UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

ANTON K. SAMAAN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	1:09-cv-00656-JAW
	)	
ST. JOSEPH HOSPITAL, et al.,	)	
	)	
Defendants.	)	

ORDER ON *DAUBERT* HEARING

Following a December 9, 2010 *Daubert* hearing, the Court grants Dr. David Kaplan's motion to exclude the expert testimony of Dr. Ravi Tikoo concerning the consequences of the failure to administer tissue plasminogen activator (t-PA) to Anton K. Samaan within three hours of the onset of his stroke symptoms. The battle line in this motion is drawn on whether it is more likely than not Mr. Samaan would have benefited if he had received timely t-PA. The Court concludes it is not.

I. STATEMENT OF FACTS

A. Mr. Samaan's Stroke and Treatment at St. Joseph

On January 14, 2006, Anton K. Samaan boarded a flight in Milan, Italy to return to New York, New York after visiting his family in Egypt for the holidays. During the flight, Mr. Samaan got up from his seat and headed toward the plane's galley for a cup of tea. When Mr. Samaan reached the galley, "he was confronted by a flight attendant who told him that he appeared sick." *Notice of Removal* at Attach 2 ¶ 9 (Docket #1), *Compl.* The flight attendant called for doctors on the plane, and

at approximately 11:30 a.m., a doctor diagnosed him with "a likely stroke in progress." *Id.* ¶ 10. In accordance with the doctor's instructions, the pilot diverted the plane to the nearest airport. *Id.*

The plane landed in Bangor, Maine and Mr. Samaan reached the emergency department at St. Joseph Hospital not later than 12:40 p.m., where he was treated by emergency room physician David Kaplan, M.D. *Id.* ¶¶ 11, 15. Dr. Kaplan did not administer t-PA. *Id.* ¶ 11. Mr. Samaan has suffered "severe deficits as a result of the ischemic stroke he suffered on 01/14/06." *Id.* ¶ 13. He filed this suit against St. Joseph and Dr. Kaplan, alleging that Dr. Kaplan's failure to administer t-PA violated the standard of medical care and caused him severe damages. *Id.* ¶ 22.

B. Defendant's Motion *in Limine* and the Subsequent Procedural History

Mr. Samaan designated Dr. Ravi Tikoo, a neurologist, to testify as his expert. Dr. Tikoo has stated that "Dr. Kaplan's decision not to administer t-PA proximately caused [Mr. Samaan's] alleged injuries." *Def. David Kaplan M.D.'s Mot.* in Limine *To Exclude Test. of Ravi Tikoo, M.D.* at 2 (Docket # 26) (*Def.'s Mot.*). In response, Dr. Kaplan says that Dr. Tikoo's opinion is inadmissible because his methodology is flawed. Dr. Kaplan maintains that Dr. Tikoo's view that "a patient would have a 51 percent or better chance of improvement if he was given t-PA as opposed to being given none" does not meet *Daubert* scientific standards for admissibility.[1] *Id.* at 3.

On October 14, 2010, the Court issued an order denying Dr. Kaplan's motion, and observing that it "would benefit from a greater understanding of the foundation

[1] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

for the experts' opinions and from more illuminating and less adjectival advocacy." *Order on Mot.* in Limine at 9 (Docket #49). Responding to the Court's suggestion, Dr. Kaplan moved for a *Daubert* hearing on the expert witness issue. *Def. David Kaplan, M.D.'s Mot. for Recons. Of the Court's Order on his Mot. for Summ. J. or in the Alternative for a* Daubert *Hearing on the Admissibility of the Opinions of the Pl.'s Causation Expert* (Docket # 53) (*Def.'s* Daubert *Mot.*). Mr. Samaan responded and Dr. Kaplan replied, and on November 15, 2010, the Court granted the motion for a *Daubert* hearing. *Pl.'s Mem. in Opp'n to Def. Kaplan's Mot. for Recons., or in the Alternative, for* Daubert *Hearing* (Docket # 65) (*Pl.'s* Daubert *Opp'n*); *Def. David Kaplan, M.D.'s Reply to Pl.'s Opp'n to Mot. for Recons. Of the Court's Order on His Mot. for Summ. J. or in the Alternative for a* Daubert *Hearing on the Admissibility of the Opinions of the Pl.'s Causation Expert* (Docket # 66); *Order Granting Mot. for* Daubert *Hearing* (Docket # 68) (*Def.'s* Daubert *Reply*). After consulting with counsel, the Court scheduled the *Daubert* hearing for December 9, 2010, following which the parties filed legal memoranda. *Defs.' Supplemental Mem. on the Use of Absolute Risk Reduction Versus Odds Ratio in Causation Analysis* (Docket # 88) (*Defs.' Supplemental Mem.*); *Pl.'s Mem. Following Daubert Hearing* (Docket # 89) (*Pl.'s Supplemental Mem.*).

