# IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

DAWN BROWN,

Plaintiff,

CIVIL ACTION NO.

v.

1:06-cv-3074-JEC

ROCHE LABORATORIES, INC. and HOFFMAN-LA ROCHE, INC.,

Defendants.

#### ORDER & OPINION

This case is before the Court on defendants' Motion to Exclude Plaintiff's Expert [143], defendants' Motion for Summary Judgment [144], and plaintiff's Motion for Leave to File an untimely Motion to Exclude Defendants' Experts [160]. The Court has reviewed the record and the arguments of the parties and, for the reasons set out below, concludes that defendants' Motion to Exclude Plaintiff's Expert [143] should be GRANTED, defendants' Motion for Summary Judgment [144] should be GRANTED, and plaintiff's Motion for Leave to File an Untimely Motion to Exclude Defendants' Experts [160] should be DENIED as moot.

### BACKGROUND

This is a pharmaceutical products liability case arising from plaintiff's use of the prescription antibiotics Bactrim and Rocephin in 2004. (Compl. [1].) Plaintiff was prescribed and began taking Bactrim on April 20, 2004 following a diagnosis of a sinus infection by her primary care clinic, Kaiser Permanente Medical Center of Gwinnett ("Kaiser"). (Pl.'s Statement of Material Facts ("PSMF") [148] at 4.) Plaintiff took Bactrim as prescribed for the next fourteen days. (Id.)

On May 3, 2004, plaintiff returned to Kaiser complaining of fever, photophobia, headache, neck pain and blisters in her mouth and throat. (Defs.' Statement of Material Facts ("DSMF") [144] at ¶ 8.) Based on her symptoms, Kaiser Dr. Puvi Seshiah feared that plaintiff had developed bacterial meningitis. (Id. at ¶ 9.) He administered two injections of Rocephin and transferred plaintiff to the Northside Hospital Emergency Room. (Id. at ¶ 10 and PSMF [148] at 5.) Dr. Seshiah was aware that plaintiff's medical records indicated a penicillin allergy, and that there is a possible cross-reactivity between penicillins and Rocephin. (DSMF [144] at ¶ 11.) However, Dr. Seshiah believed that any potential risk was heavily outweighed by the benefits in treating her suspected meningitis. (Id. at ¶ 12.)

On May 4, 2004, plaintiff returned to Kaiser with worsening symptoms. (Id. at  $\P$  13.) At that time, plaintiff's primary care

physician and consulting dermatologist agreed that plaintiff was likely experiencing Stevens-Johnson Syndrome ("SJS") rather than bacterial meningitis. (Id. at ¶ 14.) SJS is a rare and lifethreatening drug reaction that causes blistering of the mucous membranes and epidermal necrosis. (Defs.' Br. [144] at 2 and Compl. [1] at ¶ 32.) On May 5, 2004, plaintiff was admitted to Grady Memorial Hospital with a confirmed diagnosis of SJS and an additional diagnosis of Toxic Epidermal Necrolysis ("TEN"), a more severe form of SJS. (PSMF [148] at 5.)

Plaintiff subsequently filed this action in Fulton County State Court against the manufacturers of Rocephin and Bactrim asserting various product liability and other state law claims. (Compl. [1] at ¶¶ 4-12, 60-119.) The manufacturer defendants jointly removed the case to the Northern District of Georgia on the ground of diversity jurisdiction.¹ (Notice of Removal [1] at 2.) Thereafter, plaintiff abandoned her claims against the Bactrim defendants. (Pl.'s Mot. for Voluntary Dismissal of Certain Defendants [119].)

After several delays, plaintiff and the remaining Rocephin defendants completed fact and expert discovery in January, 2013.

