UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 08-MD-01928-MIDDLEBROOKS/BRANNON

IN RE: TRASYLOL PRODUCTS
LIABILITY LITIGATION - MDL-1928

This Document Relates To:

Charlotte Harper v. Bayer Corp., et al.,
Case No. 09-81484

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OMNIBUS ORDER

THIS CAUSE comes before the Court upon Defendants' (hereinafter, collectively, "Bayer") Motions: (1) to Exclude Testimony by Plaintiff's Case-Specific Experts (DE 12120 in 08-1928 and DE 45 in 09-81484); and (2) for Summary Judgment (DE 121119 in Case No. 08-md-01928, DE 44 in Case No. 09-81484). Plaintiff filed Responses to the Motions (DEs 12214 & 12215 in Case No. 08-01928 and DEs 47 & 48 in 09-81484), to which Bayer replied (DEs 12260 & 12261 in Case No. 08-01928 and DEs 51 & 52 in 09-81484).[1] The Court has reviewed the pertinent parts of the record and is advised of the premises. For the reasons stated below, Bayer's Motion shall be granted as to all Counts.

[1] This Order will hereinafter cite only to filings by their individual Harper case (09-81484) docket entries unless otherwise stated.

I. Factual Background and Plaintiff's Complaint

The following facts are established by record evidence and are uncontroverted for purposes of summary judgment.[2] Plaintiff Charlotte Harper ("Plaintiff")[3] is the Personal Representative of the Estate of decedent Vernesta Huff ("Mrs. Huff"). Mrs. Huff received Trasylol during her mitral valve replacement surgery (the "Surgery") at Oklahoma University Medical Center on August 9, 2006.[4] Plaintiff originally filed this suit against Bayer[5] (hereinafter, collectively, the "Parties") on March 16, 2009 in the district Court of Oklahoma County, Oklahoma as Case No. CJ-2009-2526. The Defendants then removed the case to the United States District Court for the Western District of Oklahoma on August 27, 2009. (DE 46 at ¶ 4- 5). The case was thereafter transferred to this Court pursuant to 28 U.S.C. § 1407 for proceedings in connection with this multidistrict litigation. (DE 11).

Mrs. Huff was admitted to the hospital during second week of August, 2006. She was assessed with severe mitral valve stenosis with "multiple previous episodes of congestive heart

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[2] Jurisdiction is premised on diversity of citizenship and is undisputed.

[3] Plaintiff was and still is a resident of Oklahoma, and Mrs. Huff was a citizen of Oklahoma at all times relevant to this action. (DE 1-2; DE 45 at Ex. B).

[4] DE 45, Ex. D at 1803-05; DE 47, Ex. 2 at 72:2 - 74:25.

[5] Defendant Bayer Corporation is an Indiana corporation with its principal place of business in Pennsylvania. Defendant Bayer HealthCare Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in New Jersey. At the time this Plaintiff's complaint was filed, Defendant Bayer HealthCare AG was a German corporation with its principal place of business in Germany. Bayer HealthCare AG was merged into Defendant Bayer Schering Pharma AG, effective December 30, 2008. Bayer Schering Pharma AG is a German corporation with its principal place of business in Germany. (DE 46 at ¶ 3). The Complaint names Bayer Corporation and Bayer Schering Pharma, A.G. as Defendants. However, Defendants assert that these two Bayer Entities have never been served. Plaintiff has not provided any evidence to refute this allegation.

failure, hypertension, renal insufficiency, history of myocardial infarction, history of stroke, glaucoma, [and] seizure disorder." (DE 44 at Ex. C). Her admission Blood Urea Nitrogen ("BUN") level was 53 and her creatinine level was 2.5, indicating renal insufficiency upon admission.[6] On August 9, Dr. Marvin Peyton performed a mitral valve replacement. During Mrs. Huff's Surgery, she was placed on bypass for two hours and fifty four minutes and received Trasylol.[7]

There were no complications during surgery, and her initial recovery from the surgery was relatively uneventful. (DE 45 at Ex. D). Immediately following her surgery, her BUN and creatinine were 32, and 1.4, respectively. On day post-operative day 4, she developed atrial fibrillation,[8] but after treatment with medication she returned to normal sinus rhythm. *Id.* During the postoperative period she also experienced incidences of hypotension (low blood pressure);

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[6] A BUN test is done to "see how well your kidneys are working. If your kidneys are not able to remove urea from the blood normally, your BUN level rises. Heart failure, dehydration, or a diet high in protein can also make your BUN level higher." "WebMD Medical Reference from Healthwise" 2010. Web. 9 August 2010.

"Creatinine is a waste product formed by the breakdown of a substance (creatine) important for converting food into energy (metabolism). The creatinine is filtered out of the blood by the kidneys and then passed out of the body in urine. . . . If the kidneys are damaged and cannot function normally, the amount . . . creatinine in the blood increases." *Id.*

Accordingly, BUN and serum creatinine are used as a measure of renal function. When their values are elevated, renal dysfunction is indicated. For BUN, a normal result falls within the range of 8-21; and for Creatinine, a normal result falls within the range of 0.7-1.2. The numbers represent the value of mg/dL. Plaintiff in the Complaint admits that the Decedent had been diagnosed with chronic renal insufficiency (Complaint at ¶ 5).

[7] DE 45 at Ex. D

[8] Atrial fibrillation is an irregular heartbeat.

leukocytosis (elevated white blood cell count); contraction alkalosis (increase in blood pH due to fluid loss); and hypovolemia (decreased blood volume). On post-operative day 6, her BUN and creatinine levels began to rise to 45 and 3.2 respectively, at which point medications to reduce fluid retention were discontinued, and she was given a bolus of fluid. On August 24, when she was discharged, her BUN and creatinine levels were 30 and 3.1, respectively.[9] (*Id.*).

