FOR PUBLICATION

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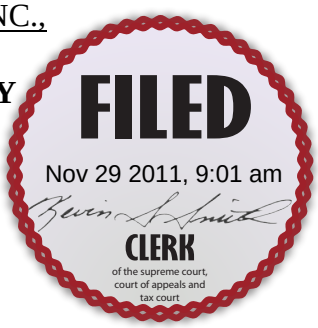

IN THE
COURT OF APPEALS OF INDIANA

NATALIE A. MILLER, Individually and as Administratrix of the Estate of Alexis J. Ritch, deceased, CHRISTINA J. MILLER, a minor by and through the mother and next friend Natalie A. Miller, and DANIEL J. RITCH, Individually,

Appellants-Plaintiffs,

vs.

L. BARRETT BERNARD, M.D., THE BETHANY CIRCLE OF KING'S DAUGHTERS HOSPITAL AND HEALTH SERVICES, CVS PHARMACY, INC., and MORTON GROVE PHARMACEUTICAL, INC.,

Appellees-Defendants.

No. 39A05-1009-PL-546

APPEAL FROM THE JEFFERSON CIRCUIT COURT
The Honorable Roger Duvall, Special Judge
Cause No. 39C01-0304-PL-182

November 29, 2011

OPINION - FOR PUBLICATION

ROBB, Chief Judge

Case Summary and Issues

Natalie A. Miller, individually and as administratrix of the estate of Alexis J. Ritch, deceased; Christian J. Miller, a minor, by and through his mother and next friend Natalie A. Miller; and Daniel J. Ritch, individually (collectively, "Plaintiffs"), appeal the trial court's entry of summary judgment to Morton Grove Pharmaceuticals, Inc. ("MGP") and CVS Pharmacy, Inc. ("CVS") (collectively, "Defendants"). Plaintiffs raise three issues for our review, which we reorder and restate as: 1) whether the trial court erred in excluding the testimony of Dr. Kevin Loeb; 2) whether Defendants were entitled to the statutory rebuttable presumption that Promethazine Syrup Plain was not manufactured defectively, and if so whether Plaintiffs failed as a matter of law to rebut the same; and 3) whether Alexis's death was not caused, as a matter of law, by MGP's production and CVS's distribution of

Promethazine Syrup Plain. On cross-appeal, Defendants request we review whether the trial court erred in denying their motion to exclude other expert testimony in support of Plaintiffs. We conclude that 1) the trial court erred in excluding the testimony of Dr. Loeb; 2) Defendants were entitled to the statutory rebuttable presumption of no defect, but whether Plaintiffs have rebutted this presumption remains a question of fact; and 3) whether MGP's production and CVS's distribution of Promethazine Syrup Plain caused Alexis's death is also a question of fact. We further conclude that the trial court did not err in denying Defendants' motion to exclude other expert testimonies in favor of Plaintiffs. Accordingly, we reverse in part, affirm in part, and remand.

Facts and Procedural History[1]

Alexis Ritch was the daughter of Natalie Miller and Daniel Ritch and the sister of Christian Miller. Alexis had a history of chronic respiratory and gastrointestinal health problems, which required numerous medications, surgeries, and periods of hospitalization. On March 19, 2002, four-year-old Alexis sustained a fever and was prescribed Omnicef for an ear infection at King's Daughters' Hospital and Health Services (the "Hospital") in Madison, Indiana. Natalie returned home and refrigerated the Omnicef consistent with a note on its label, but before administering the medicine to Alexis thought that it "didn't look right." Appellant's [sic] Appendix at 219. Natalie called the Hospital to inquire, and a pharmacist told her that the medicine should not have been refrigerated and was "no good anymore." Id. Alexis's fever continued, and on March 24, Natalie took Alexis to the

[1] We heard oral argument on August 24, 2011 at the Indiana Court of Appeals Courtroom in

Hospital emergency room with a high fever, where Alexis was prescribed Omnicef again. The next morning, Natalie was alarmed by Alexis's coughing, choking, and diarrhea, and took her to the Hospital emergency room.

Dr. L. Barrett Bernard diagnosed Alexis with a stomach virus, prescribed Phenergan, ordered a 12.5 milligram dose of Phenergan at the Hospital, and instructed Natalie to also administer Kaopectate to Alexis. Phenergan is the trade name of an antihistamine drug that provides sedative and anti-nauseam effects through its active ingredient, promethazine hydrochloride. Appellant's [sic] Brief at 5.

Natalie filled the prescription for Phenergan at a local CVS branch, which gave Natalie the generic version manufactured by MGP: Promethazine Syrup Plain. That evening, March 25, Natalie administered to Alexis a dose, and Alexis soon became extremely drowsy. Natalie called the Hospital emergency room out of concern, but a nurse told her that drowsiness was an expected side effect, so she put Alexis to bed. A few hours later, Natalie checked on Alexis, found that she was not breathing, and called paramedics. Alexis was taken to the Hospital and pronounced dead soon thereafter.

Several post-mortem laboratory tests were conducted to determine the cause of Alexis's death, including the extent to which the Promethazine Syrup Plain may have contributed to her death. First, the Jefferson County Coroner (the "Coroner") received Alexis's body, medical records, and a total body x-ray from the Hospital, and sent all on to

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Indianapolis. We thank counsel for their capable advocacy.

the Kentucky Medical Examiners' Office for a complete autopsy.[2] Appellant's [sic] App. at 206. Dr. Donna Hunsaker, M.D.,[3] performed an autopsy on March 26, 2002, the date of death. To that end, the Coroner requested a forensic toxicology analysis from AIT Laboratories ("AIT"). As to Alexis's blood, AIT's report included a finding of a "[c]oncentration" of 295 nanograms per milliliter of promethazine, and noted that the therapeutic level is 5 to 150 nanograms per milliliter. Id. at 216-17; see id. at 234-35 (stating that a blood sample included 295.5 nanograms per milliliter of promethazine). To analyze the blood, AIT used an instrument referred to as "GC/NPD." Id. at 234.

