IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: LIPITOR (ATORVASTATIN CALCIUM) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	**MDL No. 2:14-mn-02502-RMG** **CASE MANAGEMENT ORDER NO. 96** **This Order relates to:** *Wilma Daniels v. Pfizer, Inc.*, Case No. 2:14-cv-01400

Before the Court is Defendant's motion for summary judgment in this bellwether case, (Dkt. No. 1562).[1] For the reasons stated below, the motion is GRANTED.

I. Background

A. Procedural History

On February 18, 2014, the Judicial Panel on Multidistrict Ligation created this MDL, centralizing cases where female plaintiffs "allege that they have developed type 2 diabetes as a result of taking Pfizer's cholesterol-lowering drug Lipitor." (Dkt. No. 1 at 1). Plaintiffs allege that Defendant failed to warn physicians and consumers adequately of the risk of developing Type 2 diabetes from taking Lipitor, knew or should have known that taking Lipitor increased the risk of developing Type 2 diabetes, and negligently, recklessly, and carelessly marketed Lipitor without adequate instructions or warnings. (*See id.*, Dkt. No. 160). Plaintiff Daniels filed her action on February 25, 2014, alleging that Lipitor caused her to develop Type 2

[1] Unless otherwise stated, the docket numbers in this Order refer to the MDL Docket, Case No. 2:14-cv-2502.

Diabetes, (Case No. 2:14-cv-01400, Dkt. No. 1), and her case was transferred to this MDL on April 17, 2014. (Case No. 2:14-cv-01400, Dkt. No. 7).

Under Amended CMO 6, the Plaintiffs' Steering Committee (PSC) and Defendant each selected seven (7) cases for the Discovery Pool in June of 2014. (Dkt. No. 148 at 4). Defendant selected this case for the Discovery Pool, and case-specific discovery was conducted in this case in the summer and fall of 2014 concurrently with common discovery in the MDL. (*See id.* at 5).

On January 30, 2015, the Court convened the parties to randomly select the first cases for bellwether trials.[2] (Dkt. No. 739). This case was selected as the first bellwether trial. (*Id.*). Thereafter, the parties conducted additional case-specific discovery in this case as well as in *Hempstead v. Pfizer*, Case No. 2:14-cv-01879, the second case selected for trial. (*See* CMO 29, Dkt. No. 746; CMO 30, Dkt. No. 790). The parties also continued to conduct common discovery.

From the beginning of this MDL, the parties have agreed that Plaintiffs must prove both general and specific causation as elements of their claims. (*See, e.g.*, Dkt. No. 1634 at 28 (describing general and specific causation as "two different elements")). General causation is whether a substance is capable of causing a particular injury or condition (in this instance, whether Lipitor is capable of causing diabetes); specific causation is whether the substance caused the injury of the particular plaintiff at issue (in this instance, whether Lipitor caused Ms. Daniels' diabetes). *E.g., Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005). "Plaintiff[s] must first demonstrate general causation because without general causation, there can be no specific causation." *Id.* Here, if Lipitor is not capable of causing diabetes, it follows that it is not the cause of diabetes in particular plaintiffs.

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[2] By stipulation, the parties narrowed the fourteen (14) Discovery Pool cases to four (4) cases. The Court then randomly selected the first bellwether trials from these four (4) cases.

The parties served common expert disclosures, including general causation experts, in March and April of 2015. (*See* CMO 29, Dkt. No. 746). Over Defendant's objection, the Court allowed Plaintiffs to supplement these disclosures in May of 2015 "to ensure this Court has the best information possible when addressing *Daubert* motions." (CMO 34, Dkt. No. 869 at 2). The parties then served specific causation expert disclosures in the two bellwether cases, including this one, in May and June of 2015. (*See* CMO 29, Dkt. No. 746; CMO 34, Dkt. No. 869). The Court allowed Plaintiffs to serve a rebuttal report by one of these case specific experts, again over Defendant's objection. (*See* CMO 38, Dkt. No. 967).

After full discovery, Defendant filed motions to exclude Plaintiffs' general causation expert testimony as well as Plaintiffs' specific causation expert testimony in the two bellwether cases. (Dkt. Nos. 972, 1004, 1006). As explained in more detail below, the Court ultimately excluded Plaintiffs' expert testimony on general causation with respect to dosages of less than 80 mg. (*See* CMO 49, Dkt. No. 1197; CMO 68, Dkt. No. 1469). Because Plaintiff Daniels was prescribed and ingested 40 mg of Lipitor prior to her diabetes diagnosis, (Dkt. No. 1562-1at 5), she has no admissible expert testimony regarding general causation in her case.

The Court also excluded the expert testimony of Plaintiffs' specific causation experts, including Plaintiff Daniels' only expert with regard to specific causation, Dr. David Handshoe. (CMO 55; Dkt. No. 1283; CMO 76, Dkt. No. 1517). Defendant has now moved for summary judgment on the basis that Plaintiff Daniels cannot establish general and specific causation. (Dkt. No. 1562). Plaintiff Daniels has filed a response, and Defendant has filed a reply. (Dkt. Nos. 1587, 1606).

B. The Court's *Daubert* Rulings

1. General Causation

On September 24-25, 2015, the Court heard extended oral argument on Defendant's motions to exclude common expert witnesses, including Plaintiffs' general causation experts. (Dkt. Nos. 1147, 1148). One of the primary issues raised both in briefing and at oral argument was the importance of dosage.

Lipitor is prescribed in four different doses: 10 mg, 20 mg, 40 mg, and 80 mg. Plaintiffs' general causation experts initially "opine[d] that Lipitor can cause diabetes, without specifying the precise dose at which this effect begins." (Dkt. No. 1159 at 26). If a study suggested an increased risk of diabetes, the experts "ascribe[d] the risk to all doses." (*E.g.*, Dkt. No. 972 at 269). However, Pfizer argued that "[d]ose is critical to proving general causation," and that Plaintiffs lacked reliable evidence that Lipitor causes diabetes at doses less than 80 mg. (*Id.* at 49).

After reviewing the studies relied on by the experts and their opinions, the Court was concerned about whether Plaintiffs' experts had sufficient facts and data to support their causation opinions at all doses of Lipitor, and even whether the experts would be willing to offer an opinion at low doses, given the available data. *See In re Seroquel Products Liab. Litig.*, No. 6:06-MD-1769-ORL-22D, 2009 WL 3806434, at *18 (M.D. Fla. June 18, 2009) (Expert offering a causation opinion "declined to even speculate" about doses of 12.5 and 25 milligrams "because she had not seen any studies evaluating doses that low."); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1175-76 (N.D. Cal. 2007) ("It is unsurprising that most of plaintiffs' experts agree that the available evidence at 200 mg/d [as opposed to higher doses] is inadequate to prove causation."). The Plaintiffs' experts agreed, and

some even emphatically argued, that there was a dose-response relationship, meaning that any risk of diabetes is higher at higher doses of Lipitor, and the data with regard to 80 mg of Lipitor was starkly different from the data with regard to 10 mg of Lipitor.[3] Thus, the Court ordered supplemental briefing on this issue. (Dkt. No. 1149).