There is no evidence that Mrs. Huff experienced any additional medical issues after her discharge until March 9, 2007 when she was admitted to the Midwest Regional Medical Center with respiratory distress, pulmonary edema and hypotension. (DE 46 at Ex. D). She died six days later. (*Id.* at Ex. C). The death certificate lists the causes of death as cardiac and respiratory arrest, sepsis, urinary tract infection, and renal failure. *Id.*

Plaintiff has proffered one case-specific causation expert in support of her claims: nephrologist, Carl J. Blond, M.D. Plaintiff alleges that Mrs. Huff's heart failure, renal failure, and death were caused by her exposure to Trasylol during her mitral valve replacement surgery on August 9, 2006. Plaintiff's Complaint consists of seven counts: (1) negligence; (2) products liability; (3) negligent misrepresentation; (4) intentional misrepresentation; (5) breach of express warranty; (6) breach of implied warranty; and (7) punitive damages.

Bayer's Motions seek exclusion of Plaintiff's case-specific causation expert, Dr. Blond, and summary judgment on all seven counts.

II. Admissibility of Plaintiff's Case-Specific Expert's Testimony

[9] After surgery, Mrs. Huff had been retaining substantial amounts of fluid, and so she had been placed on diuretics. Doctors notes indicated that her creatinine level spike was attributable to possible fluid-depletion and dehydration. Accordingly, diuretic administration was discontinued, and Mrs. Huff was given fluids intravenously. Her creatinine levels thereafter began to decline towards her admission baseline level. (DE 45).

A. Legal Standard

The admissibility of expert testimony is governed by the framework set out in Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). The party seeking to have the expert testimony admitted bears the burden of demonstrating its admissibility by a preponderance of proof. *Davidson v. U.S. Dep't of Health & Human Servs.*, No. 7:06-129-DCR, 2007 WL 3251921, at *2 (E.D. Ky. Nov. 2, 2007) (internal citations omitted *see also United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) ("The burden of establishing qualification, reliability, and helpfulness rests on the proponent of the expert opinion.").

According to Rule 702,

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

FED. R. EVID. 702. According to the Supreme Court, the inquiry envisioned by Rule 702 is a flexible one, in which federal judges perform a "gatekeeping role" to ensure that speculative and unreliable opinions do not reach the jury. *Daubert*, 509 U.S. at 594-95, 597 ("Its [Rule 702's] overarching subject is the scientific validity and thus the evidentiary relevance and reliability–of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.").

In *Daubert*, the Supreme Court listed several factors federal judges may consider in determining whether to admit expert scientific testimony under Rule 702: whether an expert's

theory or technique can be and has been tested; whether the theory or technique has been subjected to peer review and publication; whether the known or potential rate of error is acceptable; and whether the expert's theory or technique is generally accepted in the scientific community.[10] 509 U.S. at 593-94 (declining to set forth a "definitive checklist or test").

The Supreme Court subsequently held that the *Daubert* factors "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony. . . . Too much depends upon the particular circumstances of the particular case at issue." *Kumho*, 526 U.S. at 150 (internal citations and quotations omitted). Accordingly, "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable. . . . [A] trial court should consider the specific factors identified in *Daubert* where they are reasonable measures of the reliability of expert testimony." *Id.* at 152. The trial court has the same kind of latitude in deciding how to test an expert's reliability as it enjoys when it decides whether or not that expert's relevant testimony is reliable. *Id.*

The Eleventh Circuit engages in a three part inquiry to determine the admissibility of expert testimony under Rule 702, considering whether:

> (1) [T]he expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

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[10] In *Daubert*, the Supreme Court considered the federal judge's gatekeeping role in ensuring that all *scientific* expert testimony is not only relevant, but reliable. The Supreme Court later held that this basic gatekeeping obligation and *Daubert*'s general principles apply to *all* expert testimony, not just testimony that is classified as scientific. *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 147 (1999).

Quiet Tech. v. Hurel-Dubois UK Ltd., 326 F.3d 1333, 1340-41 (11th Cir. 2003) (internal citations omitted). The Eleventh Circuit has noted that the primary purpose of a *Daubert* inquiry is to ensure that the 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." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1255 (11th Cir. 2005) (quoting *Kumho*, 526 U.S. at 152).

B. Parties' Arguments

Plaintiff proffers Dr. Carl J. Blond, M.D., Ph.D., as her specific causation[11] expert. The following information has been obtained from Dr. Blond's expert report ("Report"). Dr. Blond is a licensed medical practitioner in the state of Texas, who has practiced medicine in the San Antonio area for twenty-eight years. He graduated from medical school and completed his internal medicine residency at the University of Texas Health Science Center in San Antonio ("UTHSCSA"), and then completed a two-year fellowship in Nephrology, the first year of which was at the University of Colorado and the second year at UTHSCSA. Dr. Blond has been board-certified in Internal Medicine since 1979 and in Nephrology since 1984. In addition to his patient care, Dr. Blond is a clinical professor of Internal Medicine and Nephorology at UTHSCSA.

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[11] Specific causation refers to the issue of whether the plaintiff has demonstrated that the substance actually caused the injury in his particular case. Specific causation is distinguishable from general causation, which refers to the general issue of whether a substance has the potential to cause the plaintiff's injury. *Guinn v. AstraZenaca Pharms.*, 602 F.3d 1245, 1249 (11th Cir. 2010) (citing *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 351 (5th Cir. 2007). General causation is not in dispute in the instant motion. The Court assumes, without deciding that general causation has been established.

