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

IN RE: LIPITOR (ATORVASTATIN CALCIUM) M BNVARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	**MDL No. 2:14-mn-02502-RMG** **CASE MANAGEMENT ORDER NO. 100** **This Order relates to the cases listed in Appendix 1**

Before the Court is Defendant's Omnibus Motion for Summary Judgment, (Dkt. No. 1564).[1] For the reasons stated below, the motion is GRANTED IN PART.[2]

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).

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

[2] This Order addresses the motion with regard to Plaintiffs who allegedly ingested dosages of Lipitor less than 80 mg. The claims of other Plaintiffs are addressed in CMO 99.

This Court held an initial status conference on March 27, 2014, and, after a second status conference on April 25, 2014, discovery commenced when the Court entered CMO 4, which among other things, set forth an initial discovery plan. (Dkt. No. 101 at 17-24). This plan provided for certain document production by Pfizer (including electronic discovery), interrogatories served by Plaintiffs on Pfizer, and depositions of Pfizer and its current and former employees. (*Id*.) On May 2, 2014, the Court entered CMO 5, which required Plaintiffs to serve Plaintiff Fact Sheets and certain mandatory disclosures on Pfizer. (Dkt. No. 110).

With discovery underway, the Court turned to the process for selecting a bellwether case for trial. Under Amended CMO 6, entered on May 22, 2014, 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). More in depth case specific discovery was taken in these 14 cases in the Fall of 2014, including the propounding of written discovery on Discovery Pool Plaintiffs, depositions of Discovery Pool Plaintiffs, immediate family members and healthcare providers, depositions Pfizer sales representatives, and completion of a Defendant Fact Sheet by Pfizer. (*Id*. at 5).

On January 30, 2015, the Court convened the parties to randomly select the first cases for bellwether trials from the Discovery Pool cases. (Dkt. No. 739). 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 first case selected was *Daniels v. Pfizer*, Case No. 2:14-cv-01400, and the second case selected was *Hempstead v. Pfizer*, Case No. 2:14-cv-01879. Thereafter, the parties conducted additional case-specific discovery in these two cases. (*See* CMO 29, Dkt. No. 746; CMO 30, Dkt. No. 790).

From the beginning of this MDL, the parties have agreed that Plaintiffs must prove both general and specific causation as elements of their claims and have litigated this case as if expert testimony is needed to prove both. 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. Hempstead's 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.

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, 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 more fully explained below, after extensive briefing and oral argument, 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). The Plaintiffs at issue here all ingested dosages of Lipitor less than 80 mg.[3] Thus, the Plaintiffs here do not have admissible expert testimony on general causation.

As explained in more detail below, the Court also excluded the expert testimony of Dr. David Handshoe and Dr. Elizabeth Murphy, the two specific causation experts in the bellwether cases because their opinions were based on nothing more than an increased risk and temporal association. (CMO 55; Dkt. No. 1283; CMO 76, Dkt. No. 1517). However, Plaintiffs noted that in the SPARCL study, patients with certain characteristics and taking 80 mg of Lipitor had a relative risk ratio of developing diabetes greater than 2.0, meaning it was more likely than not that these individuals would not have developed diabetes in the absence of Lipitor.[4] Thus, it was possible that Plaintiffs with such characteristics and taking 80 mg of Lipitor might be able to proffer a specific causation expert opinion that would survive *Daubert*, even if the Court's ruling in CMO 55 was correct, and the Court entered a scheduling order to identify and take to trial such a case. (*See* CMO 61, Dkt. No. 1323).

However, in a hearing on the matter on January 22, 2016, Plaintiffs' Lead Counsel stated that there was no plaintiff in the MDL that met those criteria. (Dkt. No. 1347 at 5). Thus, the Court turned to where that left the MDL proceedings:

> THE COURT: Let's talk for just a minute about where that leaves us. . . . let me ask this first from the plaintiffs: Is there any reason to believe that if we picked a 20- or 40- milligram case to try as a bellwether that you would have any

[3] In most of these cases, the parties agree, for the purposes of this motion only, that these Plaintiffs ingested Lipitor in dosages of less than 80 mg prior to diagnosis of diabetes. (Dkt. Nos. 1658, 1680, 1748). In other cases, the parties agree that Plaintiffs allege pre-existing diabetes, i.e., that Plaintiffs were diagnosed with diabetes prior to taking Lipitor. (Dkt. No. 1680). For the cases where the parties agree that Plaintiffs were diagnosed with diabetes prior to ingesting Lipitor, it is impossible that Lipitor caused their diabetes, and the Court grants summary judgment on this ground as well.

[4] For an in depth discussion of relative risk and its implications, see CMO 55, Dkt. No. 1283.

> class of cases or factual presentation or new theory that might survive specific causation, assuming the correctness of the Murphy order? Mr. Hahn?
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> MR. HAHN: The short answer is no, sir, Your Honor, we don't. Given the Murphy order and the Court's reading of the medicine, we are not going to be able to get a differential diagnosis that's going to survive.
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> THE COURT: Well, it's not a differential diagnosis, you've got to show specific causation more likely than not. And you have an opinion to that. . . .
>
> But if we assume for a minute that the critical question then is whether the Court is correct regarding the standard, if you are telling me, Mr. Hahn, that if I'm correct, then you're not going to have a case that survives summary judgment?
>
> MR. HAHN: Yes, Sir.

(Dkt. No. 1347 at 9-10). The Court went on to discuss with counsel options for proceeding within the MDL. Defendant's Lead Counsel suggested the Court issue an order to show cause to see if any Plaintiff could differentiate her case and then, if not, grant summary judgment in all cases, and Plaintiffs' Lead Counsel agreed:

> MR. CHEFFO [Defendant's Lead Counse]: . . . So I think what is most efficient for this litigation . . . is to have that ultimately reviewed, right? And I think that what other courts in similar situations have done is they have basically said, just issue an order to show cause and said, look, you know, if anybody thinks that they are differently situated or has some kind of different argument or something else, they can come forward; if not, what we are going to do is we are going to grant judgment on that.
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> . . . . they would then . . . presumably get appealed to the Fourth Circuit and the Circuit Court would do what it's going to do. And I think that's the appropriate . . . remedy in an MDL.
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> . . . . the most efficient way is to expeditiously grant summary judgment for all the cases on that ground, and anything else, get to the Fourth Circuit and have the Court review it.
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> THE COURT: Mr. Hahn, what your thoughts?
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> MR. HAHN [Plaintiffs' Lead Counsel]: Judge, I – I believe that Mark was cheating and reading off of my notepad. We basically agree. . . . .

(Dkt. No. 1347 at 11-13).

The Court took counsel's suggestion and issued CMO 65, which stated,

> **NOTICE: THIS ORDER CONTAINS AN IMPORTANT DEADLINE FOR ALL PLAINTIFFS**.
>
> Lead Plaintiffs' counsel advised the Court in an on the record telephone conference of January 22, 2016, that, if the Court's ruling excluding the expert testimony of Dr. Elizabeth Murphy (CMO 55, Dkt. No. 1283) is correctly decided, then none of the cases now pending in the MDL will be able to survive summary judgment on the issue of specific causation. Notice is hereby given that any Plaintiff who disputes the position taken by Plaintiffs' Lead Counsel and asserts that her case can survive summary judgment on specific causation even if the Court's ruling in CMO 55 is upheld on appeal, such Plaintiff shall provide notice to the Court within 15 days of this order and set forth with specificity how her case is distinguished from the Court's ruling in CMO 55. The Court will then promptly set a schedule in each such case for identifying expert witnesses, submitting expert reports, deposing identified experts, and briefing *Daubert* and dispositive motions.

(Dkt. No. 1352). CMO 65 did not require any Plaintiff to marshal any evidence within 15 days. The Order only required that Plaintiffs give notice within the 15-day period. The Court explicitly stated that if any Plaintiff came forward, it would then set a pre-trial schedule in those case(s), allowing Plaintiffs time to develop expert testimony. However, not a single Plaintiff came forward. Nor did a single Plaintiff ask for an extension of time to file a notice in response to CMO 65. This Order was issued on January 25, 2016, and now, nearly eleven months later, still not a single Plaintiff has come forward in response to this Order and asked to proceed with her case.

On June 9, 2016, the Court held a Status Conference to discuss proceeding with summary judgment. (Dkt. No. 1550). Plaintiffs, for the first time, had appellate counsel appear in front of the Court. (*Id.*). It was in this conference that Plaintiffs' counsel indicated, for the first time in this litigation, that some plaintiffs may possibly be able to survive summary judgment despite the Court's *Daubert* rulings:

> MR. HAHN: . . . And by taking up 10, 20, and 40, your general causation opinions, and then Murphy's specific causation opinion, I don't think we can have a summary judgment as to all the other plaintiffs in the litigation, because those other plaintiffs, in some states you don't have to have [an] expert—New Mexico is one—. . . . there may be other plaintiffs that have—haven't had the opportunity, and plan to put up a specific causation expert that's going to give an opinion that would get them to a jury.
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> THE COURT: No, no, I had—I entered an order, Mr. Hahn, in which I said if any of you don't agree with the lead counsel's position about specific causation, you need, by a designated date, to identify your case and provide me the names of your experts, so we can get on with discovery.
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> MR. HAHN: Yes, sir.
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> THE COURT: So I don't think we're out there with other potential cases. Now this issue of states that do not require expert testimony on causation, . . . I wasn't aware there were such states.

(Dkt. No. 1550 at 7). The Court went on to state: "let's assume there are. Then the brief in opposition could say all claims from the following—from the State of New Mexico, we oppose it, because there's not a[n expert] requirement. . . . the plaintiff would still have to make a showing of whatever is required under that law to establish causation, even if you don't need an expert. . ." (*Id*. at 9). Thus, Court set a scheduling for briefing on summary judgment, (CMO 79, Dkt. No. 1548), and Plaintiffs had an opportunity to come forward with evidence under this new theory in opposition to summary judgment.

