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:

***Alan Miller, et al. v. Bayer Corp., et al.*,**
Case No. 09-81262
_____/

ORDER ON MOTION FOR SUMMARY JUDGMENT

THIS CAUSE comes before the Court upon Defendants' (hereinafter, collectively, "Bayer's") Motion for Summary Judgment ("Motion") (DE 12395 in 08-1928 & DE 33 in 09-81262). Plaintiffs filed a Response (DE 12568 in 08-1928 & DE 35 in 09-81262), to which Bayer replied (12660 in 08-1928 & DE 36 in 09-81262). 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 are husband and wife, Alan and Vicki Miller. They are and were at

[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.

all times relevant to the facts herein, citizens of the State of Illinois.[2] On November 3, 2004, Mr. Miller ("AM"), signed an informed consent which enumerated the potential risks and benefits of cardiac surgery including: "infection, bleeding, heart damage, stroke, kidney damage, or even death." (DEFEX B at 33-34). He then underwent double coronary artery bypass graft ("CABG") and aortic valve replacement surgery at St. Johns Hospital in Springfield, Illinois. *Id.* Upon admission, Mr. Miller's creatinine level was 1.5.[3] *Id.* At the time of his surgery, he was a former smoker with a lengthy medical history which included hypertension, hyper lipidemia, chronic renal insuffiency, and coronary artery disease. (DEFEX B at 30). His surgeon was William S. Stevens, M.D. During his surgery, Dr. Stevens performed a CABG and an aortic valve replacement, and he used Trasylol during the surgery. *Id.* at 20. During the surgery, Mr. Miller was on cardiopulmonary bypass for a total of 116 minutes, with an aortic cross-clamp time of 94 minutes. *Id.*

After his surgery, Mr. Miller experienced a "small acute left hemispheric stroke . . . probably due to a small cardiac embolus." *Id.* at 40 (consult of David Gelber, M.D.). His neurological deficits from the stroke were "relatively mild [and] his overall neurological prognosis [was] excellent." *Id.* He also experienced a transient rise in his serum creatinine which peaked at 2.4 on postoperative day 8 and which returned to nearly his pre-surgery baseline by his discharge date without any need for

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[2] (Compl. ¶ 2; DEFEX A at 4:18-25, 6:22-7:3, 49: 14-19).

[3] "Creatinine is a waste product formed by the breakdown of a substance (creatinine) 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.

Accordingly, serum creatinine level is used as a measure of renal function. When its value is elevated, renal dysfunction is indicated. For Creatinine, a normal result falls within the range of 0.7-1.2. The numbers represent the value of mg/dL. Mr. Miller's creatinine level of 1.5 indicates he was suffering from some renal impairment upon admission.

dialysis.[4] it is undisputed that those levels have remained at his approximate baseline level since that time.[5] (DEFEX B at 20, 28). Mr. Miller was not deposed in this case based on representations that he was physically unable to testify, and with agreement that he would not appear at any trial of this matter due to his stroke-related condition. (DEFEX A at 12 -13, 124:6-20).

On August 31, 2009, the Plaintiffs filed the instant case alleging claims for: (I) Strict Liability - Failure to Warn; (II) Strict Liability - 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; (XII) Survival Action; (XIII) Gross Negligence/Malice; and (XIV) Punitive Damages.

Bayer argues that summary judgment should be granted as to each of Plaintiffs' claims because (1) under Illinois law, causation is an element of each of Plaintiff's claims, and Plaintiffs' expert's causation testimony is inadmissible;[6] (2) even if Plaintiffs' expert's testimony were admissible, their claims fail because they are seeking damages for Mr. Miller's stroke, and their expert is not qualified to render an opinion as to the cause of the stroke; (3) Plaintiffs' fraud claims are due to be dismissed for the additional reason that they fail to plead fraud with specificity as required by the Court's earlier Orders; and (4) Plaintiffs' derivative claims must fail where their

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[4] Mr. Miller's admission creatines were as follows: 1.5 on11/2/04; 1.7 on11/5/04; 1.9 on 11/6/04; 2.0 on 11/8/04; 2.0 on 11/9/04; 2.1 on 11/10/04; 2.4 on11/11/04; 2.1 on 11/12/04;1.9 on 11/13/04; 1.57 on 11/14/04; and 1.7 on 11/16/04. DEFEX B at 23-28.