(Am. Scheduling Order [132].) Following discovery, defendants filed

Plaintiff is a Georgia resident and defendants are Delaware and New Jersey corporations. (Notice of Removal [1] at 4-5.) Plaintiff seeks damages in excess of \$75,000. (*Id.* at 5-7.) The Court thus has jurisdiction over the case under 28 U.S.C. § 1332.

a Daubert motion to exclude plaintiff's causation expert and a motion for summary judgment. (Defs.' Mot. to Exclude [143] and Mot. for Summ. J. [144].) Both of those motions, as well as plaintiff's request for leave to file an untimely motion to exclude defendants' experts, are now before the Court. (Pl.'s Mot. for Leave [160].)

#### DISCUSSION

## I. DEFENDANTS' DAUBERT MOTION

In support of her product liability claims, plaintiff seeks to present the expert testimony of Dr. Manfred Wolff. (Wolff Aff. [118].) Dr. Wolff opines that: (1) the drug Rocephin most likely caused plaintiff's SJS/TEN, and (2) Rocephin's warning label concerning administration of the drug to penicillin-sensitive patients was ineffective. (Id. at 12.) Defendants contend that Dr. Wolff is not qualified to render those opinions, and that his opinions are not sufficiently reliable to meet the standards of admissibility set forth in Rule 702 of the Federal Rules of Evidence and Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

In *Daubert*, the Supreme Court concluded that Rule 702 governs the admissibility of scientific expert testimony. *Daubert*, 509 U.S. at 588. Rule 702 states that a witness who is "qualified as an expert" may provide opinion testimony if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine

a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702. Pursuant to Rule 702, expert testimony is admissible when: (1) the expert is qualified to testify competently, (2) the expert's methodology is reliable, and (3) the expert's testimony will assist the trier of fact to understand the evidence or to determine a fact in issue in the case. Guinn v. AstraZeneca Pharm. LP, 602 F.3d 1245, 1252 (11th Cir. 2010). See also Allison v. McGhan Med. Corp., 184 F.3d 1300, 1309 (11th Cir. 1999)(applying Daubert).

The Daubert Court emphasized the district court's "gatekeeping" role to ensure that expert testimony is relevant and reliable before it is admitted as evidence. Daubert, 509 U.S. at 589. See also Hudgens v. Bell Helicopters/Textron, 328 F.3d 1329, 1342 (11th Cir. 2003) (noting "the repeated emphasis the Supreme Court has placed upon the district court's 'gatekeeping' role in the determination of whether expert evidence should be admitted"). The overarching goal of Daubert's gatekeeping requirement is to ensure that an expert "'employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1335 (11th Cir. 2010) (citing Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 152 (1999)).

The proponent of expert testimony bears the burden of demonstrating that the testimony meets each of the requirements of Rule 702. Hendrix ex rel. G.P. v. Evenflo Co., Inc., 609 F.3d 1183, 1194 (11th Cir. 2010). See also McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1238 (11th Cir. 2005) ("[t]he burden of establishing qualification, reliability, and helpfulness rests on the proponent of the expert opinion"). As discussed below, plaintiff has not met her burden of showing that Dr. Wolff is qualified to render the opinions offered in his Affidavit, or that his opinions are reliable. Accordingly, the Court GRANTS defendants' motion to exclude [143].

# A. <u>Dr. Wolff's Qualifications</u>

In support of his qualification as an expert, plaintiff refers to Dr. Wolff's Affidavit and CV indicating that he has a Ph.D. in pharmaceutical chemistry and extensive research and patent experience in the general area of pharmaceuticals. (Pl.'s Resp. to Mot. to Exclude [147] at 13.) However, Dr. Wolff's Affidavit and CV do not reveal any particular expertise concerning the drugs at issue in this case or their connection with SJS/TEN, as would be required to support Dr. Wolff's medical causation opinion. (Wolff Aff. [118] and Ex. A.) Nor is there any evidence that Dr. Wolff is sufficiently knowledgeable about FDA regulatory practice and requirements to render an expert opinion as to the efficacy of the Rocephin warning label.