After a thorough review of relevant caselaw and the expert opinions at issue, the Court issued an order on October 22, 2015, holding that "at least where the experts agree that there is a dose-response relationship and where there is evidence that an association no longer holds at low doses, dose certainly matters, and Plaintiffs must have expert testimony that Lipitor causes, or is capable of causing, diabetes at particular dosages." (CMO 49, Dkt. No. 1197 at 11). Over Defendant's strenuous objections, the Court re-opened expert discovery and allowed additional time for Plaintiffs to serve supplemental reports offering opinions as to whether Lipitor causes diabetes at dosages of 10 mg, 20 mg, 40 mg, and 80 mg. (*See id.*). The parties served supplemental expert reports on general causation in December of 2015 and January of 2016, and then filed supplemental briefs on Pfizer's motion to exclude Plaintiffs' general causation expert testimony in February of 2016. (*See* CMO 50, Dkt. No. 1230; CMO 60, Dkt. No. 1318). The Court heard additional oral argument on March 18, 2016. (Dkt. No. 1460).

In a forty-page order issued on March 30, 2016, the Court ultimately excluded Plaintiffs' expert opinions on general causation, except for the opinion of Plaintiffs' epidemiologist, Dr. Singh, that Lipitor 80 mg causes diabetes. (CMO 68, Dkt. No. 1469). The Court found Dr. Singh's 10 mg opinion was not based on sufficient facts and data and that Dr. Singh did not reliably apply the epidemiological/Bradford Hill method because this method requires a statistically significant association be established through studies and such studies do not exist

[3] *See* CMO 68, Dkt. No. 1469, for a full description of the data and studies relied upon by Plaintiffs' experts.

for Lipitor 10 mg. (Dkt. No. 1469 at 15-16). Plaintiffs conceded that Dr. Singh could not offer an opinion at Lipitor 20 mg or Lipitor 40 mg if the Court excluded his opinion regarding Lipitor 10 mg. (*Id.* at 24).

The Court also excluded the opinions of Dr. Quon, an endocrinologist who ostensibly reached his conclusion via a literature review but who admittedly cherry-picked studies to support his conclusion rather than considering the totality of the literature, (*id.* at 27-34); Dr. Roberts, a cardiologist, who claimed in her report to use the Bradford Hill method used by epidemiologists but who seemed to misunderstand the methodology's basic premise in deposition, who cherry-picked studies for consideration and failed to consider contrary evidence, and who failed to provide any analysis of particular dosages as required by CMO 49, (*id.* at 34-38); and Dr. Gale, who failed to provide any analysis of particular dosages as required by CMO 49 and who ascribed the risk observed at Lipitor 80 mg to all dosages of Lipitor. (*Id.* at 38-39). Thus, the only admissible opinion on general causation is Dr. Singh's opinion regarding Lipitor 80 mg.

2. Specific Causation

Diabetes is a complicated and progressive disease, and a number of factors, including genetics, diet, exercise, age, and weight play a significant role in the development of new onset diabetes. (*See, e.g.*, Dkt. No. 972 at 16-22, Dkt. No. 1047 at 9-12; Dkt. No. 1004-3 at 325-26). This makes teasing out the role of Lipitor, if there is one, in the development of a particular patient's diabetes difficult. Interestingly, none of Plaintiffs' general causation experts could think of a method to determine whether a particular patient's diabetes was caused by Lipitor or caused by other risk factors and testified that they themselves could not determine whether a particular patient's diabetes was caused by Lipitor. There are simply no tests, presenting

symptoms, or other known indicators for identifying persons whose diabetes was caused by Lipitor versus the many other risk factors for the disease. Plaintiffs' specific causation experts have never diagnosed a patient with Lipitor-induced (or statin-induced) diabetes outside of this litigation, and they could not identify anyone else who applied their methodologies to do so outside of this litigation.

Plaintiffs in this MDL are not the first to grapple with the problems of proving causation where the alleged injury is a complicated, progressive, multi-factor disease like diabetes. The Seroquel MDL also grappled with this problem. In *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245 (11th Cir. 2010), a bellwether case, the plaintiff claimed that the drug Seroquel caused her to develop diabetes, and the Eleventh Circuit upheld the exclusion of her expert testimony on causation. The expert first testified that "she knew of no methodology for ruling out alternative causes [of diabetes]" and then later testified that other potential causes were "not solely responsible" because plaintiff developed diabetes after taking Seroquel while other risk factors remained constant. *Id.* at 1249-50. The Eleventh Circuit held that this reliance on temporal proximity did not "satisfy the requirement that a differential diagnosis consider possible alternative causes." *Id.* at 1254. The Eleventh Circuit also rejected the expert's second explanation that all risk factors work together to cause diabetes, holding that "[a]n expert . . . cannot merely conclude that all risk factors for a disease are substantial contributing factors in its development." *Id.* at 1255.

Similarly, in *Haller v. AstraZeneca Pharm.* LP, 598 F. Supp. 2d 1271 (M.D. Fla. 2009), another bellwether case, the plaintiff claimed Seroquel caused her to develop diabetes. Again, plaintiff's expert could not rule out other possible causes of diabetes or the possibility that these other risk factors were solely to blame. *Id.* at 1278, 1278-79. The court held that temporal

connection is legally insufficient and the last additive factor argument was "largely temporal proximity in disguise." *Id.* at 1297-98. These same issues surfaced with Plaintiffs' specific causation experts in this MDL.

Plaintiff Daniels proffered the testimony of Dr. David Handshoe on the issue of specific causation. Plaintiff Hempstead, the second bellwether Plaintiff, proffered the testimony of both Dr. Handshoe and Dr. Murphy on the issue of specific causation. Pfizer moved to exclude the testimony of both experts, (Dkt. Nos. 1004, 1006), and the Court held two separate days of oral argument on these motions in October and December of 2015. (Dkt. Nos. 1196, 1273).