C. ***Daubert*** **Hearing**

At the *Daubert* hearing, the two experts testified by split screen videoconference; they were not only projected into the courtroom, but were able to hear and see each other.

1. The National Institute of Neurological Disorders and Stroke (NINDS) Study

In 1995, the NINDS published a paper in The New England Journal of Medicine titled "Tissue Plasminogen Activator for Acute Ischemic Stroke." The experts agree that the NINDS Study is the gold standard for assessing the effectiveness of the administration of t-PA within three hours of the onset of stroke symptoms. In general, the NINDS Study concluded that some patients who received timely t-PA improved over patients who did not. In one table, for example, using a National Institute of Health Stroke Scale Standard (NIHSS), the percentage of patients who improved after t-PA ranges from a high of 38% to a low of 31% and the percentage of patients who improved with a placebo ranges from a high of 21% to a low of 20%. Based on simple subtraction, Dr. Kaplan urges the Court to conclude that a difference of ten to eighteen percent does not begin to reach the civil standard of more than 50%.

The proper way to view improvement from t-PA, however, is disputed by the parties. Dr. Tikoo expressed the view that the NINDs Study supported his view that the likelihood of improvement was greater than 50%; Dr. Nyquist rejected Dr. Tikoo's opinion and stated that although the NINDS Study demonstrated that some patients improved, the percentage was markedly less than 50%. If Dr. Tikoo is correct, it is more likely than not that Mr. Samaan would have improved if t-PA had been timely administered; if Dr. Nyquist is correct, the failure to administer t-PA to

Mr. Samaan may have caused him to improve, but it is not more likely than not that it would have done so.

2. Examination of Dr. Tikoo

The hearing opened with testimony about Dr. Tikoo's background and experience. Dr. Tikoo's curriculum vitae (CV) confirmed that he had received an award from the NINDS, the institute that had performed the seminal NINDS Study. He testified that, in performing the research for the NINDS that led to that award, part of his job was to interpret data. Dr. Tikoo said he relied on interpretive methodologies he used with the NINDS in forming his opinions in this case.

Consistent with his deposition testimony, Dr. Tikoo reiterated that he relied on the NINDS Study and noted that the NINDS Study showed at least 30% of ischemic stroke patients who received t-PA suffered minimal or no disability three months after the stroke. He emphasized that the criteria used to reach the 30% figure—minimal or no disability—were very stringent and that a more relaxed view of improvement would expand the percentage of patients who benefit from t-PA.

In forming his opinion, Dr. Tikoo said that he relied predominantly on a figure called the Global Odds Ratio, a ratio that measures the relative likelihood of an outcome between two groups. According to Dr. Tikoo, an odds ratio of 1.0 indicates an outcome is equally likely between two groups and an odds ratio of 1.5 indicates that an outcome is 50% more likely for one group than another. Dr. Tikoo testified that the Global Odds Ratio combined the results of four measures of post-stroke function: the Barthel Index, the Modified Rankin Scale, the Glasgow

Outcome Scale, and the National Institute of Health Stroke Scale (NIHSS). He testified that the NINDS Study resulted in a Global Odds Ratio of 1.7 for patients who received t-PA versus those who did not. This figure, he said, supported his opinion that Mr. Samaan would have had a greater than 50% chance of a more favorable outcome if he had been administered timely t-PA.

Dr. Tikoo also cited a 2001 and a 2004 article from *Stroke*, a medical journal of the American Heart Association. He testified that the 2001 article examined the NINDS Study data and reanalyzed it to determine t-PA's efficacy in achieving partial improvement below the stringent criteria of the indices in the original study. Dr. Tikoo stated that the reanalysis showed that in addition to the patients who fully recovered, an additional 20 to 30% of patients receiving t-PA enjoyed partial improvement. He argued that those partial improvements should be considered in examining the efficacy of t-PA. He further testified that the 2004 article reanalyzed the NINDS data and found an odds ratio of 2.1.

Dr. Tikoo also cited the 2008 ECASS-III study, which tested whether the time window for administering t-PA after the onset of stroke symptoms should be expanded beyond its 3-hour guideline. He testified that the study showed that 52.4% of patients receiving t-PA more than 3 hours after onset of stroke symptoms had a favorable outcome while 45.2% in the placebo group had a favorable outcome. Dr. Tikoo testified that the odds ratio between the t-PA and placebo groups was 1.34.

Finally, Dr. Tikoo testified that in addition to the scientific studies, he had relied on his own clinical experience in forming his opinion. He stated that he had overseen the administration of t-PA on approximately twenty to twenty-four patients in his career. He testified that he was not aware that any of those patients died following administration of t-PA, that he had seen neurological improvement in some, and that there was no movement in the medical community to stop the administration of t-PA.