In fact, Dr. Wolff's lack of experience in both areas is apparent from his deposition testimony. Dr. Wolff admitted during his deposition that he has only a basic familiarity with Rocephin or Bactrim, and that he has not conducted any research or published any articles concerning either of those drugs. (Wolff Dep. [143] at 11-12.) Dr. Wolff further conceded that he done no research on SJS/TEN, and has not been involved in any field work related to the treatment of those conditions or the drugs alleged to cause them. (Id. at 19-20, 24.) An important issue in this case is whether plaintiff's SJS/TEN was caused by the Rocephin that her doctor administered on May 3, 2004, or instead by the course of Bactrim that she had just Remarkably, Dr. Wolff appeared to be completed on that date. unaware, until he was presented with an article on the topic during his deposition, that Bactrim has a much higher relative risk than Rocephin for the onset of SJS/TEN. (Id. at 75-76.)

As to his regulatory training and experience, Dr. Wolff acknowledged in his deposition that he has never consulted with the FDA regarding the content of a drug package insert. (Id. at 58.) Although he vaguely recalled contributing to the parts of an insert that describe the chemical and pharmacological properties of a drug, he admitted that he has no experience drafting insert warnings. (Id. at 58-59.) According to Dr. Wolff, that type of drafting would be done by the "regulatory affairs" division of a pharmaceutical

company. (Wolff Dep. at 58.) Dr. Wolff conceded that he has no training or practical experience in "regulatory affairs." (Id. at 58-60.)

That Dr. Wolff has a Ph.D. and experience in the general area of pharmaceutical chemistry is insufficient, in and of itself, to qualify him as either a medical causation or a labeling expert in this case. See United States v. Brown, 415 F.3d 1257, 1269 (11th Cir. 2005)(upholding the district court's refusal to qualify an expert with a Ph.D. in plant pathology because he had only worked with the substance at issue in the case on "isolated projects") and In re Trasylol Prod. Liab. Litig., No. 08-MD-01928, 2011 WL 7109297, at \*6 (S.D. Fla. Apr. 27, 2011)(the plaintiff's doctor was "not an expert on FDA regulations and labeling" and was therefore "not qualified to opine on this subject"). Based on his CV and deposition testimony, the Court finds that Dr. Wolff is not qualified to render either of the opinions that are asserted in his expert Affidavit.

# B. <u>Dr. Wolff's Reliability</u>

In addition, Dr. Wolff's medical causation opinion is not sufficiently reliable to be admitted under Rule 702 and the standards of *Daubert*. Even a "'supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based on some recognized scientific method.'" *McDowell v. Brown*, 392 F.3d 1283, 1298 (11th Cir. 2004)(citing *Clark v. Takata Corp.*, 192 F.3d

750, 759 (7th Cir. 1999)). To fulfill its gatekeeper obligation under *Daubert*, the Court must ensure that scientific evidence is "the product of reliable principles and methods" and "must screen out 'expert' testimony that is not sufficiently . . . trustworthy for the factfinder to consider." *Brown*, 415 F.3d at 1266-67.

The Supreme Court has identified several non-exclusive factors that a court may consider when evaluating the reliability of an expert opinion, including: (1) whether the opinion can be and has been empirically tested, (2) whether the opinion has been subjected to peer review and publication, (3) the known or potential error rate of the opinion, and (4) whether the opinion is generally accepted in the field. Daubert, 509 U.S. at 593-95. The pertinence of these factors in any given case "depends on the nature of the issue, the expert's particular expertise, and the subject of his testimony." Brown, 415 F.3d at 1268 (citing Kumho Tire, 526 U.S. at 150). The Supreme Court has emphasized that the factors should be applied flexibly. Kumho Tire, 526 U.S. at 141.

