

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SAMUEL WONIEWALA,

Plaintiff,

v.

MERCK & CO., INC. et al.,

Defendants.

CIVIL ACTION
NO. 15-3089

OPINION

Slomsky, J.

September 13, 2017

I. INTRODUCTION

In this action, Plaintiff Samuel Woniewala claims that MiraLAX®, an over-the-counter laxative, failed to warn the medical community about the risks associated with the product, which allegedly caused him to develop oxalate nephropathy, an acute renal injury characterized by calcium oxalate deposits in the kidneys. (Doc. Nos. 49 at ¶ 7; 74 at 8.) As a result of this injury, Plaintiff will require continued treatment and potentially a kidney transplant. (Doc. No. 74 at 8.) To support these claims, he seeks to admit the testimony of two causation experts: his nephrologist and a renal pathologist. A nephrologist is a physician who specializes in kidney function and a renal pathologist is a physician who studies the development of disease in the kidneys.

Defendants move to preclude the testimony of these witnesses, relying on Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), and Fed. R. Evid. 702 (Testimony By Expert Witness) (Doc. Nos. 67 and 76.) On May 10, 2017, the Court held a hearing on Defendants' Motion to Exclude Plaintiff's Causation Experts. For reasons that follow, the Court finds that Plaintiff's Causation Experts are qualified to testify in this case and that they have opinions

which are the result of reliable methodologies. Accordingly, Defendants' Motion to Exclude Plaintiff's Causation Experts (Doc. No. 67) will be denied.

II. FACTUAL BACKGROUND

Plaintiff has lived with stable, Stage III chronic kidney disease for roughly thirteen years. (Doc. Nos. 49 at 4; 74 at 7.) His disease was managed by his primary care physician, Dr. Karen Bowles, M.D. and in later years, by a nephrologist, Dr. Michael Rudnick, M.D.. (Doc. No. 74 at 7.) By July 10, 2009, his disease was also being monitored by another nephrologist at the Hospital of the University of Pennsylvania. (Doc. No. 49 at 5.)

Sometime in 2009, Plaintiff experienced problems with chronic constipation. (Id. at 4.) Both his primary care physician, Dr. Bowles, and his nephrologist, Dr. Rudnick, prescribed MiraLAX®—an over-the-counter laxative—to treat Plaintiff's constipation. (Id. at 4-5.) From 2009 until May 2013, Plaintiff continued using MiraLAX®, as his doctors advised. (Id. at 4-8.) On May 6, 2013, he was hospitalized with an acute kidney injury. (Id. at 7.) In June 2013, a renal biopsy revealed that Plaintiff had developed oxalate nephropathy. (Id.) Oxalate nephropathy is a condition in which calcium oxalate crystals are deposited in the kidneys, causing injury. (Doc. No. 67-1 at 9.)

Plaintiff initiated this action alleging claims of negligence, strict product liability, and breach of express and implied warranties arising from his use of the laxative MiraLAX®. (Doc. No. 1-1.) In support of his claims, Plaintiff will offer at trial the expert testimony of his treating nephrologist Dr. Michael Rudnick, M.D., renal pathologist Dr. Glen Markowitz, M.D., and toxicologist Dr. Lawrence H. Lash, Ph.D.¹ (Doc. No. 74 at 6.) Both Dr. Rudnick and Dr.

¹ The Daubert Motion (Doc. No. 67) filed by Defendants moves to exclude the opinions of Dr. Michael Rudnick and Dr. Glen Markowitz. In a separate motion before this Court (Doc. No.

Markowitz opine that Plaintiff developed oxalate nephropathy as a result of his use of MiraLAX®. (Id.) The active ingredient in MiraLAX® is a form of polyethylene glycol with a molecular weight of 3350, referred to as PEG-3350. (Doc. No. 67-1 at 9.) Plaintiff claims that there is a “clear relationship between polyethylene glycol and the deposit of calcium oxalate in the kidneys” (Doc. No. 80 at 30:10-13) and submits that Dr. Rudnick and Dr. Markowitz will support these claims. The focal point of the overarching case, therefore, is whether MiraLAX®’s active ingredient, PEG-3350, caused Plaintiff’s acute kidney injury.