On cross-examination, Dr. Kaplan tested the limits of Dr. Tikoo's expertise. Dr. Tikoo admitted that he had never served on a stroke team, had never made the final decision to administer t-PA, and had never published anything related to stroke care. He conceded that he did not follow the patients for whom he had administered t-PA to learn whether they suffered any adverse reactions. Dr. Tikoo acknowledged that he is not on the American Heart Association's Stroke Counsel and that his neurology expertise concentrates in the areas of epilepsy and neuro-oncology, not in stroke care. He admitted he did not know the sub-type of stroke Mr. Samaan suffered, did not know whether Mr. Samaan was taking anti-coagulants before suffering his stroke, did not know whether Mr. Samaan had suffered from seizures before his stroke, and did not know whether St. Joseph had a stroke team or a certified stroke program.

Dr. Kaplan's cross-examination also revealed that Dr. Tikoo is not familiar with certain statistical calculations. Specifically, Dr. Tikoo was unfamiliar with how to make a Number Needed to Treat (NNT) calculation and conceded that he

would not be able to determine the NNT from the NINDS Study data. However, Dr. Tikoo argued that the NNT is an efficacy calculation that does not measure whether t-PA is more likely than not to benefit a patient. He acknowledged that there are a number of ways to interpret data but reiterated that the odds ratio is the best measure of whether a patient is more likely than not to benefit from t-PA.

In his cross-examination of Dr. Tikoo, Dr. Kaplan demonstrated some weaknesses in the application of NINDS Study data to Mr. Samaan's circumstances. For example, Dr. Tikoo had assumed that Mr. Samaan arrived at St. Joseph at least two hours after the onset of his symptoms, so the portion of the NINDS Study data reflecting t-PA administration between 0 and 90 minutes after the onset of symptoms would not be applicable to him.[2] Dr. Kaplan further elicited testimony that the 2001 *Stroke* article upon which Dr. Tikoo had relied was an editorial, not a peer-reviewed publication.

Finally, the Court examined Dr. Tikoo. As an initial matter, Dr. Tikoo affirmed the Court's understanding that the NINDS Study demonstrated a roughly 30% favorable outcome rate in patients who were administered t-PA. Although the NINDS Study had been published in 1995, Dr. Tikoo testified that he was not aware of any improvements in t-PA or its administration that would have increased the rate of patient improvement between the conclusion of the NINDS Study in 1995 and Mr. Samaan's stroke in 2006. He agreed that once the NINDS Study

[2] This point, however, runs to the facts underlying Dr. Tikoo's opinion, which would be subject to proof at trial. In evaluating whether Dr. Tikoo should be allowed to testify, the Court assumes that Mr. Samaan's symptoms began when the flight attendant noticed his symptoms. There is no evidence in this record to the contrary.

demonstrated that a significant enough percentage of patients improved with the administration of t-PA over those patients who did not receive t-PA, it would be unethical to perform another clinical study in which a group of stroke victims was deliberately denied t-PA. Therefore, he agreed, the medical community has had difficulty refining its understanding of t-PA's effectiveness beyond the 1995 data.

3. Examination of Dr. Nyquist

Turning first to his background and experience, Dr. Paul Nyquist testified that he specializes in strokes and stroke care both in academic and the clinical settings. He said that he has published articles and lectured on stroke management and t-PA, that he has personally administered t-PA to at least twenty-five patients, and that he has made the decision to administer t-PA at least 100 times.[3]

Dr. Nyquist asserted that the science on administration of t-PA has improved immensely since 1995. Specifically, he said that further research has revealed the danger of t-PA to patients who present with certain contraindications and that that research has led to limits on the types of patients who receive t-PA. However, Dr. Nyquist acknowledged that neither the drug itself nor its recommended dosages has changed since 1995.

Rejecting Dr. Tikoo's odds ratio approach, Dr. Nyquist explained that the odds ratio is not a proper method of determining whether the failure to administer t-PA was more likely than not the cause of Mr. Samaan's injuries. Dr. Nyquist said

[3] Dr. Nyquist was the doctor's expert on this same issue in *Smith v. Bubak*, *Smith v. Bubak*, No. CIV 08-44023, 2010 WL 605269, at *6-8 (D. S.D. Feb. 18, 2010), in which the district court concluded that the Plaintiff had failed to demonstrate that the failure to administer t-PA more likely than not caused her injuries in that case.

that, to meet the "more likely than not" standard, Mr. Samaan would have to prove that he was more than 50% likely to benefit from administration of t-PA. He contended that an odds ratio does not address that standard because it only measures the risk of disability relative to a placebo group. To determine whether something is more likely than not to occur, Dr. Nyquist said that one needs to consider relative risk together with absolute risk to arrive at the NNT. He calculated that the results of the NINDS Study reveal an NNT of 7, meaning that for every seven patients administered t-PA, only one will experience a favorable outcome.

