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Pursuant to CMO 79, Defendants Pfizer Inc., Pfizer International LLC, and Greenstone LLC respectfully move for summary judgment. A full explanation of the motion is provided in the supporting memorandum herein.

PRELIMINARY STATEMENT

Defendants are entitled to summary judgment because Plaintiffs lack admissible expert testimony to establish causation, an essential element of all of their claims. Plaintiffs claim that Lipitor caused them to develop type 2 diabetes. “[I]n order to carry the burden of proving a plaintiff’s injury was caused by exposure to a specified substance, a plaintiff must demonstrate general and specific causation.” *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 2016 WL 1251828, at *1 (D.S.C. Mar. 30, 2016) (“CMO 68”) (quoting *Zellers v. NexTech Ne., LLC*, 533 F. App’x 192, 196 (4th Cir. 2013) (per curiam), *cert. denied*, 134 S. Ct. 911 (2014)). “General causation is whether a substance is capable of causing a particular injury or condition in the general population and specific causation is whether a substance caused a particular individual’s injury.” *Id.* (quoting *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005)). In cases like these, “[w]here a medical causal relation issue is not one within the common knowledge of the layman,” Plaintiffs must prove general and specific causation through admissible expert testimony. *In re Bausch & Lomb Inc. Contacts Lens Sol. Prods. Liab. Litig.*, 693 F. Supp. 2d 515, 518 (D.S.C. 2010) (Norton, J.) (citation omitted), *aff’d sub nom Fernandez-Pineiro v. Bausch & Lomb, Inc.*, 429 F. App’x 249 (4th Cir. 2011) (per curiam). Plaintiffs cannot do so here.

First, based on this Court’s general causation ruling, summary judgment is warranted as to all Plaintiffs who took doses of Lipitor below 80 mg before developing diabetes because they lack admissible expert testimony establishing general causation. The Court excluded *all* of Plaintiffs’ experts’ general causation opinions *except* for Dr. Sonal Singh’s opinion that the 80 mg dose is capable of causing diabetes. CMO 68, 2016 WL 1251828, at *19. All Plaintiffs who took lower doses of Lipitor – including 10, 20, and 40 mg – lack the necessary expert proof of general causation, and their claims thus fail as a matter of law.

Second, and independently, all Plaintiffs lack admissible expert testimony to prove specific causation. The Court excluded the specific causation opinions of Plaintiffs' experts in the first two cases prepared for trial, *Daniels v. Pfizer Inc.*, 2:14-cv-01400, and *Hempstead v. Pfizer Inc.*, 2:14-cv-1879. See *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 2015 WL 9165589 (D.S.C. Dec. 11, 2015) ("CMO 55"); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 2016 WL 2851445 (D.S.C. May 11, 2016) ("CMO 76"). After the Court issued CMO 55, in which it excluded Dr. Elizabeth Murphy's specific causation opinion in *Hempstead*, Plaintiffs' lead counsel "advised the Court . . . that, if the Court's ruling [in CMO 55] 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." CMO 65 [1352] at 1. In response, in CMO 65, the Court provided all Plaintiffs an opportunity to come forward and dispute that statement. No Plaintiff did so.¹ Thus, summary judgment is warranted because no Plaintiff has "distinguished [her case] from the Court's ruling in CMO 55," CMO 65 at 1, and, as a result, no Plaintiff can prove specific causation.

BACKGROUND

The parties and Court agreed from the start of this MDL that it was necessary to adopt a process for the disclosure and discovery of expert opinions on general and specific causation and a procedure for making and hearing *Daubert* motions addressing those opinions. See, e.g., Amended CMO 6 [148] at 7-11; CMO 19 [539] at 4-6; CMO 29 [746]. The Court afforded Plaintiffs ample opportunity to develop admissible and sufficient causation evidence.

General Causation. Plaintiffs proffered general causation opinions from four experts: Drs. Edwin Gale, Michael Quon, Barbara Roberts, and Sonal Singh.² After full discovery,

¹ Certain Plaintiffs filed a notice stating that "they do not intend to undertake any action in response to Case Management Order No. 65" because their cases are subject to pending remand motions. Pls.' Notice Regarding CMO 65 [1373] at 1.