AIT also tested the bottle of Promethazine Syrup Plain from which Natalie gave Alexis a dose. The Coroner requested AIT "QUANTITATE AND DETERMINE CONCENTRATION OF RX MED." Id. at 262. AIT tested the medicine using an instrument referred to as a gas chromatography electron capture detector ("GC/ECD"),[4] and reported that the contents contained 3.35 milligrams per milliliter of promethazine.[5] Id. at 218, 236. These reports were signed by Michael Evans, Ph.D., the Director of Clinical and Forensic Operations, President, and CEO of AIT. Id. at 217, 237. Dr. Evans noted that the testing of the Promethazine Syrup Plain was performed according to Forensic Laboratory

[2] It is unclear from the record why this was sent to Kentucky and not Indiana. Although we note that Madison, Indiana is near the Indiana/Kentucky border.

[3] Dr. Donna Hunsaker also went by the name of Dr. Donna Stewart during this case.

[4] Cf. Appellees/Cross-Appellants' Appendix at 203 (Dr. Evans stating that although the report states AIT used an instrument referred to as a gas chromatography nitrogen phosphorous detector (GC/NPD), AIT actually used a gas chromatography electron capture detector (GC/ECD)).

[5] 3.35 milligrams equals 3,350,000 nanograms. Neither the appellate record nor appellate briefs suggest that 3.35 milligrams is a typographical error.

Guidelines, but not in accordance to "GMP . . . [or the] USP Method (HPLC)," and the "[r]esults are not certified to GMP." Id. at 237. Dr. Evans later explained that GMP stands for Good Manufacturing Practices, which is recognized worldwide for the quality control testing of pharmaceutical products, and that the USP, U.S. Pharmacopeia, sets forth a process to test and evaluate prescription and non-prescription medications. Appellees/Cross-Appellants' Morton Grove Pharmaceuticals, Inc. and CVS Pharmacy, Inc.'s Appendix ("App. of Appellees/Cross-Appellants") at 201. Based on AIT's test results of Alexis's blood and the bottle of medication, Dr. Hunsaker concluded that Alexis "died of dehydration secondary to body volume loss as a result of acute diarrheal enteritis . . . . Promethazine intoxication is a significant factor contributing to her death . . . ." Id. at 215.

Two years later, in March 2004, National Medical Services ("NMS") tested Alexis's bottle of Promethazine Syrup Plain to determine the concentration of promethazine hydrochloride in the substance. NMS conducted its testing differently from AIT, following federal Food and Drug Administration ("FDA") requirements regarding testing and analytical procedures of the pharmaceutical preparation of promethazine hydrochloride, under a method known as high-performance liquid chromatography ("HPLC"). William Vickery of NMS stated NMS tests found the concentration of promethazine hydrochloride was 6.21 milligrams per 5 milliliters.[6] Edward Barbieri, Ph.D., a Forensic Toxicologist and Assistant Laboratory Director at NMS, explains in a thirteen-page affidavit what he views as flaws in AIT's

[6] 6.21 milligrams per 5 milliliters equals 1,242,000 nanograms per milliliter.

testing of the materials in this case, and accordingly expresses his disagreement with AIT's test results. See Appellant's [sic] App. at 326-38.

In April 2004, Dr. Evans completed an affidavit commenting on the AIT test results, in which he stated:

> 3. [AIT] received a request to perform a forensic toxicology analysis of the contents of a prescription bottle bearing a label describing the contents as promethazine syrup, prescription number . . . regarding Alexis Ritch.
> 4. The assay method employed by AIT to test that specimen was performed according to Forensic Laboratory Guidelines. The purpose of the assay was to identify the contents of the bottle.
> 5. The assay method AIT employed was not intended to reliably report the concentration of promethazine in the specimen under GMP conditions.
> 6. The assay performed by AIT was not performed according to GMP, and the results are not certified to GMP. Further, the assay was not performed according to the USP method for testing promethazine, which is HPLC.
> 7. Accordingly, the assay results from my testing at AIT cannot be used to determine, within a reasonable degree of scientific certainty under FDA Guidelines, the concentration of promethazine in Specimen . . . .
> 8. The opinions in this affidavit are stated to a reasonable degree of scientific certainty.

Id. at 107-08.

In a deposition, Dr. Evans was asked whether AIT's test results were scientifically reliable in determining the concentration of medication in the bottle. Dr. Evans explained that AIT "do[es] testing for pharmaceutical industries, . . . [so] the whole process is different from the very – very beginning. So this was not done on GMP – USP standards." Id. at 284.

Cheryl Blume, Ph.D., President of the Pharmaceutical Development Group, Inc., reviewed the AIT test results, the autopsy report of Dr. Hunsaker, the Hospital's records of Alexis, the affidavits of Vickery and Dr. Evans, professional reference documents, and FDA regulatory materials, and concluded:

> 6. It is my preliminary opinion based on the limited data that I have reviewed that the Promethazine Syrup Plain manufactured by [MGP] given to Alexis J. Ritch on the day of her death . . . was defective, that this defect caused an overdose of promethazine hydrochloride in the bloodstream of Alexis J. Ritch, and that such overdoses have been associated with pediatric fatalities.
> Id. at 188.

