IN THE SUPREME COURT OF IOWA

No. 06–1428

Filed February 5, 2010

BRYAN RANES,

Appellant,

vs.

ADAMS LABORATORIES, INC.; ADAMS RESPIRATORY THERAPEUTICS; OWL PHARMACY; FRANK REZNICEK; AMANDA MATHEWS; HY-VEE, INC.; McKESSON CORPORATION; and **MICHAEL RINALDI,**

Appellees.

Appeal from the Iowa District Court for Appanoose County, E. Richard Meadows, Jr., Judge.

Plaintiff appeals and defendants cross-appeal from various rulings by the district court in a toxic-tort case that resulted in the dismissal of the claims. **AFFIRMED.**

Curt N. Daniels, Chariton, for appellant.

Stephen R. Eckley of Belin Lamson McCormick Zumbach Flynn, P.C., Des Moines, for appellee Adams Laboratories, Inc.

Thomas H. Walton and Kristina M. Stanger of Nyemaster, Goode, West, Hansell & O'Brien, P.C., Des Moines, for appellees Owl Pharmacy, Frank Reznicek, and Amanda Mathews.

Kermit B. Anderson and Stacie M. Codr of Finley, Alt, Smith, Scharnberg, Craig, Hilmes & Gaffney, P.C., Des Moines, for appellee Hy-Vee, Inc.

Patrick H. O'Neill, Jr. of O'Neill & Murphy, LLC, St. Paul, Minnesota, and William J. Bush of Bush, Motto, Creen, Koury & Halligan, P.L.C., Davenport, for appellee McKesson Corporation.

Michael H. Figenshaw of Bradshaw, Fowler, Proctor & Fairgrave, P.C., Des Moines, for appellee Michael Rinaldi.

CADY, Justice.

In this appeal from various summary judgment rulings by the district court in a toxic-tort case involving a claim that the ingestion of prescription medication allegedly containing phenylpropanolamine caused brain injury, we primarily consider the admissibility of testimony from an expert witness that the injuries allegedly suffered by the plaintiff were caused by the ingestion of phenylpropanolamine. The district court determined the causation opinion by the expert witness would be inadmissible at trial and granted summary judgment to the defendants. On appeal, we affirm the decision of the district court.

I. Background Facts and Proceedings.

Phenylpropanolamine (PPA) is a drug that was used over the course of three decades as an ingredient in many cough and cold products, as well as in appetite-suppressant products. It was approved by the Food and Drug Administration (FDA) in the 1970s as safe and effective and eventually became one of the most commonly used drug ingredients in the United States. It was widely used in both prescription and over-the-counter drugs, with billions of doses sold each year.

In November 2000, the FDA notified manufacturers and distributors of drug products containing PPA that a recent epidemiological study, conducted by the Yale University School of Medicine in collaboration with the FDA and manufacturers of PPA, had found a low risk of hemorrhagic stroke among women who used weight-loss products containing PPA. The FDA did not initiate a drug recall in response to the study, but recommended drug companies discontinue marketing products containing PPA. The study found no increased risk of hemorrhagic stroke among men who used products with PPA. It also found no increased risk among women who used cold and cough products containing PPA, but suggested such products

presented a possible risk for hemorrhagic stroke in women based on the increased risk found with weight-loss products. *See* Walter N. Kernan, et al., *Phenylpropanolamine and the Risk of Hemorrhagic Stroke*, 343 New Eng. J. Med. 1826, 1826–32 (2000) [hereinafter Kernan].

The FDA recommendation was widely reported to the public by the news media. Most manufacturers of the drug products containing PPA promptly responded to the announcement by discontinuing the distribution of their products containing PPA, including Adams Laboratories, Inc. and Adams Respiratory Therapeutics, the manufacturers of a prescription cough and cold medicine containing PPA called "Aquatab C." Adams also notified distributors and customers to return the product. Adams then reformulated Aquatab C by substituting PPA with pseudophedrine and made the new product available in March 2001. Aquatab C was distributed for Adams by McKesson Corporation.

On February 4, 2002, Bryan Ranes ingested Aquatab C. He had gone to Mercy Medical Center in Centerville with complaints of a sore throat, congestion, and a stuffy nose. He was seen by Dr. Michael Rinaldi, who prescribed three medications, including Aquatab C. Ranes' mother went to Owl Pharmacy in Centerville to fill the Aquatab C prescription. The pharmacist who filled the prescription was Amanda Mathews. The supervising pharmacist at Owl Pharmacy was Frank Reznicek. Owl Pharmacy did not have Aquatab C in stock at the time, but obtained it for Ranes from a nearby Hy-Vee Pharmacy.

Within thirty-five minutes of ingesting a tablet of Aquatab C, Ranes claimed he began to experience intense and excruciating pain on the left side of his head and numbness in his left arm and left side of his head. These symptoms, and many others, allegedly reoccurred after Ranes ingested additional tablets of Aquatab C.

In the months and years that followed, Ranes was seen by a number of physicians at a number of medical facilities both in and outside Iowa for a growing number of symptoms and complaints. The complaints and symptoms Ranes reported included convulsions, urinary incontinence, unsteady walk, vision and hearing problems, back and chest pain, diarrhea, altered taste and smell, muscle spasms, arm pain and weakness, tremors, numbness, and even the sight of worms crawling out of his hands. Some of the symptoms predated the ingestion of PPA. Prior to Ranes' visit with Dr. Rinaldi, on November 14, 2001, Ranes was examined at the Centerville Medical Clinic by Dr. Donald Fraser for multiple complaints of pain in every body part. The results of the examination were normal, and Dr. Fraser believed the complaints may have been attributable to general psychiatric problems such as hypochondriasis and chronic anxiety.

