

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re Viagra Products Liability Litigation

MDL No. 06-1724 (PAM)

This Order Relates to:

Richard Martin,

Civil No. 06-1064 (PAM)

Plaintiff,

v.

Pfizer, Inc.,

Defendant.

MEMORANDUM & ORDER

Richard Stanley,

Civil No. 06-1065 (PAM)

Plaintiff,

v.

Pfizer, Inc.,

Defendant.

This matter is before the Court on Defendant Pfizer, Inc.'s Motions (1) to Exclude the Testimony of Plaintiffs' Specific Causation Experts, (2) to Exclude the Testimony of Cheryl Blume, Ph.D., and (3) for Summary Judgment. For the reasons that follow, Pfizer's Motion to Exclude the Testimony of Plaintiffs' Specific Causation Experts is granted; Pfizer's

Motion to Exclude the Testimony of Dr. Blume is granted in part and denied in part; and Pfizer's Motion for Summary Judgment is granted.

BACKGROUND

At the outset, the Court notes that in an Order issued simultaneously with this Order, the Court granted Pfizer's motion to exclude the general causation opinion of Dr. Gerald McGwin because it is not sufficiently reliable under Daubert. See Order Granting Pfizer's Motion to Exclude the Testimony of Dr. Gerald McGwin (Docket No. 607), in In re Viagra Prod. Liab. Litig., 06-MDL-1724 (D. Minn. Aug. 19, 2009) (Magnuson, J.). That decision effectively ended the current litigation, because, as discussed in more detail below, absent an admissible general causation opinion, Plaintiffs' claims necessarily fail and Pfizer's motion for summary judgment must be granted. However, for the sake of comprehensiveness, the Court will consider Pfizer's additional Daubert motions below.

Plaintiffs are suing Pfizer because they allege that one of Pfizer's drugs, Viagra, caused them to suffer vision loss from a disorder known as non-arteritic anterior ischemic optic neuropathy ("NAION"). At issue currently before the Court are the specific cases of Plaintiffs Richard Martin and Richard Stanley against Pfizer. Plaintiffs have offered the opinions of five experts that Viagra specifically caused Martin's NAION. Two of those experts also opine that Viagra specifically caused NAION in Stanley. All five proposed experts offer their opinions to a reasonable degree of medical certainty. Plaintiffs have also offered the opinion of one regulatory expert. Pfizer raises a number of challenges to Plaintiffs' proposed experts. Each expert will be discussed in turn.

DISCUSSION

A. Rule 702 and Daubert Standard

The Court discussed in detail in its previous orders the law surrounding the admission of expert testimony. Ultimately, the Court's role as a gatekeeper is to ensure that only relevant and reliable expert testimony is admitted. See Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589 (1993). "This gatekeeping requirement is to ensure that the proffered expert exercises the same intellectual rigor in the courtroom as does an expert in the relevant field." Bland v. Verizon Wireless, (VAW) LLC, 538 F.3d 893, 896 (8th Cir. 2008) (quotations omitted); see also Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999).

Three of Plaintiffs' proposed specific causation experts used a technique called a differential diagnosis to reach their conclusion that Viagra caused Plaintiffs' NAION.

In performing a differential diagnosis, a physician begins by "ruling in" all scientifically plausible causes of the plaintiff's injury. The physician then "rules out" the least plausible causes of injury until the most likely cause remains. The final result of a differential diagnosis is the expert's conclusion that a defendant's product caused (or did not cause) the plaintiff's injury.

Glastetter v. Novartis Pharm. Corp., 252 F.3d 986, 989 (8th Cir. 2001). A temporal relationship between the ingestion of a drug and the onset of particular symptoms, alone, "is not scientifically valid proof of causation." Id. at 990. A general causation opinion is a prerequisite to a proper differential diagnosis; it "assumes that the final, suspected cause remaining after this process of elimination must actually be capable of causing the injury." Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005) (quotation omitted) (emphasis in original). "[A] medical opinion about causation, based upon a proper

differential diagnosis, is sufficiently reliable to satisfy Daubert.” Turner v. Iowa Fire Equipment Co., 229 F.3d 1202, 1208 (8th Cir. 2000). However, a differential diagnosis that fails “to consider all the possible causes, or to exclude each potential cause until only one remain[s], or to consider which of two or more non-excludable causes [is] the more likely to have caused the condition” is not a proper differential diagnosis to determine causation, and a causation opinion based on that inadequate methodology is not admissible to show causation. Id. Differential diagnoses are presumptively admissible and a court therefore only excludes scientifically invalid diagnoses. Glastetter, 252 F.3d at 989.

B. Specific Causation Experts

1. Dr. John Williams

Dr. Williams is an ophthalmologist who most recently has focused on occupational medicine rather than ophthalmology. Dr. Williams offers an opinion that Viagra caused both Martin’s and Stanley’s NAION. Pfizer challenges the admissibility of Dr. Williams’s testimony because (1) his general causation opinion is based on Dr. Hayreh’s theory, which this Court already excluded as unreliable; (2) his differential diagnosis is not reliable because he cannot rule out that Plaintiffs’ NAION was caused by preexisting risk factors rather than by Viagra use; (3) he does not have a scientifically valid method for choosing Viagra as the most likely cause of Plaintiffs’ NAION; (4) he applied a different, lower standard to determine causation in this litigation than what he would use in the medical realm; and (5) his opinion is based solely on temporality, which is insufficient to establish causation. Plaintiffs respond by pointing to Dr. Williams’s years of experience as a practicing

ophthalmologist and by quoting his statements in his two expert reports and in his deposition that it is his opinion to a reasonable degree of certainty that Viagra provoked NAION in Plaintiffs.

