STOWELL V. DANDADE

R.R., a minor child, by and through HEATHER STOWELL, as parent and next friend,
Plaintiff-Appellant,
v.
TUSHAR DANDADE, M.D.,
Defendant-Appellee.

No. 34,998

COURT OF APPEALS OF NEW MEXICO

April 25, 2017

APPEAL FROM THE DISTRICT COURT OF SANDOVAL COUNTY, Valerie A. Huling, District Judge

COUNSEL

Law Offices of James P. Lyle, P.C., James P. Lyle, Albuquerque, NM, for Appellant

Rodey, Dickason, Sloan, Akin & Robb, P.A., Jocelyn Drennan, Edward Ricco, Albuquerque, NM, Hinkle Shanor LLP, Kathleen Wilson, Hari-Amrit Khalsa, Albuquerque, NM, for Appellee

JUDGES

JULIE J. VARGAS, Judge. WE CONCUR: JONATHAN B. SUTIN, Judge, TIMOTHY L. GARCIA, Judge

AUTHOR: JULIE J. VARGAS

MEMORANDUM OPINION

VARGAS, Judge.

{1} This is an appeal from the district court's decision to exclude the opinion testimony of Plaintiff Heather Stowell's only expert witness, a pharmacologist, as to the cause of her minor child's neurodegenerative disorder. Plaintiff also appeals the district court's entry of summary judgment in favor of Defendant Tushar Dandade, M.D., following the exclusion of Plaintiff's expert. As discussed below, we conclude that the district court did not err by excluding the testimony of Plaintiff's expert pharmacologist; and, absent other expert medical testimony on causation, the district court's entry of summary judgment for Defendant was proper.

BACKGROUND

{2} After becoming pregnant with her first child in 2008, Plaintiff sought prenatal treatment from Defendant. During the course of her pregnancy, Defendant prescribed Zoloft to Plaintiff. Zoloft is a selective serotonin reuptake inhibitor (SSRI) used to treat disorders such as depression and anxiety.

{3} Plaintiff gave birth to a baby girl, (R.R.) in April 2009. At birth, R.R. appeared to be a normal, healthy child with no apparent medical problems. Around age one, however, R.R. began displaying symptoms of neurodegeneration, which have steadily continued. Genetic and metabolic testing have failed to identify a cause for R.R.'s condition.

{4} Plaintiff filed suit against Defendant, claiming that the Zoloft he prescribed and she took during her pregnancy was the cause of R.R.'s neurodegenerative disorder. In support of her claim, Plaintiff named Dr. Patrick Ronaldson, Ph.D., as her only expert witness to testify about the medical causation of R.R.'s condition and damages.

{5} Dr. Ronaldson holds a Ph.D. in pharmacology, but is not a medical doctor and is not licensed to diagnose medical conditions. As part of his testimony, Dr. Ronaldson explained that he did not intend to offer opinions on the medical diagnosis of R.R. Instead, his testimony was limited to the etiology of R.R.'s neurodegenerative condition, specifically, the biological mechanisms that could have caused the symptoms that are apparent in R.R.

{6} In support of his theory that Zoloft was the cause of R.R.'s neurodegenerative disorder, Dr. Ronaldson explained, "[T]here is evidence in the scientific literature that hypoxia, including fetal hypoxia, can be caused by *in utero* exposure to SSRIs including [Zoloft]." According to Dr. Ronaldson, hypoxia can cause neurological damage; periventricular leukomalacia (PVL) is an established biomarker of hypoxia; and there are three references in R.R.'s very substantial medical records to PVL. These three references, along with Dr. Ronaldson's understanding that board-certified geneticists who had examined R.R. had ruled out a genetic cause for R.R.'s condition, form the basis of Dr. Ronaldson's opinion. In arriving at his conclusion, Dr. Ronaldson did not review R.R.'s testing images or actual lab results. Instead, he reviewed reports from the geneticists and radiologists who treated R.R.

{7} Dr. Ronaldson conceded that none of the studies on which he relied to reach his opinion demonstrate that Zoloft can cause a neurodegenerative disorder with the symptoms of those exhibited by R.R. He further admitted that no study to date supports his exact hypothesis.

{8} In support of his motion to exclude Dr. Ronaldson's testimony, Defendant presented evidence from R.R.'s treating pediatric geneticist and from his own expert geneticist and teratologist that a genetic explanation for R.R.'s neurodegenerative condition had not been ruled out and was the likely cause of R.R.'s condition. Dr. Randall Heidenreich, Chief of the Division of Pediatric Genetics at the University of New Mexico, evaluated R.R. in an attempt to identify a genetic cause for her condition. He was unable to identify a specific genetic basis for her neurodegeneration; however, Dr. Heidenreich continues to strongly believe that R.R. suffers from a genetic alteration that might be identified using exome or genome sequencing that has not yet been performed on R.R.

