that there is a genuine dispute as to a material fact that precludes summary judgment, a party opposing a motion for summary judgment must cite "to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." FED. R. CIV. P. 56(c)(1)(A). "The court need consider only the cited materials, but it may consider other materials in the record." FED. R. CIV. P. 56(c)(3).

FACTS

Mr. Blackburn is an accomplished golf instructor. He coaches amateur and professional players on the PGA tour. He also speaks at conferences for Titleist, a company that produces golf apparel and equipment. Mr. Blackburn must travel nationally and internationally for his work. Mr. Blackburn suffers from Crohn's disease, and the disease sometimes interferes with his work.

In November of 2013, Mr. Blackburn began taking LIALDA to treat Crohn's disease. (Doc. 188-6, p. 18). On May 14, 2015, at age 39, Mr. Blackburn's physician diagnosed Mr. Blackburn with chronic interstitial nephritis and stage four chronic kidney disease. (Doc. 188-8, p. 3). Mr. Blackburn contends that his use of LIALDA caused these conditions.

Shire has always warned that use of LIALDA could lead to kidney damage. In January of 2007, when the FDA initially approved LIALDA, the drug's label included the following information:

> **Renal:** Reports of renal impairment, including minimal change nephropathy, and acute or chronic interstitial nephritis have been associated with mesalamine medications and prodrugs of mesalamine. For any patient with known renal dysfunction, caution should be exercised and LIALDA should be used only if the benefits outweigh the risks. It is recommended that all patients have an evaluation of renal function prior to initiation of therapy and periodically while on treatment.

(Doc. 41-1, p. 5). In November of 2013, when Mr. Blackburn began taking LIALDA, the label stated:

> **5.1 Renal Impairment**
>
> Renal impairment, including minimal change nephropathy, acute and chronic interstitial nephritis, and, rarely, renal failure, has been reported in patients given products such as LlALDA that contain mesalamine or are converted to mesalamine.
>
> It is recommended that patients have an evaluation of renal function prior to initiation of LIALDA therapy and periodically while on therapy. Exercise caution when using LIALDA in patients with known renal dysfunction or a history of renal disease.

(Doc. 41-2, p. 3).

Mr. Blackburn does not contend that Shire failed to warn of possible kidney injury when using LIALDA. Instead, Mr. Blackburn alleges that the recommended "periodic" evaluation "constitutes a defective and unsafe instruction for safe use of LIALDA." (Doc. 41, p. 4, ¶ 22). He contends that the term "periodic" as generally used in drug labels refers to either semi-annual or annual testing and that Shire's warning should have "provide[d] for blood testing of renal function at intervals necessary to reasonably protect patients from LIALDA's potential renal toxicity." (Doc. 41, p. 5, ¶¶ 22, 23, 25).

Mr. Blackburn contends that the language regarding testing for renal function in Shire's warning should resemble language used by other manufacturers of mesalamine-based drugs. PENTASA, like LIALDA, is a 5-aminosalicylic acid ("5-ASA") or mesalamine-based drug. In the United Kingdom, PENTASA is marketed with the warning that patients "should have renal function monitored, with serum creatinine levels measured prior to treatment start, every 3 months for the first year, then [every 6 months] for the next 4 years and annually thereafter." (Doc. 175-8, p. 2). Similarly, OCTASA, another 5-ASA drug, is marketed in the United Kingdom with the following instruction:

> It is recommended that all patients have an evaluation of their renal function prior to initiation of Octasa therapy and repeatedly whilst on therapy. As a guideline, follow-up tests are recommended 14 days after

> commencement of treatment and then every 4 weeks for the following 12 weeks. Short monitoring intervals early after the start of Octasa therapy will discover rare acute renal reactions. In the absence of an acute renal reaction monitoring intervals can be extended to every 3 months and then annually after 5 years.

(Doc. 175-6, p. 2).

