Pfizer Wins Important Viagra Vision Litigation

Decision Ends Entire Multi-District Litigation

It is extremely rare that a single decision can terminate an entire multi-district litigation ("MDL"), but that is what happened on August 19, 2009 in the Viagra MDL, when Judge Paul Magnuson found that there was no reliable evidence that Viagra is capable of causing an eye condition resulting in permanent vision loss, known as non-arteritic anterior ischemic optic neuropathy ("NAION"). In an earlier ruling in April 2008, Judge Magnuson had excluded three of plaintiffs' general causation experts, but tentatively admitted the testimony of a fourth. However, based on evidence produced by the expert following the April 2008 ruling, Judge Magnuson took the remarkable step of reversing his prior ruling admitting the expert's testimony. Judge Magnuson recognized that his decision to exclude the plaintiffs' sole remaining general causation expert "effectively ended the current litigation."

In a second and equally important decision on the same day, Judge Magnuson alternatively considered Pfizer's challenge to plaintiffs' specific causation and regulatory experts. In a decision with broad applicability, the judge ruled that even if there were proof of general causation, he would exclude plaintiffs' specific causation experts because they failed to use a reliable methodology in attributing plaintiffs' vision loss to Viagra. Judge Magnuson also severely limited the opinions of plaintiffs' FDA regulatory expert, addressing recurring issues that frequently arise when plaintiffs attempt to convert their regulatory expert into an all-purpose storyteller.

Kaye Scholer represented Pfizer in the litigation. Together, these opinions provide important lessons for pharmaceutical and medical device litigation.

Using the MDL to Defendant's Advantage

One of the unique aspects of the Viagra litigation is that the company supported the creation of an MDL. In a prior wave of Viagra litigation, in which plaintiffs alleged that Viagra caused heart attacks and strokes, Pfizer also had a strong general causation defense, but in the absence of an MDL, the company had to litigate the same issue in cases all around the U.S., ultimately having to win summary judgment six times (three affirmed on appeal) before the cardiac litigation collapsed. In the vision cases, the company attempted to cut the litigation off at the pass; by creating an MDL, it could resolve all NAION litigation with a single victory.

Bifurcating General Causation Discovery

Prior to the first MDL status conference, Pfizer submitted a case management plan that provided a history of the cardiac cases, and used that experience as a basis for urging the court to divide discovery into two phases, with the first phase limited solely to the issue of general causation. If plaintiffs could not produce reliable evidence that Viagra could cause NAION, the litigation would be over, thereby avoiding protracted and costly liability discovery. Judge Magnuson agreed, observing that "targeted discovery and resolution of the issue of general causation serves

the interest of all parties and the court, promotes judicial efficiency, and prevents the waste of the parties' and the court's resources."

Piercing the Veil of an Expert's Published Study

One of the key lessons learned from the Viagra litigation is that, where an expert relies on a published study, the defendant should, whenever possible, seek the study's source data. In doing so, the company may be able to uncover fundamental flaws in the study, rendering it unreliable.

In April 2008, after general causation discovery was completed, Judge Magnuson excluded three of plaintiffs' four general causation experts. However, Judge Magnuson did not initially exclude plaintiffs' epidemiology expert, Dr. Gerald McGwin, whose opinion was based primarily on a published study that he authored. Pfizer objected that Dr. McGwin did not permit it to obtain the source data for his study. Judge Magnuson permitted Pfizer to take further discovery, affording Pfizer a rare opportunity to look at the underlying data supporting the key published study in the litigation.

Review of the study's underlying data revealed substantial discrepancies between the data that were collected and the data that were reported and analyzed in the published study:

- Eleven out of 27 study subjects were improperly coded as "exposed";
- The statistical methods set forth in the published paper were not followed;
- There were errors in the computer programming used to calculate the study's statistics;
- The published paper mischaracterized the question studied as to the only statistically significant result.

Recognizing that "[a]lmost every indicia of reliability the Court relied on in its previous *Daubert* Order regarding the McGwin Study has been shown now to be unreliable," Judge Magnuson held that Dr. McGwin could not properly base his opinions on his own study. He reasoned that the *Daubert* factors — peer review, publication and known rates of error — "mean little if a study is not based on accurate underlying data."

The court's opinion is instructive for future cases: publication does not guarantee reliability. By looking behind the published results to examine the underlying data, a defendant may be able to unravel plaintiffs' entire causation case.

Specific Causation: Unmasking an Expert's *Ipse Dixit* Opinion

Judge Magnuson's second opinion on specific causation addressed a recurring challenge in all personal injury litigation: how to attack the specific causation opinion of an expert who does little more to support his or her opinion than to invoke the commonly used phrases, "differential diagnosis," "substantial contributing factor," and "reasonable medical certainty."

Plaintiffs' specific-causation opinions in the Viagra litigation followed this theme. Plaintiffs' experts reviewed plaintiffs' medical records, and acknowledged that the plaintiffs had several known risk factors for NAION. However, without any explanation as to how they ruled out

plaintiffs' known risk factors for plaintiffs' NAION, plaintiffs' experts concluded that to a reasonable degree of medical certainty, Viagra substantially contributed to plaintiffs' NAION. The challenge for Pfizer was to show that there was no accepted methodology — published or otherwise — to include or exclude one factor over another, or to say that one factor was more probably the cause of plaintiffs' NAION than another.

