UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
SHREVEPORT DIVISION

CHERIE LEDET RHODES, ET AL.	CIVIL ACTION NO. 10-1695
VERSUS	JUDGE S. MAURICE HICKS, JR.
BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.	MAGISTRATE JUDGE HORNSBY

MEMORANDUM RULING

Before the Court is Bayer Healthcare Pharmaceuticals Inc.'s ("Bayer") Motion to Exclude the Proffered Opinions of Dr. Stephen Hamilton. See Record Document 30. Bayer filed the motion pursuant to Federal Rule of Evidence 702, arguing that Plaintiffs can show neither that Dr. Hamilton is qualified to make the opinions he renders nor that his opinions satisfy the requirements of Daubert. See id. Plaintiffs Cherie Ledet Rhodes and Keith Rhodes[1] opposed the motion. See Record Document 37. For the reasons set forth below, Bayer's motion is **GRANTED** and Dr. Hamilton's causation and liability opinions are excluded.

I. BACKGROUND

The instant matter is a products liability/failure to warn case under the Louisiana Products Liability Act ("LPLA"). Plaintiffs contend that Cherie Ledet Rhodes ("Ms. Rhodes") suffered peripheral neuropathy after taking two Avelox pills over a two-day span. They further allege that the Avelox pills caused Ms. Rhodes' peripheral neuropathy. Avelox is a FDA-approved prescription medication that was prescribed to treat Ms. Rhodes' sinus problems. More specifically, Avelox (moxiflaxin) is an antibiotic of the fluorquinolone class.

[1]Cherie Ledet Rhodes and Keith Rhodes are plaintiffs individually and one behalf of their minor child, Amanda Rhodes.

Dr. Hamilton is currently a Professor Emeritus of Pharmacy and Medicine (Cardiology) from the University of Oklahoma Health Sciences Center. See Record Document 30, Exhibit 1 at 1. His education and training includes a Bachelor of Science degree in Pharmacy from the University of Missouri, a Doctor of Pharmacy degree from the University of Tennessee, and a Post-Doctoral Fellowship in Clinical Pharmacy Services from the University of Texas. See id. Dr. Hamilton was asked by Plaintiffs to address the following:

> I have been asked to offer opinions on the possibility of Avelox (moxifloxacin) causing peripheral neuropathy and/or long term or permanent damage due to myopathy and if the prescribing information is adequate with regards to these adverse events.

Id. He concluded that "on the scale of definite, probable, possible or doubtful, Avelox probably ('more likely than not') caused Ms. Rhodes' symptoms and long term disability." Id. at 9. He further opined that "the prescribing information for Avelox is deficient with respect to warnings of severe peripheral neuropathy and myopathy." Id.

Plaintiffs have proffered Dr. Hamilton as an expert to establish that (1) Avelox can cause peripheral neuropathy; (2) that Ms. Rhodes suffered peripheral neuropathy as a result of her ingestion of two Avelox pills; and (3) the warnings in Avelox's labeling were inadequate. See generally Record Document 30, Exhibits 1 & 2. Bayer now moves to exclude the aforementioned opinion testimony offered by Dr. Hamilton pursuant to Federal Rule of Evidence 702. See Record Document 30.

II. LEGAL STANDARD

Rule 702 provides that "a witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

F.R.E. 702. Rule 702 "assign[s] to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand. Pertinent evidence based on scientifically valid principles will satisfy those demands." Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 597, 113 S.Ct. 2786, 2799 (1993). The Daubert court provided an illustrative list of factors that courts may use when evaluating the reliability of expert testimony. See id. at 592-594, 113 S.Ct. at 2796-2797. These factors include whether the expert's theory or technique can be or has been tested, whether it has been subjected to peer review, whether it has a known or potential rate of error or standards controlling its operation, and whether it is generally accepted in the relevant scientific community. See id. at 593-594, 113 S.Ct. at 2796-2797. "In short, expert testimony is admissible only if it is both relevant and reliable." Pipitone v. Biomatrix, Inc., 288 F.3d 239, 244 (5th Cir.2002). Thus, the Daubert factors should be applied with flexibility and the question of whether an expert's testimony is reliable is ultimately a fact-specific inquiry. See Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 138, 119 S.Ct. 1167, 1170 (1999); Burleson v. Tex. Dep't of Criminal Justice, 393 F.3d 577, 584 (5th Cir.2004).

