Case No. 20-12258-F
IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

MARK BLACKBURN, et al.,

Plaintiff-Appellant

v.

SHIRE U.S., INC.; SHIRE, LLC,

Defendants-Appellees

On Appeal from the United States District Court for the Northern District of Alabama, Southern Division,

No. 2:16-CV-00936-RDP

INITIAL BRIEF OF PLAINTIFF/APPELLANT MARK BLACKBURN

Keith Jackson
RILEY & JACKSON, P.C.
3530 Independence Drive
Birmingham, AL 35209
Telephone: (205) 879-5000
kj@rileyjacksonlaw.com

Jonathan H. Waller
Waller Law Office, PC
2001 Park Place, Suite 900
Birmingham, AL 35203
Telephone: (205) 313-
jwaller@waller-law.com

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to F.R.A.P. 26.1 and 11th Circ.R. 26-1(3), the following is a complete list of all persons, firms, partnerships, corporations or entities that have an interest in the outcome of this appeal:

Mark Blackburn: Plaintiff/Appellant.

Melissa Blackburn: Plaintiff/Appellant.

John R. Ipsaro: Counsel for Defendants/Appellees.

Keith Jackson: Counsel for Plaintiffs/Appellants.

Jeffrey F. Peck: Counsel for Defendants/Appellees.

Robert R. Riley, Jr.: Counsel for Plaintiffs/Appellants.

Riley & Jackson, P.C.: Law firm representing Plaintiffs/Appellants.

Shire, LLC (SHPG): Defendant/Appellee.

Shire U.S., Inc. (SHPG): Defendant/Appellee.

Ulmer & Berne LLP: Law firm representing Defendants/Appellees.

Jonathan H., Waller: Counsel for Plaintiffs/Appellants.

Waller Law Office, P.C.: Law firm representing Plaintiffs/Appellants.

Thomas E. Walker: Counsel for Defendants/Appellees.

White Arnold & Dowd P.C.: Law firm representing Defendants/Appellees.

Because Appellant is an individual, there are no subsidiaries, conglomerates, affiliates, parent corporations or any publicly held corporation that owns 10% or more of the stock issued by Appellant, nor any other identifiable legal entities related to Parties.

/s/Jonathan H. Waller
OF COUNSEL

STATEMENT REGARDING ORAL ARGUMENT

Appellant Blackburn respectfully requests oral argument. Oral argument is warranted because this appeal raises important issues regarding the proper application of the Learned Intermediary Doctrine under Alabama law to strict liability claims against drug makers for failure to provide instructions for safe use of a prescription drug at the summary judgment stage of litigation.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

TABLE OF RECORD REFERENCES

JURISDICTIONAL STATEMENT

Jurisdiction is proper in this case under 28 U.S.C. § 1332(a), as this appeal arises from a final judgment dismissing a civil action in the United States District Court for the Northern District of Alabama, Southern Division. The amount in controversy exceeds $75,000.00, exclusive of interest and costs, and is between citizens of different States. The District Court entered a Memorandum Opinion [R. 244] and a Final Judgment [R. 245] granting Appellees' Motion for Summary Judgment on June 1, 2020, and dismissing this action with prejudice. [R. 244].

On June 18, 2020, Appellant timely filed this Notice of Appeal. [R. 246].

On July 13, 2020, this Court directed the parties to respond to a jurisdictional question relating to the citizenship of the Shire Defendants. On July 23, 2020, the parties to this Appeal filed their joint response to the jurisdictional question of this Court. On August 26, 2020, this Court advised that it appeared that this Court has jurisdiction to consider this Appeal.

STATEMENT OF THE ISSUES

1. Whether the District Court erred in holding that there were no material issues of fact as to Appellant's strict liability claim based on the Shire Defendants' failure to provide proper instructions for the safe use of the drug known as LIALDA, based on the Learned Intermediary Doctrine.

2. Whether the District Court erred in holding that there were no material issues of fact as to whether the Shire Defendants' failure to provide proper instructions for the safe use of LIALDA proximately caused Appellant's interstitial nephritis.

3. Whether the District Court erred in entering a prior interlocutory order dismissing Appellant's claims for fraud, suppression and breach of warranty with prejudice and without leave to amend.

4. Whether the District Court erred in entering a subsequent interlocutory order denying Appellant's Motion to Alter or Amend the Order dismissing such claims to provide that the dismissal was without prejudice and allowing Appellant his "one chance" to amend.

5. Whether the District Court erred in entering a third interlocutory order denying Appellant's Motion to Reconsider the District Court's refusal to allow Appellant such "one chance" to amend his fraud-based and breach of warranty claims.

STATEMENT OF THE CASE

I. COURSE OF PROCEEDINGS AND DISPOSITION BELOW

On June 10, 2016, Appellant Mark Blackburn ("Appellant" or "Blackburn") filed his Complaint against Shire Development, LLC, Shire, LLC, Shire Pharmaceutical Development, Inc., Shire Pharmaceuticals, LLC and Shire US, Inc. (the "Shire Defendants"). [R. 1].

The Shire Defendants filed answers on July 29, 2016. [R. 11, 12, 13, 14 and 15].

On October 5, 2016, Shire filed a Motion for Judgment on the Pleadings (the "Motion for Judgment"). [R. 26]. Appellant responded in opposition to that Motion on October 24, 2016. [R. 35]. Shire filed its reply on October 31, 2016. [R. 39].

While the Motion for Judgment was pending but not yet decided, Appellant filed a Motion to Amend the Complaint and supporting Memorandum of Law on October 24, 2016. [R. 36].

On November 11, 2016, without ruling on the merits on the Motion for Judgment, the District Court granted Appellant's Motion to Amend the Complaint. [R. 40]. On November 2, 2016, Appellant filed his First Amended Complaint ("FAC"). [R. 41].

On November 16, 2016, Shire filed a Rule 12(b)(6) Motion to Dismiss the FAC and supporting Memorandum. [R. 44, 45].

Appellant filed his opposition to the Motion to Dismiss the FAC on December 8, 2016. [R. 51].

On May 8, 2017, the District Court entered its Memorandum Opinion [R. 53] and Order [R. 54] granting Shire's Motion to Dismiss Appellant's FAC with respect to Count II (Fraud), Count III (Suppression and Concealment) and Count IV (Breach of Express Warranty) and dismissed these three counts with prejudice and without leave to amend. The District Court denied Shire's Motion to Dismiss Count I (failure to warn under the AEMLD). [R. 53, 54].

On May 12, 2017, the District Court granted the unopposed Shire Motion to Dismiss the FAC for lack of personal jurisdiction as to Defendants Shire Development, LLC, Shire Pharmaceutical Development, Inc., and Shire Pharmaceuticals, LLC, without prejudice. [Doc 56]. That Order is not at issue in this Appeal. As a result of that Order, the two remaining Defendants were Shire U.S., Inc. and Shire, LLC (collectively, "Shire").

On June 29, 2017, Appellant filed his Motion to Alter or Amend the District Court's May 8, 2017 Order [R. 64] (the "Motion to Alter") to modify the Order dismissing his fraud-based and breach of warranty claims to be without prejudice and to allow Appellant his "one chance" to address the deficiencies determined by the District Court for the first time in its May 8, 2017 Memorandum Opinion. [R.

53]. The Motion to Alter was filed fifty-two (52) days after the District Court's Order on May 8, 2017.

The proposed Second Amended Complaint (the "SAC") was Exhibit A to the Motion to Alter.

On November 2, 2017, the District Court entered its Memorandum Opinion and Order [R. 85, 86] denying Appellant's Motion to Alter (principally on the basis that Appellant had "delayed too long" in filing the Motion to Alter).

On November 15, 2017, Appellant filed his Motion for Reconsideration [R. 91] on the basis that the District Court had erroneously calculated Appellant's "delay" by commencing the "delay" from the date of filing of Appellant's original Complaint [R. 1] on June 16, 2016 and the FAC [R. 41] on November 2, 2016, even though the District Court had not ruled on the merits of either the original Complaint or the FAC prior to its May 8, 2017 Opinion. [R. 53, 54].

On May 10, 2018, the District Court entered a Memorandum Opinion and Order [R. 123, 124] denying Appellant's Motion for Reconsideration.

On October 18, 2018, the Honorable R. David Proctor recused and the case was reassigned to the Honorable Madeline Hughes Haikala for all further proceedings. [R. 144].

On May 6, 2019, Shire filed its Motion for Summary Judgment. [R. 194]. The parties also filed competing *Daubert* Motions. [R. 192, 195].

On June 7 and 8, 2019, Appellant filed extensive evidentiary materials in opposition to Shire's Motion for Summary Judgment. [R. 207, 208, 209, 210, 211, 212, 213, 214, and 215].

On June 10, 2019, Appellant filed his Response in Opposition to Shire's Motion for Summary Judgment. [R. 218].

On June 1, 2020, the District Court entered its Memorandum Opinion [R. 244] and Final Order [R. 245] granting Shire's Motion for Summary Judgment and dismissing this action with prejudice. The Memorandum Opinion did not consider the parties' *Daubert* Motions or Shire's pre-emption defense. Thus, these matters are not at issue in this appeal.

II. STATEMENT OF FACTS

Appellant Mark Blackburn ("Appellant" or "Blackburn") is a top-level golf instructor who provides coaching to PGA golf professionals and also speaks at conferences for Titleist. To perform these duties, Blackburn travels extensively both nationally and internationally. [R. 244, pp. 2-3]. Blackburn was recently recognized as the National PGA Teacher and Coach of the Year. [www.pga.org/2020-pga-of-america-awards-recipients].