However, when the deadline for opposition to summary judgment came a month-and-a-half later, not a single Plaintiff came forward with evidence that she claimed precluded the entry of summary judgment. Instead, Plaintiffs argued that it was theoretically possible that some unidentified Plaintiff(s) may possibly have some unidentified circumstantial, non-expert evidence of specific causation. (Dkt. No. 1586). In this opposition, Plaintiffs readily acknowledged that any Plaintiff "who believed she could adduce a differential diagnosis that could survive *Daubert* notwithstanding the exclusion of Dr. Murphy's expert testimony in

Hempstead" should have come forward in response to CMO 65, (Dkt. No. 1586 at 13), but argued that Plaintiffs should be allowed to present non-expert testimony to transferor courts after remand.

Given this speculative response, the Court gave Plaintiffs a third opportunity to come forward if any thought her case could survive summary judgment. The Court issued CMO 81, which stated in part:

> **NOTICE IS HEREBY GIVEN** that any Plaintiff who asserts that her case can survive summary judgment on specific causation even if the Court's ruling in CMO 55 is upheld on appeal, must file a response to Defendant's motion for summary judgment (Dkt. No. 1564) within fifteen (15) days of the date of this Order. Any such response must specifically identify the particular Plaintiff opposing summary judgment, identify the substantive state law that she contends applies to her claims, and include all evidence that she asserts precludes the entry of summary judgment in her case.
>
> If any Plaintiff contends that she needs additional case-specific discovery to provide such evidence, she must comply with the requirements of Fed. R. Civ. P. 56(d) and identify the specific facts that are yet to be discovered. Should the claims of any Plaintiff survive summary judgment based on Rule 56(d), the Court will then promptly enter a scheduling order in each such case allowing for appropriate discovery and the filing of dispositive motions after discovery.

(Dkt. No. 1599 at 3-4). Again, not a single Plaintiff came forward with evidence of specific causation. Nor did a single Plaintiff make an individualized Rule 56(d) request.

Instead, Plaintiffs filed an omnibus response arguing that, other than the two bellwether Plaintiffs, no Plaintiff has had an opportunity to develop the facts of her case. (Dkt. No. 1611). Inexplicably, Plaintiffs argued that none of the Plaintiffs (other than the two bellwether Plaintiffs) have had an opportunity to "hire experts" or "prepare expert reports," (Dkt. No. 1661 at 8), despite the fact that CMO 65 offered any Plaintiff the opportunity to do just that.

In the Rule 56(d) affidavit filed with Plaintiffs' response, Plaintiffs stated that they needed an opportunity to seek (1) "[e]vidence, testimony, and (if necessary) third-party

discovery from their treating physicians," (2) "[e]xpert opinions regarding specific causation," and (3) "their patient records." (Dkt. No. 1611-1). Plaintiffs did not state any other information that they need to seek to defend against this motion for summary judgment.

Thus, the Court issued CMO 82. First, the Court held that the time for Plaintiffs to come forward and argue that they could produce expert testimony on specific causation had passed:

> As an initial matter, the time for a Plaintiff to come forward and argue that she could produce an expert opinion on specific causation that would survive *Daubert* has passed. The Court issued an order to show cause on this ***seven months ago***, and explicitly stated that it would allow any such plaintiff to proceed with discovery and pre-trial proceedings, and in the last seven months not a single Plaintiff has come forward. Plaintiffs' Lead Counsel testifies that he understood his admission at the January 22, 2016 status conference as a confirmation "on the ability of Plaintiffs to survive the evidentiary standards for specific-causation expert evidence set forth in CMO 55" and that he understood CMO 65 to "relate to whether individual Plaintiffs believe their case could survive the Rule 702 expert standards in CMO 55." (Dkt. No. 1611-1 at 6-7). Whatever the dispute about non-expert evidence, there can be no dispute, and according the Plaintiffs' Lead Counsel's affidavit, there is no dispute, that any Plaintiff who believed she could proffer expert evidence on specific causation that would survive Rule 702 and *Daubert* was required to come forward in response to CMO 65. (*See also* Dkt. No. 1611 at 17 ("CMO 65 directed any Plaintiff who thought they could survive summary judgment on specific causation in light of the Court's exclusion of Dr. Murphy in CMO 55 (Doc. 1283) to come forward with new or additional expert evidence."); Dkt. No. 1611 at 18 ("Plaintiffs continued to understand the Court's order to relate to whether individual Plaintiffs believed their case could survive the Rule 702 expert standards in CMO 55, not the separate legal issue of whether the law of their state requires expert evidence.")). No Plaintiff has done so. Therefore, Plaintiffs' argument that they have not had an opportunity to seek specific causation expert testimony is meritless. The Court provided that opportunity in CMO 65, not a single Plaintiff came forward, and by not coming forward in response to CMO 65, Plaintiffs have waived that argument.

(Dkt. No. 1616 at 7-8 (emphasis in original)).

The Court went on to provide Plaintiffs with a fourth and final opportunity to come forward with non-expert evidence:

> With regard to non-expert evidence, in an abundance of caution, the Court will provide Plaintiffs with a fourth and final opportunity to come forward. Plaintiffs have argued that 15 days is not sufficient time to marshal their evidence. Thus,

> the Court will afford them an additional 60 days. The Court notes that the only facts that Plaintiffs have stated they may need to discover (other than expert testimony) to defend against summary judgment is information from their own treating physicians and their own patient records. (Dkt. No. 1611-1 at 5). They have not requested any discovery from Defendants or other third-parties.
>
> Given the nature of the evidence that Plaintiffs claim they need time to marshal, specifically their request to marshal their own medical records and information from their own treating physicians, the Court finds 60 days sufficient.

(*Id*. at 8).[5]

In response to CMO 82, no Plaintiff made a Rule 56(d) motion. Thus, the additional 60 days did prove sufficient. In addition to the omnibus responses to summary judgment filed by the Plaintiffs' Steering Committee, (Dkt. Nos. 1586, 1611, 1684), two sets of Plaintiffs filed responses to CMO 82. Thirty-four Plaintiffs ("the Hayes Law Firm Plaintiffs") submitted their Plaintiff Fact Sheets (PFSs) and certain medical records. (Dkt. Nos. 1670, 1682, 1686, 1687, 1688). They contend that (1) they were not diabetic before taking Lipitor, (2) they were diagnosed with diabetes after taking Lipitor, and (3) they did not have certain risk factors for diabetes, even though they had others. (*See* Dkt. No. 1670 at 17-39). At oral argument counsel stated this was "the best thing I could come up with with nonexpert evidence," that "[t]hey are not diabetic before taking the medication, they took Lipitor and then they became diabetic." (Dkt. No. 1727 at 24).

The Douglas & London Plaintiffs did not initially submit any evidence to the Court and simply argued that summary judgment was precluded by:

> (a) their respective health history and conditions as documented in their medical records, pharmacy records and/or other relevant records;
>
> (b) their respective Plaintiff Fact Sheets ("PFS's") that have already been served on Defendants and any and all amendments thereto;

[5] The Court also noted that Plaintiffs had not "stated how long they need to marshal this evidence or suggested any proposed timeline for obtaining it." (*Id*. at 8 n.5).

> (c) the general causation evidence identified and discussed in Plaintiffs' Opposition to Defendants' Omnibus Motion for Summary Judgment dated July 22, 2016 [Dkt. 1586]; and
>
> (d) the substantive state law that applies to each D&L Plaintiff's respective claims.

(Dkt. No. 1689 at 5 (footnotes omitted)). The Court entered a text order stating that these Plaintiffs must submit to the Court any evidence that they wished to the Court to consider. (Dkt. No. 1695). In response, Plaintiffs literally dumped boxes upon boxes of documents on the Court, with no discernment or suggestion as to which documents they claimed precluded summary judgment. (Dkt. Nos. 1698, 1700, 1701, 1702, 1703, 1704, 1705, 1706). Nevertheless, the Court reviewed these documents as well, almost all of which were completely irrelevant. For example, the documents include pictures from colonoscopies, EKGs, and pap smear results.

The Court held oral argument on the omnibus motion on November 1, 2016, and the matter is now before the Court for a decision.

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.[6] 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

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

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 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. 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. In *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245 (11th Cir. 2010), 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 and

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), 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.

The first bellwether Plaintiff, Plaintiff Daniels, proffered the testimony of Dr. David Handshoe on the issue of specific causation. The second bellwether Plaintiff, Plaintiff Hempstead 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 CMO 55, excluding the testimony of Dr. Murphy. (Dkt. No. 1283). Dr. Murphy determined that the most reliable data suggested a relative risk ratio of developing diabetes while taking Lipitor to be around 1.6. (Dkt. No. 1006-3 at 49). Using this estimate of relative risk, 63% of the people who take Lipitor and develop

diabetes would have done so *in the absence of Lipitor*, whereas 37% of the people who take Lipitor and develop diabetes did so only because they took Lipitor.[7] Thus, the Court turned to Dr. Murphy's methodology for concluding that Plaintiff Hempstead was in the 37% that developed diabetes due to Lipitor, rather than the 63% that would have done so regardless. (Dkt. No. 1283 at 10).

Dr. Murphy testified that Plaintiff Hempstead's BMI, adult weight gain, family history, age, and hypertension were all significant or substantial contributing factors in Plaintiff Hempstead's development of diabetes. (Dkt. No. 1275-2 at 185, 186, 247). Dr. Murphy's opinion that Lipitor was also a substantial contributing factor to Plaintiff Hempstead's development of diabetes was based on population studies showing that Lipitor increases the risk of diabetes (an element of general causation) and a temporal relationship, i.e., that Ms. Hempstead took Lipitor before developing diabetes.[8] (*See* Dkt. No. 1283 at 11-15). Dr. Murphy failed to offer any explanation as to why Ms. Hempstead's other risk factors for diabetes, alone or in combination, were not solely responsible for Ms. Hempstead's diabetes. (*Id*. at 28). The Court ultimately held this data and methodology insufficient under Rule 702 and excluded the testimony. (*See id*.). The Court later denied Plaintiffs' motion to reconsider its exclusion of Dr. Murphy's testimony in CMO 75, Dkt. No. 1514.