On December 11, 2015, the Court issued a twenty-eight-page order excluding the testimony of Dr. Murphy in the *Hempstead* case. (CMO 55, Dkt. No. 1283). On May 11, 2016, the Court issued CMO 76, excluding the testimony of Dr. Handshoe in both this case and the *Hempstead* case. Dr. Handshoe, the only specific causation expert in this case, testified that the best estimate of the relative risk ratio for diabetes associated with statin use is 1.25. (Dkt. No. 1004-6 at 238-39). Using this estimate of relative risk, 80% of the people who take Lipitor and develop diabetes would have done so *in the absence of Lipitor*, whereas 20% of the people who take Lipitor and develop diabetes did so only because they took Lipitor.[4] Thus, the Court turned to Dr. Handshoe's methodology for concluding that Plaintiffs Daniels and Hempstead were in the 20% that developed diabetes due to Lipitor, rather than the 80% that would have done so regardless. (Dkt. No. 1517 at 7-8). Interestingly, Dr. Handshoe testified that if he walked into a room of 100 patients with diabetes, he could not pick out which ones would have "statin induced diabetes" as opposed to "non-statin induced diabetes." (Dkt. No. 1004-6 at 163). He testified he

[4] For an in depth discussion of relative risk and its implications, see CMO 76, Dkt. No. 1517.

could not do this with ten people or with two people. (*Id.*). Thus, the Court was curious how he accomplished it in the cases of Ms. Daniels and Ms. Hempstead.

With regard to Ms. Daniels, Dr. Handshoe did not rule out Plaintiff Daniels' obesity, adult weight gain, and family history as causes of her diabetes. (Dkt. Nos. 1004-7 at 9; Dkt. No. 1004-6 at 199). He simply did not consider other risk factors that he testified were recognized and significant risk factors for diabetes, including hypertension, hypolipidemia and metabolic syndrome. (*Compare* Dkt. No. 1004-7 with Dkt. No. 1004-6 at 118-19). He also seemed unaware of whether the fact that Ms. Daniels smoked a pack of cigarettes a day for 32 years could have been a cause of her diabetes. (*See* Dkt. No. 1517 at 12). Dr. Handshoe did not consider or compare the various magnitudes of the risks associated with various risk factors. (Dkt. No. 1004-6 at 178). Dr. Handshoe testified that all women with pre-existing risk factors for diabetes, regardless of which risk factors they have and the magnitude of these risks, who take a statin and subsequently develop diabetes have "statin induced diabetes." (Dkt. No. 1004-6 at 166, 161, 175, 176, 201). He readily admitted that his analysis was based solely on temporal proximity. (*Id.* at 201). The Court ultimately excluded Dr. Handshoe's testimony as unreliable for multiple reasons in CMO 76. (Dkt. No. 1517).

C. Summary Judgment Arguments

In their response to this summary judgment motion and their responses to two other summary judgment motions filed on the same day in this MDL, Plaintiffs raise for the first time the argument that they can survive summary judgment on both general and specific causation without expert testimony. Plaintiffs argue that Defendant has admitted that Lipitor can cause Type 2 diabetes at doses lower than 80 mg and that these alleged admissions are competent evidence of general causation. (Dkt. No. 1586 at 15-26). With regard to specific causation,

Plaintiff Daniels argues that it is an issue of first impression as to whether expert testimony is necessary to prove specific causation under Colorado law, which the parties agree govern her claims. (Dkt. No. 1587 at 5). She argues that it is possible that she might be able to survive summary judgment with "other evidence," and argues that this Court should remand the case to the transferor court to determine the legal standard under Colorado law and apply it to Plaintiff Daniels' case. (*Id.* at 6). The Court addresses each argument in turn.

II. Legal Standard

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Only material facts–those "that might affect the outcome of the suit under the governing law"–will preclude the entry of summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Id.*

At the summary judgment stage, the court must "construe the evidence, and all reasonable inferences that may be drawn from such evidence, in the light most favorable to the nonmoving party." *Dash v. Mayweather*, 731 F.3d 303, 310 (4th Cir. 2013). However, "the nonmoving party must rely on more than conclusory allegations, mere speculation, the building of one inference upon another, or the mere existence of a scintilla of evidence." *Id.* at 311.

III. Discussion

Here, Defendant has moved for summary judgment on the basis that Plaintiff Daniels has no evidence to support two essential elements of her claims – general and specific causation. "Rule 56(c) mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on

which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Thus, to survive summary judgment, Plaintiff must cite to evidence in the record that would allow a jury to infer that Lipitor 40 mg is capable of causing diabetes and that it did in fact cause Ms. Daniels' diabetes.

A. General Causation

As explained above, the Court excluded Plaintiffs' expert testimony on general causation with respect to dosages of less than 80 mg. (*See* CMO 49, Dkt. No. 1197; CMO 68, Dkt. No. 1469). Because Plaintiff Daniels was prescribed and ingested 40 mg of Lipitor prior to her diabetes diagnosis, (Dkt. No. 1562-1at 5), she has no admissible expert testimony regarding general causation in her case. However, Plaintiff Daniels argues that alleged admissions by Defendant are sufficient to survive summary judgment.

Plaintiff argues that four pieces of evidence constitute admissions by Defendant that Lipitor can cause diabetes at dosages less than 80 mg:

(1) An email from Senior Vice President David DeMicco;

(2) the U.S. Lipitor label stating that "[i]ncreases in HbA1c and fasting serum glucose levels have been reported with [statins], including LIPITOR";

(3) Parke-Davis's[5] New Drug Application (NDA) data showing that Lipitor was associated with increases in blood glucose levels;

(4) The official Lipitor website, which states that "[e]levated blood sugar levels have been reported with statins, including LIPITOR."; and

(5) Pfizer's Japanese label insert for Lipitor.

[5] Parke-Davis is the predecessor of Pfizer.

(Dkt. No. 1586 at 16). Plaintiffs argue that these pieces of evidence are admissible under Rule 801(d)(2) for the truth of the matter asserted. Except for the Japanese label, Pfizer does not dispute the admissibility of the evidence put forward by Plaintiffs.[6] Pfizer, however, does dispute that this evidence is sufficient to survive summary judgment in the absence of expert testimony.

1. *Erie* Question

Plaintiffs generally argue that state substantive law controls whether expert evidence of causation is needed to survive summary judgment in products liability cases.[7] (Dkt. No. 1586 at 26-35). However, Plaintiffs also argue that state law does ***not*** control whether expert evidence of causation is needed to survive summary judgment if the non-expert evidence of causation at issue is a party opponent admission under Rule 801(d)(2). (Dkt. No. 1634 at 32-33). In the specific instance where non-expert testimony of causation consists of a party opponent admission, Plaintiffs argue that Rule 56 supersedes state law and requires denial of summary judgment. (*Id.*). Plaintiffs cannot have it both ways. Either Rule 56 supersedes any state law on what type of evidence is sufficient to survive summary judgment or substantive state law governs whether expert testimony is required to survive summary judgment. Thus, the Court first addresses whether federal or state law controls this question under *Erie*.

"Under the familiar *Erie* doctrine, [courts] apply state substantive law and federal procedural law when reviewing state-law claims." *Kerr v. Marshall Univ. Bd. of Governors*, 824 F.3d 62, 74 (4th Cir. 2016). To the extent that Plaintiffs argue that the standard of Federal Rule

[6] Pfizer has filed a motion in limine to exclude the Japanese label. (Dkt. No. 1163).