Dr. George Nichols, II, M.D., explained that both a forensic method of testing substances and a USP method of testing substances are scientifically reliable, and that in "layman's" terms, this case involves two scientifically reliable procedures or methods of testing that have produced different results. Id. at 66-67. Dr. Kenneth Kulig, M.D., was deposed at length on at least two occasions. Because NMS did not complete testing until about two years after Alexis died, the rate of degradation of samples became an issue of contention among experts. At one point, Dr. Kulig stated that he does not know the rate of degradation of MGP's Promethazine Syrup Plain, and asserted that a test for concentration of a sample can only indicate the concentration at the time of the testing. Id. at 388-92. Dr. Barbieri came to the opposite conclusion, and opined that MGP's stability test results shows otherwise. Id. at 338.

Plaintiffs filed suit in 2003 against Dr. Bernard, the Hospital, MGP, and CVS and amended their complaint in 2006.[7] Dr. Bernard and the Hospital were the subject of a medical review panel hearing per Indiana law regarding allegations of medical malpractice,

[7] Plaintiffs also filed suit in Kentucky, but the Kentucky suit was dismissed for lack of personal and subject matter jurisdiction and under the doctrine of forum non conveniens. The Court of Appeals of Kentucky affirmed dismissal. See Miller v. Bernard, No. 2003-CA-000590-MR, 2004 WL 1635789 (Ky. Ct. App. 2004).

and are not parties to this appeal.[8] As to Defendants, parties to this appeal, Plaintiffs allege negligence, product liability, strict liability, misrepresentation, breach of express warranty, breach of implied warranty, negligent infliction of emotional distress, intentional infliction of emotional distress, and negligent distribution by CVS.[9] These allegations are "based upon the defective manufacture of the medication [(Promethazine Syrup Plain)] which rendered it super-potent." Appellant's [sic] Br. at 2; accord Appellant's [sic] App. at 49. In 2004, Defendants moved for summary judgment, which the trial court denied following a hearing.

In 2009, Defendants again moved for summary judgment and to exclude[10] the expert opinion testimonies of Dr. Kevin Loeb, Dr. Kulig, and Dr. Nichols. Dr. Loeb, a doctor of osteopathic medicine, was a member of the medical review panel for Plaintiffs' malpractice claim against Dr. Bernard and the Hospital. Following a hearing, the trial court entered findings of fact and conclusions of law, granted the motion to exclude Dr. Loeb's testimony, denied the motion to exclude the testimonies of Drs. Kulig and Nichols, and granted summary judgment for Defendants. Plaintiffs now appeal and Defendants cross-appeal. Additional facts will be supplied as appropriate.

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[8] Claims against Dr. Bernard and the Hospital proceeded to jury trial in July 2010. The trial court granted a directed verdict to Dr. Bernard at the close of Plaintiffs' case, and entered judgment as to the jury verdict finding the Hospital liable to Natalie Miller individually and as administratrix of Alexis's estate.

[9] Counsel for MGP, speaking on behalf of MGP and CVS at oral argument, stated that it would be impossible for either MGP or CVS to be liable and the other not liable because CVS does not alter the drug at all, but simply divides and distributes it. But for CVS to be liable, CVS must have been guilty of negligent conduct or a negligent omission. See 57Am. Jur. 2d Negligence § 435 (2011) (if negligence has not been established the question of proximate cause is not reached).

[10] Whether this motion to exclude and the ruling thereon pertain to summary judgment only, or summary judgment and any future proceedings in the event summary judgment was denied, is unclear from the appellate briefs, the trial court order, and Defendants' motion.

Discussion and Decision

I. Standard of Review

We review a trial court's summary judgment order de novo. Kovach v. Caligor Midwest, 913 N.E.2d 193, 196 (Ind. 2009). We apply the same standard as the trial court: whether the designated evidence shows that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Ind. Trial Rule 56(C); Freidline v. Shelby Ins. Co., 774 N.E.2d 37, 39 (Ind. 2002). In making this determination, we construe all facts and reasonable inferences in a light most favorable to the non-moving party, Boggs v. Tri-State Radiology, Inc., 730 N.E.2d 692, 695 (Ind. 2000), and resolve all doubts as to the existence of a factual issue against the moving party, Tibbs v. Huber, Hunt & Nichols, Inc., 668 N.E.2d 248, 249 (Ind. 1996). The moving party has the initial burden to prove that there are no genuine factual issues and that judgment as a matter of law is appropriate, and only then must the non-moving party respond by setting forth specific facts in the designated evidence demonstrating the opposite is true. Stephenson v. Ledbetter, 596 N.E.2d 1369, 1371 (Ind. 1992).

A genuine issue of material fact exists where facts concerning an issue which would dispose of the litigation are in dispute, or where undisputed facts are capable of supporting conflicting inferences on such an issue. Briggs v. Finley, 631 N.E.2d 959, 963 (Ind. Ct. App. 1994), trans. denied. We may affirm a trial court's grant of summary judgment upon any theory supported by the designated materials. Sims v. Barnes, 689 N.E.2d 734, 735 (Ind. Ct.

App. 1997), trans. denied. Additionally, we "may determine in the context of summary judgment a mixed question of law and fact." Ebbinghouse v. FirstFleet, Inc., 693 N.E.2d 644, 647 n.2 (Ind. Ct. App. 1998), trans. denied.

II. Opinion of Dr. Loeb

Plaintiffs request our review of the trial court's decision to grant Defendants' motion to exclude the testimony of Dr. Loeb. In their list of expert witnesses, Plaintiffs introduced and described Dr. Loeb as follows:

> Dr. Kevin Loeb, Indiana State University Student Health Center . . . . Dr. Loeb is not a retained expert but was a member of the Medical Review Panel in this case. His testimony will be based upon his education, experience and training as well as his review of the material provided during the Medical Review Panel. It is anticipated Dr. Loeb will testify in conformance with the opinion he concluded in the performance of his duties as a member of the Medical Review Panel. More specifically, it is anticipated that Dr. Loeb will testify that Alexis's death was caused by the toxic level of the Promethazine Hydrochloride in her system. Moreover, it is Dr. Loeb's opinion that the Promethazine Syrup Plain given to Alexis was overly concentrated with the active ingredient Promethazine Hydrochloride as a result of a manufacturing defect by the pharmaceutical company, [MGP]. It is further anticipated that he will opine that the over-concentration of Promethazine Hydrochloride in the syrup given to Alexis manufactured by [MGP] was a proximate and substantial factor in causing the death of Alexis Ritch. . . .