Judge Magnuson's decision makes it clear that the invocation of the words "differential diagnosis," "substantial contributing factor" and "reasonable degree of medical certainty" are not sufficient to get past the *Daubert* threshold. There are several ways to attack such naked, conclusory opinions.

- Some differential diagnoses are reliable, others are not. In Judge Magnuson's words, "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." Judge Magnuson excluded several of plaintiffs' specific causation experts because they could not rule out other causes.
- Where an expert claims to have excluded all other risk factors, he or she must articulate a scientifically valid method for being able to include, exclude or rank various risk factors. In Judge Magnuson's words, there must be a "test or methodology for determining" that defendant's product, "and not underlying risk factors" caused the injury. In the Viagra litigation, plaintiffs' experts conceded there was no test or examination or published method that enabled doctors to distinguish among the various potential causes of NAION. That left only a temporal relationship, and as Judge Magnuson held, "temporality alone could not form the basis of a specific causation opinion."
- Plaintiffs' experts cannot use a different standard for assigning causation in litigation than they would in their practice. Plaintiffs' experts will often admit that if they were to see a patient in a clinical setting, as opposed to a litigation setting, they would use a different — *i.e.*, higher — standard for determining causation. Judge Magnuson rejected the notion that an expert can rely on some standard for determining causation different from what he or she would use in a clinical setting. Specifically, in excluding one of plaintiffs' experts, Judge Magnuson noted that "in reaching his conclusion about causation in Plaintiffs' cases," the expert improperly "employed a lower standard than what would be used in the medical realm."

Limiting a Regulatory Expert to Regulatory Issues

Another recurring challenge in litigation is the expert whose "intended role is more to argue the client's cause from the witness stand than to bring to the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit." *In re Rezulin*, 309 F. Supp. 2d 531 (S.D.N.Y. 2004). Judge Magnuson affirmed a continuing trend to prohibit this type of pseudo-expert opinion, excluding plaintiffs' regulatory expert's attempt to provide "advocacy-based interpretation of documents in the record" that did not "benefit from her regulatory expertise in any way."

Judge Magnuson also limited the expert's regulatory opinions, confronting issues often faced in litigation involving FDA-regulated products. Judge Magnuson ruled that:

- foreign labels could not be used to impugn the United States label;
- adverse events unrelated to the plaintiffs' injuries were inadmissible;
- FDA criticisms of advertisements that plaintiffs did not see were inadmissible; and
- comparisons of adverse-event reporting rates of drugs in different therapeutic classes were inadmissible.

Conclusion

Pfizer took a fresh approach to the Viagra litigation, and in the end, its strategy produced the type of certainty and finality that is rarely achieved in such actions.

Copies of Judge Magnuson's opinions are attached.

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UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Viagra Products Liability Litigation MDL No. 06-1724 (PAM)

This Order Relates to All Cases.

ORDER

This matter is before the Court on Defendant Pfizer, Inc.'s Motion to Exclude the Testimony of Gerald McGwin, Ph.D. and on Plaintiffs' Motion for Leave to File a Supplemental Expert Report of Gerald McGwin, Ph.D. For the reasons that follow, Pfizer's Motion is **GRANTED** and Plaintiffs' Motion is **DENIED**.

BACKGROUND

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"). Plaintiffs' sole remaining general causation expert is Dr. Gerald McGwin. Dr. McGwin was the principle author of a study published by the British Journal of Ophthalmology (the "Journal") in February 2006, entitled Non-Arteric Ischaemic Optic Neuropathy and the Treatment of Erectile Dysfunction (the "McGwin Study").[1]

In order to conduct the McGwin Study, 38 patients from the University of Alabama at Birmingham ("UAB") ophthalmology clinic that had been diagnosed with NAION were

[1] Gerald McGwin, et al., Non-Arteric Ischaemic Optic Neuropathy and the Treatment of Erectile Dysfunction, 90 British J. Ophthalmology 154 (2006).

age-matched with 38 patients who had not been diagnosed with NAION. Trained UAB researchers asked via telephone the 76 patients a series of questions regarding the patients' medical history, personal background, and health information. The patients were asked whether they ever taken Viagra or Cialis,[2] and if so, when they first took the drug. The telephone survey conductors wrote the patients' responses to the questions on survey forms. The information from the telephone surveys was consolidated into an electronic dataset. Dr. McGwin used the electronic dataset to conduct the study. Prior to publishing his study, Dr. McGwin did not compare the information from the original survey forms to the electronic dataset.

The McGwin Study found that men with a history of myocardial infarction and Viagra/Cialis use had a statistically significant increased risk of suffering from NAION, and that men with hypertension and Viagra/Cialis use had a non-statistically significant increased risk of suffering NAION. Dr. McGwin submitted an expert report in this litigation offering his opinion that Viagra use could cause NAION. In May 2007 Pfizer subpoenaed the underlying documents and data for the McGwin Study. After deposing Dr. McGwin about his opinion in June 2007, Pfizer filed a motion challenging the reliability of Dr. McGwin's general causation opinion. While that Motion was under advisement with the Court, Plaintiffs filed a new affidavit by Dr. McGwin without asking leave of the Court to do so. Over Pfizer's objection, the Court considered Dr. McGwin's untimely affidavit, but granted

[2] Cialis, like, Viagra, is a PDE-5 inhibitor used to treat erectile dysfunction.