Dr. Williams's specific causation opinion in both Plaintiffs' cases is inadmissible. The Court does not doubt Dr. Williams's credentials as an ophthalmologist. Rather, the Court finds that the methodology that Dr. Williams used in reaching his opinions is not scientifically valid. Plaintiffs argue that Dr. Williams's used a differential diagnosis to reach his conclusions. However, Dr. Williams admitted in his deposition that he could not rule out underlying risk factors as the cause of Plaintiffs' NAION. Plaintiff has not produced any evidence that Dr. Williams used any particular test or methodology for determining that Viagra and not underlying risk factors caused Plaintiffs' NAION. To the extent that Dr. Williams relied on temporality in conducting his differential diagnosis, as noted above, temporality is insufficient alone to establish causation. Further, Dr. Williams admitted that, in reaching his conclusion about causation in Plaintiffs' cases, he employed a lower standard than what would be used in the medical realm. The Eighth Circuit Court of Appeals affirmed a district court's exclusion of an expert that "admitted that the causation standard she employed . . . was a much lower standard than medical causation." Marmo v. Tyson Fresh Meats, Inc., 457 F.3d 748, 758 (2006). Finally, based on the record before it, Dr. Williams "ruled in" Viagra as a potential cause of Plaintiffs' NAION based on Dr. Hayreh's theory that the Court previously deemed inadmissibly unreliable. Dr. Williams cannot have an admissible specific causation opinion regarding Viagra without a scientifically valid reason

for concluding that Viagra can cause NAION in the first place.

Although Daubert may have done away with Frye's rigid reliance on "general acceptance," it clearly envisioned that as a "gatekeeper," the Court would exclude expert opinions that are unreliable. For the reasons discussed above, the Court finds that Dr. Williams's differential diagnosis was methodologically flawed and that his specific causation opinion is therefore inadmissible under Federal Rule 702.

2. Dr. Andrew Lee

Dr. Lee is a neuro-ophthalmologist. He only offers a specific causation opinion regarding Martin. Pfizer challenges the admissibility of Dr. Lee's testimony because (1) he discredits the general causation opinion of Dr. Hayreh upon which he relied; (2) he cannot connect Dr. Hayreh's theory with Martin; (3) his differential diagnosis is not reliable because he cannot rule out that Martin's NAION was caused by coincidence or another prescription drug that Martin was taking; (4) he does not have a scientifically valid method for choosing Viagra as the most likely cause of Plaintiffs' NAION; (4) his characterization of Martin as a rechallenge case is not supported by the record; (5) he applied a different, lower standard to determine causation in this litigation than what he would use in science; and (6) his reliance on temporality is legally insufficient. Pfizer does not challenge Dr. Lee's general qualifications to render an opinion, but instead attack his methodology.

Pfizer argues that Dr. Lee relied on Dr. Hayreh's inadmissible nocturnal hypotension theory in his specific causation opinion, but later admitted that it was just a theory and had not been proven. Plaintiffs respond that Dr. Lee based his specific causation opinion not on

Dr. Hayreh's theory but on the Bradford Hill criteria. However, the Bradford Hill criteria are used to establish general causation from epidemiological studies—they are not used to establish specific causation. See Wells v. SmithKline Beecham Corp., No. A-06-CA-126-LY, 2009 WL 564303, at *11 (W.D. Tex. Feb. 18, 2009) (citing Merrell Dow Pharmaceuticals, Inc. v. Havner, 953 S.W.2d 706, 718 (Tex. 1997); Michael D. Green, et al., Reference Guide on Epidemiology, at 374-79)). Dr. Lee appears, in fact, to base his theory of specific causation on nocturnal hypotension. See Lee dep. at 160-62.

Dr. Lee has at least twice publicly stated—once in an editorial and again in a symposium—that no causal connection between NAION and PDE-5 inhibitors has been established. At a symposium Dr. Lee was assigned the “con” side of an argument over whether there was a causal association between Viagra and vision loss. As part of his argument Dr. Lee argued that the “biological mechanism for NAION in ED agents was weak” because no studies had demonstrated a link between the drop in blood pressure and the drop in blood flow. See Lee Dep. at 100-01. Dr. Lee has since said that his positions in the editorial and the symposium were consistent and that his opinion has not changed. Lee dep. at 108, 158-59. Plaintiffs argue that Dr. Lee was assigned the “con” side of the argument and that his statements in that context cannot be fairly relied on to show Dr. Lee's full opinion. This argument is hard to square with Dr. Lee's position in the editorial and his later affirmation of his arguments in both the editorial and the symposium. However, the Court can decide Pfizer's challenge to Dr. Lee without relying on Dr. Lee's statements at the symposium.