{9} Dr. Margaret Adam, M.D., a clinical geneticist and teratologist who testified on behalf of Defendant, agreed with the assessment of Dr. Heidenreich. Dr. Adam testified that, in her opinion, to a reasonable degree of medical probability, the cause of R.R.'s neurodegenerative condition was genetic. According to Dr. Adam, that R.R. was normal at birth but began exhibiting degenerative features around one year of age, that the degenerative features continued to progress, and that R.R.'s whole brain was affected all support her and Dr. Heidenreich's conclusions that the cause of R.R.'s condition is genetic. Dr. Adam confirmed Dr. Ronaldson's testimony that there were no studies in the field of genetics, teratology, or pediatrics that support the conclusion that prenatal exposure to Zoloft can cause a neurodegenerative condition such as R.R.'s. Further, Dr. Adam testified that the well-described effects of Zoloft on a fetus *in utero* are typically in the form of autonomic dysfunction and respiratory issues, none of which were present in R.R.

{10} Finally, Defendant submitted evidence from at least three separate sources, concluding that R.R. did not suffer from hypoxia or PVL, the conditions relied upon by Dr. Ronaldson to reach his conclusion. Dr. Adam testified that nowhere in R.R.'s medical records had any physician made a diagnosis of PVL in R.R. Another of Defendant's expert witnesses, Gail McCarver, M.D., a board certified pediatrician, neonatologist, and clinical pharmacologist, submitted an affidavit refuting Dr. Ronaldson's assumption that hypoxia is the medical cause of R.R.'s condition, instead concluding that R.R.'s "clinical presentation does not correlate with chronic hypoxia *in utero*." Finally, Dr. Marvin Nelson, M.D., a pediatric neuroradiologist submitted his affidavit, concluding "that the head imaging findings [for R.R.] do not suggest hypoxia during the perinatal period and this is not HIE (hypoxic-ischemic encephalopathy) or PVL (periventricular leukomalacia)."

STANDARD OF REVIEW

{11} The admissibility of expert testimony lies in the sound discretion of the district court. *Loper v. JMAR*, 2013-NMCA-098, ¶ 18, 311 P.3d 1184.

> An abuse of discretion standard of review, however, is not tantamount to rubber-stamping the trial judge's decision, and we are not prevented from conducting a meaningful analysis of the admission of the expert testimony to ensure that the trial judge's decision was in accordance with the Rules of Evidence and the evidence in the case.

Id. (internal quotation marks and citation omitted); *see State v. Alberico*, 1993-NMSC-047, ¶ 63, 116 N.M. 156, 861 P.2d 192. We resolve doubts regarding the admissibility of an expert opinion in favor of admission rather than exclusion of the evidence. *Parkhill v. Alderman-Cave Milling & Grain Co. of N.M.*, 2010-NMCA-110, ¶ 60, 149 N.M. 140, 245 P.3d 585 (Vigil, J., specially concurring).

DISCUSSION

A. Admissibility of Expert Testimony

{12} Whether testimony of an expert witness is admissible depends on three requirements: "(1) that the expert be qualified; (2) that the testimony be of assistance to the trier of fact; and (3) that the expert's testimony be about scientific, technical, or other specialized knowledge with a reliable basis." *State v. Downey*, 2008-NMSC-061, ¶ 25, 145 N.M. 232, 195 P.3d 1244.

{13} To be admissible, testimony of a medical expert must explain both "how and why [the expert] arrives at an opinion that a defendant physician's conduct has been substandard." *Sewell v. Wilson*, 1982-NMCA-017, ¶ 23, 97 N.M. 523, 641 P.2d 1070. The qualifications required of a medical expert turn on "the type of negligence claimed and the medical complexity involved." *Lopez v. Reddy*, 2005-NMCA-054, ¶ 16, 137 N.M. 554, 113 P.3d 377. Testimony from a medical professional who does not specialize in the area of medicine at issue may be admitted if the professional is qualified and competent to do so. *See Sewell*, 1982-NMCA-017, ¶ 23. "[T]he mere fact that a medical witness is not a specialist goes to the weight, not to admissibility, of the witness' expert testimony." *Id.* "Nevertheless, to give scientific or specialized opinion testimony, an expert witness must be qualified to do so by knowledge, skill, training or education." *Id.*

{14} On appeal, Plaintiff first argues that the district court wrongfully usurped the function of the jury by resolving the divergent opinions regarding medical causation in favor of Defendant's experts. Plaintiff further argues that the district court committed error when it rejected Dr. Ronaldson's opinion as untested and unsupported. We reject Plaintiff's arguments for two reasons and affirm the decision of the district court.