III. ANALYSIS

First, Bayer argues that Dr. Hamilton is not qualified to give the opinions he renders. See Record Document 30-1 at 2. Additionally, Bayer maintains that Dr. Hamilton's opinions lack valid and reliable scientific predicate and foundation, and are not products of reliable scientific methodologies. See id. For these reasons, Bayer moves to exclude Dr. Hamilton's "so-called expert opinions." Id.

A. Causation Opinions[2]

1. Qualifications

Dr. Hamilton offers the opinion that Ms. Rhodes suffers from peripheral neuropathy, a neurological condition. Plaintiffs have not offered any other expert support or foundation for this opinion. They have also failed to provide evidence from a trained neurologist or a medical doctor on this issue.

Dr. Hamilton is a pharmacist, not a medical doctor or more specifically, a neurologist. He is likewise not a diagnostician or an epidemiologist. Thus, his testimony regarding a medical diagnosis or medical condition, i.e., that Ms. Rhodes suffers from peripheral neuropathy, must be excluded. Dr. Hamilton admitted in his deposition that he was not a licensed physician, he was not licensed to prescribe, and he was not licensed to diagnose. See Record Document 30, Exhibit 2 at 11-12. In fact, the only medical doctor identified as an expert witness by either party in this matter is Dr. Mary Elise McWilliams, a neurologist. See Record Document 30, Exhibit 3. Dr. McWilliams opined that Ms. Rhodes

[2]Dr. Hamilton's report implies that he was asked to offer expert opinions on general causation; however, his deposition testimony includes purported expert opinions as to specific causation. See Record Document 30, Exhibits 1 & 2.

does not have peripheral neuropathy, but rather carnitine deficiency, a genetic disorder which is unrelated to the prescription medication Avelox. See id.

Dr. McWilliams further testified at her deposition that the curriculum of a doctor of medicine is different than the curriculum of a doctor of pharmacy. See id., Exhibit 4 at 69. Dr. McWilliams explained that pharmacists have no training in disease and lack the training required to make a differential diagnosis. See id. at 68-69. Dr. McWilliams unequivocally stated that pharmacists without medical degrees are not qualified to diagnose diseases such as peripheral neuropathy or carnitine deficiency in individual patients. See id. at 70.

Dr. McWilliams' opinion is also supported by case law. See In re Vioxx Products Liability Litigation, 401 F.Supp.2d 565 (E.D.La. 2005). In the Vioxx case, the court considered whether a Ph.D. professor of preventive medicine was qualified to testify on what doctors should prescribe to patients and on the specific cause of plaintiff's death. See id. at 587. The court held that the professor could not "opine on these issues," as he was not a medical doctor and was "not qualified to testify as to the risk-benefit analysis performed by medical doctors." Id. Additionally, the professor was "not qualified to review the clinical information of [the plaintiff]" and was "lacking in the necessary training to testify as to what doctors should have done and to what was the specific cause of [plaintiff's] death." Id.