Mr. Blackburn asserts that an appropriate label for LIALDA, a mesalamine-based drug, should include instructions recommending "evaluation of 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." (Doc. 41, p. 5, ¶¶ 23, 25). Mr. Blackburn contends that Shire's failure to include this testing regimen in the LIALDA package warning in the fall of 2013 proximately caused his kidney injury. (Doc. 41, p. 5, ¶ 26). Embedded within this causation contention are the suppositions that the physician who prescribed LIALDA for Mr. Blackburn, Dr. Dino Ferrante, would have ordered specific interval testing per the instructions that Mr. Blackburn proposes and that Mr. Blackburn would have complied with those orders. Mr. Blackburn's medical history undermines those suppositions.

Mr. Blackburn first saw Dr. Ferrante at the Center for Colon & Digestive Disease on September 6, 2013 based on a referral from Dr. Craig Young. (Doc. 162-1, p. 5, tr. 17; Doc. 188-6, pp. 12–13). In his deposition, Dr. Ferrante testified:

> [Dr. Young] called me personally first before I saw [Mr. Blackburn], said I'm sending you this guy, Mark Blackburn. He's having some

> loose bowels, diarrhea. We talked about him a little bit. [Dr. Young] said he had done some basic workup . . . , some blood work, I think some stool tests, possibly, and everything checked out okay and he wanted me to do some further gastrointestinal evaluation in regards to his symptoms, which the main one being he was having, basically, diarrhea or loose bowel movements.

(Doc. 162-1, p. 5, tr. 18).

At his initial visit with Dr. Ferrante, Mr. Blackburn complained of "diarrhea or alteration of his stools" and "urgency," without abdominal pain, bleeding, or fever. (Doc. 162-1, p. 5, tr. 20). Dr. Ferrante stated:

> So based on his symptoms, we decided to do what's called a C-reactive protein, which is an inflammatory marker, looking for -- we use it as a marker for inflammatory bowel disease. The tissue transglutaminase level is a marker of celiac disease. So, again, these are – we're checking for what causes loose bowels, and so these are two markers of things that are fairly common. And then, of course, we set him up for a colonoscopy to assess for his symptoms.

(Doc. 162-1, p. 6, tr. 22). Mr. Blackburn's lab work was normal. (Doc. 162-1, p. 7, tr. 26). The colonoscopy revealed "chronic colitis," otherwise known as "inflammation of the colon," and "non-caseating granulomas," which are "diagnostic for Crohn's disease." (Doc. 162-1, p. 9, tr. 34). Dr. Ferrante was not sure whether Mr. Blackburn had Crohn's disease or ulcerative colitis, so he scheduled Mr. Blackburn for a sigmoidoscopy. (Doc. 162-1, p. 9, tr. 36). That procedure revealed "caseating granulomas." (Doc. 162-1, p. 11, tr. 41-42). Dr. Ferrante also ordered blood tests to rule out ulcerative colitis. (Doc. 162-1, p. 10, tr.

37). Based on the results of these tests, Dr. Ferrante diagnosed Mr. Blackburn with Crohn's disease. (Doc. 162-1, pp. 11, 14, tr. 42, 55).

On November 5, 2013, Dr. Ferrante prescribed LIALDA and gave Mr. Blackburn an initial prescription for a six-month course of treatment. (Doc. 162-1, pp. 14, 30, tr. 55, 117; Doc. 188-6, p. 18). Dr. Ferrante acknowledged that prescribing LIALDA for Crohn's disease was an off-label use of the product. (Doc. 162-1, p. 27, tr. 108). Dr. Ferrante stated, "you want to tailor your therapy based on the individual." (Doc. 162-1, p. 19, tr. 73). In Dr. Ferrante's opinion, "a mesalamine product" such as LIALDA was the "drug of choice" for Mr. Blackburn "because it's the least invasive . . . and probably easiest to administer in someone who would be traveling," like Mr. Blackburn. (Doc. 162-1, p. 19, tr. 73). The alternative would have been "either oral medications that do require some monitoring or IV infusion therapies which require even more intensive type monitoring." (Doc. 162-1, p. 19, tr. 73; *see also* Doc. 162-1, p. 19, tr. 74).