None of the reliability factors instill confidence in Dr. Wolff's causation opinion. Dr. Wolff admitted during his deposition that plaintiff had been exposed to both Rocephin and Bactrim during the relevant time frame, and that either drug can cause SJS/TEN. (Wolff Dep. at 63, 76.) In his Affidavit, Dr. Wolff summarily stated that Rocephin was likely the precipitating factor in plaintiff's

case. (Wolff Aff. [118] at 12.) However, there is no indication that Dr. Wolff tested his opinion or estimated its potential error rate. (Wolff Dep. at 24, 62-63.) Neither did he publish the opinion or otherwise subject it to peer review. (Id. at 12.) As to general acceptance in the field, the only available evidence suggests that Bactrim is more likely to cause SJS/TEN than Rocephin. (Id. at 76.)

In addition, it is evident that Dr. Wolff ignored or dismissed highly relevant and unfavorable evidence in reaching his causation Immediately after she finished her two-week course of opinion. Bactrim and prior to being prescribed Rocephin, plaintiff returned to her doctor complaining of fever, photophobia, headache, neck pain and blisters in her mouth and throat. (DSMF [144] at  $\P$  8.) symptoms are well-known early indicators of SJS, and they were exhibited by plaintiff during the typical one to four-week latency period for the onset of SJS after exposure to a precipitating drug. (Defs.' Mot. to Exclude [143] at Ex. F.) The record evidence thus suggests that plaintiff was already suffering from the initial symptoms of SJS when she ingested Rocephin, and that her SJS was most likely caused by Bactrim. Yet, Dr. Wolff did not rule out or meaningfully address that possibility in reaching his causation opinion. (Wolff Aff. [118] and Wolff Dep. at 40-45.)

Daubert's reliability inquiry is focused on the methodology underlying an expert's opinions. Kilpatrick, 613 F.3d at 1341. Dr.

Wolff's "methodology" consists solely of pointing out a supposed temporal relationship between plaintiff's ingestion of Rocephin and the onset of her SJS/TEN symptoms. (Wolff Dep. at 33-34.) Even a strong temporal connection is "generally not a reliable indicator of a causal relationship." Guinn, 602 F.3d at 1254. Especially is that so in this case, where the undisputed evidence suggests that plaintiff's SJS symptoms preceded her ingestion of Rocephin. Given the obvious lack of both a sound methodology and evidentiary support in the record, and in consideration of the applicable reliability factors, the Court finds that Dr. Wolff's opinions "lack the indicia of reliability necessary to survive a Daubert inquiry and challenge under Rule 702." McClain, 401 F.3d at 1240.

#### II. DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Defendants contend that without Dr. Wolff's testimony, plaintiff's product liability claims fail as a matter of law. (Defs.' Mot. for Summ. J. [144].) The parties agree that plaintiff's claims are governed by Georgia law. See Grupo Televisa, S.A. v. Telemundo Commc'n Grp., Inc., 485 F.3d 1233, 1240 (11th Cir. 2007)(a federal court sitting in diversity applies the conflicts rules of its forum state to determine which state law applies) and Bullard v. MRA Holding, LLC, -- S.E.2d --, No. S12Q2087, 2013 WL 1247976, at \*2 (Ga. Mar. 28, 2013)("for over 100 years, the state of Georgia has followed the doctrine of lex loci delicti in tort cases"). According to

defendants, plaintiff cannot maintain a product liability action under Georgia law without supporting expert testimony. (Defs.' Br. [144] at 10.) Defendants also argue that (1) plaintiff's failure to warn claim is barred by the learned intermediary doctrine and (2) any remaining state law claims are either derivative of the product liability claims or otherwise baseless. (Id. at 13-22.)

## A. <u>Summary Judgment Standard</u>

Summary judgment is appropriate when the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). A fact's materiality is determined by the controlling substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). An issue is genuine when the evidence is such that a reasonable jury could return a verdict for the nonmovant. Id. at 249-50.