1. Dr. Ronaldson's Opinion Was Based on a Misunderstanding of R.R.'s Medical Diagnosis and He Is Not Qualified to Offer an Alternative Diagnosis

{15} Both in his expert report and in his testimony before the district court, Plaintiff's expert contended that there was no dispute between the parties regarding R.R.'s medical diagnosis. This is not the case. Dr. Ronaldson is correct that Plaintiff and Defendant agree that R.R. suffers from a neurodegenerative medical condition of unknown etiology, however, the parties do not agree on the manner in which R.R.'s condition manifested itself. In reaching his conclusion, Dr. Ronaldson relied on two premises that have been refuted by Defendant's medical experts.

{16} In forming his opinion, Dr. Ronaldson relied on his understanding that R.R. had been diagnosed with PVL, a biomarker of hypoxia. Hypoxia, Dr. Ronaldson concluded, can cause neurological damage. Dr. Ronaldson's understanding that R.R. had been diagnosed with PVL was based on three references to PVL in R.R.'s medical records. However, notwithstanding that R.R.'s medical records mention PVL on three instances, we note that Defendant's medical experts testified that R.R. was never diagnosed with PVL or hypoxia and did not suffer from either condition.

{17} Dr. Adam testified that nowhere in her medical records was R.R. diagnosed with PVL. Dr. Nelson, a pediatric neuroradiologist, agreed that R.R.'s head imaging revealed neither PVL nor hypoxia. Finally, Dr. McCarver, Defendant's expert pediatrician, neonatologist, and clinical pharmacologist, concluded that R.R.'s "clinical presentation did not correlate with chronic hypoxia *in utero*." As Dr. Ronaldson is not a medical doctor, did not review R.R.'s testing images and lab results, and admitted he is not qualified to diagnose medical conditions, he is not qualified to refute the conclusions of Defendant's three medical experts that R.R. suffers from neither PVL nor hypoxia. Without diagnoses of PVL and hypoxia, the foundational basis of Dr. Ronaldson's opinion—that Zoloft caused hypoxia (evidenced by PVL) in R.R., which resulted in her neurodegenerative condition—lacks any factual or medical support. *See Downey*, 2008-NMSC-061, ¶ 30 ("[T]he reasoning or methodology underlying the testimony must not only be scientifically valid, it also must be properly applied to the facts in issue." (omission, alteration, internal quotation marks, and citation omitted)).

{18} Further compromising Dr. Ronaldson's opinion is his exclusion of any possible genetic cause for R.R.'s condition. Among the factors cited by Dr. Ronaldson in support of his conclusion was the fact that a genetic cause had not been identified for R.R.'s condition. The absence of a genetic cause, Dr. Ronaldson surmised, made it more likely that the harm to R.R. was caused by Plaintiff's ingestion of Zoloft during pregnancy. Both Dr. Adam and Dr. Heidenreich, however, provided testimony that the cause of R.R.'s condition was genetic. Dr. Adam testified that it was her opinion to a reasonable degree of medical probability that the cause of R.R.'s neurodegenerative condition was genetic, pointing to the delay in the onset of her degenerative condition, as support. Dr. Heidenreich opined that R.R.'s specific genetic alteration might be identified using exome or genome sequencing that has not yet been performed. Dr. Ronaldson has no background, training, or experience in genetics that qualifies him to contradict the conclusions of Dr. Adam and Dr. Heidenreich that the cause of R.R.'s condition was genetic. As Dr. Ronaldson admits he is not qualified to offer a contrary diagnosis of R.R.'s medical condition, we are unpersuaded by Plaintiff's argument that the district

court improperly weighed the opinions of the experts in excluding Dr. Ronaldson's testimony.

2. Plaintiff Failed to Show That Dr. Ronaldson's Opinion Was Reliable

{19} Plaintiff also argues on appeal that the district court improperly rejected Dr. Ronaldson's opinion as untested and unsupported. However, Plaintiff failed to establish that the science that forms the basis of Dr. Ronaldson's conclusion is reliable and therefore admissible. To be admissible, expert testimony that is scientific or technical in nature, or that requires specialized knowledge must have a reliable basis. *See id.* ¶ 25. "[T]he determination of the external cause of a patient's disease is a complex process that is unrelated to diagnosis and treatment, and which requires specialized, scientific knowledge regarding the external agents involved." *Parkhill*, 2010-NMCA-110, ¶ 23. Dr. Ronaldson's testimony as to the causation of R.R.'s condition is admissible only if it is reliable. We have adopted several factors, frequently referred to as the *Daubert-Alberico* factors, to determine whether scientific testimony is reliable. Those factors are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known potential rate of error in using a particular scientific technique and the existence and maintenance of standards controlling the technique's operation; . . . (4) whether the theory or technique has been generally accepted in the particular scientific field[; and (5)] whether the scientific technique is based upon well-recognized scientific principle and whether it is capable of supporting opinions based upon reasonable probability rather than conjecture.