Appellant's [sic] App. at 89.

In an affidavit, Dr. Loeb expressed his opinion "to a reasonable degree of medical certainty, as to the cause of Alexis Ritch's death." Id. at 137. Specifically:

> 4. It is my opinion that the Promethazine Syrup Plain ingested by Alexis Ritch promethazine hydrochloride, as a result of a manufacturing defect by the pharmaceutical company, [MGP].
> 5. In my opinion, the overconcentration of promethazine hydrochloride in the Promethazine Syrup Plain manufactured by [MGP] was a proximate and substantial factor in causing the death of Alexis Ritch on March 26, 2002.

Id. at 138.

The admission or exclusion of expert testimony lies within the sound discretion of the trial court, and will not be reversed absent an abuse of that discretion. Hannan v. Pest Control Servs., Inc., 734 N.E.2d 674, 679 (Ind. Ct. App. 2000), trans. denied. Indiana Evidence Rule 702, governing expert testimony, contains two requirements for a witness to qualify as an expert: "(1) the subject matter is distinctly related to some scientific field, business or profession beyond the knowledge of the average lay person; and (2) the witness is shown to have sufficient skill, knowledge or experience in that area so that the opinion will aid the trier of fact." Bacher v. State, 686 N.E.2d 791, 800 (Ind. 1997). Further, "[e]xpert scientific testimony is admissible only if the court is satisfied that the scientific principles upon which the expert testimony rests are reliable." Evid. R. 702(b). "The focus of the admissibility test must remain on the methodology of the theory or technique, not on the conclusions generated." Ollis v. Knecht, 751 N.E.2d 825, 829 (Ind. Ct. App. 2001) (citing Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993)), trans. denied.

The trial court did not determine whether Dr. Loeb qualifies as an expert, but granted Defendants' motion to exclude Dr. Loeb's opinion because Defendants were unable to participate in the Medical Review Panel proceedings, and those proceedings did not concern them and only concerned Dr. Bernard.[11]

[11] The proceedings before the Medical Review Panel also concerned the Hospital, but this mistaken omission is irrelevant to our analysis.

At the outset, we note that it is unclear which opinion by Dr. Loeb Plaintiffs sought to enter as designated evidence and the trial court excluded. Plaintiffs do not intend to enter into evidence Medical Review Panel opinions regarding the liability of Dr. Bernard or the Hospital, and the panel did not opine on the liability of Defendants.[12] See Appellant's [sic] App. at 93-99. It appears that Plaintiffs only seek to enter Dr. Loeb's April 8, 2008 affidavit quoted above, in which he opined that MGP's defective manufacturing of Promethazine Syrup Plain was a "proximate and substantial factor in causing" Alexis's death. Id. at 138. He did not render this opinion as part of his service to a medical review panel. While Plaintiffs indicated in their list of experts that Dr. Loeb would testify consistent with his conclusions reached as a member of the medical review panel, the conclusions articulated by the medical review panel – which are very brief in their own right – do not refer to the liability of Defendants. But rather than exclude any and all opinions by Dr. Loeb as irrelevant, it is reasonable to presume that Plaintiffs intended to enter into evidence Dr. Loeb's April 2008 affidavit quoted above, and accompanying testimony regarding the liability of Defendants.

Accordingly, this intended evidence would be admissible so long as it constitutes expert testimony. It would not matter that Dr. Loeb relied on evidence that might not be admissible (i.e., for the sake of argument, evidence presented during the Medical Review Panel to which Defendants were not a party), because experts "may testify to opinions based

[12] Nor do Plaintiffs intend to enter into evidence Dr. Loeb's February 22, 2007 affidavit amending his opinion for the Medical Review Panel report regarding Dr. Bernard's liability.

on inadmissible evidence, provided that it is of the type reasonably relied upon by experts in the field." Evid. R. 703.

Nor would it matter that Dr. Loeb was part of the panel and expressed an opinion regarding the liability of Dr. Bernard and the Hospital. The following analogy demonstrates the error of concluding otherwise. Suppose an expert is to testify regarding cause of death in two related criminal trials. In the first trial, as to Defendant A, the expert testifies that the victim died as a result of a gunshot wound. In the second trial, as to co-Defendant B tried separately, the expert can certainly testify again that the victim died as a result of a gunshot wound (although the transcript of Defendant A's trial would be inadmissible). Defendant B could not exclude the expert's testimony solely because the expert first offered his opinion in the trial of Defendant A. Similarly here, Defendants cannot exclude Dr. Loeb's testimony solely because he first offered his opinion as a member of the Medical Review Panel.

The trial court abused its discretion in excluding Dr. Loeb's affidavit on the grounds that he participated in the Medical Review Panel and Defendants were not parties to those proceedings.

