IN THE SUPREME COURT OF FLORIDA

CASE NO. SC09-1771

WILLIAM COX and MARTHA COX,

Petitioners,

vs.

ST. JOSEPH'S HOSPITAL , ERIC CASTELLUCCI, M.D. and EMERGENCY MEDICAL ASSOCIATION OF FLORIDA, LLC,

Respondents.
_____/

ON DISCRETIONARY REVIEW FROM THE DISTRICT COURT OF APPEAL OF FLORIDA, SECOND DISTRICT

RESPONDENT, ST. JOSEPH'S HOSPITAL'S ANSWER BRIEF ON THE MERITS

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STATEMENT OF CASE AND FACTS

Respondents, Mr. and Mrs. Cox are residents of Canada who sued St. Joseph's Hospital, Dr. Eric Castellucci, an emergency medicine physician, Dr. Ajoy Kotwal, an internist, and their professional associations, for medical negligence alleged as a result of the medical care and treatment given to Mr. Cox who suffered an ischemic stroke. (R. 19-51) The allegations in the Amended Complaint against St. Joseph's alleged the hospital staff breached the prevailing professional standard of care when they failed to determine the time of onset of Mr. Cox's stroke. Petitioners alleged that but for this alleged failure Mr. Cox would have received Tissue Plasminogen Activator (tPA), a clot-busting drug, and as a result more likely than not Mr. Cox would have had no effects from his stroke. (R. 191-239). The Amended Complaint did not contain allegations that the hospital failed to advise Mrs. Cox of the risks and benefits of tPA to permit her to give "informed consent" to the administration of tPA. (R. 191-239). St. Joseph's denied all allegations of breach of the standard of care and reckless disregard, and further contested proximate causation between the alleged negligence and Mr. Cox's inury. (R. 241-47).

On the morning of the stroke, Mr. Cox was found in an enclosed room working on a model airplane with paint and glue, was slumped over and pale. (T.878-9). 911 was called and the Tampa Fire Rescue responded. (T. 6332-6; R.

3228-30). When Mr. Cox arrived at St. Joseph's, the EMT team told the triage nurse, Nurse Phelps, that Mr. Cox was a possible stroke victim, discovered by a "worker", and the time of stroke onset was unknown (T. 665-7; R. 3244-56; 3257-61; 3262-4). Nurse Phelps, recorded in the hospital chart the time of the stroke was unknown. (T. 1331) Respondents' expert Dr. Bruce Medoff, testified that it was reasonable for the hospital's nurses and emergency room staff to rely upon that information. (T.865). Mr. Cox had experienced a previous small stroke two years earlier, and three years prior had sustained a prior "subdural hematoma", which was also characterized as "intracranial bleeding" or a "bruise on the brain." (T. 910; 1633-50).

Petitioners theory of causation against St. Joseph's was that Mr. Cox should have been administered "tPA therapy" which they contend would have diminished or eliminated his stroke symptoms and damages. (R. 191-239). The manufacturer of tPA advises it may be administered to ischemic stroke victims if not contraindicated and if given within 3 hours of the onset of the stroke. (T.898-9). Together with the defenses to breach of duty, St. Joseph's challenged the basis for legal causation because Petitioners could not show that anything the hospital did, or failed to do, was "more likely than not" the cause of the injuries he sustained as a result of the stroke. (R. 241-47). Petitioners' own experts cited to an authoritative study which concluded tPA is never "more likely than not" going to have a

favorable effect on a stroke victim. (T. 1128). In addition, the FDA and the manufacturer advised that tPA should not be administered to a patient with a history of a prior subdural hematoma and Petitioners' expert agreed it is reasonable for neurologists to follow FDA Guidelines. (T. 894-900; 1128).