Pfizer permission to conduct further discovery of Dr. McGwin regarding the affidavit. The Court denied Pfizer's Daubert challenge to Dr. McGwin, largely because "the McGwin et al. and Margo et al. studies were peer-reviewed, published, contain[ed] known rates of error, and result[ed] from generally accepted epidemiologic research." In re Viagra Products Liab. Litig., 572 F. Supp. 2d 1071, 1081 (2008). The Court further found that "[t]he fact that the data appear not to result from post-litigation research further establishes its reliability for general-causation purposes on a Daubert Motion." Id. at 1081-82.

In May 2008 Pfizer again subpoenaed all of the underlying documents and data for the McGwin Study. It is undisputed that Dr. McGwin was one of the parties responsible for gathering and producing those documents in response to Pfizer's request. The deadline for filing a supplement to Dr. McGwin's expert report passed in November 2008 without Plaintiffs filing a supplement. Pfizer deposed Dr. McGwin for the second time in December 2008. At that deposition Pfizer raised issues with the McGwin Study as published, including discrepancies it found between information on the original survey forms and the electronic dataset that Dr. McGwin used to conduct the study. For example, Pfizer pointed to a number of patients that reported their first use of Viagra or Cialis as occurring after their diagnosis for NAION. However, in the electronic dataset that Dr. McGwin used, those patients were coded as "exposed," meaning they were coded as having taken Viagra or Cialis prior to their NAION diagnoses. At the same deposition, Plaintiffs raised the possibility that someone from UAB may have recontacted study participants and updated some of the information that was originally provided, specifically the dates of first use.

Shortly after the second deposition of Dr. McGwin, Pfizer requested to conduct additional discovery of Dr. McGwin and UAB. Pfizer also moved for a further Daubert hearing regarding Dr. McGwin. The Court granted Pfizer's motion for additional discovery. In March 2009 Pfizer subpoenaed from Dr. McGwin any reanalysis he had conducted of the data or statistics in the McGwin Study, but Dr. McGwin did not produce anything. UAB did produce some documents that were found in the files of Irene Xie, the statistician in charge of the McGwin Study. Later that month, Pfizer conducted its third deposition of Dr. McGwin. At the time of his third deposition, Dr. McGwin still had not conducted a reanalysis of any of the data or statistics in the McGwin Study. Dr. McGwin said that he had not done so at least in part at the direction of Plaintiffs' counsel:

> A. [A]t the time after I realized that having run age, I should likely check to see whether I should be checking all the numbers in this paper, I was told that I should not do that at the present time – or at that time.
>
> Q. Who told you not to do that?
>
> A. It was in consultation with Mr. Overholtz and Jason Richards.

(McGwin 3/24/09 Dep. at 627.)

Just one week after this deposition, Dr. McGwin requested UAB's permission to conduct a reanalysis of the data from his study. A month and a half later, UAB produced to Pfizer a copy of a letter that Dr. McGwin sent to the Journal detailing his reanalysis (the "Letter"). The Letter noted that "several aspects of [the] manuscript require[d] modification." (Pls.' Opp'n Mem., Ex. B at 1.) Ultimately, Dr. McGwin concluded in the Letter that "the results presented [in the Letter] are consistent with those in our original

manuscript with the exception that any increased risk appears to be limited to Viagra." (Id. at 2.) More than one month after UAB produced the Letter to Pfizer and just three weeks prior to the hearing on Pfizer's multitude of Motions,[3] Plaintiffs provided a copy of the Letter to Pfizer at the same time they moved to file a supplement to Dr. McGwin's expert report based on Dr. McGwin's reanalysis. The Journal has referred the Letter and questions about Dr. McGwin's reanalysis of the data to the Committee on Publication Ethics. As of the writing of this Order, the Journal has not taken any further action regarding Dr. McGwin's Letter.

This Order resolves Pfizer's renewed Daubert challenge to Dr. McGwin and Plaintiffs' motion for leave to supplement the expert report of Dr. McGwin.

DISCUSSION

A. Rule 702 and Daubert Standard

The Court discussed in detail in its previous Order the law surrounding the admission of expert testimony. Ultimately, the Court's role is to ensure that expert testimony is reliable. See Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589 (1993). As the Court previously explained, factors the Court should examine when determining reliability include whether (1) a theory or technique can be and has been tested, (2) the theory or technique has been subjected to peer review and publication, (3) there is a known or potential rate of error and

[3] At the hearing, the Court heard argument on Pfizer's Motion to Exclude the Testimony of Dr. McGwin, Dr. Cheryl Blume, and Plaintiffs' Specific Causation Experts, as well as Pfizer's Motion for Summary Judgment.

whether there are standards for controlling the error, and (4) whether the theory or technique enjoys general acceptance within the relevant scientific community. Id. at 592-95. Additional factors include whether (5) the expertise was developed for litigation or naturally flowed from the expert's research, (6) the proposed expert ruled out other alternative explanations, and (7) the proposed expert sufficiently connected the proposed testimony with the facts of the case. Sappington v. Skyjack, Inc., 512 F.3d 440, 449 (8th Cir. 2008). An expert offering an opinion in litigation must use "in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999).