State v. Anderson, 1994-NMSC-089, ¶ 15, 118 N.M. 284, 881 P.2d 29 (internal quotation marks and citation omitted).

{20} Following an evidentiary hearing to determine whether Dr. Ronaldson's testimony should be excluded, the district court found that there was no literature in the fields of genetics, teratology, or pediatrics that concludes that the ingestion of Zoloft can cause a neurodegenerative condition such as R.R.'s. The court further found that there were no cases or other reports of Zoloft exposure during pregnancy causing later neurodegeneration after birth in humans or animals. Finally, the court found that there are no studies demonstrating that Zoloft can cause a neurodegenerative disorder such as that of R.R. or that support Dr. Ronaldson's opinions that the ingestion of Zoloft by pregnant women can cause the type of condition seen in R.R.

{21} In his report and at the hearing on Defendant's motion to exclude his testimony, Dr. Ronaldson relied on two scientific articles. The first, referred to by the parties as the Rurak article, considered the effects of fetal exposure to different types of SSRI medications. *See* Dan Rurak, et al., *Third Trimester Fetal Heart Rate and Doppler Middle Cerebral Artery Blood Flow Velocity Characteristics During Prenatal Selective Serotonin Reuptake Inhibitor Exposure*, 70 Pediatric Res. J. 96 (2011), http:///www.nature.com/pr/journal/v70/n1/pdf/pr2011139a.pdf. Included in the results

reported in the Rurak article were four cases of fetal exposure to Zoloft. Acknowledging that, "[t]o date, very little is known about SSRI effects on the human fetal physiologic functions[,]" the Rurak article concluded, after studying the effects of different SSRIs on twenty-nine subjects, that the observed results suggest *possible* fetal hypoxia. Rurak, et al., *supra*, at 96 (emphasis added). While the Rurak article opined that it was "*conceivable* that [SSRIs] alter early brain development[,]" the study neither discussed nor concluded that SSRIs caused neurodegenerative disorders such as the one seen in R.R. Rurak, et al., *supra*, at 96. In addition to the Rurak article, the only other peer-reviewed article on which Dr. Ronaldson relied was an article reporting the results of a study of the effects of high serotonin levels in mouse embryos. *See* Chi Chiu Wang, et al., *Serotonin Receptor 6 Mediates Defective Brain Development in Monoamine Oxidase A-deficient Mouse Embryos*, 289 J. Biological Chemistry 8252 (2014), http://www.jbc.org/content/289/12/8252.full.pdf. While the Wang study concluded that the presence of an SSRI in mouse embryos can initiate a series of events that impairs the central nervous system of the embryos, the study did not determine the manner in which the impairment manifested itself, as the embryo cultures did not go to term.

{22} Rather than support a conclusion that Dr. Ronaldson's opinion is based on well-recognized scientific principles, *see Anderson*, 1994-NMSC-089, ¶ 15, the peer-reviewed articles on which he relies fail to connect the use of Zoloft with R.R.'s neurodegenerative condition. Dr. Ronaldson provided no other peer-reviewed information to support his hypothesis that R.R.'s condition was caused by *in utero* ingestion of Zoloft, and Dr. Ronaldson admitted that there are no other studies that support his exact hypothesis. Defendant's expert, Dr. Adam, confirmed this, testifying there is no medical literature to support the proposition that Zoloft or any prescription medication causes a neurodegenerative condition such as the one suffered by R.R., either in humans or animals. Dr. Adam further testified that studies and case reports she has examined demonstrate that there does not appear to be any significant neurological effects to individuals exposed to Zoloft. In the absence of additional research, Dr. Ronaldson's testimony and opinion are merely conjecture and do not satisfy any of the *Daubert-Alberico* factors utilized to determine scientific reliability. *See Anderson*, 1994-NMSC-089, ¶ 15.

{23} Dr. Ronaldson testified and Plaintiff argues on appeal that his education, training, and experience as a pharmacologist render him qualified to testify about the biological mechanisms associated with this case that could have caused the symptoms that are apparent in R.R. According to Plaintiff, his opinions are sound, notwithstanding that he does not diagnose patients. *See Sewell*, 1982-NMCA-017, ¶ 23.