Although St. Joseph's did not learn about Mr. Cox's history of a prior subdural hematoma until later, nothing would have changed in the care administered because the attending neurologist testified he would have adhered to the restrictions give by the FDA and the manufacturer which both advise that tPA should not be given, under these circumstances. (T. 577;1593). On the day of the stroke, Mrs. Cox knew that Mr. Cox had had a bruise on his brain, which was a hematoma and would have advised St. Joseph's. (T. 1426). Mrs. Cox understood what a "hematoma" meant and demonstrated that she was highly educated, with a PhD in economics. (T. 1350; 1426-7).

During trial, Petitioners' counsel inquired of Mrs. Cox whether she had been advised of the risks and benefits of tPA therapy by anyone. (T. 1376-8). Over Respondents' objections, Mrs. Cox was asked on direct examination that if she had been aware of the potential for negative consequences as a result of giving tPA to Mr. Cox whether she would have authorized it anyway. (T. 1457-9). St. Joseph's objected to testimony regarding informed consent since there were no allegations pled that there was a failure on its part of the hospital to obtain informed consent,

and that such testimony was speculative. (T. 1068-77; 1453; 1130-3). Initially the trial court sustained the objection. (T. 1075; 1131). However, when Petitioners' counsel again attempted to introduce the same testimony, the trial court overruled St. Joseph's objections and permitted Mrs. Cox to tell the jury that if she had been advised by Respondents of the risks and benefits of tPA she would have elected to have it administered to Mr. Cox. (T. 1457-8). In closing argument, Petitioners' counsel emphasized that it was the alleged failure of the doctor and the hospital to explain the risks and benefits of tPA therapy which led to Mr. Cox's damages. (T. 2005).

Dr. Eric Castellucci was the emergency medicine physician who saw Mr. Cox when he arrived at the hospital (T. 476-81). He noted the time of onset of the stroke was unknown when Mr. Cox arrived. (T.509-13). Dr. Castellucci also noted that Mr. Cox had a history of "TIA" which stands for "transient ischemic attack" which is suggestive of a stroke and which lasts less than 24 hours. (T.597). TIA is caused by the interruption of blood supply to the brain (T.597). Dr. Castellucci believed that he received the information about Mr. Cox's prior TIA from Mrs. Cox (T.599). Dr. Castellucci testified that a patient with a prior intracranial hemorrhage should not be given tPA. (T. 577).

Petitioners called Dr. Steven Miley, a former emergency physician, to give an expert opinion regarding the treatment by Dr. Castellucci, and not for the care

by St. Joseph's nurses. (T. 968). Dr. Miley testified he had only used tPA in his practice a total of 6 to 9 months for stroke victims before he ceased the active practice of medicine. (T. 1007). He called tPA "a very dangerous drug." (T. 972). Dr. Miley testified that a physician who follows the drug manufacturer's guidelines and the restrictions imposed by the FDA would be within the standard of care. (T.989). Dr. Miley agreed that the hospital triage nurse had accurately recorded in Mr. Cox's chart the information given her by EMT, that the time of onset of the stroke was unknown. (T.995). He also agreed that if the time of onset is unknown, tPA should not be given. (T. 996).

Dr. David Crisp, treated Mr. Cox in Canada approximately three years before the incident. Mr. Cox was referred to him for a CAT scan because he reported symptoms of throbbing headaches for 2 months. (T. 1633-6, 1636-40). According to the record, Dr. Crisp treated Mr. Cox for a subdural lesion in 1998. (T. 1637-8). Mr. Cox had been going to Dr. Crisp because of a series of headaches he was having in 1998. (T. 1636-40). Dr. Crisp testified that Mr. Cox had some susceptibility to the occurrence of subdural hematoma occurring. (T. 1650).

Petitioners called as their expert on causation, Dr. Nancy Futrell, who is board certified in neurology. (T. 1037-113, 1041). She acknowledged that if Mr. Cox had experienced an "acute hemorrhage" that would have kept him from being a candidate for tPA. (T.1063-4). She explained this is because the main

complication of tPA is bleeding, and in such a case, the chance of tPA causing his death would be very high. (T.1064). She disagreed that Mr. Cox had a prior hematoma based on her review of a CT scan taken after the stroke. (T.1059-63). She did not review any prior CT scans which had charted the prior subdural hematomas. (T. 1053).