Dr. Ferrante was aware when he prescribed LIALDA to Mr. Blackburn that mesalamine products contain warnings that "renal impairment may occur" and directions to "assess renal function at the beginning of treatment and periodically during treatment." (Doc. 162-1, pp. 15–16, tr. 60–61).[2] But Dr. Ferrante did not

[2] Quoting the exact language from the LIALDA warning, counsel asked Dr. Ferrante if he knew that:

look at the LIALDA label before he prescribed the drug to Mr. Blackburn. (Doc. 162-1, p. 24, tr. 93).

Dr. Ferrante testified that before prescribing any medication "if there's anything that needs to be checked prior, we will typically do that." (Doc. 162-1, p. 15, tr. 59). Then, "during the follow-up process, I will ask [patients], you know, how they're doing on the medication." (Doc. 162-1, p. 15, tr. 59). Dr. Ferrante testified that he would have relied on discussions with Mr. Blackburn. (Doc. 162-1, p. 17, tr. 67). Dr. Ferrante stated: "I usually ask have you had blood work done by your primary care doctor before you came here or any other doctor, and if the answer is no, then I'll take it upon myself to go ahead and check that." (Doc. 162-1, p. 17, tr. 67). But Dr. Ferrante did not evaluate Mr. Blackburn's renal function before he prescribed LIALDA for him, and when he selected LIALDA for Mr. Blackburn, Dr. Ferrante did not know whether Dr. Young had performed renal testing on Mr. Blackburn. (Doc. 162-1, p. 23, tr. 91).

> renal impairment, including minimal change nephropathy, acute and chronic interstitial nephritis, and rarely, renal failure, has been reported in patients given products such as LlALDA that contain mesalamine or are converted to mesalamine.

(Doc. 162-1, p. 23, tr. 92). Dr. Ferrante stated that he was aware of these problems and stated that he had been aware "for some time prior to prescribing LIALDA for Mr. Blackburn" because "that language had been in labeling for mesalamine products in the United States for a long period of time." (Doc. 162-1, pp. 23–24, tr. 92–93).

Dr. Ferrante testified that he ordinarily checked renal function "at least once a year" when prescribing LIALDA. (Doc. 162-1, pp. 15-16, tr. 60-61). When asked in his deposition what "periodically" means to him, to Dr. Ferrante responded:

> Currently, I'm doing one year. This condition, like Crohn's disease, ulcerative colitis, is typically a condition in younger patients, so most of the time, they don't have a lot of other medical conditions. So I think once a year is probably adequate in those patients. If it's a patient who has other medical conditions, I might be more aggressive with that. Most of the time, these patients also come from their primary care doctor or some other doctor being referred, and they may have already had or are getting yearly testing or biyearly testing for other reasons.

(Doc. 162-1, p. 16, tr. 61-62). Later in his deposition Dr. Ferrante acknowledged that "periodically" can mean other time periods as well and that there is no specific definition of "periodically" in the medical profession. (Doc. 162-1, p. 23, tr. 90). Dr. Ferrante explained that in his 17 years of practice he had "never seen kidney problems from these [mesalamine] medications." (Doc. 162-1, p. 28, tr. 109–110).

To understand a medication's side effects, Dr. Ferrante relies on mailers from drug companies, conferences, and drug company representatives. (Doc. 162-1, p. 16, tr. 62–63). When asked in his deposition what he relied on "for information, data, and guidance on instructions for safe use of medications such as Lialda," Dr. Ferrante responded:

> typically, like the package insert, if you will, of the medicines. I mean, we're pretty well trained on what's the most common side effects, adverse reactions. If anything new comes out, many times, again, that comes out as a mailer, actually. We have seen that in other medications before.

(Doc. 162-1 pp. 16-17, tr. 64–65). In his deposition, Dr. Ferrante reviewed the LIALDA warning in place when he prescribed the medication to Mr. Blackburn. (Doc. 162-1, p. 17, tr. 65). The following exchange then took place:

> Q. . . . [I]s this information the type of information you rely on in determining whether a medication is appropriate for your patient?
>
> * * *
>
> A. Yes. We would look at -- before we start a medicine, we'd want to make sure that they would be a good candidate for that medication, sure.
>
> Q. Is this information also the type of data you rely on in determining what safe use protocol or testing recommendations you give your patients?
>
> * * *
>
> A. Correct.
>
> Q. And did you rely on this information when determining [if] you want[ed] to prescribe Lialda for Mark Blackburn?
>
> * * *
>
> A. Yes.