[7] Indeed, one of the reasons Plaintiffs argue that the Court should suggest remand of all cases to their transferor courts for resolution of specific causation issues is that state law controls this question. (Dkt. No. 1586 at 35-43).

of Civil Procedure 56 applies to the claims at issue, they are clearly correct.[8] *See Jones v. Meat Packers Equip. Co.*, 723 F.2d 370, 372 (4th Cir. 1983) ("A federal standard determines the sufficiency of the evidence for submission of an issue to a jury."); *Fitzgerald v. Manning*, 679 F.2d 341, 346 (4th Cir. 1982) ("[W]hether there is sufficient evidence to create a jury issue of those essential substantive elements of the action, as defined by state law, is controlled by federal rules."); *Millers Mut. Ins. Ass'n of Ill. v. S. Ry. Corp.*, 483 F.2d 1044, 1046 (4th Cir. 1973) ("We apply a federal standard to determine whether the plaintiff's case presented a jury question."). However, this is not the end of the inquiry.

The substantive elements of a state claim, including the applicable standard of care, whether the standard has been violated, and whether the alleged violation is the cause of a plaintiff's injury, are all questions determined by state law when a court sits in diversity. *Fitzgerald*, 679 F.2d at 346. And a number of federal courts sitting in diversity have held that whether a plaintiff must offer admissible expert testimony regarding medical causation in complex products liability cases is a matter of substantive state law because such a rule is part of the substantive element of causation. *See, e.g.*, *In re Mirena IUD Prod. Liab. Litig.*, No. 13-MC-2434 (CS), 2016 WL 4059224, at *8 (S.D.N.Y. July 28, 2016) ("[T]he issue here is not so much whether the alleged admissions are admissible against [defendant] as a matter of the law of evidence, but whether as a matter of substantive products liability law admissions can substitute for expert evidence of causation, given the widely held principle that expert testimony is required in cases involving a complex or technical question outside the ken of the average lay juror."); *Silverman v. Watson Pharm., Inc.*, No. CIV.A. H-10-1952, 2013 WL 1645771, at *2 (S.D. Tex. Apr. 16, 2013) ("[Defendant] asks the court to conflate federal procedural law governing the

[8] Indeed, this is the standard cited by the Court above as the legal standard governing the motion at issue.

admissibility of expert testimony with Texas substantive law regarding the levels of proof required to demonstrate causation in a toxic tort case.").

In other words, while the question of whether evidence is sufficient to survive summary judgment is generally a matter of federal procedural law, "the 'expert testimony' rule" may be "so closely interrelated with the substantive cause of action . . . that federal courts sitting in diversity cases should apply the state rule in order to fully realize state substantive policy." *Hemingway v. Ochsner Clinic*, 722 F.2d 1220, 1225 (5th Cir. 1984); *see also Milam v. State Farm Mut. Auto. Ins. Co.*, 972 F.2d 166, 170 (7th Cir. 1992) ("[W]here a state in furtherance of its substantive policy makes it more difficult to prove a particular type of state-law claim, the rule by which it does this, even if denominated a rule of evidence or cast in evidentiary terms, will be given effect in a diversity suit as an expression of state substantive policy."); *Burke v. Air Serv Int'l, Inc.*, 685 F.3d 1102, 1109 (D.C. Cir. 2012) ("[S]tate law controls where it makes a precondition to recovery in a medical-malpractice action the proffer of expert testimony to prove an element of the substantive-law claim, such as standard of care or causation.") (quoting 9 Charles Alan Wright & Victor James Gold, Federal Practice & Procedure: Evidence § 6263, at 204 (1997)); *Bryte ex rel. Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (noting the difference between "a procedural rule governing admissibility" of expert testimony and "substantive state rules on the sufficiency of evidence"). Like other federal courts that have addressed the issue,[9] this Court finds that a state law requirement that expert testimony is

[9] *See, e.g., Lewis v. Johnson & Johnson*, 601 F. App'x 205, 211 (4th Cir. 2015) (per curiam), (holding that under Texas law "expert testimony is necessary to establish causation as to medical conditions outside the common knowledge and experience of jurors."); *Root v. Tempe St. Luke's Hosp.*, 368 F. App'x 848, 848–49 (9th Cir. 2010) (applying Arizona law requiring expert testimony to establish causation); *Yih-Ling Shieh Wu v. Home Depot U.S.A., Inc.*, No. C13-955-JPD, 2014 WL 2987338, at *2 (W.D. Wash. July 2, 2014) (applying Washington requiring expert testimony to establish causation between an accident and an injury); *Duke v. Garcia*, No.

necessary to establish a particular element of a cause of action, such as causation, is a statement of state substantive policy, "intimately bound up with the state right or obligation." *DiAntonio v. Northampton-Accomack Mem'l Hosp.*, 628 F.2d 287, 291 (4th Cir. 1980) (quoting *Szantay v. Beech Aircraft Corp.*, 349 F.2d 60, 63 (4th Cir. 1965)). Because such a rule defines and limits the primary rights and obligations of the parties, it "must be applied under the *Erie* doctrine." *Mattison v. Dallas Carrier Corp.*, 947 F.2d 95, 109 (4th Cir. 1991).

To the extent that state substantive law requires causation to be established by expert testimony, it is also a question of state substantive law whether party-opponent admissions can substitute for expert evidence of causation. *In re Mirena*, 2016 WL 4059224 at *8. However, as explained more fully below, the argument that party-opponent admissions can substitute for expert evidence is a recent and novel one created by plaintiffs in multi-district litigations where expert evidence has been excluded under *Daubert*. Thus, the state courts have not had an opportunity to pass on the specific question, and the Court must "predict what the Supreme Court of [various states] would decide." *Doe v. Doe*, 973 F.2d 237, 240 (4th Cir. 1992). In doing so, the Court is guided by the Fourth Circuit's admonition that "a federal court in the exercise of its diversity jurisdiction should act conservatively when asked to predict how a state court would proceed on a novel issue of state law," *Rhodes v. E.I. du Pont de Nemours & Co.*, 636 F.3d 88, 97–98 (4th Cir. 2011), and the few federal cases that address the issue.

11-CV-784-BRB/RHS, 2014 WL 1333151, at *1 n.1 (D.N.M. Feb. 28, 2014) (applying New Mexico law requiring expert testimony to establish medical causation); *In re Trasylol Prod. Liab. Litig.*, No. 08-MD-1928, 2013 WL 1343529, at *3 (S.D. Fla. Apr. 2, 2013) (applying New York law that requires causation to be established by expert testimony).