As noted, Defendants move to preclude the testimony of the proffered experts, Dr. Rudnick and Dr. Markowitz. (Doc. No. 67.) Defendants argue that Dr. Rudnick: (1) is not qualified to offer a “biological plausibility” opinion or a specific causation opinion, and (2) did not use reliable methodology in forming his opinions. (Doc. No. 67-1 at 13-28.) Similarly, Defendants argue that Dr. Markowitz: (1) is not qualified to offer a specific causation opinion, and (2) did not use reliable methodology in forming his opinions. (Id. at 28-34.) Relying upon Feit v. Great West Life & Annuity Ins. Co., 271 F. App’x 246, 254 (3d Cir. 2008), insofar as reliable methodology is concerned, Defendants claim that the experts improperly employed differential diagnosis² as a methodology because they did not consider all possible causes of Plaintiff’s oxalate nephropathy and then rule out through the process of elimination all possible causes, leaving the remaining potential cause as the most likely cause. Defendants also

66), Defendants moved to strike Dr. Lawrence H. Lash’s Rebuttal Report (“the Lash Report”). The Court denied this latter motion. (See Doc. No. 81.) Defendants, however, requested the right to fully brief any issues arising under Rule 702 and Daubert relating to the Lash Report. (Doc. No. 66-1 at 1 n.1.) As of this date, Defendants have not filed such a brief. Therefore, the Court will not further discuss Dr. Lash or his report in the Opinion.

² As explained in further detail later in this Opinion, differential diagnosis is a methodology employed by medical practitioners to determine the causation of a certain condition.

challenge the fact that Dr. Markowitz relied on Dr. Rudnick's report without ever having met Plaintiff and merely formulated a "piggybacked opinion." (Doc. No. 67-1 at 34.)

A. Dr. Michael Rudnick's Report

Dr. Michael Rudnick is Plaintiff's treating nephrologist. His expert report essentially is comprised of knowledge of his own treatment and medical records of Plaintiff. In order to prepare his expert report,³ Dr. Rudnick also reviewed the following materials:

1. Medical Records of Michael Rudnick, M.D.
2. Medical Records of Karen Bowles, M.D.
3. Admission records at Mercy Hospital 5/6/13
4. Admission records at the Hospital of the University of Pennsylvania 5/13/13
5. Deposition of Dr. Sanjeev Sethi
6. Deposition of Samuel Woniewala
7. Deposition of Karen Bowles

(Doc. No. 67-9 at 1.)

Dr. Rudnick led a team of physicians to uncover the cause of and treat Plaintiff's acute kidney injury. (Doc. No. 74 at 7.) He ordered the biopsy of Plaintiff's kidney, which was sent to the Mayo Clinic in Rochester, Minnesota. (Id. at 8.) There, Dr. Sanjeev Sethi, the renal pathologist at the Mayo Clinic, discovered the oxalate nephropathy and disclosed his findings to Dr. Rudnick. (Id.)

Based upon the above information, Dr. Rudnick concluded that Plaintiff's kidney injury was due to oxalate nephropathy resulting from his ingestion of MiraLAX®.

B. Dr. Glen Markowitz's Report

Dr. Glen Markowitz is a renal pathologist and a professor of pathology and cell biology at Columbia University's College of Physicians and Surgeons. (Doc. No. 74-3.) Dr. Markowitz

³ Dr. Rudnick's Report is attached to Defendants' Daubert Motion as Exhibit 8. (Doc. No. 67-9.)

has given lectures and has written extensively on the pathology of drug-induced renal injury.

(Id.)

In order to prepare his expert report,⁴ Dr. Markowitz reviewed the following materials:

1. Deposition transcript, Dr. Sanjeev Sethi
2. Deposition transcript, Samuel Woniewala
3. Expert report of treating nephrologist, Dr. Michael Rudnick
4. Review of medical records from Dr. Karen Bowles, MD, Primary Care doctor (2005-2016)
5. Review of medical records from admission to Mercy Hospital (5/6/13-5/13/13)
6. Renal biopsy specimen processed & evaluated at Mayo Clinic in Rochester, Minnesota

(Doc. No. 67-6 at 2.)