[5] The record reflects that Mr. Miller's creatinine levels have continued to improve after his surgery. His levels were 1.4 on 1/3/07 and 1.36 on 6/9/08. Mr. Miller's most recent creatinine level was 1.3. Under the analyzing laboratory's statistical range, a creatinine level of 1.3 is within normal limits, which would reflect an improvement in Mr. Miller's renal function since his surgery. *See* DEFEX B at 20.

[6] It is undisputed that the substantive law of the State of Illinois applies to Plaintiffs' claims.

substantive claims are dismissed. (DE 33 at 2).

Plaintiffs argue that summary judgment should be denied because (1) Plaintiffs are not seeking damages due to Mr. Miller's stroke, but for his "acute renal failure"; (2) Dr. Blond is qualified to testify; and (3) "the temporal connection between Mr. Miller's acute renal failure and the injection of Trasylol, together with the absence of renal disease or issues prior to the surgery and the fact that Trasylol is known to be a nephrotoxic agent, standing alone leads to the conclusion that Trasylol was a substantial contributing factor in causing Mr. Miller's injuries and his increased risk of mortality from the use of Trasylol." (DE 35 at 1-2).

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."[7] FED.R.CIV.P. 56(c). The purpose of 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,

[7] 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.*

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)); *Modrowski v. Pigatto*; 712 F.3d 1166 (7th Cir. 2013). 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); *Lindemann v. Mobil Oil Corp.*, 141 F.3d 290, 293 (7th Cir. 1998). 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. at 324; *Modrowski*, 712 F.3d at 1167 . "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]."[8] *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.

[8] 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).

III. Analysis

A. Causation

Bayer asserts that each of Plaintiffs' claims are due to be dismissed due to a lack of causation – a required element of each claim. Plaintiffs' claims for fraud and consumer fraud are due to be dismissed for the additional reason that they are barred by this Court's previous orders. Lastly, Plaintiffs' unjust enrichment and punitive damages claims are derivative and must fail where the substantive counts they are premised upon are dismissed.[9] With each of the relevant legal standards set forth above in mind, I turn first to Bayers' causation argument.

Specifically, Bayer asserts Plaintiffs' claims require expert testimony to establish specific causation, and Plaintiff lacks any competent evidence that Trasylol caused Mr. Miller's injuries.[10] (DE 33 at 2). Expert medical opinion evidence is usually required to show the cause of an injury or disease because the medical effect on the human system of the infliction of injuries is generally not within the sphere of the "common knowledge of the lay person." *See Fuesting v. Zimmer, Inc.*, 421 F.3d 528, 536 (7th Cir. 2005), *rev'd on other grounds by Fuesting v. Zimmer, Inc.*, 448 F.3d 936 (7th Cir. 2006)*; Ancho v. Pentek Corp.*, 157 F.3d 512, 519 (7th Cir. 1998); *Goffman v. Gross*, 59 F.3d 668, 672 (7th Cir. 1995);*Wallace v. McGlothan*, 606 F.3d 410, 420 (7th Cir. 2010). Claims for negligence, strict liability, breach of express warranty, breach of implied warranty, fraudulent misrepresentation, fraudulent concealment, violation of consumer protection statutes, wrongful death, and loss of companionship, as well as a survival claim" must fail where a plaintiff has no

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[9] Plaintiffs have withdrawn their loss of consortium claim in Count X and their survival claim in Count XII, and so no further discussion as to those two claims is warranted.

[10] Mr. Miller's treating physician has indicated that he does not believe that Mr. Miller had renal failure and that if he did, then Trasylol likely did not cause it because a "transient increase in serum creatinine is a fairly common postoperative (CABG) issue." (See DEFEX C at 11-12).

evidence of specific causation.[11] *See Schrott v. Bristol-Myers Squibb Co.*, 403 F.3d 940 (7th Cir. 2005). To avoid summary judgment, the Plaintiffs must come forward with evidence that would allow a reasonable jury to find causation. *Id.* Causation must be established by provable facts; it cannot be based on guess, conjecture, surmise, possibility, speculation, or mere allegation. *See id.*"

Expertise is a rational process and a rational process implies expressed reasons for judgment." *Mid-State Fertilizer Co. v. Exchange Nat. Bank of Chicago*, 877 F.2d 1333, 1339 (7th Cir. 1989). "An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process." *Id.* (citing to *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 829-32 (D.C. Cir. 1988) as holding that "an expert's declaration, full of assertion but empty of facts and reasons, won't get a case past a motion for summary judgment, for the judge must 'look behind the expert's' ultimate conclusion . . . and analyze the adequacy of its foundation."). According to Bayer, Plaintiffs' only causation expert's testimony is based on speculation and conjecture, and is therefore 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) *Porter v. Whitehall Lab., Inc.*, 9 F.3d 607 (7th Cir. 1993). The party seeking to have the expert testimony admitted bears the burden of demonstrating its admissibility by a preponderance of proof. *See Porter*, 9 F.3d at

