UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 08-MD-1928-MIDDLEBROOKS/JOHNSON

IN RE: TRASYLOL PRODUCTS LIABILITY LITIGATION - MDL-1928

This Document Relates To:

DAVID QUINONES, et al. V. BAYER CORPORATION, ET AL., Case No. 09-80682

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ORDER ON MOTION FOR SUMMARY JUDGMENT

THIS CAUSE comes before the Court upon Defendants' (hereinafter, collectively, "Bayer's") Motion for Summary Judgment ("Motion") (DE 13259 in 08-1928 & DE 53 in 09-80682). Plaintiff filed a Response (DE 13354 in 08-1928 & DE 57 in 09-80682), to which Bayer replied (DE13366 in 08-1928 & DE 58 in 09-80682). The Court has reviewed the pertinent parts of the record and is advised in the premises. For the reasons stated below I find that the Motion is due to be granted as to all Counts.

I. Factual Background[1]

In this case Plaintiffs seek damages for a postoperative complication which was: a known

[1] The following facts are either undisputed or established by evidence attached as Exhibits to either the Defendant's Motion ("DEFEX") or the Plaintiffs' Response ("PLEX"). They shall be referred to DEFEX __ at__ – or PLEX __ at __ accordingly.

complication; brief; wholly resolved; and of no long-term impact.[2] Plaintiffs David and Regina Quinones (the "Plaintiffs") are citizens of the State of Colorado. On July 9, 2003, Plaintiff David Quinones ("DQ") underwent a Coronary Artery Bypass Grafting ("CABG") "re-do" procedure by Dr. Shriram Nene.[3] (DEFEX C). Dr. John Propp assisted in the procedure, and Dr. James Sederberg was the anesthesiologist.[4] (PLEX F at 6:11-16; PLEX G at 7:23-8:2). At the time of his surgery, DQ had numerous preexisting conditions, including Stage III chronic kidney disease, severe vascular disease (including 100% obstructions in both the circumflex and right coronary arteries),[5] diabetes, hypertension, hyperlipidemia, significant coronary artery disease, a prior heart attack, prior CABG surgery, multiple coronary artery stents, two lower extremity stents, numerous angioplasty procedures and a history of renal stones. (DEFEX E at 2; DEFEX D at 64:18- 65:1, 132:8-133:6; DEFEX C, F & G). DQ signed a consent which informed him that the re-do CABG surgery involved significant risks, including: bleeding; infection; heart, lung, or kidney damage; stroke; and even death. (DEFEX C at 2-3). At the time of his admission, DQ was taking the following medications:

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[2] Also, the injury was already arguably pre-existing as the Plaintiff already had chronic renal insufficiency prior to the medical procedure.

[3] A re-do procedure indicates a previous CABG surgery.

[4] Both Dr. Propp and Dr. Sederberg testified that they did remember whether or not they made the decision to utilize Trasylol in DQ's CABG surgery. Dr. Propp said that it was "probably [DQ's surgeon,] Dr. Nene," that would have made the decision to use Trasylol. DEFEX J at 10. Dr. Sederberg said that "the way it typically went, Dr. Nene would say, we should apritinin, or I would ask him if he wanted to use aprotinin, and he would say yes." DEFEX I at 3. I note that there is no evidence that Dr. Nene, DQ's surgeon, was ever deposed.

[5] Due to significant right carotid disease, it was necessary for DQ to undergo a cardiac intervention procedure and an endarterectomy surgery on June 3 & 10, 2003, respectively before he could undergo the CABG re-do. He experienced transient ventricular fibrillation after the first procedure, but no complications after the second procedure. (DEFEX C at 28).

Atenolol; Pravastatin; Zetia; Folate; Avapro; Prinivil; MGB Vitamins; Slow Niacin; Lasix; Potassium; and Avandia. (DEFEX C at 8). The admission report notes that these medications would be continued during DQ's hospitalization unless change became necessary.[6] His creatinine level at the time of his June surgeries was 1.1 - 1.3. (*Id.* at 15) (report of renal consultation), but had risen to 1.8-2.0 by the time of the July surgery, and his BUN was 25. *Id.*[7]

The CABG surgery lasted eleven hours, during which time he was on cardiobypass for two hours and twenty-six minutes with a cross-clamp time of ninety-eight minutes. DQ received Trasylol during the CABG surgery.[8] During the surgery, DQ also received Protamine when Dr. Nene tried to take him off bypass.[9] Shortly after he received the Protamine, DQ developed sudden and dangerous drop in blood pressure and needed to be placed back on bypass again. (DEFEX C at 20).

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[6] He had also been on Aspirin and Plavix, but those medications were discontinued five days before the admission in anticipation of the surgery. (DEFEX C at 8).

[7] "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." "WebMD Medical Reference from Healthwise" 2010. Web. 9 August 2010.

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." *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. DQ's BUN and creatinine levels of 25 and 1.8, respectively, indicate renal impairment.

[8] Specifically, he received a 1 ml test dose, followed by a bolus dose of 100 ml and a .25 ml/hr continuous drip. (DEFEX I at 5-6).

[9] Protamine is a medication intended to reverse the effect of heparin, a drug which is used to prevent clotting while a patient is on bypass.

He received medications and blood transfusions and stabilized. (DEFEX D at 68-79; C at 20-21). He was then given Protamine again and removed from bypass. (*Id.*). However, while Dr. Nene was closing his chest, DQ experienced ventricular fibrillations[10] without warning and he needed manual heart massage and compressions along with electronic shocks to restart his heart.[11] He responded and resumed a normal sinus rhythm. As he had received heparin again, he needed to be coagulated again, so this time Dr. Nene used Fresh Frozen Plasma instead of Protamine. There were no additional complications. (DEFEX C at 20). His serum creatinine level immediately post-op was 1.8 mg/dL.