Dr. Markowitz also submitted a supplemental report after his deposition,⁵ stating that he reviewed the following additional materials:

1. Records of Dr. Michael Rudnick, 1/28/11-11/2/16
2. Records of the Hospital of University of Pennsylvania, 5/13/13-5/21/13
3. Records of the Hospital of University of Pennsylvania, 5/13/13-5/21/13
4. Records of Penn Presbyterian Medical Center, 6/7/13-6/12/13 (Bone marrow biopsy); 6/19/13-6/20/13 (Renal biopsy); 8/2/13 (ER visit); 10/4/13 (esophagogastroduodenoscopy); 1/24/14 (esophagogastroduodenoscopy)
5. Records of Crozer Chester Medical Center, 7/29/13-7/31/13
6. Records of Dr. Brendan Weiss, Oncology, 9/18/14-2/15/16
7. Records of Dr. Alden Doyle, Drexel Nephrology, Transplant Evaluation, 9/9/15
8. Deposition transcript of Dr. Karen Bowles

(Doc. No. 67-5 at 2.)

Based upon his review of the above materials, Dr. Markowitz concluded that Plaintiff's development of oxalate nephropathy was caused by Plaintiff's long-term exposure to MiraLAX®. (Doc. No. 67-6.)

⁴ Dr. Markowitz's Report is attached to Defendants' Daubert Motion as Exhibit 5. (Doc. No. 67-6.)

⁵ Dr. Markowitz's supplemental report is attached to Defendants' Daubert Motion as Exhibit 4. (Doc. No. 67-5.)

III. STANDARD OF REVIEW

In Daubert v. Merrell Dow Pharms., Inc., the United States Supreme Court provided the analytical framework to determine the admissibility of expert testimony under Federal Rule of Evidence 702. 509 U.S. 579 (1993). Rule 702 provides:

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.

Fed. R. Evid. 702.

A trial court acts as a “gatekeeper” and “must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.” Daubert, 509 U.S. at 589. Rule 702 “embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit.” Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (Schneider) (citing In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741-43 (3d Cir. 1994) (footnote omitted) (Paoli II)).

Qualification refers to the requirement that the witness possess specialized expertise. We have interpreted this requirement liberally, holding that a broad range of knowledge, skills, and training qualify an expert. Secondly, the testimony must be reliable; it must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; the expert must have good grounds for his or her belief. In sum, Daubert holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity. Finally, Rule 702 requires that the expert testimony must fit the issues in the case. In other words, the expert's

testimony must be relevant for the purposes of the case and must assist the trier of fact. The Supreme Court explained in Daubert that Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Id. (internal marks and citations omitted). “The Rules of Evidence embody a strong and undeniable preference for admitting any evidence which has the potential for assisting the trier of fact. Rule 702, which governs the admissibility of expert testimony, has a liberal policy of admissibility.” Kannankeril v. Terminix Int’l., Inc., 128 F.3d 802, 806 (3d Cir. 1997) (citations omitted). As the Supreme Court in Daubert stated: “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” 509 U.S. at 595.

IV. ANALYSIS

A. Plaintiff’s Experts Are Qualified to Offer Their Causation Opinions Under Rule 702

The Third Circuit has consistently emphasized a liberal policy of admissibility under Rule 702, which extends to the formal qualification of experts. Paoli II, 35 F.3d at 741; see also Pineda v. Ford Motor Co., 520 F.3d 237, 243 (3d Cir. 2008). In addition, the Third Circuit has “eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications.” Paoli II, 35 F.3d at 741.

i. Dr. Rudnick’s Qualifications

Defendants argue that Dr. Rudnick is not qualified to offer his opinions specifically because he is not a toxicologist or a pharmacologist, by training or in practice. (Doc. No. 67-1 at 14-15.) Plaintiff argues that under the liberal qualification standard, Dr. Rudnick is qualified in this case to render an opinion under Rule 702. (Doc. No. 74 at 17-18.)