2. Colorado law

Under Colorado law, a plaintiff must show that the defendant's negligence is the "but for" cause of her injury, that "[i]t is a cause without which the claimed injury would not have happened." *E.g., Reigel v. SavaSeniorCare L.L.C.*, 292 P.3d 977, 988 (Colo. App. 2011). "Under Colorado law, products liability claims involving matters outside the experience of the average layperson, like negligence claims involving such complex or technical issues, require expert testimony to prove issues such as causation." *Xtreme Coil Drilling Corp. v. Encana Oil & Gas (USA), Inc.*, No. CIV.A. 08-CV-02750, 2010 WL 3777303, at *7 (D. Colo. Sept. 19, 2010) (citing *Truck Ins. Exch. v. MagneTek, Inc.*, 360 F.3d 1206, 1214 (10th Cir. 2004)); *see also Howell v. Centric Grp., LLC*, 508 F. App'x 834, 836 (10th Cir. 2013) ("Preliminarily, we note that causation is a necessary component of all Colorado product-liability claims. . . . And when such claims target allegedly toxic substances or pharmaceuticals, courts throughout the country routinely require plaintiffs to show both general and specific causation."); *Brown v. Johnson & Johnson*, No. 14-CV-3279-WJM-NYW, 2016 WL 897021, at *1 (D. Colo. Mar. 9, 2016) ("[C]ourts allow lay testimony on th[e] question [of causation] only in cases where causation is fairly obvious."). Whether particular elements like the standard of care or causation are matters of common knowledge or matters that require expert testimony "is a determination committed to the sound discretion of the trial court." *Oliver v. Amity Mut. Irrigation Co.*, 994 P.2d 495, 497 (Colo. App. 1999); *MagneTek*, 360 F.3d at 1214.

The Court finds that whether Lipitor is capable of causing diabetes is not a matter of common knowledge and does generally require expert testimony under Colorado law. However, the Court can find no cases applying Colorado law that shed light on the question of whether

party opponent admissions can substitute for expert testimony when it is normally required. Thus, the Court turns to few cases in the county to have addressed the issue.

This "novel argument" that party opponent admissions can substitute for expert testimony was raised in the Meridia MDL and "create[d] an issue of first impression" for the Meridia MDL court. *In re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d 791, 808 (N.D. Ohio 2004), *aff'd sub nom. Meridia Prod. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861 (6th Cir. 2006).[10] The *Meridia* court had to reach the issue because it excluded plaintiffs' expert testimony on general causation under Rule 702 and *Daubert*. *Id.* at 802-07. The court held that the statement in the drug's label regarding blood pressure was sufficient to survive summary judgment on the issue of general causation but that statements regarding numerous other medical conditions were not.

With regard to blood pressure, the label stated "MERIDIA SUBSTANTIALLY INCREASES BLOOD PRESSURE IN SOME PATIENTS . . . " *Id.* at 810. The *Meridia* court held this language constituted "admissions of Meridia's potential to cause substantial increases in blood pressure *in some patients*" and held this was sufficient to survive summary judgment on general causation. *Id.* (emphasis in original). Importantly, however, the *Meridia* court went on to hold that:

> The insert lists the other conditions as being "associated" with Meridia. Such admissions of temporal associations (or reports of temporal associations) are insufficient to create admissions of causation. Therefore, Plaintiffs have met their burden of showing a genuine issue of material fact only with respect to Meridia's capacity to cause substantial increases in blood pressure. For all other conditions, Plaintiffs have not met their burden. The Court therefore **GRANTS** Defendants' motion for summary judgment with regard to all tort claims involving harms not related to increased blood pressure.

[10] In *Meridia*, "[r]ather than undertake an analysis of all fifty states' laws to determine which do and which do not require expert testimony on the issue of general causation," the court assumed "*arguendo* that no states' laws erect such a requirement." *Id.* at 802.

Id. The *Meridia* court went on to grant summary judgment with regard to the blood pressure claims, holding that the language with regard to increased blood pressure was a sufficient warning as a matter of law. *Id.* at 814.

The Sixth Circuit's affirmance in the *Meridia* case found "no fault with the district court's treatment of the causation factor." *Meridia Prod. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 866 (6th Cir. 2006). In doing so, the court noted that (1) the district court "contrasted the strong language of 'substantially increases' with milder warning language such as 'is associated with'"; (2) the district court did not rely "*on the fact* of the warning to find causation" but "instead on the specific wording" (emphasis in original); and (3) "according to several record depositions," the specific wording was "the product of discussion between the FDA and the regulated party." *Id.*

The *Mirena* MDL court also addressed this issue and came to the following conclusion:

> A review of the cases cited by Plaintiffs—as well as common sense—suggest that if it is conceivable at all that a statement by a party opponent could be used in place of expert testimony to prove causation, the circumstances in which this might occur would be exceedingly rare, especially in the pharmaceutical or medical contexts. . . . the most that can be wrung from the authority cited by Plaintiffs is that if admissions could ever substitute for expert testimony in a complex case that requires expert testimony as to causation under state law, those admissions would have to be clear, unambiguous, and concrete, rather than an invitation to the jury to speculate as to their meaning.

In re Mirena IUD Prod. Liab. Litig., No. 13-MC-2434 (CS), 2016 WL 4059224, at *8 (S.D.N.Y. July 28, 2016). The *Mirena* court noted that the *Meridia* court assumed no state law required expert testimony to prove causation. The *Mirena* court, on the other hand, did not "make the same assumption," as all jurisdictions at issue in *Mirena* did "have such a requirement." *Id.* at *9. The *Mirena* court found this distinction "fatal to Plaintiffs' argument," *id.*, and ultimately concluded, after a review of case law, that:

> no court has held that admissions can substitute for required expert testimony, and this Court will not be the first. Such a ruling would disregard the purpose of the requirement for expert testimony, leaving jurors to speculate, and would chill free and frank discussion by manufacturers of drugs or devices.

Id. at 12. Wading into the policy implications of such a holding, the court stated:

> there may be myriad reasons, including an abundance of caution or the avoidance of lawsuits, why a manufacturer may warn of a possible phenomenon without being convinced that it is a genuine risk, and permitting the label to substitute for expert testimony here would present a wholly conjectural basis for a jury to determine general causation. And allowing a label to substitute for expert testimony would discourage manufacturers from exercising caution, providing potential users with less information rather than more where the science is debatable, a result inimical to the public health.

Id. at 14.[11] The only other courts to have addressed the issue have either done so in a conclusory fashion, *see Meade v. Parsley*, No. 2:09-CV-00388, 2010 WL 4909435, at *7 (S.D.W. Va. Nov. 24, 2010) ("PLIVA's drug label, which merely warns of metoclopramide's potential side-effects without explaining the scientific basis for the warning, is no substitute for expert testimony that establishes causation in terms of reasonable probability."), or like *Meridia*, relied on the fact that association evidence is not evidence of causation:

> Defendants' labeling changes and notification letters merely relayed information about a possible association between their drug and optic neuropathy. Spontaneous reporting by a pharmaceutical company should be encouraged; it serves "as a signaling system for adverse drug reactions that may not have been detected during pre-market testing." *Haggerty v. Upjohn Co.*, 950 F.Supp. 1160, 1164 (S.D.Fla.1996). Such reporting does not, however, indicate causation.