Dr. Dino Ferrante, a Huntsville gastroenterologist, first saw Appellant on September 6, 2013 based upon a referral from Appellant's primary care physician, Dr. Craig Young. [R. 244, p. 5]. On November 5, 2013, Dr. Ferrante prescribed

LIALDA for Appellant and gave him an initial prescription for a six-month course of treatment. [R. 244, p. 7]. LIALDA is a 5-aminosalicylic acid ("5-ASA") or mesalamine-based drug. Blackburn began taking LIALDA to treat Crohn's disease at that time. [R. 188-6, p.18].

Blackburn voluntarily stopped taking LIALDA in February 2015. [R. 160-1, p. 22, tp. 84:13-18; p. 27, tp. 104:25-105:8]. He did so because he wasn't having a dramatic improvement in his symptoms. [R. 160-1, p. 30, tp. 114:16-115:7].

On May 14, 2015, at age 39, Blackburn's physician diagnosed Blackburn with chronic interstitial nephritis and stage IV kidney disease. [R. 244, pp. 2-3].

Both Appellant's treating nephrologist, Dr. Przekwas, and his expert nephrologist, Dr. Jonathan Winston, have determined that Appellant's disease was caused by LIALDA. [R. 163, pp. 74:1-75:14; R. 210, ¶¶ 6-21]. Appellant is currently a well-qualified candidate for a kidney transplant on the UAB transplant waiting list. [R. 163, pp. 76:16-77:6].

When 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 LIALDA 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.

[R. 41-2, p.3; R. 244, p.3]. The same "periodic" recommendation was included in the original LIALDA label in 2007. [R. 41-2, p.3; R. 244, p.3].

Blackburn does not contend that Shire failed to warn of possible kidney injury when using LIALDA. Instead, Blackburn alleges that the recommended "periodic" evaluation "constitutes a defective and unsafe instruction for safe use of LIALDA." [R. 41, p. 4, ¶22]. He contends that the term "periodic" as generally used in drug labels refers to 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." [R. 41, p. 5, ¶¶ 22, 23, 25; R. 244, pp 4-5].

Specifically, Blackburn asserts that the LIALDA label should have provided an instruction for safe use providing for "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." [R. 244, p. 5; R. 41, p. 5, ¶¶ 23, 25] (hereafter referred to as "Specific Interval Testing".)

Blackburn further contends that the language regarding testing for renal function of Shire's warning should resemble language used by other manufacturers

of mesalamine-based drugs. The European labels[1] for mesalamine drugs, including a 5-ASA product marketed by Shire in the United Kingdom, include recommendation for testing kidney function at specific intervals.

The Shire Defendants market a mesalamine product manufactured by Ferring Pharmaceuticals under the trade name Pentasa in the United States. That U.S. label contains no recommendation for baseline renal function evaluation whatsoever, stating only that "Caution should be exercised if PENTASA is administered to patients with impaired renal function[.]" [R. 175-7, p.3].

In stark contrast, the Warning for Pentasa in the UK states: "Patients on any formulation of Mezalazine [mesalamine]. should have renal function monitored, with serum creatinine measured prior to treatment start, every 3 months for the first year, then 6 months for the next 4 years, and annually thereafter. Treatment with mesalazine should be discontinued if renal function deteriorates." (emphasis added) [R. 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

[1] The European labels were filed as Exhibit I (Octasa), Exhibit J (Pentasa – US), Exhibit K (Pentasa – United Kingdom), and Exhibit L (Mezavant) to the proposed Second Amended Complaint. [R. 64-1] and Appellant's evidentiary submissions. [R. 175-5, 175-6, 175-7, 175-8]. *See also* Memorandum Opinion. [R. 144, pp. 4-5].

> 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.

[R. 175-6, p. 2].[2]

Shire also marketed Mezavant, a 5-ASA drug identical to LIALDA, in England. The Mezavant label recommended serum creatinine testing prior to initiation of the therapy and at least twice a year while on treatment. [R. 175-5, pp.1-2].

Mr. Blackburn contends that Shire's failure to include such a testing regimen in the LIALDA label in the fall of 2013 proximately caused his kidney injury. [R. 41, p. 5, ¶ 26; R. 244, p.5].

Unlike a condition such as bronchitis, acute kidney injury is typically asymptomatic. [R. 177-1[3], p. 27, tp. 103:7-104:15]. However, acute kidney injury is detectable by a routine serum creatinine blood test. Such blood tests are, according to Shires' own expert, Dr. Feigal, routinely administered millions of times each year by family physicians at annual physicals and do not have meaningful risk. [R. 177-1, p. 25, tp. 96:7-98:15]. Serum creatinine tests are accepted in the medical community as the standard test to detect kidney impairment. [R. 177-1, p. 25, tp. 96:7-98:15].

[2] The European labels for 5-ASA drugs are discussed in the Memorandum Opinion. [R. 244, pp. 4-5].

[3] Deposition of Shires' expert, Dr. David W. Feigal, Jr.

Cessation of a nephrotoxic drug such as LIALDA, which is causing kidney injury, is critical as soon as acute injury is detected. [R. 177-1, p. 47, tp. 182:1- 18; p. 61, tp. 240:15-241:2]. The obvious purpose of withdrawal of the drug is to avoid the progression in a patient such as Blackburn from acute injury to chronic and irreversible injury. [R. 178-1[4], p. 71, tp. 284:20-285:5]. Appellant's nephrology expert, Dr. Jonathan Winston, explains in detail why it is critical to cease 5-ASA therapy as soon as serum creatinine tests detect acute renal injury. [R. 210, ¶¶ 22, 30-31, 36, 47].

If Blackburn had lived in the United Kingdom when he was taking a 5-ASA drug, appropriate Specific Interval Testing of his serum creatinine would have detected Blackburn's acute kidney injury and would have prevented his chronic and irreversible interstitial nephritis. [R. 167-2, pp. 14-15; R. 210, ¶26].

Shires' conduct in the United States is particularly egregious because Shire prepared form or standard responses to physicians who inquired about LIALDA, including, specifically, about the "periodic" recommendation for monitoring renal function and off-label prescription of LIALDA for Crohn's disease. The responses were known as Standard Response Documents ("SRDs").

Specifically, Shires' Dory Solomon, M.D. testified regarding Shires' preparation of SRD's to provide to physicians who made inquiries regarding the

[4] Deposition of Shires' expert, Dr. Gaurav Jain.

LIALDA label. [R. 186-1, pp. 47-48, tp. 183:7-187:4; R. 186-4]. There is an SRD titled "Effects of Mesalamine on the Kidneys." [R. 186-4, p.27].

In that SRD, Shire discusses the relationship between 5-ASA and kidney injury. Most importantly, under the heading "Monitoring Recommendations for Renal Function," Shire discusses in detail the recommendations in the World and Corrigan articles for serum creatinine testing at specified intervals. [R. 175-1; R. 175-2].[5]

Thus, if Dr. Ferrante had sent an inquiry to Shire asking about the recommendation in the LIALDA label to monitor renal function "periodically," Dr. Ferrante would have received this SRD and it is probable that Blackburn would not have suffered his chronic, irreversible kidney injury.[6] [R. 210, ¶ 34].

Dr. Ferrante testified that Appellant's primary care physician, Dr. Craig Young, referred Blackburn to him. The first patient visit was on September 6, 2013. [R. 162-1, p. 5, tp. 17:8-14]. Dr. Ferrante testified that he and Dr. Young had a telephone conversation at that time in which Dr. Young advised that he had done "a basic work-up," including blood work and stool tests "and everything checked out okay". [R. 162-1, p. 5, tp. 17:15-18:13]. Dr. Ferrante testified that it was his practice to rely on

[5] These are medical articles by widely recognized nephrologists which discuss the importance of testing renal function at specified intervals.

[6] As discussed, *infra*, Dr. Ferrante unambiguously testified that, if the LIALDA label had provided for Specific Interval Testing, he would have followed that instruction for safe use.

information about prior testing, including blood work, from referring physicians. [R. 162-1, p. 17, tp. 67:11-17].

In addition, Appellant's expert gastroenterologist, Dr. Mark Janich, has testified in his Declaration and in his deposition that it was consistent with the standard of care for Dr. Ferrante to rely upon his conversation with Dr. Young as confirmation that a prior blood test had been done, which was unremarkable. [R. 211, p. 4; R. 164-1, p. 12, tp. 39:8-43:3]. Shire has offered no affirmative testimony from any internal medicine physician or gastroenterologist that Dr. Ferrante deviated from the applicable standard of care in any respect.

After Dr. Ferrante prescribed LIALDA to the Appellant on November 5, 2013, he (or his staff) scheduled a follow-up appointment for January 14, 2014. [R. 195 at 21]. This appointment was not for the purpose of performing blood work but was simply to see if Appellant was having any possible physical, symptomatic reaction to LIALDA. [R. 162-1, p. 12, tp. 45:14-49:4].

There is no evidence in Dr. Ferrante's testimony or records that he would have evaluated Appellant's kidney function with a serum creatinine test on the scheduled January 14, 2014 visit, if Appellant had kept that appointment. In fact, as discussed, *infra*, Dr. Ferrante understood the "periodic" recommendation to refer to annual evaluation of kidney function, so there was no reason for him to do a serum creatinine test in January, 2014.

Dr. Ferrante did not tell Blackburn to return for blood testing January or in a couple of months. [R. 162-1, pp. 17-18, tp. 68:19-69:2]. Dr. Ferrante's regular practice is to perform blood tests to evaluate renal function on an annual basis. [R. 162-1, pp. 22-23, tp. 88:21-89:19].