Dr. Nyquist also contended that the specific circumstances of Mr. Samaan's presentation at St. Joseph generated further doubt as to whether he would have benefited from t-PA. Dr. Nyquist noted that no one at St. Joseph could have known exactly when Mr. Samaan's stroke symptoms began. Although they had been told that Mr. Samaan's symptoms had begun at least two hours before presentation at the ER, his symptoms could well have started over three hours earlier. He testified that medical practitioners understand t-PA is more effective the earlier after the onset of symptoms it is administered. Furthermore, he observed that the doctors at St. Joseph were unaware of Mr. Samaan's of medical history, precluding them from fully evaluating the presence of any contraindications for t-PA.[4]

Dr. Nyquist turned to the NINDS Study's failure to measure partial recoveries from stroke. He acknowledged this as a weakness of the NINDS Study

[4] As noted earlier, this portion of Dr. Nyquist's testimony addresses whether Mr. Samaan was a candidate for t-PA to begin with, not whether if he had been administered timely t-PA, he would have likely improved.

but stated that a peer reviewed article by Jeffrey Saver, published in 2004, had reanalyzed the data to take a broader range of outcomes into account (Saver Article).[5] Dr. Nyquist pointed out that the Saver Article presented its results using the NNT calculation. Dr. Nyquist noted that the Saver Article found an NNT of roughly 3. He explained that this means one out of three patients administered t-PA will receive some benefit. He asserted that this represents the most generous empirically-derived figure for the efficacy of t-PA to date but observed it still does not reach the greater than 50% figure necessary to satisfy the "more likely than not" standard.

Mr. Samaan cross-examined Dr. Nyquist. Dr. Nyquist conceded that he is not certified in statistical analysis, but added that his stroke certifications required him to complete a program that included training in statistical analysis. He agreed that as a general principle, he wants to increase the number of people with safe access to t-PA. He acknowledged that odds ratios are the traditional expression of the relative likelihood of outcomes. Noting the word "novel" in the Saver Article's title, Mr. Samaan asked Dr. Nyquist whether the Saver Article had employed an unconventional statistical analysis. Dr. Nyquist responded that the Saver Article's statistical methodology was well established and that the word "novel" referred to the analysis of multiple levels of disability. He added that the Saver Article is frequently cited in scholarship on strokes and is featured on the American Heart Association's website. Finally, Dr. Nyquist conceded that although he read Dr.

[5] Jeffrey L. Saver, *Number Needed to Treat Estimates Incorporating Effects Over the Entire Range of Clinical Outcomes: Novel Derivation Method and Application to Thrombolytic Therapy for Acute Stroke*, 61 ARCH NEUROL. 1066 (2004).

Kaplan's record of his treatment of Mr. Samaan, he did not recall any mention of t-PA in the medical chart.

The Court asked Dr. Nyquist about the changes in t-PA administration guidelines between 1995 and 2006. Dr. Nyquist testified that there had been significant improvements in the administration of t-PA, but those improvements had not been in the dosage or administration of the drug. Rather, medical science has a greater appreciation for the categories of patients who respond best to t-PA. He explained that immediately after the NINDS Study, many emergency departments used t-PA over-aggressively without taking contraindications into account. He noted that since then, there have been studies on contraindications, which have allowed physicians to more accurately determine which subsets of patients can safely receive t-PA. He stated that the adoption of quality assurance programs and stroke teams at hospitals has also made the administration of t-PA safer. Finally, he testified that he would not have treated Mr. Samaan with t-PA if he had been the physician treating him at St. Joseph Hospital because too many factors were undeterminable at the time, including when Mr. Samaan had last been observed without stroke symptoms.

4. Closing Statements

The parties made brief closing statements following the experts' testimony. Mr. Samaan asserted that the standard for admissibility is reliability. He noted that Dr. Tikoo obtained his odds ratio calculation directly from the NINDS Study, which is recognized as the authoritative study on the efficacy of t-PA.

Dr. Kaplan responded that expert testimony has to be not only reliable but also the testimony must have bearing on the facts, and that Dr. Tikoo's testimony does not meet the latter prong. He contended that the statistics Dr. Tikoo relied upon in forming his opinion merely reflect that t-PA treatment yields a better chance of recovery than a lack of t-PA treatment. Although this evidence may meet the causation standard in a jurisdiction that recognizes the loss of chance doctrine, he argued that the state of Maine has not recognized the loss of chance doctrine. Instead, he said that the Maine standard is articulated in *Merriam v. Wanger*, 2000 ME 159, 757 A.2d 778: a plaintiff in a medical malpractice case must prove that breach of the standard of care was more likely to have caused the plaintiff's injury than any other potential cause. He argued that under that standard, Mr. Samaan must proffer expert testimony suggesting that the failure to administer t-PA was the most likely cause of his injury. Dr. Kaplan further contended that Mr. Samaan failed to do so because Dr. Tikoo's statistics support the proposition that Mr. Samaan would have been at least 50% likely to suffer the same level of injury regardless of t-PA.