(Doc. 162-1, p. 17, tr. 65–66). During his deposition, Dr. Ferrante also reviewed the PENTASA and OCTASA monitoring language set out above. (Doc. 162-1, p. 18, tr. 69–72). Dr. Ferrante averred that if the LIALDA label had had similar language, and he had known about it, he "would have followed those protocols." (Doc. 162-1, p. 18, tr. 71-72; *see also* Doc. 162-1, p. 20, tr. 77 ("Again, if I would have known

about that, I would have followed those protocols."); Doc. 162-1, p. 24, tr. 95 ("If I would have known about that protocol, then yes.")).

After prescribing LIALDA, Dr. Ferrante did not tell Mr. Blackburn to come back for renal testing. (Doc. 162-1, pp. 17–18, tr. 68–69). Dr. Ferrante believes that his office scheduled Mr. Blackburn to return on January 14, 2014. (Doc. 162-1, pp. 12, 14, 29, tr. 45, 47, 53, 113). That visit would have been a follow-up to gauge the effectiveness of the LIALDA therapy and the side effects of the medication. (Doc. 162-1, p. 12, tr. 47–48). Mr. Blackburn did not keep that appointment, and Dr. Ferrante never saw Mr. Blackburn again. (Doc. 162-1, p. 29, 114).

Despite Mr. Blackburn having missed his only follow-up appointment and despite having not seen Mr. Blackburn for almost 18 months, on March 6, 2015, Dr. Ferrante's office approved a new four-month prescription of LIALDA for Mr. Blackburn. (Doc. 188-6, p. 19). Dr. Ferrante did not know that his office had given Mr. Blackburn this new prescription. (Doc. 162-1, p. 30, tr. 117) ("I'm not aware of that. I don't know if he got that through our office. Maybe he called or -- you know, I'm not aware of that. I don't remember seeing anything about that.").

ANALYSIS

Mr. Blackburn's remaining claim against Shire is for "strict liability for failure to warn" under the Alabama Extended Manufacturer's Liability Doctrine – the AEMLD. (Doc. 41, pp. 25–28). Under the AEMLD, "'a manufacturer, or supplier,

or seller, who markets a product not reasonably safe when applied to its intended use in the usual and customary manner, [is] negligen[t] as a matter of law.'" *DISA Indus., Inc. v. Bell*, 272 So. 3d 142, 149 (Ala. 2018), *reh'g denied* (Sept. 14, 2018) (quoting *Casrell v. Altec Indus., Inc.*, 335 So. 2d 128, 132 (Ala. 1976)) (emphasis in *DISA*). Alabama law deems prescription drugs "unavoidably unsafe." *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1304 (Ala. 1984). Accordingly, "'the adequacy of the accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous.'" *Bodie v. Purdue Pharma Co.*, 236 Fed. Appx. 511, 518 (11th Cir. 2007) (quoting *Stone*, 447 So. 2d at 1304).

In Alabama, "[a] prescription-drug manufacturer fulfills its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the learned intermediaries who prescribe the drug." *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 673 (Ala. 2014). The Alabama Supreme Court has explained:

> The principle behind the learned-intermediary doctrine is that prescribing physicians act as learned intermediaries between a manufacturer of a drug and the consumer/patient and that, therefore, the physician stands in the best position to evaluate a patient's needs and to assess the risks and benefits of a particular course of treatment for the patient. A consumer can obtain a prescription drug only through a physician or other qualified health-care provider. Physicians are trained to understand the highly technical warnings required by the FDA in drug labeling.

Weeks, 159 So. 3d at 672–73 (citations omitted). The doctrine "recognizes the role of the physician as a learned intermediary between a drug manufacturer and a patient." *Weeks*, 159 So. 3d at 673.