Following Ranes' visit with Dr. Rinaldi on February 4, 2002, Ranes was examined by a variety of physicians. An examination at Mercy Hospital in Des Moines on February 8, 2002, four days after Ranes was prescribed Aquatab C, included an MRI of the brain. The MRI was unremarkable, and the neurological examination by Dr. Paul Babikian was normal. Dr. Babikian testified he did not believe Ranes suffered from vasculitis of the cerebral vascular system. Subsequently, on March 6, 2002, Ranes was seen by Dr. Hala Shamsuddin, an infectious disease specialist at the University of Iowa Hospitals and Clinics. The accompanying neurological examination was normal, although Dr. Shamsuddin's records indicate Ranes may have been suffering from somatization disorder (a multisymptomatic disorder characterized by multiple physical complaints with no known medical explanation) and delusions of parasitosis. A CT scan at Mercy Medical Center in Des Moines on March 13, 2002, was normal, with no indication of intracranial hemorrhage. Ranes was subjected to a multispecialty team

evaluation conducted at Mayo Clinic in Rochester, Minnesota, from March 25, 2002, to April 26, 2002. A CT scan of the brain was normal, and no neurological disorder was observed by neurologist Dr. Jeffrey Britton. Doctors could find no indication of a stroke, intracranial hemorrhage, or seizure. An MRI, MRA, CT scan, and spinal tap conducted at St. Anthony's Regional Medical Hospital in Rockford, Illinois, on April 30, 2002, showed no abnormalities. St. Anthony's neurosurgeon Dr. Charles Wright could not diagnose Ranes with a neurological disorder, but his summary reported possible significant depression. Still unsatisfied with the results, Ranes went to the University of Nebraska Medical Center on August 8, 2002. An MRI of the brain and an MRA of the heart conducted at the University of Nebraska Medical Center were normal. A neurological exam conducted at Creighton Medical Center on September 10, 2002, was normal. Finally, on November 11, 2003, an examination performed at Washington University School of Medicine by Dr. Jin-Moo Lee, a stroke neurologist and assistant professor of neurology, concluded the symptoms displayed by Ranes from February of 2002 to date were not consistent with a stroke. Dr. Lee considered PPA in his analysis and ruled it out due to the absence of stroke in Ranes' case.

On March 5, 2004, Ranes filed a lawsuit against multiple individuals and corporations based on multiple legal claims, including negligence, strict liability, fraudulent nondisclosure, breach of fiduciary duty, battery, and infliction of emotional distress. Underlying each legal claim was an allegation that the ingestion of Aquatab C supplied by the defendants was the cause of a brain stroke or other neurological event that resulted in his myriad ailments.

Ranes continued to seek out medical evaluations after he filed his lawsuit. In April of 2004, Ranes was examined at the McFarland Clinic in

Ames by Dr. Michael Kitchell, a neurologist. Dr. Kitchell found some indication of neurological problems, but no evidence of a stroke. Dr. Kitchell believed, to a reasonable degree of medical certainty, that Ranes' symptoms were not associated with PPA. In April and May of 2005, Dr. Terry Rolan and Dr. Dale Vaslow at the University of Missouri School of Medicine similarly found Ranes suffered from neurologically related symptoms, but his problems were not associated with a cerebral hemorrhage. They too did not believe Ranes' case was associated with PPA, but rather most likely a "parainfectious autoimmune event leading to a brain stem encephalitis." Dr. Rolan also believed Ranes likely had a psychological aspect to his problems.

During the course of the legal proceedings, Ranes identified Dr. Mark Thoman as an expert witness who would testify at trial in support of his claim that his ailments resulted from a brain stroke or otherwise permanent, progressively degenerative neurological sequelae caused by the ingestion of Aquatab C containing PPA. Dr. Thoman is a specialist in toxicology and has primarily practiced medicine as a pediatrician. He is not a neurologist and has not authored any reports or articles on the effects of PPA. He is not one of Ranes' treating physicians and has never examined him. Dr. Thoman agrees that his diagnosis of vasculitis is not supported by any imaging tests or other medical tests. Dr. Thoman diagnosed Ranes with vasculitis because he believed Ranes' continual signs and symptoms are consistent with the toxic effects of PPA. The defendants identified Dr. Michael Jacoby, a neurologist, as one of their expert witnesses for trial. Dr. Jacoby concluded the symptoms identified by Ranes did not result from a stroke, but were consistent with a progressive degenerative neurological condition. Dr. Jacoby agreed with other neurologists who concluded Ranes did not suffer from vasculitis. He disagreed with Dr. Thoman's diagnosis.

Defendants eventually moved for summary judgment on a variety of grounds, including the claim that Dr. Thoman was not qualified to render an opinion that the ingestion of PPA caused Ranes' alleged injuries, and such an opinion failed to satisfy the standard of reliability. The defendants claimed summary judgment was proper because Ranes could not establish the causation element of any of his claims without expert opinion evidence. The motion for summary judgment was preceded by a motion to exclude the opinion testimony of Dr. Thoman from trial. Ranes acknowledged Dr. Thoman was the only witness who would testify at trial that the ingestion of PPA was a cause of Ranes' alleged injuries. However, he claimed Dr. Thoman was qualified to provide opinion testimony on causation, and his opinion was reliable and admissible.

In a detailed and well-written decision, the district court found Dr. Thoman's testimony on causation should be excluded from trial. The court found Dr. Thoman was unqualified to testify about his diagnosis that Ranes suffered from a neurological injury. It further found the differential diagnosis methodology used by Dr. Thoman, purporting to link PPA to the alleged neurological injuries by Ranes, was unreliable under Iowa law and relevant considerations. The court granted the motion to exclude his opinion from trial and granted summary judgment for all defendants.

Ranes appealed from the decision by the district court to exclude the opinion testimony of Dr. Thoman and to grant summary judgment. Defendants cross-appealed from various prior summary judgment rulings by the district court. On appeal, Ranes claims the district court abused its discretion to exclude the opinion testimony of Dr. Thoman from trial and erred in granting summary judgment.

II. Standard of Review.

We review a trial court's decision to admit or exclude expert testimony for an abuse of discretion. *Hyler v. Garner*, 548 N.W.2d 864, 868 (Iowa 1996). Thus, we will reverse a decision by the district court concerning the admissibility of expert opinions only when the record shows "the court exercised [its] discretion on grounds or for reasons clearly untenable or to an extent clearly unreasonable." *State v. Maghee*, 573 N.W.2d 1, 5 (Iowa 1997). "A ground or reason is untenable when it is not supported by substantial evidence or when it is based on an erroneous application of the law." *Graber v. City of Ankeny*, 616 N.W.2d 633, 638 (Iowa 2000). This standard applies the same to rulings admitting and rulings denying the testimony. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142, 118 S. Ct. 512, 517, 139 L. Ed. 2d 508, 517 (1997) (noting federal courts apply abuse-of-discretion standard in reviewing decisions to admit or exclude expert testimony).

We review a district court decision to grant or deny a motion for summary judgment for correction of errors at law. *Kolarik v. Cory Int'l Corp.*, 721 N.W.2d 159, 162 (Iowa 2006). We examine the record to determine whether a material fact is in dispute and, if not, whether the district court properly applied the law. *Robinson v. Fremont County*, 744 N.W.2d 323, 325 (Iowa 2008). Summary judgment is proper when the plaintiff's claim lacks evidence to support a jury question on an essential element of the claim. *Parish v. Jumpking, Inc.*, 719 N.W.2d 540, 543 (Iowa 2006).