² Plaintiffs also offered related opinions on association from Prof. Nicholas Jewell, a biostatistician, the majority of which were excluded. See *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 2015 WL 7422613 (D.S.C. Nov. 20, 2015) ("CMO

briefing, and two days of argument on Pfizer’s motion to exclude those opinions, the Court requested supplemental briefing to address “whether Plaintiffs’ experts have offered sufficient evidence to support their opinions that Lipitor causes diabetes in female patients at a dosage level less than 80 mg.” Sept. 25, 2015 Text Order [1149]. Following supplemental briefing and another hearing, the Court ruled that “Plaintiffs must have expert testimony that Lipitor causes, or is capable of causing, diabetes at particular dosages.” *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 2015 WL 6941132, at *6 (D.S.C. Oct. 22, 2015) (“CMO 49”). The Court allowed Plaintiffs to submit supplemental reports to address “whether Lipitor causes diabetes at dosages of 10 mg, 20 mg, 40 mg, and 80 mg.” *Id.* Plaintiffs proffered supplemental reports from Drs. Quon, Roberts, and Singh.

After briefing and another hearing on Plaintiffs’ experts’ dose-specific opinions, the Court excluded the general causation opinions of Drs. Gale, Quon, and Roberts in their entirety as unreliable and inadmissible under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and Rule 702. CMO 68, 2016 WL 1251828, at *19. The Court also excluded Dr. Singh’s opinion that Lipitor 10 mg could cause type 2 diabetes. *Id.* The Court held that “Dr. Singh’s 10 mg opinion is not based on sufficient facts and data and that he did not reliably apply the epidemiological/Bradford Hill method.” *Id.* at *11. With respect to general causation at the 20 mg and 40 mg dosages of Lipitor, “Dr. Singh testifie[d] that he cannot reach an opinion about whether 20 mg and 40 mg of Lipitor causes diabetes without the conclusion that 10 mg of Lipitor causes diabetes.” *Id.* And “[b]ecause the Court . . . disallowed Dr. Singh’s causation opinion for Lipitor 10 mg, . . . Dr. Singh, by his own testimony, is unable to offer a causation opinion regarding Lipitor 20 mg or Lipitor 40 mg.” *Id.* The Court permitted Dr. Singh to proceed with his general causation opinion as to Lipitor 80 mg. *Id.* at *7.

Specific Causation. As to specific causation, Plaintiffs proffered the opinion of Dr. David Handshoe in *Daniels* and *Hempstead* and the opinion of Dr. Murphy in *Hempstead*. After

54”), *motion for reconsideration granted in part, amended by* 2016 WL 827067 (D.S.C. Feb. 29, 2016) (“CMO 67”).

full discovery, briefing, and hearings, the Court granted Pfizer's motions to exclude both experts' opinions in their entirety. *See* CMO 55, 2015 WL 9165589; CMO 76, 2016 WL 2851445. In CMO 55, the Court held that Dr. Murphy's specific causation opinion was unreliable and inadmissible under *Daubert* and Rule 702 because it was "not based on 'sufficient facts or data,' and to the extent that she purports to be applying a differential diagnoses methodology, she has not reliably applied this methodology." CMO 55, 2015 WL 9165589, at *14. The Court denied Plaintiffs' motion for reconsideration of its order. *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 2016 WL 2940782 (D.S.C. May 6, 2016) ("CMO 75"). The Court explained in its rulings that while "Dr. Murphy recognized that Plaintiff had a number of statistically significant risk factors for diabetes beyond ingestion of Lipitor," CMO 55, 2015 WL 9165589, at *13, "she never provided any explanation as to why these other risk factors, alone or in combination, were not sufficient to cause diabetes independent of Lipitor exposure." CMO 75, 2016 WL 2940782, at *2.

After the Court issued CMO 55 excluding Dr. Murphy, it held a conference and asked Plaintiffs' lead counsel if Plaintiffs "would have any class of cases or factual presentation or new theory that might survive specific causation, assuming the correctness of the Murphy order." 1/22/16 Hr'g Tr. at 9:12-20. Plaintiffs' counsel responded: "The short answer is no, sir, Your Honor, we don't." *Id.* at 9:21-24. The Court asked: "[I]f 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 are not going to have a case that survives summary judgment?" *Id.* at 10:10-14. Plaintiffs' counsel responded: "Yes, sir." *Id.* at 10:15. Plaintiffs' lead counsel also agreed at the conference that an order to show cause would be an appropriate procedure to determine if any other plaintiff or plaintiff's counsel disagreed with his representation. *Id.* at 10:16-13:10.