"'[T]he adequacy of [a drug manufacturer's] warning is measured by its effect on the physician, to whom it owe[s] a duty to warn, and not by its effect on the consumer." *Weeks*, 159 So. 3d at 673 (quoting *Toole v. Baxter Healthcare Corp*., 235 F.3d 1307, 1313-14 (11th Cir. 2000)) (citations, quotations and changes omitted).

> Once the manufacturer has met its duty to warn, the manufacturer holds no further duty to warn the patient directly. *See Weeks*, 159 So. 3d at 673. If, however, the warning to the learned intermediary is insufficient or is a misrepresentation of risks, "the manufacturer remains liable for the injuries sustained by the patient." *Id*. In such a situation, the patient must show that:
>
> > the manufacturer failed to warn the physician of a risk not otherwise known to the physician and that the failure to warn was the actual and proximate cause of the patient's injury. In short, the patient must show that, but for the false representation made [or the insufficient information provided] in the warning, the prescribing physician would not have prescribed the medication to his patient.
>
> *Id.* at 673–74.

Tutwiler v. Sandoz, Inc., 726 Fed. Appx. 753, 756 (11th Cir. 2018). "[P]roof 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." *Blackburn v. Shire U.S., Inc.*, No. 2:16-CV-963-RDP, 2017 WL 1833524 at *8 (May 8, 2017) (citing *Barnhill v. Teva Pharm, USA, Inc.*, 819 F. Supp. 2d 1254, 1261 (S.D. Ala. 2011); and *Fields v. Eli Lilly & Co.*, 116 F. Supp. 3d 1295, 1307 (M.D. Ala. 2015)).

If an alternative warning would not have impacted a prescribing physician's conduct in the use and monitoring of a drug, then a plaintiff cannot establish the causation element for a products liability claim against the drug's manufacturer. Under Alabama law, in warnings cases concerning a prescription drug, plaintiffs:

> must demonstrate a causal link between the allegedly inadequate warning and the injury. In cases such as these, that means that the plaintiffs must demonstrate that, had the [drug manufacturer] given an adequate warning, it would have been read and heeded by the prescribing physicians.

Brasher v. Sandoz Pharm. Corp., No. CV 98-TMP-2648-S, 2001 WL 36403362, at *13 (N.D. Ala. Sept. 21, 2001) (citing *Gurley v. American Honda Mtr. Co.*, 505 So. 2d 358, 361 (Ala. 1987)); *see also, Wyeth*, 159 So. 3d at 677 n.11 ("[W]e are not deciding the merits of the underlying case. It may be that a jury finds that . . . [the] physician did not rely on the warnings on the label[.]"); *see also Wyeth*, 159 So. 3d at 681 (Moore, dissenting) ("For example, if [the] prescribing physician did not rely on the . . . labeling when prescribing the drug, then the [plaintiffs] will have failed to prove causation and their claims will fail.").

A drug manufacturer is entitled to judgment as a matter of law on a warnings claim when the record demonstrates that the prescribing physician would not have read or followed an alternative warning. *Bodie v. Purdue Pharma Co.*, 236 Fed. Appx. 511, 521 (11th Cir. 2007) ("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."); *Emody v. Medtronic, Inc*., 238 F. Supp. 2d 1291, 1296 (N.D. Ala. 2003) (failure to warn claim failed in light of doctor's testimony that he did not rely on warnings); *In re Wright Med. Tech. Inc., Conserve Hip Implant Prod. Liab. Litig.*, 127 F. Supp. 3d 1306, 1359 (N.D. Ga. 2015) ("[W]here a warning is provided, but a physician does not read it or rely on it, a person cannot assert a failure to warn claim, even if the warning is defective."); *Salyards ex rel. Salyards v. Metso Minerals Tamper OY*, No. 1:04 CV 05798 OWW LJ, 2005 WL 3021959, at *9 (E.D. Cal. Nov. 10, 2005) ("If the doctor fails to read or heed the warning, the manufacturer is absolved of liability."). There is no presumption in Alabama that an adequate warning would have been read and heeded by the prescribing physician. *Barnhill* 819 F. Supp. 2d at 1262. "[A]s concerns proximate cause, a negligent-failure-to-warn-adequately case should not be submitted to the jury unless there is substantial evidence that an adequate warning would have been read and

heeded and would have prevented the [injury]." *Deere & Co. v. Grose*, 586 So. 2d 196, 198 (Ala. 1991) (citing *Gurley*, 505 So. 2d at 361).