Dr. Blond has confined his practice to the areas of nephrology and internal medicine, and his practice primarily involves patient care. A routine part of his practice involves treating post-operative heart surgery patients who suffer renal problems. Specifically, this included patients who encounter renal problems after coronary artery bypass surgery (CABG), heart valve surgery, heart transplants and other cardiac surgeries. Because of his clinical experience, Dr. Blond is familiar with the etiologies of renal dysfunction and renal failure, as well as the mortality and morbidity associated with renal dysfunction and renal failure.

After setting forth his qualifications as an expert,[12] Dr. Blond's report provides as follows:

BRIEF NARRATIVE OF EVENTS

> The late Mrs. Vemesta Huff was a 54[sic][13]-year-old black female when she was admitted to Presbyterian Tower (OU Medical Center) on 08/08/2006. She reportedly had a history of multiple prior admissions for congestive heart failure and severe mitral stenosis. In the past the patient, apparently after consulting with family members had declined surgery. I currently do not [sic] detailed prior records. An echocardiogram from 06/06 was described showing concentric LVH, a hyperdynamic left ventricular, severe mitral stenosis with a calculated mitral valve area of 0.8 cm2
> • Prior medical problems included a CVA in 1998, with a history of seizures, the last that occurred also in 1998. Prior surgical history included 3 C-sections, hemorrhoid surgery and appendectomy. Medical problems noted in the records provided included hypertension, glaucoma, chronic kidney disease, migraine

[12] Defendants do not dispute that Dr. Blond - in general- qualifies as an expert under the first prong of *Daubert* analysis.

[13] Mrs. Huff was 64 years old at the relevant time. Dr. Blonde in his deposition recognized this error in his report.

headaches and depression. The patient had a brief smoking history, approximately 2-3 pack years.

Mrs. Huff underwent mitral valve replacement surgery on 08/09/2006 performed by Dr. Marvin Payton [sic]. A serum creatinine prior to surgery was 2.5 mg/dL. The patient had an uncomplicated surgery. Blood pressure was well maintained with a Cardene drip(blood pressure lowering agent). No pressor agents were instituted. Oxygen saturation was well maintained throughout.

Anesthesia was induced and maintained with Versed, fentanyl, Nimbex and Isoflurane. Aprotinin was infused as an anti-fibrinolytic agent. Total pump time was 2 hours and 54 minutes. Cross-clamp time was 2 hours and one minute. During surgery urine output was 450 cc. The patient received 2 units of packed red blood cells during surgery. Moderate hypothermia was instituted. After cardiopulmonary bypass recorded pulmonary artery pressure was 48/17 rom Hg. A25 rom Mosaic valve was placed and felt to be well seated by transesophageal echocardiogram. The patient was weaned off of cardiopulmonary bypass without difficulty in stable condition. A hemodialysis temporary catheter was also placed at the time of surgery in the right subclavian vein, as well as a femoral artery line for blood pressure monitoring. The patient's postoperative course included extubation on postoperative day #1. Additional problems that developed included transient atrial fibrillation, leukocytosis, and acute kidney injury. Antibiotic coverage included primarily Levaquin, patient also received doses of Zosyn, and cefuroxime. Cultures did not reveal a specific pathogen or source of infection. The patient's serum creatinine rose to 3.2 mg/dL, and at the time of discharge was 3.1 mg/dL. Some sections of the inpatient records are not presently available. The patient was discharged to Grace Living Center. A serum creatinine obtained at this facility on 09/20/2006 was 1.6 mg/dL. Unfortunately Mrs. Huff passed away on 03/15/2007 when she presented with sepsis, renal failure and respiratory failure to Mid West Regional Medical Center.

MEDICAL OPINION REGARDING MRS. VERNESTA HUFF

Each of the opinions stated below are stated to a reasonable degree of medical certainty. Patients undergoing cardiopulmonary bypass surgery are at risk for developing acute kidney injury. When this

occurs, it is usually a transient phenomena, though some degree of permanent injury may occur with each episode of acute kidney injury. Causes frequently include hypotension, hypoxia, oxidative stress and nephrotoxic agents. Unfortunately even transient acute kidney injury in the cardiopulmonary bypass setting is associated with increased short and long-term morbidity and mortality. Nephrotoxic agents often include IV contrast, nonsteroidal drugs, and rarely anesthetic agents. Vasopressor agents, frequently used for maintaining blood pressure, may cause diminished renal blood flow. Hypotension perioperatively is often multifactorial, and maybe secondary to impaired cardiac function, blood loss, pericardial tamponade, hypovolemia, and occasionally sepsis. Cardiopulmonary bypass is associated frequently with a transient drop in glomerular filtration. Additional problems that may occur and be associated with acute kidney injury include hemolysis, atheroemboli, and renal vasoconstriction associated with aortic cross clamping. The majority of patients that undergo cardiopulmonary bypass do not develop an acute kidney injury. Multiple risk factors have been identified that are associated with a higher risk of developing an acute kidney injury. Many of these risk factors are interrelated. Both advanced age, and female sex are associated with a higher risk. The presence of chronic kidney disease is a significant risk factor. Additional factors include diabetes mellitus, chronic obstructive pulmonary disease, hypertension, congestive heart failure, smoking history, and peripheral vascular disease. Urgent surgery and recent IV contrast are also associated preoperative risks. Surgical risk factors include both complex, and prolonged surgery. This includes bypass times of greater than 2 hours. The use of aprotinin, an agent that was used to diminish blood loss, has been associated with an increased risk of acute kidney injury. In the postoperative period, risk factors include hypotension, sepsis, and drug toxicity including antibiotics that rarely can cause renal injury by a number of mechanisms including tubular toxicity and acute interstitial nephritis. The late Mrs. Huff suffered a stage I or mild acute kidney injury (Acute Kidney Injury Network) associated with her mitral valve surgery.