Summary judgment is not properly viewed as a device that the trial court may, in its discretion, implement in lieu of a trial on the merits. Instead, Rule 56 of the Federal Rules of Civil Procedure mandates the entry of summary judgment against a party who fails to make a showing sufficient to establish the existence of every element essential to that party's case on which that party will bear the burden of proof at trial. Celotex Corp. v. Catrett, 477 U.S. 317,

322 (1986). In such a situation, there can be no genuine issue as to any material fact, as a complete failure of proof concerning an essential element of the non-moving party's case necessarily renders all other facts immaterial. *Id.* at 322-23 (quoting FED. R. CIV. P. 56(c)).

The movant bears the initial responsibility of asserting the basis for his motion. Id. at 323. However, the movant is not required to negate his opponent's claim. The movant may discharge his burden by merely "'showing' -- that is, pointing out to the district court--that there is an absence of evidence to support the non[-]moving party's case." Id. at 325. After the movant has carried his burden, the non-moving party is then required to "go beyond the pleading" and present competent evidence designating "'specific facts showing that there is a genuine issue for trial.'" Id. at 324. While the court is to view all evidence and factual inferences in a light most favorable to the non-moving party, Samples v. City of Atlanta, 846 F.2d 1328, 1330 (11th Cir. 1988), "the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Anderson, 477 U.S. at 247-48 (1986).

# B. <u>Product Liability Claims</u>

In Counts I and II of the complaint, plaintiff asserts product liability claims based on theories of negligence and strict liability. (Compl. [1] at ¶¶ 60-84.) Whether proceeding in negligence or strict liability, "[t]he sine qua non of a product[] liability claim . . . is a defect in the product." Boswell v. OHD Corp., 292 Ga. App. 234, 235 (2008). Plaintiff also must prove that there is a causal connection between the alleged defect and her injury. Id. Disregarding Dr. Wolff's testimony, there is insufficient evidence to create a material issue of fact as to either of these essential elements. The Court thus GRANTS defendants' motion for summary judgment [144] as to Counts I and II.

# 1. <u>Evidence of a Defect</u>

Plaintiff vaguely states in her response that the Rocephin she received in May, 2004 was "not of merchantable quality, nor fit for [its] intended use." (Pl.'s Resp. [148] at 6.) However, plaintiff does not present any evidence of a defect in the "merchantability" or "fitness" of Rocephin generally or of the specific dose of Rocephin that she received. In fact, even Dr. Wolff recognized that there was no evidence that Rocephin is defectively designed or that the particular batch of Rocephin that plaintiff ingested was defectively manufactured. (Wolff Dep. at 77-78.)

The only potential defect that Dr. Wolff identified concerns the Rocephin label. (Id.) According to Dr. Wolff, the label "does not clarify to the medical practitioner . . . the cautionary procedures that need to be followed prior to determining whether it is appropriate to administer Rocephin to a penicillin-sensitive patient." (Wolff Aff. [118] at 12.) Given Dr. Wolff's testimony, and the lack of evidence to establish any other kind of defect, it appears that plaintiff's product liability claim is based solely on a failure to warn theory. See Daniels v. Bucyrus-Erie Corp., 237 Ga. App. 828, 829-30 (1999)(describing the difference between failure to warn and design and manufacturing defect claims).

During the relevant time period, the Rocephin label contained the following statement:

WARNINGS: BEFORE THERAPY WITH ROCEPHIN® IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICILLINS OR OTHER DRUGS. THIS PRODUCT SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. ANTIBIOTICS SHOULD BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS DEMONSTRATED SOME FORM OF ALLERGY, PARTICULARLY TO DRUGS.

(Wolff Aff. [118] at ¶ 16.) Dr. Wolff's conclusion that this warning is somehow "vague" or "ambiguous" is questionable. (Id. at ¶ 17.) But in any case, Dr. Wolff is not qualified by education or experience to render an expert opinion as to the efficacy of Rocephin's FDA-mandated warning label. Accord In re Trasylol Prod.

