United States Court of Appeals
For the Eighth Circuit

No. 13-1685

Scott Johnson, as guardian ad litem of H.T.P., a minor

Plaintiff - Appellant

v.

Mead Johnson & Company, LLC

Defendant - Appellee

No. 13-2681

Scott Johnson, as guardian ad litem of H.T.P., a minor

Plaintiff - Appellant

v.

Mead Johnson & Company, LLC

Defendant - Appellee

Appeal from United States District Court
for the District of Minnesota - Minneapolis

Submitted: February 11, 2014
Filed: June 6, 2014

Before SMITH, BEAM, and BENTON, Circuit Judges.

BEAM, Circuit Judge.

Scott Johnson, guardian ad litem for minor H.T.P., appeals the district court's adverse grant of summary judgment in this products liability case. The district court excluded Johnson's experts' testimony and accordingly entered judgment in favor of Mead Johnson (Mead). The district court also assessed costs in the amount of $18,442 against Johnson. Because we find the district court abused its discretion in excluding the experts, we reverse and remand.

I. BACKGROUND

In this summary judgment appeal we view the facts in the light most favorable to Johnson, the non-moving party. Sappington v. Skyjack, Inc., 512 F.3d 440, 445 (8th Cir. 2008). H.T.P. was born via Cesarean section on May 4, 2005. H.T.P's mother decided to feed H.T.P. infant formula. While in the hospital and for a short time upon returning home, H.T.P. was fed a sterile liquid infant formula, and then upon H.T.P.'s pediatrician's recommendation, a powdered infant formula (PIF) thereafter. Mead manufactures and sells PIF products which are not sterile, and have been occasionally found to be contaminated with a bacterium Enterobacter sakazakii, a/k/a Cronobacter sakazakii, or C. sak. Mead has issued two nationwide recalls of PIF products because of C. sak contamination, one in March 2002, and the other in January 2003. H.T.P. was fed Enfamil Lipil with Iron, a Mead PIF product, when he was a "neonate" (less than 28 days old). Because their immune and gastrointestinal systems have not yet fully developed, neonates are less able to cope with bacteria than

even slightly older infants and are thus more susceptible to infection. H.T.P.'s mother always prepared the PIF in their kitchen with tap water, warmed in the microwave, anywhere from 20 to 60 seconds, and then allowed to cool to room temperature. H.T.P.'s mother was also apparently an extremely fastidious cleaner, wiping the kitchen clean with antibacterial agents over 20 times a day. She also boiled the nipples and bottles for five minutes after washing. She prepared only enough formula for one feeding at a time and discarded any unused formula after feedings. H.T.P's mother testified that the baby was not fed outside of their home prior to his illness; H.T.P was fed primarily by her; and H.T.P was fed nothing other than liquid sterile formula and Mead PIF mixed with tap water.

On May 20, 2005, H.T.P. was taken to the St. Cloud, Minnesota, hospital emergency room because he was fussy, not eating well, and had a fever. A septic work-up was done, including a lumbar puncture, and H.T.P.'s cerebral spinal fluid was cloudy. H.T.P. was treated with antibiotics for presumed bacterial meningitis. On May 21, H.T.P. had seizures and a respiratory arrest, requiring ventilation and anti-seizure medications. Tests began to show brain inflamation and other abnormalities. He continued to be irritable and had seizures, but was sufficiently stable by May 31 to be transferred from pediatric intensive care to a medical floor. On June 6, H.T.P. was discharged and returned home. Two days later, H.T.P. returned to the St. Cloud emergency room because he was fussy, vomiting and had decreasing activity. He was admitted for intravenous hydration, and discharged home on June 10. On June 17, H.T.P. returned to the St. Cloud Hospital with hydrocephalus. He was transferred to the St. Paul Children's Hospital where a brain MRI showed extensive cerebral destruction. This is the first point at which doctors recognized possible C. sak infection. An external ventricular shunt was placed, and indeed, the spinal fluid culture subsequently grew the bacterium C. sak. On June 17, doctors discussed options with H.T.P.'s parents, including the option of withdrawing life support given H.T.P.'s brain damage, but the family desired continued treatment. H.T.P. survived the infection but sustained severe permanent brain damage.

On June 20, Children's Hospital contacted the Minnesota Department of Health (MDH) to report the C. sak infection, and MDH then interviewed H.T.P.'s family and collected all of the unopened Mead PIF cans at H.T.P.'s house, as well as one open can H.T.P.'s mother was then using. MDH was unable to collect one can of Enfamil that H.T.P's mother had completely used and discarded. MDH gave the cans to the Food and Drug Administration (FDA) and Centers for Disease Control (CDC) for testing. Their tests did not detect any bacteriological contamination.[1] H.T.P.'s home environment was not tested, nor was the specific Mead plant where this Enfamil was manufactured tested.