B. The Published McGwin Study

Pfizer argues that a number of errors in the McGwin Study discovered since the Court's previous Daubert Order undermine the Court's prior ruling and call into question the reliability of the McGwin Study as published. The Court agrees. Most telling is Plaintiffs' admission that "acknowledged inaccuracies in the published study" require Dr. McGwin to supplement his expert report. (Pls.' Reply Mem. at 4.) The Court discusses some of the "acknowledged inaccuracies" below.

1. Miscoding

The McGwin Study stated: "When defining the primary exposure variable – that is, Viagra and/or Cialis use, we were able to define as exposed only those subjects who reported using Viagra and/or Cialis before NAION diagnosis. This allowed us to minimize misclassification by limiting the definition of exposed to aetiologically relevant medication

use." McGwin Study, at 156. The Court previously recognized the McGwin Study's discussion of temporality as a satisfying one of the Bradford criteria for causation.[4] See In re Viagra Prod. Liab. Litig., 572 F. Supp. 2d at 1080.

Pfizer argues that the McGwin Study's treatment of temporality is illusory because numerous patients were coded in Dr. McGwin's electronic dataset as having been exposed to Viagra or Cialis before being diagnosed with NAION when in fact those patients reported their first Viagra or Cialis use as being after they were diagnosed. There are eleven instances where the date of first use on the original telephone survey forms is later than the date of NAION diagnosis on the same form. However, each of those individuals was still coded as exposed in Dr. McGwin's electronic dataset. Dr. McGwin acknowledged that the statistics in the McGwin Study would have been different had those individuals (11 of 27 patients who reported Viagra or Cialis use) been coded as unexposed rather than as exposed. The discrepancies between the dates of first use on the original survey forms and in Dr. McGwin's electronic dataset weaken the McGwin Study's assessment of temporality, thereby undermining the McGwin Study's ability to contribute meaningfully to Dr. McGwin's opinion about general causation.

Plaintiffs make two arguments regarding these discrepancies. They argue first that

[4] "The Bradford Hill factors are strength of relationship, consistency, specificity, temporality, dose response, biologic plausibility, coherence, experimental evidence, and analogy." Dunn v. Sandoz Pharma. Corp., 275 F. Supp. 2d 672, 677 n.5 (M.D.N.C. 2003).

the survey forms on which Pfizer relies are inadmissible hearsay, and second that Dr. McGwin's electronic dataset is based on information gathered when someone recontacted the patients, and not solely on the original survey forms.[5]

The Court finds that the original survey forms are admissible as business records and therefore form a reliable basis on which to decide the current Daubert challenge to Dr. McGwin. Pfizer produced evidence that the survey forms on which it relies were recorded at the time the surveys were conducted and were kept by UAB pursuant to approved protocol. UAB provided the survey forms in response to Pfizer's request for the documentation underlying the McGwin Study. Plaintiffs argued that many of the documents underlying the McGwin Study have been destroyed, but Plaintiffs failed to point the Court to any admissible evidence supporting that contention. The underlying survey forms are records of regularly conducted activity under Federal Rule of Evidence 803(6) and may be considered to impeach the reliability of the McGwin Study as published.

Plaintiffs next seek to downplay the impact of the inconsistencies between the survey forms and the electronic dataset by arguing that the data from the original survey forms was not the data that was actually used to create the electronic dataset:

> Pfizer nevertheless asks this Court [to] leap to the conclusion that, because some of the information contained in Step "A" (the questionnaires) appears

[5] Plaintiffs raised for the first time at the hearing the argument that Pfizer had been given two incorrect survey forms, and that the correct survey forms for those two patients were not inconsistent with Dr. McGwin's electronic dataset. Even if this argument were properly before the Court, Plaintiffs' argument does not explain away all of the inconsistencies between the original survey forms and the electronic dataset.

> inconsistent with the information contained in Step "C" (the dataset), the fundamental errors exist that render the entire Study unreliable. Again, this argument might have validity but for the fact that the newly discovered evidence provides support for the fact that a middle step, or Step "B," was undertaken to verify that the information obtained in the questionnaires was accurate before that information was electronically coded into the final dataset.

(Pls.' Opp'n Mem. at 5.)

The "newly discovered evidence" includes a document entitled "Recontact Info. for Viagra/Cialis Dates" (the "Recontact Sheet") that was found in the files of Irene Xie, the statistician in charge of the McGwin Study. The Recontact Sheet listed the patients by their study identification number and listed each patient's NAION diagnosis date, date of first use of Viagra, and date of first use of Cialis. Handwritten on the Recontact Sheet over certain dates is the word "OK," and next to some of the patients are written the words "use pre DX."[6] On another document entitled "Ever taken Viagra or Cialis?" found in Ms. Xie's files, there is what appears to be a sticky note attached over a list similar to the one on the Recontact Sheet. In what Dr. McGwin confirmed to be his handwriting, the sticky note reads: "Confirm all dates as pre-DX — hard code all changes." Dr. McGwin said in his deposition that it appeared to him that he had directed someone to verify the dates of first use and make the changes to the electronic dataset. However, he could not confirm that anyone actually verified the dates or hard coded any changes. Plaintiffs also introduced evidence that UAB regularly recontacts study participants to clarify patients' answers that were ambiguous.

Although this evidence could be consistent with Plaintiffs' theory that there was a

[6] DX is short hand for diagnosis.