Liab. Litig., 2011 WL 7109297, at \*6 (disqualifying a doctor who was "not an expert on FDA regulations and labeling"). Plaintiff does not offer any other evidence to support her claim that the Rocephin warning label is inadequate.

# 2. <u>Causation</u>

Neither does plaintiff offer any evidence other than Dr. Wolff's conclusory and unsubstantiated opinion to establish causation. prevail on her product liability claim, plaintiff must establish both general and specific causation. Toole v. Georgia-Pacific, LLC, No. A10A2179, 2011 WL 7938847, at \*8 (Ga. App. Jan. 19, 2011). See also Butler v. Union Carbide Corp., 310 Ga. App. 21, 25 (2011)(distinguishing between general and specific causation). plaintiff must prove both that Rocephin "is capable of causing" SJS/TEN in the general population and that Rocephin in fact caused plaintiff's SJS/TEN. Id. at 25. General causation is not a problem here because defendants do not dispute that Rocephin is capable of causing SJS/TEN. (Defs.' Br. [144] and Mot. to Exclude [143] at 19-20.) But having excluded Dr. Wolff's testimony, there is no evidence from which a jury could rationally conclude that Rocephin caused plaintiff's SJS/TEN in this particular case.

As discussed above, it is undisputed that plaintiff had just completed a two-week course of Bactrim when she ingested Rocephin. (DSMF [144] at  $\P$  7.) Bactrim is known to be associated with SJS/TEN

and in fact has a higher relative risk for the onset of SJS/TEN than Rocephin. (Defs.' Mot. to Exclude [143] at 19 and Ex. D.) Plaintiff's medical records indicate that she was likely experiencing the initial symptoms of SJS when she returned to the Kaiser Clinic and was prescribed Rocephin. (DSMF [144] at ¶ 8.)

Under the circumstances, that Rocephin caused plaintiff's SJS/TEN "is not a natural inference that a juror could make through human experience." Allison, 184 F.3d at 1320 (applying Georgia product liability law). Expert testimony is therefore essential to establish causation in this case. Id. See also Wilson v. Taser Int'l, Inc., 303 Fed. App'x 708, 715 (11th Cir. 2008)("In product liability cases, proof of causation generally requires reliable expert testimony"(citing Rodrigues v. Georgia-Pacific Corp., 290 Ga. App. 442 (2008)). Again, the only expert testimony plaintiff proffers is the excluded opinion of Dr. Wolff.

In addition, and as an alternative ground for summary judgment, any inference of causation on plaintiff's failure to warn claim is precluded by the learned intermediary doctrine. Under the learned intermediary doctrine, a manufacturer has a duty to warn the patient's doctor of the dangers associated with a prescription drug rather than the patient herself. Talton v. Arnall Golden Gregory, LLP, 276 Ga. App. 21, 27 (2005). The doctor acts as a learned intermediary between the patient and the manufacturer, the rationale

being that the doctor is in the best position to warn the patient of any medical risks associated with the drug. *Id*.

To invoke the protection of the learned intermediary doctrine, a manufacturer ordinarily must provide an adequate warning of the alleged risk to the plaintiff's doctor. Id. However, where the doctor has actual knowledge of the risk and would have taken the same course of action even with the warning that plaintiff claims should have been provided, the learned intermediary doctrine bars recovery. Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1363-64 (N.D. Ga. 1999)(Story, J.). See also Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1283 (11th Cir. 2002) (under Georgia law, the learned intermediary doctrine applies where the doctor is independently aware of the risks or the risks are well-known to the medical community). In such a case, the learned intermediary doctrine breaks any causal link between the alleged failure to warn and the plaintiff's injury. Wheat, 46 F. Supp. 2d at 1363-64.