III. Expert Testimony on Proof of Causation in Iowa.

Generally, we have been committed to a liberal view on the admissibility of expert testimony. *See Leaf v. Goodyear Tire & Rubber Co.*, 590 N.W.2d 525, 532 (1999) (citing court's history of maintaining liberal view on admissibility). Our broad test for admissibility of expert testimony has two preliminary areas of judicial inquiry that must be considered before

admitting expert testimony. *See* Iowa R. Evid. 5.702. The court must first determine if the testimony "will assist the trier of fact" in understanding "the evidence or to determine a fact in issue." *Id.* This preliminary determination not only requires the court to consider the existence of a reliable body of "scientific, technical, or other specialized knowledge," but it also requires the court to ensure the evidence is relevant in assisting the trier of fact. *See Johnson v. Knoxville Cmty. Sch. Dist.*, 570 N.W.2d 633, 637 (Iowa 1997) (stating that, to be relevant, the evidence must be reliable, and reliability is an implicit requirement of admissibility under Iowa Rule of Evidence 5.702 because "unreliable testimony cannot assist the trier of fact"); *see also Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929 (8th Cir. 2001) ("The rule's concern with 'scientific knowledge' is a reliability requirement, while the requirement that the evidence 'assist the trier of fact to understand the evidence or determine a fact in issue' is a relevance requirement."). Second, the court must determine if the witness is qualified to testify "as an expert by knowledge, skill, experience, training, or education." Iowa R. Evid. 5.702.

In assessing the reliability of scientific evidence under the first area of preliminary inquiry, we essentially utilize an ad hoc approach to decide if the scientific area of expertise produces results that are reliable enough to assist the trier of fact. *State v. Hall*, 297 N.W.2d 80, 85 (Iowa 1980) (rejecting *Frye* test of general scientific acceptance). When the scientific evidence is particularly novel or complex, however, we have suggested that courts consider the relevant factors identified by the United States Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593–94, 113 S. Ct. 2786, 2796–97, 125 L. Ed. 2d 469, 482–83 (1993). *Leaf*, 590 N.W.2d at 532. These factors help assess reliability of expert evidence by evaluating the scientific validity of the reasoning and methodology as applied to the facts of the case. *Daubert*, 509 U.S. at 592–93, 113 S. Ct. at 2796, 125

L. Ed. 2d at 482; *see also Bonner*, 259 F.3d at 929 (recognizing the purpose of *Daubert* factors). These factors are:

> (1) whether the theory or technique is scientific knowledge that can and has been tested, (2) whether the theory or technique has been subjected to peer review or publication, (3) the known or potential rate of error, or (4) whether it is generally accepted within the relevant scientific community.

Leaf, 590 N.W.2d at 533. The target of the court's scrutiny is on the principles and methodologies used to reach the expert's conclusions, not the conclusions themselves. *Daubert*, 509 U.S. at 595, 113 S. Ct. at 2797, 125 L. Ed. 2d 484.

We emphasize that the ad hoc *Hall* test remains our general approach to evaluating reliability, but the rapid advancements in science and medicine have presented particularly unique challenges for courts seeking to ensure the integrity of scientific evidence used by juries. This judicial role has become increasingly difficult and complex, yet important, as the access to and availability of sources of information and opinions continue to expand. Thus, we encourage a more expansive judicial gatekeeping function in difficult scientific cases. At the same time, it follows that application of *Daubert* considerations is not appropriate in cases involving "technical[] or other specialized knowledge" because such nonscientific evidence is not as complex. *Johnson*, 570 N.W.2d at 639. As a result, the foundational showing of reliability for nonscientific evidence is correspondingly lower. *See id.* at 637. For example, we have previously noted the inapplicability of *Daubert* to "general medical issues." *Id.* at 638 (quoting *Thornton v. Caterpillar, Inc.*, 951 F. Supp. 575, 578 (D.S.C. 1997)).

In all circumstances involving expert testimony, the proponent of the evidence has the burden of demonstrating to the court as a preliminary question of law the witness's qualifications and the reliability of the witness's

opinion. Iowa R. Evid. 5.104(*a*); *see State v. Myers*, 382 N.W.2d 91, 93 (Iowa 1986); *see also McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1238 (11th Cir. 2005). Although it is the province of the jury to evaluate the credibility of expert witnesses, trial courts have a well-recognized role as guardians of the integrity of expert evidence offered at trials. *See*, *e.g.*, 31A Am. Jur. 2d *Expert and Opinion Evidence* § 47, at 73 (2002) ("The qualifications of an expert witness must be carefully scrutinized by the court to guard against a pseudolearned person or charlatan who may give erroneous testimony or opinions without a sound foundation." (citing *Webb v. Olin Mathieson Chem. Corp.*, 342 P.2d 1094, 1097 (Utah 1959))); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149, 119 S. Ct. 1167, 1174–75, 143 L. Ed. 2d 238, 251 (1999); *see also* Iowa R. Evid. 5.104(*a*) official cmt.; *Leaf*, 590 N.W.2d at 534 (noting "issues of admissibility of expert testimony will be raised prior to trial").

Like *Daubert*, the case before us is a toxic-tort case. The proffered testimony at issue involves complex medical issues, including the potential biological effect of PPA on the human body and on Ranes, a corresponding differential diagnosis, and the alternative diagnosis of a complex neurological disease. Such testimony is certainly complex, and it has the "potential to achieve an exaggerated impact on the fact-finding process." *Leaf*, 590 N.W.2d at 534. The facts presented are far from "general," and unlike the cases cited in *Johnson*, the methodology in this case is not "based on practical experience and acquired knowledge," but on a somewhat novel scientific procedure characteristic of "scientific knowledge." 570 N.W.2d at 638. Additionally, *Daubert* itself was a toxic-tort case involving a complex issue of causation. *See Daubert*, 509 U.S. at 582, 113 S. Ct. at 2791, 125 L. Ed. 2d at 476. Thus, the district court's application of relevant *Daubert* considerations in preliminarily assessing the reliability of Dr. Thoman's

methodology was appropriate under Iowa law as an exercise of the court's gatekeeping function.[1]

IV. Qualification of an Expert.

A witness is qualified to assist the jury as an expert to resolve a disputed fact if the witness has adequate "knowledge, skill, experience, training, or education" on the subject matter in question. Iowa R. Evid. 5.702. All expert witnesses must be qualified in the area of their testimony based on one of the five areas of qualification. Yet, a particular degree or type of education is not needed. *Leaf*, 590 N.W.2d at 535. Moreover, an expert does not need to be a specialist in the area of the testimony as long as the testimony is within the general area of expertise of the witness. *Mensink v. Am. Grain*, 564 N.W.2d 376, 379 (Iowa 1997). However, the qualifications of an expert can only be properly assessed in the context of the issues to be determined by the fact finder.