Even if Dr. Lee properly relied on the nocturnal hypotension theory for “ruling in” Viagra as a possible cause of Martin’s NAION, he failed to properly rule out all other possible causes. Dr. Lee said that he could not rule out predisposing conditions, coincidence, or another prescription that Martin was taking at the time of his NAION onset. As discussed above with regard to Dr. Williams, Dr. Lee’s failure to “rule out” all of the other possible causes makes his differential diagnose scientifically unreliable. Further, Dr. Lee conceded that there is no test for ruling out Catapres—another medication Martin was taking. Without a scientifically valid method for ruling out Catapres, the Court concludes that Dr. Lee’s differential diagnosis is insufficiently reliable to be admitted under Rule 702 or Daubert. Further, Plaintiffs have not pointed the Court to any evidence showing that Dr. Lee used a scientifically reliable method to rule out Martin’s predisposing conditions or coincidence. These failures cast sufficient doubt on Dr. Lee’s specific causation opinion to mandate its exclusion.

3. Dr. Neal Sher

Dr. Sher is an ophthalmologist and a professor. He offers specific causation opinions for both Martin and Stanley. Pfizer challenges the admissibility of Dr. Sher's testimony because (1) he does not have an admissible opinion on general causation; (2) he cannot rule out possible alternative causes of Plaintiffs' NAION; and (3) he does not have a scientifically valid method for choosing Viagra as the most likely cause of Plaintiffs' NAION. Plaintiffs' response ignores Pfizer's specific arguments against Dr. Sher's methodology, and instead spends considerable time defending Dr. Sher's general qualifications, which are commendable, and quoting Dr. Sher's recitation of the legal standard for admitting expert medical opinions. However, "an expert who supplies nothing but a bottom line supplies nothing of value to the judicial process" Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996). Daubert clearly envisioned a greater role for a trial judge than simply rubberstamping any expert who could say that he held opinion to a reasonable degree of medical certainty after reviewing all of the evidence. The Court does not doubt that Dr. Sher is qualified to offer an opinion. However, the Court must exercise its gatekeeper role to ensure that the opinions that Dr. Sher has offered in this case are sufficiently reliable to make their way to a jury. The Court concludes that they are not.

Dr. Sher appears to "rule in" Viagra as a cause of Plaintiffs' NAION based on Dr. Hayreh's nocturnal hypotension theory. He also relies on Dr. McGwin's research, as well

as an additional article by Levin and Daesh-Meyer¹ that provides an alternative theory for how PDE5 inhibitors cause NAION. The latter article is labeled a hypothesis and the authors acknowledge that their theory is just that—a theory. Dr. Sher conceded that the theory remained untested. The Court previously excluded Dr. Hayreh’s theory because it was untested. See In re Viagra, 572 F. Supp. at 1085-86. The alternative theory relied on by Dr. Sher in his expert report must be excluded for the same reason. Likewise, the Court has excluded the general causation opinion of Dr. McGwin. Finally, Dr. Sher partially relied on case reports to establish causation. Case reports alone cannot reliably establish causation. See In re Viagra, 572 F. Supp. 2d at 1085-86. Without a proper basis for ruling in Viagra as a cause of NAION, Dr. Sher cannot offer an admissible specific causation opinion.

Like Drs. Williams and Lee, Dr. Sher also fails to describe any scientifically valid methodology for determining that Viagra was the cause of Plaintiffs’ NAION. Dr. Sher said that he came to his conclusion after looking at all the facts and the totality of the evidence. However, Dr. Sher said that he did not do a differential diagnosis. He also said that he could not rule out the possibility that Stanley would have gotten NAION absent his Viagra consumption. Dr. Sher said that he reviewed Plaintiffs’ clinical findings, but admitted that, although the clinical findings support the diagnosis of NAION, nothing in the clinical findings leads to the conclusion that Viagra caused Plaintiffs’ NAION. Dr. Sher also reviewed Plaintiffs’ medical history and the temporal relationship between Plaintiffs’

¹ L.A. Levin & H.V. Danesh Meyer, A Venous Etiology for Nonarteritic Anterior Ischemic Optic Neuropathy, 126 Archives Ophthalmology 1582 (2008).

ingestion of Viagra and the onset of their NAION. That review showed that both exhibited several risk factors for NAION, and that both reported taking Viagra before the onset of their NAION. Dr. Sher did not explain how he determined that Viagra, and not Plaintiffs' risk factors alone, caused Plaintiffs' NAION. Dr. Sher's opinion appears to hinge on the temporal relationship of Plaintiffs' ingestion of Viagra and the onset of their NAION. Just as with Drs. Williams and Lee, however, temporality alone cannot form the basis of a specific causation opinion. Therefore, Pfizer's motion to exclude Dr. Sher's testimony should be granted.

4. Dr. Gerald McGwin

This Order deals only with Dr. McGwin's specific causation opinion that Viagra caused Martin's NAION. Dr. McGwin is an epidemiologist, not a medical doctor. He is not licensed to diagnose the cause of a patient's vision loss. The Court does not doubt, and Pfizer does not challenge, Dr. McGwin's general expertise in epidemiology. However, Dr. McGwin is not qualified to render an opinion about the cause of a specific patient's NAION. Accordingly, Dr. McGwin's specific causation opinion must be excluded.

Plaintiffs cite Robinson v. GEICO General Insurance Co., 447 F.3d 1096 (8th Cir. 2006) for the proposition that an expert does not have to be of the same medical specialty as the opponent's expert. Id. at 1100. The medical expert in question, however, must still be qualified to render the opinion offered. In Robinson, the court affirmed the trial court's decision to allow a neurologist to testify in response to an orthopedist because the subject of his testimony was "within his realm of expertise as a neurologist," physician, and

examining doctor. Id. at 1101. Dr. McGwin’s proposed specific causation opinion simply falls outside the realm of his expertise, and must therefore be excluded.