Following the conference, the Court issued CMO 65, giving notice "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 . . . 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.” CMO 65 at 1. The Court stated that if a Plaintiff gave notice, the Court would set a schedule for expert discovery and *Daubert* briefing. *Id.* No Plaintiff provided notice that she could offer specific causation testimony that would survive the Court’s analysis in CMO 55 or that she could prove specific causation without admissible expert testimony.

In CMO 79, the Court permitted Defendants to file “an omnibus summary judgment motion” based on “the lack of general causation and specific causation expert testimony.” CMO 79 [1548] at 1.

ARGUMENT

“The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56. The “plain language” of Rule 56 “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). “[A] complete failure of proof concerning an essential element of the [plaintiff’s] case necessarily renders all other facts immaterial,” *id.* at 323, and “necessitates a grant of summary judgment in favor of the defendant.” *Zellers*, 533 F. App’x at 200.

Causation is a required element of product liability claims. *See, e.g., Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001). “To establish medical causation in a product liability case, a plaintiff must show both general causation and specific causation.” *In re Bausch & Lomb*, 693 F. Supp. 2d at 518. Proof of causation requires “relevant and reliable expert testimony, as the health effects of toxic exposure to chemicals are beyond the knowledge and experience of the average layperson.” *Zellers*, 533 F. App’x at 200; *accord McClure v. Wyeth*, 2012 WL 952856, at *1 (D.S.C. Mar. 20, 2012) (Herlong, J.); *In re Bausch & Lomb*, 693 F.

Supp. 2d at 518.³ Because Plaintiffs lack the expert testimony necessary to prove causation here, Defendants are entitled to summary judgment.

I. SUMMARY JUDGMENT IS REQUIRED AS TO PLAINTIFFS WHOSE CLAIMS ARE BASED ON USE OF LIPITOR BELOW 80 MG BECAUSE THEY LACK ADMISSIBLE AND SUFFICIENT EVIDENCE OF GENERAL CAUSATION

As this Court has explained, “Plaintiffs must demonstrate, with general causation testimony, that particular doses of Lipitor are capable of causing diabetes.” CMO 49, 2015 WL 6941132, at *6. None of the Plaintiffs who ingested Lipitor only at doses below 80 mg – including the 10, 20, and 40 mg doses – can make this showing because this Court has excluded their experts’ general causation opinions at those doses. *See* CMO 68, 2016 WL 1251828, at *19. Because these Plaintiffs lack admissible expert testimony on general causation, “there is a complete failure of proof on the critical element of causation,” and summary judgment is warranted. *Zellers*, 533 F. App’x at 200.

It is well established that where “expert opinion evidence regarding causation is inadmissible . . . summary judgment *must* be granted to defendants.” *Rutigliano v. Valley Bus. Forms*, 929 F. Supp. 779, 783 (D.N.J. 1996) (emphasis added), *aff’d*, 118 F.3d 1577 (3d Cir. 1997); *accord Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 381 (5th Cir. 2010). Courts around the country routinely grant and affirm summary judgment where, as here, plaintiffs failed to pass the *Daubert* threshold on general causation. *See, e.g., Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1316-17 (11th Cir. 2014), *cert. denied*, 135 S. Ct. 2312 (2015); *Wells*, 601 F.3d at 381; *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254-55 (2d Cir. 2005); *Norris*, 397 F.3d at 884-86; *Miller v. Pfizer, Inc.*, 356 F.3d 1326, 1335-36 (10th Cir. 2004), *cert. denied*, 543 U.S. 917 (2004); *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 2016

³ Plaintiffs’ counsel recently asserted for the first time that New Mexico may be an exception to the general rule that all states require expert testimony to prove causation in cases like these. *See* 6/8/16 Hr’g Tr. at 11:13-18. New Mexico case law, however, confirms that “[e]xpert testimony is necessary” to show general and specific causation in cases that, like these, involve complex medical and scientific issues outside the knowledge and experience of a lay juror. *Farris v. Intel Corp.*, 493 F. Supp. 2d 1174, 1186 (D.N.M. 2007); *accord Andrews v. U.S. Steel Corp.*, 250 P.3d 887, 890 (N.M. Ct. App. 2011).