Mr. Samaan responded that the loss of chance doctrine is available in Maine. Citing *Phillips v. Eastern Maine Medical Center*, 565 A.2d 306 (Me. 1989), he said that *Phillips* left open the possibility that the loss of chance doctrine has been adopted in Maine. Dr. Kaplan responded that what the Maine Supreme Judicial Court avoided in *Phillips*, it decided in *Merriam*: that the Maine standard for causation in a medical malpractice case is "more likely than not."

D. Legal Contentions

Mr. Samaan contends that the admissibility of expert testimony in the First Circuit depends solely on whether "the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion." *Pl.'s Supplemental Mem* at 2 (quoting *United States v. Mooney*, 315 F.3d 54 63 (1st Cir. 2002)). He contrasts this with the test used by the Fifth Circuit in *Young v. Memorial Hermann Hospital Services*, 573 F.3d 233 (5th Cir. 2009), which, according to Mr. Samaan, would allow a court to choose to admit only that "expert testimony it regarded as more authoritative or more persuasive." *Pl.'s Supplemental Mem.* at 2. Mr. Samaan argues that Dr. Tikoo's analyses meet the First Circuit test because they are "well founded in scientifically sound and accepted principles and reliable methods." *Id.* at 2.

Mr. Samaan further argues that in *Merriam*, the Maine Supreme Judicial Court addressed the burden of proof for demonstrating proximate cause at trial, which does not "equate to the test under Rule 702 for the admissibility of expert opinion testimony." *Id.* at 5. He contends that making "a qualitative comparative decision between competing expert opinions" is "for the sole discretion of the jury." *Id.*

Dr. Kaplan responds that Dr. Tikoo's expert testimony should not be admitted because it does not shed light on t-PA's absolute benefit to Mr. Samaan. Dr. Kaplan contends that, given Maine's "more likely than not" causation standard, "this Court must look to the data showing t-PA's absolute benefit to Mr. Samaan,

not the data showing t-PA's relative benefit." *Defs.' Supplemental Mem.* at 1. He asserts that Dr. Nyquist's NNT calculation expresses the absolute benefit of t-PA and establishes that "approximately seven people need to be treated to achieve one positive outcome". *Id.* at 1. He argues not only that an odds ratio is "a poor metric to use in the legal question before the Court," but also that the conclusion Dr. Tikoo derives from the odds ratio is wrong. *Id.* at 2. He asserts that "the law has recognized that, even if odds ratio is a useful methodology in a particular case, the odds ratio must exceed 2.0 to establish that a positive outcome was more likely than not." *Id.* (citing *Vanderwerf v. SmithKlineBeecham Corp.*, 529 F. Supp. 2d 1294, 1302 n.10 (D. Kan. 2008)). Finally, Dr. Kaplan cited a recent United States District Court decision granting summary judgment to a defendant in a similar case because "the showing of an absolute benefit of 12% that could have been achieved through treatment with t-PA did not establish that 'failure to administer TPA was the proximate cause of [the plaintiff's] injuries.'" *Id.* at 3 (quoting *Dannenberg v. U.S.*, No. 04-CV-4897 (NGG)(JMA), 2010 WL 4851341, at *10 (E.D.N.Y. November 22, 2010)). He urges the Court to follow the Eastern District of New York's reasoning.

II. DISCUSSION

A. Legal Standards

1. Admissibility of Expert Testimony

Federal Rule 702 governs the admissibility of expert testimony:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or

> otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. The trial judge is responsible for screening expert testimony to determine "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." *Daubert*, 509 U.S. at 592. Under this standard, courts should consider the following non-exhaustive list of factors:

> (1) whether the theory or technique can be and has been tested;
> (2) whether the technique has been subject to peer review and publication;
> (3) the technique's known or potential rate of error; and
> (4) the level of the theory or technique's acceptance within the relevant discipline.

Mooney, 315 F.3d at 62 (citing *Daubert*, 509 U.S. at 593-94).

Furthermore, an expert's conclusions must not be too remote from his methodologies. Mr. Samaan asserts that the First Circuit limits a trial court's consideration to whether "the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion."[6] *Pl.'s Supplemental Mem.* at 2. He quotes *Mooney*:

> Daubert does not require that the party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct . . . . It demands only that the proponent of the

[6] After the *Daubert* hearing, Mr. Samaan supplied *Ellison v. United States*, No. 09cv331, 2010 WL 4670359 (E.D. Pa. Nov. 10, 2010) presumably for its discussion of the proper standard for evaluating the admissibility of expert testimony. *Ellison* does not advance his argument. Under the Third Circuit formulation, the proponent of an expert must demonstrate the expert's qualification, reliability, and fit, the third criterion being another way of expressing the Supreme Court's and First Circuit's requirement that there must not be too great an analytic gap between expert's testimony and the underlying data.