In reviewing the case of Mrs. Huff, predisposing factors for increased renal risk included her sex, the presence of chronic kidney disease, hypertension, and valvular surgery. Her baseline renal function is reported to be abnormal as is her admission creatinine of 2.5 mg/dL. In view of her significantly lower creatinine level in her convalescence of 1.6 mg/dL, I will need

> additional pre-surgical medical records to elucidate her baseline renal function. Additionally she was on an ACE inhibitor prior to surgery, but not post surgery, which may also have affected her renal function. The surgical procedure was well tolerated, without any significant hypotension. Surgical time was greater than 2 hours as an additional risk factor. The postoperative course included antibiotic exposure, transient value depletion and leukocytosis. Levaquin may rarely have nephrotoxicity. The anesthetic agents used are not associated with nephrotoxicity. The patient did not receive any nonsteroidal drugs preoperatively.. Mrs. Huff did receive aprotinin, an anti-fibrinolytic agent, that is now recognized as a nephrotoxin, with both structural and functional renal abnormalities associated with its use. There is a large volume of medical and scientific literature regarding the association of acute kidney injury with aprotinin, as listed in my attachment Aprotinin accumulates in renal tubular cells, and causes cellular injury and death. In addition to direct renal tubular toxicity, additional mechanisms of renal injury by aprotinin may include prostaglandin inhibition, anti-kallikrein effects, and micro-thrombosis of blood vessels. The expert report of F. Gary Toback, M.D. PhD sets out in detail the mechanisms and manner in which aprotinin effects renal function. In addition, aprotinin has been associated with an increased mortality when used in cardiopulmonary bypass surgery, compared to other antiepileptic agents. The development of even mild acute kidney injury in general, as well as in the setting of cardiopulmonary bypass surgery, is associated with a markedly increased mortality rate. A number of medical references are included in regards to the association of acute kidney injury in cardiothoracic surgery and mortality. In the case of Mrs. Huff, the cause of her renal injury was likely multifactorial, including cardiopulmonary bypass, hypovolemia and aprotinin. In all medical certainty, aprotinin was a significant contributing factor. The presence of acute kidney injury, even when mild, has a significant long-term mortality risk. If the treating physicians had been aware of the increased mortality risk associated with aprotinin, in all likelihood this drug would not have been used.

(DE 44 at Exh. A, p 4) ("Blond Rep.").

In summary, Dr. Blond would opine that, "In the case of Mrs. Huff, the cause of her renal injury was likely multifactorial, including cardiopulmonary bypass, hypovolemia and aprotinin.

In all medical certainty, [trasylol] was a significant contributing factor." (Blond Rep. at 4).

Dr. Blond also would opine that, " The presence of an acute kidney injury, even when mild, has a significant long-term mortality risk. If the treating physicians had been aware of the increased mortality risk associated with [Trasylol], in all likelihood this drug would not have been used."

Bayer argues that Dr. Blond's opinions should be excluded because : (1) he "does not opine that Trasylol caused Mrs. Huff's death," but instead opines that "[i]n all medical certainty, [Trasylol] was a *significant contributing factor*" to her "renal injury;"[14] (2) he disregards the fact that before surgery she was subject to a "moderate to high" risk of experiencing renal insufficiency after the surgery regardless of whether Trasylol use was factored in; (3) he relies on incomplete medical records and fails to conduct a proper differential diagnosis in arriving in his conclusion; (4) his opinion that Trasylol is associated with increased mortality is irrelevant in this case; and (5) his opinion relating to Dr. Peyton should be excluded because he is not qualified to opine as to whether Dr. Peyton would not have prescribed Trasylol if he had been aware of safety information which was allegedly not disclosed to the medical community because such opinion is speculative and not based on scientific knowledge. (DE 44 at 9-14).[15]

Plaintiff appears to argue in response to Bayer's first exclusion argument – that Dr. Blond's opinion only goes to Trasylol's impact on Mrs. Huff's post-operative renal impairment,

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[14] I note that Dr. Blond only relates an acute renal injury with an increased chance of mortality. He does not opine that Trasylol was a direct cause of Mrs. Huff's death.

[15] This type of speculative opinion by Dr. Blond and other proposed medical experts, as to what another doctor might or might not have done if provided particular information, has been repeatedly rejected by this Court. Accordingly, this opinion is inadmissible and requires no further discussion.

and not her death – by asserting that Dr. Blond cites to medical literature which "proves that a renal injury, even when mild, has a significant impact on mortality . . . [which] makes it more likely that Trasylol contributed to Mrs. Huff's death," and that such citation and reliance sufficiently ties her renal injury to her death. (DE 48 at 7). As to Defendants' remaining bases for exclusion, Plaintiff counters that Dr. Blond conducted a legally sufficient differential diagnosis and, to the extent that he had not reviewed all of Mrs. Huff's medical records before issuing his report, such deficiency was cured at his Deposition. Plaintiff does not respond to Bayers' argument relating to Dr. Blond's opinion regarding what Dr. Peyton would or would not have done. *See supra* note 15.

Bayer, in its Reply asserts that Plaintiff's Response is insufficient to establish the admissibility of Dr. Blond's opinions.

C. Analysis

It is well-established that a differential diagnosis, properly performed, constitutes a reliable methodology for determining medical causation under *Daubert*. *See Guinn v. Astrazeneca Pharms. LP*, 602 F.3d 145, 153 (11th Cir. 2010). While a differential diagnosis can provide a valid basis for a medical causation opinion, "an expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient." *McClain*, 401 F.3d at 1253. Instead, a court must examine whether the expert correctly applied the differential diagnosis methodology. 602 F.3d at 1253. The reasonableness of applying this approach, along with the validity of the expert's particular methodology for analyzing the data and drawing conclusions from the data, will determine whether the differential diagnosis is reliable. *Hendrix v. Evenflo Co.*, 609 F.3d 1183, 1195 (11th

Cir. 2010).