"Step B," Plaintiffs have failed to produce any competent witness or documentary evidence to verify that such a step was actually taken. Indeed, as Plaintiffs concede, "Dr. McGwin was unable to authenticate any of the underlying documents, unable to authenticate the handwriting on these documents, and unable to offer an opinion (without speculating) as to the maker's intent with respect to various notations made on these documents." (Pls.' Opp'n Mem. at 12.) Plaintiffs confirmed that Ms. Xie was never deposed, and Plaintiffs have not cited to any other admissible testimony from Ms. Xie or someone else who is able to verify that patients were recontacted. The Court cannot rely on Plaintiffs' speculation as to what might have occurred between the original data collection and the production of the electronic dataset.[7] The Court finds that the discrepancies between the dates of first use on the original survey forms and in the electronic dataset raise serious concerns about the reliability of the McGwin Study as originally published.

2. Statistical Methods Used

Pfizer also argues that the statistical methods used to produce the numbers in the McGwin Study as published were not the statistical methods that the McGwin Study said were used. The McGwin Study said that it used a paired t-test; Dr. McGwin admitted that

[7] Having found that Plaintiffs' recontact theory is based only on inadmissible evidence, the Court need not consider Pfizer's arguments that recontacting the study participants violated IRB protocol, that the patients' changed answers render the underlying data unreliable according to UAB's own standards, and that the data gathered during the recontacts are unreliable because they were not properly documented.

he in fact used a two sample t-test instead, which he conceded was "not the most appropriate." (McGwin 3/24/09 Dep. at 626.) Pfizer's expert, Dr. Stephen E. Kimmel, also argued that McNemar's test was not used, contrary to what the McGwin Study as published said. (Kimmel Supp. Rep. at ¶ 15.) Pfizer argues further, based on Dr. Kimmel's addendum to his supplemental report, that the code that Dr. McGwin wrote to produce the numbers in the McGwin Study contained errors that would affect the odds ratios and confidence intervals regarding hypertension. Plaintiffs do not directly address Pfizer's arguments in their briefs—rather, Plaintiffs rely almost entirely on the fact that Dr. McGwin's reanalysis is consistent with the original findings. Even if the reanalysis confirms the findings of the original study, the fact that the methodologies described in the study were not the actual methodologies used undermines the reliability of the McGwin Study as published.

3. History of Myocardial Infarction

Pfizer also argues that the McGwin Study as published is unreliable because it mischaracterizes one of its main findings—that men with a personal history of myocardial infarction and Viagra or Cialis use have a significantly higher risk of NAION. The patients were actually asked whether they had a <u>family</u> history of myocardial infarction; no one was asked about <u>personal</u> history. Dr. McGwin conceded that he mistakenly assumed that the variable "MI" in his electronic dataset referred to a personal history of myocardial infarction. Pfizer contends that this level of carelessness by the principal author of the study renders the study unreliable. Pfizer also argues that at least one patient was miscoded regarding the MI variable and that the numbers in the McGwin Study as published regarding myocardial

infarction are inaccurate. Dr. McGwin conceded that there was at least one miscoding of the MI variable. Plaintiffs respond that the fact that the MI variable refers to a family history simply expands the population that may be at risk for NAION as a result of Viagra or Cialis use, and that Dr. McGwin's reanalysis fixes any problems that may have resulted from previous miscodings.

Dr. McGwin's mistake regarding the MI variable does not appear to have significantly affected the way the study was conducted—in other words, it does not appear that Dr. McGwin would have employed a different methodology had he correctly surmised the meaning of the MI variable. Pfizer's contention that the entire study is rendered unreliable simply because of Dr. McGwin's mistaken characterization of the MI variable is overreaching. However, the miscodings regarding myocardial infarction do add yet another layer of unreliability to the McGwin Study as published.

4. Reliability of the McGwin Study as Published

Taken together, the miscodings and errors described above effectively undermine the reliability of the McGwin Study as published. As Plaintiffs concede, there are "acknowledged inaccuracies in the published study" that need to be corrected. In light of those acknowledged inaccuracies, the Court finds good reason to vacate its original Daubert Order permitting Dr. McGwin to testify as a general causation expert based on the McGwin Study as published. Almost every indicia of reliability the Court relied on in its previous Daubert Order regarding the McGwin Study has been shown now to be unreliable. Peer review and publication mean little if a study is not based on accurate underlying data.

Likewise, the known rate of error is also meaningless if it is based on inaccurate data. Even if the McGwin Study as published was conducted according to generally accepted epidemiologic research and did not result from post-litigation research, the fact that the McGwin Study appears to have been based on data that cannot now be documented or supported renders it inadmissibly unreliable. The Court concludes that under Daubert, Dr. McGwin's opinion, to the extent that it is based on the McGwin Study as published, lacks sufficient indicia of reliability to be admitted as a general causation opinion.

C. Reanalysis

Plaintiffs argue that Dr. McGwin's reanalysis cures all of the original McGwin Study's ills and confirms the conclusions of the McGwin Study, especially with regard to Viagra use. In his proposed supplemental report, Dr. McGwin detailed the process by which he generated his recent Letter to the Journal. To conduct his reanalysis, Dr. McGwin submitted for Institutional Review Board approval, adjusted data in the electronic dataset to match the data from the original survey forms, and recomputed the odds ratios and confidence intervals under a variety of assumptions. In his supplemental report, Dr. McGwin concludes that the "results are consistent with those in our original manuscript with the exception that any increased risk appears to be limited to Viagra." (McGwin Supp. Report at 3.)