> evidence show that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion.

315 F.3d at 63.

Mr. Samaan seeks too much from *Mooney*. In *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997), the Supreme Court observed that a district court may exclude expert testimony if the expert's conclusion does not logically follow from his methodology:

> Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

The Court does not read *Mooney* as conflicting with *Joiner*. In *Mooney*, the defendant challenged the sufficiency of the standards and testing in the field of handwriting analysis. *Mooney*, 315 F.3d at 63. Because the reliability of the field of expertise itself was being challenged, the First Circuit focused on the soundness of the science and the reliability of the methodologies. *Id.* However, the First Circuit also noted that an expert's ultimate opinion must be linked to the reliable methodologies of the field. *Id.* (stating that the district court judge "explained that the reliability of the handwriting comparison testimony and the expert's ultimate opinion on authorship were inevitably linked because they were based on the same methodology.") *Mooney* is consistent with the Supreme Court's holding that there must not be "too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146. In fact, the First Circuit has repeatedly quoted

with approval this exact language in *Joiner*. *United States v. 33.92356 Acres of Land*, 585 F.3d 1, 7 (1st Cir. 2009); *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998); *see United States v. Raymond*, 700 F. Supp. 2d 142, 146 (D. Me. 2010).

Finally, in *Mooney*, the First Circuit emphasized that these matters are largely within a district court's discretion. *Mooney*, 315 F.3d at 63. It held that the district court did not abuse its discretion in admitting opinion testimony by a handwriting expert, but noted that it was not deciding whether another district court would have abused its discretion by excluding similar testimony. *Id.* (citing *United States v. Hines*, 55 F. Supp. 2d 62 (D. Mass. 1999) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 158 (1999)).

2. Maine Causation Standard

Mr. Samaan correctly notes that in *Phillips*, the Law Court identified two potential standards of causation in malpractice actions. The "more likely than not" standard requires "the plaintiff to show a better than even chance of avoiding harm in the absence of medical negligence,"[7] *Phillips,* 565 A.2d at 308. The loss of chance doctrine requires a plaintiff to show "that he was deprived of a significant chance of avoiding harm." *Id.* *Phillips* did not decide whether Maine adopted the loss of chance standard because the Law Court concluded that the jury could have "rationally determine[d] that the plaintiffs satisfied even the more stringent requirement." *Id.*

[7] The Law Court's articulation is consistent with the "more likely than not" standard. *See Spickler v. York*, 566 A.2d 1385, 1390 (Me. 1989).

The Court agrees with Mr. Samaan that it is critical to identify the proper standard in Maine. If Maine has adopted the "loss of chance" doctrine, Mr. Samaan would not necessarily have to demonstrate that he would have stood a better than 50% chance of improvement if he had received a timely dose of t-PA. Instead, he would only need to demonstrate that by failing to administer t-PA, Dr. Kaplan "deprived [him] of a significant chance of avoiding harm." *Id.* Under the "more likely than not" standard, Mr. Samaan may not proffer Dr. Tikoo's opinion; under the "loss of chance" standard, he may.

Current Maine law favors Dr. Kaplan's position. The Maine Supreme Judicial Court has not mentioned the loss of chance doctrine since 1989 and at the same time, has consistently reiterated that the standard for causation in Maine is "more likely than not." Just months after *Phillips*, the Maine Law Court stated that Maine uses the more likely than not standard in malpractice actions. *Spickler v. York*, 566 A.2d 1385, 1990 (Me. 1989) (agreeing that a jury instruction asking whether the result "could" have been different "diluted the 'more likely than not' burden of proof imposed on malpractice plaintiffs"). In 2000, the Law Court clarified that Maine's "more likely than not" standard mirrors that of other jurisdictions, and requires a showing that the negligence was the most likely cause of injury when weighed against other possible causes. *Merriam*, 2000 ME 159, ¶ 8, 757 A.2d at 781 (stating that "[t]he mere possibility of such causation is not enough, and when the matter remains one of pure speculation or conjecture, *or even if the probabilities are evenly balanced*, a defendant is entitled to summary judgment"

(emphasis added)); *accord Roney v. Wendy's Old Fashioned Hamburgers of New York, Inc.*, No. Civ. 2:05-CV-109-GZS, 2006 WL 696251, at *10 (D. Me. Mar. 17, 2006) (quoting *Merriam*, 2000 ME 159, ¶8, 757 A.2d 778, 780.))