WL 1320799, at *10-11 (E.D. Pa. Apr. 5, 2016), *appeal filed*, (3d Cir. May 12, 2016); *In re Bausch & Lomb Inc. Contacts Lens Sol. Prods. Liab. Litig.*, 2010 WL 1727807, at *1-3 (D.S.C. Apr. 26, 2010) (Norton, J.), *aff'd sub nom Fernandez-Pineiro*, 429 F. App'x 249; *In re Bausch & Lomb*, 693 F. Supp. 2d at 517-19; *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 967-69 (D. Minn. 2009); *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 690-91 (D.N.J. 2008); *In re Rezulin Prods. Liab. Litig.*, 441 F. Supp. 2d 567, 579 (S.D.N.Y. 2006); *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 577-78 (W.D. Pa. 2003); *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1373-74 (N.D. Ga. 2001), *aff'd*, *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194 (11th Cir. 2002), *reh'g denied*, 48 F. App'x 330 (11th Cir. 2002); *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1485-86 (D.V.I. 1994), *aff'd*, 46 F.3d 1120 (3d Cir. 1994).

In the Zolofit MDL, for example, after excluding the opinions of plaintiffs' general causation experts as unreliable and inadmissible, the court held that summary judgment was warranted because "[a]t the end of the day, Plaintiffs have failed to raise a jury question on the necessary predicate to success in any case: that Zolofit was capable of causing their injuries." *In re Zolofit*, 2016 WL 1320799, at *11. Likewise, in the Bausch & Lomb MDL, in which plaintiffs alleged that a contact lens solution caused their eye injuries, Judge Norton granted summary judgment as to plaintiffs who alleged that the product caused them to develop "non-*Fusarium*" eye infections. *In re Bausch & Lomb*, 693 F. Supp. 2d at 517. "With the exclusion of plaintiffs' causation expert regarding eye infections other than *Fusarium* keratitis, it has become clear that the remaining plaintiffs have no admissible evidence to support their allegation that defendant's . . . contact lens solution caused the eye infections they experienced. Consequently, these plaintiffs cannot prove an essential element in each of their cases." *Id.* at 517. The Fourth Circuit affirmed. *Fernandez-Pineiro*, 429 F. App'x 249.

For the same reason, Defendants here are entitled to summary judgment as to the claims of Plaintiffs who took Lipitor doses below 80 mg.⁴

II. SUMMARY JUDGMENT IS REQUIRED BECAUSE ALL PLAINTIFFS LACK ADMISSIBLE AND SUFFICIENT EVIDENCE OF SPECIFIC CAUSATION

After Plaintiffs' counsel acknowledged that no case can "survive[] summary judgment" under this Court's order in CMO 55 excluding Dr. Murphy's specific causation opinion, CMO 65 provided all Plaintiffs ample opportunity to come forward if any Plaintiff disagreed and believed she could survive summary judgment on specific causation.⁵ No Plaintiff did so. By agreeing with Plaintiffs' lead counsel and by declining to file a notice in response to CMO 65, Plaintiffs have conceded that Defendants are entitled to summary judgment.

Like general causation, specific causation is an essential element of all of Plaintiffs' claims. The Fourth Circuit and district courts within it have repeatedly held that summary judgment is warranted where a plaintiff cannot demonstrate specific causation through admissible expert testimony. *See, e.g., Cooper*, 259 F.3d at 203; *Christian v. Cook Inc.*, 2015 WL 3557242, at *2 (S.D. W. Va. June 4, 2015); *McClure*, 2012 WL 952856, at *1-2; *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 478 (M.D.N.C. 2006); *Jones v. Danek Med., Inc.*, 1999 WL 1133272, at *5 (D.S.C. Oct. 12, 1999) (Houck, J.). In *Cooper*, for example,

⁴ In addition, because "[e]vidence concerning specific causation in toxic tort cases is admissible only as a follow-up to admissible general-causation evidence," *In re Bausch & Lomb*, 693 F. Supp. 2d at 518 (citation omitted), "there can be no specific causation" in cases involving Plaintiffs who took Lipitor doses below 80 mg. CMO 49, 2015 WL 6941132, at *1 (quoting *Norris*, 397 F.3d at 881).

⁵ Other MDL courts have employed a similar process of giving notice and an opportunity to all plaintiffs to advise the court if any plaintiff believes she should not be subject to a ruling that was issued with respect to one or certain cases but as to which the record and law support a finding that it applies more broadly to cases in the MDL. *See, e.g., In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, No. 3:08-cv-00008, Order to Show Cause Why the Claims of Plaintiffs Alleging Injury Prior to September 14, 2010 Should Not Be Dismissed [Dkt. 2895] (D.N.J. Aug. 15, 2013) (attached as Ex. 1); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-md-2226, Order Directing Plaintiffs to Show Cause Why Claims as to Generic Defendants Should Not Be Dismissed [Dkt. 1645] (E.D. Ky. Apr. 10, 2012) (attached as Ex. 2); *In re Viagra Prods. Liab. Litig.*, No. 06-md-1724, Order to Show Cause [Dkt. 623] (D. Minn. Aug. 25, 2010) (attached as Ex. 3).