DQ experienced numerous post-operative complications including sepsis-like symptoms, respiratory failure requiring intubation, hypotension, and liver dysfunction. He was seen by, Dr. Sakiewicz, a nephrologist, who diagnosed him with "hypotension-induced acute liver injury and acute tubular necrosis superimposed on chronic renal failure." (DEFEX C at 14-16).[12] DQ never required dialysis, and he was discharged on post-operative day #11. Eight years later, DQ's creatinine levels remain improved from his levels seen immediately prior to the July, 2003 surgery.[13] The Complaint alleges the following claims: (I) Strict Liability - Failure to Warn; (II) Strict Liability -

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[10] According to the American Heart Association: "[v]entricular Fibrillation is the most serious cardiac rhythm disturbance. The lower chambers quiver and the heart can't pump any blood, causing cardiac arrest. Available at: http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/Ventricular-Fibrillation_UCM_324063_Article.jsp.

[11] During his heart massage he was again administered heparin to prep him for bypass in case it became necessary again.

[12] I note that the record does not reflect any deposition testimony for Dr. Sakiewicz as to DQ's renal injury.

[13] DEFEX G; D at 138.

Design Defect; (III) Negligence; (IV) Negligence Per Se; (V) Fraud, Misrepresentation, and Suppression; (VI) Constructive Fraud; (VII) Breach of Implied Warranties; (VIII) Unfair and Deceptive Trade Practices; (IX) Unjust Enrichment; (X) Loss of Consortium; (XI) Gross Negligence; and (XII) Punitive Damages.

Bayer argues that summary judgment should be granted as to each of Plaintiffs' claims because (1) under Colorado law,[14] each of these claims is barred by the relevant statute of limitations; (2) each claim must be established by expert testimony and Plaintiffs' experts' causation testimony is inadmissible; and (3) Plaintiffs fail to plead fraud with specificity as required by the Court's earlier Orders. (DE 53).

Plaintiffs argue that summary judgment should be denied because: (1) their claims are timely; (2) they are not required to establish "but for" causation; and (3) they have provided sufficient admissible expert testimony that exposure to Trasylol was "a significant contributing factor" in causing DQ's renal injury, and so because "a reasonable person could believe that the []product was the cause of the injury, 'causation' is a question of fact [for the jury]." (DE 57).

II. Legal Standard

Summary judgment is appropriate when "there is no genuine issue as to any material fact" and "the movant is entitled to judgment as a matter of law."[15] FED.R.CIV.P. 56(c). The purpose of

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[14] The Parties agree that the law of Colorado governs this action.

[15] 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.*

summary judgment is to "isolate and dispose of factually unsupported claims or defenses." *Celotex v. Catrett*, 477 U.S. 317, 323-24 (1986). In considering 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 party seeking summary judgment "always 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 movant can meet this burden by presenting evidence showing 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. *Celotex*, 477 U.S. at 322-23.

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]."[16] *Anderson v. Liberty Lobby*, 477 U.S. 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.

III. Analysis

A. Statutes of Limitations

i. Non-Warranty Claims.

Bayer first asserts that Plaintiffs' non-warranty claims are subject to a two-year limitations period under Colorado Rev. Stat. 13-80-106.[17] Under this section, a claim arises "on the date both the injury and its cause are known or should have been known by the exercise of reasonable diligence. Colo. Rev. Stat. §13-80-108 (hereinafter "Colorado's Discovery Rule"). This has been interepreted to mean that "[o]nce a plaintiff has suspicion of wrongdoing, [he] is under a duty to attempt to find the [relevant] facts. Uncertainty as to the full extent of the damages does not stop the accrual of a cause of action." *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 887 (10th Cir. 2005) (citing *Trinity Broad. of Denver, Inc.*, 848 P.2d 916, 926-27 (Colo. 1993) and *Taylor v. Goldsmith*, 870 P.2d 1264, 1266 (Colo. App. 1994)).

"Whether a plaintiff knew or with reasonable diligence should have known of a cause of action is normally a question of fact for the jury." *See Norris v. Baxter Healthcare Corp.*, 397 F.3d

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[16] 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).

[17] Plaintiffs do not dispute Bayers allegations as to the applicable statutory sections or the limitations periods set forth therein. At issue is the date at which limitations period began to run as to Plaintiffs' causes of actions.

878, 888 (10th Cir. 2005); *Maughan v. SW Servicing, Inc.*, 758 F.2d 1381 (10th Cir. 1985); *Miller v. Armstrong World Ind., Inc.*, 817 P.2d 11, 113-14 (Colo. 1991). "However, where there is no genuine issue of material fact that a plaintiff discovered or reasonably should have discovered a defendant's wrongful conduct as of a particular date, the issue may be decided as a matter of law." *Lefthad v. City of Okmulgee*, 968 P.2d 1224, 1226 (Okla. 1998); *Morris v. Geer*, 720 P.2d 994 (Colo. App. 1986).

Bayer argues that there is no genuine issue of material fact that DQ "reasonably should have discovered" the fact that Trasylol might have caused his renal injury no later than January of 2006. Specifically, Bayer asserts that Plaintiff was in possession of his medical records since at least 2003; he knew he had experienced renal insufficiency in the hospital in July of 2003, and so he was on notice that he may have suffered a legal injury at the earliest in July of 2003. Listing a media onslaught commencing in January of 2006, consisting of a series of publications, public service advisories, and other types of news reports, Bayer urges me to find, as I have done in some other individual MDL cases, that "a reasonable person exercising due diligence – who knowingly suffered kidney dysfunction following open heart surgery less than three years earlier [-- especially one who had all of his medical records in his possession and who was admittedly able to quickly figure out that he had received Trasylol during his surgery with no help from any doctor or lawyer--] -- would have discovered [Trasylol's] alleged risks, that Trasylol had been administered, and a possible connection to his alleged injuries" no later than January of 2006.