Here, the evidence demonstrates that Dr. Ferrante did not follow the instructions that Shire provided in November 2013 for renal evaluation when prescribing LIALDA, so Mr. Blackburn cannot prove that Dr. Ferrante would have read and heeded an alternative instruction. It is undisputed that Shire warned that LIALDA could cause interstitial nephritis and kidney disease, the conditions Mr. Blackburn claims he developed after taking the drug. Dr. Ferrante testified that he had been aware for some time that 5-ASA drugs such as LIALDA could cause these conditions. He prescribed the drug to Mr. Blackburn anyway because LIALDA was the "drug of choice . . . because it's the least invasive . . . and probably easiest to administer in someone [like Mr. Blackburn] who would be traveling." (Doc. 162-1, p. 19, tr. 73). Dr. Ferrante prescribed LIALDA for Mr. Blackburn because the drug required less monitoring and had fewer serious side effects than alternative treatments for Crohn's disease. (Doc. 162-1, p. 19, tr. 73–74).

In November 2013, Shire "recommended" to prescribing physicians "that patients have an evaluation of renal function prior to initiation of LIALDA therapy and periodically while on therapy." (Doc. 41-2, p. 3). But Dr. Ferrante did not read this information before he prescribed LIALDA to treat Mr. Blackburn's Crohn's disease, an off-label use of the drug. And Dr. Ferrante neither ordered tests to

evaluate Mr. Blackburn's renal function before he prescribed LIALDA nor checked with Mr. Blackburn's referring physician, Dr. Young, to determine whether Dr. Young had evaluated Mr. Blackburn's renal function. (Doc. 162-1, p. 23, tr. 91). And though Dr. Ferrante testified that it was his practice to test renal function annually when prescribing LIALDA (Doc. 162-1, p. 16, tr. 61–62), his office authorized CVS to refill Mr. Blackburn's November 2013 prescription in March 2015 without conducting a renal evaluation of Mr. Blackburn. (Doc. 188-6, p. 19). Dr. Ferrante's inattention to Shire's November 2013 renal evaluation protocol may stem from the fact that in 17 years of practice as a gastroenterologist, Dr. Ferrante had "never seen kidney problems" from mesalamine products. (Doc. 162-1, p. 28, tr. 109–110).

Even if Dr. Ferrante had ordered a renal evaluation of Mr. Blackburn after prescribing LIALDA, there is no evidence that Mr. Blackburn would have complied with the instruction. Dr. Ferrante scheduled an appointment with Mr. Blackburn in January 2014 to monitor Mr. Blackburn's treatment, but Mr. Blackburn did not keep the appointment. After Dr. Ferrante prescribed LIALDA for Mr. Blackburn in November 2013, Mr. Blackburn did not return to Dr. Ferrante.

Mr. Blackburn correctly points out that Dr. Ferrante testified that he would have followed an alternative recommended testing schedule if he "had known about it." (Doc. 162-1, p. 18, tr. 71–72; see also Doc. 162-1, p. 20, tr. 77; Doc. 162-1, p.

24, tr. 95). But that testimony amounts to unsubstantiated speculation, given Dr. Ferrante's conduct, and a jury verdict may not rest on speculation. *See Pennsylvania R. Co. v. Chamberlin*, 288 U.S. 333, 340–44 (1933) ("And the desired inference is precluded for the further reason that respondent's right of recovery depends upon the existence of a particular fact which must be inferred from proven facts, and this is not permissible in the face of the positive and otherwise uncontradicted testimony of unimpeached witnesses consistent with the facts actually proved, from which testimony it affirmatively appears that the fact sought to be inferred did not exist . . . Leaving out of consideration, then, the inference relied upon, the case for respondent is left without any substantial support in the evidence, and a verdict in her favor would have rested upon mere speculation and conjecture. This, of course, is inadmissible.") (internal marks and citations omitted).