Plaintiffs concede "that Dr. Hamilton is not qualified to make a medical diagnosis," but argue that he "is allowed to rely on data that experts in his field reasonably rely on." Record Document 37 at 5. Plaintiffs contend that Dr. Hamilton "was relying on the diagnoses of medical doctors in [his] consulting work" and, specifically in this instance, he was relying on the medical records of Ms. Rhodes that contain the diagnosis of peripheral

neuropathy. See id. at 5-6. The Court first notes that the medical records in this matter reference many diagnosis, ranging from mitochondrial disease to peripheral myopathy. While it may be true that Dr. Hamilton relied on Ms. Rhodes' medical records, he is simply not qualified to render a diagnosis after consideration of the many diagnostic alternatives contained in those medical records. While the Fifth Circuit has held that a medical doctor testifying as to issues of causation may base his testimony upon a review of medical records, the doctor's experience, and a broad review of the literature, Plaintiffs have failed to point this court to any such holding in regards to a pharmacist. See Carroll v. Morgan, 17 F.3d 787, 789-790 (5th Cir. 1994).

2. Dr. Hamilton's Opinions Do Not Satisfy Daubert

General Causation

Considering the record evidence, the Court further finds that Dr. Hamilton's opinion that Avelox can cause peripheral neuropathy is nothing more than a hypothesis. Under Daubert, "the role of the district court [is] to ensure that scientific expert testimony is of sufficient validity to warrant its admission into evidence." Kelley v. American Heyer-Schulte Corp., 957 F.Supp. 873, 876 (W.D.Tex. 1997). One factor governing the admission of scientific expert testimony is "the sufficiency of the expert's methodology." Id. With regard to this factor, "a scientific expert's testimony must be supported by appropriate validation—that is, it must have a reliable basis in the knowledge and experience of the expert's discipline." Id. "The hallmark of acceptable testimony turns on whether the scientific conclusion is testable and has been tested. Lesser, but still important, considerations are whether the scientific conclusion has been published in a peer reviewed journal, the amount of error associated with the expert's technique, and whether the theory

is generally accepted in the scientific community." Id.

Dr. Hamilton admitted during his deposition that he has never tested his theory and that he had never conducted any studies or clinical research regarding either mitochondrial myopathies or carnitine deficiencies. See Record Document 30, Exhibit 2 at 26. He specifically acknowledged that he had never (1) authored any publications regarding clinical studies where the issue of risks and benefits of Avelox was evaluated; (2) authored any publications where the risks and benefits of any fluoroquinolone antibiotic was evaluated in a clinical trial or study; (3) published a review article involving fluoroquinolones or Avelox; (4) submitted a case report to a medical journal involving a patient that allegedly suffered a condition or a side effect related to Avelox; or (5) submitted a case report to a medical journal or any publication where a patient allegedly suffered a side effect related to any fluoroquinolone. See id. at 13-14. In fact, Dr. Hamilton confessed that his research focused on cardiovascular issues. See id. at 10. Moreover, Dr. Hamilton could not point to any epidemiological study that had studied whether Avelox is associated with peripheral neuropathy. See id. at 41. Based on the foregoing, there is simply no record evidence to support that Dr. Hamilton's opinion/theory has been tested. The record is likewise devoid of evidence that his theory has achieved any type of validation, recognition or general acceptance. His opinion/theory appears to be nothing more than a hypothesis and it must be excluded pursuant to this Court's role under Daubert.

The Court further scrutinizes Dr. Hamilton's theory due to a lack of causative links. Dr. Hamilton has acknowledged the lack of any epidemiological study that has evaluated the potential association between Avelox and peripheral neuropathy. See Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 315 (5th Cir. 1989) ("[S]peculation unconfirmed

by epidemiologic proof cannot form the basis for causation in a court of law."). Despite this hurdle, he bases the purported causative link between Avelox and peripheral neuropathy on (1) a single case study that possibly contains a reference to Avelox; (2) medical literature related to other fluoroquinolones; and (3) adverse event reports.

"Nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." General Elec. Co. v. Joiner, 522 U.S. 136, 146, 118 S.Ct. 512, 519 (1997). The proponent of the expert testimony "must demonstrate that the expert's findings and conclusions are based on the scientific method, and therefore, are reliable." Curtis v. M&S Petroleum, Inc., 174 F.3d 661, 668 (5th Cir. 1999).