Dr. Rudnick is a nephrologist with over 41 years of experience. In 1972, he received his degree as a Doctor of Medicine from Hahnemann Medical College. (Doc. No. 74-1 at 25.) After a residency at Hahnemann Hospital, Dr. Rudnick completed a Clinical and Research Fellowship in Nephrology at the Hospital of the University of Pennsylvania in 1976. (Id.) Since then, Dr. Rudnick has been actively engaged in the practice of nephrology and is board-certified in internal medicine and in the subspecialty of nephrology. (Doc. No. 74 at 17.) For the past forty-one years, he has also held numerous faculty appointments at medical schools including Temple, MCP Hahnemann, and the University of Pennsylvania School of Medicine where he is still an Associate Professor. (Id.; see also Doc. No. 74-1 at 25-29.) Dr. Rudnick has also written 37 articles in peer-reviewed journals on the topic of nephrology, in addition to writing over 90 editorials, reviews, and chapters in nephrology textbooks. (Doc. No. 74-1 at 34-43.)

Given this considerable amount of background information on Dr. Rudnick, it is evident that he is qualified to render an opinion in this case on the cause of the injury to Plaintiff's kidneys. The fact that Dr. Rudnick is not a pharmacologist or toxicologist goes to the weight of his testimony, not its admissibility.

ii. Dr. Markowitz's Qualifications

Plaintiff presents Dr. Markowitz also as a qualified causation expert under the Rule 702 standard. Defendants challenge whether he is qualified to provide specific causation opinions because he is a pathologist and not a clinician. (Doc. Nos. 67-1; 76.)

Dr. Markowitz is a renal pathologist and a professor of pathology and cell biology at Columbia University's College of Physicians and Surgeons, specializing in research on drug-induced kidney injuries. (Doc. No. 74 at 18.) He completed a residency in Anatomic Pathology and a Fellowship in Renal Pathology at Columbia University. (Id. at 32.) He currently teaches

the second year medical school pathology course and is a lecturer in renal pathology at both Albert Einstein College of Medicine and Columbia University. (Doc. No. 74-3 at 32.) Since 1999, Dr. Markowitz has given numerous lectures on renal pathology at conferences and symposiums. (*Id.* at 34-36.) He has also authored over 175 peer reviewed publications and chapters in textbooks specifically on the topic of how certain laxatives can and do lead to a phosphate nephropathy. (Doc. No. 74 at 19.) In addition to his active role in the Renal Pathology Society, Dr. Markowitz is the recipient of numerous awards, including “Distinguished Lecturer” and the Gloria Gallo Award, presented by the Renal Pathology Society for mid-career achievement. (Doc. No. 74-3 at 33-34.)

Given the substantial amount of experience and expertise that Dr. Markowitz has in the specialty of renal pathology, he is qualified to testify about the cause of kidney injury under Fed. R. Evid. 702. The fact that he is not a clinician goes to the weight of his testimony, not its admissibility.

B. Plaintiff’s Experts Used Reliable Methodologies to Form Their Opinions

A methodology is defined as “a particular procedure or set of procedures” typically used in a certain discipline. See *Methodology*, *Merriam-Webster’s Collegiate Dictionary* (11th ed. 2004). In this regard, the Third Circuit has laid out factors that a district court should consider to determine whether proposed expert testimony, including methodology, is reliable:

- (1) whether a method consists of a testable hypothesis;
- (2) whether the method has been subject to peer review;
- (3) the known or potential rate of error;
- (4) the existence and maintenance of standards controlling the technique's operation;
- (5) whether the method is generally accepted;
- (6) the relationship of the technique to methods which have been established to be reliable;
- (7) the qualifications of the expert witness testifying based on the methodology; and
- (8) the non-judicial uses.