On May 11, 2016, the Court issued CMO 76, excluding the testimony of Dr. Handshoe in both this case and the *Daniels* case. Dr. Handshoe testified that the best estimate of the relative

[7] For an in depth discussion of relative risk and its implications, see CMO 55, Dkt. No. 1283. For purposes of the motion to exclude Dr. Murphy's testimony, the Court assumed that general causation could be established. (Dkt. No. 1283 at 1).

[8] Ms. Hempstead began taking Lipitor in 1998 and was diagnosed with diabetes in 2004. (Dkt. No. 1004-34 at 4, 5).

risk ratio for diabetes associated with statin use was 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. 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 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. Hempstead, Dr. Handshoe stated that he felt her overweight BMI was "not clinically significant given that . . . she had multiple normal blood sugars even with this weight." (Dkt. No. 1004-42 at 109). He testified that he did not know whether adult weight gain increased a patient's risk of diabetes and, therefore, did not consider it. (Dkt. No. 1004-42 at 109, 110). Dr. Handshoe acknowledged that Plaintiff Hempstead's ethnic background and age increased her risk of diabetes but summarily dismissed these as potential causes of her diabetes based on his "clinical judgment." (*Id*. at 142, 144, 206-08). Dr. Handshoe simply did not consider other risk factors that he testified were independent risk factors for diabetes, such as hypertension, elevated triglycerides and low HDL. (*Id*. at 181, 194). In the *Daniels* case, Dr. Handshoe testified that the diabetes risk factors were additive: "you have this risk, you have that risk, I think the risks are additive. I mean, how can you tease out that only one thing caused somebody's diabetes . . ." (Dkt. No. 1004-6 at 134). However, Dr. Handshoe took the opposite

position in his deposition in this case. He testified that Lipitor was "the only factor" in Ms. Hempstead's development of diabetes, finding that all other factors were "not significant to my clinical judgment." (*Id*. at 236, 237). He testified that his analysis was based solely on temporal relationship: Ms. Hempstead took Lipitor and developed diabetes after taking Lipitor. (*Id*. at 145-46). The Court 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 in response to the summary judgment motions filed in the two bellwether cases 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, Plaintiffs argue that they may be able to survive summary judgment with some evidence other than expert testimony and argue that the Court should remand all of the cases in the MDL back to the transferor courts for those courts to take up the issue on specific causation. 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 Plaintiffs have 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, Plaintiffs must cite to evidence in the record that would allow a jury to infer that Lipitor is capable of causing diabetes at dosages of less than 80 mg and that it did in fact cause individual Plaintiffs to develop 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 Plaintiffs at issue here were prescribed and ingested Lipitor is dosages of less than 80 mg prior to their diabetes diagnosis, they have no admissible expert testimony regarding general causation. However, Plaintiffs argue that alleged admissions by Defendant are sufficient to survive summary judgment.

Specifically, Plaintiffs argue 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[9] 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.

(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.[10] 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.[11] (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

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

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

[11] 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).

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 of Civil Procedure 56 applies to the claims at issue, they are clearly correct.[12] *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

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

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 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,[13] this Court finds that a state law requirement that expert testimony is 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

[13] *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. 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).

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.[14]

2. Expert Testimony is Required Under State Substantive Law.

As an initial matter, Plaintiffs dispute whether state substantive law requires expert testimony in this instance. Plaintiffs argue that state law "reflects a spectrum of subtly varying rules" that ranges from the requirement of expert testimony to no requirement at all. (Dkt. No. 1586 at 27). The variance is not nearly as great as Plaintiffs would have the Court believe.

While the specific language used by courts vary to some degree, all jurisdictions require expert testimony at least where the issues are medically complex and outside common knowledge and lay experience. *See, e.g., Ex parte Trinity Indus., Inc.*, 680 So. 2d 262, 269 (Ala.

[14] If the Court's ruling is incorrect, and Plaintiffs are correct that Fed. R. Civ. P. 56 supersedes any state law on what type of evidence is required to survive summary judgment, then that rule would also apply here. Federal law, under Rule 56, would govern whether expert testimony is required to survive summary judgment, and the Court need not engage in the 53 jurisdiction analysis below but simply rely on the ample federal precedent that expert testimony is required when medical causation is outside the common knowledge of lay jurors. *See, e.g., Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1316 (11th Cir. 2014) ("To prove Fixodent caused [plaintiff's injury], [plaintiffs] were required to have *Daubert*-qualified, general and specific-causation-expert testimony that would be admissible at trial to avoid summary judgment."), *cert. denied*, 135 S. Ct. 2312, (2015); *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002) ("[T]o establish causation, they must offer admissible expert testimony regarding both general causation, i.e., that xylene exposure can cause the type of ailments from which [plaintiff] claims to suffer; and specific causation, i.e., that xylene exposure actually caused his alleged neurological problems.").

1996) (expert testimony required to establish causation where "the nature and origin" of the injury is "beyond the understanding of the average person"); *E.C. ex rel. Crocker v. Child Dev. Sch., Inc*., No. 3:10-CV-759-WKW, 2011 WL 4501560, at *9 (M.D. Ala. Sept. 29, 2011) ("[E]xpert medical testimony, and not lay testimony, is required to demonstrate proximate cause, given the complexity of E.C.'s heart condition."); *Choi v. Anvil*, 32 P.3d 1, 3 (Alaska 2001) (expert testimony required to establish a causal connection "where there is no reasonably apparent . . . causal relationship between the event demonstrated and the result sought to be proved"); *Voyles v. State*, No. A-9377, 2008 WL 4951416, at *18 (Alaska Ct. App. Nov. 19, 2008) ("The test is whether the basis of the [casual] conclusion (once explained) can be readily understood and assessed by lay jurors."); *Rasor v. Nw. Hosp., LLC*, 373 P.3d 563, 566 (Ariz. Ct. App. 2016) (expert testimony required to establish causation "unless a causal relationship is readily apparent to the trier of fact"); *Gentry v. Daugherity*, No. CV-13-02136-PHX-ESW, 2015 WL 1346097, at *3 (D. Ariz. Mar. 24, 2015) ("Unless an injury is obvious to the jury, expert medical testimony is required to establish the nature and extent of the injury as well as its relationship to the accident.") (citing Arizona cases); *Isham v. Booneville Cmty. Hosp*., No. 2:14-CV-2018, 2015 WL 4133098, at *2 (W.D. Ark. July 8, 2015) ("Under Arkansas law, expert witness testimony is required to prove that any negligence of Defendants was a proximate cause of Plaintiff's injuries, as Plaintiff in this case alleged medical injuries based on a theory that involved complex determinations of medical issues that would not and could not be commonly understood by a lay person."); *Richardson v. Union Pac. R. Co*., 386 S.W.3d 77, 80 (Ark. App. Ct. 2011) ("[W]hen there is no obvious origin to an injury and it has multiple potential etiologies, expert testimony is necessary to establish causation."); *Miranda v. Bomel Const. Co*., 115 Cal. Rptr. 3d 538, 545–46 (Cal. App. 4th 2010) ("The law is well settled that in a personal injury

action causation must be proven within a reasonable medical probability based upon competent expert testimony."); *Sclafani v. Air & Liquid Sys. Corp.*, 14 F. Supp. 3d 1351, 1355 (C.D. Cal. 2014) ("Under California law, although juries are normally permitted to decide issues of causation without guidance from experts," issues of causation "beyond the experience of laymen and can only be explained through expert testimony."); *Howell v. Centric Grp., LLC*, No. 09-CV-02299-MSK-CBS, 2011 WL 4499372, at *5 (D. Colo. Sept. 27, 2011) ("Although causation may sometimes be inferred simply from circumstantial evidence, where questions of causation are beyond the knowledge and experience of ordinary persons, expert testimony may be required.") (applying Colorado law), *aff'd*, 508 F. App'x 834 (10th Cir. 2013); *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) ("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."); *Metro. Prop. & Cas. Ins. Co. v. Deere & Co.*, 25 A.3d 571, 584 (Conn. 2011) ("If lay witnesses and common experience are not sufficient to remove the case from the realm of speculation, the plaintiff will need to present expert testimony to establish a prima facie case."); *White v. Mazda Motor of Am., Inc.*, 54 A.3d 643, 650 (Conn. App. 2012) ("[W]e . . . consistently have held that expert testimony is required when the question involved goes beyond the field of the ordinary knowledge and experience of judges or jurors.") (internal quotations omitted), *aff'd*, 99 A.3d 1079 (Conn. 2014); *Roache v. Charney*, 38 A.3d 281, 286 (Del. 2012) ("When the plaintiff's claim involves bodily injuries, the causal connection between the defendant's alleged negligent conduct and the plaintiff's alleged injury must be proven by the direct testimony of a competent medical expert."); *Money v. Manville Corp. Asbestos Disease Comp. Trust Fund*, 596 A.2d 1372,