Based on the aforementioned legal standard, Dr. Hamilton's causative bases fail to satisfy Daubert. Dr. Hamilton's recollection that the Leone case study had a possible reference to Avelox and peripheral neuropathy is misplaced. See Record Document 30, Exhibit 2 at 34-36. Bayer has included a copy of the Leone study as part of the record and a review of such reveals no cases of patients who have taken Avelox and allegedly suffered from peripheral neuropathy. See id., Exhibit 5. Where there is no proof of association, there can be no scientific basis for a causal opinion. See Reference Manual on Scientific Evidence 391-392 (Fed. Judicial Ctr. 2d ed. 2000).

Dr. Hamilton further relies upon rare occurrences of neuropathy in connection with the use of other fluoroquinolone antibiotics to prove causation. This causative link likewise fails. Courts have generally rejected the idea that an expert can extrapolate causation to a medication simply due to its being part of class. In In re Baycol Products Litigation, MDL

No. 1431, 2008 WL 6259241, *6 (D.Minn. Sept. 9, 2008), the court reasoned:

> Despite the fact that Dr. Chalasani purports to rebut Dr. McGuire's opinion that cerivastatin could not cause autoimmune hepatitis because it was not specifically mentioned in the literature, the Court agrees with Dr. McGuire, and finds that the literature does not directly address Baycol and AIH, rather Dr. Chalasani's opinions address the ability of statins as a class to cause AIH. Plaintiff must do more then simply demonstrate that statins as a class have the possibility of causing a particular injury. Plaintiff must demonstrate that Baycol is capable of causing the type of injury Plaintiff experienced, and that Baycol did in fact cause Plaintiff's injuries. Thus, even with Dr. Chalasani's opinions, Plaintiff has failed to demonstrate that Baycol caused Plaintiff's specific injuries in this matter.

Id.; see also Wells v. SmithKline Beecham Corp., 601 F.3d 375 (5th Cir. 2010). Thus, the Court finds that Dr. Hamilton's proffered opinion testimony is not sufficiently tied to the facts of this case and there is an analytical gap that renders his causation theory unreliable.

Dr. Hamilton's reliance on adverse event reports is also unimpressive, as such reports do not demonstrate the requisite degree of reliability demanded by Daubert. In McClain v. Metabolife Intern., Inc., 401 F.3d 1233 (11th Cir. 2005), the court explained:

> The FDA's adverse events reports . . . and other consumer complaints . . . provided another important source for [the expert's] opinions. But these FDA reports reflect complaints called in by product consumers without any medical controls or scientific assessment. Under the adverse events reporting system, consumers call in to describe medical problems that they think they are experiencing from taking a product. These complaints provide the basis for the AERs. [The expert] also considered the same type of complaints called into the "Metabolife health-line." Yet, [the expert] . . . testified that such anecdotal reports do not prove causation.
>
> Uncontrolled anecdotal information offers one of the least reliable sources to justify opinions about both general and individual causation. . . . It also shows that [the expert] relied on data that lacks the indicia of scientific reliability.

Id. at 1250.

Finally, the Court concludes that Dr. Hamilton's methodology is unreliable under

Daubert standards. Dr. Hamilton relied upon the "Naranjo" method for causality assessment. See Record Document 30, Exhibit 2 at 37. He explained during his deposition that this method is a way to classify adverse event reports. See id. at 39. He further explained that he applied the Naranjo criteria to the adverse event reports related to Avelox and assigned the event a probability category, which then allowed him to determine the probability that an adverse event was associated with Avelox. See id. at 37-38, 40.