5. Dr. Gerald McEllistrem

Dr. McEllistrem was Martin’s treating urologist from 1996 through 2008. He is not an ophthalmologist and does not diagnose or treat eye conditions. “[M]erely possessing a medical degree is not sufficient to permit a physician to testify concerning any medical-related issue.” Ralston v. Smith & Nephew Richards, Inc., 275 F.3d 965, 970 (10th Cir. 2001). Dr. McEllistrem appears eminently qualified in his field of expertise—urology—but is not qualified to offer an opinion that Viagra caused Martin’s NAION. His proposed testimony must be excluded.

C. Dr. Cheryl Blume

Dr. Blume is Plaintiffs’ proposed FDA regulatory expert. She has more than 25 years of experience in the pharmaceutical industry. Dr. Blume opines that Pfizer should have changed the label on Viagra no later than 2000 and conducted additional studies based on information Pfizer had regarding Viagra and NAION. The Court’s role vis-a-vis a regulatory expert’s proposed testimony is similar to its role vis-a-vis an expert offering a more scientific opinion—the Court acts as a gatekeeper to ensure that the proposed expert testimony is both relevant and reliable. See Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999). Ultimately, the Court must ensure that the proposed expert “employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” Id. at 152. Pfizer challenges several aspects of Dr. Blume’s proposed testimony.

Those challenges will be taken in turn.

1. FDA Guidelines

Pfizer argues that Dr. Blume's testimony should be excluded because it is not based on the applicable FDA guidelines. Dr. Blume's opinion deals with Pfizer's pharmacovigilance efforts, which are "all scientific and data gathering activities relating to the detection, assessment, and understanding of adverse events." FDA, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment 4 (Mar. 2005) [hereinafter Guidance for Industry]. Dr. Blume opines that information Pfizer received constituted a safety signal and that Pfizer should have therefore changed its label to add a warning about NAION at the latest in 2000.

One of the principle disputes between the parties is over the role of Guidance for Industry. It is produced by the FDA to "provide[] guidance to industry on good pharmacovigilance practices and pharmacoepidemiologic assessment of observational data regarding drugs" Id. at 1. Pfizer argues that, where Dr. Blume's methodology or opinion differs from Guidance for Industry, her testimony is contrary to FDA regulation and should be excluded. Plaintiffs argue that Guidance for Industry contains non-binding recommendations, and that "[a]t most it suggests a standard of care." (Pls.' Opp'n Mem. at 14.) Guidance for Industry specifies in its introduction that "FDA's guidance documents, including [Guidance for Industry], do not establish legally enforceable responsibilities" and "should be viewed only as recommendations." Id. Further, it states that an alternative approach may be used "if the approach satisfies the requirements of the applicable statutes

and regulations.” Id. Based on the plain reading of the document, the Court concludes that Dr. Blume’s opinion is not excludable solely because it differs from Guidance for Industry.

Dr. Blume opined that there was a safety signal in 2000 that should have caused Pfizer to change its label regarding NAION. Guidance for Industry defines a safety signal as “a concern about an excess of adverse events compared to what would be expected to be associated with a product’s use.” Guidance for Industry at 4. Dr. Blume defined a safety signal as “any issue that you observe with your data that makes you think differently.” (Blume Dep. at 85.) She specified that she does not typically “qualify whether something is a signal or not based on what I would anticipate to see in a given population, simply because we are instructed not to do that.” (Id.) Pfizer argues that, because Dr. Blume’s suggested definition cannot be squared with the FDA’s, it is strictly her opinion and should therefore be excluded. Plaintiffs argue that Dr. Blume based her definition on her years of experience, and argue that Dr. Blume’s definition is entirely consistent with differently worded definitions of a safety signal by FDA and Pfizer employees. Given the non-binding nature of Guidance for Industry, the Court concludes that Pfizer’s challenge to Dr. Blume’s definition of a safety signal is most appropriately dealt with in cross-examination rather than in a motion to exclude.

The decision to exclude a regulatory expert in In re Diet Drugs, No. MDL 1203, 2001 WL 454586, at *17-18 (E.D. Pa. Feb. 1, 2001), does not compel a different result. There the regulatory expert offered an opinion that directly contradicted labeling laws and regulations and the learned intermediary doctrine. Id. Pfizer has not cited to any statute or regulation

that directly contradicts Dr. Blume's definition of a safety signal, and unlike the expert in In re Diet Drugs, Dr. Blume does appear to base her definition "on an interpretation of FDA regulations or [Dr. Blume's] experience in applying those regulations." See id. at *18. Pfizer's motion to exclude Dr. Blume's definition of a safety signal is denied.