1375 (Del. 1991) ("[I]f the matter in issue is one within the knowledge of experts only and not within the common knowledge of laymen, it is necessary for the plaintiff to introduce expert testimony in order to establish a prima facie case.") (internal quotations omitted); *Lasley v. Georgetown Univ.*, 688 A.2d 1381, 1385 (D.C. 1997) ("Expert testimony is not required if the issue of causation can be resolved wholly within the realm of ordinary human knowledge and experience . . . or if the proof is so obvious as to lie within the ken of the average lay juror.") (internal quotations omitted); *Baltimore v. B.F. Goodrich Co.*, 545 A.2d 1228, 1231 (D.C. 1988) (expert testimony required "in cases presenting medically complicated questions due to multiple and/or preexisting causes"); *Benitez v. Joseph Trucking, Inc.*, 68 So. 3d 428, 431 (Fla. Dist. Ct. App. 2011) (expert testimony is necessary "to establish legal causation where the issue is beyond the common knowledge of laymen"); *Gouveia v. Phillips*, 823 So. 2d 215, 227 (Fla. Dist. Ct. App. 2002) (expert testimony required "when the discrete issue to be decided is not within the abilities of lay jurors"); *Cowart v. Widener*, 697 S.E.2d 779, 784 (Ga. 2010) (expert testimony required "where the existence of a causal link between the defendant's conduct and the plaintiff's injury cannot be determined from common knowledge and experience and instead requires the assistance of experts with specialized medical knowledge."); *Gilbert v. R.J. Taylor Mem'l Hosp., Inc.*,, 458 S.E.2d 341, 342 n.4 (Ga. 1995) ("Although it is conceded that the cause of action is one for simple negligence, rather than for professional malpractice, medical questions are raised, requiring expert evidence."); *Barbee v. Queen's Med. Ctr.*, 194 P.3d 1098, 1121 (Haw. Ct. App. 2008) ("Hawai'i does recognize a 'common knowledge' exception to the requirement that a plaintiff must introduce expert medical testimony on causation. . . . The exception is similar to the doctrine of *res ipsa loquitur*, and . . . rare in application.") (internal quotations omitted); *Bernard v. Char*, 903 P.2d 676, 682 (Haw. Ct. App.) (expert testimony required where "lay

jurors are ill prepared to evaluate complicated technical data for the purpose of determining . . . whether there is a causal relationship between the violation of a duty and an injury to the patient"), *aff'd*, 903 P.2d 667 (Haw. 1995); *Easterling v. Kendall*, 367 P.3d 1214, 1226 (Idaho 2016) (expert testimony required where "the causative factors are not ordinarily within the knowledge or experience of laymen composing the jury"), *reh'g denied* (Mar. 31, 2016); *Dodge-Farrar v. Am. Cleaning Servs. Co.*, 54 P.3d 954, 959 (Idaho Ct. App. 2002) (expert testimony required where the matter is not within "the usual and ordinary experience of the average person"); *Brown v. Baker*, 672 N.E.2d 69, 71 (Ill. App. 1996) ("[A] plaintiff in a personal injury case must present the testimony of a medical expert to establish causation if the relationship between the claimed injury and the event in question requires special knowledge and training to establish."); *Willis v. Westerfield*, 839 N.E.2d 1179, 1188 (Ind. 2006) ("[E]xpert testimony is required where the question involves medical factors beyond the common knowledge of the layman."); *Topp v. Leffers*, 838 N.E.2d 1027, 1035 (Ind. Ct. App. 2005) (expert testimony not required "[w]hen the issue of causation is within the understanding of a lay person."); *Welte v. Bello*, 482 N.W.2d 437, 441 (Iowa 1992) (expert testimony not required when causation is "within the common experience of laypersons"); *Donovan v. State*, 445 N.W.2d 763, 766 (Iowa 1989) ("[H]ighly technical questions of diagnoses and causation which lie beyond the understanding of a layperson require introduction of expert testimony."); *Pope By & For Juby v. Ransdell*, 833 P.2d 965, 973 (Kan. 1992) ("Expert testimony is necessary where normal experience and qualifications of lay persons serving as jurors does not permit them to draw proper conclusions from the facts and circumstances of the case."); *Azmat v. Bauer*, No. 2015-CA-000399-MR, 2016 WL 4709135, at *3 (Ky. Ct. App. Sept. 9, 2016) (expert testimony required in medical negligence case "in instances where causation is not so obvious as to amount

to res ipsa loquitur"); *Wilson v. Thyssenkrupp Budd Co*., No. 2005-CA-001567-WC, 2005 WL 3116045, at *3 (Ky. Ct. App. Nov. 23, 2005) ("When the cause of a condition is not readily apparent to a lay person, medical testimony supporting causation is required."); *Burgett v. Troy-Bilt LLC*, 970 F. Supp. 2d 676, 683 (E.D. Ky. 2013) (expert testimony required for topics "beyond the ken of ordinary persons"), *aff'd*, 579 F. App'x 372 (6th Cir. 2014); *Johnson v. E.I. DuPont deNemours & Co*., 7 So. 3d 734, 740 (La. App. 5 Cir. 2009) ("When a conclusion regarding medical causation is not one within common knowledge, expert medical testimony is required in a tort action."); *Hutchinson v. Shah*, 648 So. 2d 451, 452, (La. App. 1 Cir. 1994) ("When the conclusion regarding medical causation is not one within common knowledge, expert medical testimony is required."), *writ denied* 653 So. 2d 570 (La. 1995); *Darney v. Dragon Prod. Co., LLC*, 640 F. Supp. 2d 117, 123 (D. Me. 2009) ("[A] jury may not 'infer causation on complex medical facts without the aid of expert testimony.'") (quoting *Merriam v. Wange*r, 757 A.2d 778, 782 (Me. 2000)); *Walter v. Wal-Mart Stores, Inc.*, 748 A.2d 961, 972 (Me. 2000) (expert testimony not required where the "harmful results" of a negligent act "are sufficiently obvious as to lie within common knowledge"); *Wood v. Toyota Motor Corp*., 760 A.2d 315, 319 (Md. Ct. Spec. App. 2000) ("It is well settled that expert testimony is required when the subject of the inference is so particularly related to some science or profession that it is beyond the ken of the average layman.") (internal quotations omitted); *Miskin v. Baxter Healthcare Corp.*, 107 F. Supp. 2d 669, 672 (D. Md. 1999) (expert testimony is necessary under Maryland law when "the evidence relating to causation involves technical medical questions beyond the common knowledge of laypersons"), *aff'd*, 213 F.3d 632 (4th Cir. 2000) (table decision); *Case of Canavan*, 733 N.E.2d 1042, 1051 (Mass. 2000) ("Because understanding medical causation is beyond the knowledge of the ordinary layman proof of if it must rest upon

expert medical testimony.") (internal quotations and alterations omitted); *Pitts v. Wingate At Brighton, Inc.*, 972 N.E.2d 74, 78 (Mass. App. Ct. 2012) ("Expert testimony is necessary where proof of medical causation lies outside the ken of lay jurors."); *Hendrian v. Safety-Kleen Sys., Inc.*, No. 08-CV-14371, 2015 WL 4770966, at *4 (E.D. Mich. Aug. 13, 2015) ("[E]xpert testimony is often required because the alleged injuries are not immediately obvious and the connection between exposure and injury is not a matter of common sense or everyday experience.") (internal quotations omitted); *Dow v. Rheem Mfg. Co.*, No. 09-13697-BC, 2011 WL 4484001, at *22 (E.D. Mich. Sept. 26, 2011) ("Though not always required, expert testimony on causation is necessary, where the claim presents 'technical issues that are beyond the common experience and understanding of the common juror.'") (quoting *Schaendorf v. Consumers Energy Co.*, No. 281001, 2009 WL 563904, at *7–8 (Mich. Ct. App., March 5, 2009)), *aff'd*, 527 F. App'x 434 (6th Cir. 2013); *Gross v. Victoria Station Farms, Inc.*, 578 N.W.2d 757, 762 (Minn. 1998) ("Expert opinion is required to prove causation if the issue is outside the realm of common knowledge."); *Walton v. Jones*, 286 N.W.2d 710, 715 (Minn. 1979) ("[W]hen the causal relation issue is not one within the common knowledge of laymen, causation in fact cannot be determined without expert testimony.") (quotation omitted); *Denham v. Holmes ex rel. Holmes*, 60 So. 3d 773, 789 (Miss. 2011) ("Expert testimony is required unless the matter in issue is within the common knowledge of laymen") (quoting *Palmer v. Biloxi Reg'l Med. Ctr., Inc.*, 564 So. 2d 1346, 1355 (Miss. 1990)); *Berry v. Sw. Airlines Co.*, No. CIVA 307CV305TSL-JCS, 2008 WL 3874368, at *2 (S.D. Miss. Aug. 15, 2008) ("While in less complex cases where causation may be understood with only common sense, causation may be proved by lay testimony alone; however, with injuries that are medically complicated . . . expert testimony is required to prove causation."); *Wright v. Barr*, 62 S.W.3d 509, 524 (Mo. Ct. App.

2001) ("If there is a sophisticated injury, one that requires surgical intervention or other highly scientific techniques for diagnosis, expert medical testimony is required to prove causation."); *Pro Serv. Auto., L.L.C. v. Lenan Corp.*, 469 F.3d 1210, 1214 (8th Cir. 2006) (holding that under Missouri law, "expert testimony is necessary where the lay jury does not possess the experience or knowledge of the subject matter sufficient to enable them to reach an intelligent opinion without help") (internal quotations and alteration omitted); *Hinkle v. Shepherd Sch. Dist. No. 37*, 93 P.3d 1239, 1246 (Mont. 2004) ("[E]xpert testimony is required when the issue presented is sufficiently beyond the common experience of the trier of fact and the expert testimony will assist the trier of fact in determining the issue or understanding the evidence."); *Moralli v. Lake Cty., Mont.*, 839 P.2d 1287, 1291 (Mont. 1992) (expert testimony required in personal injury cases unless "the nature of the injury is such that laymen can plainly see, or infer from the injury, its cause"); *Bernhardt v. Cty. of Scotts Bluff*, 482 N.W.2d 262, 263 (Neb. 1992) ("Unless its nature and effect are plainly apparent, an injury is a subjective condition requiring an expert opinion to establish a causal relationship between the incident and the injury or disability."); *Saigen T. by & through Jacynda G. v. Mosaic*, No. A-15-299, 2016 WL 4045204, at *4–5 (Neb. Ct. App. July 26, 2016) (expert testimony required except where "a causal connection between negligence . . . and the resulting injury [is] apparent," i.e., "a layperson could clearly conclude that the[] injuries obviously stemmed from [the negligent act]") (citing cases); *Neal-Lomax v. Las Vegas Metro. Police Dep't*, 574 F. Supp. 2d 1193, 1199 (D. Nev. 2008) ("Under Nevada law, Plaintiffs must produce medical expert testimony to establish causation, particularly where the cause of death is not immediately apparent."), *aff'd*, 371 F. App'x 752 (9th Cir. 2010); *Layton v. Yankee Caithness Joint Venture, L.P.*, 774 F. Supp. 576, 580 (D. Nev. 1991) ("[W]here a question of fact is beyond the comprehension of the ordinary lay person, expert testimony is