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[11] These represent Counts I, II, III, IV, V, VI, VII, VIII, X, XI, XII, and XIII. *See, e.g.*, *Schrott v. Bristol-Myers Squibb Co.*, 403 F.3d 940, 944 (7th Cir. 2005) (affirming dismissal of a plaintiff's products liability, negligence, failure to warn, Illinois consumer protection statute, and warranty claims due to lack of any evidence of causation, and citing to citing to *Lewis v. Lead Industries Ass'n., Inc.*, 793 N.E. 2d 869, 873 (Ill. 2003) which held that "[a]n essential element of a plaintiff's cause of action for any tort is that there be a proximate causal relationship between the act or omission of the defendant and the damages which the plaintiff has suffered.").

611. *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.[12] 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

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[12] 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).

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.*

Both the Eleventh and Seventh Circuits, when evaluating the admissibility of an expert's testimony under Rule 702, consider 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); *Clark v. Takata Corp.*, 192 F.3d 750, 757 (7th Cir. 1999). 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." *American Honda Motor Co., Inc. v. Allen*, 600 F.3d 813, 818 (7th Cir. 2010) (quoting *Kumho*, 526 U.S. at 152); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1255 (11th Cir. 2005) (same); *Fuesting*, 421 F.3d at 536; *Clark*, 192 F.3d at 757.

ii. Parties' Arguments

Plaintiffs proffer Dr. Carl J. Blond, M.D., Ph.D., as their specific causation[13] 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.

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, Dr. Blond's report provides as follows:

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[13] Specific causation refers to the issue of whether the plaintiff has demonstrated that the substance actually caused the injury in her 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.

BRIEF NARRATIVE OF EVENTS

Mr. Allen Miller was a 65-year-old white male admitted 11/02/2004 to St. John's Hospital, He had a known history of aortic valve stenosis, and coronary artery disease. An echocardiogram revealed critical aortic stenosis, with a valve area of 0.9 cm2, and a valve gradient of 65 mm Hg. Subsequently, the patient had been asymptomatic. Cardiac catheterization also confirmed two-vessel coronary artery disease. This included a 70% obtuse marginal stenosis, and a 60% right coronary stenosis, Mr, Miller had a past history of hypertension, and hyperlipidemia. He had a remote history of tobacco use, Surgical history included a prior appendectomy and tonsillectomy, as well as a vasectomy. Medications at the time of admission included baby aspirin, Lipitor, and lisinopril, A creatinine prior to surgery was 1.5 mg/dL. Urinalysis was completely normal. Mr. Miller underwent surgery performed by William Stevens, M.D., on 11/03/2004. This included an aortic valve replacement with a St, Jude's 23 master series valve, coronary artery bypass x2, saphenous vein to obtuse marginal, and saphenous vein to right coronary artery. Moderate hypothermia was incorporated. Anesthetic agents included Forane, Brevital, Versed, etomidate, and Sufenta. Aprotinin was used as an antifibrinolytic agent. Ancef was given prophylactically, Blood pressure was well maintained pre-bypass, and was initially elevated in the 180 mm Hg range, and dropped to the 100 systolic prior to cardiopulmonary bypass.

Oxygenation was well maintained, Post-bypass systolic blood pressure ranged from 110-120 mm Hg systolic. Total bypass time was 116 minutes, with cross-clamp time of 94 minutes. Estimated blood loss was 750 cc, 2500 cc of crystalloid were infused, The patient was weaned from bypass without difficulty. The patient tolerated the procedure well and was transferred to the recovery room in stable condition, On postoperative day #1, the patient appeared to be doing well. Blood pressure was stable at 132/60 mm Fig and CV was 12 mm Hg. Cardiac index was recorded at 3.0 liters per minute, Urine output was nonoliguric, and the plan was to diurese for hypervolemia, The serum creatinine had risen to 1.7 mg/dL later that day. The patient was noted to have dysarthria, and a right facial droop and hemiparesis of the right side. A CT scan revealed a small right hemispheric infarction. Carotid ultrasound showed no significant stenosis. Mr. Miller was anticoagulated at the time of the stroke, He had transient atrial fibrillation converted chemically, The patient's serum creatinine continued to rise slowly, It peaked on postoperative day #6 at 2.4 mg/dL. The patient gradually recovered from his stroke.