A. Overview of Analysis. In this case, the disputed factual issue is whether the PPA contained in Aquatab C medication caused the plaintiff's injuries. The district court in this case examined the issue in terms of "general" and "specific" causation. Courts have commonly bifurcated toxic-tort-causation analysis into two separate but related parts: general causation and specific causation. *See* David E. Bernstein, *Getting to Causation in Toxic Tort Cases*, 74 Brook. L. Rev. 51, 52–53 ns.4, 6 (2008) [hereinafter Bernstein]; *see also Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1155 (E.D. Wash. 2009) ("Courts in toxic tort cases often separate the causation inquiry into general causation and specific

[1]Federal Rule of Evidence 702 was amended following the Supreme Court's holding in *Daubert* and is consistent with *Daubert*'s holding. *See* 3 David L. Faigman, et al., *Modern Scientific Evidence: The Law and Science of Expert Testimony* § 22:8 & n.2, at 127–28 (2008–2009 ed.). Because we determine *Daubert* principles should apply in this case, we proceed with our analysis using relevant authority that applies and interprets Federal Rule of Evidence 702.

causation."); *Anderson v. Hess Corp.*, 592 F. Supp. 2d 1174, 1178 (D.N.D. 2009); *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 401–02 (S.D.N.Y. 2005); *Bourne ex rel. Bourne v. E.I. Dupont de Nemours & Co.*, 189 F. Supp. 2d 482, 485 (S.D. W. Va. 2002); 3 David L. Faigman, et al., *Modern Scientific Evidence: The Law and Science of Expert Testimony* § 21:2 & n.1, at 8 (2008–2009 ed.) [hereinafter Faigman] ("Cause-in-fact in toxic tort cases is usually thought of as two separate issues: general causation and specific causation."). General causation is a showing that the drug or chemical is capable of causing the type of harm from which the plaintiff suffers. Mary Sue Henifin, et al., *Reference Guide on Medical Testimony, in Reference Manual on Scientific Evidence* 439, 444 (Fed. Judicial Ctr. 2d ed. 2000) [hereinafter Henifin]. Specific causation is evidence that the drug or chemical in fact caused the harm from which the plaintiff suffers. *Id.* One scholar has traced American courts' usage of the bifurcated causation analysis to a 1983 Agent Orange case. *See* Joseph Sanders, *The Controversial Comment C: Factual Causation in Toxic-Substance and Disease Cases*, 44 Wake Forest L. Rev. 1029, 1048 n.5 (2009) (referring to *In re "Agent Orange" Prod. Liab. Litig.*, 570 F. Supp. 693, 695 (E.D.N.Y. 1983)). The Third Restatement of Torts has recognized this relatively recent common practice as a "device[] to organize a court's analysis" and not as additional elements of the tort. Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 28 cmt. *c*, at 405 (2010). The Restatement authors supplement their explanation by asserting factual causation is a necessary element in every tort case; the "general and specific" language has simply become more prevalent in toxic-tort cases. *See id.* at 402 ("The special problem in these cases, however, is proving the connection between a substance and development of a specific disease. In all of these cases, the requirement to prove factual causation remains the same[.]"). The primary

difference between toxic-tort cases and other types of tort cases is that, in nontoxic-tort cases, both general and specific causation are often easily proven with the same evidence. *Id.* (noting when a plaintiff is injured in an automobile accident, for example, "potential causal explanations other than the collision are easily ruled out [i.e., specific causation]; common experience reveals that the forces generated in a serious automobile collision are capable of causing a fracture [i.e., general causation]").

This bifurcated analysis has not been explicitly used as the standard in Iowa. However, due to its general acceptance among scholars and courts of other jurisdictions, as well as the relative ease of application the analysis offers to courts examining complex issues of causation, we believe it is appropriate for courts to use the bifurcated causation language in toxic-tort cases. In the toxic-tort case before us, both types of causation must be proven, and expert medical and toxicological testimony is unquestionably required to assist the jury. Consequently, Ranes offered the testimony of Dr. Mark Thoman to not only show the effects that PPA is capable of producing, but also that the PPA contained in Aquatab C actually caused the neurological injuries alleged by Ranes.

The relevant expert or experts on causation in toxic-tort cases must be qualified to testify competently to both general and specific causation. *See Hyler*, 548 N.W.2d at 868 (recognizing "[t]he witness must be qualified to answer the particular question propounded"). Yet, we have previously determined "there is no requirement that the expert be able to express an opinion with absolute certainty. A lack of absolute certainty goes to the weight of the expert's testimony, not to its admissibility." *Johnson*, 570 N.W.2d at 637 (citation omitted). Thus, the plaintiff's expert must only be qualified to offer a theory of causation for the jury's consideration, not absolute certainty. There must be evidence that would permit a reasonable

person to conclude the drug probably caused the injury claimed. With this in mind, we turn to consider the "knowledge, skill, experience, training or education" of Dr. Thoman.

B. Qualification of Dr. Thoman. Dr. Thoman is a toxicologist. Toxicologists study the nature, effects, and detection of poisons and specialize in the treatment of poisoning. Commonly accepted traits of a qualified expert in toxicology include a degree in toxicology (a recently developed postgraduate program at many universities), certification by the American Board of Toxicology, and membership in professional toxicological organizations, such as the Academy of Toxicological Sciences. Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology, in Reference Manual on Scientific Evidence* 401, 415–17 (Fed. Judicial Ctr. 2d ed. 2000) [hereinafter Goldstein & Henifin].

Dr. Thoman appears to be qualified to testify about the effects of PPA on the human body, including common symptoms of PPA poisoning, and whether those effects appeared in the plaintiff's medical records. Dr. Thoman holds a medical degree, is certified by the American Board of Medical Toxicology, and is a member of a variety of national toxicology associations. The record also reflects that Dr. Thoman has extensive experience in the practice of toxicology. Although Dr. Thoman has not personally conducted a study involving PPA, it is the commonly accepted practice of toxicologists to review the relevant research literature and treatises before rendering an expert opinion. *See* Goldstein & Henifin at 415. Dr. Thoman testified that he reviewed numerous case studies in medical journals before arriving at his conclusion. Thus, the district court did not abuse its discretion by concluding Dr. Thoman was qualified to render an opinion on general causation, and we proceed to consider whether

Dr. Thoman was also qualified to opine that PPA probably caused the specific harm alleged in this case.