The specific decisions Bayer cites to are: *Coleman v. Bayer Corp.*, 2012 WL 1662151 (S.D. Fla. May 9, 2012)(utilizing Texas law in determining that "[p]laintiff should have been on notice of her alleged injuires and their link with Trasylol" by January 2006); *McNeil v. Bayer*, 2010 WL

6098571 (S.D. Fla. Aug. 16, 2011) (same); and *Bechara v. Bayer Corp.*, 2010 WL 6098571 (S.D. Fla. Mar. 16, 2010) (applying California law and finding that plaintiffs "should have discovered their personal injury claims against Bayer no later than January 2006," in part because Trasylol's allegedly dangerous propensities "were widely circulated in the national and local media" at that time, such that a reasonable investigation would have put plaintiffs on notice of their claims).

Plaintiffs disagree that DQ knew or should have known that Trasylol caused DQ to suffer renal injury immediately after his surgery by January of 2006. (*See* DEFEX H at 3; Comp. At ¶ 4). They state that it is irrelevant that DQ requested and received full copies of his medical records shortly after his discharge, because he testified that he only first became aware of the potential claim against Bayer on October 17, 2007 when he saw an internet advertisement offering compensation to persons whom had been exposed to Trasylol during heart surgeries. (DEFEX A at 12-13).[18] According to Plaintiffs a question of fact precludes entry of summary judgment as to when DQ reasonably should have discovered his injury. Plaintiffs are correct on this point.

I find the cases Bayer cites distinguishable because in each of those cases I found that the plaintiffs therein had a duty to reasonably investigate their claims by January of 2006, not due to the existence of the Nation wide media surge alone, but more so because of the facts of the individual

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[18] I note that DQ also testified that he didn't "remember [any injury that he thought Trasylol had caused him, but that he] did it because it said on there about the compensation and if . . . they had given that medication or that anesthesia. And [he] looked at [his] records, and . . . said, "hey" he had been "given that stuff." So [he] filled out the form." *Id.* He does not believe that he suffers from any injury today that was caused by Trasylol. This gives me pause because in essence this translates into a theory that any person who experiences a temporary and completely anticipated adverse complication after a highly complex medical procedure - a risk of which that person knew about and specifically consented to- and without suffering any long-term effects, may years later serendipitously obtain a potential windfall. While this does not relate to when DQ knew or should have known about the relationship between Trasylol for statute of limitations purposes, it does relate to causation issues which will be discussed *infra*.

case. Specifically, in both *Coleman and McNeil*, Bayer filed its summary judgment motions, but the plaintiffs never responded. There was no question of disputed fact as to the running of the limitations period for either plaintiff. In *Bechara*, I found that the plaintiff should have reasonably discovered his claim no later than the January 2006 date for several reasons: (1) because he had obtained all of his medical records in order to sue the hospital for his renal failure; (2) he admitted that he had read something about Trasylol causing renal failure at some point in 2006; (3) his medical records contained Trasylol's label with is warning of nephrotoxic risk; and (4) he subscribed to the Los Angeles Times, which ran on its front page the news relating to Trasylol's association with renal failure.

None of these cases stand for the proposition that a patient who has copies of his medical records at home, without more, should be deemed to be on notice as to the existence of a possible claim every time that a drug on the market is associated with a new injury.[19] Accordingly, Bayers' motion as it relates to the statute of limitations basis for Plaintiffs' non-warranty claims must be denied.

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[19] I find this even though DQ previously filed another products liability case against the maker of Avandia. *See Massey, et al. v. Glaxosmithkline, et al.*, Case No. BC 409893 filed in the Superior Court of California, County of Los Angeles. The *Massey* case was filed on March 17, 2009. This case was filed on May 7, 2009. It is unclear when, but DQ first alleged that the drug Avandia caused him to suffer a "heart attack, heart damage, kidney and liver shutdown" from July 9, 2003 - July 20, 2003. At some point in time, DQ amended his Plaintiff Fact Sheet ("PFS") in the Avandia case to reflect that he was only seeking damages for "heart problems." The Avandia PFS also states that DQ had never previously experienced any heart problems. This is contrary to all of the medical evidence supplied in this case. This leads me to believe that it is possible that DQ was a plaintiff in search of a case, and so therefore should as a matter of law be presumed to be under a duty to investigate any alleged injury hidden in his medical records. But I find that without anything more it cannot be said that DQ had any particular reason to be aware of the Trasylol media blitz in January of 2006, or that Trasylol, out of the myriad of drugs he had received, was to blame for his transient rise in creatinine levels after his July surgery.

ii. Plaintiffs' Warranty Claims

In response to Bayers' statute of limitations assertion against Plaintiffs' warranty claims, Plaintiffs suggest that the result is exactly the same as for their non-warranty claims. However, the Plaintiffs' warranty claims which are governed by Colo. Rev. Stat. §§4-2-725(1)-(2), 13-80-101. This section provides for a strict three year statute of limitations running from "when tender of delivery is made . . . regardless of the aggrieved party's lack of knowledge of the breach." *See Curragh Queensland Mining Ltd. v. Dresser Indus., Inc.*, 55 P.23d 235, 239 (Colo. App. 2002). Plaintiffs seek to impute the same Colorado Discovery Rule discussed above to their claims for breach of express and implied warranty. However, I find that their warranty claims are subject to a three year limitations period to which no discovery exception applies. Accordingly, their warranty claims are untimely and due to be dismissed.[20]

B. Causation

Bayer alternatively asserts that even if Plaintiffs' claims are deemed timely, their products liability and negligence claims are still due to be dismissed due to a lack of causation – a required element of each claim. Additionally, Plaintiffs' claims for fraud and consumer fraud are due to be dismissed as barred by this Court's previous orders. Lastly, Plaintiffs' unjust enrichment, loss of consortium, and punitive damages claims are derivative and must fail where the substantive counts they are premised upon are dismissed. With each of the relevant legal standards set forth above in mind, I turn first to Bayers' causation argument.