Schneider v. Fried, 320 F.3d at 405 (citing Paoli II, 35 F.3d at 742 n.8). The Third Circuit further noted that “expert testimony does not have to obtain general acceptance or be subject to peer review to be admitted under Rule 702.” Id. at 406. In fact, in Daubert, “the Supreme Court specifically held that Rule 702 overruled the requirement that an opinion must gain general acceptance in order to qualify as admissible expert testimony; instead general acceptance and peer review are only two of the factors that a district court should consider when acting as gatekeeper.” Id. (citing Daubert, 509 U.S. at 589).

As noted earlier, Defendants attack as unreliable in this case the method used by the doctors to reach their opinions on the causation of the kidney injuries. This methodology is known as differential diagnosis. The Third Circuit defines differential diagnosis as a “technique that involves assessing causation with respect to a particular individual.” Kannankeril, 128 F.3d at 807 (citing Paoli II, 35 F.3d at 758). Most courts view differential diagnosis as a permissible and reliable methodology to prove causation. See Jack B. Weinstein et al., Weinstein’s Federal Evidence 119 (2nd ed. 2017). The Third Circuit has stated that employing a differential diagnosis methodology “makes it a different type of science than science designed to produce general theories; [but] it does not make it unreliable science.” Paoli II, 35 F.3d at 755 n.3. The Third Circuit has also noted that “differential diagnosis generally is a technique that has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results” in terms of evaluating causation for an individual patient. Id. Finally, in reaching a differential diagnosis, a medical expert is not required to eliminate all other possible causes. Heller v. Shaw Indus. Inc., 167 F.3d 146, 156 (3d Cir. 1999) (“A medical expert’s causation conclusion should not be excluded because he or she has failed to rule out every possible cause of a plaintiff’s illness”).

i. Dr. Rudnick's Methodology

Here, Dr. Rudnick formed his conclusion that Plaintiff's oxalate nephropathy resulted from MiraLAX® by employing a differential diagnosis methodology. In his report, Dr. Rudnick recites his comprehensive approach to determine the cause of Plaintiff's oxalate nephropathy. (Doc. No. 67-9 at 10.) He reviewed Plaintiff's medical records and renal biopsy results and interviewed Plaintiff to assess his medical history. From this information, Dr. Rudnick learned about Plaintiff's oxalate nephropathy. (Id.)

Dr. Rudnick's report states that there are three known causes of oxalate nephropathy: (1) primary hyperoxaluria; (2) enteric hyperoxaluria; and (3) ingestion of high amounts of oxalate or oxalate precursors. (Id.) He considered all these causes and systematically, through process of elimination, identified the source of Plaintiff's kidney injuries.

Dr. Rudnick ruled out primary hyperoxaluria as the cause of Plaintiff's injuries because Plaintiff has no medical history of primary hyperoxaluria, recurrent calcium oxalate stones, or end-stage renal disease, which evidently are key characteristics that accompany this condition. (Id.) Similarly, he eliminated enteric hyperoxaluria as a cause, which is characterized by the bowels' inability to absorb nutrients from food and is associated with frequent diarrhea and weight loss. (Doc. No. 67-9 at 9; see also Malabsorption, Dorland's Illustrated Medical Dictionary 1097 (32d ed. 2012). Since Plaintiff did not exhibit any of these symptoms, Dr. Rudnick excluded primary hyperoxaluria and enteric hyperoxaluria as causes for the renal injuries at issue. (Id.)

Finally, Dr. Rudnick was left with the possibility that the oxalate nephropathy was the result of ingesting high amounts of oxalate or oxalate precursors. Through interviews with Plaintiff, Dr. Rudnick did not think the renal injuries were caused by excessive consumption of

oxalate-rich foods, such as star fruit, rhubarb, or peanuts. (Id.) Dr. Rudnick also knew that ingestion of ethylene glycol—the primary component of antifreeze—could lead to oxalate nephropathy. (Id.) However, after interviewing Plaintiff, he determined that ingestion of antifreeze was unlikely to be the cause of the renal injury. (Id.) Dr. Rudnick then discovered that for years Plaintiff had been taking MiraLAX® twice a day for two weeks. MiraLAX® contains polyethylene glycol, which is composed of ethylene glycol. (Id.)