The district court found Dr. Thoman was not qualified to testify that PPA caused Ranes' specific injuries because Dr. Thoman is not a neurologist, and he purported to include a neurological diagnosis as the foundation of his opinion. The district court considered Dr. Thoman's testimony as an offer of proof that Ranes suffered from vasculitis. However, we believe the inquiry is narrower. Although Dr. Thoman is not a specialist in neurology, he may nevertheless be qualified to offer an expert opinion on the cause of Ranes' alleged injury if he otherwise has adequate knowledge, skill, experience, or training that would aid the jury in deciding if Ranes' injuries were in fact caused by PPA. An expert's qualification "should always relate to his or her background, education, and experience, rather than to a label which may be applied to a profession or trade." 31A Am. Jur. 2d *Expert and Opinion Evidence* § 41, at 66–67 (2002). Indeed, our rule of evidence does not include a requirement for how the qualifications to testify should be obtained, and our previous cases have held "[t]he criteria for qualifications under rule 702 . . . are too broad to allow distinctions based on whether or not a proposed expert belongs to a particular profession or has a particular degree." *Hutchison v. Am. Family Mut. Ins. Co.*, 514 N.W.2d 882, 887–88 (Iowa 1994). Once qualified adequately as a toxicologist by education, background, and experience, the expert may render an opinion on specific causation by applying a scientifically valid methodology to the facts of the case. *See* Goldstein & Henifin at 419. Thus, Dr. Thoman is not unqualified to give an opinion on specific causation in this case solely because he is not a neurologist.

The evidence in this case showed Dr. Thoman has read literature on the effects that PPA potentially has on the human brain. Dr. Thoman's

clinical experiences as a physician and toxicologist have generally made him familiar with the biological effects of sympathomimetics such as cocaine, amphetamine, and PPA. As a board-certified medical toxicologist, Dr. Thoman was certainly qualified to discuss the potential effects of PPA on the human body, but Dr. Thoman was also qualified to offer an analysis of PPA's potential effects on Ranes. Consequently, we next turn to consider whether Dr. Thoman's analysis in this case was scientifically sound. In doing so, we must decide whether the district court abused its discretion by excluding Dr. Thoman's testimony as unreliable.

V. Reliability of the Scientific Knowledge of a Qualified Expert.

Dr. Thoman offered a differential diagnosis to show both general and specific causation in this case. In order to determine whether this differential diagnosis is reliable, we must first decide whether a sufficiently reliable scientific foundation existed for Dr. Thoman's decision to "rule in" PPA as a potential cause of Ranes' alleged injuries. We begin by scrutinizing Dr. Thoman's opinion on general causation because his differential diagnosis rests on the necessary assumption that the underlying methodology used to rule PPA in as a cause is sound. Failure to reliably "rule in" the defendant's drug as a cause of the injuries in a particular case is commonly fatal to plaintiffs seeking to survive summary judgment in toxic tort cases. *See* Faigman § 21:2, at 9 ("[A] failure to lay a sufficient general causation predicate is often cited as grounds for excluding an expert's differential diagnosis testimony."); *id.* § 21:6, at 25 ("The 'rule in before ruling out' position of *Cavallo [v. Star Enter.*, 892 F. Supp. 756 (E.D. Va. 1995), *aff'd in relevant part*, 100 F.3d 1150, 1159 (4th Cir. 1996)] presumes that at least in toxic tort cases a differential diagnosis, no matter how well done, can rarely, by itself, prove general causation."); *see also Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1210–11 (10th Cir. 2002) ("In order to 'rule in' Parlodel

as a scientifically plausible cause of Ms. Hollander's stroke, the Hollanders' experts would need to present reliable evidence that the drug can cause strokes . . . ."); *Meister v. Med. Eng'g Corp.*, 267 F.3d 1123, 1130 (D.C. Cir. 2001) (no causal link between silicone breast implants and scleroderma, thus no liability); *Raynor v. Merrell Pharms. Inc.,* 104 F.3d 1371, 1376 (D.C. Cir. 1997) ("[T]estimony on specific causation had legitimacy only as follow-up to admissible evidence that the drug in question *could* in general cause birth defects. That first step, establishing a link between Benedectin and human birth defects (general causation) is missing here."); *Kolesar v. United Agri Prods., Inc.*, 412 F. Supp. 2d 686, 697 (W.D. Mich. 2006) (explaining that a valid differential diagnosis entails excluding alternative causes of a disease to arrive at a conclusion); *Coastal Tankships, U.S.A., Inc. v. Anderson,* 87 S.W.3d 591, 609–10 (Tex. App. 2002) ("In the toxic-tort context, a plaintiff must establish general causation for a differential diagnosis to be relevant to show specific causation."). Due to the inherent logic in the "rule in before ruling out" approach, and the intricate ties in this case between Dr. Thoman's differential diagnosis of causation and proof of general causation, we will begin our reliability analysis with a discussion of general causation.

A. Overview of Reliability Under General Causation Analysis. Rule 5.702 places a gatekeeping function with the district court to "[ensure] that evidence submitted to the jury meets [the rule's] criteria for relevance and reliability." *Bonner*, 259 F.3d at 929. The evaluation of reliability is a factually sensitive analysis. *Id.* The amount of foundation necessary to show reliability necessarily increases with the complexity of the case and the corollary likelihood the expert testimony will have a substantial impact on the fact finder. *Johnson*, 570 N.W.2d at 637. Yet, reliability should be assessed by examining the expert's " 'principles and methodology, not . . .

the conclusions that they generate.' " *Bonner*, 259 F.3d at 929 (quoting *Daubert*, 509 U.S. at 595, 113 S. Ct. at 2797, 125 L. Ed. 2d at 484). As applied to this case, the expert's methodology underlying his opinion must be evaluated both as to general and specific causation. *See id.* at 931–32 (reviewing expert's methodology in arriving at conclusion with respect to both types of causation). Thus, we will review the reliability of Dr. Thoman's methodology in reaching a conclusion on each type of causation.