required to prove that fact."); *Estate of Sicotte v. Lubin & Meyer, P.C.*, 959 A.2d 236, 239 (N.H. 2008) ("Expert testimony is required where the subject presented is so distinctly related to some science, profession or occupation as to be beyond the ken of the average layperson. Expert testimony is not required where the subject presented is within the realm of common knowledge and everyday experience."); *Tormenia v. First Inv'rs Realty Co*., 251 F.3d 128, 132 (3d Cir. 2000) ("New Jersey law *does* require expert testimony . . . in cases where lay jurors confront causation issues that are too complex to be understood without the assistance of specialized expert testimony.") (emphasis in original); *Kelly v. Borwegen*, 230 A.2d 532, 534 (N.J. Supp. Ct. App. Div. 1967) ("[W]here a claimed disability is the natural result of the injuries sustained, the jury may, without expert opinion, find that the injuries caused such disability. However, when an injury is such as to require skilled men to determine its cause and extent, the question is one of science, and must be established by skilled professional persons.") (quoting 25A C.J.S. Damages § 162(5)); *Am. Mech. Sols., L.L.C. v. Northland Process Piping, Inc.*, No. CV 13-1062 JB/SCY, 2016 WL 3124633, at *21 (D.N.M. Apr. 30, 2016) ("New Mexico, along with other jurisdictions, has required expert testimony when the issue of causation is presented in a context which is not a matter of common knowledge."); *State v. Campbell*, 546, 157 P.3d 722, 725 (N.M. 2007) (noting the distinction between when expert testimony "is *required* to establish an element of a claim or defense [because] it would assist the jury to understand issues in the case that are beyond their knowledge" and expert testimony that is "*helpful* to increase a jury's existing base of knowledge"); *Folz v. State*, 797 P.2d 246, 260 (N.M. 1990) ("Although in many cases expert testimony will be required to establish causation and damages, such testimony is not always necessary. . . .the use of expert medical testimony should be employed when the trial court reasonably decides that it is necessary to properly inform the jurors on the issues.") (internal

citations omitted)[15]; *Fane v. Zimmer, Inc.*, 927 F.2d 124, 131 (2d Cir. 1991) (under New York law, expert testimony required when the subject-matter is not "within the common knowledge and experience . . . of the ordinary jurymen") (quoting *Meiselman v. Crown Heights Hospital*, 34 N.E.2d 367, 370 (N.Y. 1941)); *Amorgianos v. Nat'l R.R. Passenger Corp.*, 137 F. Supp. 2d 147, 160 (E.D.N.Y. 2001) ("Under New York law, when the determination of whether an illness or injury was caused by some event or conduct is presumed not to be within common knowledge and experience, a plaintiff must produce expert opinion evidence based on suitable hypotheses in order to support a finding of causation.") (internal quotations omitted), *aff'd*, 303 F.3d 256 (2d Cir. 2002); *Young v. Hickory Bus. Furniture*, 538 S.E.2d 912, 915 (N.C. 2000) ("Due to the complexities of medical science, particularly with respect to diagnosis, methodology and determinations of causation, this Court has held that where the exact nature and probable genesis of a particular type of injury involves complicated medical questions far removed from the ordinary experience and knowledge of laymen, only an expert can give competent opinion

[15] Plaintiffs rely heavily on New Mexico, pointing to one products liability cases that survived summary judgment without direct expert testimony on specific causation. This case, *Carter Farms Co. v. Hoffman-Laroche, Inc.*, 492 P.2d 1000 (N.M. Ct. App. 1971), is not apposite. In *Carter Farms*, the plaintiff, a sheep farmer, brought a products liability action against the manufacturer of a vaccine-type solution he used on his animals. Of the first 1000 lambs injected with the solution, over 40% developed infected abscesses at the point of injection, and 192 died within three weeks of being injected. *Id*. at 1001-02. In the animals that died, the abscesses at the point of injection grew until "the leg literally rotted off the animal." *Id*. A pathologist expert testified that that the abscesses were caused by bacteria, but there was no expert testimony that the vaccine itself was contaminated with bacteria. *Id*. at 1002. A veterinarian expert testified that if the vaccine had been infected with bacteria, "it was a reasonable medical probability that an abscess would develop and a leg rot off within two weeks after the leg had been injected; that it was not possible for malignant edema or blackleg to be involved; that it was '(n)ot a very good possibility at all' that the feeders (the lambs that were purchased) may have been diseased; that the existence of organisms (bacteria) on the skin of the sheep before they were purchased would be a (v)ery faint' explanation." *Id*. at 1002. There was also evidence that the "lambs were in good health prior to the injection" and evidence that "the method of injection did not cause the abscesses." *Id*. at 1002. The Court found that under these circumstances, it would be reasonable for a jury to conclude that the vaccines were contaminated with bacteria and caused the deaths of the lambs. *Id*. at 1003. These circumstances are not analogous to the ones here.

evidence as to the cause of the injury.") (internal quotations omitted); *Halvorson v. Sentry Ins.*, 757 N.W.2d 398, 400 (N.D. 2008) ("[W]hen the causal relationship between a condition affecting the human body and a [negligent act] is not a matter within the common knowledge or comprehension of a layperson, the party bearing the burden of proof must present expert medical testimony establishing that relationship."); *Klimple v. Bahl*, 727 N.W.2d 256, 259 (N.D. 2007) ("[E]xpert testimony is required if the issue is beyond the area of common knowledge or lay comprehension, or the issue is not within the ordinary experience of the jurors.") (internal quotations and citations omitted); *Terry v. Caputo*, 875 N.E.2d 72, 77 (Ohio 2007) ("Except as to questions of cause and effect which are so apparent as to be matters of common knowledge, the issue of causal connection between an injury and a specific subsequent physical disability involves a scientific inquiry and *must* be established by the opinion of medical witnesses competent to express such opinion.") (emphasis in original); *Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1214 (10th Cir. 2002) ("[U]nder Oklahoma law, a plaintiff must introduce expert testimony if 'the fact in issue is not within the realm of ordinary experience of mankind.'") (quoting *Strubhart v. Perry Mem'l Hosp. Trust Auth.*, 903 P.2d 263, 274 (Okla.1995)); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1068 (D. Or. 2013) ("Under Oregon law, when the element of causation involves a complex medical question, a plaintiff must present expert testimony that there is a reasonable medical probability of causation.") (citing *Chouinard v. Health Ventures*, 39 P.3d 951 (Or. Ct. App. 2002)); *Hamil v. Bashline*, 392 A.2d 1280, 1285 (Pa. 1978) ("Although in certain situations involving physical injury, it is possible for a jury reasonably to infer causation from the circumstances of an accident or occurrence, it is generally acknowledged that the complexities of the human body place questions as to the cause of pain or injury beyond the knowledge of the average layperson. For a plaintiff to make out his cause of action in such a

case, therefore, the law requires that expert medical testimony be employed.") (internal citations omitted); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 525 (W.D. Pa. 2003) ("In a case such as this one involving complex issues of causation not readily apparent to the finder of fact, plaintiff must present admissible expert testimony to carry her burden."); *Velazquez v. Abbott Labs.*, 901 F. Supp. 2d 279, 293 (D.P.R. 2012) ("The necessity of expert opinion evidence, however, is whether the question is one of common knowledge such that lay people could reach the conclusion as intelligently as the witness.") (internal quotations omitted) (applying Puerto Rico law); *In re Bausch & Lomb Inc. Contacts Lens Sol. Prod. Liab. Litig.*, 693 F. Supp. 2d 515, 520 (D.S.C. 2010) ("Regarding expert testimony, to prove causation Puerto Rico law requires an expert's opinion when the matter is sufficiently beyond common experience.") (internal quotations omitted), *aff'd sub nom. Fernandez-Pineiro v. Bausch & Lomb, Inc.*, 429 F. App'x 249 (4th Cir. 2011); *Mills v. State Sales, Inc.*, 824 A.2d 461, 468 (R.I. 2003) ("[E]xpert testimony is required to establish any matter that is not obvious to a lay person and thus lies beyond common knowledge."); *Babb v. Lee Cty. Landfill SC, LLC*, 747 S.E.2d 468, 481 (S.C. 2013) ("The general rule in South Carolina is that where a subject is beyond the common knowledge of the jury, expert testimony is required."); *Burley v. Kytec Innovative Sports Equip., Inc.*, 737 N.W.2d 397, 407 (S.D. 2007) ("[E]xpert testimony is required when the issue falls outside the common experience of a jury.") (citing *Caldwell v. John Morrell & Co.*, 489 N.W.2d 353 (S.D.1992)); *Tomazin v. Lincare, Inc.*, No. 3:13-CV-0875, 2015 WL 4545658, at *12 (M.D. Tenn. July 27, 2015) ("Under Tennessee law, a plaintiff must provide admissible expert testimony as to both causation and product defect in order to prove liability in a products action. . . . Moreover, under Tennessee law, medical causation must be established by expert testimony.") (citing cases); *Jastrebski v. Smith & Nephew Richards, Inc.*, No. 02A01-9803-CV-00068, 1999