Because Dr. Ferrante did not consult Shire's November 2013 warning before prescribing the drug, the Court does not have to accept his self-interested statement that he would read an alternative warning or that a different warning would have altered his decision to prescribe LIALDA without evaluating Mr. Blackburn's renal function. In a decision that is binding precedent in the Eleventh Circuit Court of Appeals, the Fifth Circuit Court of Appeals explained:

[S]elf-serving statements alone do not create a jury question:

> In our opinion, the isolated self-serving statements of the Cal-Florida officers were not enough to constitute substantial evidence for the jury on the causation issue under Boeing Co. v. Shipman.
>
> *Yoder Bros., Inc. v. California-Florida Plant Corp.*, 537 F.2d 1347, 1371 (5th Cir. 1976). A trier of facts need not ignore powerful self-interest, and where there is no relevant support for self-interested testimony a jury must not be allowed to speculate as to causation. A directed verdict, or judgment notwithstanding the verdict, is the proper safeguard against such speculation by the jury . . .

Ralston Purina Co. v. Hobson, 554 F.2d 225, 729 (5th Cir. 1977) (footnotes omitted).[3] A summary judgment likewise safeguards against a jury verdict based on a non-party witness's self-interested, speculative testimony regarding causation that is wholly contradicted by historical fact. This is not the type of evidence that creates a question of disputed fact for a jury to resolve.[4]

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[3] *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (adopting as binding precedent in the Eleventh Circuit Court of Appeals decisions that the Fifth Circuit Court of Appeals rendered before October 1, 1981).

[4] When considering a summary judgment motion, a district court must view the evidence in the record and draw reasonable inferences from the evidence in the light most favorable to the non-moving party. *Asalde v. First Class Parking Sys. LLC*, 898 F.3d 1136, 1138 (11th Cir. 2018). "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 Feliciano v. City of Miami Beach*, 707 F.3d 1244, 1253 (11th Cir. 2013) ("To be sure, Feliciano's sworn statements are self-serving, but that alone does not permit us to disregard them at the summary judgment stage."). The self-serving statements of a non-party witness do not have the same power when that witness's conduct directly contradicts his self-interested projections of future conduct, rendering those projections unsubstantiated speculation. A district court does not have to draw favorable inferences from speculation. *Daniels v. Twin Oaks Nursing Home*, 692 F.2d 1321, 1324 (11th Cir. 1982) ("[A]n inference is not reasonable if it is 'only a guess or a possibility,' for such an inference is not based on the evidence but is pure conjecture and speculation.") (internal citation omitted).

And even if a jury could consider Dr. Ferrante's testimony, Mr. Blackburn's failure to keep his January 2014 appointment and follow up with Dr. Ferrante severs the causal chain. In the absence of admissible evidence of a causal link between Shire's instructions for renal evaluations when prescribing LIALDA and Mr. Blackburn's injury, Mr. Blackburn's AEMLD warnings claim against Shire must fail.

CONCLUSION

By separate order, for the reasons discussed above, the Court will enter judgment for the Shire defendants on Mr. Blackburn's AEMLD failure to warn claim as a matter of law. Because that is the only remaining claim in this case, the Court will dismiss this case with prejudice. The Court thanks the parties for their excellent briefs and oral argument. The issues in this case were fully explored and presented carefully for consideration. This decision renders moot the pending motions *in limine*.

In light of the public health emergency caused by the COVID-19 virus, the parties are reminded that under Rule 4(a)(5) of the Federal Rules of Appellate Procedure, a party may request an extension of time for a notice of appeal. In addition, pursuant to Rule 4(a)(6), a party may ask a district court to reopen the time to file a notice of appeal for 14 days. Parties are advised to study these rules carefully

if exigent circumstances created by the COVID-19 public health emergency require motions under FRAP 4(a)(5) or 4(a)(6).

DONE and **ORDERED** this June 01, 2020.

MADELINE HUGHES HAIKALA
UNITED STATES DISTRICT JUDGE