United States Court of Appeals FOR THE EIGHTH CIRCUIT

No. 10-1587		
Tami Smith, as Personal Representative of the Estate of Velda Smith, deceased, Plaintiff-Appellant, v.	* * * * * * * *	Appeal from the United States District Court for the District of South Dakota.
Gary Bubak, M.D.; Wagner Community Memorial Hospital, a South Dakota Corporation; Bubak Medical Clinic; Avera Health, a South Dakota Corporation; Avera Sacred Heart Hospital, Defendants-Appellees.	* * * * * * * * *	
Submitted: February 16, 2011		

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Before LOKEN, MELLOY, and SHEPHERD, Circuit Judges.

MELLOY, Circuit Judge.

Tami Smith, as a personal representative of the estate of Velda Smith, sued Dr. Bubak and the remaining Defendants (collectively referred to as "Dr. Bubak") for medical malpractice, claiming that Dr. Bubak negligently failed to transfer Velda Smith to a medical facility where she could have received tissue plasminogen activator

("tPA") to treat her stroke. To establish that Dr. Bubak's negligence proximately caused Velda Smith's injuries, Tami Smith offered expert medical evidence showing that Velda Smith possessed approximately a fifty-eight percent chance of at least a partial recovery had she timely received tPA. Dr. Bubak moved to exclude this expert evidence and moved for summary judgment. The district court¹ granted both motions, finding that Tami Smith's medical evidence was unreliable, and as result, Tami Smith failed to prove causation. Tami Smith appeals, and we affirm.

I.

On February 9, 2006, Velda Smith arrived for work at the Fort Randall Casino outside of Pickstown, South Dakota, exhibiting stroke-like symptoms. As a result, she was transported by ambulance to Wagner Community Memorial Hospital. Upon arrival at 5:09 p.m., she was seen by Dr. Bubak, who immediately began treating her after noting left-facial weakness and elevated blood pressure of 213/100. Shortly thereafter, at either 5:30 or 6:00 p.m., Dr. Bubak made preparations to transfer Velda Smith to Douglas Memorial Community Hospital in Armour, South Dakota, in order for her to undergo a Computerized Axial Tomography ("CT") scan. At that time, Wagner Community Memorial Hospital did not have a CT machine, and Douglas Memorial Community Hospital was the closest medical facility with an available CT machine. After being stabilized, at approximately 7:15 p.m., Velda Smith was transferred, and at 8:15 p.m., Dr. Bubak was notified that Velda Smith's CT scan was negative for a cerebral hemorrhage. Velda Smith was eventually transported back to Wagner Community Memorial Hospital, where she remained until being transferred to another facility on February 14, 2006. Velda Smith subsequently passed away on September 4, 2009.

¹The Honorable Lawrence Piersol, United State District Judge for the District of South Dakota.

In the amended complaint, Tami Smith alleges that "[a]t no time on February 9, 2006, or thereafter, did Dr. Bubak chart any consideration of transfer, treatment by tissue plasminogen activator (tPA), nor did he discuss any such options with [Velda Smith], her family, significant other or other medical professionals." When timely given, tPA can mitigate the effects of ischemic strokes through restoring blood flow. According to Tami Smith, the failure of Dr. Bubak to transfer Velda Smith to a facility where she could have timely received tPA constituted a breach of the applicable standard of care and ultimately resulted in the death of Velda Smith. For support, Tami Smith offered the testimony of three expert witness: Dr. John Owens ("Dr. Owens"), Dr. Jerry Walton ("Dr. Walton"), and Dr. James McDowell ("Dr. McDowell"). Dr. Owens and Dr. Walton testified in their respective depositions that Dr. Bubak breached the relevant standard of care by failing to transfer Velda Smith to a hospital where she could have received tPA; however, neither doctor opined as to whether Velda Smith was harmed by Dr. Bubak's inaction. In contrast, Dr. McDowell opined that approximately fifty-eight percent of stroke patients, such as Velda Smith, who timely receive tPA show measurable improvement.

When questioned about the basis of his estimate, Dr. McDowell cited a 1995 National Institute of Neurology and Communicative Disorders Stroke Study ("1995 NINDS Study"). As reanalyzed by a subsequent study in 2004, the 1995 NINDS Study found that thirteen percent of stroke patients recover due to the administration of tPA, another nineteen percent of stroke patients show measurable improvement due to tPA, and twenty-six percent of stroke patients spontaneously improve *without* tPA. Dr. McDowell testified in his deposition that he arrived at his specific estimate through simply adding each of the three percentages together. Later, however, after the district court voiced its concerns about the propriety of just adding these three percentages together to determine the overall efficacy of tPA, Dr. McDowell began relying on the results of a study published in the Archives of Neurology entitled *Review of Tissue Plasminogen Activator, Ischemic Stroke, and Potential Legal Issues* ("Zivin Paper"). The Zivin Paper concluded that stroke patients who timely receive

tPA are 57.3% more likely to show measurable improvement than stroke patients who do not timely receive the medication.² The Zivin Paper arrived at this result after conducting a statistical reanalysis of the 1995 NINDS Study using the Wilcoxon matched-pairs test ("Wilcoxon test").