B. Reliability of Dr. Thoman's Testimony. In order to establish general causation, Ranes must show PPA is capable of causing the injuries he claims. *See* Henifin at 469 ("The third step [in determining external causation] is to demonstrate that the medical and scientific literature provides evidence that in some circumstances the exposure under consideration can cause the outcome under consideration. This step is synonymous with establishment of general causation."). Problems can often arise in showing reliability of causation testimony in toxic-tort cases because of the "uncertainties concerning the mechanisms by which medical conditions develop from [exposure to a toxic substance] and the difficulties of ruling out other potential causes of those conditions." 4 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence* § 702.06(c)(i), at 702–127 (Joseph M. McLaughlin ed., 2d ed. 2009). When no scientific basis exists for conclusively identifying causation between the plaintiff's medical condition and the alleged wrong, medical experts recognize certain protocols to permit an opinion on causation to be expressed in terms of a reasonable medical certainty. *Id.* at 702–128.

The proffered evidence by Ranes on general causation was based primarily on case studies and case reports on the association between PPA and incidents of diagnosed stroke or vasculitis. Dr. Thoman did not conduct his own study on the effects of PPA on Ranes or on any other patients.

Thus, with *Daubert* considerations in mind, we assess the validity of Dr. Thoman's methodology based on the research and literature available to him.

The district court examined whether Dr. Thoman's theory is "scientific knowledge that can and has been tested" and whether the theory or technique "has been subjected to peer review or publication." We have also highlighted one particular factor in our previous case law: "proof of acceptance of the theory or technique in the scientific community." *Leaf*, 590 N.W.2d at 534. As the district court correctly points out, there is no dispute Dr. Thoman's personal theory that PPA can cause progressive, degenerative neurological symptoms, based on studies suggesting PPA may cause risk of stroke and vasculitis, has not been published or subjected to peer review. The main considerations under scrutiny are whether Dr. Thoman's theory "is scientific knowledge that can and has been tested" and whether his methodology is generally accepted in the fields of medicine and toxicology. Normally, general causation can be satisfied in part by medical and scientific literature supporting the conclusion that a drug is capable of causing the relevant injury. *See* Henifin at 469. However, the scientific value of various studies must be considered to fully understand the evidence an expert is justified in relying upon in any particular causation methodology.

Dr. Thoman relied on two different types of studies in formulating his general causation opinion: a case-control study and case reports (also referred to as "case studies"). Dr. Thoman did not use any clinical trials. In epidemiological parlance, clinical trials are considered the "gold standard" for determining the relationship between a drug and a health outcome. *See* Michael D. Green et al., *Reference Guide on Epidemiology*, *in Reference Manual on Scientific Evidence* 333, 338 (Fed. Judicial Ctr. 2d ed. 2000). In

clinical trials, participants are divided into two groups: one group is exposed to the substance under study and the other group, a "control group," is left unexposed. *Id.* Yet, clinical trials are not commonly available for the study of harmful toxins because ethical constraints preclude it. *See id.* at 339 (observing "[w]hen an agent's effects are suspected to be harmful, we cannot knowingly expose people to the agent"). Thus, medical experts are accustomed to using other methods of arriving at a causation opinion.

One such alternative method is to consider relevant case-control studies. Case-control studies "measure and compare the frequency of exposure in the group with the disease (the 'cases') and the group without the disease (the 'controls'). . . . [C]ase-control studies begin with individuals who are selected based on whether they have the disease or do not have the disease . . . ." *Id.* at 340. Experts assess the validity of using these studies in a particular case according to the studies' direct relevance to the injuries alleged in a case and according to the studies' known sources of error. *See id.* at 354; *see also In re Rezulin*, 369 F. Supp. 2d at 426 (noting " '[e]ven if an expert's proposed testimony constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge *for purposes of the case*' " (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743 (3d Cir. 1994))).

Dr. Thoman used one case-control study—the Yale study in the *New England Journal of Medicine*—in his general causation analysis. The study concluded PPA was likely to cause hemorrhagic stroke in women, but also concluded "[a]n analysis in men showed no increased risk of hemorrhagic stroke in association with the use of cough or cold remedies containing phenylpropanolamine." Kernan at 1826. Dr. Thoman reasoned, from this study, PPA can likely cause stroke, and since Ranes likely suffered a "stroke-like event," this study tended to show a relevant causal connection.

This study is simply not relevant to the case before us. It excludes men and only references hemorrhagic stroke in women. Moreover, the study does not describe an injury following PPA ingestion called "stroke-like event." In fact, stroke does not appear to be the injury at issue in this case at all. Dr. Michael Jacoby, a neurologist, testified "[t]here is no medically recognized 'death-like' condition of brain cells . . . [and] there is no such recognized medical condition as a stroke-like event . . . ." Dr. Thoman acknowledged he deferred to neurologists to determine whether a stroke in fact occurred, and all eight neurologists involved with Ranes' case refuted the diagnosis of stroke. Dr. Thoman did not attempt to explain his extrapolation from the study's reference to "stroke" to Ranes' so-called "stroke-like event," involving a progressive neurologic degeneration. As such, this case-control study is not relevant to the injuries alleged in this case and cannot be the basis of any general causation opinion.

Next, the record shows Dr. Thoman relied heavily upon several case reports from various sources. Case reports are reports in medical journals describing clinical events involving one individual or a few individuals. *See* Henifin at 474. The reports may show, among other things, an association between a specific exposure and a disease or injury. *Id.* Case report results are often confirmed or dismissed later by clinical trials or case-control studies. *Id.* Because unconfirmed case reports lack controls, they do not provide as much useful information to medical experts in directly assigning causation as controlled epidemiological studies. *Id.* at 475. As a result, "[c]ausal attribution based on case studies must be regarded with caution." *Id.* As the eleventh circuit has articulated,

> case reports are merely accounts of medical events. They reflect only reported data, not scientific methodology. . . .
>
> . . . Even these more detailed case reports, however, are not reliable enough, by themselves, to demonstrate the causal

> link the plaintiffs assert that they do because they report symptoms observed in a single patient in an uncontrolled context. . . . As such, while they may support other proof of causation, case reports alone ordinarily cannot prove causation.

Rider v. Sandoz Pharms. Corp., 295 F.3d 1194, 1199 (11th Cir. 2002).