By properly using a differential diagnosis methodology, Dr. Rudnick was able to form a plausible and supported medical opinion that Plaintiff’s oxalate nephropathy was caused by his ingestion of polyethylene glycol, an active ingredient in MiraLAX®. He considered all possible causes and systematically eliminated them until he arrived at his final conclusion. His opinion is based on a reliable methodology and is admissible here under Fed. R. Evid. 702.

ii. Dr. Markowitz’s Methodology

Defendants also contend that Dr. Markowitz rendered opinions that were not reached through reliable methodology, portraying him as a “‘me too’ expert” and arguing that he merely endorsed Dr. Rudnick’s report and provided opinions which lacked certainty. (Doc. No. 67-1.) Defendants hone in on Dr. Markowitz’s inability to specify the duration within which oxalate crystals were present in Plaintiff’s kidneys and challenge the emphasis that both he and Dr. Rudnick place on the temporal association between Plaintiff’s ingestion of MiraLAX® and his development of oxalate nephropathy. (Id.) They also take issue with the fact that Dr. Markowitz formed his opinion for the purposes of litigation. (Id.)

Based upon his review of Plaintiff’s medical history and biopsy specimens and Dr. Rudnick’s comprehensive report, Dr. Markowitz opined that MiraLAX® contributed to Plaintiff’s oxalate nephropathy. (Id. at 146.) In his deposition, Dr. Markowitz stated that he did

not review every single document that was sent to him, knowing that Dr. Rudnick's expert report was sufficiently detailed because it was produced by a treating physician. (Doc. No. 67-3 at 3:15-3:21.) In fact, Dr. Markowitz testified that he actually had more information to formulate an opinion to a reasonable degree of medical certainty than he normally does in his practice as a renal pathologist. (Doc. No. 74-4 at 142-143.) Though he was not Plaintiff's treating physician,⁶ Dr. Markowitz was still able to employ a differential diagnosis methodology to arrive at the same conclusion as Dr. Rudnick. He, too, determined the causation of oxalate nephropathy by considering established causes and evaluating those against Plaintiff's medical history and renal biopsy. (Doc. No. 74-3 at 29.) Neither doctor solely relied upon temporal proximity; both doctors thoroughly examined Plaintiff's renal biopsies to discover the presence of oxalate crystals and reviewed his medical records to eliminate known causes of oxalate nephropathy. As explained above, the Third Circuit does not require that medical experts rule out all possible causes to offer a differential diagnosis. Nevertheless, Plaintiff's experts endeavored to eliminate any other causes of oxalate nephropathy that were inconsistent with Plaintiff's medical history.

Finally, in response to Defendants' contention that Dr. Markowitz derived his opinion solely for the purposes of litigation, Fed. R. Evid. 702 allows for the liberal admission of expert testimony. Therefore, both parties in litigation may retain experts in furtherance of their case.

As permitted under Third Circuit standards, Plaintiff's causation experts have employed acceptable methodologies to form an opinion under Fed. R. Evid. 702. They provide relevant information helpful to the trier of fact. The present case involves a myriad of complicated

⁶ There is no requirement that an expert witness have personal knowledge of the underlying facts. Daubert, 509 U.S. at 592 (“[A]n expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation”).

medical terminology that is foreign to most laypeople. Plaintiff's experts have knowledge that can assist the fact finder in understanding the causation of oxalate nephropathy in connection with consuming MiraLAX®, which is the crux of this case. Defendants can still attack the qualifications of Plaintiff's experts, as well as the methodologies used, through cross-examination and by offering their own expert witnesses.

V. CONCLUSION

For the foregoing reasons, the Court will deny Defendants' Motion to Exclude the Opinions of Plaintiff's Causation Experts Dr. Michael Rudnick and Dr. Glen Markowitz, Pursuant to Daubert and Fed. R. Evid. 702. (Doc. No. 67.) An appropriate Order follows.