On November 9, 2010, Scott Johnson was appointed H.T.P.'s guardian ad litem, and in January 2011, Johnson brought this lawsuit against Mead in Minnesota state court asserting causes of action for products liability, negligence and failure to warn–alleging that Enfamil was defective or unreasonably dangerous due to C. sak contamination. Mead successfully removed the case based upon diversity jurisdiction. The case proceeded through discovery, including extensive expert witness depositions. Subsequently, Mead moved the district court to exclude or substantially limit the testimony of Johnson's expert witnesses and also moved for summary judgment. The district court held a Federal Rule of Evidence 702 hearing, and ultimately granted Mead's motions, finding that Johnson's experts' opinions were not sufficiently reliable/helpful to the trier of fact because three of the experts–Drs. Jason,

[1]According to Johnson's experts, the testing, isolation and identification techniques used by the FDA do not isolate, detect and/or identify all C. sak. The testing cannot detect an isolated clump or clumps of C. sak present in an individual feeding of PIF. Clinically significant C. sak contamination can exist in a single can of PIF, without it being present in other cans in that lot. Accordingly, even if the remaining portion of an implicated lot, or even of an implicated can, were tested and found to be negative for C. sak, the consumed portion could have contained clinically significant clumps of C. sak.

Farmer and Donnelly–did not do an adequate "differential diagnosis" in that they did not adequately "rule out" other possible sources of C. sak contamination.[2]

The district court took issue with the way that Johnson's experts "ruled out" other possible sources of H.T.P.'s C. sak infection such as the municipal water supply or the pipes and/or the environment in H.T.P.'s home. The district court found that Johnson's expert, Dr. Jason, had reliably "ruled in" the Enfamil as a possible source of the C. sak, but found that Dr. Jason's "ruling out" of the other sources was based upon unreliable methodology, primarily because there was no testing of the home environment and also because the water tests did not specifically test for C. sak. With regard to Johnson's other two experts, the district court found that both had neglected to properly "rule in" Enfamil as the source of the C. sak, but the district court excluded their testimony not because of the ruling in process, but instead excluded the reports on the same basis as Dr. Jason's–because of alleged deficiencies in the "ruling out" stage of the differential diagnosis. The district court, accordingly, granted summary

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[2]A differential diagnosis determines all of the possible causes for the patient's symptoms and then eliminates each of these potential causes until reaching one that cannot be ruled out, or deduces which of those that cannot be excluded is the most likely. Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999). On the other hand, "differential etiology" is a term used to describe the similar process by which the cause of an injury is determined. Guinn v. AstraZeneca Pharm., LP, 602 F.3d 1245, 1253 n.6 (11th Cir. 2010). Courts often use the term differential diagnosis to refer to both concepts, but in the instant case, we are actually referring to etiology, though we will continue to use the term "diagnosis." Thus, the experts "rule in" the reasonably plausible causes of injury and then "rule out" or eliminate them from least to more plausible until a most plausible cause emerges. We have previously ruled that this form of expert testimony is acceptable causation testimony under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), and in fact have termed it "presumptively admissible," noting that a district court may not exclude such expert testimony unless the diagnoses are "scientifically invalid." Glastetter v. Novartis Pharm. Corp., 252 F.3d 986, 989 (8th Cir. 2001) (per curiam) (citing Turner v. Iowa Fire Equip. Co., 229 F.3d 1202, 1208 (8th Cir. 2000)).

judgment to Mead because without the foregoing expert testimony, Johnson could not establish the specific causation necessary to prevail on his products liability causes of action. Johnson appeals, arguing the district court abused its discretion in refusing to allow its experts' testimony pursuant to Rule 702.

II. DISCUSSION

We review the district court's decision to exclude expert testimony for an abuse of discretion. Kuhn v. Wyeth, 686 F.3d 618, 624 (8th Cir. 2012). Although Minnesota law governs whether Johnson can ultimately prevail on the merits of this products liability action, the sole issue on appeal is the propriety of the district court's exclusion of Johnson's experts' reports. Admissibility of expert testimony is governed by Federal Rules of Evidence 702 and 703. The screening requirement of Rule 702 has been boiled down to a three-part test:

> First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

Polski v. Quigley Corp., 538 F.3d 836, 839 (8th Cir. 2008) (quotation omitted). An expert's opinion is to be based on "facts or data in the case that the expert has been made aware of or personally observed." Fed. R. Evid. 703.