Merriam establishes that foreseeability of a risk does not suffice to prove causation in Maine. In *Merriam*, two of the plaintiff's experts testified that the defendant's negligence created a reasonably foreseeable risk to the plaintiff. *Id.* ¶¶ 11-13, 757 A.2d at 781-782. However, the Law Court held that "foreseeability of a risk does not permit a jury to infer causation." *Id.* ¶ 16, 757 A.2d at 782. Because the experts did not testify that the plaintiff's damages "would have been avoided had [the defendant] acted properly," the *Merriam* Court held that the plaintiff was unable to prove causation and granted the defendant judgment as a matter of law. *Id.* at 18, 757 A.2d at 782.[8]

The role of the federal court in blazing new trails in state law is decidedly limited. *Ryan v. Royal Ins. Co. of Am.*, 916 F.2d 731, 744 (1st Cir. 1990). A federal court considering state law claims is "bound by the teachings of the state's highest court." *N. Am. Specialty Ins. Co. v. Lapalme*, 258 F.3d 35, 37-38 (1st 2001). Although a federal court is allowed to "make an informed prophecy" about what rule

[8] Mr. Samaan's case is a hard one. At least as presented, while he was in the ER at St. Joseph Hospital, he had some chance for a degree of recovery if he had received t-PA. Tragically, according to his attorney, Mr. Samaan suffered a truly catastrophic injury and has not recovered. If given a risk–reward option, a person in Mr. Samaan's situation might well elect to receive t-PA and hope for improvement, running the risk of greater injury or death. But there is no evidence Mr. Samaan was given that option, and he will never know what his life would have been like if the dose had been administered. His case resolves not on negligence but on causation.

At the same time, the Court is aware that it has not heard Dr. Kaplan's side of this story and defense counsel cautioned that the doctor's explanation for why Mr. Samaan did not receive t-PA is convincing. The Court is in no position to evaluate Dr. Kaplan's professional judgment at the ER on January 14, 2006 and does not do so.

the state courts would likely follow, the First Circuit has stressed that federal courts should do so "only on interstitial questions." *Phoung Luc v. Wyndham Mgmt. Corp.*, 496 F.3d 85, 88 (1st Cir. 2007). A federal court must not "create new rules or significantly expand existing rules. We leave those tasks to the state courts." *Id.*

Within these constraints, the Court is unable to predict with any confidence that the Maine Supreme Judicial Court, if presented with a loss of chance case, would adopt the doctrine. Starting with the decisions of Maine's highest court, reviewing the decisions of its lower courts, examining the precedents in other jurisdictions, and surveying "the collected wisdom found in learned treatises," *Andrew Robinson Int'l, Inc. v. Hartford Fire Ins. Co.*, 547 F.3d 48, 51-52 (1st Cir. 2008), the result is inconclusive. Maine courts have been silent on the question since 1989, other jurisdictions are split, and the authors of MAINE TORT LAW have said only that Maine has not decided whether to adopt the doctrine. Jack H. Simmons, Donald N. Zillman & David G. Gregory, MAINE TORT LAW § 9.05 (2004 ed.) (stating that "[t]he Maine Law Court has not to date decided whether it will follow the traditional approach to evaluating causation in medical malpractice cases, or whether it will adopt one of the competing 'lost chance' approaches").

B. Analysis

Dr. Tikoo's opinion that Mr. Samaan was more likely than not to have recovered but for Dr. Kaplan's failure to administer t-PA is not supported by sound science or reliable methodologies. Even assuming the scientific reliability of the methodologies used to generate the data Dr. Tikoo relied upon and the accuracy of

his calculations, none of his statistics supports the conclusion that the failure to administer t-PA, more likely than not, caused Mr. Samaan's injury. Therefore, the Court cannot admit Dr. Tikoo's testimony because it would not assist a trier of fact in determining a fact in issue. *Daubert*, 509 U.S. at 592 (1993).

To satisfy Maine's causation standard, Mr. Samaan must prove that his failure to receive t-PA was more than 50% likely to cause his injury. To sustain his burden, Dr. Tikoo proffers an odds ratio calculation, which he says demonstrates that stroke patients who receive t-PA experience favorable outcomes 50% more frequently than stroke patients who do not receive t-PA.

The question in this case focuses on Mr. Samaan and asks whether it is more likely than not that he would have improved if he had received t-PA. The NINDS Study confirms that Mr. Samaan's chance for improvement over his chance for improvement without t-PA ran between ten and eighteen percent, which in absolute terms, does not reach the 50% threshold for maintaining a civil malpractice action. It is true that if the number of patients who improved without t-PA is subtracted from the number of patients who improved with t-PA, the resulting percentage is greater than fifty percent of the placebo group. But that figure is a relative benefit, not an absolute benefit, and says little about Mr. Samaan's individual chance of improvement with t-PA. *See Young v. Mem'l Hermann Hosp. Sys.*, No. H-03-1859, 2006 U.S. Dist. LEXIS 47920 *17-18 (S.D. Tx. Jul. 14, 2006) (discussing absolute versus relative benefit in the context of t-PA injections).