As the record stands, this process appears to be unreliable on multiple grounds. Bayer has pointed the Court to Methods for Causality Assessment fo Adverse Drug Reactions: A Systemic Review, which provides that "there is still no method universally accepted for causality assessments of [adverse drug reasons]." Taofikat B. Agbabiaka, Methods for Causality Assessment fo Adverse Drug Reactions: A Systemic Review, 31(1) Drug Safety 21, 21 (2008). Moreover, the Naranjo algorithm/methodology appears, in actuality, to be a classification system, not a method used to determine actual causal relationships and/or causality assessments. See id. at 28-29; Tejal K. Gandhi, et al., Identifying Drug Safety Issues: From Research to Practice, 12(1) Int. J. Quality Health Care 69, 73 (2000) ("Another classification tool is the Naranjo algorithm."). Thus, the Court finds that Plaintiffs have not met their burden of establishing that Dr. Hamilton's opinions based on his application of the Naranjo method are reliable. See Curtis, 174 F.3d at 668.

Specific Causation

The Fifth Circuit has held that "evidence concerning specific causation . . . is admissible only as a follow-up to admissible general causation evidence." Knight v. Kirby Inland Marine Inc., 482 F.3d 347, 351 (5th Cir. 2007). "There is a two-step process in

examining the admissibility of causation evidence": (1) "the district court must determine whether there is general causation"; and (2) "if it concludes that there is admissible general causation evidence, the district court must determine whether there is admissible specific causation evidence." Id.

Absent evidence of general causation,[3] there is no valid factual predicate for Dr. Hamilton's opinion regarding specific causation, that is, Avelox caused Ms. Rhodes' alleged peripheral neuropathy. As previously noted, Dr. Hamilton has failed to point to any published, scientific literature establishing a causal link between Avelox and peripheral neuropathy. Notwithstanding, he appears to make a medical diagnosis, rule out other possible causes, and conclude that Avelox caused Ms. Rhodes' condition based on nothing more than temporal proximity (her ingestion of Avelox and the suddenness of her symptoms) and his own beliefs. See Record Document 30, Exhibit 2 at 52. The lack of general causation evidence necessarily prohibits such a finding of specific causation in this matter. Additionally, even if there were general causation evidence, Dr. Hamilton's specific causation opinion based on temporal connection is unconvincing because "[t]emporal connection standing alone is entitled to little weight in determining causation." Curtis, 174

[3]In opposing the motion, Plaintiffs argue that Bayer has admitted that Avelox can cause peripheral neuropathy in its own labeling/medication guide (general causation evidence). See Record Document 37 at 6 ("Medication Guide states, 'Damage to the nerves in arms, hands, legs, or feet can happen in people taking fluoroquinolones, including Avelox.'"). Bayer responded that such "allegation is a manipulation of the facts and is entirely false," as it has never made such an admission. See Record Document 38 at 4-5. The Court agrees with Bayer's position and further notes the exact language of the Medication Guide: "rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones." Record Document 38, Exhibit B.

F.3d at 670. Thus, there is no factual basis for Dr. Hamilton's specific causation opinion in this matter.

B. Liability Opinions

Bayer argues that Plaintiffs have also failed to carry their burden regarding Dr. Hamilton's liability opinion relating to Avelox's warnings and labeling. See Record Document 30-1 at 19. Bayer first seeks to exclude Dr. Hamilton's opinions as to the adequacy of Avelox's warning on the grounds that he is neither a regulatory nor a labeling expert. Dr. Hamilton admitted in his deposition that he has never provided opinions to any regulatory agency regarding the adequacy of a drug's warning; that he has never consulted with pharmaceutical companies in developing labeling; and that he has never written any labeling himself. See id., Exhibit 2 at 75, 77. When asked, Dr. Hamilton stated that he had never held himself out to the community as an expert in labeling, appropriate labeling, or regulatory matters. See id. at 75.