Pfizer also argues that Dr. Blume's opinion should be excluded because she did not read the individual adverse event reports or consider the background rate of NAION, both contrary to FDA guidelines. By the end of 2000, there were only 12 adverse event reports of ischemic optic neuropathy in the FDA's database. Also by the end of 2000, Viagra had been prescribed to more than 10 million patients. Plaintiffs respond with the general argument that Dr. Blume used her years of experience to place the 12 adverse event reports in context, and based on her evaluation she concluded that the 12 adverse event reports constituted a safety signal. The Court concludes that, again, Pfizer's challenges to Dr. Blume's methodologies are better dealt with on cross-examination rather than in a motion to exclude. Pfizer's citation to In re Diet Drugs on this point is unpersuasive. There, the proposed regulatory expert admitted that he had "no experience or expertise in drug testing or adverse event reporting," and that his opinion that "100 adverse event reports . . . should have triggered more warnings, evaluation and testing [was] based on his own personal opinion rather than any particular methodology." In re Diet Drugs, 2001 WL 454586, at *16. Dr. Blume has made no such admissions here. Rather, Dr. Blume purports to base her opinion off of her experience in the industry. That her methodology may not comply with Pfizer's reading of the FDA's guidelines does not render her opinion inadmissible under

Daubert. The Court finds that her methodology is sufficiently reliable to be admitted under Daubert. Pfizer may highlight whatever weaknesses it finds in her opinion or methodology on cross examination.

Next, Pfizer argues that Dr. Blume improperly used data mining² to compare reporting rates of adverse events for Viagra versus other drugs. Pfizer argues this was improper because none of the other drugs that Dr. Blume compared to Viagra are in the same therapeutic class, and because data mining, if appropriate, requires significantly more analysis than Dr. Blume did. Plaintiffs argue that Dr. Blume did not do any data mining, but instead simply compared reporting rates of various drugs that had a label warning for NAION, and when the labels were changed to include the warning for NAION. Plaintiffs also cite to two examples of when the FDA considered reporting rates for other drugs.

However, in both of the examples that Plaintiffs cite, the FDA compared a drug to other drugs in the same therapeutic class. Plaintiffs do not cite an example where the FDA considered non-related drugs because the labels included warnings for the same disease. “[Adverse event report] data and analyses have not been a generally accepted method by which to compare drugs” In re Baycol Prod. Litig., 532 F. Supp. 2d 1029, 1051-52 (D. Minn. 2007) (Davis, J.). In light of the unreliability of comparing drugs using adverse event reports, Dr. Blume’s comparison of the reporting rates for ischemic optic neuropathy for drugs in a different therapeutic class than Viagra must be excluded. Plaintiffs citation of

² Data mining is the “systematic examination of the reported adverse events by using statistical or mathematical tools.” Guidance for Industry at 8.

Guidance for Industry is misplaced. Plaintiffs cite a paragraph in Guidance for Industry that would allow for comparisons of reporting rates of different drugs in particular situations. See Guidance for Industry at 9. However, that paragraph specifically refers to data mining “approaches;” it lends no support to Plaintiffs’ position on this issue because Plaintiffs specifically disclaim that Dr. Blume did any data mining.

2. Chart from Plaintiffs’ Counsel

After she issued her expert report, Dr. Blume received a chart prepared by Plaintiffs’ counsel summarizing the number of adverse event reports for Viagra and three other drugs. Pfizer argues that her receipt of the summary after she produced her report renders her opinion inadmissible because she reached her conclusion prior to conducting all of the necessary research to support that conclusion. Plaintiffs argue that Dr. Blume considered numerous documents before rendering her opinion in her expert report, and that receiving corroborating information after signing her opinion does not render her opinion inadmissible. Common sense and Federal Rule of Evidence 702 require the exclusion of any expert opinion that was reached prior to conducting the research necessary to form that opinion. See In re Rezulin Products Liability Litigation, 309 F. Supp. 2d 531, 550 (S.D.N.Y. 2004) (“Courts applying the principles outlined in Daubert have held that an expert may not reach his conclusion first and do the research later.”). Although it is undisputed that Dr. Blume did not receive the chart summarizing the adverse event reports for Viagra and other drugs from Plaintiffs’ counsel until after she issued her report, the record also supports Plaintiffs’ contention that Dr. Blume reviewed voluminous materials prior to reaching her conclusion.

Again, Pfizer is welcome to point out any weaknesses it may find in Dr. Blume's methodology during cross-examination.

Dr. Blume's opinion is also not inadmissible simply because she received the adverse event reports summary from Plaintiffs' counsel. Pfizer cites MTX Communications Corp. v. LDDS/WorldCom, Inc., 132 F. Supp. 2d 289 (S.D.N.Y. 2001), in support of this argument. In that case, the court excluded an expert because he relied on information supplied him by a third-party attorney. The court found that "[t]he information from the . . . attorney was neither verified nor submitted in a way that permits meaningful review." Id. at 292-93. MTX is inapposite. Here, there is no indication that the chart Plaintiffs' counsel prepared for Dr. Blume was incapable of verification or meaningful review. Pfizer does not argue that the chart misrepresents the data available. Dr. Blume also had a long-term working relationship with Plaintiffs' counsel, Mr. Altman. Thus, she likely knew from experience that she could rely on his summaries of data. This is in contrast to the expert in MTX who was working with an unknown third-party attorney. Pfizer's motion to exclude Dr. Blume's opinion for this reason must be denied.

3. Eye Conditions Other Than NAION

In her report, Dr. Blume considered several adverse event reports for Viagra for eye conditions other than NAION. In her deposition she admitted that she did not know whether any of the non-NAION conditions were related to NAION, and Plaintiffs failed to identify anywhere in her report where Dr. Blume connects the "visually-related adverse events" to NAION. Although it may be possible, as Plaintiffs suggest in their brief, that "given the

rarity of NAION, there could be some variations in the labeling” or that “[i]t is also possible that the event would have been described only as blindness without any further details,” (Pls.’ Opp’n Mem. at 25) there is no evidence to suggest that either of those scenarios panned out. Rule 702 requires expert testimony to be both reliable and relevant. Absent a showing that the adverse event reports for eye conditions other than NAION are somehow related to NAION, the Court finds Dr. Blume’s reference to those non-NAION adverse event reports irrelevant. Pfizer’s motion to exclude reference to those reports is granted.