Of particular importance, Dr. Ferrante was fully familiar with the "periodic" recommendation for evaluation of renal function in the LIALDA label. [R. 162-1, pp. 15-16, tp. 60:18-61:6]. In his practice, Dr. Ferrante understood "periodically" to indicate checking renal function "once a year." [R. 162-1, p. 16, tp. 61:4-62:6]. Dr. Ferrante specifically relies on warnings and precautions in a label for drugs such as LIALDA. [R. 162-1, p. 17, tp. 65:12-23]. Dr. Ferrante confirmed that this is the type of data on which he relies "in determining what safe use protocol or testing recommendations you give your patients" and that he relied on this information in prescribing LIALDA for Blackburn. [R. 162-1, p. 17, tp. 66:1-20]. Thus, before prescribing LIALDA for Blackburn, Dr. Ferrante was familiar with the testing recommendation in the LIALDA label and knew that the label recommended monitoring renal function "periodically." [R. 162-1, p. 31, tp. 122:15-23:9].

Dr. Ferrante affirmatively testified that if the LIALDA label had included a protocol for monitoring serum creatinine on a monthly basis for three months and every three months thereafter, he would have followed that protocol. [R. 162-1, p. 18, tp. 69:6-72:20]. Dr. Ferrante specifically confirmed that "if the LIALDA label had

included a testing protocol such as what we saw on the Pentasa label or the Octasa label," he would have provided this information to Blackburn and would have followed those protocols. [R. 162-1, p. 20, tp. 77:8-78:1].

Dr. Ferrante was asked about the recommendations for Specific Interval Testing in the Octasa and Pentasa labels and confirmed that, if such a Specific Interval Testing protocol had been included in the LIALDA label, "It would have been a recommendation for patient monitoring that was critical to safe use of LIALDA by Blackburn." [R. 162-1, p. 24, tp. 93:8-95:10; p. 25, tp. 96:16-97:19]. Finally, Dr. Ferrante specifically confirmed that, in treating Blackburn and prescribing LIALDA for Blackburn, he complied "with the standard of care in all respects." [R. 162-1, p. 15, tp. 57:8-19].

Appellant's LIALDA prescription was refilled by Dr. Ferrante's office in the summer of 2013. [R. 195, p. 22]. Dr. Ferrante has testified that he complied with the standard of care in treating Blackburn. [R. 162-1, p.57, tp. 8-23].

Similarly, Appellant's gastroenterology expert, Dr. Mark Janich testified by Declaration that Dr. Ferrante complied with the applicable standard of care in initially prescribing LIALDA for Blackburn, in relying on the information about blood work provided to him by Dr. Young when Dr. Ferrante initially prescribed LIALDA for Mr. Blackburn, and when Dr. Ferrante refilled that prescription in 2014. [R. 211, pp. 3-5].

The District Court mentioned the "off-label" prescription by Dr. Ferrante of LIALDA for Appellant's Crohn's disease. [R. 244, p. 7]. Shire makes no affirmative claim that this was improper nor could it. Physicians routinely use their medical judgment to prescribe prescription drugs "off-label". Shires' gastroenterology expert, Dr. Bloomfeld, testified that there is nothing wrong with a physician using his or her medical judgment to prescribe a drug for "off-label" use. Indeed, he has frequently done so. [R. 176-1, pp. 11-12, tp. 41:17-42:7]. And, as stated, *supra*, Dr. Ferrante and Dr. Janich have testified that Dr. Ferrante complied with the applicable standard of care in prescribing LIALDA for Blackburn.

Blackburn knew from reviewing the LIALDA label and his conversation with Dr. Ferrante that renal function was supposed to be periodically monitored. [R. 160-1, p.30, tp. 4-9]. Blackburn testified, "When it said get tested periodically, I assume that to mean the next time I would see a doctor, there was a nerve a, like adamant you need to get tested on this date." [R. 160-1, p.43, tp. 167:12-16]. Appellant Blackburn further explained repeatedly that the term "periodic" was vague and he took it to mean 12, 18 months, or "however long." [R. 160-1, p. 56, tp. 219:3-220:3]. Additionally, Blackburn testified that "so I felt like I did everything, I took the drug as recommended, as I was told to take it, and, follow the procedures." [R. 160-1, p. 56, tp. 220:11-18].

In cursory fashion, the Memorandum Opinion states, in a single sentence: "Failure to keep his January 2014 appointment and follow up with Dr. Ferrante severs the causal chain." [R. 244, p. 20].

However, the conclusive evidence is that the January 14, 2014 visit was not for the purpose of evaluating Appellant's kidney function with a serum creatinine test. This is because Dr. Ferrante and Appellant both understood the "periodic" recommendation to mean evaluation in a year or more. Dr. Janich confirmed this understanding of the "periodic" recommendation. [R. 211, p. 5]. Dr. Winston explained in detail that "periodic" may refer to the next physical, which may be annually, "or longer for relatively young and healthy patients." [R. 210, ¶ 34].

Further, there is no undisputed evidence for summary judgment purposes that Appellant would not have complied with a recommendation for Specific Interval Testing, if Dr. Ferrante had provided that recommendation (which Dr. Ferrante testified he would have done).

Actually, the evidence is to the contrary. Specifically, Dr. Young, Appellant's internist, noted when Appellant had blood work done on March 9, 2012, that his PSA was "high normal". Accordingly, Dr. Young asked Appellant to return in six months for additional laboratory testing of his PSA. Blackburn fully complied with this recommendation for testing and had blood work done for his PSA (which was normal) on September 25, 2012. [R. 161-1; pp. 14-15; tp. 49:16-50:18]. In fact, the

evidence is that Appellant affirmatively complied with this physician recommendation to have future laboratory testing.

Appellant specifically directed the District Court's attention to this evidence of Appellant's compliance with a recommendation for testing. [R. 218, pp. 49-52]. Thus, the only evidence in the record regarding whether Appellant would have complied with a recommendation for Specific Interval Testing is the evidence that Appellant complied with Dr. Young's recommendation that he return for PSA testing in six months.

III. STANDARD OF REVIEW

The Eleventh Circuit reviews *de novo* a grant of summary judgment. *Fitzpatrick v. City of Atlanta*, 2 F.3d 1112, 1117 (11th Cir. 1993). Summary judgment is proper only if 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). "In reviewing a grant of summary judgment, we resolve all ambiguities and draw reasonable factual inferences from the evidence in the non-movant's favor." *Layton v. DHL Express (USA), Inc.*, 686 F.3d 1172, 1175 (11th Cir. 2012).

SUMMARY OF ARGUMENT

The District Court granted summary judgment as to Appellant's strict liability claim on the basis of the Alabama Learned Intermediary Doctrine. The core of the District Court's Opinion appears at page 5 as follows:

> "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." (R. 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. (R. 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.

The District Court noted that the prescribing gastroenterologist, Dr. Ferrante, did not follow the LIALDA label's recommendation for kidney function before the prescription of LIALDA. The District Court also referenced an out of context "snippet" of Dr. Ferrante's testimony that he did not review the LIALDA label before prescribing LIALDA for Appellant.

Finally, in finding that there was an absence of causation as a matter of law, the District Court noted that the Appellant failed to keep a January 2014 appointment with Dr. Ferrante.

Respectfully, the District Court simply disregarded substantial, indeed overwhelming, record evidence of material issues of fact with respect to each of these grounds for granting summary judgment. In short, the District Court considered the summary judgment record, and the reasonable inferences from that record, in favor of Shire, the moving party, rather than in favor of Appellant. Respectfully, the District Court's Memorandum Opinion and Order were, therefore, contrary to the controlling authorities in this Circuit reversing summary judgment in pharmaceutical cases on the basis of the Learned Intermediary Doctrine and the related issue of proximate cause. *Horrillo v. Cook Inc.*, 2012 WL 6553611, at *5 (11th Cir., 2012) (applying Florida law which is substantively indistinguishable from applicable Alabama law)[7]; *Tatum v. Schering Corp.*, 795 F.2d 925 (11th Cir. 1986) applying Alabama law). Thus, the District Court made impermissible factual determinations properly reserved for the jury.

Appellant's primary doctor, Dr. Craig Young, referred Appellant to Dr. Ferrante. Dr. Ferrante testified that he spoke with Dr. Young at the time of the referral and that Dr. Young informed him that he had done blood work on Appellant and that the results were normal. Dr. Ferrante specifically testified that relying upon information regarding blood work from a referring physician was within the standard

[7] *Levine v. Wyeth Inc.*, 2010 WL 5137424 at 6 (M.D. Fla. 2010) (Florida and Alabama both apply the Learned Intermediary Doctrine in analyzing a failure to warn claim against a prescription drug manufacturer).

of care. Appellant's gastroenterology expert, Dr. Mark Janich provided expert opinion confirming that Dr. Ferrante had complied with the standard of care in relying upon Dr. Young and not performing an independent evaluation of Appellant's kidney function before prescribing LIALDA.

Further, Dr. Ferrante's failure to do a prior evaluation of Appellant's kidney function cannot be conclusive proof, as a matter of law, that Dr. Ferrante would not have provided an instruction for safe Specific Interval Testing if such a recommendation had been including in the LIALDA label. These are two entirely separate matters. The former is not dipositive of the latter.

Dr. Ferrante testified that, although he did not specifically review the LIALDA label before prescribing LIALDA for Appellant, he had been familiar with the label and the recommendation for "periodic" evaluation of kidney function for years.

In addition, the District Court acknowledged that Dr. Ferrante specifically testified that if the LIALDA label had included an instruction for Specific Interval Testing, he would have given that instruction to Appellant. However, rather than granting the Appellant the benefit of this testimony and all reasonable inferences, the District Court rejected that testimony of Dr. Ferrante as "speculation" and engaged in the inference that Dr. Ferrante would <u>not</u> have provided a recommendation for Specific Interval Testing, contrary to his specific testimony.

Without explanation, the District Court held, as a matter of law, that Appellant's failure to keep his January 2014 appointment broke the chain of causation even though that appointment was not for the purpose of a serum creatinine test or to otherwise evaluate renal function. The District Court also disregarded the evidence that Appellant had recently complied with a similar testing recommendation by Dr. Young.