Nelson v. Am. Home Prod. Corp., 92 F. Supp. 2d 954, 969 (W.D. Mo. 2000); *see also In re Zoloft (Sertralinehydrochloride) Prod. Liab. Litig.*, No. 12-MD-2342, 2016 WL 1320799, at *9 (E.D. Pa. Apr. 5, 2016) ("Neither these [internal] documents, nor draft product documents or

[11] Such substantive policy implications reinforces the Court's conclusion that to the extent substantive state law requires expert testimony to prove a particular element of claim, state law also determines whether alleged admissions can substitute for such expert testimony.

foreign product labels containing language that advises use of birth control by a woman taking Zoloft constitute an admission of causation, as opposed to acknowledging a possible association."). [12]

The Court need not determine whether Colorado would ***ever*** allow party opponent admissions to replace expert testimony where it is required. The Court finds that the evidence submitted by Plaintiff here is insufficient to replace required expert testimony.

3. DeMicco Email

The primary piece of evidence relied on Plaintiffs is a one-sentence email by Pfizer VP, Dr. DeMicco sent on September 27, 2009. On September 25, 2009, Dr. DeMicco sent an earlier email to Dr. David Waters at the University of California, San Fransico, with the statistical

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[12] The other two cases cited by Plaintiffs are inapposite. In *Westberry v. Gislaved Gummi AB*, 178 F.3d 257 (4th Cir. 1999), the Fourth Circuit considered the admissibility of expert testimony under *Daubert*. One of the pieces of evidence considered by the expert was a Material Safety Data Sheet (MSDS) for talc provided by the defendant, which stated "[i]nhalation of dust in high concentrations irritates mucous membranes." *Id.* at 264. As the *Merina* court noted:

> the issue was not whether the MSDS statement could substitute for expert testimony. Rather, the comment regarding the MSDS was made in the context of evaluating whether the plaintiffs' expert had a sufficient basis for his specific causation opinion. The *Westberry* court's discussion shows no more than that an MSDS is properly considered by an expert. Nothing in *Westberry* suggests that a manufacturer's statement suffices to defeat summary judgment in the absence of expert testimony.

Mirena, 2016 WL 4059224, at *9.

In *Lewis v. Johnson & Johnson*, 601 F. App'x 205 (4th Cir. 2015) (per curiam), the Fourth Circuit held that under Texas law, "expert testimony is necessary to establish causation as to medical conditions outside the common knowledge and experience of jurors." *Id.* at 211. The court went on to hold that "whether any of these defects [at issue] caused [plaintiff's] pain involves complex and technical medical issues beyond common knowledge and experience" and, therefore, her "failure to present . . . expert testimony doomed her design defect claim." *Id.* In the last paragraph of the opinion, the panel noted "plaintiff does not argue that the remaining testimony—by, for instance, employees of the defendant—establishes causation." *Id* at 212. Plaintiffs have apparently interpreted this sentence to mean that "the court in *Lewis* accepted that admissions by defendant's employees could prove general causation as a matter of law." (Dkt. No. 1586 at 19). However, *Lewis* did not pass on the issue, but simply noted that the plaintiff had not raised it so it need not be addressed.

analysis for the occurrence of diabetes in SPARCL.[13] Dr. Waters replied via email that SPARCL data "dovetail nicely with the TNT results," and stated:

> I would draw these conclusions based on this data:
> 1. Atorvastatin increases the risk of developing diabetes.
> 2. The risks of 10 and 80 mg are similar.
> 3. Fasting blood sugar and features of the metabolic syndrome are strong predictors of the development of diabetes in both populations.

(Dkt. No. 1591-1 at 2). Dr. DeMicco then replied, in the email at issue, that "[a]s far as the conclusions, I concur with your assessment below." (*Id.*).

First, this email is, at best, evidence of an association, not causation. An association does not equal causation, and epidemiologists engage in a rigorous analysis of multiple factors to determine whether an association is causal.[14] *E.g., In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 174 F. Supp. 3d 911, 916 (D.S.C. 2016); *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1175 (E.D. Wash. 2009); *In re Neurontin Mktg., Sales Practices, & Prod. Liab. Litig.*, 612 F. Supp. 2d 116, 125 (D. Mass. 2009) (citing the Reference Manual on Scientific Evidence (2d. ed. 2000) at 336, 374); *see also Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1315 (11th Cir. 1999) ("[S]howing association is far

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[13] SPARCL was a randomized clinical trial that tested whether Lipitor was effective for reducing the incidence of stroke in patients who had previously had a stroke or TIA. (Dkt. No. 972-28). Participants were randomly assigned to 80 mg of Lipitor or a placebo. (*Id.* at 2). Diabetes was not an endpoint in this study, but adverse event information was collected, and Pfizer conducted a post hoc analysis of the data. (Dkt. No. 972 at 24). A post hoc analysis of data from the clinical trial found a statistically significant increase in the risk of diabetes for patients randomized to 80 mg of Lipitor versus those on placebo. (Dkt. No. 972-29 at 2).

[14] These factors are (1) strength of the association, (2) replication of the findings, (3) specificity of the association, (4) temporal relationship, (5) dose-response relationship (aka biological gradient), (6) biological plausibility, (7) consistency with other knowledge (aka coherence), (8) consideration of alternative explanations, and (9) cessation of exposure. Reference Manual on Scientific Evidence 600 (3d. ed. 2011); *see also* Sir Austin Bradford Hill, The Environment and Disease: Association or Causation?, 58 Proc. Royal Soc'y Med. 295, 295-300 (1965)), *available at* Dkt. No. 972-32.

removed from proving causation."); Reference Manual on Scientific Evidence (RMSE) 218 (3d ed. 2011) ("[W]ork is needed to bridge the gap between association and causation."). Thus, evidence of an association does not create a genuine issue of material fact as to causation.

Plaintiffs argue that the statement "increases the risk" is synonymous with "causes," and thus, they argue, Dr. DeMicco's statement, "I concur with your assessment" is an admission that Lipitor causes diabetes. Plaintiffs are "follow[ing] human nature, which is to confuse association and causation." *Siharath v. Sandoz Pharm. Corp.,* 131 F. Supp. 2d 1347, 1372 (N.D. Ga. 2001), *aff'd sub nom. Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194 (11th Cir. 2002). An increase in statistical risk, like the one acknowledged by Dr. DeMicco here, is evidence of association, not causation.