Postoperatively he maintained in hemodynamic stability. The patient was discharged with a serum creatinine of 1.7 mg/dL on postoperative day #14, and was transferred to rehabilitation, Later records revealed a serum creatinine of 1.3 mg/dL on 02/05/2009.

MEDICAL OPINION REGARDING MR. ALLEN MILLER

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 hernolysis 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, A large number of risk factors have been identified in the setting of cardiopulmonary bypass surgery for acute kidney injury. This is of particular importance, as the presence of acute kidney injury in the setting of cardiopulmonary bypass surgery will greatly increase acute and chronic mortality. Significant long-term risk for mortality may persist independent of recovery of kidney function. Many of these risk factors are interrelated, and have markedly variable degrees of severity, Some are extremely frequent in the population undergoing cardiopulmonary bypass surgery, such as hypertension. The presence of advanced age, and prior chronic kidney disease are prominent risks. Other risk factors identified are female sex, congestive heart failure, COPD, tobaccoism, ASPVD, pulmonary hypertension, diabetes, and anemia. Recent contrast exposure, as well as urgent surgery are significant risk factors. Prolonged and complex surgery,

and prolonged bypass times greater than 2 hours, as well as blood transfusions are additional risks. The Acute Kidney Injury Network has devised a simple classification system for staging acute kidney injury, ranging from stage I (mild, with an increase in serum creatinine of 0.3 mg/dL, or increase equal to 150-200%), stage II (200-300% baseline), and stage III, severe (requiring renal replacement therapy or 300%). Mr. Allen suffered a stage I (AKIN criteria, mild) acute kidney injury, nonoliguric associated with his cardiopulmonary bypass surgery. Risk factors that predispose Mr. Miller to acute kidney injury included probable stage 2-3 chronic kidney disease, hypertension, and complex surgery including valvular and coronary bypass procedures. The surgery appeared to be well tolerated, without significant hypotension or any technical problems. Operative time was not prolonged, anesthetic agents used are not associated with nephrotoxicity. Aprotinin was used as an antifibrinolytic agent, now associated with nephrotoxicity. There was no exposure to nonsteroidal drugs postoperatively, Mr. Miller was hemodynamically stable, cardiac function was well maintained, and there was no evidence of infection, He would be considered a moderate risk for acute kidney injury. The majority of patients who undergo cardiopulmonary bypass surgery do not develop an acute kidney injury, In the case of Mr. Miller, causation was likely multifactorial, Significant contributing factors included cardiopulmonary bypass surgery, associated blood pressure fluctuations, and the use of aprotinin, as an antifibrinolytic agent. Aprotinin, in all medical certainty, was a significant contributing factor. Aprotinin is a nonspecific serine protease inhibitor, which was used to attenuate inflammatory and antifibrinolytic pathways that are upregulated during cardiopulmonary bypass surgery. This occurs through a number of mediators, including kallikrein, plasmin, and thrombin. The expert report of P, Gary Toback, M.D., Ph.D. sets out in detail the general manner in which aprotinin effects renal function, as well as the mechanisms of renal injury. Aprotinin was thought to cause renal injury to renal tubular cells by a number of mechanisms, including microthrombosis, inhibition of vasodilatory prostaglandins, and direct toxicity to renal tubular cells. There is a large volume of medical and scientific literature regarding this association with acute kidney injury with aprotinin, as listed in my attachment, Additionally, aprotinin has been associated with increased mortality in cardiopulmonary bypass surgery, when compared to other antifibrinolytic agents, such as aminocaproic acid. The occurrence of acute kidney injury in patients undergoing cardiopulmonary bypass surgery is associated with a greatly increased morbidity and mortality rate, The increased risk of mortality persists for many years, even

> with resolution of the acute kidney injury, I have listed a number of literature references in my attachment regarding this. If physicians caring for Mr. Miller had been aware of this association, in all certainty, this drug would not have been used.
>
> I reserve the right to amend the medical opinions expressed in this report if additional information is provided to me, The opinions expressed in this report are based on reasonable medical certainty. Please feel free to contact me if you have any questions regarding this report.