Finally, the District Court should have allowed Appellant one chance to amend his Complaint after the Court's first Order identifying deficiencies in the pending Complaint.

ARGUMENT

A. Substantial Evidence Exists that LIALDA's Instructions for Use are Inadequate

Under Alabama law (and the laws of virtually every other jurisdiction), adequate instructions for safe use are part of the warnings drug manufacturers such as the Shire Defendants are required to give their products.

Adequacy of warnings is almost always a jury question, as it involves the knowledge of the manufacturer and whether the warning was "reasonable under the circumstances". *See Toole v. McClintock,* 999 F.2d 1430, 1433 (11th Cir. 1993) ("[U]nder Alabama law, "the existence of a duty to warn and the adequacy of the warning are questions of fact for the jury."), quoting *State Farm Fire & Cas. Co. v. J.B. Plastics*, 505 So.2d 1223, 1227 (Ala. 1987); *Hicks v. Commercial Union Ins. Co.,* 652 So.2d 211, 217 (Ala. 1994) ("Whether the provision of the operating instructions…adequately apprises users of the risk of injury and death…is a question of fact for the jury."); *Gurley v. American Honda Motor Co*., 505 So.2d 358, 361 (Ala. 1987); *Campbell v. Robert Bosch Power Tool Corp.,* 795 F.Supp. 1093, 1098 (M.D.Ala. 1992) ("The adequacy of the warning is usually a question for the jury."), citing *State Farm, supra*.

Appellant's expert nephrologist, Dr. Jonathan Winston, has explained in detail why the "periodic" recommendation for renal monitoring was both inadequate and

proximately caused Appellant's kidney injury. [R. 210, ¶¶ 21-24, 31-44]. This evidence fully supports a claim for failure to warn under the AEMLD.

B. Appellant's AEMLD Claim is not Barred by the Learned Intermediary Doctrine Because Dr. Ferrante Would Have Followed a Specific Interval Testing Protocol.

Judge Proctor explained in detail in his May 5, 2017, Memorandum Opinion denying Shire's motion to dismiss the AEMLD claim that the learned intermediary doctrine has no application where, as here, the warning given to the prescribing physician is inadequate. [R. 53, pp. 13-16]; *see Toole v. Baxter Healthcare Corp.,* 235 F.3d 1307, (11th Cir. 2000) (denying manufacturer's motion for directed verdict on learned intermediary ground where, as here, evidence suggested that an enhanced warning would have caused the physician to have behaved differently, *i.e.,* that the warning was inadequate); *Wyeth, Inc. v. Weeks*, 159 So.3d 649, 673-74 (Ala. 2014) ("[I]f the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient.").

Appellant is not required to prove that his proposed instructions for use would have caused Dr. Ferrante to refrain from prescribing LIALDA for him. Judge Proctor properly rejected that argument by Defendants in his May 8, 2017 Order:

> Defendants' contention that Plaintiff's claims fail for lack of proximate cause is similarly off the mark. Defendants argue that Plaintiff has not alleged that a different warning would have altered Dr. Ferrante's decision to prescribe LIALDA to Plaintiff, and as such, Plaintiff has not pled that LIALDA's allegedly defective label caused his injury. (Doc.#45 at p. 27). This is a typical way of assessing the proximate

> cause inquiry. *Weeks,* 159 So.3d at 673-74. However, it is not the only way. Indeed, proof of proximate cause could 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. (*emphasis added*)[8]

[R. 53; p. 16], citing *Barnhill v. Teva Pharm., USA, Inc.,* 819 F.Supp.2d 1254, 1261 (S.D.Ala. 2011); *Fields v. Eli Lilly & Co.,* 116 F.Supp.3d 1295, 1307 (M.D.Ala. 2015); *see Toole, supra*, 999 F.2d 1433 (in rejecting manufacturer's motions for directed verdict and JNOV, the 11th Circuit found sufficient evidence of proximate cause, which it described as evidence "that a different warning from [the defendant manufacturer] would have caused [treating physician] to behave differently"); *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254 (5th Cir. 2002).

While it is true that Judge Proctor's opinion that the learned intermediary doctrine does not bar Appellant's claims was issued at the Motion to Dismiss stage, the summary judgment record establishes that the LIALDA "periodic" instruction for use was unsafe and proximately caused Appellant's injury.

Dr. Ferrante testified that he understood "periodic" to mean one year or an annual examination.

> Q. And I believe you may have forecasted my next question and answered it, but in your practice as a board certified

[8] The District Court specifically recognized this principle, citing Judge Proctor's above quoted order and the *Barnhill Fields* and *Brasher* cases. [R. 244, pp. 13-14]. Respectfully, the District Court simply misapplied these authorities, as well as this Circuit's *Horrillo* and *Tatum* cases to the summary judgment record in this case.

> gastroenterologist who prescribes, not just LIALDA, but this class of drugs, what does "periodically" mean to you?
> A. 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.

[R. 162-1; p. 16; 61:7-21] (objection omitted).

Dr. Ferrante testified that he relied on the LIALDA label, and would have followed adequate instructions for Specific Interval Testing had Defendants provided them in the label:

> Q. Who are you relying on for information, data, and guidance on instructions for safe use of medications such as LIALDA?
> A. Again, as stated earlier, typically, like the package insert, if you will, of the medicines.

[R. 162-1, p. 16; 64:16-23] (objection omitted)

> Q. If the LIALDA label had called for this type of testing protocol, these types of instructions for safe use, would you have followed the labeling recommendation when giving the prescription advice to Mr. Blackburn?
> A. If I had known about it, yes, I would have followed those protocols.

[R. 162-1, p. 18; 72:12-20] (objection omitted).

> Q. If the LIALDA label had included a testing protocol such as what we saw on the Pentasa label or the Octasa label, would you have relayed that information to Mr. Blackburn?

> A. Again, if I would have known about that, I would have followed those protocols.
> Q. Is part of that telling the patient?
> A. Yes.

[R. 162-1, p. 20, 77:12-78:1].

Dr. Ferrante explained that, had Shire recommended Specific Interval Testing in order to avoid permanent kidney injury, he would have followed that recommendation, as he agreed instructions or Specific Interval Testing, such as those contained in the European labels, are "critical":

> Q. Is it your view that language that we just said, "As a guideline, follow-up tests are recommended 14 days after commencement of treatment and then every four weeks for the following 12 weeks," is it your view that that would have been patient monitoring language that was critical to safe use of LIALDA by Mr. Blackburn and other patients taking LIALDA?
>
> A. We're talking about Octasa, so I'm not—
>
> Q. If that language was in the LIALDA label.
>
> A. Oh, okay. If I would have known about that protocol, then yes. Yes.
>
> Q. You would have considered it to be critical to safe use of LIALDA by Mr. Blackburn, correct?
>
> A. Yes.
> Q. Okay. You would agree that that language that was in the Octasa label, "As a guideline, follow-up tests are recommended 14 days after commencement of treatment and then every four weeks for the following 12 weeks," if that had been in the LIALDA label,

> that, in your view, would have been a measure that could be taken to prevent or mitigate harm to Mr. Blackburn and other patients taking LIALDA, correct?
>
> A. Correct.

[R. 162-1, pp. 24-25, tp. 94:12-95:22] (objections omitted).

> Q. And it would be, in your view, if that language from the Pentasa label was in the LIALDA label, it would have been a recommendation for patient monitoring that was critical to safe use of LIALDA by Mr. Blackburn, correct?
>
> A. Yes.
>
> Q. And it would have, that language, if it had been in the LIALDA label, that language being the Pentasa, would have been a-- was a measure that could be taken to prevent or mitigate harm to Mr. Blackburn form use of LIALDA, correct?
>
> A. Yes.

[R. 162-1, p. 25, tp. 97:12-98:4] (objections omitted).

The summary judgment record was more than sufficient to allow the issue of causation to be determined by the jury. *See, e.g., In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prod. Liab. Litig.,* 144 F. Supp. 3d 699, 723–24 (E.D. Pa. 2015) (to demonstrate proximate cause for failure to warn under Alabama law, a Appellant must simply demonstrate that, had the defendant manufacturer given an adequate warning, it "would have been read and heeded by the prescribing physicians"), quoting *Brasher, supra,* at *13.

Brasher v. Sandoz Pharmaceuticals Corp., 2001 WL 36403362 (N.D.Ala. Sept. 21, 2001) in which a consumer brought failure to warn, fraud, strict liability and other tort claims against the manufacturer of Parlodel, is instructive.

> The fact that some warning is given to the doctor, however, is not dispositive of the failure-to-warn issue. Where a warning has been provided, a question arises as to *whether the warning was adequate, and adequacy of the warning is a question of fact for the jury*.

Id., *13, citing *Toole v. McClintock*, 999 F.2d 1430, 1433 (11th Cir. 1993) (emphasis supplied).[9]

Any disputes regarding the adequacy of Shire's warnings and resulting applicability of the learned intermediary doctrine should be resolved by the jury.

[9] *See also, e.g., In re Tylenol (Acetaminophen) Mktg. Sales Practices & Prod. Liab. Litig.*, 144 F. Supp.3d 699, 721-22 (E.D.Pa. 2015) ("Where a warning has been provided, a question arises as to whether the warning was adequate, and adequacy of the warning is a question of fact for the jury."), citing Brasher, *supra* at *13; *Frazer v. Wyeth,* 857 F.Supp.2d 244, 254 (D. Ct. 2012) (denying manufacturer's motion for summary judgment on learned intermediary grounds because "only *adequate* warnings obviate the need for drug manufacturers to directly warn consumers", and the plaintiff had adduced "sufficient evidence here for a reasonable jury to find that Wyeth did not adequately warn [prescribing physician]."") (emphasis in the original); *Pittman v. Upjohn Co.,* 890 S.W.2d 425, 429 (Tenn. 1994) (whether a warning is adequate involves a number of factors, including the consideration that "a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it"); *Thom v. Bristol-Myers Squibb,* 353 F.3d 848, 853-855 (10th Cir. 2003) (denying manufacturer's motion for summary judgment on learned intermediary grounds because a physician does not become a learned intermediary until he or she has received adequate warnings from the drug manufacturer, and because adequacy of warnings involves questions of fact, including the manufacturer's knowledge of the danger of the product).