A differential diagnosis is a "patient-specific process of elimination that medical practitioners use to identify the most likely cause of a set of signs and symptoms from a list of possible causes." *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005). It requires an expert to "determin[e] the possible causes for the patient's symptoms and then eliminat[e] each of the potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely." *Guinn*, 602 F.3d at 1253 (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999).

At the first of the two steps, the "rule in" step, the expert must compile a comprehensive list of theories that could explain the patient's symptoms. *Hendrix*, 609 F.3d at 1195; *McClain*, 401 F.3d at 1253; *Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1057 (9th Cir. 2003). "Expert testimony that rules in a potential cause [of a patient's symptoms or mortality] that is *not* so capable is unreliable." *McClain*, 401 F.3d at 1253 (quoting *Clausen*, 339 F.3d at 1158). This is because "a fundamental assumption underlying [differential diagnosis] is that the final, suspected 'cause' . . . must actually be capable of causing the injury." *Id.* (alteration in original). At the second step of a differential diagnosis, the "rule out" step, the expert must at least consider the other causes that could have solely given rise to plaintiff's injury. *Guinn*, 602 F.3d at 1253. However, the expert "need not rule out all possible alternative causes" for his differential diagnosis to be reliable. *Id.*; *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 181 (6th Cir. 2009); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 265; *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999); *In re Mentor Corp.*, 711 F. Supp. 2d 1348, 1372 (M.D.Ga. 2010). *But see Hendrix*, 609 F.3d at 1195 ("[T]he expert must eliminate all causes but one.").

Critical to both steps, however, is the rule that in making both the "rule in" and "rule out" determinations, an expert must engage in the same level of "intellectual rigor that characterizes the practice of an expert in the relevant field." *Guinn,* 602 F.3d at 1255 (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152, 119 S. Ct. 1167, 1176 (1999). An expert engaging in a differential diagnosis must adhere to their standard diagnostic techniques to be considered reliable. *Id.* With these concepts in mind, I turn to Dr. Blond's proffered testimony.

Dr. Blond opines that "the cause of [Mrs. Huff's] *renal injury* was likely multifactorial, including cardiopulmonary bypass, hypovolemia and aprotinin." A review of the evidence reveals that Mrs. Huff suffered from numerous pre-existing conditions, many of which placed her at risk of experiencing a postoperative decline in kidney function. These conditions included chronic kidney disease, hypertension, diabetes, congestive heart failure, smoking, and previous strokes. Complicated and prolonged surgery, extended placement on heart bypass, transfusion with blood products only added to the list of risk factors she faced before and during the surgery. Post-operative factors increasing her risk of renal stress included antibiotics, hypovolemia, leukocytosis, diuretic administration, atrial fibrillation, and contraction alkalosis. (DE 44 at Ex. A); (*id.* at Ex. B).

In assessing whether Dr. Blond engaged in a reliable methodology, I keep in mind the Eleventh Circuit's instruction that "the primary purpose of any *Daubert* inquiry is for the district court to determine whether that 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.'" *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1255 (11th Cir. 2005) (quoting *Kumho*, 526 U.S. at 152.). I cannot say that Dr.

Blond has employed the same level of intellectual rigor that one would hope characterizes the practice of an expert in his relevant field. Dr. Blond makes his conclusions on a woefully incomplete set of medical records.

Specifically, of the above-referenced potential risk factors, Dr. Blond, in both his Report and his Deposition, failed to sufficiently consider Mrs. Huff's diabetes, congestive heart failure,[16] smoking,[17] diuretic treatment, atrial fibrillation,[18] hypertension,[19] and contraction alkalosis at the "rule in" stage.[20] Additionally, even for those risk factors that he did consider, his opinion was

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[16] Dr. Blond testified that he did "not see any medical records indicating Ms. Huff's past history of myocardial infarctions." He didn't "have those records." When presented with medical records revealing such past history of myocardial infarctions, he admitted that she had indeed had such a history of heart attacks. (Blond Dep. at 58: 12-17 ("I don't know her - - I don't have those records [relating to Mrs. Huff's history of myocardial infarctions]. Reportedly, she had no coronary artery disease in the other report").

[17] Dr. Blond testified that he did not have the correct information on Mrs. Huff's smoking or recreational drug-use history. (Blond Dep. at 62:23 - 25 ("No, sir. And perhaps she didn't inhale. . ." in response to a question about the inaccuracy of Mrs. Huff's smoking history noted in his expert report); 63-64 (noting he didn't see records indicating Mrs. Huff's occasional use of recreational drugs).

[18] Dr. Blond testified that atrial fibrillation can lead to renal injury if the heart is beating at a "very rapid rate," and that he had no knowledge of what Mrs. Huff's heart rate was during her episode of atrial fibrillation. (Blond Dep. at 72-73).

[19] *Id.* at 62:12-20 (" I haven't reviewed those records [of Mrs. Huff's treating physicians revealing that her kidney disease was secondary to her hypertension]; but certainly severe hypertension is a common cause of chronic kidney disease.").

[20] In pertinent part, Dr. Blond's list of "predisposing factors for increased renal risk included" her sex, the presence of chronic kidney disease, hypertension, and valvular surgery . . . , [a purportedly] abnormal [baseline] renal function . . . , [a]dditionally she was on an ACE inhibitor prior to surgery, but not post surgery, which may also have affected her renal function." As for the post-operative factors, Dr. Blond opined that Mrs. Huff tolerated the surgical procedure well, "without any significant hypotension," but noted that the surgical time being over 2 hours was as an additional risk factor, along with "antibiotic exposure, transient value depletion

not based on reliable methodology. A review of all of the medical records, the depositions, and the filings reveals that Dr. Blond made his conclusions with a glaringly incomplete medical history. Specifically, in making his conclusions, Dr. Blond never reviewed any records predating Mrs. Huff's August 2006 hospitalization for her surgery, nor did he have a complete set of medical records for the August 2006 hospitalization. (Blond Dep. At 51:2-5).