4. Epidemiology Study

Dr. Blume opined that Pfizer should have conducted an epidemiology study in 2000 based on the information Pfizer had received about serious ophthalmologic adverse events. She estimated that such a study would take two or more years to complete. Pfizer argues that Dr. Blume’s opinion about the study is irrelevant because a study could not have been completed before Martin and Stanley were diagnosed with NAION in 2000 and 2002. The Court agrees that Dr. Blume’s testimony regarding whether Pfizer should have conducted a study in 2000 is irrelevant to the cases of Martin and Stanley and is therefore inadmissible. Because the Court finds this portion of Dr. Blume’s testimony irrelevant, it need not consider Pfizer’s additional arguments against it.

5. Motives, Intent, and State of Mind of Pfizer, Patients, and Doctors

In her report, Dr. Blum opined that Pfizer’s response to early reports of NAION “seemed to focus on deflecting negative publicity which they [Pfizer] knew would result.” (Blume Rep. at 13.) Dr. Blume based this opinion on her interpretation of several

documents. Pfizer argues that Dr. Blume's interpretation of the documents is not helpful to the jury because she does not rely on her expertise in rendering this portion of her opinion. Plaintiffs argue that Dr. Blume interpreted the documents in light of her years of experience, making her opinion an admissible expert opinion. The Court finds In re Baycol Products Litigation, 532 F. Supp. 2d 1029, 1067 (D. Minn. 2007) (Davis, J.), directly on point. There the court excluded a proposed expert's opinion that a pharmaceutical company inadequately evaluated concerns over one of its drugs and that the company ignored its own scientists' safety concerns during the development process. Id. The Court held that the jury could determine the company's motives for acting the way it did without the assistance of an expert. Id. There is no indication in the record that the jury here would require special assistance to interpret the documents on which Dr. Blume bases her opinion that Pfizer was more worried about bad publicity than safety. Because the jury is equally capable of evaluating this particular evidence, Dr. Blume's opinion on this matter must be excluded. See U.S. v. Shedlock, 62 F.3d 214, 219 (8th Cir. 1995) ("Expert testimony is helpful to a jury if it concerns matters beyond the knowledge of average individuals; however, it cannot supplant the jury's role in evaluating the evidence.") (citing United States v. French, 12 F.3d 114, 116 (8th Cir. 1993)).

Dr. Blume also opined that "men do not always share with their ophthalmologist their use of an erectile dysfunction drug." (Blume Dep. 367.) Pfizer argues that Dr. Blume relies on nothing but her personal experience in reaching this opinion and, because she does not have expertise in this area, it should be excluded. Plaintiffs argue that Dr. Blume relied on

documents from Pfizer that supported her opinion. Although Dr. Blume did say in her deposition that she based this opinion on her personal experience, other parts of her deposition support Plaintiffs' position that Dr. Blume's opinion is based on documentation from Pfizer. Pfizer's dispute with this portion of Dr. Blume's opinion goes to the weight of the evidence and not its admissibility.

Finally, Dr. Blume opined that "many health care providers do not associate a patient's complaints or symptoms with a drug-related adverse event." (Blume Report at 7.) Pfizer argues that Dr. Blume is not qualified as an expert to render this opinion because she is not a medical doctor and it does not deal with regulatory matters. The Court finds that Dr. Blume's years of experience related to pharmacovigilance qualify her to discuss the underreporting of adverse events and the reasons behind the underreporting. Pfizer will have the opportunity to cross-examine Dr. Blume about whatever issues it has with her opinion or the bases of her opinions.

6. Foreign Regulatory Actions

Dr. Blume opined that "[t]he collective worldwide experience provided clear notice to Pfizer regarding the need for continued product labeling amplifications relating to NAION and the obligation to initiate/conduct clinical trials." (Blume Rep. at 28.) Pfizer argues that Dr. Blume is not qualified to render that opinion because she is not a foreign regulatory expert. It also argues that the worldwide experience, to the extent it involves foreign regulations, is irrelevant. Plaintiffs argue that Dr. Blume's opinion on this issue is relevant because the FDA requires drug companies to report all adverse events wherever they occur,

as well as reporting major foreign marketing changes. See 21 C.F.R. §§ 314(b) & 312.33(f). Further, they argue that Dr. Blume’s expertise in foreign regulatory matters is irrelevant because she is an expert in domestic regulatory matters, which, as discussed immediately above, require the reporting of foreign adverse events.

The Court finds that any discussion of foreign regulatory actions is irrelevant to the current litigation and should therefore be excluded. See In re Baycol Prod. Litig., 532 F. Supp. 2d at 1054 (collecting cases). Plaintiffs made no effort to distinguish the cases cited by Pfizer in support of its position, and the Court does not see any principled way to do so. Further, the Court finds that to the extent that foreign regulatory information is relevant, “its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury” Fed. R. Evid. 403. In light of the unfair prejudice and jury confusion that could result from introducing foreign regulatory actions, the Court finds that Dr. Blume’s discussion of foreign regulatory actions must be excluded.