In its previous Daubert ruling, the Court placed great weight on the fact that the McGwin Study had been peer-reviewed and published by the Journal, and that the study had not been produced using post-litigation data. As noted above, however, numerous

miscodings and errors have rendered the McGwin Study as published unreliable. Dr. McGwin's reanalysis and proposed supplement to his expert opinion seek to address those sources of unreliability. However, Dr. McGwin's recent Letter to the Journal lacks several important indicia of reliability. First, it has not been peer-reviewed. Second, the Letter has not been published. The Journal referred the Letter to the Committee on Publication Ethics. Third, unlike the original McGwin Study, the Letter was produced post-litigation. Dr. McGwin conceded that the Letter only became necessary after "several valid concerns that were identified over the past two years" were raised in the course of this litigation. (McGwin Supp. Rep. at 2.) The Court finds the lack of peer-review and publication particularly important in this case because the reanalysis and Letter were produced in response to concerns raised in litigation. Further, whatever the motives may have been for the timing of the Letter and supplemental report, the Court finds the inability of Pfizer to conduct any meaningful cross-examination of Dr. McGwin regarding the supplemental report another factor that supports the heightened importance of peer review in this situation.

In light of the "acknowledged inaccuracies of the published study," the lack of peer-review and publication of the Letter, and the fact that the reanalysis and Letter were produced in response to concerns raised in this litigation, the Court finds that the reanalysis and Letter do not form a reliable basis under Daubert on which Dr. McGwin can form an admissible general causation opinion in this litigation. It is conceivable that, should the Court wait long enough, the Journal might review Dr. McGwin's reanalysis and publish his Letter. Indeed, it is conceivable that, should the Court wait long enough, some study not yet begun could

conclusively prove that Viagra causes NAION. To be fair, it is equally conceivable that the Journal will take a dim view of Dr. McGwin's reanalysis and Letter, or that some study not yet begun will prove conclusively that Viagra is incapable of causing NAION. The Court, however, is not concerned with what is conceivable. Rather, the Court must base its decision based on the information and evidence before it. At this point in time and based on the evidence before it, the Court concludes that neither the McGwin Study as published, nor Dr. McGwin's reanalysis and Letter to the Journal, possess sufficient indicia of reliability to form the basis of an admissible general causation opinion in this case. Therefore, Pfizer's Motion to exclude the testimony of Dr. McGwin regarding general causation must be granted.

Plaintiffs disagree that Dr. McGwin cannot render a general causation opinion without the McGwin Study. The Court noted in its previous Daubert Order that Dr. McGwin based his opinion on two epidemiologic studies—his own, and the Margo et al. study—to support his general causation opinion. In re Viagra Products Liab. Litig., 572 F. Supp. 2d 1071, 1080 (D. Minn. 2008) (Magnuson, J.).[8] The Margo et al. study, alone, cannot form the basis of a general causation opinion because "temporality could not be assessed in the Margo et al. study." Id. As the Court noted, Dr. McGwin's assessment of the temporality criterion of the

[8] At oral arguments, Plaintiffs' counsel mischaracterized the Court's prior ruling. The Court's discussion of the merits of Dr. McGwin's general causation opinion was limited to a discussion of the epidemiologic studies. There was no reference to Dr. McGwin's discussion of case reports or challenge/rechallenge cases, as Plaintiffs suggested. However, in light of the limitations of such evidence in proving causation, see, e.g., Viagra, 572 F. Supp. 2d at 1079, the Court's conclusion on this issue would be the same even had the court ruled as Plaintiffs desired.

Bradford Hill criteria was limited to the McGwin Study. Although the failure to satisfy the Bradford Hill criteria does not necessarily compel exclusion of an opinion as unreliable, see id. at 1081, the Court finds that Dr. McGwin's general causation opinion is insufficiently supported by the remaining epidemiologic studies to be admitted under Daubert.

4. Motion to Supplement

Also before the Court is Plaintiffs' motion for leave to file the supplement to Dr. McGwin's expert report that includes his reanalysis. In response to Plaintiffs' motion, Pfizer argues (1) that Federal Rule of Civil Procedure 37(c)(1) prohibits Plaintiffs from relying on the supplement; (2) that the reanalysis described in the supplement fails to correct all of the errors in the McGwin Study as published; and (3) the supplement renders Dr. McGwin's opinion unreliable because he announced his conclusions prior to having accurate information supporting that conclusion. As noted above, the Court finds the research and Letter on which Dr. McGwin bases his supplemental report insufficiently reliable to be admitted under Daubert. However, even if the research and Letter were sufficiently reliable, the Court finds good reason to deny Plaintiffs' motion for leave to file the supplement.

A party must file a supplement to one of its expert's reports "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect . . . ." Fed. R. Civ. P. 26(e)(1) (emphasis added). Rule 37(c)(1) provides that "[i]f a party fails to provide information . . . as required by Rule 26(a) or (e), the party is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless." A party's untimely disclosure

is not substantially justified when the party was aware of the need for a late disclosure but failed to move for an extension of the deadline. See Trost v. Trek Bicycle Corp., 162 F.3d 1004, 1008 (8th Cir. 1998). In determining whether an untimely disclosure is "harmless," a court is to consider both the harm to the opposing party as well as harm that a continuance may cause to a court's calendar. See id. at 1009; Travelers Express Co. v. Transation Tracking Tech., Inc., No. 03-2848, 2005 WL 5979355, at *12 (D. Minn. May 2, 2005) (Doty, J.)