For example, Dr. Blond testified that Mrs. Huff's admission creatinine level of 2.5 was not sufficient to establish a history of "chronic renal disease" because it was a sample from just one point in time, and so without more, it was not likely contributory to her "acute" post-operative renal injury. However, he repeatedly testified that he had wanted to look at other medical records to establish the validity of the 2.5 admission creatinine level, but had not. (Blond Dep. 20: 6-14; 21:3-6; 40:11-12 ("I think that there were some pages missing that I'd like to look at at some point"); 41:1-6 ("she has evidence of preexisting kidney disease on her laboratory; but I don't have the details of - - that. And that's one of the things I'd like to look at, what her . . . to further verify what her baseline kidney function is or was because certainly one test doesn't give – necessarily establish the true baseline. So I would - - you know, if I have some more prior records and can review those, it give me more information regarding [her preexisting kidney disease]"); 44: 9-11 ("I'd like to see some additional pre-hospitalization records [relating to Mrs. Huff's true creatinine baseline]"); 44: 13-18 (" she was on an ACE inhibitor. I don't know when [it] was started, did it affect her kidney function"); 51: 2-6 (answering "no" to the question of whether Dr. Blond had reviewed any of Mrs. Huff's medical

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and leukocytosis." "Levaquin may rarely have nephrotoxicity. The anesthetic agents used are not associated with nephrotoxicity. The patient did not receive any nonsteroidal drugs preoperatively."

records for hospitalization admissions prior to the August 2006 admission); 51-53 (detailing Dr. Blond's lack of review of any of Mrs. Huff's prior hospitalizations and diagnosis); 64-65 (noting that he had not seen records of two hospital admissions from February and June of 2006 where Mrs. Huff's creatinine levels were elevated between 1.7 - 2.4, and 1.5 - 2.3, respectively.); 66 (noting that he had not seen records of two hospital admissions from early and late July 2006 where Mrs. Huff's creatinine levels were elevated between 2.0-2.6, and 2.6, respectively.).

The validity of Mrs. Huff's pre-surgery creatinine level and degree of chronic renal failure would appear to be critical to assessing Mrs. Huff's post-operative spike in renal deficiency. Dr. Blond completely side-steps the fact that Mrs. Huff's surgeon so believed that she would experience post-surgical kidney distress that he inserted a line for renal dialysis, which fortunately, was never required. (Blond Dep. at 68: 14 - 20). After being provided with additional medical records, Dr. Blond testified that Mrs. Huff would have had a "moderate to high risk" of post-operative renal failure, with or without administration of Trasylol. *Id.* at 68:2-6.[21] However, at no point during his deposition, does he explain why, despite her moderate to high risk of renal failure, and despite the surgeon's anticipation of renal insufficiency, her complex surgery, her previously unknown or partially known history of myocardial infarction, recreational drugs, smoking, and hypertension, Mrs. Huff's "'mild'acute renal injury" was attributable to Trasylol. Further, Dr. Blond, in his report, indicates that one of the factors that he relied upon in making his determination was the fact that immediately post-surgery, Mrs. Huff's

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[21] In his report, Dr. Blond noted that he "[did not have] detailed prior records," and "will need additional pre-surgical medical records to elucidate her baseline renal function." Dr. Blond never amended his report to reflect receipt of such additional medical records neither before nor after his deposition.

creatinine decreased to 1.4. This, according to his testimony, led him to believe that her 2.5 baseline had been an anomaly and not an accurate reflection of ongoing chronic renal disease. However, during his deposition, Dr. Blond was presented with Mrs. Huff's pre and post- surgical weights of 50.9 and 65.6 kilos, respectively amounting to some extra 30 pounds of fluid. Upon review of these records, Dr. Blond stated that it was "likely that the [post-surgical creatinine level of 1.4] was somewhat related to a very large amount of [fluid retention]" which did not accurately reflect her renal function. (Blond Dep. at 70:6 - 83:7). These are but a few of the deficiencies that I find in Dr. Blond's differential diagnosis. As with the physician in *Guinn*, Dr. Blond only "reviewed selections from [Mrs. Huff's] medical records prepared by her attorneys. Not only does this cast doubt on [his] differential diagnosis, but it also violates a primary purpose of *Daubert*: to ensure the expert 'employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Guinn*, 602 F3d at 1255 (11th Cir. 2010). Accordingly, I find that Dr. Blond's expert opinions are not based on a reliable methodology and will not assist the trier of fact. They are therefore inadmissible.

III. Summary Judgment

A. Legal Standard

Summary judgment is appropriate if "there is no genuine issue as to any material fact" and "the movant is entitled to judgment as a matter of law."[22] FED. R. CIV. P. 56(c);

[22] According to the Supreme Court, "As to materiality, the substantive law will identify which facts are material. Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Furthermore, "Summary judgment will not lie if the dispute about a material fact is 'genuine,' that is, if the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Id.*

Celotex v. Catrett, 477 U.S. 317, 322 (1986). In deciding a motion for summary judgment, the trial court "must consider all the evidence in the light most favorable to the non-moving party," and "resolve all reasonable doubts in favor of the non-moving party." *Earley v. Champion Int'l Corp.*, 907 F.2d 1077, 1080 (11th Cir. 1990) (internal citations omitted).