{24} Plaintiff urges that our Supreme Court's ruling in *Acosta v. Shell Western Exploration & Production, Inc.*, 2016-NMSC-012, 370 P.3d 761, supports the admissibility of Dr. Ronaldson's testimony. In *Acosta*, a toxic tort case, our Supreme Court declined to adopt the ruling of the United States Supreme Court in *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997), which allows a judge to "reject expert testimony where the 'analytical gap' between the underlying evidence and the expert's conclusion is 'too great[.]' " *Acosta*, 2016-NMSC-012, ¶ 27. In declining to adopt the

Joiner rule, *Acosta* determined it was inconsistent with the policy of our courts to leave credibility determinations and weighing of evidence to the trier of fact. *Acosta*, 2016-NMSC-012, ¶ 28. Reasoning that it would be unfair to bar the claims of the first several victims of a new toxic tort "simply because scientific analysis on a particular chemical cause has not yet been fully developed[,]" the Court utilized the nonformulaic guidelines of Sir Austin Bradford Hill to assess whether the plaintiff's epidemiological study finding an association between exposure to a mixture of benzene and other organic solvents and autoimmune disease supported an inference of causation. *Id.* ¶¶ 31-32. The Bradford Hill factors, the Court reasoned, "measure the ability of an epidemiological study to determine whether an association found by the study is sufficient to satisfy an ultimate question of fact regarding causation or whether the association is merely spurious." *Id.* ¶ 33.

{25} Initially, we note that unlike *Acosta*, Plaintiff's expert, Dr. Ronaldson, has not conducted or participated in any epidemiological or other studies or done any work on the effects of Zoloft on pregnant women or their fetuses. *Cf. Parkhill*, 2010-NMCA-110, ¶ 45 (" 'One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for the purpose of testifying[.]' " (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995))). Plaintiff does not ask us to conclude the results of Dr. Ronaldson's scientific study to be sufficiently reliable evidence to prove causation in this case. There is no study to consider. Instead, Plaintiff offers Dr. Ronaldson's conclusions with regard to a single patient based on the two scientific articles he cites along with his pharmacology education, training, and experience in studying how drugs cross biological membranes and accumulate in the body.

{26} This case is not akin to *Acosta*, as the effects of SSRI medications, such as Zoloft have been scientifically studied on pregnant women. Dr. McCarver explained that Defendant's prescription of Zoloft to Plaintiff is consistent with its use within the medical community, and the drug is commonly used in pregnancy. Dr. Adam testified that several studies of the effects of Zoloft have been conducted, and the effects on fetuses, if any, manifest themselves in the form of autonomic dysfunction and respiratory issues, neither of which afflicted R.R. Notwithstanding Dr. Ronaldson's significant pharmacology credentials, these deficiencies, coupled with the inability to satisfy any of the *Daubert-Alberico* factors, render his opinion unreliable, and therefore inadmissible. The district court did not abuse its discretion by excluding Dr. Ronaldson's testimony.

B. Grant of Summary Judgment

{27} Concluding that Plaintiff had not disclosed a medical expert qualified to establish a causal connection between Defendant's conduct and R.R.'s injuries, the district court granted Defendant's motion for summary judgment. We review, de novo, whether the district court properly granted summary judgment, viewing the facts in the light most favorable to the party opposing summary judgment and indulging all reasonable inferences in favor of a trial on the merits. *Acosta*, 2016-NMSC-012, ¶ 20.

{28} "In any medical malpractice action, the plaintiff has the burden of proving that . . . [the defendant's] actions complained of were the proximate cause of [the] plaintiff's injuries." *Schmidt v. St. Joseph's Hosp.*, 1987-NMCA-046, ¶ 8, 105 N.M. 681, 736 P.2d 135. As we noted in *Parkhill*, a determination of the external cause of a patient's condition requires specialized, scientific knowledge regarding those external agents involved. 2010-NMCA-110, ¶ 23. Dr. Ronaldson was Plaintiff's only expert to testify about the medical causation of R.R.'s condition and damages. With the exclusion of his testimony, Plaintiff has no medical expert to testify about the cause of R.R.'s harm and cannot prove the elements of her medical malpractice claim against Defendant. The district court properly granted summary judgment.

CONCLUSION

{29} We affirm the district court's exclusion of Dr. Ronaldson's expert causation testimony, as well as summary judgment granted on the basis of that exclusion.

{30} IT IS SO ORDERED.

JULIE J. VARGAS, Judge

WE CONCUR:

JONATHAN B. SUTIN, Judge

TIMOTHY L. GARCIA, Judge