But Defendants articulate other reasons why the trial court's exclusion of Dr. Loeb's opinion was proper. First, Defendants contend that Dr. Loeb's opinion was inadmissible because "the information relied on by the panel is the same flawed data [Plaintiffs] ha[ve] relied on throughout this litigation." Appellees/Cross-Appellants' Br. at 27. Specifically, Defendants note that Dr. Loeb's participation in the panel is governed by statute, and that his opinion as to claims "unrelated to the provision of medical care or treatment," would be

beyond the scope of his legal authority as a panel member. Id. at 28 (quoting H.D. v. BHC Meadows Hosp., Inc., 884 N.E.2d 849, 855 (Ind. Ct. App. 2008) (quotation omitted), trans. denied). Given our analysis above, this argument is unpersuasive because Plaintiffs do not intend to enter into evidence Dr. Loeb's or the panel's opinion regarding the Hospital or Dr. Bernard. Further, to the extent Defendants challenge the reliability of Dr. Loeb's opinion because most of the evidence before him as a panel member likely pertained to the liability of Dr. Bernard and the Hospital and not the liability of Defendants, Defendants challenge the weight and not admissibility of the evidence. See Dorsett v. R.L. Carter, Inc., 702 N.E.2d 1126, 1128 (Ind. Ct. App. 1998) ("[T]he admissibility of expert testimony does not hinge on the expert's disclosure of the facts and reasoning that support his opinion. The lack of facts and reasoning, which may be brought out on cross-examination of the expert, goes to the weight to be given the expert's opinion, not its admissibility.") (interpreting Evid. R. 705), trans. denied.

Defendants next contend, similarly, that the items of evidence upon which Dr. Loeb based his opinion, the medical examiner's report and the AIT test results, are inherently inadequate as a basis because: 1) he is unqualified to determine the reliability of the AIT test results, 2) he has not reviewed evidence regarding defective manufacturing of the MGP product, and 3) the trial court found that the medical examiner's report and the AIT results are insufficient to satisfy the Plaintiffs' burden to show a genuine issue of material fact.

As to Dr. Loeb's qualification to determine the reliability of the results, that is for the trial court to determine in accordance with Evidence Rule 702. As to his review of the

evidence regarding MGP's purported defective manufacturing, we agree that it is not completely clear whether the evidence Dr. Loeb reviewed warrants his stated conclusion that MGP defectively manufactured the drug, but for our court or the trial court to make that determination would require an expert analysis and weighing of the evidence, which is improper at the summary judgment stage and an issue for the fact-finder. Nevertheless, even if we were to agree with the trial court's determination that the medical examiners' report and AIT test results themselves do not demonstrate a genuine issue of material fact, Dr. Loeb's opinion based on that evidence warrants a separate determination of admissibility.

The trial court erred in excluding Dr. Loeb's opinion solely because Defendants were unable to participate in the Medical Review Panel proceedings which formed part of the basis for Dr. Loeb's opinion. Defendants' other reasons for excluding Dr. Loeb's opinion are also unpersuasive. For these reasons, we reverse the trial court's decision to exclude Dr. Loeb's opinion and remand for the trial court to determine whether Dr. Loeb satisfies the requirements of Evidence Rule 702. This reversal and remand alone could be sufficient to reverse the trial court's entry of summary judgment because the designated evidence supplemented by Dr. Loeb's opinion might demonstrate a genuine issue of material fact. However, in the interest of judicial economy, we address the other issues as well even without considering Dr. Loeb's opinion.

III. Defective Manufacturing

A. Application of Statutory Presumption

The next issue is whether the rebuttable presumption contained in the Indiana Product Liability Act applies to MGP and the Promethazine Syrup Plain that is the subject of this case. Indiana Code section 34-20-5-1 provides, in pertinent part:

> In a product liability action, there is a rebuttable presumption that the product that caused the physical harm was not defective and that the manufacturer or seller of the product was not negligent if, before the sale by the manufacturer, the product:
> (1) was in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, and labeled; or
> (2) complied with applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States or by Indiana, or by an agency of the United States or Indiana.

Plaintiffs contend the trial court erred in concluding that the presumption applies because MGP concedes it cannot identify the specific lot from which Alexis's medication came. Defendants have explained that the lot number was on the label of the stock bottle at the CVS branch in Madison, and the remaining Promethazine Syrup Plain contained in that bottle was sold and the bottle discarded. However, MGP has determined from its records that there were only twenty-six potential lots of Promethazine Syrup Plain that could have been used to fill Alexis's prescription in March 2002, and that before the sale or even distribution of these lots by MGP, each were tested using HPLC to quantify the promethazine hydrochloride therein. App. of Appellees/Cross-Appellants at 719-20.

MGP's HPLC test results show that each lot conformed to the FDA-approved strength of promethazine hydrochloride: 5.625 to 6.875 milligrams per 5 milliliters, with a labeled concentration of 6.25 milligrams per 5 milliliters. Id. The designated evidence is clear that HPLC is the method recommended by the USP and approved by the FDA for quantitative analysis of promethazine hydrochloride in a pharmaceutical product. Id.

Contrary to Plaintiffs' appellate argument, the designated evidence is clear that an earlier formulation of Promethazine Syrup Plain, of which the concentration of promethazine hydrochloride was less stable and more likely to be defective, was out of circulation and could not have been included in Alexis's bottle. Id. at 720. Although Plaintiffs strenuously argue to the contrary, they designate no evidence in support of such argument. Thus, the rebuttable presumption contained in Indiana Code section 34-20-5-1 applies.

B. Rebuttal of Statutory Presumption

We now turn to the question of whether Plaintiffs designated admissible evidence to rebut the statutory presumption of Indiana Code section 34-20-5-1. This presumption may be rebutted, at least for purposes of summary judgment, if the designated evidence demonstrates a question of fact remains as to whether the product was defective. See Schultz v. Ford Motor Co., 857 N.E.2d 977, 985 (Ind. 2006).

Here, the voluminous designated evidence focuses on whether the Promethazine Syrup Plain was defective. The long list of conflicting designated evidence includes the following that at least arguably support Plaintiffs' position: the autopsy report and opinion of Dr. Hunsaker, the AIT test results, the affidavit and testimony of Dr. Evans, the affidavit of

Dr. Blume, and the opinions of Dr. Kulig and Dr. Nichols. Defendants' challenge to the AIT test results and any expert opinions interpreting or based on those results is a challenge to the weight of the evidence inappropriate at the stage of summary judgment. Therefore, although the statutory presumption applies, Plaintiffs designated admissible evidence to rebut this presumption for purposes of summary judgment.