The opinion Dr. Futrell gave on causation was "to a high degree of medical probability that if Mr. Cox had received tPA he would have "had a very good recovery and have minimal or no neurological deficit". (T.1076-7). Dr. Futrell testified she had never given tPA to a stroke victim when there was a prior intracranial hematoma, however. (T.1120). She characterized Mr. Cox's brain as "super normal" because it did not show the same signs of aging she would expect. (T. 1064). She recognized as authoritative a study by the National Institute of Neurological Disorders and Stroke ("NINDS") and concurred in the results. (T. 1097-1100). The NINDS trial determined patients treated with tPA were 30% more likely to have minimal or no disability at 3 months, as measured by the outcome scales (absolute increase in favorable outcome of 11% to 13%), and as compared to placebo-treated patients. *Nat'l Inst of Neurological Disorders and Stroke rt-PA Stroke Study Group*, N. Engl. J. Med. 1995. The NINDS Study concluded 20% of stroke patients need almost complete recovery from a stroke without tPA, and 31% made an almost complete recovery from stroke with tPA. (T. 1099-1100). Dr.

Futrell concurred with these results. (T. 1099-1100). Dr. Futrell agreed tPA has never been studied in patients with the contraindication of subdural hematoma. (T. 891-2; 1097-8; 1123).

The NINDS Study lists "intracranial hemorrhage as a contraindication. (T. 1126-8). Dr. Futrell has administered tPA when contraindicated three times but never, to her knowledge, when there was a prior intracranial hemorrhage. (T.1120)

Petitioners' emergency medicine expert, Dr. Medoff, agreed that the manufacturer's package insert for tPA indicates a subdural hematoma is a contraindication for the administration of tPA. (T.894). Dr. Medoff testified that he was familiar with the contraindications for tPA, and the reason it is not given to particular patients is because there is too high a risk of doing more harm than good. (T. 888). According to Dr. Medoff, tPA can actually cause a stroke in one out of 20 times even when a patient has no risk factors such as a prior subdural hematoma. (T.889).

Mr. Cox's treating neurologist was Dr. Eddy Berges. (T. 564). Dr. Berges initially refused to render any expert opinions on Respondents' care of Mr. Cox. (T.1558). Petitioners moved to compel his expert testimony on Respondents' treatment, which the trial court granted. (T. 1558). Dr. Berges was subsequently deposed and his testimony was read at trial. (T.1558-1611). The "letter" Petitioners refer to was not admitted into evidence. Although he initially testified

he clarified that if there had been a moderate size subdural hematoma or intracranial bleed within two and a half years of the stroke, that would be a "different ballgame." (T. 1567). Dr. Berges testified that this is because tPA therapy is contraindicated in that circumstance. (T.1568). No one had previously provided Dr. Berges with information regarding a subdural hemorrhage and he was therefore unaware of it. (T. 1568-9). Dr. Berges testified that even with the application of tPA in the appropriate patient, there is a high incidence of complication including progression and death even with its use in ideal circumstances. (T. 1571).

Petitioners called as an expert witness Nurse Debra Chambers, who was employed at Tampa General Hospital. (T.930-62). Over St. Joseph's objection, Nurse Chambers was permitted to testify regarding anecdotal incidents of administration of tPA at Tampa General to patients with prior subdural hematomas or intracranial hemorrhage. (T.925-29; 934-36). St. Joseph's objections to her testimony included her inability to testify out of her area of expertise, and that her testimony was irrelevant (T. 925-8). Nurse Chambers could not name a single patient who received the tPA therapy under the stated circumstances at Tampa General. (T. 951-3). The trial court overruled the objection and permitted Nurse Chambers to testify "as a fact witness" of what happens at Tampa General and the

"fact" that tPA is administered to a patient with prior subdural hematomas, and not that to do so was "proper." (T. 928-9).