C. Substantial Evidence Supports Proximate Cause

The fact that Dr. Ferrante knew the general risk of renal toxicity prior to prescribing LIALDA has no bearing on whether Shire's instructions for safe use, or use of the ill-defined term "periodic", were adequate, or whether Dr. Ferrante and Appellant would have changed their behavior and avoided permanent injury had Shire provided the specific testing protocol.

The District Court referenced Dr. Ferrante's testimony out of context to suggest that he never read the LIALDA label prior to prescribing LIALDA for Appellant (and that, thus, the chain of causation was broken). ("He did not actually look at the LIALDA label prior to prescribing LIALDA for Appellant."). [R. 244, pp. 7-8]. Respectfully, this lifts a single question and answer from Dr. Ferrante's deposition out of its context. ("Q. Okay. Did you actually look at the LIALDA label before you prescribed LIALDA to Mr. Blackburn? A. No."). [R. 162-1, p. 24, tp. 93:4-7].

This testimony came in the context of Dr. Ferrante's explaining that he already knew the contents of the LIALDA label, and had for "some time", including the disclosure of renal risks, prior to prescribing the drug to Appellant. [R. 162-1; p. 23, tp. 92:8-93:7]. In other words, Dr. Ferrante did not testify that he was not familiar

with or had not ever read the label, but rather that he did not *re*read the LIALDA label at the time of prescribing it to Appellant. [10]

Dr. Ferrante specifically testified that he was familiar with the contents of the LIALDA label, and relied on such information in prescribing drugs to patients:

> Q. In the second paragraph, the label tells us again "It is recommended that patients have an evaluation of renal function prior to initiation of LIALDA therapy and periodically while on therapy" were you familiar with that recommendation prior to prescribing LIALDA to Mr. Blackburn?
>
> A. Yes. It's my common practice to usually check a renal function at least once a year at this point. (*emphasis added*)

[R. 162-1, p. 15-16, tp. 60:18-61:6] (objection omitted).

> Q. Who are you relying on for information, data, and guidance on instructions for safe use of medications such as LIALDA?
>
> A. Again, as stated earlier, typically, like the package insert, if you will, of the medicines….

[R. 162-1, p. 16, tp. 64:16-23] (objection omitted).

> Q. Well, if we look at Exhibit 13, this are we just looked at on page 2 in the LIALDA label, section 5.1, renal impairment, is

[10] Defendants cannot seriously assert that a prescribing doctor must re-read every prescription drug label, with which he or she has become familiar, every time she prescribes it, or else break the chain of proximate causation for manufacturer liability. If this were the case, it would be the end of drug manufacturer liability for failure to warn. *See, e.g., Russell v. Ethicon, Inc.*, 2020 WL 4732102, at *5-6 (N.D. Ala. August 14, 2020) (denying device manufacturer summary judgment on AEMLD/failure to warn claims, despite the fact that treating physician testified that "although he had read the warning on the package insert, *he did not read them every time* he performed surgery" because physician also testified elsewhere that he does rely in part on the warnings provided by the manufacturer) (emphasis added).

> 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.

[R. 162-1, p. 17, tp. 65:12-66:6] (objections omitted).

> Q. Were you familiar with the testing recommendations that are in the label before you prescribed LIALDA to Mr. Blackburn?
>
> A. Yes, I knew that renal function needs to be monitored, as well as liver function and different tests like that, yes
>
> Q. Did you know that the recommendation was to monitor renal function periodically while on therapy?
>
> A. Periodically, yes.
>
> Q. And you knew that before you prescribed it to Mr. Blackburn?
>
> A. Yes.

[R. 162-1, p. 31, tp. 122:17-123:10] (objection omitted) (*emphasis added*).

The learned intermediary doctrine and proximate causation are inextricably linked in pharmaceutical cases. Numerous district court opinions have rejected manufacturers' summary judgment motions on these related grounds based upon factual records similar or less favorable to plaintiffs than the record in this case. *See,*

e.g., Aldridge v. Ethicon, Inc., 2020 WL 1308335, at *4 (S.D. Ala. Mar. 19, 2020) (denying manufacturer summary judgment because of genuine issues of material fact as to causation, despite an "isolated snippet" of testimony by the treating physician that he still would have used the allegedly defective product even if he had had a more in-depth discussion of all the risks, because in other places in his deposition, the physician had testified that it would have been important for him to know all the risks, that the manufacturer never adequately alerted the physician to the risks, and so he never consulted with the plaintiff about them); *Fields v. Eli Lilly and Co.,* 116 F.Supp.3d 1295, 1307-09 (M.D. Ala. 2015) (denying manufacturer summary judgment because district court found "that, in accordance with *Toole,* under Alabama's learned-intermediary doctrine" the plaintiff could demonstrate factual causation by proving that, had the manufacturer given the treating physician a stronger warning, the physician would have informed the plaintiff and "his warning would have resulted in a different outcome").[11]

[11]*See also McWilliams v. Novartis AG,* 2018 WL 3369655, at *6-7 (S.D. Fla. 2018) (genuine issues of material fact precluding summary judgment existed on issue of proximate cause even if plaintiff could not show that the treating physician would not have prescribed the drug at all if proper warnings and instructions had been issued by manufacturer, because evidence existed that the physician would have given the plaintiff "different warnings or instructions"); *Johnson v. Ethicon, Inc*., 2020 WL 3542872, at *4–5 (S.D. Ill. 2020) (while treating physician stated that he still would have prescribed the medical device to patient, he also testified that he was unaware of certain information regarding risks and would have factored any new information into his prescription decision, and that "seemingly inconsistent testimony about whether his decision would have changed had he had more information is enough to put the question to the jury"); *Wiltgen v. Ethicon, Inc*., 2017 WL 4467455, at *7 (N.D. Ill. 2017) (doctors who receive insufficient warnings cannot be considered learned intermediaries); *In re Tylenol (Acetaminophen) Marketing, Sales Practices and Products Liability Lit.,* 144 F.Sup.3d 699, 721-22 (E.D. Pa. 2015) ("Where a warning has been provided, a question arises as to whether the warning was adequate, and adequacy of the warning is a

D. The District Court's May 8th Order Dismissing Appellant's Fraud-Based and Warranty Claims With Prejudice Was Error

(1) The Applicable Legal Standard.

This Court reviews *de novo,* an order granting a motion to dismiss for failure to state a claim, accepting all the allegations in the complaint as true and construing all reasonable inferences in the plaintiff's favor. *Brisson v. Ford Motor Co.,* 349 Fed.Appx. 433, 434 (11th Cir. 2009); *Meyer v. Gwinnett County,* 636 Fed. Appx.

---

question of fact for the jury."), citing *Brasher, supra,* at *13 (citing Toole, supra, at 1433); *Huskey v. Ethicon, Inc.,* 2015 WL 4944339, at *9 (S.D. Va. Aug. 19, 2015) (if an issue of fact exists regarding whether the learned intermediary would have acted differently with different warnings, summary judgment should not be granted), *aff'd,* 848 F.3d 151 (4th Cir. 2017); *Kirchman v. Novartis Pharms. Corp.,* 2014 WL 2158519, at *5 (M.D. Fla. 2014) ("[A] reasonable jury could find that [treating physician], had he been adequately warned, would have changed his prescribing practices by giving different warnings or instructions to [plaintiff] in 2002 and 2003."), citing *Guenther v. Novartis Pharms. Corp.,* 2014 WL 657919, at *2-3 (M.D. Fla. Feb. 20, 2014) (denying Rule 50(e) motion on proximate cause issue when there was sufficient evidence that a different warning would have prevented the plaintiff's injury by "prompting the physician to pass along a more detailed warning) and *Toole, supra.,* 999 F.2d 1430, 1433 (11th Cir. 1993) ("…a different warning…would have caused [the physician] to behave differently"); *Rutz v. Novartis Pharmaceuticals Corp*., 2012 WL 6569361, at *8 (S.D. Ill. 2012) ("For these reasons, the Court concludes that summary judgment is not warranted on the issue of whether a different warning would have prevented Rutz's [injury] or changed the outcome of her treatment."); *In re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Products Liability Litigation*, 2011 WL 6732245, at *14 (S.D. Ill. 2011) ("[O]ne need only glance at the expert opinions, depositions and pleadings relevant to the instant dispute to determine the adequacy of Bayer's warnings is a factual dispute underlying the bulk of plaintiff's claims. Accordingly, Bayer's motion for partial summary judgment is **DENIED**.") (emphasis in the original); *Levine v. Wyeth, Inc.,* 2010 WL 5137424, at *6 (M.D. Fla. 2010) (denying manufacturer's motion for summary judgment on issue of causation because genuine issues of material fact existed as to whether a better warning/instruction by the manufacturer would have caused the treating physician to pass that on to the plaintiff, and whether the plaintiff would have headed such a warning), citing *Munroe v. Barr Labs., Inc.,* 670 F.Supp.2d 1299, 1301 (N.D. Fla. 2009); *In re Zyprexa Products Liability Litigation,* 688 F.Supp.2d 130, 149 (E.D.N.Y. 2009) (applying Alabama law and denying summary judgment to manufacturer because of fact issues regarding whether treating physician had sufficient knowledge of the specific nature and scope of drug's metabolic risks).