The trial court concluded that Plaintiffs failed to rebut the presumption for several reasons. First, the trial court found the tests by Dr. Hunsaker and AIT to be unreliable because neither considered or factored into their tests the difference between blood and plasma or serum, and neither considered the principle of post-mortem redistribution. Other experts testified regarding the importance of these concepts, and the trial court independently recalculated the promethazine level in Alexis's blood to be within the therapeutic range.[13]

Trial courts are charged with the difficult work of grappling with large volumes of information in a wide variety of subject areas, determining the credibility of witnesses, and

[13] The relevant finding by the trial court is included in full below:

> 19. Turning to the test of the blood sample taken form [sic] Alexis, as previously stated, the reported therapeutic or reference range for promethazine is 5-150 ng/ml. This range is based upon studies of promethazine in plasma or serum. The test results reported by AIT Laboratories and the findings of the Kentucky Medical Examiners [sic] office did not take into consideration the difference between blood and plasma or serum. Additionally there is the concept of post mortem redistribution which also was not considered by those two offices. Plaintiffs' expert, Dr. Kenneth Kulig, acknowledged the concept of post mortem redistribution and applied that concept in this case by a factor of 1.6. When considering this redistribution factor, the blood level was then found to be 184ng/ml, a still toxic level according to Dr. Kulig. Neither Dr. Kulig nor other experts or witnesses designated by Plaintiffs took into consideration the blood to plasma ration. Relying upon the same authority cited by Dr. Kulig, Disposition of Toxic Drugs and Chemicals in Man, Randall C. Baselt, there is a blood to plasma ration of 0.6 to 0.7. An average of this range factors to a promethazine level in blood plasma of 120 ng/ml, a level within the therapeutic or reference range.

Appellant's [sic] App. at 43.

making findings of fact as to the same. However, a trial court's role at the summary judgment stage does not involve the weighing of evidence, nor does it involve analyzing the results of laboratory tests, comparing these results with experts' reference materials, or independently calculating the therapeutic range of prescription medications. See Dickerson v. Strand, 904 N.E.2d 711, 714-15 (Ind. Ct. App. 2009). "Where the evidence is in conflict, or undisputed facts lead to conflicting inferences, summary judgment should not be granted, even if it appears that the nonmovant will not succeed at trial. . . . [S]ummary judgment should not be used as an abbreviated trial." Id. at 715 (quotation omitted). Here, the trial court erred in deeming Plaintiffs' expert opinion to be unreliable when compared with the trial court's own calculation of the concentration level of promethazine in Alexis's blood. Therefore, although MGP and CVS are entitled to the rebuttable presumption that the Promethazine Syrup Plain was not defective, a genuine issue of material fact remains as to whether the Plaintiffs rebutted this presumption, and summary judgment is inappropriate.

IV. Cause of Death

Plaintiffs next challenge the trial court's finding that Alexis's death was not, as a matter of law, caused by MGP's production of Promethazine Syrup Plain and CVS's distribution of the same. "Only in plain and indisputable cases, where only a single inference or conclusion can be drawn, are the questions of proximate cause and intervening cause matters of law to be determined by the court." Peters v. Forster, 804 N.E.2d 736, 743 (Ind.

It is not completely clear whether the trial court recalculated this number independently, relying on the Baselt text, or relied on some expert's opinion that for some reason was not highlighted in the record. Regardless, the trial court erred by weighing conflicting evidence.

2004). "When an event is the reasonably foreseeable, natural and probable consequence of an act or omission, the act or omission is a proximate cause of the event. There may be more than one proximate cause of an event." Board of Comm'rs of Adams Cnty. V. Price, 587 N.E.2d 1326, 1333 (Ind. Ct. App. 1992) (citations omitted), trans. denied.

At this point, we deem it helpful to describe how Indiana's summary judgment procedure "abruptly diverges" from federal practice. Jarboe v. Landmark Cmty. Newspapers of Indiana, Inc., 644 N.E.2d 118 (Ind. 1994). In federal practice, a defendant seeking summary judgment is not required to negate an plaintiff's claim, but need only indicate the basis for its motion and designate evidence to show that the plaintiff failed to establish an essential element of its claim. Dennis v. Greyhound Lines, Inc., 831 N.E.2d 171, 173 (Ind. Ct. App. 2005), trans. denied. The burden then rests upon the non-moving party to make a showing sufficient to establish the existence of each challenged element upon which the non-movant has the burden of proof. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

In Indiana, however, "[m]erely alleging that the plaintiff has failed to produce evidence on each element" of its claims is insufficient to sustain summary judgment for defendants. Jarboe, 644 N.E.2d at 123. Rather, "the party seeking summary judgment must demonstrate the absence of any genuine issue of fact as to a determinative issue, and only then is the non-movant required to come forward with contrary evidence." Id.; accord Kennedy v. Murphy, 659 N.E.2d 506, 508 (Ind. 1995) ("[A] non-movant is not required to come forward with contrary evidence until the party seeking summary judgment demonstrates the absence of a genuine issue of material fact.").

At oral argument, Defendants repeatedly made statements to the effect of "we produced evidence, but Plaintiffs have not produced any evidence."[14] Most of these statements were made in the context of causation, i.e., "Plaintiffs have not designated evidence that Defendants caused Alexis's death, so summary judgment is appropriate." This oral advocacy misses the distinction between the federal and Indiana procedures for summary judgment.