WL 144935, at *6 (Tenn. Ct. App. Mar. 18, 1999) ("The product in dispute is a technically complex prescription medical device, and expert testimony is required to establish the causal connection between the alleged defect in the device and Plaintiff's claimed injuries."); *Guevara v. Ferrer*, 247 S.W.3d 662, 665 (Tex. 2007) ("The general rule has long been that expert testimony is necessary to establish causation as to medical conditions outside the common knowledge and experience of jurors."); *Graves v. N. E. Servs., Inc.*, 345 P.3d 619, 627 (Utah 2015) (expert testimony required on "scientific matters beyond the capacity of an ordinary juror"); *Fox v. Brigham Young Univ.*, 176 P.3d 446, 451–52 (Utah App. 2011) ("In Utah, the need for positive expert testimony to establish a causal link between the defendants' negligent act and the plaintiff's injury depends on the nature of the injury. . . . Thus, where the injury involves obscure medical factors which are beyond an ordinary lay person's knowledge, necessitating speculation in making a finding, there must be expert testimony that the negligent act probably caused the injury. . . . It is only in the most obvious cases that a plaintiff may be excepted from the requirement of using expert testimony to prove causation.") (internal quotations, alterations, and citations omitted); *Egbert v. Book Press*, 477 A.2d 968, 969 (Vt. 1984) ("When the facts to be proved are such that any layman of average intelligence would know from his own knowledge and experience that the accident was the cause of the injury, no expert testimony is needed to establish the causal connection; however, where the causal connection is obscure, expert testimony is required."); *Zellers v. NexTech Ne., LLC*, 533 F. App'x 192, 200 (4th Cir. 2013) ("To prove causation in a toxic tort action, a plaintiff must offer relevant and reliable expert testimony, as the health effects of toxic exposure to chemicals are beyond the knowledge and experience of the average layperson.") (applying Virginia law); *Gauthreaux v. United States*, 694 F. Supp. 2d 460, 465 (E.D. Va. 2009) ("[I]n a products liability action, proof

of causation must ordinarily be supported by expert testimony because of the complexity of the causation facts.") (applying Virginia law); *Washington v. HOVENSA, LLC*, No. CIV.A. 06-97, 2011 WL 6965855, at *1 (D.V.I. Dec. 13, 2011) ("[E]xpert testimony is required to prove causation in cases where the complexities of the human body place questions as to the cause of pain or injury beyond the knowledge of the average layperson.") (internal quotations omitted); *Anders v. Puerto Rican Cars, Inc.*, No. CIV.A. 04-0036, 2009 WL 3007367, at *9 (D.V.I. Sept. 15, 2009) ("Proving that an alleged defect was the legal cause of an injury requires testimony from a qualified expert who can testify about specific causation, just as expert testimony is required to establish the standard of care and causation in medical malpractice cases in the Virgin Islands.") (internal quotations omitted), *aff'd*, 409 F. App'x 539 (3d Cir. 2011); *Bruns v. PACCAR, Inc.*, 890 P.2d 469, 477 (Wash. App. Div. 1 1995) ("Expert testimony is required to establish causation when an injury involves obscure medical factors that would require an ordinary lay person to speculate or conjecture in making a finding."); *Strahin v. Cleavenger*, 603 S.E.2d 197, 211 (W.V. 2004) (expert testimony is required "where the injury is obscure, that is, the effects of which are not readily ascertainable, demonstrable or subject of common knowledge"); *Rohrbough v. Wyeth Labs., Inc.*, 916 F.2d 970, 972 (4th Cir. 1990) (holding that under Virginia law, plaintiff had to prove that defendant's vaccine caused plaintiff's injuries and had to do so "by expert testimony"); *Kolesar v. United Agri Prod., Inc.*, 246 F. App'x 977, 981 (6th Cir. 2007) ("Under Wisconsin law, '[e]xpert testimony is required to prove causation if the matter does not fall within the realm of ordinary experience and lay comprehension.'") (quoting *Menick v. City of Menasha*, 547 N.W.2d 778, 782 (Wis. App. 1996)); *City of Cedarburg Light & Water Comm'n v. Allis-Chalmers Mfg. Co.*, 149 N.W.2d 661, 662 (Wis. 1967) ("There may be cases where the issue of causation, like the issue of negligence, involves technical, scientific or

medical matters which are beyond the common knowledge or experience of jurors and without the aid of expert testimony the jury could only speculate as to what inferences to draw if it were left to determine the issue. The lack of expert testimony in such cases results in an insufficiency of proof."); *Bodily v. State, ex rel., Wyoming Workers' Safety & Comp. Div.*, 320 P.3d 240, 250 (Wyo. 2014) ("[E]xpert testimony is required to establish causation unless the injury is immediately and directly or naturally and probably the result of an accident.") (internal quotations omitted); *Sayer v. Williams*, 962 P.2d 165, 168 (Wyo. 1998) (expert testimony required "[i]f the origin of the injury is obscure and not readily apparent to a layman, or if there are several equally probable causes of the condition").

To be sure, Plaintiffs are correct that there are instances where expert testimony is not required to prove causation, but those circumstances—where a lay juror can infer causation from common knowledge and lay experience—are not present here. Such circumstances include an immediate onset of symptoms that naturally follow from an accident or a complete lack of any other possible cause. *E.g., Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1210 (8th Cir. 2000); *Lasley v. Georgetown Univ.*, 688 A.2d 1381, 1385 (D.C. 1997); *see also Galloway v. Horne Concrete Const.*, 524 F. App'x 865, 872 (4th Cir. 2013) (under Maryland law, "a plaintiff was not required to prove causation by expert evidence when she drank from a spigot and developed chemical burns in her mouth immediately thereafter"); *Cowart v. Widener*, 697 S.E.2d 779, 784 (Ga. 2010) ("[I]t does not require expert testimony for a lay jury to determine that a gunshot wound to the head of an otherwise healthy person who died shortly thereafter was the proximate cause of her death."); *Pagett v. N. Elec. Supply Co.*, 167 N.W.2d 58, 64 (Minn. 1969) (expert testimony on causation was not required where it was "undisputed that plaintiff stepped into the coalhole, did a so-called 'spread-eagle,' and received emergency treatment at a hospital;

sustained abrasions of the legs; had accompanying pain in the lower back, left hip, and upper part of the left leg, with other obvious injuries and discomforts"); *Pitts v. Wingate At Brighton, Inc.*, 972 N.E.2d 74, 79 (Mass. App. Ct. 2012) ("No expert testimony is necessary for lay jurors to appreciate that allowing a nursing home patient to fall to the floor could cause a broken bone."); *Dodge-Farrar v. Am. Cleaning Servs. Co.*, 54 P.3d 954, 959 (Idaho Ct. App. 2002) ("[T]he causal relationship between [plaintiff's] fall and her immediate symptoms in the ankle, knee and back (the pain, swelling, and the inability to sit, stand or walk without assistance) is within the usual and ordinary experience of the average person."); *Brown v. Baker*, 672 N.E.2d 69, 71 (Ill. App. 1996) ("[I]f a plaintiff suffers a cut in an accident, the jury can readily determine without expert testimony that the accident caused the cut.").

On the other hand, the effects of drugs on the human body and the causation of a complicated, progressive diseases like diabetes do require expert testimony. *See, e.g.*, *Hollander*, 289 F.3d at 1214 ("The alleged effect of Parlodel is not within the realm of ordinary experience: in order to assess the arguments regarding the alleged effects of the drug, the factfinder would be required to assess the wide variety of scientific evidence . . . . As a result, the [plaintiffs] cannot prove their claim without expert testimony."); *Sullivan v. Pfizer, Inc.*, No. 3:14-CV-1374 (MPS), 2016 WL 868155, at *4 (D. Conn. Mar. 4, 2016) ("[E]xpert testimony is necessary to determine the effect of a prescription drug, Lipitor, on the human body, and to determine whether it caused [plaintiff's] injuries, including, among others, medical diagnoses . . ."); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1068 (D. Or. 2013) (under Oregon law, plaintiff must present expert testimony on both general and specific causation to survive summary judgment in pharmaceutical product liability case); *In re Baycol Prods. Litig.*, 321 F.Supp.2d 1118, 1126 (D. Minn. 2004) ("Expert testimony is particularly important in personal injury cases

involving pharmaceuticals because they involve complex questions of medical causation beyond the understanding of a lay person."); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 525 (W.D. Pa. 2003) (expert testimony required on both general and specific causation in pharmaceutical product liability case); *Blanchard v. Eli Lilly & Co.*, 207 F. Supp. 2d 308, 322 (D. Vt. 2002) ("Without expert testimony that Prozac caused the deaths, it is not possible to show that any inadequacy in warning about Prozac was a substantial factor in bringing about the deaths."); *Hinkle v. Shepherd Sch. Dist. No. 37*, 93 P.3d 1239, 1246 (Mont. 2004) (development of Type I diabetes is "beyond the common experience and understanding of the trier of fact"); *Swallow v. Emergency Med. of Idaho, P.A.*, 67 P.3d 68, 75 (Idaho 2003) ("Whether or not the Cipro taken by [plaintiff] was a cause of his heart attack is a matter of science that is far removed from the usual and ordinary experience of the average person. A jury, comprised of lay people, is simply not qualified to determine that issue without the assistance of expert testimony establishing that Cipro can cause a myocardial infarction."); *Mills v. State Sales, Inc.*, 824 A.2d 461, 468 (R.I. 2003) ("[W]e do not hesitate to conclude that the existence of a causal relationship between a particular toxin and its effect on the human body would have to be established through expert testimony."); *Ellis v. Hartford Run Apartments LLC*, 779 S.E.2d 103, 108 (Ga. App. 2015) ("Because the plaintiffs failed to submit expert medical testimony linking [plaintiff's] exposure to mold to her medical conditions, the defendants were entitled to summary judgment on the claim for damages for personal injury."), *reconsideration denied* (Dec. 7, 2015), *cert. denied* (Apr. 4, 2016).

Here, expert testimony is certainly required. Diabetes is a complicated, progressive disease with a number of risk factors. Whether the drug Lipitor is capable of causing diabetes is

a medically complex question outside of a lay jurors knowledge and experience, and Plaintiffs have not pointed any authority that would suggest otherwise.

3. Admissions Cannot Substitute for Expert Testimony When Required Under State Law.

The Court can find no state law cases 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).[16] 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

[16] 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.