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[20] To the extent that Plaintiffs are seeking to assert that the Plaintiffs could not have discovered any breach due to the Defendants wrongful or fraudulent conduct, such claims are dismissed without further discussion for the same reasons that Plaintiffs' fraud claims fail, as discussed, *infra.*

Specifically, Bayer asserts Plaintiffs' claims lack causation because none of DQ's treating physicians opine that Trasylol caused his injuries. (*See* DEFEX J (Propp Dep.) at 43-44; DEFEX I (Sederberg Dep.) at 48-19). Further, DQ has testified that no physician has ever informed him that Trasylol injured him. (DEFEX A (DQ Dep.) At 14, 15, 18, and 19. Moreover, Plaintiff testified that he does not believe that he "has any current medical condition caused by the use of Trasylol." *Id.* at 136. And, because Plaintiffs must have admissible expert testimony to establish the causation element required by each of their products liability and tort claims, these claims must fail. *See Franklin v. Shelton,* 250 F.2d 92, 97 (10th Cir. 1957); *Lynch v. L'Oreal USA S/D, Inc.,* 2012 WL 4356231 (D.Colo. 2012). According to Bayer, this is because Plaintiffs' only causation expert's testimony is unreliable and inadmissible. I agree.

i. 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.[21] 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

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[21] 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).

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.

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).

ii. Parties' Arguments

Plaintiffs proffer Dr. Carl J. Blond, M.D., Ph.D., as their specific causation[22] expert. The following information has been obtained from Dr. Blond's expert report ("Report"). Dr. Blond is

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[22] 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.

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.

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,[23] Dr. Blond's report provides as follows:

> MY. Quinones was having 8-10 episodes of chest pain daily brought on by mild exertion, relieved by nitroglycerin; Medications at the time of admission included Avapro, ACCOD, Lipitor, TriCor, Toprol, Avandia, Plavix, aspirin, nitroglycerin [as needed], and Isordil. Hypotension was noted in the emergency room with a blood pressure of 96/46 . . . . He underwent cardiac catheterization on 5/30/2003. Findings included total occlusion of the proximal circumflex and right coronary artery, diffuse atherosclerosis of the LAD of approximately 90% proximal stenosis, and . . . . he had a 99%

[23] The Parties do not dispute that Dr. Blond qualifies as an expert under the first prong of *Daubert* analysis.

stenosis of the ostium of the saphenous vein graft to the right coronary artery. and proximal stenosis of the saphenous vein graft to the obtuse diagonal branch of approximately 80%, with mid-stenosis of approximately 90%. Left ventricular systolic function was preserved with an ejection fraction of 65%. It was anticipated he would undergo coronary artery bypass grafting, but his work-up revealed significant right carotid disease, requiring endarterectomy prior to bypass surgery. In view of this, he underwent a cardiac intervention on 6/03/2003, successfully performed by Dr. Pacheco. including a saphenous vein graft stent placement to the obtuse marginal, and balloon angioplasty of the right coronary artery. Complications included transient ventricular fibrillation, opening blood pressure was 82/48 . . . and closing aortic pressure was 108/61. Mr. Quinones then underwent. right carotid endarterectomy on 06/10/2003 without complication. A serum creatinine (Cr) on postoperative day #1 was 1.1 mg/dL. Spirometry done at that time was in the normal range. with an FEVI/FVC ratio of 84%, and an FEVI of 83% of predicted. Mr. Quinones was readmitted for cardiac bypass surgery on 07/09/2003. Admitting lab included a serum Cr of 1.8 mgldL, and normal liver function tests. Medications listed at the time of admission included aspirin and Plavix, which had been discontinued 5 days prior. Additional medications listed included Zetia, atenolol, pravastatin, Lasix, Avapro, Prinivil, niacin, Lasix [sic], and Avandia.

Mr. Quinones underwent surgery on 07/09/2003, performed by Dr. Nene. including a redo sternotomy, coronary artery bypass grafting x2, including a reverse saphenous vein graft to the distal right coronary artery. The cross-clamp time was 98 minutes, with a bypass time of 146 minutes. The anesthetic agents included desflurane, fentanyl, midazolam, hydromorphone, and rocuronium. Aprotinin was infused as an antifibrinolytic. Blood pressure prior to bypass was well maintained with mild hypotension initially. with induction in the 90-100 mm Hg systolic range. but then stabilized in the 100-140 mm Hg range with a nitroglycerin drip. Hypothermia was mild, with temperature to 34°C. [Oxygen] saturation was well maintained at 100%. Post cardiopulmonary bypass after weaning was without difficulty, protamine was infused, and Mr. Quinones developed sudden hypotension, and ST segment elevation was noted. The patient was placed back on bypass, and recovered quickly. Mr. Quinones then developed ventricular fibrillation during closing; the patient was cardioverted, and was given open cardiac massage with a downtime of less than one minute. Pressors given included

dopamine and Levophed. Six units of fresh frozen plasma were also given to reverse the anticoagulation, no further protamine was given. Additional drips given included milrinone. The patient was then closed successfully. The patient was described in the surgical note as doing extremely well despite this "sinking spell" and was extubated the following morning.