Nevertheless, consistent with the process for seeking summary judgment in Indiana courts, Defendants have designated evidence tending to suggest the absence of an issue as to causation. Namely, the most significant evidence in support of this position includes MGP's test results of the Promethazine Syrup Plain before MGP distributed the drug to CVS, which suggests that at one point the drug was not defective and therefore it could not have – via a defect – caused Alexis's death. Defendants also produced the NMS test results and an affidavit by Dr. Barbieri, in which he meticulously explains why the NMS test results are accurate and the AIT test results should not be given much weight.

Finally Defendants point to Dr. Evans's affidavit and deposition testimony commenting on the AIT test results. Defendants contend Dr. Evans's comments undermine the AIT test results and all expert opinions relying on it. This contention is based on our court's opinion in Hagerman Constr., Inc. v. Copeland, 697 N.E.2d 948, 957 (Ind. Ct. App. 1998), trans. denied, in which we stated that "[w]hile any scientific test is subject to error, [a

[14] Some of these statements were made in reference to the rebuttable presumption discussed above. In that context, we agree that such statements are consistent with the governing burden and procedure, but for the reasons discussed above, we conclude that Plaintiffs did produce evidence sufficient to rebut the

prior Indiana appellate opinion] cannot extend so far that evidence becomes admissible where even the laboratory conducting the test provides testimony questioning the test's reliability." In Hagerman, the issue was whether a well-recognized method of testing blood was sufficiently reliable for test results to be admissible when used to test a blood sample that was not properly cared for. The parties disputed whether the laboratory's results could be admissible when the laboratory staff discredited their results by describing improper care for the sample.

Here, however, the parties do not dispute whether the scientific test was reliable – all agree that AIT's test results are scientifically reliable "for the purpose of which it was intended." Appellant's [sic] App. at 456. The dispute, on which conflicting designated evidence was provided, is over what precise purpose AIT tested the materials, and to some extent whether the test results may also be reliable as to other data produced by the test. On one hand, Dr. Evans agreed at a deposition that the Coroner "wanted to know what the concentration of the medication was in the bottle." Id. at 457. Based on this statement and others, Plaintiffs and their experts point to the AIT test results as evidence of super-potency of the Promethazine Syrup Plain, and draw a direct causal link to Alexis's death. On the other hand, Defendants direct us to other parts of Dr. Evans's deposition testimony in which he explains that AIT's tests were not intended to determine the concentration of the medicine. The discussion at oral argument confirmed the lack of designated evidence regarding whether AIT's test results reporting the concentration of the medicine – purpose of the test

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presumption for purposes of avoiding summary judgment.

aside – is scientifically reliable. This dispute over the purpose of AIT's testing and the degree to which results may be reliable beyond AIT's original intention is a factual dispute that differs in kind from the dispute in Hagerman. It is properly the role of a fact-finder to determine Dr. Evans's and AIT's intentions and actions.

Consequently, because Dr. Evans's deposition testimony does not render the AIT test results inadmissible and does not significantly undercut the reliability or admissibility of other experts relying on the AIT test results, there is ample designated evidence to support Plaintiffs' contention that the Promethazine Syrup Plain caused or was at least a significant contributing factor to Alexis's death. This includes the report of Dr. Hunsaker and opinion of Dr. Blume. Therefore, even if we did not consider the opinions of Drs. Loeb, Kulig, and Nichols, and considered the NMS test results and the opinions of Vickery and Dr. Barbieri as persuasive evidence negating causation, we are left with conflicting evidence and a genuine issue of material fact. Sharply conflicting designated evidence exists as to whether the Promethazine Syrup Plain manufactured by MGP and distributed by CVS contributed to Alexis's death. This case is anything but plain and indisputable, thus, summary judgment is inappropriate.

V. Cross-Appeal

We next address Defendants' issues on cross-appeal because we reverse the trial court's order granting summary judgment to Defendants. On cross-appeal, Defendants contest the trial court's denial of their motion to exclude the expert opinions of Dr. Kulig and

Dr. Nichols because Defendants' challenges were aimed at the weight and not admissibility of the experts' opinions. The following principles guide our review of this issue:

> The decision to admit or exclude evidence lies within the sound discretion of the trial court. The trial court's determination is afforded great discretion [sic] on appeal. To that end, we will not reverse the trial court's decision absent a showing of manifest abuse of discretion. An abuse of discretion occurs when the trial court's decision is against the logic and effect of the facts and circumstances before it.
>
> Affidavits in support of or in opposition to a motion for summary judgment are governed by Indiana Trial Rule 56(E), which provides, in relevant part: "Supporting and opposing affidavits shall be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein." The requirements of T.R. 56(E) are mandatory; hence, a court considering a motion for summary judgment should disregard inadmissible information contained in supporting or opposing affidavits. Further, the party offering the affidavit into evidence bears the burden of establishing its admissibility.

City of Gary v. McCrady, 851 N.E.2d 359, 363 (Ind. Ct. App. 2006) (citations omitted).

Defendants argue the opinions by Drs. Kulig and Nichols are inadmissible because they do not agree with each other, and are therefore unreliable. But for the same reason that a disagreement of opinion with Defendants' experts is an improper basis for excluding the opinions of Plaintiffs' experts, a disagreement of opinion (to the extent one exists) among Plaintiffs' experts is an improper basis for excluding the opinion of one or more of them.

In Saliba v. State, 475 N.E.2d 1181 (Ind. Ct. App. 1985), trans. denied, this court reviewed whether a trial court erred in excluding the criminal defendant's expert opinion regarding an opinion poll he took, after an expert of the State testified to his view of flaws in how the poll was conducted. We noted that expert opinion cannot be excluded for merely technical inadequacies, and concluded that the trial court erred in excluding the defendant's

expert. Id. at 1190. Although the experts in Saliba did not testify in support of the same party, so the trial court's error may seem more obvious than here, the following explanation from Saliba in the context of the experts' disagreement as to proper methodology is analogous to the issue here.