> 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.

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.[17] 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

[17] 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.

> 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 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."). [18]

[18] 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.

4. 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 analysis for the occurrence of diabetes in SPARCL.[19] 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.[20] *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.*

[19] 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).

[20] 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.

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 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.")[21] (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

[21] 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.

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.*

Here, viewing the evidence in the light most favorable to Plaintiffs,[22] 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.[23]

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 state 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

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[22] 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.").

[23] 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).

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 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 state 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 expert testimony requirements under substantive state law without any indication the they would do so. Therefore, the Court finds this email cannot create a genuine issue of material fact as to general causation.

5. 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.[24]

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.[25] 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.

6. 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

[24] 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).

[25] 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.

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 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,[26] 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 state courts were to allow certain types of party opponent admissions to replace expert testimony when it is substantively required by state law, they 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

[26] See Dkt. No. 1181.

summary judgment on the ground that Plaintiff has failed to create a genuine issue of material fact as to general causation.

B. Specific Causation

1. Expert Testimony is Required.

As explained above, all jurisdictions at issue here require expert testimony at least where the issues are medically complex and outside common knowledge and lay experience. Courts have held that effects of drugs on the human body and the causation of a complicated, progressive diseases like diabetes do require expert testimony.[27] *See, e.g.*, *Hollander*, 289 F.3d at 1214 ("The alleged effect of Parlodel is not within the realm of ordinary experience: in order to assess the arguments regarding the alleged effects of the drug, the factfinder would be required to assess the wide variety of scientific evidence . . . . As a result, the [plaintiffs] cannot prove their claim without expert testimony."); *Sullivan*, 2016 WL 868155, at *4 ("[E]xpert testimony is necessary to determine the effect of a prescription drug, Lipitor, on the human body, and to determine whether it caused [plaintiff's] injuries, including, among others, medical diagnoses . . ."); *In re Baycol Prods. Litig.*, 321 F.Supp.2d at 1126 ("Expert testimony is particularly important in personal injury cases involving pharmaceuticals because they involve complex questions of medical causation beyond the understanding of a lay person."); *Hinkle*, 93 P.3d at 1246 (development of Type I diabetes is "beyond the common experience and understanding of the trier of fact").

Here, expert testimony is certainly required. Diabetes is a complicated, progressive disease with a number of risk factors. Plaintiff's general causation experts cannot even figure

[27] If the mythic state existed that allowed pharmaceutical products liability cases to go to a jury without any expert testimony on causation, it would be a black hole for all such cases. Plaintiffs have not cited a single case in any jurisdiction that has allowed a case to survive summary judgment in circumstances analogous to the ones here.

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. A jury's finding of causation in the absence of any expert testimony would be based on impermissible speculation or conjecture. *Dash*, 731 F.3d at 311.

2. Expert Testimony on General Causation Combined with Non-expert Evidence

Plaintiffs next argue that in some jurisdictions, a plaintiff can survive summary judgment with a combination of (1) specific causation expert testimony that a substance is a possible cause of a plaintiff's injury and (2) "non-expert evidence." (Dkt. No. 1586 at 29). Again, this statement is true as far as it goes, but is not applicable here. *See, e.g.*, *Benkendorf v. Advanced Cardiac Specialists Chartered*, 269 P.3d 704, 706 n.4 (Ariz. Ct. App. 2012) ("Under some circumstances, a plaintiff's expert may opine as to possible causes of an injury if other evidence supports a causal connection."); *Rodrigues v. Georgia-Pac. Corp.*, 661 S.E.2d 141, 143 (Ga. App. 2008) ("[M]edical testimony stated only in terms of a 'possible' cause *may* be sufficient when supplemented by probative non expert testimony on causation.") (emphasis in original).

The non-expert evidence present in these cases is probative of causation and, at least in combination with expert testimony on a "possible causes," is sufficient for a jury to infer causation without engaging in speculation; indeed, this non-expert evidence often consists of the same type of evidence that is sufficient to get to a jury without ***any*** expert testimony, such as in the case of immediate onset of symptoms. *See, e.g.*, *Smith v. Hines*, 261 P.3d 1129, 1135 (Okla. 2011) (expert testimony that accident could have caused curvature of the spine combined with

evidence "that there was no curvature of the spine before, but was shortly after, the accident" and plaintiff's evidence that "reasonably tended to exclude every other possible cause" was sufficient); *Ketcham v. Thomas*, 283 S.W.2d 642, 649–50 (Mo. 1955) (expert opinion that collision was a "possible" cause of plaintiff's constant menstrual bleeding combined with evidence "that immediately after the accident her condition changed to constant bleeding which could not be controlled and that this constant bleeding was not common and was not a symptom . . . before the collision" was sufficient to survive summary judgment on whether "the accident was the cause of the constant bleeding"); *Ideal Food Prod. Co. v. Rupe*, 261 P.2d 992, 993, 994 (Ariz. 1953) (evidence sufficient to survive summary judgment where plaintiff put forward expert testimony that her injury, which was diagnosed after the fall at issue, was "caused by a fall or some injury"; there was "no evidence of a prior trauma or injury that could have been the cause"; and plaintiff testified "to extreme pain after the accident and that prior to this fall she had never experienced any pain in and about her left hip"); *Rodrigues*, 661 S.E.2d at 144 (holding that expert testimony "unequivocally stated" that chlorine substantially contributed to plaintiff's pneumonia but noting that "even if the physician's testimony here were expressed only in terms of the chlorine being a 'possible' cause of [plaintiff's] injuries, other nonexpert evidence . . . [that] he was in apparent good health, he immediately became ill upon his exposure to the chlorine, which continuously worsened into the pneumonia he suffered when he presented at the emergency room" was sufficient to survive summary judgment.). [28]

[28] Plaintiffs point to one jurisdiction—Pennsylvania—that has found in medical malpractice cases that expert evidence of an "increased risk of harm" along with evidence that the harm in fact occurred is sufficient to warrant a jury trial. (Dkt. No. 1586 at 33). The Pennsylvania Supreme Court first found such evidence sufficient in a medical malpractice case in *Hamil v. Bashline*, relying on Section 323 of the Restatement of Torts, a.k.a., the Good Samaritan Rule. 392 A.2d 1280, 1286–87 (Pa. 1978); *see also Oxford Presbyterian Church v. Hindman Plumbing, Heating & Air Conditioning*, 35 Pa. D. & C.4th 289, 294 (Pa. Ct. Com. Pl. 1998)

However, for the cases at issue here, Plaintiff have not produced ***any*** expert evidence at all, not even expert evidence that Lipitor is a possible cause of diabetes. To the extent Plaintiffs attempt to rely on relative risk estimates of Dr. Murphy and Dr. Handshoe, Plaintiffs never disclosed either of these experts as general causation experts, and the Court has excluded the testimony of both in any event.

Furthermore, even if Plaintiffs had such expert testimony, they have not pointed to any probative, non-expert evidence to combine with it. Plaintiffs first state that "the MDL includes numerous patients with no history of diabetes prior to their initial Lipitor exposures." (Dkt. No. 1586 at 39). This is undoubtedly true. It is impossible that Lipitor would have caused a Plaintiff's diabetes if she developed the disease prior to ever taking the drug. However, the converse of this statement is not true. Plaintiffs may have developed diabetes after taking Lipitor, after having a grandchild, after tasting creme brulee for the first time, or after she turned

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("Ever since the case of *Hamil v. Bashline*, 481 Pa. 256, 392 A.2d 1280 (1978), liability has been imposed upon medical care providers under section 323 of the Restatement . . . for failing to take steps which would have prevented injury, thus increasing the 'risk' of harm."). However, "[t]he Pennsylvania Supreme Court limited its holding in *Hamil* to cases where the issue is 'the adequacy of medical services rendered in a fact situation to which section 323(a) applies, ...'" *Gans v. Gray*, 612 F. Supp. 608, 614 (E.D. Pa. 1985). Thus, for *Hamil* to be applicable, a case must "involve circumstances where one party undertook 'gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of the other's person or things.'" *Cooper v. Frankford Health Care Sys., Inc.*, 960 A.2d 134, 146 (Pa. Super. Ct. 2008) (quoting Restatement (Second) of Torts § 323); *see also Gans*, 612 F. Supp. at 614 ("The language of the Restatement indicates that a plaintiff under this section must have suffered a physical injury resulting from the negligent rendition of services, whether gratuitous or contracted for."); *Ettinger v. Triangle-Pac. Corp.*, 799 A.2d 95, 107 (Pa. Super. Ct. 2002) (upholding trial court's finding that "[t]he doctrine of increased risk of harm is inapplicable absent the undertaking of a service either gratuitously or for consideration"). While Section 323 is "often applied in medical malpractice suits," Pennsylvania courts have never invoked the section "in the context of a negligence-based products liability case." *Lempke v. Gen. Elec. Co.*, No. CIV.A. 11-1237, 2012 WL 94547, at *4 (W.D. Pa. Jan. 11, 2012). Such cases do not involve the rendition of services directly to a person, and attempting to apply the theory in such a case "stretches Section 323 beyond its plain meaning and beyond the cases decided by the Supreme Court of Pennsylvania." *Id.* This Court agrees and declines to extend *Hamil* and its progeny to products liability cases such as this one.

65. However, the fact that Plaintiff developed diabetes after these events does allow a reasonable jury to infer causation, without speculation and conjecture. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 264 (4th Cir. 1999) ("[T]he mere fact that two events correspond in time does not mean that the two necessarily are related in any causative fashion."); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1243 (11th Cir. 2005) ("[S]imply because a person takes drugs and then suffers an injury does not show causation. Drawing such a conclusion from temporal relationships leads to the blunder of the post hoc ergo propter hoc fallacy.").