Dr. Bubak subsequently moved to exclude Dr. McDowell's expert opinion and for summary judgment. Dr. Bubak claimed first that Dr. McDowell improperly included the twenty-six percent of stroke patients who naturally improved without the tPA when calculating the overall effectiveness of the drug. Dr. Bubak secondly claimed that Dr. McDowell could not properly rely on the results of the Zivin Paper when formulating his estimate because the Zivin Paper is methodologically flawed.

The district court generally agreed and granted summary judgment in favor of Dr. Bubak after finding Dr. McDowell's expert opinion unreliable. More specifically, the district court concluded that under South Dakota's law on proximate cause, Tami Smith needed to show that the administration of tPA would have more likely than not caused Velda Smith to improve. Applying this standard, the district court discounted Dr. McDowell's fifty-eight percent estimate from the 1995 NINDS Study because his calculation included the large percentage of stroke patients who naturally recovered without tPA. The Court reasoned that Dr. McDowell could not reliably state whether giving tPA to Velda Smith would have more likely than not caused her to improve when his calculation included patients who did not receive any benefit from the drug.

The district court also discounted Dr. McDowell's reliance on the Zivin Paper. The district court concluded that the Zivin Paper was unreliable in part because Tami Smith had failed to present sufficient evidence demonstrating that the Wilcoxon test

²The Zivin Paper further found that after controlling for patients who arrived at the hospital either "essentially moribund" or exhibiting few signs of stroke, 58.6% of stroke patients who timely receive tPA improved *as compared to* stroke patients who did not receive the medication.

was an appropriate means of discerning the efficacy of tPA. The district court went further, however, and concluded that even if the Zivin Paper were methodologically sound, Dr. McDowell could not reliably use the Zivin Paper to extrapolate whether giving Velda Smith tPA would have more likely than not caused her to improve. This is because the results of the Zivin Paper did not account for the twenty-six percent of stroke patients who improve without tPA, and as such, the results could not be used to discern the overall effectiveness of the drug. Finding no other evidence of causation, the district court granted the motion for summary judgment.

II.

On appeal, Tami Smith challenges both the exclusion of Dr. McDowell's expert opinion and the resulting grant of summary judgment.³ Federal Rule of Evidence 702 governs the admissibility of expert testimony, and it requires that district courts "ensure that all scientific testimony is both reliable and relevant." Marmo v. Tyson Fresh Meats, Inc., 457 F.3d 748, 757 (8th Cir. 2006). As we recently explained:

To satisfy the reliability requirement, the party offering the expert testimony "must show by a preponderance of the evidence both that the expert is qualified to render the opinion and that the methodology underlying his conclusions is scientifically valid." <u>Id.</u>; [<u>Daubert v. Merrell Dow Pharm., Inc.</u>, 509 U.S. 579, 589–90 (1993)]. To satisfy the relevance requirement, the proponent must show that the expert's reasoning or methodology was applied properly to the facts at issue.

<u>Barrett v. Rhodia, Inc.</u>, 606 F.3d 975, 980 (8th Cir. 2010). When examining a district court's decision to exclude expert testimony, we review for an abuse of discretion.

³The parties further dispute whether the district court's grant of a summary judgment is supported by alternative grounds. However, we need not consider this issue given our conclusion regarding the admissibility of Dr. McDowell's testimony.

<u>Dunn v. Nexgrill Indus., Inc.,</u> F.3d ____, No. 09-2722, 2011 WL 668062, at *4 (8th Cir. Feb. 25, 2011).

Tami Smith argues that the district court abused its discretion when excluding Dr. McDowell's testimony because of his reliance on the Zivin Paper.⁴ Tami Smith asserts that the Zivin Paper is reliable because the scientific evidence in the record shows the Wilcoxon test is a well-established method of analyzing the efficacy rates of medications, including tPA. Tami Smith further asserts that the district court erred in discerning South Dakota's proximate cause standard, which resulted in the court improperly concluding that the Zivin Paper was irrelevant. According to Tami Smith, South Dakota's law on proximate cause requires a plaintiff to show only that the relative benefit of a drug is greater than fifty percent to establish that the failure to give the drug is more likely than not the cause of the patient failing to recover. The relative benefit from a drug is the increased likelihood that a patient will improve as compared to patients who do not receive the drug. South Dakota law, Tami Smith continues, does not require a plaintiff to show that the absolute benefit of a drug is greater than fifty percent, as the district court found. The absolute benefit of a drug is the measure of a drug's overall effectiveness.⁵ Since the Zivin Paper finds that 57.3% of stroke patients who receive tPA improve as compared to stroke patients who do not receive the drug, Tami Smith maintains that the Zivin Paper is relevant and that

⁴Tami Smith does not challenge the district court's finding that Dr. McDowell's estimate directly from the 1995 NINDS Study was unreliable.