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

In summary, Dr. Blond would opine that "in all medical certainty causation [of Mr. Miller's renal failure] was likely multifactorial, [sic] Significant contributing factors included cardiopulmonary bypass surgery, associated blood pressure fluctuations, and the use of aprotinin as an antifibrinolytic agent. Aprotinin, in all medical certainty, was a significant contributing factor." Additionally "in all certainty," the physicians caring for Mr. Miller "would not have used" this drug had they been aware of the association of mortality and acute kidney injury. *Id.*[14]

Bayer argues that Dr. Blond's opinions should be excluded as unreliable and unhelpful to the trier of fact because: (a) he is unqualified to render any opinion regarding Mr. Miller's stroke; and (2) his opinions as to renal injury result from a flawed methodology.

Plaintiffs' response first focuses on Dr. Blond's qualifications to testify as an expert. As Dr. Blond's qualifications to testify as an expert in general have not been challenged, no discussion is required. Plaintiff next asserts that Mrs. Miller's testimony that she and Mr. Miller are seeking damages only related to Mr. Miller's stroke, and are not seeking damages related to Mr. Miller's

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[14] 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.

renal failure should be disregarded. Plaintiffs lastly assert that as for Mr. Miller's renal injury, Dr. Blond conducted a legally sufficient differential diagnosis because "[t]he temporal connection between Mr. Miller's acute renal failure and the injection of Trasylol, together with the absence of renal disease or issues prior to the surgery and the fact that Trasylol is known to be a nephrotoxic agent, standing alone leads to the reasonable conclusion that Trasylol was a substantial contributing factor in causing Mr. Miller's injuries and his increased risk of mortality." (DE 35 at 2) (emphasis added).

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

iii. Discussion

I must first address Bayers' argument as it relates to Mr. Miller's stroke. When deposed, Mrs. Miller testified that she and Mr. Miller (who was unable to testify, and so has provided no position on this or any other point) were seeking damages only for Mr. Miller's post-operative stroke. (DEFEX A at 7 (13:4-9), 8 (21:14-20), 11 (33:14-21), 13 (37:4-9), 18 (98:1-5). She also testified that she was not aware of whether Mr. Miller had ever had any renal problems. *Id.* at 19 (101:3-8). Defendants assert that Dr. Blond, as a board certified nephrologist, is unqualified to render an opinion as to the cause of Mr. Miller's stroke. Plaintiffs' counsel asserts that the complaint, medical records, and other filings establish that Plaintiffs are seeking compensation for Mr. Miller's renal injury, and that Mrs. Miller's testimony to the contrary should be disregarded. The issue, however, is Dr. Blond's competence to testify as to Trasylol's role in causing Mr. Miller's stroke. As Dr. Blond in neither his report or his deposition proffers such an opinion, I find no need

for discussion.[15] I turn now to Dr. Blond's opinion as to Trasylol and Mr. Miller which utilizes a differential diagnosis in determining that Mr. Miller suffered renal failure substantially due to administration of Trasylol.

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); *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007). 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; *Ervin*, 492 F.3d at 904. 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). *See also Ervin v. Johnson & Johnson,* 492 F.3d 901, 903 (7th Cir. 2007); *Meyers v. Illinois Central R. Co.*, 829 F.3d 639, 644 (7th Cir. 2010) (It requires an expert to "rule in all the potential causes of a patient's ailment and

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[15] I do note however, that "[j]ust as a qualified and board certified hear surgeon does not possess sufficient knowledge of orthopaedic medicine to render an expert opinion on spine surgery," a board certified nephrologist does not possess sufficient knowledge of neurology and cardiac surgery to render an expert opinion on stroke. *Ancho v. Pentek Corp.*, 157 F.3d 512, 519 (7th Cir. 1998).

then by systematically ruling out causes that would not apply to the patient, the physician arrives at what is the likely cause of the ailment." *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. *Ervin*, 492 F.3d at 904; *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); *Ervin*, 492 F.3d at 904. 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 Plaintiffs' 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 at 265; *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999).