These emails discuss a statistical analysis that, as the later published article on the data states, found that the 80 mg dose of Lipitor "is ***associated*** with a slightly increased risk of new-onset [type 2 diabetes]." (Dkt. No. 972-29 at 2) (emphasis added). This increased statistical risk was shown by a hazard ratio of 1.37, with a 95% confidence interval of 1.08 to 1.75. (*Id.*). A hazard ratio, like a relative risk ratio or odds ratio, is a "measure of ***association*** used in epidemiology." RSME at 295 (defining relative risk) (emphasis added); *see also* RSME at 291 (defining odds ratio and describing it as a "measure of association, often used in epidemiology"). As a statistical analysis comparing two groups, all it can show is an association, i.e. a correlation or increased risk; it cannot show causation. *See In re Neurontin Mktg., Sales Practices, & Prod. Liab. Litig.*, 612 F. Supp. 2d 116, 125 (D. Mass. 2009) ("'An association is not equivalent to causation,' and so epidemiological studies, on their own, 'cannot objectively prove causation.'") (quoting RMSE 336, 374 (2d. ed. 2000)).

Explained in another way, "risk" is "[a] probability that an event will occur." RSME at 627. An "increased risk" is an "increased probability that an event will occur." Here, diabetes is more probable, more likely to occur, in the group taking Lipitor. This is the very definition of an association, and says nothing about causation. *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 150 F. Supp. 3d 644, 649 (D.S.C. 2015) ("[E]ven if Plaintiffs establish that there is an association between Lipitor and diabetes (***i.e., that Lipitor increases the risk of diabetes***) and that Lipitor is capable of causing diabetes, it does not necessarily follow the Lipitor caused the development of diabetes in a particular plaintiff.")[15] (emphasis added). As the Reference Manual on Scientific Evidence explains, an association is

> [t]he degree of statistical relationship between two or more events or variables. Events are said to be associated when they occur more or less frequently together than one would expect by chance. Association does not necessarily imply a causal relationship.

RMSE at 619.

The Reference Manual on Scientific Evidence provides an analogous example. Studies found that women with herpes were more likely to develop cervical cancer than other women. RMSE at 219. In other words, herpes ***increased the risk*** of cervical cancer; having herpes increased the probability that women would develop cervical cancer. Some assumed this association was causal. However, "[l]ater research showed that the primary cause of cervical cancer was a human papilloma virus (HPV)," and that herpes was simply a marker of sexual activity, not the cause of cervical cancer. *Id.*

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[15] Later in this opinion, the Court stated that Dr. Murphy's opinion was "based only on (1) the fact that Lipitor increases the risk of diabetes (general causation) and (2) that Ms. Hempstead developed diabetes after taking Lipitor." *Id.* at 652. With this parenthetical, the Court was emphasizing that information regarding an increase in risk went to the matter of general causation, not specific causation. It was not equating the phrase "increased risk" with general causation.

Here, viewing the evidence in the light most favorable to Plaintiffs,[16] Dr. DeMicco is agreeing with Dr. Waters' assessment that, according to the SPARCL data, Lipitor increases the risk of diabetes, i.e., that the probability of developing diabetes in the Lipitor group was higher, i.e., that taking 80 mg of Lipitor is associated with higher rates of diabetes. This statement speaks to association and does not create a genuine issue of material fact as to causation.[17]

Furthermore, even if the one-sentence email indicated that Dr. DeMicco thought Lipitor caused diabetes, the Court finds such an email could not replace expert testimony when expert testimony is required by substantive Colorado law. A single statement by a single employee (even a Vice President) in a single email about a single study is not the type of clear declaration made in the *Meridia* case, where the label stated that "MERIDIA SUBSTANTIALLY INCREASES BLOOD PRESSURE IN SOME PATIENTS . . ." 328 F. Supp. 2d at 810. *Meridia* is the only case where a statement by a party has been held sufficient to survive

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[16] Viewing the evidence in the light most favorable to Plaintiff does not require the Court to conflate association and causation. *See Llewellyn v. Allstate Home Loans, Inc.*, 711 F.3d 1173, 1187 (10th Cir. 2013) ("Although our summary judgment standard requires us to view the facts in the light most favorable to the non-moving party, it does not require us to make unreasonable inferences in favor of the non-moving party."); *Scalisi v. Fund Asset Mgmt., L.P.*, 380 F.3d 133, 137 (2d Cir. 2004) ("[W]e are not required to accept as true . . . unwarranted deductions of fact drawn by the non-moving party.").

[17] Courts have occasionally used "increased risk" as shorthand for general causation when differentiating general causation from specific causation. *See Jenkins v. Slidella L.L.C.*, No. CIV.A.05-370, 2008 WL 2649510, at *4 (E.D. La. June 27, 2008) ("Defendants state that where a plaintiff claims that a substance caused his injury, he must show not merely general causation (i.e., that exposure to the substance at issue increases the risk of a particular injury), but specific causation (i.e., that the substance in question did, in fact, cause a particular individual's injury."). Establishing an association is the first, threshold step in establishing general causation, and it is not surprising that courts may invoke this language to help differentiate the inquiries of general and specific causation. However, this fact does not change voluminous and well-established precedent that association, alone, is not sufficient to establish causation and does not change the simple factual truth that association is not causation. The parties have always agreed that establishing association is just the first step of a two-step process for establishing general causation. (*See* Dkt. No. 972 at 27-28; Dkt. No. 1053 at 13).

summary judgment on general causation. In affirming the *Meridia* case, the Sixth Circuit specifically noted the district court's contrast of this "strong language," reliance on the "specific wording." 447 F.3d at 866. The *Meridia* court reached the opposite conclusion when weaker wording, like that in the DeMicco email, was at issue. 328 F. Supp. 2d at 810. The wording in *Meridia* was also "the product of discussion between the FDA and the regulated party," not a statement by one employee shot off in an email. 447 F.3d at 866.

Finally, in *Meridia*, the court assumed state law did not require expert testimony. *Id.* at 802. By contrast this Court has found that Colorado substantive state law requires expert testimony to prove general causation in this case. "[A] federal court in the exercise of its diversity jurisdiction should act conservatively when asked to predict how a state court would proceed on a novel issue of state law." *Rhodes*, 636 F.3d at 97–98. Allowing a single sentence email to replace expert testimony that is required by substantive state law is novel and would dramatically change the substantive rights of parties. The Court declines to so dramatically change Colorado's expert testimony requirements under substantive state law without any indication the Colorado Supreme Court would do so. Therefore, the Court finds this email cannot create a genuine issue of material fact as to general causation.