Many courts, like the eleventh circuit, have found expert opinions based in part on case studies and reports and in part by other data and individual research to be reliable. *See id.*; *see also* Goldstein & Henifin at 475 & n.132. On the other hand, courts generally conclude, as the district court concluded in this case, that a bare analogy from case reports to the injuries alleged in a particular case is unreliable. *See McClain*, 401 F.3d at 1253–54; *In re Rezulin*, 369 F. Supp. 2d at 426–27; *Lennon v. Norfolk & W. Ry.*, 123 F. Supp. 2d 1143, 1151–53 (N.D. Ind. 2000). While there is no requirement that a medical expert cite published epidemiological studies on general causation to make a reliable conclusion, the methodology used by the expert becomes suspect when it is only supported by case reports of limited use to the medical field. *See Bloomquist v. Wapello County*, 500 N.W.2d 1, 5 (1993) (noting "while epidemiological evidence is helpful, it should not be held to be an absolute requirement in establishing causation"); *see also Bonner*, 259 F.3d at 929–31 (noting the general rule and finding the expert's subsequent reliance on case reports in addition to other facts reliable). We likewise believe it is important to the integrity of expert evidence presented to a jury that case reports are not given more weight in the courtroom than they would ordinarily be given in the medical field. Although generally " 'the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility,' . . . if an expert's opinion is 'so fundamentally unsupported . . . it can offer no assistance to the jury . . .,' " it must be excluded. *Hose v. Chicago Nw. Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1995) (quoting *Loudermill v. Dow Chem. Co.*, 863 F.2d 566, 570

(8th Cir. 1988)); *see also* Laurie Kratky Dorè, 7 *Iowa Practice: Evidence* § 5.703:1, at 625 (2009) ("Without reference to some facts pertinent to the matter in issue, an expert cannot state an opinion that will be of assistance to the trier of fact."). Here, the case reports used by Dr. Thoman to support general causation were not only unaccompanied by additional reliable methodology and facts, but the disorders addressed in the case reports described symptoms different from the symptoms experienced by Ranes. Thus, we proceed to examine these deficiencies.

Dr. Thoman attempted to support the case study conclusions by offering his own clinical experience with children and some adults in whom exposure to PPA caused headaches, photophobia, ataxia, chest pain, weakness, and inappropriate behavior. Yet, in Dr. Thoman's experience, these symptoms disappeared when the patient stopped taking the substance. In contrast, Ranes' symptoms not only continued after he stopped taking Aquatab C, but multiplied. Dr. Thoman made no attempt to offer an independent analysis in tandem with the case study to explain the differences between Ranes' symptoms and existing cases of PPA-induced injury. Instead, Dr. Thoman continuously testified there were no existing case reports that tended to show a patient with or without a diagnosis of vasculitis had the same symptomology as Ranes. This analysis amounts to a bare case report analogy, with no accompanying facts or circumstances to support the analogy. Moreover, if Dr. Thoman had taken his opinion in this case to a medical journal for publication, it would be in the form of another case report related to PPA, not a clinical trial or case-control study. *See McClain,* 401 F.3d at 1254. Reasonable medical experts would not rely upon the presented anecdotal information, standing alone, as providing a sufficient scientific basis to support the view that PPA causes vasculitis in males in light of the lack of controls, details, and further analysis.

Similarly, courts should not admit opinions based upon unreliable methodology.

Dr. Thoman sought to sidestep criticism that the case reports described disorders dissimilar to the disorder suffered by Ranes by diagnosing Ranes with vasculitis and then connecting this diagnosis with those particular case reports tending to show a specific instance of vasculitis may have been caused by the ingestion of PPA. This analysis, of course, does not aid in establishing the reliability of the case reports to support causation because a diagnosis of a disorder does not constitute additional evidence of causation of the disorder. A diagnosis of vasculitis relates to a description of the disorder, not additional scientific methodology or evidence to make the case reports reliable proof of a causal link between PPA and vasculitis. In the end, Dr. Thoman merely described his own isolated case report. He does not advance the reliability of his opinion that PPA can cause vasculitis.

Moreover, the diagnosis of vasculitis made by Dr. Thoman gives rise to additional concerns normally addressed in the analysis of specific causation.[2] Even assuming there was reliable evidence that PPA can cause vasculitis, such an opinion is relevant only if Dr. Thoman meets the foundational standards to diagnosis Ranes with vasculitis. If PPA can cause vasculitis in men, then part of specific causation requires a showing that the

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[2]In toxic-tort cases, both general and specific causation address the link between a drug and a disorder. The evidence to support general causation, however, normally focuses on the science that shows a causal connection between drugs and disorders in people. In turn, this science further tends to define the scope or range of disorders linked to the drug. Thus, if reliable science supports a causal connection between a specific drug and a particular brain disorder, the plaintiff completes the general causation analysis by alleging he or she suffered from that brain disorder. The evidence to support specific causation generally focuses on facts specific to a particular case that show a drug was an actual cause of the disorder suffered by the plaintiff. Thus, supporting evidence not only pertains to the cause of disorder, but also relates to a diagnosis of the disorder.

disorder suffered by the plaintiff is vasculitis. The diagnosis of vasculitis by Dr. Thoman is critical to the analysis because he was the only physician to diagnose Ranes with the disorder.

C. Reliability Under Specific Causation Analysis. Specific causation in toxic-tort cases examines whether the toxin at issue could have reasonably caused the plaintiff's specific alleged injuries. As noted previously, a differential diagnosis in a proper specific causation analysis assumes the toxin at issue is capable of causing the outcome under consideration. *See* Goldstein & Henifin at 469–70. A differential diagnosis involves "ruling in" specific causes, followed by a process of elimination, and "the final suspected 'cause' remaining after this process of elimination must actually be *capable* of causing the injury." *Cavallo*, 892 F. Supp. at 771. Since Ranes has failed to reliably show PPA is an external factor to be "ruled in" to a differential causation diagnosis, it follows he cannot establish PPA caused his specific injuries.

Additionally, even assuming PPA could be "ruled in" to a differential causation diagnosis to support the specific causation of the claimed disorder, Ranes must first show he suffered from the disorder alleged. Although doctors are ordinarily qualified to render a medical diagnosis, both the parties presented evidence that vasculitis is a rare disease that is difficult to diagnose. In the context of this complex toxic-tort case, and mindful of the complicated nature of the alleged disease at issue, we proceed to analyze the admissibility of Dr. Thoman's diagnosis testimony under our legal principles and the relevant *Daubert* considerations.

1. *Qualification of Dr. Thoman as a diagnosing medical expert.* In Dr. Thoman's deposition, he concluded Ranes suffered from PPA-induced vasculitis because his symptoms were consistent with symptoms characteristic of vasculitis. Vasculitis is the inflammation of blood vessels.

Dr. Jacoby testified vasculitis is "a very rare disorder," complex and difficult to diagnose, with symptoms that are often fatal if left untreated appropriately. As we have said before, the ability of a witness to testify is determined according to the specific issue presented. *Tappe ex rel. Tappe v. Iowa Methodist Med. Ctr.*, 477 N.W.2d 396, 402 (Iowa 1991). The plaintiff bears the burden of proving the expert is qualified under rule 5.702. *Myers*, 382 N.W.2d at 93.