Plaintiff claims that she was injured as a result of defendants' failure to provide an adequate warning concerning the administration of Rocephin to penicillin-sensitive patients. (Pl.'s Resp. [148] at 23-25.) It is undisputed that plaintiff's prescribing physician Dr. Seshia was aware both of plaintiff's reported penicillin sensitivity and of the possible cross-reactivity between penicillins and Rocephin. (DSMF [144] at ¶ 11.) He nevertheless administered

Rocephin to plaintiff because he believed that any risk associated with the drug was heavily outweighed by the benefits of treating what he suspected was bacterial meningitis, a potentially fatal condition. (Id. at ¶ 12.) Given Dr. Seshia's actual knowledge of the risk presented by Rocephin and his considered decision to prescribe the drug in spite of the risk, the learned intermediary doctrine precludes a finding of causation and bars plaintiff's recovery in this case. Wheat, 46 F. Supp. 2d at 1363-64 and Ellis, 311 F.3d at 1283.

## C. Remaining Claims

## 1. Breach of Warranty and Misrepresentation

In Counts III, IV and V, plaintiff asserts claims for breach of warranty and fraudulent and negligent misrepresentation. (Compl. [1] at ¶¶ 85-119.) Based on the arguments presented in plaintiff's response brief, these Counts appear to be merely a reframing of plaintiff's failure to warn claim. (Pl.'s Resp. [148] at 23-27.) To the extent that is the case, summary judgment on Counts III, IV and V is **GRANTED** for the reasons discussed above.

In the interest of caution, the Court also notes that plaintiff has not produced any evidence to support a stand-alone breach of warranty or misrepresentation claim. Plaintiff fails to allege or prove privity, a required element of a breach of warranty claim under Georgia law. See Cobb Cnty. Sch. Dist. v. MAT Factory, Inc., 215 Ga.

App. 697, 702 (1994)(applying the privity requirement) and Bryant v. Hoffmann-La Roche, Inc., 262 Ga. App. 401, 411 (2003)(affirming summary judgment in favor of the defendant pharmaceutical company on an implied warranty claim, citing a lack of privity). Plaintiff's allegations concerning fraudulent and negligent misrepresentation are similarly lacking as to the essential elements of either claim, and do not come close to meeting the special pleading requirements of Federal Rule 9(b). See Thompson v. Floyd, 310 Ga. App. 674, 683 (2011)(describing the elements of a claim for fraud under Georgia law) and Fed. R. Civ. P. 9(b)(requiring a plaintiff to "state with particularity the circumstances constituting fraud"). For these additional reasons, defendants' motion for summary judgment [144] is GRANTED as to Counts III, IV and V of the complaint.

## 2. Damages, Punitive Damages, and Joint Liability

In Counts VI, VII and VIII, plaintiff asserts claims titled "Joint and Several Liability," "Plaintiff's Damages" and "Punitive Damages." (Compl. [1] at ¶¶ 120-125.) These claims are derivative of plaintiff's substantive claims. See Racette v. Bank of Am., N.A., 318 Ga. App. 171, 181 (2012)("An award of . . . punitive damages is derivative of a plaintiff's substantive claims") and Lilliston v. Regions Bank, 288 Ga. App. 241, 246 (2007)(holding that plaintiff's claim for damages was properly dismissed as derivative of the substantive tort claims in the case). In light of the Court's ruling

on plaintiff's product liability and other substantive state law claims, defendants' motion for summary judgment [144] is **GRANTED** as to Counts VI, VII and VIII.

## CONCLUSION

For the foregoing reasons, the Court GRANTS defendants' Motion to Exclude Plaintiff's Expert [143], GRANTS defendants' Motion for Summary Judgment [144], and DENIES as moot plaintiff's Motion for Leave to File an untimely Motion to Exclude Defendants' Experts [160]. The clerk is directed to CLOSE this case.

SO ORDERED, this 6th day of June, 2013.

/s/ Julie E. Carnes

JULIE E. CARNES

CHIEF UNITED STATES DISTRICT JUDGE