487, 488 (11th Cir. 2016), citing *La Grasta v. First Untion Sec., Inc.,* 358 F.3d 840, 845 (11th Cir. 2004).

The specific issue for purposes of this appeal is whether the District Court erred by dismissing Appellant's fraud-based and breach of warranty claims *with prejudice and without leave to amend.* While a district court's allowance or disallowance of amendments is subject to an abuse of discretion standard, such discretion is "severely restrict[ed]" under Federal Rule of Civil Procedure 15(a)(2) and Eleventh Circuit decisions construing it. *Bryant v. Dupree*, 252 F.3d 1161, 1163 (11th Cir. 2001), quoting *Thomas v. Town of Davie*, 847 F.2d 771, 773 (11th Cir. 1988).

Specifically, a district court abuses its discretion by making such a clear error of judgment or by applying the wrong legal standard. *See, e.g., Meyer, supra,* 636 Fed. Appx. at 488, citing *Amlong & Amlong, P.A. v. Denny's Inc.,* 500 F.3d 1230, 1238 (11th Cir. 2006). A district court also abuses its discretion if it appears that deficient allegations could be remedied through more specific or carefully drafted pleading. *Bryant*, *supra*, 252 F.3d at 1163.

(2) <u>The May 8th Order is inconsistent with the *Bryant* "one chance" rule.</u>

The *Bryant* case is on point and dispositive. This is especially true as the District Court itself acknowledged in its May 8th Order that differently drafted fraud allegations might state claims for relief. [R. 53, p.19].

Specifically, this Court in *Bryant, supra,* held that, where a more detailed or carefully drafted complaint might state a viable claim, a plaintiff should be given *at least one chance* to amend his complaint before a district court dismisses the action with prejudice (the "*Bryant* rule"). *Bryant*, 252 F.3d at 1163*,* quoting *Bank v. Pitt*, 928 F.2d 1108, 1112 (11th Cir. 1991); *see also Evans v. Georgia Reg'l Hosp.,* 850 F.3d 1248, 1254 (11th Cir. 2017).

Moreover, this Court in *Bryant* also made clear that an amended complaint, filed "as a matter of course" under Rule 15 in response to a prior motion to dismiss the original complaint, and prior to any substantive court order determining any pleading deficiencies, is simply not plaintiff's "one chance" to cure. *Bryant,* 252 F.3d at 1163-64. The Bryant court rejected as an abuse of discretion the holding that the filing of a first amended complaint as a matter of course under Rule 15(a) in response to the defendants' original motion to dismiss, but before the district court had addressed the merits of that motion, constituted that "one chance". *Id.* The Court opined that the plaintiffs should have been allowed to amend because they had not "failed to cure deficiencies through previously allowed amendments." *Id.,* 1164.

Bryant rejected the district court's reasoning that dismissal with prejudice was appropriate because the Appellants "already had been given notice of the possible deficiencies in their complaint", and thus squandered the opportunity to correct those deficiencies. *Bryant,* 252 F.3d at 1164. There were simply no court-determined

pleading deficiencies of which the *Bryant plaintiff* could have had notice, much less corrected.

Thus, *Bryant* provides that an Appellant's "one chance" to cure deficiencies is triggered by a district court's determination of pleading deficiencies in a pending complaint, *not* by the filing of a prior motion to amend. *Bryant,* 252 F.3d at 1164. The *Bryant* rule has been applied by federal courts for decades, and is still good law. *Romer v. Corin Group, PLC,* 2018 WL 4281470, at *7 (M.D. Fla. 2018); *see also Higdon v. Tusan,* 746 Fed. Appx. 805, 815 (11th Cir. 2018) (citing *Bryant*, "[P]laintiffs typically should be allowed to file a *second amended complaint* when the Appellants only have amended their complaint once as a matter of course, have not employed delaying tactics, and have indicated that, if given the chance to amend, they will meet the pleading requirements.").

A district court may only avoid the *Bryant* rule if one of three recognized exceptions exists: (1) undue delay, bad faith, dilatory motive, or failure to cure deficiencies by amendments previously allowed; (2) where allowing amendment would cause undue burden to the opposing party; or, (3) where amendment would be futile. *Bryant,* 252 F.3d at 1163, citing, *Foman v. Davis,* 371 U.S. 178, 182 (1962); *see also, e.g., Karnath v. Daniels,* 405 Fed.Appx. 114, 115 (9th Cir. 2010). As demonstrated, infra none of these exceptions is applicable here.

E. The District Court's November 2nd Order Erroneously Denied Appellant's Motion To Alter Or Amend The May 8th Order And To Allow Him To File the Proposed SAC

Here, the District Court first determined deficiencies in Appellant's express warranty and fraud- based claims in its May 8th Order when the Court ruled on Appellees' motion to dismiss the FAC and dismissed the fraud-based and breach of warranty claims on the merits.

Following the May 8th Order of dismissing those claims with prejudice, Appellant moved the District Court, under Federal Rule of Civil Procedure 54(b), to alter or amend the May 8th Order to state that the claims were dismissed without prejudice, based on *Bryant*. [R. 64, Ex. A].

(1) None of the exceptions to Rule 15(a)(2) or the *Bryant* "one chance" rule was applicable.

None of the three limited exceptions to Rule 15(a)(2)'s liberal mandate and the "one chance" rule addressed, *supra*, was applicable or available to support the District Court's November 2nd Order. Although the Order suggested "undue delay" on Appellant's part, and related concerns for "judicial efficiency", and made reference to purported prejudice, none of these considerations were at issue or properly applied.

(a) The District Court miscalculated the applicable timeframe with regard to the "undue delay" and related "judicial efficiency" exceptions to Rule 15(a)(2).

The District Court's November 2nd Order relied primarily on the undue delay

exception to Rule 15(a)(2)'s requirement that amendments be "freely given", focusing on Appellant's making his request for leave to amend by filing the proposed SAC only *after* the District Court determined that the fraud and warranty allegations. [R. 85; pp. 3-4] ("Rather than requesting leave to amend his complaint a second time *before* the court ruled on this motion to dismiss, Appellant 'sat idly by as he awaited the district court's determination' of Defendants' second motion to dismiss.").

In considering the issue of undue delay, the District Court erroneously relied on the dates of the filing of the original Complaint [R. 1] on June 16, 2016, and the FAC [R. 41] on November 2, 2016, to suggest Appellant had been given "ample opportunity" to correct deficiencies in his fraud and warranty claims. [R. 85; p.3]. The District Court referred to having granted Appellant's unopposed motion to amend the original Complaint [R. 36] a year earlier, which motion, as discussed, *supra*, was filed in response to Shire's Motion for Judgment on the Pleadings and before the District Court determined the sufficiency of the allegations in the Complaint.

But, under *Bryant*, the proper starting point from which to calculate any "delay" in moving to amend the FAC is the District Court's first determination of deficiencies in the FAC which would warrant amending, or the May 8, 2017 Order, not from the original Complaint, unopposed motion to amend, or the Court's November 1, 2016 Text Order granting such unopposed motion without

commentary. Correctly calculating from the May 8th Order until Appellant filed his Motion to Alter or Amend seeking leave to file the proposed SAC to correct the deficiencies outlined in the May 8th Order results in a "delay" of just fifty-two (52) days, which simply cannot be said to be "undue". No Eleventh Circuit authority supports the District Court's denial of Appellant's Motion to Alter or Amend based upon a 52-day timeframe or under the circumstances of this case.

The District Court's single reference to "judicial efficiency" is inextricably related to its flawed calculation of delay, and so also cannot serve as the basis for denying Appellant his "one chance" to cure. In fact, this Court has stated that waste of judicial resources does not exist where, as here, "no federal judges have yet considered the substance of [plaintiff's] complaint against [defendant]." *H.R. Huff Asset Management Co. v. Kohlberg,* 209 Fed. Appx. 931, 935 (11th Cir. 2006).

(b) No undue prejudice to Appellees would have occurred had Appellant been granted his "one chance" to cure.

The November 2nd Order also cites, without reference to any supporting record evidence, prejudice to Appellees as a basis for denying Appellant his chance to cure the deficiencies in the FAC. [R. 85, p.4]. But claimed prejudice alone, when unsupported by specific facts demonstrating that such prejudice is "undue", simply cannot defeat a plaintiff's right to cure. The mere passage of time, without any other evidence of bad faith on the part of the plaintiff, does not constitute "undue prejudice" to Defendants or justify denying plaintiff an opportunity to amend his

Complaint. *Bryant, supra,* 252 F.3d at 1164, citing *Floyd v. Eastern Airlines, Inc.,* 872 F.2d 1462, 1490 (11th Cir. 1989). Shire failed to articulate any actual prejudice in their Opposition to Appellant's Motion to Alter or Amend [R. 73] and none is specified in the November 2nd Order.

In general, a non-moving party is unduly prejudiced only when an amended complaint significantly changes his theory of recovery, especially when the litigation has substantially progressed. *See, e.g., Tampa Bay Water v. HDR Eng'g, Inc.,* 2013 WL 5305346, at *13 (11th Cir. 2013)(change in theory of case was unduly prejudicing where nonmoving parties had already expended significant resources litigating the prior theory); *Davis v. Piper Aircraft Corp*, 615 F.2d 606, 613 (4th Cir. 1980) ("Because defendant was from the outset made fully aware of the events giving rise to the action, an allowance of the amendment could not in any way prejudice the preparation of defendant's case.").