When the Supreme Court decided Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), federal courts were divided over the issue of whether the test from Frye v. United States, 293 F. 1013 (D.C. Cir. 1923) or the standards set forth in the Federal Rules of Evidence (which were not in existence when Frye was

decided), governed the admissibility of expert testimony. Daubert, 509 U.S. at 586-87 & n.5. The restrictive Frye test allowed scientific expert testimony only with regard to concepts that had "general acceptance in [a] particular field." Frye, 293 F. at 1014. The Daubert Court held that the 1972 adoption of the Federal Rules of Evidence superseded the Frye test, finding that the admissibility of scientific evidence no longer was limited to knowledge or evidence "generally accepted" as reliable in the relevant scientific community. 509 U.S. at 588-89. Instead, Rule 702 mandates that the district court screen the admission of novel scientific evidence, and it must conclude, pursuant to Rule 104(a), that the proposed testimony is scientific knowledge, derived from the scientific method, that will assist the trier of fact, i.e., is relevant. Id. at 589-93. The district court's screening "entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id. at 592-93. While the Daubert Court acknowledged that many factors would be instructive to the district court, it focused on four non-exclusive factors: (1) whether the scientific technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review and/or publication; (3) the known rate of error for the technique or theory and the applicable standards for operation; and (4) whether the technique is generally accepted. Id. at 593-94.

Daubert and Rule 702 thus greatly liberalized what had been the strict Frye standards for admission of expert scientific testimony. Id. at 588 (highlighting the "liberal thrust" of the Federal Rules and their attempt to relax the previous roadblocks to expert testimony (quotation omitted)); see also Sappington, 512 F.3d at 448 (noting Rule 702's liberalization of expert testimony admission standard). Then in Kumho Tire Co. v. Carmichael, the Court expressly extended its Daubert reasoning to all expert testimony, not simply that which was considered "scientific." 526 U.S. 137, 147 (1999). Interestingly, the liberalization of the standard for admission of expert testimony creates an intriguing juxtaposition with our oft-repeated abuse-of-discretion standard of review. While we adhere to this discretionary standard for

review of the district court's Rule 702 gatekeeping decision, cases are legion that, correctly, under Daubert, call for the liberal admission of expert testimony. See, e.g., United States v. Finch, 630 F.3d 1057, 1062 (8th Cir. 2011) (holding that we resolve doubts about the usefulness of expert testimony in favor of admissibility); Robinson v. GEICO Gen. Ins. Co., 447 F.3d 1096, 1100 (8th Cir. 2006) (holding that expert testimony should be admitted if it "advances the trier of fact's understanding to any degree" (quotation omitted)); Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001) (Rule 702 "clearly is one of admissibility rather than exclusion" (internal quotation omitted)); Wood v. Minn. Mining & Mfg. Co., 112 F.3d 306, 309 (8th Cir. 1997) (holding that exclusion of expert's opinion is proper "only if it is so fundamentally unsupported that it can offer no assistance to the jury" (internal quotation omitted)). Further, district courts are admonished not to weigh or assess the correctness of competing expert opinions. Wyeth, 686 F.3d at 625. As long as the expert's scientific testimony rests upon "good grounds, based on what is known" it should be tested by the adversary process with competing expert testimony and cross-examination, rather than excluded by the court at the outset. Daubert, 509 U.S. at 590, 596.

The district court in the instant case violated these liberal admission standards by resolving doubts in favor of keeping the testimony out and relying upon its own assessment of the correctness of the expert opinions. By doing so, it disallowed the adversarial process to work. Considering the three factors from the Rule 702 test of admissibility, the first two–that the subject is one needing testimony and that the experts in question are qualified[3]–are not seriously in dispute. It is the third–that the

[3]Dr. Jason is a pediatrician, epidemiologist, clinical pediatric infectious disease physician, and board eligible immunologist. She completed the CDC epidemiology intelligence service training program and worked at CDC for over 20 years, and was on the Emory University School of Medicine faculty during that same time frame, teaching in the Department of Pediatric Immunology, Infectious Diseases and Epidemiology. Dr. Farmer is the retired chief of the Enteric Reference Laboratories,

evidence is trustworthy enough to assist the trier of fact–that is in dispute. The key inquiry is whether the methodology of the three experts–using a differential etiological method to first "rule in" the scientifically plausible causes and then rule out the least plausible causes–was reliable enough to assist the trier of fact. The district court concluded it was not, and ostensibly relied upon our precedent, Glastetter v. Novartis Pharmaceuticals Corp., 252 F.3d 986 (8th Cir. 2001) (per curiam), in so ruling.