> There are doubtless many formulas and principles which experts use in this field or any other to arrive at their ultimate opinions. The determination of which factors, formulas or calculations are necessary . . . to form an expert opinion is within the knowledge and judgment of the expert and, again, is a subject which can be approached and examined in the cross-examination or by bringing forward other expert witnesses.

Id. at 1189 (quoting Martin v. Roberts, 464 N.E.2d 896 (Ind. 1984)) (emphasis original to Saliba) (citation omitted). This court then stated:

> It is not the trial court's function to dispute the validity of an opinion rendered by a competent and qualified expert. Once the basis for an expert's opinion is established, . . . the effect of objections or competing expert testimony is restricted to the weight attributed to the opinion by the fact-finder.

Id.

The disagreement that Defendants highlight is that Drs. Kulig and Nichols hold different theories on how promethazine caused Alexis's death. This is immaterial at the summary judgment stage, as is Defendants' claim that Drs. Kulig and Nichols "employ backward reasoning" in arriving at the same conclusion. Appellees/Cross-Appellants' Br. at 29.

Defendants next contend the opinions of Drs. Kulig and Nichols are unreliable and inadmissible because the data upon which they rely – the AIT test results – are unreliable. However, the AIT test results were only part of the basis for the opinions of Drs. Kulig and

Nichols, and even if the AIT test results are inadmissible, experts may base their opinions on inadmissible evidence. See Evid. R. 703. Defendants argue that Plaintiffs' experts "should be precluded from offering any opinions that have AIT's test results as their foundation (or the Autopsy Report as it is based on the AIT test results)[.]" Appellees/Cross Appellants' Br. at 33. Evidence Rule 703 precludes this general exclusion of expert opinions based on arguably inadmissible evidence.

Defendants next argue Dr. Kulig is not qualified to testify as an expert that the Promethazine Syrup Plain at issue was super-potent because he appeared relatively unfamiliar with AIT testing procedures. But Dr. Kulig was not called on to critique AIT's testing procedures; his opinion refers to Alexis's cause of death, for which he relied in part on AIT's test results. Dr. Kulig's unfamiliarity with various laboratory testing procedures is irrelevant to his expertise in evaluating test results, and therefore does not render him unqualified to testify as an expert regarding Alexis's cause of death.

Defendants then piece together portions of Dr. Kulig's testimony to emphasize the presumptions and estimates in his opinion. Dr. Kulig admitted he made estimates for the purpose of demonstrating in simplified terms his conclusion that Alexis received a super-potent dosage of promethazine. Although his testimony is somewhat confusing, Dr. Kulig appears to contend that AIT's test results of extraordinarily high levels of promethazine are not so unreasonable that they must be dismissed out of hand (a position he presumes Defendants take). He bases this contention on his estimates and calculations that are not intended to determine the specific level of concentration, but to demonstrate that the AIT

results are within the realm of the scientifically accurate. So long as the trial court agrees with Dr. Kulig that his assessment is beyond the knowledge of the average lay person, that it will aid the trier of fact in understanding the evidence, and that the scientific principles upon which he bases his estimates and calculations are reliable, then the trial court may allow Dr. Kulig's opinion. See Evid. R. 702. Defendants also challenge Dr. Kulig's calculations that account for post-mortem redistribution, but this argument also focuses on the weight and not admissibility of his opinion. The same goes for Defendants' challenges to Dr. Kulig's opinion as to causation because he did not rule out other possible causes of death.

> [T]he admissibility of a[n] [expert]'s testimony should not be determined by examining the level of certainty in his opinions since the court would be invading the province of the jury. Rather, the expert's opinion is admissible if a proper foundation establishes the need for expert testimony and the expert's credentials establish an expertise in the area and the methods employed. Once these factors are established, the evidence is admissible and the jury is left to perform its function of assessing the reliability of the evidence.

Yang v. Stafford, 515 N.E.2d 1157, 1162 (Ind. Ct. App. 1987) (quotation and citation omitted), trans. denied.

Defendants challenge Dr. Nichols's testimony as establishing only a temporal relationship between Alexis taking Promethazine Syrup Plain and her death, but this challenge is not supported by Dr. Nichols's deposition testimony. He based his opinion on the AIT test results and his medical expertise, to ultimately opine that Alexis's dehydration was due to water loss sufficient to cause her death, and that the concentration of promethazine found in her blood was a significant and contributing factor to her dehydration. App. of Appellees/Cross-Appellants at 417. Dr. Nichols also opined that the level of

promethazine in Alexis's blood led to her sedation, leaving her unable to ask her mother for fluids or rehydrate herself. Defendants contend this is not supported by facts (because Natalie was instructed to put Alexis on a liquid diet for twenty-four hours) or scientific literature. But this amounts to another attack on the weight of Dr. Nichols's opinion, and does not affect its admissibility. See Yang, 515 N.E.2d at 1162. In sum, the trial court did not err in allowing the expert opinions of Drs. Kulig and Nichols.

Conclusion

The trial court erred in excluding the opinion of Dr. Loeb. Defendants are entitled to the statutory rebuttable presumption that the Promethazine Syrup Plain was not manufactured defectively, but whether Plaintiffs rebutted and overcame this presumption remains a genuine issue of material fact. The causal connection between MGP's manufacturing Promethazine Syrup Plain and CVS's distribution of the same and Alexis's death is also a question of material fact. As to Defendants' cross-appeal, the trial court did not err in allowing the opinions of Drs. Kulig and Nichols. The trial court's order is hereby reversed in part, affirmed in part, and remanded for further proceedings consistent with this opinion.

Reversed in part, affirmed in part, and remanded.

RILEY, J., and SULLIVAN, S.J., concur.