"Although a reliable differential diagnosis need not rule out all possible alternative causes, it must at least consider other factors that could have been the sole cause of the plaintiff's injury. . . . [A] 'differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.'" *Guinn v. Astrazeneca Pharms. LP*, 602 F.3d 1245, 1253 (11th Cir. 2010) (internal citations omitted). "[A]n expert must provide a reasonable explanation as to why he or she has concluded that [any alternative cause

suggested by the defense] was not the sole cause of the plaintiff's injury." *Id*. (internal citations and quotations omitted). The "'temporal connection between exposure to chemicals and an onset of symptoms, standing alone, is entitled to little weight in determining causation.'" *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1254 (11th Cir. 2005) (internal citations omitted). *Accord Happel v. Walmart Stores, Inc.*, 602 F.3d 820 (7th Cir. 2010) (relying on "past experience and the temporal proximity of [a patient's symptoms] . . . does not an expert opinion make."); *Ervin*, 492 F.3d at 904. Temporal proximity is "especially unreliable" where conditions independent of exposure to the drug could have been the sole cause of the plaintiff's injury, and the expert fails to explain the relative contribution of the drug to the injury. *Id.; Guinn*, 602 F.3d at 1254-55 (excluding differential diagnosis opinion where evidence "appeared to equally indicate that Guinn may have already developed diabetes before ever taking Seroquel," Guinn's numerous other risk factors for diabetes put her at high risk for diabetes, and opinion failed to explain Seroquel's relative contribution to her diabetes).

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); *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996). 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 Fuesting v. Zimmer, Inc.*, 421 F.3d 528, 536 (7th Cir. 2005), *rev'd on other grounds by Fuesting v. Zimmer, Inc.*, 448 F.3d 936 (7th Cir. 2006); *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)). Where an expert testifies that a particular injury "could have numerous causes and . . . simply picks the cause that is most advantageous to [a plaintiff's] claim, . . . [such testimony] is not admissible." *Viterbo v. Dow Chemical Co.*, 826 F.2d 420, 423 (5th Cir. 1987). *See also In re Paoli R.R. Yard PCB Lit.*, 35 F.3d 717, 763-65 (3d Cir. 1994) .

The main flaw in Dr. Blond's methodology is his failure to account for or appropriately address numerous risk factors at both the rule in and rule out stage. Factors which either alone or in combination could explain Mr. Miller's alleged renal injury. These factors include, but are not limited to: pressure stabilizing medications; extended pre-surgical and post-operative hypertension; and pre-surgical chronic renal failure. Even to those factors which Dr. Blond did rule in, he either gives them short shrift at the rule-out stage, or dismisses them without discussion.

In his report Dr. Blond states that many risk factors are "extremely frequent in the general population undergoing cardiopulmonary bypass surgery, such as hypertension. . . , advanced age, . . . , prior chronic kidney disease . . . , female sex, congestive heart failure, CODA, tobaccoism, ASPVD,[16] pulmonary hypertension, diabetes . . . , anemia . . . , recent contrast exposure, [and] urgent surgery." "Prolonged and complex surgery, and prolonged bypass times greater than 2 hours, as well as blood transfusions are additional risks." In explaining the mechanism for how these factors could result in renal injury, Dr. Blond's report stated that

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[16] ASPVD is an acronym for Atherosclerotic Peripheral Vascular Disease. Dictionary of Medical Abbreviations. Found at http://www.medicabbreviations.com/abbreviations/21402.html

> [t]he 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 proinflammatory 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.

As for Mr. Miller's individual specific risk factors, Dr Blond stated that

> Risk factors that predispose Mr. Miller to acute kidney injury included probable stage 2-3 chronic kidney disease, hypertension, and complex surgery including valvular and coronary bypass procedures. The surgery appeared to be well tolerated, without significant hypotension or any technical problems. Operative time was not prolonged, anesthetic agents used are not associated with nephrotoxicity. Aprotinin was used as an antifibrinolytic agent, now associated with nephrotoxicity. There was no exposure to nonsteroidal drugs postoperatively, Mr. Miller was hemodynamically stable, cardiac function was well maintained, and there was no evidence of infection, He would be considered a moderate risk for acute kidney injury. The majority of patients who undergo cardiopulmonary bypass surgery do not develop an acute kidney injury, In the case of Mr. Miller, causation was likely multifactorial, Significant contributing factors included cardiopulmonary bypass surgery, associated blood pressure fluctuations, and the use of aprotinin, as an antifibrinolytic agent. Aprotinin, in all medical certainty, was a significant contributing factor.

Dr. Blond in his neither his report nor deposition provides any explanation for why he concluded that Mr. Miller's various risk factors other than exposure to Trasylol were not the sole cause of his injuries. In fact, during his deposition, he identified several additional risk factors for Mr. Miller that he had failed to consider in rendering his opinion, and further testified that many of those risk factors, either alone or in concert, could have caused Mr. Miller's transient creatinine rise. (*See* DEFEX D at 10-11). These risk factors included: the surgery; the associated fluctuations in Mr.