Here, the issue is whether Ranes suffered from the effects of vasculitis. The plaintiff presented no evidence that Dr. Thoman has knowledge, skill, experience, training, or education suitable to an expert testifying about a neurological diagnosis of a complex nature. Dr. Thoman is undisputedly neither a qualified neurologist, nor one of Ranes' treating physicians. The diagnosis of vasculitis does not fall within his general area of expertise. *See Hunter v. Bd. of Trs.*, 481 N.W.2d 510, 520 (Iowa 1992) ("[T]he witness need not be a specialist in the particular area of testimony so long as the testimony falls within the witness['s] general area of expertise."). Additionally, no evidence was offered to reveal sufficient experience, knowledge, or training to show Dr. Thoman was qualified to render such a complex diagnosis.

2. *Reliability of methodology used by Dr. Thoman.* Dr. Thoman's purported methodology in reaching his diagnosis was also unreliable. In making a clinical diagnosis, it is common practice among medical experts to perform a differential diagnosis[3] by developing a "list of all the possible

[3]The phrase "differential diagnosis" is used by the medical profession to refer to two different processes: the process of determining the disease responsible for causing a particular patient's symptoms in a specific case, and the process of determining the cause of a diagnosed disease in a specific case. Henifin at 443. Some courts and expert witnesses use the phrase "differential etiology" to identify the process of determining causation and "differential diagnosis" for the process of diagnosing disease because the term "etiology" refers to the cause of disease, but this distinction is not by the medical profession. *Id.* The same scientific process may be used in both general and specific causation analyses, and

diseases that could produce the observed signs and symptoms," then comparing the expected clinical findings for each of the possible diseases with the patient's actual symptoms and test results. *See* Goldstein & Henifin at 463. Although the process of medical diagnosis is not an exact science, there does appear to be a medically accepted method of arriving at a diagnosis in any given case. *See generally id.* at 463–64 (describing the process for clinical diagnosis). Probabilities of disease are combined with a physician's "knowledge of the frequency of signs and symptoms in a given disease and competing diseases to progressively modify and ultimately arrive at their view of the likelihood of the disease under consideration." *See id.* at 467.

In this case, Dr. Thoman departed from a recognized medical process of diagnosing disease. First, evidence was presented to show Dr. Thoman did not consider the variety of diseases that tend to mimic the symptoms of vasculitis. Instead of considering the negative imaging results for vasculitis, Dr. Thoman dismissed all neurological tests performed over the course of three years as faulty. Of course, all diagnostic imaging tests that would have likely revealed inflammation to support the vasculitis, including an angiogram, were performed on Ranes and showed no abnormalities. Yet, a diagnosis of vasculitis, while seemingly far-fetched, is not impossible. Indeed, diagnostic imaging tests are known to be limited by potential error. *See* Goldstein & Henifin at 458. Dr. Vaslow testified that "standard MRI sequences may fail to detect acute stroke in 10 to 20 percent of patients." MRIs with diffusion and profusion weighted imaging are more accurate at detecting stroke. While Ranes was tested with an MRI machine within days

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here, we use it to refer to the process by which Dr. Thoman arrived at his diagnosis of vasculitis, a disease. We use the phrase "differential diagnosis" in this opinion the same way the medical profession uses it in order to maintain clarity and consistency.

of the first headache following prescribed dosages of Aquatab C, Dr. Vaslow could not determine whether the machine used at that time was an MRI with a diffusion and profusion weighted imaging. It is the plaintiff's burden to demonstrate it is more likely than not that the imaging technology in this case was too inaccurate to detect Ranes' alleged brain lesion, and such evidence does not appear on the record.

Notwithstanding, the state of the technology used to diagnose Ranes is only one of many potential considerations in diagnosing a patient. Importantly, Dr. Thoman's diagnosis of vasculitis and subsequent brain cell death was premised solely on Ranes' degenerative symptoms. Dr. Thoman did not perform a proper differential analysis to arrive at his diagnosis of vasculitis. Instead, Dr. Thoman summarily dismissed as many as eight mimicking conditions due to his lack of background and experience in diagnosing neurological diseases. Several other neurologists, including Dr. Babikian, dismissed vasculitis as a diagnosis in the course of their individual differential diagnoses. In the end, the record shows Dr. Thoman relied only on symptoms Ranes reported to tie the case reports he located to Ranes' case. This analysis is clearly inconsistent with the accepted methodology. Expert analysis that discusses only the evidence the expert believes will advance the plaintiff's position, and ignores a large amount of information that calls the expert's theory into question, cannot be considered reliable. *See In re Rezulin,* 369 F. Supp. 2d at 425–26.

Regardless of the reasons or motives for Dr. Thoman to diagnose Ranes with vasculitis in order to reach his opinion that PPA is capable of causing the injuries alleged by Ranes, the methodology he used to diagnose vasculitis is contrary to the methodology described by the scientific literature. Our standard for admission of expert evidence does not seek to exclude scientific hypotheses merely because they are "novel" or "unusual."

However, "scientific knowledge" implies the opinion is based on more than unsupported speculation. *Daubert*, 509 U.S. at 590, 113 S. Ct. at 2795, 125 L. Ed. 2d at 481. Although scientists do not purport to assert facts they believe are immutably true, "in order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation—i.e., 'good grounds,' based on what is known." *Id.* The courtroom must not be an arena "for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996). As such, we cannot conclude the district court abused its discretion in refusing to admit Dr. Thoman's diagnosis of vasculitis.[4]

VI. Conclusion.

We conclude the district court did not abuse its discretion by finding Dr. Thoman did not practice a reliable methodology in reaching his opinion that the ingestion of PPA was the cause of Ranes' alleged injuries. Consequently, Ranes failed to offer sufficient evidence to generate a factual question for the jury on the issue of causation to support his cause of action, and the district court properly granted summary judgment. Because the summary judgment dismissed the case against all defendants, we need not address any remaining issues in the case, and we do not consider the issues presented in the cross-appeals by defendants.

AFFIRMED.

All justices concur except Wiggins, J., who takes no part.

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[4]Prior to submission of this case, the plaintiff offered a "Notice of Additional Authority" for consideration. Generally, courts may consider authority outside the record in interpreting statutes and legislative facts. However, the facts the plaintiff proposes to include are evidentiary, not legal, in nature and will therefore be excluded from our discussion. Even assuming the facts offered are not precluded, such evidence would not support the plaintiff's efforts to establish the reliability of Dr. Thoman's methodology in this case due to Dr. Thoman's unqualified and unreliable process in diagnosing Ranes with vasculitis.