In Glastetter, the plaintiff sought to admit expert testimony that the drug Parlodel, which she took to suppress lactation after giving birth, can cause intracerebral hemorrhages (stroke). The expert used a differential diagnosis, which we found was, generally speaking, a reliable method under Daubert. Id. at 989. However, the expert in Glastetter opined that Parlodel might cause strokes because Parlodel likely caused arteries to constrict, and vasoconstriction is a known cause of strokes. The problem with this testimony was that the experts had no scientific proof that Parlodel caused vasoconstriction. Id. As we noted, "its major premise remains unproven" because there was no "scientifically convincing evidence that Parlodel causes vasoconstriction." Id. Although the experts attempted to present such evidence in the form of case reports and medical texts, we found these sources to be unreliable. Id. at 989-90.

Here, no one disputes that Enfamil can be and has been a source of C. sak. Thus, the major premise of Johnson's experts does not remain unproven. Glastetter is an example of a case wherein experts failed to properly "rule in" the accused source

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Foodborne and Diarrheal Diseases Laboratory section of the CDC. He first named the Enterobacter sakazakii as a bacterial species distinct from Enterobacteriaceae. Dr. Donnelly is a microbiologist on the faculty at University of Vermont since 1983, and also served a six-year term on the National Advisory Committee on the Microbiological Criteria for Food from January 1999 through 2005, a time when C. sak was being addressed by the FDA and CDC as a pathogen of concern in PIF.

of the problem. The district court agreed that Dr. Jason[4] at least properly "ruled in" Enfamil as a likely source. Other than providing the general framework that differential diagnoses are admissible under Daubert unless "scientifically invalid," id. at 989, we fail to see how Glastetter is particularly relevant to this case. In the instant case, the district court found that Johnson's experts did not efficaciously "rule out" the other plausible sources of C. sak. However, we have consistently ruled that experts are not required to rule out all possible causes when performing the differential etiology analysis. Lauzon, 270 F.3d at 693; In re Prempro Prods. Liab. Litig., 586 F.3d 547, 566-67 (8th Cir. 2009) (rejecting the argument that expert testimony on the cause of plaintiff's breast cancer must be excluded because the cause of breast cancer is generally unknown and because the plaintiff had known risk factors). And, a differential expert opinion can be reliable even "with less than full information." In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 759 (3d Cir. 1994). Instead, such considerations go to the weight to be given the testimony by the factfinder, not its admissibility. In re Prempro, 586 F.3d at 566.

As previously noted, we have already affirmed the fundamental principle that differential diagnoses in general pass muster under the four considerations identified in Daubert. Turner v. Iowa Fire Equip. Co., 229 F.3d 1202, 1208 (8th Cir. 2000) (agreeing with other circuits who have held that "a differential diagnosis is a tested methodology, has been subjected to peer review/publication, does not frequently lead to incorrect results, and is generally accepted in the medical community"). So even

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[4]Upon examination of the Declarations of Drs. Donnelly and Farmer, we fail to see a noticeable distinction in the manner they ruled in Enfamil as a possible source of the C. sak versus the way Dr. Jason approached the issue. Each of the experts discussed the studies by the World Health Organization or the CDC concerning C. sak contamination in PIF; the current protocols in the United States for PIF manufacturers for detecting C. sak; the C. sak testing routinely performed by Mead with regard to PIF; and the conditions at the particular Mead plant where H.T.P.'s Enfamil was manufactured. Accordingly, we find that Drs. Donnelly and Farmer adequately "ruled in" Enfamil as a possible source of H.T.P's C. sak.

if the district court believed there were better grounds for some alternative conclusion (perhaps that the microwave killed any C. sak), or there were some flaws in the experts' methods (for not having tested the household environment or that water testing was incomplete), because the expert testimony in this case was within "the range where experts might reasonably differ," the jury, not the trial court, should be the one to "decide among the conflicting views of different experts." Kumho Tire, 526 U.S. at 153.

The district court abused its discretion in excluding Johnson's experts. The methodology employed by Johnson's experts was scientifically valid, could properly be applied to the facts of this case, and, therefore, was reliable enough to assist the trier of fact. Daubert, 509 U.S. at 593-94. With the expert testimony proposed, Johnson has created an issue of fact for a jury on the issue of the specific cause of H.T.P's C. sak infection. Accordingly, he is entitled to attempt to prove his claim for products liability pursuant to Minnesota law.

III. CONCLUSION

We reverse the orders of the district court excluding the testimony of Johnson's experts, and granting summary judgment and costs in favor of Mead, and remand this matter for proceedings consistent with this opinion.