Miller's blood pressure; a previously unconsidered transfusion, a previously unconsidered hematoma, a previously unconsidered twenty-pound weight loss resulting from post-surgical diuresis, post-operative congestive heart failure, diastolic dysfunction, and Mr. Miller's extended history of chronic renal disease and hypertension. Dr. Blond specifically testified that Mr. Miller, without Trasylol, "could have had the same postoperative course."

In this case, Dr. Blond concedes that Trasylol was not the sole cause of Mr. Miller's "injury," and in fact, "there's no way [to] determine that one factor had more of an effect than the others. . . . the theory is multiple hits, that the kidney can take one factor and tolerate it well but the more factors involved, the more likely you're going to have an injury." (DEFEX B at 38). In other words, Dr. Blond's opinion is that despite the multiple hits to Mr. Miller's kidneys from other factors, Trasylol somehow tipped the scales causing his renal injury.

After sorting through Dr. Blond's opinions and the Plaintiffs' response to Defendants' Motion, I find that Dr. Blond improperly relies on temporal proximity. As stated previously, the "temporal connection between exposure to chemicals and an onset of symptoms, standing alone, is entitled to little weight in determining causation." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1254 (11th Cir. 2005) (internal citations omitted)*; Tucker v. SmithKline Beecham Corp.*, 701 F.Supp. 2d 1040; *Ervin*, 492 F.3d at 904. Temporal proximity is "especially unreliable" in circumstances such as this where a patient's conditions independent of exposure to the drug could have been the sole cause of the plaintiff's injury, and the expert fails to explain the relative contribution of the drug to the injury. *See Guinn v. Astrazeneca Pharmaceuticals LP*, 602 F.3d 145, 153 (11th Cir. 2010); *Porter*, 791 F. Supp. 2d at 1349. As with the expert in *Guinn*, I find exclusion is warranted because the evidence "appear[s] to equally indicate that [Mr. Miller] may have [developed renal injury

either] . . . without ever taking [Trasylol]." *Id.* Also as with *Guinn*, Mr. Miller had numerous other risk factors which placed him at a high risk for renal failure, and Dr. Blond's opinion fails to explain Trasylol's relative contribution to his transient injury.

Dr. Blond's reliance on temporal proximity in this Case is not a reliable methodology. He fails to provide a reasonable explanation for why he concluded that Mr. Miller's various risk factors other than exposure to Trasylol were not the sole cause of his renal injury. Under Illinois law, a party cannot create a genuine issue of fact merely by presenting an expert witness who is willing to express an unsupported opinion that favors the party's position. *See Lewis v. CITGO Petroleum Corp*, 561 F.3d 698, 705 (7th Cir. 2009). "Qualifications alone do not suffice. A supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method and are reliable and relevant under the test set forth by the Supreme Court in *Daubert*." *Id.* "Expertise is a rational process and a rational process implies expressed reasons for judgment." *Mid-State Fertilizer Co. v. Exchange Nat. Bank of Chicago*, 877 F.2d 1333, 1339 (7th Cir. 1989). "An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process." *Id.* (citing to *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 829-32 (D.C. Cir. 1988) as holding that "an expert's declaration, full of assertion but empty of facts and reasons, won't get a case past a motion for summary judgment, for the judge must 'look behind the expert's' ultimate conclusion . . . and analyze the adequacy of its foundation."). Where an expert testifies that a particular injury "could have numerous causes and . . . simply picks the cause that is most advantageous to [a plaintiff's] claim, . . . [such testimony] is not admissible." *Id.*; *Viterbo v. Dow Chemical Co.*, 826 F.2d 420, 423 (5th Cir. 1987). *See also In re Paoli R.R. Yard PCB Lit.*, 35 F.3d 717, 763-65 (3d Cir. 1994).

I note that his report is deficient for additional reasons, some of which I briefly summarize: (1) Although he lists a history of smoking as a pre-surgical risk factor in the general population, he does not list that as a specific risk factor for Mr. Miller;[17] and (2) in the rule-in stage he admittedly did not see or review medical records which indicate that Mr. Miller had been diagnosed with "renal failure and hypertension" as far back as August of 2004, nor other early medical records suggesting the relation between Mr. Miller's renal insufficiency and his pre-surgical "severe" hypertension.[18] Accordingly, for the reasons set forth above, I find that Dr. Blond's causation opinions will not assist the trier of fact and are therefore inadmissible. Plaintiffs' claims for "negligence, strict liability, breach of express warranty, breach of implied warranty, fraudulent misrepresentation,[19] fraudulent

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[17] DEFEX D at 18-19.