"[D]epending on the circumstances, a temporal relationship between exposure to a substance and the onset of a disease or a worsening of symptoms can provide compelling evidence of causation." *Westberry*, 178 F.3d at 264 (finding expert testimony admissible). Indeed, the examples of immediate onset of symptoms cited above are such examples. *See Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 931 (8th Cir. 2001) ("Under some circumstances, a strong temporal connection is powerful evidence of causation . . . if a person were doused with chemical X and immediately thereafter developed symptom Y, the need for published literature showing a correlation between the two may be lessened"); *Westberry*, 178 F.3d at 265 (temporal relationship compelling where it was "undisputed that inhalation of high levels of talc irritate[d] mucous membranes," plaintiff "worked in clouds of talc . . . that covered him and his clothes," and every time the plaintiff stayed out of work, his sinuses improved, whereas every time plaintiff returned to work, they worsened).

But such circumstances are not present here. Plaintiffs here developed diabetes months or years after taking Lipitor and while they had other substantial risk factors for the disease.[29] The Court has already found that the temporal relationship at issue here is insufficient to form the basis of a reliable causation opinion under *Daubert*. (*See* CMO 55, Dkt. No. 1283 at 20-27). Therefore, it is necessarily insufficient to create an issue of fact as to causation. *See Hollander*, 289 F.3d at 1214 ("We have already ruled that five of the eight categories of evidence on which they rely did not constitute sufficiently reliable grounds under *Daubert* for their experts' opinions. As a result, these categories of evidence do not raise questions of fact on issues of causation."). The attenuated temporal relationship at issue here simply leaves a jury to speculate.

3. Hayes Law Firm Plaintiffs

These Plaintiffs submitted their Plaintiff Fact Sheets (PFSs) and certain medical records. (Dkt. Nos. 1670, 1682, 1686, 1687, 1688).[30] They contend that (1) they were not diabetic before taking Lipitor, (2) they were diagnosed with diabetes after taking Lipitor, and (3) they did not have certain risk factors. (*See* Dkt. No. 1670 at 17-39). At oral argument counsel stated this was "the best thing I could come up with, with nonexpert evidence," that "[t]hey are not diabetic before taking the medication, they took Lipitor and then they became diabetic." (Dkt. No. 1727 at 24). As explained above, the fact that Plaintiffs took Lipitor and sometime thereafter developed diabetes is not enough to create a genuine issue of material fact as to whether Lipitor did in fact cause their diabetes. *E.g.*, *McClain*, 401 F.3d at 1243. Any finding would be mere

[29] Every Plaintiff who submitted case-specific evidence in response to Pfizer's omnibus motion has at least one other, and often multiple other, risk factors for diabetes according the evidence submitted by her.

[30] The facts listed in Plaintiff's brief do not always correspond to the information in the PFS, and the facts in the PFSs (such as Plaintiff's weight) are often contradicted by Plaintiff's medical records.

speculation by the jury. Therefore, the Court grants summary judgment as to these plaintiffs as well.

4. Douglas & London Plaintiffs

These Plaintiffs did not initially submit any evidence to the Court and simply submitted a separate brief that argued that summary judgment was precluded by:

> (a) their respective health history and conditions as documented in their medical records, pharmacy records and/or other relevant records;
>
> (b) their respective Plaintiff Fact Sheets ("PFS's") that have already been served on Defendants and any and all amendments thereto;
>
> (c) the general causation evidence identified and discussed in Plaintiffs' Opposition to Defendants' Omnibus Motion for Summary Judgment dated July 22, 2016 [Dkt. 1586]; and
>
> (d) the substantive state law that applies to each D&L Plaintiff's respective claims.

(Dkt. No. 1689 at 5 (footnotes omitted)). The Court entered a text order stating that these Plaintiffs must file any evidence that they wished to the Court to consider. (Dkt. No. 1695). In response, Plaintiffs literally dumped boxes upon boxes of documents on the Court, with no discernment or suggestion as to which documents they claimed precluded summary judgment. (Dkt. Nos. 1698, 1700, 1701, 1702, 1703, 1704, 1705, 1706). Nevertheless, the Court reviewed these documents as well, almost all of which were completely irrelevant. The Court has found nothing in these records that would create an issue of fact as to causation, and Plaintiffs have pointed to none. Therefore, the Court enters summary judgment as to these Plaintiffs as well.

C. The Court Need Not Suggest Remand

The PSC and the specific Plaintiffs who responded to CMO 82, complain that the Court has overstepped its role as an MDL court by addressing specific causation. Plaintiffs cite MDL courts that have declined to address "cumbersome, case-specific legal issues." *In re*

Phenylpropanolamine Prod. Liab. Litig., No. MDL 1407, 2004 WL 2034587, at *2 (W.D. Wash. Sept. 3, 2004). Certainly if case-specific causation issues are cumbersome, MDL courts have the discretion to suggest remand prior to resolving case-specific issues.[31] *See In re Evergreen Valley Project Litig.*, 435 F. Supp. 923, 924 (J.P.M.L. 1977) ("It is not contemplated that a Section 1407 transferee judge will necessarily complete all pretrial proceedings in all actions transferred and assigned to him by the Panel, but rather that the transferee judge in his discretion will conduct the common pretrial proceedings with respect to the actions and any additional pretrial proceedings as he deems otherwise appropriate.").

However, it is equally clear that "[a]n MDL transferee judge has authority to dispose of cases on the merits–for example, by ruling on motions for summary judgment." Manual for Complex Litigation, § 22.36 (4th ed. 2004); *accord In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 113 F.3d 484, 1488 (8th Cir. 1997) (holding that "transferee court in federal multidistrict proceedings has the authority to enter dispositive orders terminating cases consolidated under 28 U.S.C. § 1407" and affirming summary judgment); *see also In re Food Lion, Inc., Fair Labor Standards Act Effective Scheduling Litig.*, 73 F.3d 528, 532 (4th Cir. 1996) ("In practice, however, the vast majority of transferred cases are disposed of completely in the transferee court, either through pretrial dispositions such as summary judgment, or by trial."); *In re Norplant Contraceptive Prod. Litig.*, 165 F.3d 374, 376 (5th Cir. 1999) (affirming MDL

[31] This decision is in the court's discretion. Some MDL courts have chosen to address case specific causation issues with regard to motions for summary judgment and suggest remand only after a case has survived a motion for summary judgment. In *In re: Asbestos Products Liability Litigation (No. VI)*, MDL No. 875, the MDL court has addressed at least 791 separate motions for summary judgment in individual cases from a variety jurisdictions. (*See* http://www.paed.uscourts.gov/documents/MDL/MDL875/MASTER%20Robreno%20MDL-875%20Decisions%20Chart%20-%20Updated%2011-6-15.xls).

court's entry of summary judgment based on the learned intermediary doctrine—a state law doctrine).

As the United States Supreme Court recently noted in a unanimous decision, "Congress anticipated that, during the pendency of pretrial proceedings, final decisions might be rendered in one or more of the actions consolidated pursuant to § 1407," by specifying that "'at or before the conclusion of ... pretrial proceedings,' each of the transferred actions must be remanded to the originating district '*unless [the action] shall have been previously terminated*.'" *Gelboim v. Bank of Am. Corp*., 135 S. Ct. 897, 904 (2015) (quoting 28 U.S.C. § 1407(a)) (emphasis in original). *Lexecon*'s holding that Section 1407 requires transfer back to the original court when "pretrial proceedings have run their course," *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 34 (1998), does not limit the ability of an MDL court to conduct pretrial proceedings, including ruling on dispositive motions, before suggesting remand.

In considering whether the Court should rule on such motions prior to transfer, the Court considers the "aims" of Section 1407 to "eliminate duplication in discovery, avoid conflicting rulings and schedules, reduce litigation cost, and save the time and effort of the parties, the attorneys, the witnesses, and the courts." *Gelboim*, 135 S. Ct. at 903 (quoting Manual for Complex Litigation § 20.131, p. 220 (4th ed. 2004)). Ruling on an omnibus motion for summary judgment that involve issues common to all cases, such as whether a claim can survive summary judgment without expert testimony on specific causation, "will promote the just and efficient conduct" of these actions and, thus, is the type of "coordinated or consolidated pretrial proceedings" envisioned by Section 1407. *See* Manual for Complex Litigation § 22.36 (4th ed. 2004) ("If the summary judgment motions involve issues common to all the cases centralized before the MDL court, . . . the transferee judge may be in the best position to rule."); *see also In*

re Activated Carbon-Based Hunting Clothing Mktg. & Sales Practices Litig., 840 F. Supp. 2d 1193, 1198 (D. Minn. 2012) ("Generally speaking, whether to remand 'turns on ... whether the case will benefit from further coordinated proceedings as part of the MDL.'") (quoting I*n re Air Crash Disaster at Tenerife, Canary Islands,* 461 F.Supp. 671, 672-73 (J.P.M.L.1978)). In this case, where no Plaintiff claims that she can produce an expert on specific causation that will survive *Daubert* if the Court's ruling in CMO 55 is correctly decided, it is inefficient, costly, and contrary to the purposes of the statute to suggest remand without ruling on summary judgment. This Court is familiar with the science and issues present and can dispose of the issues far more quickly and efficiently than dozens of courts spread across the country. The Court will have to consider the law of multiple jurisdictions, but it is competent to do so. Therefore, the Court declines Plaintiffs' invitation to essentially "disregard the entire course of the MDL proceedings" and suggest remand of these cases so Plaintiffs can avoid the writing on the wall. *See In re Zoloft (Sertralinehydrochloride) Prod. Liab. Litig.*, No. 12-MD-2342, 2016 WL 1320799, at *10 (E.D. Pa. Apr. 5, 2016).

IV. Conclusion

For the reasons stated above, Defendant's Omnibus Motion for Summary Judgment, (Dkt. No. 1564), is **GRANTED IN PART**. The Court GRANTS Defendant's motion as to Plaintiffs' claims listed in Appendix 1, and these claims are **DISMISSED WITH PREJUDICE**.

AND IT IS SO ORDERED.

Richard Mark Gergel
United States District Court Judge

January 3, 2017
Charleston, South Carolina