Nodd v. Integrated Airline Services, Inc., 41 F.Supp.3d 1355, 1368-69 (S.D. Ala. 2014) is on point. It explains the error in the District Court's erroneous justification for denying Appellant the opportunity to cure the deficiencies in his fraud and warranty claims, specifically, that Appellant was somehow obligated to request to request leave to file his proposed SAC in response to Appellees' motion to dismiss the FAC, i.e., *before* the District Court ruled on that motion and pointed out the purported deficiencies in that pleading. [R. 85; p. 4]. No such obligation

exists in the Federal Rules or in Eleventh Circuit jurisprudence. Indeed, nothing in the Federal Rules requires a plaintiff to be clairvoyant and predict whether a district court will read his allegations as plausibly stating a claim, or prevents a plaintiff from waiting to seek leave to amend until he learns that the allegations are somehow wanting. *See, e.g., Czeremcha v. International Association of Machinists, 724 F.2d 1552 (11th Cir. 1984).*

F. The District Court's Erroneous May 2018 Order Denying Appellant's Motion for Reconsideration

The District Court erred by dismissing Appellant's fraud and warranty claims with prejudice and without leave to amend in its May 8th Order, and by denying Appellant's Motion to Alter and Amend in its November 2nd Order. Therefore, Appellant filed a Motion for Reconsideration, with supporting memorandum on November 15, 2017. [R. 91, 96]. The District Court denied Appellant's Motion for Reconsideration of its May 2018 Order [R. 123, 124] primarily on the basis of futility.

In the Eleventh Circuit, a proposed amendment is futile only when the allegations of the proffered complaint would be unable to withstand a motion to dismiss. *See Perlman v. Wells Fargo Bank,* 559 Fed.Appx. 988, 994 (11th Cir. 2014), citing *Burger King, supra*, 169 F.3d at 1320. In determining whether a claim is futile, the Eleventh Circuit errs "on the side of generosity to the plaintiff". *Carter v. HSBC Mortg. Services, Inc.,* 622 Fed.Appx. 783, 788 (11th Cir. 2015); *Johnson v. Boyd,*

568 Fed.Appx. 719, 723 (11th Cir. 2014), citing *O'Halloran v. First Union Nat'l Bank of Fla.,* 350 F.3d 1197, 1206 (11th Cir. 2003).

(1) Legal Standard for Reconsideration

A Motion for Reconsideration under Federal Rule of Civil Procedure 54(b) is subject to the same abuse of discretion standard as are Rules 59(e) and 60(b) motions. *Region 8 Forest Serv. Timber Purchasers Counsil v. Alcock,* 993 F.2d 800, 805-806 (11th Cir. 1993). However, a district court by definition abuses its discretion when it makes an error of law. *Koon v. U.S.* 518 U.S. 81, 100 (1996); *see also Florida Association of Rehab. Facilities, Inc. v. State of Florida,* 225 F.3d 1208 (11th Cir. 2000); *Summit Medical Ctr. V. Riley,* 284 F.Supp.2d 1350 (M.D. Ala. 2003). In addition, when a district court's denial of leave to amend a complaint is based on a legal determination that the amendment would be futile, this Court reviews such decision *de novo*. *Gonzolez v. City of Deerfield Beach,* 549 F.3d 1332-33 (11th Cir. 2008), *cert. denied,* 130 S.Ct. 76 (2009);

(2) Appellant's Express Warranty Claim Is Not Futile.

The District Court denied Appellant's Motion for Reconsideration in part on the basis that it did not believe that additional allegations contained in the proposed SAC regarding §5.1 of the Warnings and Precautions information on the LIALDA label providing instructions for safe use could be construed as an express warranty of safety. [R. 123; pp. 5-6] (citing its prior decision dismissing the FAC with

prejudice [R. 53]). The District Court stood by its prior analysis in its May 8th Order concluding that a prescription drug label was not a "description" of goods within the meaning of Alabama's Uniform Commercial Code ("U.C.C.") [R. 123; pp. 5-6] (citing [R. 53; pp.17-18]), and, even if it were, the language of the LIALDA label was "contrary to an express warranty of safeness because it expressly states that its use may cause a number of side effects [R. 123; pp. 5-6] (citing [R. 53; p.18]). Respectfully, the District Court's finding of futility is an error of law.

Under Alabama law, any description of goods, such as LIALDA, which is made part of the basis of the bargain, creates an express warranty that the goods shall conform to that description. Ala. Code § 7-2-313(1)(1975). Such a description may be in the form of a promise on affirmative regarding the use of the product or a description of the product under the express terms of § 7-2-313(1). It is not necessary that the seller use formal words such as "warrant" or "guarantee", or that he have a specific intention to make a warranty. *Id.,* § 7-2-313(2).

Section 5 of the 2013 label, in general, and at § 5.1, "Renal Impairment", constituted an affirmation and promise by Shire that LIALDA could be safely used if the patient followed the "Warnings and Precautions", and obtained unspecified "periodic" testing. Accordingly, § 5.1 was a basis of the bargain and, as such, constituted an express warranty under § 7-2-313(1). [R. 64, Exh. A (the proposed

SAC), ¶¶267-273.].[12]

In addition, § 5.1 of the 2013 label also constituted a description of LIALDA, including instructions for its safe use, which was a basis of the bargain and constituted an express warranty for this additional reason. The statements in § 5 of the 2013 label, including § 5.1, are for the specific purpose of describing the manner in which LIALDA may be safely used by a patient such as Appellant Blackburn. [*See* R. 64, Exh. A (the proposed SAC), ¶274.].

In short, the "Warnings and Precautions" section of the 2013 label is a false affirmation of fact and a false promise that a patient such as Appellant could safely take LIALDA, if he had unspecified "periodic" evaluation of his renal function. Section 5 also constitutes a false description of the proper use of LIALDA. The proposed SAC more specifically alleged and explained why § 5.1 of the "Warnings and Precautions" in the 2013 label were both an affirmation and a promise, and also a description of the good as part of the basis of the bargain. [*See* R. 64, Exh. A (the proposed SAC), ¶¶274-283].

(3) <u>Appellant's Fraud-Based Claims Not Futile</u>

The November 2018 Order denying reconsideration held that the proposed

[12] The Alabama Supreme Court has determined on certified question from the Eleventh Circuit that the AEMLD does not subsume other common law claims, including a claim for breach of warranty, which is "separate and distinct from an AEMLD claim and is viable to redress an injury caused by an unreasonably dangerous product". *Spain v. Brown & Williamson Tobacco Corp.,* 872 So.2d 101, 111 (Ala. 2003).

SAC did not cure the deficiencies in fraud-based and breach of warranty claims. Both Orders focused on the District Court's misapprehension that the LIALDA label's instructions for safe use, recommending only unspecified "periodic" evaluation, rather than the Specific Interval Testing that would have prevented Appellant's permanent kidney injury, was a mere "recommendation", rather than a misrepresentation of a material fact. [See R. 53; p. 19; 123; pp. 7-8]. The District Court also viewed fraud-based claims as *failure to warn* about the risks associated with long-term use of LIALDA, rather than material misrepresentations and suppression concerning *instructions for the drug's safe use.* [R. 123; pp.7-8]. The District Court erroneously concluded that the LIALDA label's general warnings about side effects precluded a failure to warn claim.

Yet the proposed SAC substantially enhanced and clarified Appellant's fraud allegations through detailed citations to FDA regulations requiring proper instructions for safe use and alleging in detail the material facts that Appellees misrepresented and concealed from Appellant, to his great harm. The proposed SAC [R. 64, Exh. A]. summarizes the false statements in § 5 of the 2013 label at ¶204. The specific reasons that the 2013 label includes misrepresentations are alleged in detail at ¶¶188-205. [R. 64, Exh. A].

In the proposed SAC, Appellants made detailed factual allegations that statements in the 2013 label regarding safe use and periodic testing were

intentionally and knowingly false. The proposed SAC also contained detailed allegations regarding FDA regulations, medical literature, adverse event reports, and labels on other mesalamine-based drugs, establishing that Appellees had actual knowledge that the stated "Warnings and Precautions" were unsafe and false, and that Appellees had the specific intent of defrauding Appellant by their misrepresentations and concealments.

The proposed SAC alleged in detail that Appellees had actual knowledge of, and misrepresented, suppressed and concealed, the following facts:

(a) That unspecified "periodic" evaluation of renal function was not only unsafe, but extremely dangerous for patients such as Appellant;

(b) That Proper Interval Testing was essential to detect acute renal impairment on a timely basis;

(c) That a patient should immediately cease LIALDA therapy as soon as acute renal impairment was detected;

(d) That absent cessation of LIALDA therapy, there was a significant risk that acute impairment would progress to irreversible, chronic interstitial nephritis and chronic renal failure;

(e) That steroidal treatment was also critical to limit the progression of renal impairment and to reverse renal impairment in its acute stage; and,

(f) That the defective and unsafe "Warnings and Precautions" posed a direct

threat to patients' health and well-being and would cause irreversible, chronic interstitial nephritis in patients such as Appellant.

As alleged in the proposed SAC, detailed FDA regulations and Alabama law require a drug maker to provide instructions for safe use including, where appropriate, proper instructions for testing. Thus, the entirety of the "Warnings and Precautions" in § 5 of the 2013 label constitute a representation that a patient who follows these instructions may safely use LIALDA.

The District Court's May 8th Opinion implicitly recognized that Appellant's fraud-based claims were not irredeemably futile when it stated that amended allegations could cure the deficiencies it found: "Indeed, if Plaintiff alleged that Defendants misrepresented (or concealed) the existence of certain adverse events or potential side effects of LIALDA, the present analysis would be different." [R. 53, p.19], citing *Brasher v. Sandoz Pharm. Corp.,* 2001 WL 36403362, at *11 (N.D. Ala.). The above-referenced allegations of the proposed SAC explain in detail why § 5.1 of the 2013 LIALDA label is a legally mandated statement of instructions for safe use and a material misrepresentation regarding safe use. *See* [R. 64, Exh. A (proposed SAC), ¶¶188-205].