In the Diet Drugs Products Liability Litigation case, the court was tasked with determining if two doctors were qualified to give expert testimony regarding whether drug labels were, from a regulatory vantage point, proper. See In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation, MDL No. 1203, 2000 WL 876900, *11 (E.D.Pa. June 20, 2000). Both doctors admitted they were not experts in the regulatory field. The court concluded:

> Although [the doctors] are fully qualified within their specialties, that does not qualify them to speak as experts in the field of the requirements of the federal regulations regarding labeling and warnings for FDA approved drugs.
>
> . . .
>
> The court can easily preclude, from a Daubert viewpoint, the rendering of

> opinions by either of these witnesses as to a label's compliance with federal regulatory requirements . . . because the witnesses are not qualified for that.

Id. at *11-12. Here, based on the record before it and cognizant of the reasoning set forth in the Diet Drugs Products Liability Litigation case, this Court cannot find that Dr. Hamilton is qualified to render an opinion as to the adequacy of Avelox's warnings.[4]

Additionally, the Court questions Dr. Hamilton's "specialized knowledge" under Rule 702 as to the adequacy of warnings. For example, during his deposition, Dr. Hamilton testified that he would add a black box warning regarding peripheral neuropathy to Avelox's label; yet, when asked whether he knew the FDA standards for the addition of black box warnings, Dr. Hamilton admitted that he did not. See id. at 80-81. He also stated that he did not know how Avelox's warnings for peripheral neuropathy came about and/or whether certain provisions of the warnings were mandated by the FDA or suggested by Bayer. See

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[4]Plaintiffs argue that Bayer's argument is flawed "because FDA rules do not preempt the states from creating their own labeling rules." Record Document 37 at 7; see also Wyeth v. Levine, 555 U.S. 555, 129 S.Ct. 1187 (2009). Plaintiffs further note that the LPLA requires a manufacturer to use reasonable care in providing warnings and that the LPLA does not require expert testimony to establish the unreasonableness of a warning. See Malbrough v. Crown Equipment Corp., 392 F.3d 135, 137 (5th Cir. 2004) ("No language or provision of the statute requires that a cause of action alleging a design defect must, as a matter of law, be supported by expert testimony. To the extent the statute allocates burdens of proof or production, it simply states that '[t]he claimant has the burden of proving the elements of [his or her claim]'. La.Rev.Stat. Ann. § 9:2800.54."). Thus, Plaintiffs contend that Dr. Hamilton's testimony, at a minimum, would be admissible as lay opinion testimony due to his qualifications, knowledge of case reports, and knowledge of medical literature." Record Document 37 at 7. However, as noted by Bayer in its reply (Record Document 38 at 6), the Court believes that Plaintiffs' repeated reference to Dr. Hamilton's qualifications, knowledge of case reports, and knowledge of medical literature does not suggest testimony by a lay witness, but rather an attempt to backdoor the opinion of an unqualified expert on the issue of adequacy of warnings. See F.R.E. 701(c) ("If a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is . . . not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.").

id. at 68-69.

The Court further holds that Dr. Hamilton's opinion regarding Avelox's labeling is not based on sufficient evidence and is not a product of a reliable methodology. One of the objectives of Daubert's gatekeeping requirement "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire, 526 U.S. at 152, 119 S.Ct. at 1176. Here, Dr. Hamilton's suggested three ways to remedy the inadequacies of Avelox's warning label. See Record Document 30, Exhibit 2 at 64, 77-78. However, he either did not explain how he reached such conclusions, i.e., "I can give you some things off the top of the head," or he explained his conclusions as a "rough guesstimate." See id. at 78, 81. Such speculative explanations do not demonstrate the level of "intellectual rigor" envisioned by Daubert.

IV. CONCLUSION

For the reasons stated above, the Court finds that Plaintiffs have not met their burden of establishing the admissibility of Dr. Hamilton's causation and liability opinions. The instant motion filed pursuant to Rule 702 is, therefore, **GRANTED** and Dr. Hamilton's opinions are excluded.

THUS DONE AND SIGNED, in Shreveport, Louisiana, this 26th day of March, 2013.

S. MAURICE HICKS, JR.
UNITED STATES DISTRICT JUDGE