On postoperative day #1, Mr. Quinones was alert and oriented post extubation. Vital signs included a blood pressure of 101/57, temperature of 100.5 degrees Fahrenheit, heart rate of 92. Urine output was nonoliguric. and serum Cr was 1.8 mg/dL, white blood cell count was 10.6. platelets 113,000, and hemoglobin 11.1. The milrinone drip was tapered, hypomagnesemia was treated. and heparin infusion continued. Antibiotic coverage included Ancef. On postoperative day #2, thrombocytopenia was noted and heparin was discontinued. A serum Cr was 1.6 mg/dL, and urinary output was noted to be decreased later in the day and Lasix was ordered, as well as one unit of packed red blood cells. That evening, oxygen saturation was diminished into the 70s, Mr. Quinones was given Narcan, and placed on BiPAP by pulmonary. Urine output was improved with Lasix, but the serum creatinine had risen to 3.3 mg/dL. A chest x~ray showed ateleotasis and cardiomegaly, unchanged from an earlier x-ray that day. Early the following morning re-intubation was required due to marginal oxygenation. Swan-Ganz catheter readings showed decreased peripheral resistance (SVR 626 DS/cm5), well maintained cardiac output (cardiac index 2.99 L/min/M2). Lactic acid level was not elevated. alkalosis was present on blood gas measurements. Broad-spectrum antibiotic coverage including vancomycin, Flagyl. and Levaquin on postoperative day #3 were begun. Abnormal liver function tests were noted with marked elevation of hepatic enzymes. General surgery was consulted due to concern regarding possible ischemic bowel. Renal consultation was obtained on postoperative day #3. Impression from nephrology, Dr. Sakiewicz, was a sepsis-like syndrome, hypotension-induced acute liver injury, and acute tubular necrosis superimposed on chronic renal failure. An echocardiogram done on postoperative day #3revealed a small pericardial effusion, and an ejection fraction of 62%. Serum. Cr peaked on postoperative day #5 at 3.7 mg/dL. Fortunately, Mr. Quinones turned the corner, with serum Cr beginning to drop by postoperative day #7. Cultures were not revealing of a pathogen for suspected sepsis. The elevated liver enzymes rapidly improved after postoperative day #3. Mr. Quinones was discharged on postoperative day #11, serum Cr was 1.4 mg/dL at that time. In review of later

records, Mr. Quinones continued to have multiple vascular problems, renal function was maintained at stage III chronic kidney disease.

MEDICAL OPINION REGARDING MR. DAVID QUINONES

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 renal failure. This is usually a transient phenomena associated with hypotension, hypoxia, oxidative stress and nephrotoxic agents. Nephrotoxic agents include IV contrast, nonsteroidal drugs, and rarely, anesthetic agents. Hypotension is frequently related to blood loss, hypovolemia, impaired cardiac function and occasionally sepsis. Cardiopulmonary bypass is associated with a transient drop in glomerular filtration, Additional risk factors for developing acute renal failure includes the presence of chronic kidney disease, prolonged and complex surgery, as well as underlying congestive heart failure. The mechanism for renal dysfunction, in general, can be from factors associated with cardiopulmonary bypass surgery including decreased renal perfusion and associated ischemic inflammatory mediators. The pro-inflammatory state of bypass surgery also can have an associated toxicity to renal tubular cells. Atheroembolic injury can occur in this setting also, as well as hypoxia or hemolysis to produce renal injury. In the postoperative period, causes of renal dysfunction can include infection, antibiotic toxicity, worsening cardiac dysfunction and volume depletion. The use of aprotinin also has been found to be associated with an increased risk of renal failure. In reviewing the records of Mr. Quinones, he suffered a stage II or moderate acute kidney injury (AKIN criteria) associated with cardiopulmonary bypass surgery. A serum Cr at the time of admission was elevated from his baseline from his prior records but returned to baseline at the time of discharge. The etiology of this was not evaluated at the time of admission, but was clearly transient in view of his recovery to a serum Cr of 1.4 mg/dL, compatible with his previous baseline from the month prior. Major risk factors for renal injury were present in Mr. Quinones, including chronic kidney disease, peripheral vascular disease, and diabetes mellitus. A pump time greater than 2 hours would be an additional risk factor. Modifying factors decreasing risk include normal left ventricular function, age, and male sex. The majority of patients undergoing cardiopulmonary bypass surgery, even with multiple risk factors do not develop acute kidney injury. It should be noted tbat Mr. Quinones tolerated IV contrast, hypotension, and ventricular fibrillation during his angioplasty the prior month,

without evidence of renal injury. An MRI done [sic] 2005 showed no evidence of significant renal vascular disease., Mr, Quinones developed acute renal injury which in all likelihood is multifactorial in origin. Renal function was not at baseline at the time of surgery. The mechanism of this was not ascertained, but in view of his recovery, most likely factors would include volume depletion related to diuretics, or blood pressure medication, including the use in combination of an ACE inhibitor and angiotensin receptor blocker, Cardiopulmonary bypass surgery and aortic cross-clamping would be contributing factors, including a hypotensive reaction to protamine, vasopressor infusion and transient ventricular fibrillation. Aprotinin was used as an antifibrinolytic agent, now recognized to be a nephrotoxin, and associated with acute kidney injury. Despite these events, renal function initially appeared stable in the immediate post-operative period. Additional hypotension and respiratory failure with hypoxia developed on postoperative day #2 with evidence of acute kidney injury, Intubation occurred prior to any respiratory arrest. There was no evidence of severe acidosis. Sepsis was suspected, although no pathogen was cultured nor source of infection ascertained. Mr. Quinones had low-grade fever, but did not show evidence of leukocytosis during this episode. In all medical certainty, aprotinin was a major significant contributing factor to the development of a kidney injury. Aprotinin is a nonspecific serine protease inhibitor that was used in cardiopulmonary bypass surgery to attenuate the activated fibrinolytic and inflammatory response that is upregulated in this setting. This occurs through the effects of a wide range of mediators including thrombin, plasmin, and kallikrein. The expert report of F. Gary Toback, M.D., PhD sets out in detail the general manner in which aprotinin effects renal function as well as mechanisms of renal cellular injury. Aprotinin was thought to cause renal cellular toxicity by a number of mechanisms including direct cellular toxicity. microthrombosis, and inhibition of the vasodilatory renal prostaglandins. The presence of aprotinin in the proximal tubular cells likely tipped the scales in the development of acute tubular necrosis. There is a large volume of medical and scientific literature regarding the association of acute kidney injury with aprotinin, listed in my attachment, In addition, aprotinin has been associated with increased mortality in patients undergoing cardiopulmonary bypass surgery, when compared to other antifibrinolytic agents such as aminocaproic acid. The development of an acute kidney injury in cardiopulmonary bypass surgery is associated with both greatly increased short and long-term increased mortality when compared to other patients. A number of references