[18] DEFEX D at 29 (53:10-14). Dr. Blond testified that he had no knowledge as to how long Mr. Miller had been experiencing renal insufficiency, nor how severe it had been. *Id.* He also did not know the extent of Mr. Miller's hypertension or about his pre-surgical hospitalizations. *Id.* at 9. He had not looked at any records relating to Mr. Miller's kidney stones which also would have been relevant to rendering his opinion. *Id.* at 21.

[19] Bayer correctly asserts that Plaintiffs' fraud claims are due to be dismissed for the additional reasons set forth in numerous previous summary judgment orders. Plaintiffs' 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).

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 does she support her broad claims of fraud with any evidence of reliance, an essential element of these claims. *See Teamsters Local 282 Pension Trust Fund v. Angelos*, 839 F.2d 366, 370 (7th Cir. 1988) ("Under Illinois law, one essential element [in fraud-based claims] is justifiable on the alleged fraudulent

concealment, [and] violation of consumer protection statutes . . . must fail." *See Fuesting,* 594 F. Supp. 2d at 536-38.[20]

B. Failure to Warn

Bayer next asserts that Plaintiffs' failure to warn claim is precluded by Illinois's Learned Intermediary Doctrine. Under Illinois law a plaintiff bringing suit against a drug manufacturer based upon a failure to warn, "must demonstrate that the warning was inadequate and that the failure to adequately warn of the dangers of the drug was a proximate cause of his or her injuries. *See Walton v. Bayer Corp.*, 643 F.3d 994, 999-1000 (7th Cir. 2011); *Phelps v. Sherwood Medical Industries*, 836 F.2d 296, 299 (7th Cir. 1987); *Kirk v. Michael Reese Hospital and Med. Ctr.*, 513 N.E. 2d 387 (Ill. 1987). The Plaintiff "bears the burden of proving that a defect exists and that this defect is the proximate cause of [his or her] injury." *See Ziliak v. AstraZeneca LP*, 324 F.3d 518 (7th Cir. 2003); *Haddix v. Playtex Family Products Corp.*, 138 F.3d 681, 683 (7th Cir. 1998); *Moss v. Crosman Corp*, 136 F.3d 1169, 1171 (7th Cir. 1998).

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

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statement). Accordingly, Plaintiffs' misrepresentation and fraud claims are due to be dismissed in full for this additional reason.

[20] I briefly note that Dr. Blond offers testimony that Mr. Miller also has an increased risk of death due to Trasylol administration. While Dr. Blond's opinion that acute renal injury may result in a long-term increased risk of premature mortality may be correct, it is irrelevant in this case. If he cannot testify that Trasylol was a substantial contributing factor to Mr. Miller's injury, then it logically flows that he may not testify that his Trasylol administration somehow poses a risk to Mr. Miller's early demise due to renal failure. There being no record evidence to support any such opinion, this portion of his testimony is dismissed without further discussion.

discussed relating to Plaintiffs' other claims.[21] Specifically, the Failure to Warn claim is due to be dismissed due to lack of any credible evidence that Trasylol caused Mr. Miller 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.

C. Unjust Enrichment and Punitive Damages

Summary judgment is granted on Plaintiffs' Unjust Enrichment and Punitive Damages claims because they are derivative of their underlying substantive claims each of which have failed. *See e.g., Ass'n. Benefit Servs. Inc. v. Caremark Rx, Inc.*, 493 F.3d 841, 855 (7th Cir. 2007) (loss of consortium); *Bayh v. Sonnenburg*, 573 N.E.2d 398, 408 (Ind. 1991) (unjust enrichment); *Franz v. Calaco Dev. Corp.*, 818 N.E. 2d 357, 367 (Ill. Ct. App. 2004) (punitive damages).

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 12395 in 08-1928 & DE 33 in 09-81262) as to each Count of the Complaint is GRANTED.

DONE and ORDERED, in Chambers, at West Palm Beach, Florida this 20th day of June, 2013.

DONALD M. MIDDLEBROOKS
UNITED STATES DISTRICT JUDGE

[21] I additionally note that Plaintiffs do not set forth any record evidence that a different warning would have impacted the decision to use the drug.