The moving party "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex*, 477 U.S. at 323 (citing FED. R. CIV. P. 56(c)). The moving party can meet this burden by presenting evidence showing that there is no dispute of material fact, or by pointing out to the district court that the nonmoving party has failed to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof. *Id.* at 322-23, 325.

Once the moving party has met its burden, the non-moving party bears the burden of coming forward with evidence of each essential element of its claim, such that a reasonable jury could find in its favor. *See Earley*, 907 F.2d at 1080 (11th Cir. 1990). Rule 56(e) "requires the nonmoving party to go beyond the pleadings and by [its] own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *Celotex*, 477 U.S. 324. "The mere existence of a scintilla of evidence in support of the [non-movant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [non-movant]."[23] *Anderson v. Liberty Lobby*, 477 U.S.

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[23] According to the *Anderson* court, "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (internal citations omitted).

242, 252 (1986). The failure of proof concerning an essential element of the non-moving party's case necessarily renders all other facts immaterial and requires the court to grant the motion for summary judgment. *Celotex*, 477 U.S. at 322-23.

Bayer argues that summary judgment should be granted as to each of Plaintiff's claims because (1) under Oklahoma law,[24] each of these claims requires "but for" proof of causation in fact; (2) Plaintiff cannot establish proximate causation without admissible expert testimony and Plaintiff's experts' causation testimony is inadmissible; and (3) Plaintiff's fails to plead fraud with specificity as required by the Court's earlier Orders. (DE 45 at 2-3).

Plaintiff argues that summary judgment should be denied because Plaintiff is not required to establish "but for" causation and she has provided sufficient admissible expert testimony that exposure to Trasylol was "a significant contributing factor" in causing Mrs. Huff's renal injury, and so "if a reasonable person could believe that the []product was the cause of the injury, "causation" is a question of fact [for the jury]." (DE 47 at 3-4).

B. Analysis

Plaintiff's Complaint consists of seven counts: (1) negligence; (2) products liability; (3) negligent misrepresentation; (4) intentional misrepresentation; (5) breach of express warranty; (6) breach of implied warranty; and (7) punitive damages. I take these claims out of order for simplification of the analysis.

Under Oklahoma law, a plaintiff seeking damages for personal injury allegedly caused by a defective or dangerous product must establish three elements: (1) the product caused the plaintiff's injury; (2) the product was defective when it left the defendant's control; and (3) the

[24] The Parties agree that the law of Oklahoma governs this action.

defect rendered the product unreasonably dangerous. (*See Kirkland v. General Motors Corp.*, 521 P.2d 1353, 1363 (Okla. 1974). It is well established that in order to satisfy the first prong, a plaintiff must have an expert to establish medical causation. *See, e.g.*, *Christian v. Gray,* 65 P.3d 591, 601-02 (Okla. 2003) ("When an injury is of a nature requiring a skilled and professional person to determine cause and the extent thereof, the scientific question presented must necessarily be determined by testimony of skilled and professional persons."); *Lefthand v City of Okmulgee*, 968 P.2d 1224, 1226 (Okla. 1998); *Williams v. Safeway Stores, Inc.*, 515 P.2d 223, 227 (Okla. 1973); *Agee v. Purdue Pharmaceuticals, Inc.*, 2004 WL 5352989 at *4 (W.D. Okla. 2004).

A review of the evidence reveals that Plaintiff has no such expert to establish causation. First, I have just excluded Dr. Blond's causation testimony for the reasons set forth above. Second, even if Dr. Blond's testimony were permissible, it would not establish that Trasylol was the cause of Plaintiff's decedent's death. At best, it would establish that Trasylol caused a temporary rise in Plaintiff's already elevated serum creatinine level which required no dialysis and which resolved within days.

Additionally, Plaintiff's claims fail for failure to establish proximate causation which is an essential element of product liability and negligence actions under Oklahoma law. *See, Jackson v. Jones*, 907 P.2d 1067, 1072 (Okla. 1995) (negligence); *Blair v. Eagle-Picher Industries, Inc.*, 962 F.2d 1492, 1495-96 (10th Cir. 1992); *Kirkland v. General Motors Corp.*, 521 P.2d 1353, 1363 (Okla. 1974). The "proximate cause of an event or injury must be that which in a natural and continuous sequence, unbroken by an independent or supervening cause, produces the event or injury and without which the event or injury would not have occurred."

Gaines-Tabb v. ICI Explosives, USA, Inc., 995 F. Supp. 1304, 1311 (W.D. Okla. 1996); *Gaines v. Providence Apartments*, 750 P.2d 125, 126-27 (Okla. 1987).

"Ordinarily, what constitutes the proximate cause of an injury is a question of fact . . . [h]owever, the question of proximate cause becomes a question of law when the facts are undisputed and there is no evidence from which a jury could reasonably find a causal connection between the allegedly wrongful act and the injury." *Lefthand v. City of Okmulgea,* 968 P.2d 1224, 1226 (Okla. 1998); *Thompson v. Presbyterian Hosp.*, 652 P.2d 260, 263 (Okla. 1982); *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1017 (10th Cir. 2001); *Bannister v. Town of Noble, Okla.*, 812 F.2d 1265, 1267 (10th Cir. 1987). Plaintiff, therefore, has the burden of producing sufficient evidence to allow a reasonable jury to find that it is more likely than not Mrs. Huff's exposure to Trasylol was a cause which, in a natural and continuous sequence, produced her renal injury and without which her injury would not have occurred. *See id.* For the same reasons discussed as to direct causation above,[25] I find that the record lacks any competent evidence of proximate causation, and because such evidence is essential to Plaintiff's claims, summary judgment is granted in favor of Bayer on Plaintiff's products liability and negligence claims.