"When fashioning a remedy, the district court should consider, inter alia, the reason for noncompliance, the surprise and prejudice to the opposing party, the extent to which allowing the information or testimony would disrupt the order and efficiency of the trial, and the importance of the information or testimony." Wegener v. Johnson, 527 F.3d 687, 692 (8th Cir. 2008). A district court enjoys "wide discretion" in fashioning a remedy for violations of Rule 37, but that "discretion narrows as the severity of the sanction or remedy [the district court] elects increases." Id. Courts should consider lesser sanctions where exclusion of the proposed supplement is "tantamount to a dismissal of [the plaintiff's] claims." Heartland Bank v. Heartland Home Finance, Inc., 335 F.3d 810, 817 (8th Cir. 2003). However, even though "exclusion of evidence is a harsh penalty and should be used sparingly," see ELCA Enters. v. Sisco Equip. Rental & Sales, 53 F.3d 186, 190 (8th Cir. 1995), the facts and circumstances of a particular case may make exclusion an appropriate remedy. See Bi-Rite Petroleum, Ltd. v. Coastal Refining & Mktg., Inc., 282 F.3d 606, 609 (8th Cir. 2002) (affirming the district court's order excluding an expert's untimely testimony

even though exclusion necessarily led to dismissal of one of the plaintiff's claims).

There is no dispute that Plaintiffs' proposed supplement to Dr. McGwin's expert report is untimely. The deadline for filing a supplemental report to Dr. McGwin's report was November 17, 2008. Plaintiffs argue, however, that their untimely submission of Dr. McGwin's supplemental report is substantially justified because it became necessary only as a result of Court-approved additional discovery conducted by Pfizer after the November 2008 deadline. Plaintiffs also argue that the untimely submission is harmless because Pfizer has already had a chance to submit a rebuttal affidavit by its own expert, and because there is no trial date set. Despite Plaintiffs' arguments, the Court finds Plaintiffs' untimely submission of Dr. McGwin's supplemental report neither substantially justified nor harmless.

Although this is not the exact case presented in Trost v. Trek Bicycle Corp., 162 F.3d 1004 (8th Cir. 1998),[9] the principle announced in that case applies here:

> It is risky for a plaintiff in a products liability case to sit back and wait to see what a defense expert might say before seeking an expert report. If [a plaintiff has] a legitimate need to await [the defendant's] report before producing the evidence necessary to meet his burden of proof, then [the plaintiff's] proper course of action would have been to seek an extension of the deadline.

Id. at 1008. Implicit in Trost is that a party should move to extend the deadline as soon as it discovers the need for a supplement. That the deadline had already passed in this case before Plaintiffs discovered the need for a supplement to Dr. McGwin's report does not alter

[9] In Trost, the Eighth Circuit Court of Appeals affirmed the district court's exclusion of an untimely expert report because the plaintiff failed to move for an extension of the deadline for filing expert reports prior to the deadline.

Plaintiffs' duty to timely apprise the Court of its developing need for additional expert supplemental reports and to file those reports in a timely manner. Indeed, it would be an unfair result if one litigant's expert supplemental report was excluded because it discovered the need for additional briefing the day before the deadline, but a litigant who discovered the need for additional briefing the day after the deadline was permitted to file the supplement whenever it found it convenient to do so.

In Wegener v. Johnson, 527 F.3d 687 (8th Cir. 2008), the Eight Circuit Court of Appeals found that a district court judge did not abuse her discretion by excluding from consideration a supplemental report from one of the party's experts that was untimely submitted. The court found that the untimely submission was neither substantially justified nor harmless in part because granting a continuance would have further delayed already protracted proceedings. The court also reasoned that exclusion was justified because

> [the expert's] supplemental testimony was based on hospital records that were easily discoverable, patently relevant to [the plaintiff's] case, and which [the plaintiff's] counsel knew the defense had subpoenaed five months prior to the disclosure deadline. [The plaintiff's] failure to exercise due diligence with respect to her expert's review of relevant medical records also does not substantially justify her untimely disclosure.

Id. at 693.

The case for exclusion is even stronger here than in Wegener. First, although there is no trial date set for the individual cases, the Court has already heard oral arguments on Pfizer's second Daubert challenge to Dr. McGwin, in addition to hearing oral arguments on case-specific summary judgment motions and motions to exclude Plaintiffs' regulatory and

specific causation experts. If Dr. McGwin is allowed to supplement his expert report at this stage of the litigation, Pfizer must be permitted to depose Dr. McGwin, which would further delay the resolution of this Court's role in the pretrial stage of this multidistrict litigation. That Pfizer has already filed its own expert's response to Dr. McGwin's reanalysis does not alter the fact that Pfizer would be entitled to question Dr. McGwin about his new methodology and findings.

Second, whereas the hospital records in Wegener were easily discoverable by the plaintiff, Dr. McGwin had direct access to the documents that prompted his reanalysis. Although it appears undisputed that Dr. McGwin had not seen the original survey forms prior to his deposition in December 2008, it also appears undisputed that Dr. McGwin could have had unfettered access to them without going through the process of formal discovery. In any event, Dr. McGwin's untimely supplement was not substantially justified because he did have access to the documents prompting the reanalysis.