Similarly, the odds ratio calculation does not respond directly to Maine's causation standard. The 50% figure in Dr. Tikoo's calculation relies on a comparison between two groups. A figure comparing one group's likelihood to recover solely in relation to another group's likelihood to recover does not demonstrate an individual's overall likelihood to recover. That is to say, an odds ratio could indicate a drug is highly effective as compared to a placebo, but that comparison does not inform an individual patient's overall likelihood of recovery. *See Vanderwerf v. SmithKlineBeecham Corp.*, 529 F. Supp. 2d 1294, 1303 n.10 (D. Kan. 2008) (discussing the relative risk or odds ratio in the context of a products liability case). Dr. Tikoo's odds ratios indicate that t-PA is successful compared to a placebo, but the ratios fail to speak to t-PA's overall effectiveness. Based on this record, the Court remains unconvinced. There is simply "too great an analytical gap" from the odds ratio to the conclusion that Mr. Samaan's injuries were more likely than not caused by his failure receive t-PA. *See Joiner*, 522 U.S. at 146.

Dr. Tikoo's reference to the ECASS-III study similarly does not support his opinion that the failure to administer t-PA was more likely than not the proximate cause of Mr. Samaan's injuries. While 52.4% of t-PA recipients in that study experienced a favorable outcome, 45.2% of patients in the placebo group also experienced a favorable outcome. An efficacy figure above 50% alone is insufficient to meet the "more likely than not" standard because it includes patients who would have recovered without t-PA. The 45.2% figure demonstrates that there is a cause of recovery independent of t-PA. That undermines the argument that t-PA was the

cause of the favorable outcome in the 52.4% of t-PA recipients who experienced a favorable outcome. To satisfy the "more likely than not standard," "epidemiological evidence must show that the risk of an injury or condition in the exposed population [*i.e.* placebo recipients] was more than double the risk in the unexposed or control population, [*i.e.* t-PA recipients]." *Young*, 573 F.3d at 236. Because Dr. Tikoo can offer no scientific evidence to meet this standard, his opinion will not assist the trier of fact.

The Court's conclusion is consistent with the opinions of other courts that have addressed this precise issue, including whether the statistics in the NINDS Study satisfy a plaintiff's burden of proof on causation. *See generally Young*, 573 F.3d at 233; *Dannenberg v. United States*, No. 04-CV-4897 (NGG)(JMA) 2010 WL 4851341, at *10 (E.D.N.Y. Nov. 22, 2010) (stating that "Plaintiff has failed to prove by a preponderance of the evidence that – assuming she was a [t-PA] candidate – the lack of treatment with [t-PA] was a substantial contributing factor to her injuries"); *Smith v. Bubak*, No. CIV 08-44023, 2010 WL 605269, at *6-8 (D. S.D. Feb. 18, 2010) (concluding that "Plaintiff has failed to present reliable expert medical testimony that had Smith been treated with tPA she would have had a greater than 50 percent chance of receiving a benefit"); *Ensink v. Mecosta Cnty. Gen. Hosp.*, 687 N.W.2d 143, 156 (Ct. App. Mich. 2004) (stating that the "plaintiffs failed to establish that defendants' alleged malpractice deprived plaintiff of an opportunity to achieve a better result greater than fifty percent"). By the same token, the Court has found no case in which a court has allowed an expert to testify

that the failure to administer t-PA more likely than not caused an injury. Though given an opportunity to develop the record, Mr. Samaan provided no basis to break from the other courts. In addition, Dr. Tikoo was unable to testify to changes in the administration of t-PA between 1995 and 2006 that would have made Mr. Samaan's chances of a favorable outcome greater than the favorable outcome rates in the NINDS Study. In short, Dr. Kaplan has successfully challenged the legal sufficiency of Mr. Samaan's proffered expert testimony.

III. CONCLUSION

The Court GRANTS David Kaplan, M.D.'s motion to exclude Dr. Tikoo's expert testimony *Defendant David Kaplan, M.D.'s Motion for Reconsideration of the Court's Order on his Motion for Summary Judgment or in the Alternative for a* Daubert *Hearing on the Admissibility of the Opinions of the Plaintiff's Causation Expert* (Docket # 53).

SO ORDERED.

/s/ John A. Woodcock, Jr.
JOHN A. WOODCOCK, JR.
CHIEF UNITED STATES DISTRICT JUDGE

Dated this 21st day of December, 2010