7. FDA Letters Regarding Viagra Advertisements

Dr. Blume refers to three letters that the FDA sent to Pfizer regarding three advertisements for Viagra that did not contain certain risk information. The letters were issued in 2000, 2004, and 2008. Both Martin and Stanley had stopped using Viagra by 2004. Pfizer argues that the 2004 and 2008 letters are irrelevant in the Martin and Stanley cases because both Plaintiffs had already stopped taking Viagra when the advertisements in question were shown. The Court agrees that these two letters are irrelevant in the two

specific cases before it and should be excluded.³

Pfizer argues that the 2000 letter should also be excluded as irrelevant because (1) there is no evidence that Martin, Stanley, or their prescribing doctors saw the Viagra ads in question, and (2) the letter does not discuss NAION. Plaintiffs argue that all three letters are admissible to support Dr. Blume's opinion that Pfizer "habitually engaged in a course of conduct the result of which was to minimize risks associated with the use of Viagra." (Pls.' Opp'n Mem. at 38.) Three letters are not enough to show a habit under Federal Rule of Evidence 406, especially in light of the number of advertisements for Viagra that have been produced. See Fed. R. Evid. 406 1972 proposed rules notes ("['Habit'] describes one's regular response to a repeated specific situation. . . . A habit . . . is the person's regular practice of meeting a particular kind of situation with a specific type of conduct . . .").

Regarding whether Martin, Stanley, or their doctors saw the advertisements in question, Dr. Blume said in her deposition that she did not know how anyone with a television could have not seen Viagra advertisements. Plaintiffs make much of the fact that the special master overruled Pfizer's objection that this was outside Dr. Blume's area of expertise. However, Dr. Blume's speculation that Plaintiffs most likely saw the advertisements is different than evidence that Plaintiffs actually saw the advertisements.

³ The Court declines Plaintiffs' invitation to rule on the general admissibility of these letters for cases in which the dates of ingestion differ from the two specific cases at issue here. Although it can be expected that Dr. Blume will act as an expert witness in additional cases, this Motion pertains only to two cases and the Court will not reach beyond the cases that are currently before it on this Motion. The Court's decision on this issue does not preclude Plaintiffs from offering, or Pfizer from challenging, the FDA letters in other cases.

Absent that evidence, the Court finds the 2000 letter irrelevant and excludable.

The letter is also excludable for the independent reason that the letter did not deal with NAION. The FDA did not require Pfizer to include NAION information on the Viagra label until 2005. Plaintiffs argue that all three “letters are evidence of what Plaintiffs could not have known whether they saw the advertisements or not - accurate information concerning the risk of serious eye adverse events.” (Pls.’ Opp’n Mem. at 39.) Plaintiffs are suing Pfizer because Viagra allegedly causes NAION; there is no evidence that the risk of serious eye adverse events unrelated to NAION have any bearing on the current litigation. Accordingly, the Court concludes that all three FDA letters regarding Viagra advertising are irrelevant and inadmissible. Dr. Blume’s opinion based on these letters is likewise inadmissible.

8. Factual History

Dr. Blume devotes a significant portion of her opinion to summarizing the regulatory history of Viagra. Pfizer argues that her summary simply strings together a narrative that the jury is equally capable of completing, and that her factual history should therefore be excluded. See In re Rezulin Prod. Liability Litig., 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004); Fisher v. CIBA Specialty Chems. Corp., 238 F.R.D. 273, 281 (S.D. Ala. 2006). Plaintiffs argue that Dr. Blume’s history of Viagra is admissible as a summary of voluminous materials under Federal Rule of Evidence 1006, and because it forms the basis of her opinion.

The Court finds little to distinguish Dr. Blume’s factual history of Viagra from the histories that were excluded in Rezulin and Fisher. Although, as Plaintiffs argue, Dr. Blume no doubt used her expertise to wade through the multitude of possibly relevant documents,

“[t]he vast majority of [Dr. Blume’s] report simply summarizes and states her advocacy-based interpretation of documents in the record concerning” regulatory activity related to Viagra. Fisher, 238 F.R.D. at 281. The question is not whether the jury could review all 700,000 pages of material and recreate the history that Dr. Blume provided in her report, but whether the jury could interpret the documents that Dr. Blume highlights in her report without the assistance of an expert. Dr. Blume’s chronology does not appear to benefit from her regulatory expertise in any way, nor does her chronology appear to be “any more or less persuasive than that of a layperson.” Id. Accordingly, Dr. Blume’s chronology of Viagra regulatory events must be excluded.

Dr. Blume’s chronology is not a summary of voluminous materials under Rule 1006. Dr. Blume’s chronology does not summarize 700,000 documents, but instead chooses a few documents among many to highlight. As noted above, there is no evidence that the jury could not be presented with these same documents and draw from them the relevant regulatory history of Viagra, and the presentation of those documents will likely not cause the logistical problems that Rule 1006 was created to solve.

Plaintiffs also urge that this matter is not ripe for review and Pfizer should bring a motion in limine closer to the time of trial. Plaintiffs correctly note that the basis of an expert’s opinion needs not be admissible itself in order for the expert’s opinion to be admissible. Fed. R. Evid. 703. For that reason, the fact that the Court has ruled Dr. Blume’s chronology inadmissible does not automatically render her opinion inadmissible. Rather, Dr. Blume would be permitted to testify as to her opinions, consistent with this Order, even

though her chronology itself is excluded.