Third, the original survey forms were patently relevant to Plaintiffs' case. Even if Dr. McGwin was justified in not verifying his electronic dataset against the original survey forms when he first published his study, the original survey forms became relevant at the latest when they became the focus of Pfizer's second deposition of Dr. McGwin. As discussed above, the discrepancies between the originals survey forms and the electronic dataset that Dr. McGwin used for the McGwin Study as published undermines the reliability of that study. The McGwin Study is obviously relevant to Plaintiffs' case because Dr. McGwin is the only potential general causation expert left in this case and the McGwin Study forms the

basis of his general causation opinion.

Fourth, just as the defense in Wegener subpoenaed the documents five months before the disclosure deadline, Pfizer here subpoenaed the original survey forms long before Plaintiffs submitted the proposed supplement. Pfizer subpoenaed "all underlying data and documents" for the McGwin Study as early as May 4, 2007. It did so again one year later. Pfizer deposed Dr. McGwin concerning the content of the original survey forms in December 2008. In its Motion for Additional Discovery filed in late December 2008, Pfizer moved for "a further Daubert hearing regarding the reliability and admissibility of Dr. McGwin's expert opinion." (Docket 533.) Plaintiffs knew at least by December 2008 that Pfizer had an active interest in the original survey forms and the impact those forms might have on the admissibility of Dr. McGwin's general causation opinion. By the end of December 2008 Pfizer had in fact taken formal action to rechallenge Dr. McGwin's testimony. Based on all of the above, the Court concludes that Plaintiffs knew or should have known nearly five months before they sought to supplement Dr. McGwin's expert report that such a supplement would be necessary.

Finally, Dr. McGwin's failure to consider the challenges that were being mounted to the McGwin Study in a more timely manner does not substantially justify Plaintiffs' untimely submission of the supplemental report. Dr. McGwin admitted earlier in a deposition that he had thought to recheck the numbers in the McGwin Study at some point prior to his March 2009 deposition but that Plaintiffs' counsel had told him not to do so at that time. Although the deadline for filing a supplemental report had passed before Plaintiffs became aware of

the need for a supplemental report, the wait-and-see tactic employed by Plaintiffs' counsel in this case is precisely the kind of behavior that the court in Trost denounced. See Trost, 162 F.3d at 1008-09.

In light of the preceding analysis, the Court concludes that Plaintiffs' untimely submission of Dr. McGwin's supplemental report is not substantially justified. Nor is it harmless. If the Court were to permit the supplemental report to be considered, Pfizer would need to depose Dr. McGwin for a fourth time. The Court does not doubt that the parties would feel slighted if they did not have the opportunity to then present additional oral argument in addition to rebriefing Pfizer's Motion to Exclude Dr. McGwin. The resolution of Pfizer's case-specific Motions for Summary Judgment would necessarily be delayed because the Motion to Exclude Dr. McGwin directly affects the viability of Plaintiffs' claims. The net result of permitting Plaintiffs' untimely submission would be to delay further these already protracted proceedings, imposing unnecessary additional costs on the parties and the Court. In addition, as noted above, because the supplemental report itself is based on the Letter that Dr. McGwin wrote the Journal, and because the Letter has not been peer reviewed or published, the supplemental report is not reliable enough to form the basis of an admissible general causation opinion. Plaintiffs' Motion for Leave to File a Supplement to Dr. McGwin's expert report is denied. Because the Court concludes that Dr. McGwin's supplement should be excluded under Rule 37, the Court declines to discuss Pfizer's remaining arguments against allowing the supplement.

The Court recognizes that exclusion is a harsh penalty. However, in light of the facts

and circumstances of this case—particularly given the Court's conclusion above about the reliability of the supplemental report—the Court concludes that exclusion is the most appropriate remedy. It has been three years since this multidistrict litigation began. The parties, including each individual Plaintiff and Pfizer, deserve to have this matter resolved in a timely manner. Although it may be true that, with even more time, the issues with the McGwin Study and Dr. McGwin's expert testimony could be resolved, the matter is now before the Court and ripe for a decision. Further delaying the proceedings cannot be justified and the Court declines to do so. See Wells v. SmithKline Beecham Corp., No. A-06-CA-126-LY, 2009 WL 564303, at *12 (W.D. Tex. Feb. 18, 2009) ("The Court recognizes that sometimes 'waiting until an association found in one study is confirmed by others will mean that early claimants will be denied a recovery.' [Merrell Dow Pharm., Inc. v. Havner, 953 S.W.2d 706, 708 (Tex. 1997)]. Despite this, Havner expressly rejects a more lenient standard, stating '[l]aw lags science; it does not lead it.'" Id. at 728 (quoting Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996))).

CONCLUSION

Dr. McGwin's general causation opinion is shrouded in too many of questions and doubts to be admissible under Daubert. Accordingly, **IT IS HEREBY ORDERED** that:

1. Pfizer's Motion to Exclude the Testimony of Dr. Gerald McGwin (Docket No. 550) is **GRANTED**; and
2. Plaintiffs' Motion for Leave to File Supplemental Expert Report of Dr. Gerald McGwin (Docket No. 564) is **DENIED**.

Dated: Wednesday, August 19, 2009

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

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 nuero-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-Meyer[1] 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. at1085-86. 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 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 a orthopedist because the subject of his testimony was "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 mining[2] 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 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