> regarding this are also listed in my attachment. In all likelihood, this drug would never have been used by the physicians caring for Mr. Quinones if they had been aware of the association of acute kidney injury and mortality risk with aprotinin.

(Blond Report - DEFEX E at 2- 6).

In summary, Dr. Blond would opine that "[i]n all medical certainty, aprotinin was a major significant contributing factor to the development of [Mr. Quinones's multi-factorial] kidney injury." *Id.* at 5. 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." *Id.*[24]

Bayer argues that Plaintiffs Dr. Blond's opinions should be excluded as unreliable and unhelpful to the trier of fact because: (1) they rely on a mistaken assumption about the Trasylol dosage received and whether such dosage is sufficient to potentially cause the transient rise in serum creatinine seen in DQ's post-operative period;[25] (2) they do not establish "but-for" causation as required under Colorado law; and (3) they result from a flawed methodology.

Plaintiffs' response focuses on Bayers' dosage argument, but also counters that:(1) Bayer mistakenly places a "but-for" causation standard into a question of expert admissibility; and (2) Dr. Blond conducted a legally sufficient differential diagnosis.

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[24] 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.

[25] I have previously considered Bayers' "doseage" related arguments, and find them to be an inappropriate basis for exclusion under the circumstances. Accordingly, they are dismissed without further discussion. *See, e.g., Durkin v. Bayer*, Case No. 08-80419 (S.D. Fla. November 23, 2011) (DE 77).

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

iii. Analysis

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.* Any analytical gap in an expert's methodology can be a sufficient basis to exclude expert testimony under *Daubert*. *See Trucks Ins. Exchange v. MagneTek, Inc.*, 360 F.3d 1206, 1212-13 (10th Cir. 2004); *Goebel v. Denver & Rio Grande Western R. Co.*, 346 F.3d 987, 992 (10th Cir. 2003). Under *Daubert*, "'any step that renders the analysis unreliable ... renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely

misapplies that methodology.'" *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 783 (10th Cir.1999) (citing *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 745 (3d Cir.1994)). With these concepts in mind, I turn to Dr. Blond's proffered testimony.

It is important to first address the causation standard applicable to this case. Plaintiffs assert that Bayer is attempting to impose a "but-for" causation on my determination as to the admissibility of Dr. Blond's testimony. Such is not the case. In cases such as this, Colorado law requires admissible expert testimony to establish causation. *See Franklin v. Shelton,* 250 F.2d 92, 97 (10th Cir. 1957); *Lynch v. L'Oreal USA S/D, Inc.,* 2012 WL 4356231 (D.Colo. 2012). That expert must be able to establish that Trasylol was "a" "but-for" cause of DQ's alleged injury. Contrary to Plaintiff's argument, this does not mean that Dr. Blond has to opine that Trasylol is the sole cause of DQ's alleged injury. Rather, this means that Dr. Blond must establish that "but-for" the administration of Trasylol, DQ's injury would not have occurred. *See Reigel v. SavaSeniorCare, L.L.C.*, 2011 WL 6091709 at *8 (Colo. App. 2011) ("[The Colorado Supreme Court] has not retreated from the requirement that the defendant's conduct be a cause without which the injury would not have occurred."); *June v. Union Carbide Corp.*, 577 F.3d 1234 (10th Cir. 2009) (finding that the Colorado Supreme Court has consistently followed the "but-for" causation test).

"Where several concurring acts or conditions of things-one of them the wrongful act or omission of the defendant- produces the injury and it would not have been produced but for such act or omission, such wrongful act or omission is the proximate cause of the injury." *In re Swine Flu Immunization Products Liability Litigation*, 495 F. Supp. 1188 (D. Colo. 1980). In practice then, this means that even though multifactorial, Dr. Blond must opine to a reasonable degree of

medical certainty that DQ's complicated medical chain of events would not have led to his alleged injury absent Trasylol administration. Stated another way, Dr. Blond must establish that Trasylol's contribution to the injury is more than a mere possibility or speculation. *Lamme v Ortega*, 267 P.2d 115 (Colo. 1954). A review of the evidence leads me to the conclusion that Dr. Blond's opinions fall short of this standard, and by his own admission, do not establish to a reliable degree of medical certainty that Trasylol was a "but-for" cause of DQ's injuries. He testified that it is possible that even without Trasylol, DQ could have had the same postoperative course, and the same temporary rise in his creatinine level. (*See* DEFEX P at 160-169).