8. Rule 26 Disclosures

Pfizer raises numerous and specific challenges to portions of Dr. Blume's testimony because she failed to make proper Rule 26 disclosures. The Court will deny without prejudice Pfizer's specific objections because it finds that those objections are better dealt with closer to trial in motions in limine.

D. Summary Judgment

1. Standard of Review

Summary judgment is proper if there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The Court must view the evidence and the inferences that may reasonably be drawn from the evidence in the light most favorable to the nonmoving party. Enterprise Bank v. Magna Bank, 92 F.3d 743, 747 (8th Cir. 1996). However, as the United States Supreme Court has stated, "summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to secure the just, speedy, and inexpensive determination of every action." Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986).

The moving party bears the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. Enterprise Bank, 92 F.3d at 747. A party opposing a properly supported motion for summary judgment may not rest on mere allegations or denials, but must set forth specific facts in the record showing that

there is a genuine issue for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986); Krenik v. Le Sueur, 47 F.3d 953, 957 (8th Cir. 1995).

2. Causation

Plaintiffs brought eight causes of action against Pfizer: (1) strict product liability in design defect; (2) failure to warn; (3) negligent failure to warn; (4) negligence per se; (5) breach of implied warranty of merchantability and implied warranty of fitness for a particular purpose; (6) breach of express warranty; (7) fraud/misrepresentation; and (8) unjust enrichment. Plaintiffs do not dispute that causation is a requisite element of all of their claims against Pfizer, with the exception of unjust enrichment. As the Court noted previously, Plaintiffs must show both general and specific causation. In re Viagra Prods. Liab. Litig., 572 F. Supp. 2d 1071, 1078 (D. Minn. 2008) (Magnuson, J.). Absent a showing of both types of causation, Plaintiffs claims necessarily fail. Further, “[u]nder Minnesota law, expert testimony is required to prove causation in cases involving complex medical issues with which a jury is unlikely to have experience.” Johnson v. Zimmer, Inc., No. Civ. 02-1328, 2004 WL 742038, at *6 (D. Minn. Mar. 31, 2004) (Tunheim, J.) (citing Willert v. Ortho Pharm. Corp., 995 F. Supp. 979, 983 (D. Minn.1998) (Rosenbaum, J.)); see also Stahlberg v. Moe, 166 N.W.2d 340, 345 (Minn. 1969).

Plaintiffs have failed to raise a genuine issue of material fact regarding causation. In an Order in the general MDL case filed simultaneously with this Order, the Court granted Pfizer’s motion to exclude the testimony of Dr. Gerald McGwin as unreliable. Dr. McGwin

was Plaintiffs' sole remaining general causation expert. See Viagra, 572 F. Supp. 2d 1071. And, as noted above, the Court has also granted Pfizer's motion to exclude the testimony of Plaintiffs' specific causation experts. In this case involving complicated questions of medical causation, Plaintiffs must show both general and specific causation by expert testimony. Because Plaintiffs have failed to produce admissible expert testimony that Viagra caused their NAION, Pfizer's motion for summary judgment must be granted.⁴

Plaintiffs' unjust enrichment claim does not explicitly require a showing of causation. "To establish an unjust enrichment claim it must be shown that a party has knowingly received something of value, not being entitled to the benefit, and under circumstances that would make it unjust to permit its retention." Southtown Plumbing, Inc. v. Har-Ned Lumber Co., Inc., 493 N.W.2d 137, 140 (Minn. Ct. App. 1992). However, Plaintiffs' unjust enrichment claims still fail for two reasons. First, Plaintiffs have an adequate remedy at law—they pled several causes of action sounding in tort, and there is no dispute that those causes of action would provide adequate relief if Plaintiffs succeeded in proving up their claims. See, e.g., Drobnak v. Andersen Corp., 2008 WL 80632, at *8 (D. Minn. Jan. 8, 2008) (Magnuson, J.) (dismissing unjust enrichment claim because plaintiffs had adequate remedies at law). Second, in light of the dearth of reliable evidence that Viagra causes NAION, there is nothing in the record to suggest that Pfizer received anything of value "under

⁴ In addition, the majority of Plaintiffs' substantive claims fail on the merits. A discussion of the merits is unnecessary, however, given the Court's resolution of the overarching causation issues.

circumstances that would make it unjust to permit its retention.” Accordingly, Pfizer’s motion for summary judgment on Plaintiffs’ unjust enrichment claim must be granted.

CONCLUSION

Accordingly, **IT IS HEREBY ORDERED** that:

1. Pfizer's Motion to Exclude the Testimony of Dr. Cheryl Blume (Docket No. 14 in 06-1064; Docket No. 13 in 06-1065) is **GRANTED in part** and **DENIED in part**;
2. Pfizer's Motion to Exclude the Testimony of Plaintiffs' Specific Causation Experts (Docket No. 16 in 06-1064; Docket No. 15 in 06-1065) is **GRANTED**; and
3. Pfizer's Motion for Summary Judgment (Docket No. 18 in 06-1064; Docket No. 17 in 06-1065) is **GRANTED**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: Wednesday, August 19, 2009

s/ Paul A. Magnuson _____
Paul A. Magnuson
United States District Court Judge