⁵To illustrate the distinction between the absolute and relative benefits of a drug, assume that a certain drug increased the recovery rate of an illness from ten percent to sixteen percent. A *relative* measure of the medication's effectiveness, such as what the Zivin Paper measured, would capture the proportional difference between the ten-percent recovery rate and the sixteen-percent recovery rate and conclude that patients receiving the medication would be sixty percent more likely to improve than patients who do not receive the medication. An *absolute* measure of the medication's effectiveness would calculate the difference between the two recovery rates and conclude that the drug increases a patient's chance of recovery by six percent.

Dr. McDowell can reliably use its results to opine on whether Velda Smith would have more likely than not improved had she receive tPA. We disagree.

For purposes of our analysis, we assume without deciding that the Zivin Paper is methodologically sound and consider only whether Dr. McDowell's expert opinion should be excluded because the results of the Zivin Paper are irrelevant under South Dakota's law on proximate cause. In <u>Jorgenson v. Vener</u>, which was later abrogated by statute, the Supreme Court of South Dakota adopted the "loss of chance doctrine." 616 N.W.2d 366, 371 (S.D. 2000), abrogated by S.D. Codified Laws § 20-9-1.1. "The loss of chance doctrine involves the idea that a doctor, by doing something wrong, has decreased the patient's chance of recovery or survival" and that this loss is compensable even though the patient would have likely suffered the same injury had the physician not been negligent. <u>Id.</u> at 368–70. For example, if a doctor's negligence reduced a patient's chance of recovery from thirty-percent to twenty-percent, the patient could recover under the loss of chance doctrine even though the patient would have likely sustained the same injury in the absence of any negligence by the physician. See id. at 370. In contrast, a plaintiff alleging medical malpractice under a traditional proximate cause standard would need to show by a preponderance of the evidence that the physician's negligence caused an injury, which would preclude recovery when the plaintiff would have likely sustained the injury in the absence of any negligence. <u>Id.</u> at 369. When the South Dakota legislature decided to abrogate the <u>Jorgenson</u> decision, South Dakota effectively reverted to the traditional proximate cause standard. SDCL § 20-9-1.1.

Under the traditional proximate cause standard, we do not believe that the results of the Zivin Paper are sufficiently relevant to allow Dr. McDowell's testimony to be admissible under Rule 702. As stated earlier, the Zivin Paper found that stroke patients receiving tPA are 57.3% more likely to improve than stroke patients who do not timely receive tPA. While this finding does indicate that tPA causes some stroke patients to improve, this result does not reveal whether giving a patient tPA will more likely than not cause a stroke patient to improve, which is the material inquiry under

a traditional proximate cause regime. See Young v. Mem'l Hermann Hosp. Sys., 573 F.3d 233, 236 (5th Cir. 2009) (affirming a district court's grant of summary judgment in favor of defendants because the plaintiff had failed to show that tPA benefits more than fifty percent of stroke patients who timely receive it); Samaan v. St. Joseph Hosp., ___ F. Supp. 2d ___, No. 1:09-cv-00656-JAW, 2010 WL 5177740, at *10 (D. Me. Dec. 21, 2010) (excluding as irrelevant under Maine's traditional proximate cause standard expert evidence demonstrating "that stroke patients who receive t-PA experience favorable outcomes 50% more frequently than stroke patients who do not receive t-PA"); Ensink v. Mecosta Cnty. Gen. Hosp., 687 N.W.2d 143, 152–54 (Mich. Ct. App. 2004). Indeed, Tami Smith has offered no expert evidence or explanation showing how such a purely relative finding of tPA's effectiveness could be used to estimate whether giving tPA to a stroke patient would more likely than not cause the patient to improve. Accordingly, since Dr. McDowell's testimony is predicated upon the findings of the Zivin Paper, we conclude that the district court did not abuse its discretion in excluding his expert opinion and granting the motion for summary judgment.

III.

For the foregoing reasons, we affirm the decision of the district court.

⁶To illustrate the inherent difficulty of using relative measures alone to discern whether a medication will more likely than not cause a patient to improve, assume again that a particular medication increases the recovery rate from an illness from ten percent to sixteen percent. Even though the *relative* measure of the drug's efficacy is sixty percent, the *absolute* efficacy of the drug is only six percent, thereby indicating that the administration of the medication will almost certainly not *cause* the patient to improve.