plaintiff claimed a pedicle screw fixation device caused his back surgeries to fail and led to related side effects. *Cooper*, 259 F.3d at 196-98. The Fourth Circuit affirmed the exclusion of plaintiff's specific causation expert because (like Plaintiffs' specific causation experts here) his differential diagnosis was not reliable. *Id.* at 202-03. "And without [the expert's] testimony, [plaintiff] could not make the requisite showing of causation. The district court therefore properly granted [the manufacturer's] motion for summary judgment on all claims." *Id.* at 203 (footnotes omitted). Similarly, in *McClure*, plaintiff alleged that her ingestion of hormone therapy medication caused her breast cancer. 2012 WL 952856 at *1. Judge Herlong excluded plaintiff's specific causation experts as unreliable and then granted summary judgment because "expert testimony is necessary to establish causation for cases involving [] complex medical condition[s]." *Id.*

Federal appellate courts have repeatedly affirmed similar rulings. For example, in *Chapman v. Procter & Gamble Distributing, LLC*, in which plaintiff claimed that her use of a denture adhesive caused her to develop a neurological disorder, the Eleventh Circuit affirmed summary judgment based on the exclusion of plaintiffs' causation experts. 766 F.3d at 1316-17. Plaintiffs "were *required* to have *Daubert*-qualified, general and specific-causation expert testimony that would be admissible at trial to avoid summary judgment." *Id.* at 1316; *see also*, e.g., *Milward v. Rust-Oleum Corp.*, 2016 WL 1622620, at *5-6 (1st Cir. Apr. 25, 2016); *Nelson v. Matrixx Initiatives, Inc.*, 592 F. App'x 591, 592 (9th Cir. 2015), *cert. denied*, 136 S. Ct. 76 (2016); *In re Aredia & Zometa Prods. Liab. Litig.*, 483 F. App'x 182, 191 (6th Cir. 2012), *cert. denied*, 133 S. Ct. 576 (2012); *Guinn v. AstraZeneca Pharms. LP*, 602 F.3d 1245, 1257 (11th Cir. 2010) (per curiam); *In re Baycol Prods. Liab. Litig.*, 596 F.3d 884, 892 (8th Cir. 2010).

Consistent with these authorities, CMO 65 made clear that if, as Plaintiffs' lead counsel asserted, Plaintiffs lacked admissible expert testimony on specific causation under this Court's opinion in CMO 55, Plaintiffs' cases would be subject to "summary judgment on the issue of specific causation." CMO 65 at 1. In CMO 55, this Court identified a number of flaws in Dr.

Murphy's specific causation methodology that rendered her opinion unreliable and inadmissible.

The Court concluded:

Dr. Murphy's opinion is based only on (1) her conclusion that Lipitor increases the risk of diabetes and (2) . . . the fact that Ms. Hempstead was diagnosed with diabetes after taking Lipitor. She failed to point to any evidence, other than a (belated) temporal relationship, that Lipitor contributed to the development of diabetes in Ms. Hempstead's case. She failed to offer any explanation as to why Ms. Hempstead's other risk factors for diabetes . . . , alone or in combination, are not solely responsible for Ms. Hempstead's diabetes.

CMO 55, 2015 WL 9165589, at *14; *accord* CMO 75, 2016 WL 2940782, at *1-2.

Under CMO 65, Plaintiffs had the opportunity to advise the Court that they disputed the position taken by Plaintiffs' lead counsel and that they would assert that their cases can survive summary judgment on specific causation even if the Court's ruling in CMO 55 is affirmed on appeal. The Court further made clear that it was prepared to set schedules for the disclosure of experts and for *Daubert* motions in such cases. No Plaintiff came forward purporting to distinguish her case from the Court's ruling on Dr. Murphy in CMO 55. As a result, Defendants are entitled to summary judgment in all cases.

CONCLUSION

For the foregoing reasons, this Court should grant Defendants' motion for summary judgment.

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CERTIFICATE OF SERVICE

I hereby certify that, this 24th day of June 2016, I have electronically filed a copy of the above and foregoing with the Clerk of the Court using the ECF system, which sent notification of such filing to counsel of record.

/s/ Mark S. Cheffo
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