Even if Dr. Blond's opinion could be construed as satisfying the causation standard, I find that it is due to be excluded for failure to engage in reliable methodology. In support of his opinion that DQ's injury was multi-factorial, and that Trasylol was a significant contributing factor, Dr. Blonde explains as follows:

> Quinones developed acute renal injury which in all likelihood is multifactorial in origin. Renal function was not at baseline at the time of surgery. The mechanism of this was not ascertained, but in view of his recovery, most likely factors would include volume depletion related to diuretics, or blood pressure medication. including the use in combination of an ACE inhibitor and angiotensin receptor blocker, Cardiopulmonary bypass surgery and aortic cross-clamping would be contributing factors, including a hypotensive reaction to protamine, vasopressor infusion and transient ventricular fibrillation. Aprotinin was used as an antifibrinolytic agent, now recognized to be a nephrotoxin, and associated with acute kidney injury. Despite these events, renal function initially appeared stable in the immediate post-operative period. Additional hypotension and respiratory failure with hypoxia developed on postoperative day #2 with evidence of acute kidney injury, Intubation occurred prior to any respiratory arrest. There was no evidence of severe acidosis. Sepsis was suspected, although no pathogen was cultured nor source of infection ascertained. Mr. Quinones had low-grade fever, but did not show evidence of

> leukocytosis during this episode. In all medical certainty, aprotinin was a major significant contributing factor to the development of a kidney injury. (Blond Rep. at 4).

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.). "[T]he application of the *Daubert* factors is germane to evaluating whether the expert is a hired gun or a person whose opinion in the courtroom will withstand the same scrutiny that it would among his professional peers." *Watkins v. Telsmith, Inc.*, 121 F.3d 984, 991 (5th Cir.1997).

I first note that Dr. Blond testified that many of the co-factors he enumerates, such as extended bypass time, previous kidney disease, hypotension, could have led to a transient rise in DQ's creatinine level without introduction of Trasylol. Although he does attempt to explain why he does not believe any of them, by themselves, was responsible for the renal injury, I note that there were several factors that he ignored in making his conclusion. For example, he notes that DQ's creatinine level was elevated at the time of his July 9 surgery, but explains that he had been unable to ascertain the basis for this elevation. He then explains away the role DQ's complicated surgery and extended bypass time played in his renal injury, by stating that he

> A serum Cr at the time of admission was elevated from his baseline from his prior records but returned to baseline at the time of discharge. The etiology of this was not evaluated at the time of admission, but was clearly transient in view of his recovery to a

> serum Cr of 1.4 mg/dL, compatible with his previous baseline from the month prior.

This assumption is circular and therefor flawed for the following reasons. First, in making this determination, Dr. Blond assumes that DQ's "baseline" creatinine is approximately 1.1 as evidenced by his 1.1 level on the first post-operative date following his right carotid endarterectomy on June 10, 2003. Thirty days later, DQ's admission creatinine was 1.8. Dr. Blond attributes this elevated level to factors including "volume depletion related to diuretics, or blood pressure medication, including the use in combination of an ACE inhibitor and agiotensin receptor blocker." No where in that list of factors relating to DQ's deviation from his creatinine baseline, does he refer to either of the June 2003 surgeries as the source of DQ's renal injury. Trasylol was not used in either previous surgery. DQ had a heart attack during the first procedure, and yet, despite Dr. Blond's testimony that anesthesia and heart attacks alone could cause renal injury, he fails to even consider the rise in DQ's serum creatinine between the procedures and the July, 2009 operation could have been a result of the one or both of the two procedures.

Further, each admission report states that DQ was taking several medications, some of which may have nephrotoxic capabilities. Dr. Blond's report either makes short shrift of DQ's medications or ignores them completely. In fact, as discussed *supra* note 19, one of the medications, Avandia, is the subject of another product liability litigation where plaintiffs are making claims of, inter alia, renal injury.[26] Additionally, Mr. Quinones' July operative report lists

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[26] I also find that because DQ has submitted a claim in the Avandia case, and because at one point in time DQ allegedly attributed his renal injury to the drug, Dr. Blond should have, as an expert in his field, at a minimum addressed the role, if any, that Avandia could have played in DQ's alleged renal injury.

his "significant comorbities in the way of "chronic renal insufficiency. . . ." Dr. Blond's *ipse dixit* claim that DQ's baseline creatinine level of 1.8 was not "at baseline at the time of his surgery," does not, without at least attempting to ascertain what DQ's true baseline level was, make it a true statement, nor does it represent the level of intellectual rigor contemplated by *Daubert.*

As with another case in this MDL, I find that the validity of DQ's pre-surgery creatinine level and degree of chronic renal failure would appear to be critical to assessing his post-operative spike in renal deficiency. Dr. Blond testified that DQ would have had a "moderate to high risk" of post-operative renal failure, with or without administration of Trasylol. (DEFEX D at 64). He further testified, after questioning into the myriad of risk factors DQ possessed prior to his July surgery, that he would be speculating if he said "within a reasonable degree of medical certainty that Mr. Quinones would not have had an increase in serum creatinine postoperatively if he had not received Trasylol." *Id.* at 169. Additionally, as with the physician in *Guinn*, Dr. Blond only "reviewed selections from [DQ's] medical records prepared by his attorneys. While it is common place for attorneys to furnish medical records to experts for their review, this does not mean that a court is bound to accept an expert's opinion based on incomplete and selective evidence. Not only does this cast doubt on an expert's 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). *See also*, *McDowell v. Brown*, 392 F. 3d 1283, 1299 (11th Cir. 2004) (holding that where an expert's opinion is "imprecise" and "unspecific," . . . [it lacks] reliability, [and] they fail to assist the trier of fact in any meaningful way.").

For these reasons, I find that Dr. Blond's causations opinions are not based on a reliable

methodology and will not assist the trier of fact. They are therefore inadmissible.

Additionally, Dr. Blond's opinion as to mortality is irrelevant and not helpful to the trier of fact. Not only is DQ alive and well, there is no record testimony that he faces an increased risk of death for any reason other than his long and complicated medical history. Allowing Dr. Blond to opine that his longevity is endangered by the same drug which cannot be legally associated with DQ's temporary renal injury would only serve to confuse a jury.