Plaintiff also brings claims for breach of express and implied warranty. Oklahoma products liability laws have subsumed a breach of implied warranty claim in this type of drug manufacturing liability claim. *See, Kirkland*, 521 P.2d at 1365); *Alexander v. Smith & Nephew, P.L.C.*, 90 F. Supp. 2d 1225, 1235 (N.D. Okla. 2000). This leaves only Plaintiffs breach of

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[25] Specifically, even if Dr. Blond's testimony were admissible, he only opines that the drug was a "significant contributing factor" in Mrs. Huff's elevated creatinine level. He does not testify that Trasylol was a "but for" cause of Mrs. Huff's temporary serum creatinine level rise, nor did he opine that it was a "but for" cause of her death.

express warranty claim. In Oklahoma, in order to recover for breach of warranty, a plaintiff must establish: (1) existence of the warranty; (2) that the warranty was broken; and (3) that the breach was the proximate cause of the loss sustained. *Id.* As noted above, Plaintiff has no evidence that Trasylol proximately caused Mrs. Huff's injury. Accordingly, the warranty claims are due to be dismissed.

Plaintiff's claim for Failure to Warn is similarly deficient under Oklahoma law and is due to be dismissed. To establish a *prima facie* case of failure to warn, Plaintiff must establish: (1) that Trasylol in fact caused Mrs. Huff's injury; and (2) that Bayer's failure to warn was the proximate cause of her injury. *See Eck*, 256 F.3d at 1017; *Ingram v. Novartis Pharmaceuticals Corp.*, 2012 WL 2922716 at *2 (W.D. Okla. 2912). Oklahoma adheres to the Learned Intermediary Doctrine which means that in cases involving prescription medications, a manufacturer is required to warn, not the patient, but the prescribing physician. *Id.* This means that Plaintiff must establish that had Bayer provided Dr. Peyton with a different warning, he would have changed his risk-benefit analysis and would not have prescribed Trasylol to Mrs. Huff. *Eck,* 256 F.3d at 1022-24; *Ingram*, 2012 WL 29922716 at *2.

I first note that Plaintiff cannot as a matter of law establish the first prong, that Trasylol in fact caused Mrs. Huff's injury, for the same reasons that her products liability and negligence claims fail. That being said, her failure to warn claim fails for the additional reason that Dr. Peyton testified that at the time he prescribed Trasylol for use during Mrs. Huff's surgery, he was aware of the drug's potential association with both renal failure and temporary rises in serum creatinine levels, had weighed the risks versus benefits of using the drug, and he decided that the potential benefits in Mrs. Huff's case outweighed the risks of using the medication. (*See* Peyton

Dep. At 67-73).[26] Dr. Peyton's independent knowledge of the risk of renal complications potentially associated with Trasylol requires dismissal of Plaintiff's failure to warn claim under the Learned Intermediary Doctrine.

Plaintiff also brings claims for negligent and intentional misrepresentation. "Under Oklahoma law, a claim of misrepresentation is analyzed as a fraud claim because Oklahoma has not recognized an intentional misrepresentation cause of action separate from an action based on fraud." *Dobbs v. Wyeth Pharmaceuticals*, 848 F. Supp. 2d 1335, 1339 (W.D. Okla. 2012); *Nichols v. Pray, Walker, Jackman, Williamson & Marler, P.C.*, 144 P. 3d 907, 912 (Okla. Civ. App. 2006). Plaintiff's claim for fraud was dismissed pursuant to my previous Orders dated April 1, 2009 (Order to Show Cause, DE 916 in Case No. 08-md-01928) (dismissing any common law fraud claims in accordance with the March 5 Order, unless a plaintiff timely responded or amended the complaint), and March 5, 2009 (Order on Motions to Dismiss, DE 809 in Case No. 08-md-01928 (stating that "a broad claim that a plaintiff or a plaintiff's physician relied on fraudulent or misleading statements . . . absent some recitation of what oral or written statement a particular drug representative made to a specific physician at what particular point in time, is an insufficient basis for allowing plaintiffs to proceed with a claim for fraud," and giving plaintiffs thirty days within which to plead fraud with specificity). Plaintiff did not respond to these Orders. Plaintiff's fraud and misrepresentation claims were accordingly dismissed in part allowing her thirty days to provide specific allegations of fraud and reliance. There is no record evidence that Plaintiff relies on specific misleading statements that caused the use of Trasylol in

[26] Dr. Peyton also testified that he was aware of the Mangano article published in the New England Journal of Medicine at the time of Mrs. Huff's surgery.

the decedent's case, nor does she support his broad claims of fraud with any evidence of reliance, an essential element of these claims. *See Howell v. Texaco, Inc.*, 112 P.3d 1154, 1161 (Okla. 2004) (reliance is an essential element for a claim of both actual and constructive fraud in Oklahoma). Accordingly, Plaintiff's misrepresentation and fraud claims are due to be dismissed in full.

Summary judgment is granted on Plaintiff's punitive damages claim because it derivative of her underlying claims each of which have failed. *See, Thiry v. Armstrong World Industries*, 661 P.2d 515, 516 (Okl. 1983).

IV. Conclusion

For the reasons set forth herein, it is accordingly,

ORDERED AND ADJUDGED that Bayers' Motions: (1) to Exclude Testimony by Plaintiff's Case-Specific Experts (DE 12120 in 08-1928 and DE 45 in 09-81484); and (2) for Summary Judgment (DE 121119 in Case No. 08-md-01928, DE 44 in Case No. 09-81484) be and are HEREBY **GRANTED.**

DONE AND ORDERED in Chambers at West Palm Beach, Florida, this 13th day of March, 2013.

DONALD M. MIDDLEBROOKS
UNITED STATES DISTRICT JUDGE

Copies to: Counsel of Record