4. Evidence Regarding Blood Glucose

The next three pieces of evidence are (1) statements of association only and (2) statements regarding blood glucose, not diabetes. The U.S. Lipitor label states that "[i]ncreases in HbA1c and fasting serum glucose levels have been reported with [statins], including LIPITOR." (Dkt. No. 1586-9). This statement never mentions diabetes, only blood glucose levels, and the two are not synonymous. (*See* Dkt. No. 1159 at 12 stating that "diagnosis of diabetes requires more than a single elevated plasma glucose level"). Furthermore, the language

"have been reported" indicates temporal association, not causation. For both reasons, it fails to create a genuine issue of material fact as to whether Lipitor causes diabetes in dosages less than 80 mg.[18]

Next, Plaintiffs point to the NDA data allegedly showing that Lipitor was associated with increases in blood glucose levels. Again, increased blood glucose levels are not synonymous with full blown diabetes, and the data only indicates, at best, an association, not causation.[19] For both reasons, it fails to create a genuine issue of material fact as with whether Lipitor causes diabetes in dosages less than 80 mg.

Next, Plaintiffs point to the official Lipitor website, which states that "[e]levated blood sugar levels have been reported with statins, including LIPITOR." Again, this fails to create a genuine issue of material fact for the same reasons. It does not mention or say anything about diabetes, and it is, at best, evidence of an association. Thus, it does not create a genuine issue of material fact as to causation.

5. Japanese Label

Finally, Plaintiffs point to the Japanese label insert for Lipitor. The Japanese label states that "[h]yper-glycemia and diabetes melitis may occur. . . ." (Dkt. No. 1586-5 at 4). Again, this is not a clear statement that Lipitor causes diabetes, like in *Meridia*, but an acknowledgement of a possible association. *See In re Zoloft*, 2016 WL 1320799, at *9 ("Neither these [internal] documents, nor . . . foreign product labels containing language that advises use of birth control by a woman taking Zoloft constitute an admission of causation, as opposed to acknowledging a

[18] Plaintiffs acknowledge that the U.S. label's language "is not as supportive of our position" and may not be sufficient alone to survive summary judgment. (Dkt. No. 1634 at 47).

[19] Whether the data even indicates this is disputed by the parties. However, for the purposes of this motion, the Court assumes the NDA data does indicate an association between Lipitor usage and increased blood glucose levels.

possible association."). The label change was based on 30 adverse event reports, (Dkt. No. 1163-3 at 174-77, Dkt. No. 1762-4 at 2, Dkt. No. 1762 at 3), which "are not even sufficient to show association, because there is no comparison group." RSME at 218.

Regardless, it cannot be used to replace state substantive law requiring expert testimony. Unlike the U.S. label in *Meridia*, the Japanese label change at issue here was ordered by Japanese officials, specifically Japan's Ministry of Health Labor, and Welfare (MHLW), "without even discussing it with [the Japanese licensee/distributor of Lipitor]." (Dkt. No. 1761-3 at 193). There is no evidence in the record that Pfizer had any input regarding the inclusion, or wording of, the statement placed on the Japanese label or that Pfizer manifested a belief in its accuracy. Indeed, as Plaintiffs point out, Pfizer ***disagreed*** with the label change, but it went into effect anyway. (Dkt. No. 1181 at 5; Dkt. No. 1761-2 at 9-10). In short, the statement is one by MHLW, not Pfizer, and is not an admission by Pfizer.

While such a label change may have relevance to Pfizer's knowledge of adverse events, the purpose for which Plaintiffs' originally intended to introduce it,[20] it does not create a genuine issue of material fact as to whether Lipitor is capable of causing diabetes. The Court finds that even if the Colorado Supreme Court were to allow certain types of party opponent admissions to replace expert testimony when it is substantively required by state law, it would not find a statement placed on a foreign label by a foreign agency without any input from, or discussion with, the defendant to constitute an acceptable admission to replace expert testimony. Therefore, the Court grants summary judgment on the ground that Plaintiff has failed to create a genuine issue of material fact as to general causation.

[20] See Dkt. No. 1181.

B. Specific Causation

Plaintiff argues that "it is a matter of first impression in Colorado whether expert testimony is necessary to prove specific causation." (Dkt. No. 1587 at 5). The Court disagrees. As explained above, "[u]nder Colorado law, products liability claims involving matters outside the experience of the average layperson, like negligence claims involving such complex or technical issues, require expert testimony to prove issues such as causation." *Xtreme Coil Drilling*, 2010 WL 3777303 at *7; *see also Brown*, 2016 WL 897021 at *1 ("A lay jury does not have the competence to conclude, based on everyday experience, that Levaquin in fact caused [plaintiff]'s injuries."); *Howell*, 508 F. App'x at 836 ("Preliminarily, we note that causation is a necessary component of all Colorado product-liability claims. . . . And when such claims target allegedly toxic substances or pharmaceuticals, courts throughout the country routinely require plaintiffs to show both general and specific causation."). Whether particular elements like the standard of care or causation are matters of common knowledge or matters that require expert testimony "is a determination committed to the sound discretion of the trial court." *Oliver*, 994 P.2d at 497; *MagneTek*, 360 F.3d at 1214.

The Court finds that whether Lipitor caused diabetes in a particular individual is not a matter of common knowledge but one that requires expert testimony under Colorado law. Diabetes is a complicated, progressive disease with a number of risk factors. Plaintiff's general causation experts cannot even figure out how to determine whether an individual's diabetes was caused by Lipitor or other factors, and Plaintiff's specific causation expert cannot determine which people in a room of 100 people or 10 people had "statin-induced" diabetes as opposed non-statin-induced diabetes. (Dkt. No. 1004-1 at 210-11; Dkt. No. 1004-4 at 162; Dkt. No.

1004-5 at 71; Dkt. No. 1004-6 at 163). If these experts cannot make this determination, it is certainly not within the common knowledge of a lay person.

Furthermore, even if Colorado law did allow specific causation to be proved by means other than expert testimony in this instance, summary judgment would still be appropriate. Plaintiff Daniels has put forward no evidence of causation in any form. She states that Dr. Handshoe's relative risk estimate of 1.25 "when combined with other evidence," "may . . . be enough to prove specific causation."[21] (Dkt. No. 1587 at 6). However, Plaintiffs never disclosed Dr. Handshoe as a general causation expert, and this Court has excluded the testimony of Dr. Handshoe in any event. (CMO 76, Dkt. No. 1517). Furthermore, Plaintiff has not even speculated as to what this "other evidence" might be, much less submit it to the Court. Therefore, the Court finds that Plaintiff has put forward no evidence of specific causation, and grants summary judgment on this ground.

IV. Conclusion

For the reasons stated above, Defendant's motion for summary judgment (Dkt. No. 1562) is GRANTED.

AND IT IS SO ORDERED.

Richard Mark Gergel
United States District Court Judge

December 21, 2016
Charleston, South Carolina

[21] Plaintiff recognizes that the relative risk alone, even if provided in admissible expert testimony form, is insufficient under Colorado law. *See Reigel*, 292 P.3d at 987 (rejecting increased risk of harm test).