Without reliable expert testimony, the fact that a patient experiences a brief medical complication, one he both knew about consented to, and one which fully resolved, required no traumatic long-term therapy, or had any ascertainable effects, falls far short of an adequate "injury" for purposes of products liability recovery.

C. Failure to Warn

Bayer next asserts that Plaintiffs' failure to warn claim is precluded by Colorado's Learned Intermediary Doctrine. Under Colorado law, prescription pharmaceuticals are considered inherently dangerous and courts throughout the Country routinely find that "where prescription drugs are concerned, the manufacturers duty to warn has be limited to advise the prescribing physician of any potential dangers that may result from the drug's use." *O'Connell v. Biomet, Inc.*, 250 P. 2d 1278, 1281 (Colo. App. 2010) (addressing issue of first impression to any Colorado Appellate court, and determining that Learned Intermediary Doctrine is applicable to actions for drug products liability failure to warn claims); *Caveny v. CIBA-GEIGY Corp.*, 818 F. Supp. 1404 (D. Colo. 1992). Under the Doctrine, a "warning is adequate when it explains to the physician the risk that the plaintiff asserts is associated with the drug and that caused the injury, . . . [and it] is the responsibility of the physician as a learned intermediary to assess the risks and benefits of a

particular course of treatment." *Id.*

I find it unnecessary to decide the applicability of the Learned Intermediary Doctrine to Plaintiffs' Failure to Warn claim because this claim is due to be dismissed for the same reasons discussed relating to Plaintiffs' product liability claims.[27] Specifically, the Failure to Warn claim is due to be dismissed due to lack of any credible evidence that Trasylol caused DQ any injury. It is only logical that if a drug can not be attributable to a specific injury, whether the drug warned about that specific injury is irrelevant. Accordingly, Plaintiffs failure to warn claim is due to be dismissed.

D. Consumer and Common Law Fraud

Bayer correctly asserts that Plaintiffs fraud claims are due to be dismissed for the same reasons set forth in numerous previous summary judgment orders. 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

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[27] I additionally note that the Plaintiffs present no evidence whatsoever that the doctor who made the decision to use Trasylol, Dr. Nene (See DEFEX I at 3 (Sederberg Dep.) and DEFEX J at 3 (Propp Dep.)) would not have made the decision to use Trasylol with a different warning. As noted *supra*, there is no evidence that Dr. Nene was ever deposed.

specificity).

Plaintiffs did not respond to these Orders. Plaintiffs' fraud and misrepresentation claims were accordingly dismissed in part allowing them thirty days to provide specific allegations of fraud and reliance. There is no record evidence that Plaintiffs relied on specific misleading statements that caused the use of Trasylol in the decedent's case, nor do they support their broad claims of fraud with any evidence of reliance, an essential element of these claims. *See Green v. Thomas.*, 662 P.2d 491, 495 (Colo. App. 1982) (reliance is an essential element for fraud claims in Colorado). Accordingly, Plaintiff's misrepresentation and fraud claims are due to be dismissed in full.

However, Bayer's assertion that Plaintiffs consumer fraud claim is due to be dismissed under this premise is misguided. A plaintiff asserting a claim under Colorado's consumer protection statute must establish:

> (1) that the defendant engaged in an unfair or deceptive trade practice; (2) that the challenged practice occurred in the course of defendant's business . . .; (3) that it significantly impacts the public as actual or potential consumers of the defendant's goods. . . that the plaintiff suffered the injury in fact to a legally protected interest; and (5) that the challenged practice *caused* the plaintiff's injury.

Crow v. Tull, 126 P.3d 196, 201 (Colo. 2006)(quoting *Rhino Linings USA, Inc. v. Rocky Mountain Rhino Lining, Inc.*, 62 P.3d 142, 146-47 (Colo. 2003)) (emphasis added). I find that the Consumer Protection claim is due to be dismissed for the same lack of causation applicable to Plaintiffs' products liability and failure to warn claims.

E. Unjust Enrichment, Loss of Consortium, and Punitive Damages

Summary judgment is granted on Plaintiffs' Unjust Enrichment, Loss of Consortium, and

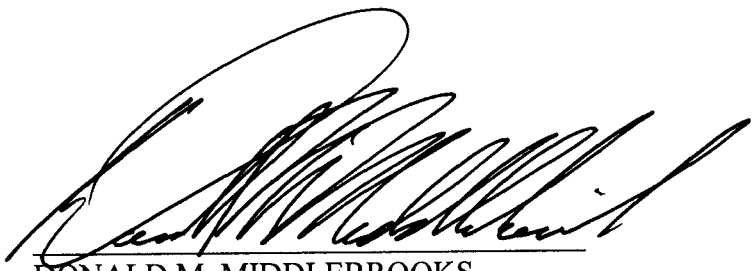
Punitive Damages claims because they are derivative of their underlying substantive claims each of which have failed. *See e.g., Elgin v. Bartlett*, 994 P. 2d 411, 417 (Colo. 1999) ("Claims for derivative damages turn upon the right of the injured person to recover and are subject to the same defenses available to the underlying claims.").

IV. Conclusion

Accordingly, for the reasons set forth above, it is hereby

ORDERED AND ADJUDGED that the Motion be **GRANTED.** Bayer's Motion for Summary Judgment (DE 13259 in 08-1928 & DE 53 in 09-80682) as to each Count of the Complaint is GRANTED.

DONE and ORDERED, in Chambers, at West Palm Beach, Florida this 22 day of March, 2013.



DONALD M. MIDDLEBROOKS
UNITED STATES DISTRICT JUDGE

Copies to: Counsel of Record