

**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 family history of myocardial infarction; no one was asked about personal 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 original 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 ‘[I]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