The amended allegations in the proposed SAC fall squarely within *Brasher.* The manufacturer defendant in *Brasher* understated in the package insert the number of strokes and seizures that had been reported to be caused by its drug, Parlodel,

reporting only 15 when it had internal knowledge of more than 30, and did not report any deaths associated with the drug although it had received reports of approximately 20. *Brasher v. Sandoz Pharm. Corp*., 2001 WL 36403362 at *4 (N.D. Ala.). The *Brasher* court found such underreporting and omissions in a package insert both a fraudulent misrepresentation and a fraudulent concealment[13] under Alabama law, and denied the defendant's motion for partial summary judgment on those claims. *Brasher,* at *9-11.

The viability of the fraud-based claims in the proposed SAC, with its detailed allegations regarding Appellees' (a) understatement of a safe testing protocol, as required by specific FDA regulations; (b) failure to disclose the criticality of cessation of LIALDA therapy immediately upon detection of acute impairment; and, (c) the need for steroidal therapy, is substantively indistinguishable from those in *Brasher*.[14]

Wyeth, Inc. v. Weeks, 159 So.3d 649, 676 (Ala. 2014), is also instructive, as

[13]In fact, the *Brasher* court found the question of whether the package insert constituted a fraudulent concealment "an even simpler one". *Brasher*, at *10 ("Under Alabama law, the failure to tell the whole truth, or to provide only partially correct information, may constitute fraudulent concealment.").

[14] With the benefit of discovery, the plaintiff in *Brasher* was able to establish that the defendant manufacturer there had actual knowledge of the true number of strokes and deaths associated with Parlodel and "had admitted *internally* that Parlodel could cause hypertension and seizures", but nevertheless omitted them from the package insert. *Brasher,* *2 (emphasis in original). Appellant undoubtedly would have been able to discover similar internal memoranda and email establishing that Appellees had actual knowledge that evaluation of renal function on an unspecified "periodic" basis was unsafe and extremely hazardous to patients such as Appellant.

the Alabama Supreme Court there answered a certified question as follows: "Under Alabama law, a brand-name-drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name-drug." *Weeks*, 159 So.3d at 676. The *Weeks* opinion makes clear that this principle directly applies to fraud-based claims that Wyeth "manufactured or sold brand-name Reglan and purportedly either misrepresented or failed to adequately warn Mr. Weeks or his physician about the risks of using Reglan long-term". *Id* at 653. The *Weeks* fraud claims are substantially indistinguishable from Appellant's fraud-based claims in the proposed SAC.

As in *Weeks,* Appellant's fraud-based claims center on what the Shire Defendants said or did not say, namely, their misrepresentations and omissions in the LIALDA label, respectively. The Alabama court squarely held in *Weeks* that a false statement in a label about how a drug may be safely taken may constitute a misrepresentation and a concealment. *Weeks*, 159 So.3d at 676.

What Appellees *said* in their LIALDA label unquestionably constitutes a misrepresentation of material fact. *Bhandari v. Bittner*, 2004 WL 2284582, *1 (W.D.N.Y Oct. 5, 2004), underscores why Appellant's fraud-based claims are not futile as the District Court concluded. There, the plaintiff alleged that his deceased wife sustained grievous liver damage as a result of taking the defendant's drug, Arava, which ultimately lead to her death. Like Appellant, the *Bhandari* plaintiff

brought strict liability, breach of warranty, fraudulent misrepresentations and fraud claims against the defendant pharmaceutical company. *Bhandari* at *1. The district court initially dismissed plaintiff's fraud-based claims as deficient under Rule 9(b) because it found, among other things, that the plaintiff did "not allege specific statements or misrepresentations". *Bhandari* at *2.

After the plaintiff amended his fraud-based claims to cure the court-determined deficiencies, the defendants again filed a motion for dismissal under both Rules 9(b) and 12(b)(6), which the district court denied. *Bhandari,* 2004 WL 2284582, at *2. The *Bhandari* court found that the plaintiff had adequately specified in his amended complaint the statements that he contended were fraudulent.[15]

See also Garner v. Boehringer Ingelheim Pharmaceuticals, Inc., 888 F.Supp.2d 911, 925 (S.D. Ill. 2012)(one of numerous cases against the manufacturer of Pradaxa® where plaintiffs' fraud, fraudulent concealment, and consumer fraud claims based on the drug's labeling and prescribing information were not preempted

[15] Specifically, the *Bhandari* court stated:

> Plaintiff alleges that the "package insert provides that the liver toxicity effects of the drug were generally reversible, when, in fact, the effects were known [by defendants] not to be reversible" and "[d]efendants knew at the time the package insert was prepared that [the required] loading dose [initiated upon commencement of the taking of the drug] could and would, in patients such as *** [decedent] cause severe and permanent liver damage[.]" These are the statements plaintiff alleges to be fraudulent which gives defendants fair notice of the basis of plaintiff's claim.

Bhandari at *3 (brackets in the original; citations omitted).

and survived motions to dismiss).[16]

Regarding suppression and concealment, the proposed SAC further alleged, and expert testimony underscores, that Shire's misrepresentation and concealment regarding the necessity of Specific Interval Testing are highly material to prescribing physicians and to patients, and, indeed, critical for the health and safety of patients.

Finally, the proposed SAC contained plausible and detailed allegations concerning the reasonable reliance of Appellant's treating physician, Dr. Ferrante, and Appellant on § 5.1's "Warnings and Precautions," and that the defective, unsafe and false representations and concealment regarding "periodic" evaluation, proximately caused Appellant's injuries.

To summarize, (1) FDA regulations and Alabama case law require a drug

[16] The *Garner* court stated:

> The Court further notes, as to the content of the alleged misrepresentations, the plaintiff alleges the Pradaxa Marketing Campaign, as well as Pradaxa's labeling and prescribing information, contained knowing misrepresentations or omissions regarding the safety and efficacy of Pradaxa, including the following: (1) Pradaxa's efficacy and safety in relation to the prescription anticoagulant Warafin; (2) Pradaxa's additional benefits; (3) Pradaxa's allegedly higher risk of serious bleeding; (4) the lack of an effective reversal agent or protocol in the event of a serious bleeding event; (5) the difficulty or impossibility of assessing the level or extent of anticoagulation in patients using Pradaxa; and (6) the safety risks in certain patient populations. The plaintiff also alleges intent to deceive on the part of [defendant] and that both the plaintiff and her prescribing physician were exposed to and deceived by the allegedly deceptive information.

Garner, 888 F.Supp.2d at 925.

manufacturer to include instructions for safe use, including appropriate testing, in a drug label; (2) any label, including its instructions for safe use or "Warnings and Precautions", is a manufacturer's representation of a material fact, namely, how to safely use the drug; and (3) a label that contains erroneous or incomplete instructions for safe use, or defective warnings and precautions, is a misrepresentation of a material fact.[17]

[17]*See, e.g., Rhoton v. 3M Co.,* 2015 WL 7770234, at *3 (N.D. Ala. 2015)(denying defendant manufacturer's motion to dismiss injured plaintiff's fraud-based claims, stating "Because [plaintiff's] fraud claims in Counts Seven, Eight, and Nine are against medical device manufacturers, it would be erroneous for the court to take an overly rigid view of the [Rule 9] formulation. Instead, defendants may be held liable for fraud or misrepresentation (by misstatement or omission) based on information and warning deficiencies on a [device's or] drug's labeling.")(internal citations and quotation marks omitted); *Houston v. Bayer Healthcare Pharmaceuticals, Inc.,* 16 F.Supp.3d 1341, 1350 (N.D. Ala. 2014)("In Alabama, a drug manufacturer may be held liable for fraud or misrepresentation (by misstatement or omission) based on information and warning deficiencies on a drug's labeling)(internal quotation marks omitted); *Brasher v. Sandoz Pharmaceuticals Corp*., 2001 WL 36403362 at *9-11 (N.D. Ala.)(finding a false representation and a suppression in the defendant's drug package insert concerning the drug's purported safety, where the plaintiff produced evidence that the defendant knew but did not disclose a causal relationship between its drug and vasoconstrictive reactions such as ischemic stroke); *In re Tylenol (Acetaminophen) Marketing, Sales Practices and Products Liability Litigation,* 144 F.Supp.3d 699, 721 (E.D. Pa. 2015)(applying Alabama law in denying defendant manufacturer's motion for summary judgment on failure to warn claims where plaintiff offered evidence that the label was deficient).

CONCLUSION

For the forgoing reasons, Appellant Blackburn respectfully requests that this Court reverse the District Court's Order granting summary judgment in favor of Shire and remand the case to the District Court for further proceedings.

CERTIFICATE OF COMPLIANCE

Undersigned counsel certifies that this brief complies with the limitations set forth in Fed. R. App. P. 32(a)(7) and the type-volume limitation. This brief contains 12,754 words.

/s/Jonathan H. Waller
OF COUNSEL

Respectfully submitted,

Jonathan H. Waller
Jonathan H. Waller (WAL073)

OF COUNSEL:

Jonathan H. Waller
Waller Law Office, P.C.
2001 Park Place, Suite 900
Birmingham, AL 35203
jwaller@waller-law.com
(205) 313-7330

Keith Jackson
Keith Jackson (JAC067)

Keith Jackson
RILEY & JACKSON, P.C.
3530 Independence Drive
Birmingham, AL 35209
Telephone: (205) 879-5000
kj@rileyjacksonlaw.com

Attorneys for Plaintiff/Appellant Mark Blackburn

CERTIFICATE OF SERVICE

Pursuant to Rule 25 of the Federal Rules of Appellate Procedure, I hereby certify that I have on this 8th day of September, 2020, served a copy of the foregoing documents electronically through the Court's CM/ECF system on all registered counsel and or via U.S. Mail.

/s/Jonathan H. Waller
Jonathan H. Waller