Nurse Amy Ashby Brown was a nurse in the emergency room at St. Joseph's on the day of the stroke. (T. 688). She testified that on admission Mr. Cox was assigned to her as the primary care nurse (T. 688). She noted on the chart that upon Mr. Cox's admission she went to find the closest relative, which was Mrs. Cox (T. 702). She did not note the time of onset of the stroke because the triage nurse had charted the onset was unknown and she would not have made a separate note if she had no additional information. (T. 735).

St. Joseph's requested a special jury instruction to include the holding of *Gooding v. University Hospital Building, Inc.,* 455 So. 2d 1015 (Fla. 1984) and to instruct the jury that St. Joseph's negligence must be shown to be "more likely than not" the cause of injury. (R. 3472-3485). Instead, the trial court gave the standard jury instruction that "a physician, nurse or unit secretary acts with reckless disregard for the consequences of their actions if they knew or should have known at the time they rendered emergency services their conduct *would likely* result in injury or death…." (T. 2105-6) (emphasis added). St. Joseph's raised the failure to give the requested instruction as part of its motion for JNOV (R. 2563-2621; 2622-2626; 3472-3485). Respondent moved for directed verdict at trial based on Petitioners' failure to prove the elements of their case and causation in particular.

(T.). The jury returned a verdict in favor of Petitioners. (T. 2143; R. 3512-4). Following the jury verdict, St. Joseph's filed a Motion for Judgment Notwithstanding the Verdict and Motion for a New Trial. (R.3472-85). The Second District reversed on the sole issue relating to causation ("the Opinion").

St. Joseph's timely objected to the introduction of the collateral source payments to Petitioners as insureds from the Ontario Ministry of Health, Green Shield and World Access before trial. (R. 1480-82; 1527; 2348-2437; 1733-5). St. Joseph's requested a new trial or the reduction in the verdict in the amount of these payments totalling $100,487.73 Canadian according to section 768.76, Florida Statutes. (R. 1523-39; 3472-85; 3486-97). These payments were non-recoverable by the Ministry. (T. 1528).

SUMMARY OF THE ARGUMENT

The Petition should be denied because the Petitioners failed to establish legal causation as required by Florida law.

Petitioners sued St. Joseph's for failing to record Mr. Cox's stroke onset such that tPA could be given him. According to the warning from the drug manufacturer and approved by the Food and Drug Administration, tPA is not to be given to patients with a prior history of subdural hematoma because it can cause additional or extensive bleeding or death. This "contraindication" is contained in the manufacturer's package insert, in the Physician's Desk Reference (PDR), and is

approved by the FDA. Petitioners' own expert testified that it would not be a breach to refuse to give tPA when contraindicated.(T. 1128). The contraindications were included in the Physician's Desk Reference (PDR) which the expert also upon upon. (T. 1080-1). In addition, the evidence failed to show that administration of tPA more likely than not will prevent a stroke victim from sustaining the same injuries from the stroke. At the time of the stroke, the protocol for tPA required its administration to the patient within 3 hours of onset of the stroke. Because Mr. Cox was not a candidate for tPA according to FDA and the manufacturer, the failure to give him the drug cannot be a legal cause of his injuries as a matter of law. Additionally the NINDS Study, recognized as authoritative by Petitioners' expert witness on causation reflects that tPA would only improve Mr. Cox's recovery 11% of the time and therefore could not more likely than not prevent the same injuries. (T. 1099-1101). The Second District was correct in its holding that there was no legal causation established between the allegations of negligence against St. Joseph's and Mr. Cox's injuries. Even if tPA had been administered, no legal causation was established by Petitioners because the manufacturer's warnings approved by the FDA and the NINDS Study all concluded that tPA is not to be given to a patient with a prior subdural hematoma. Dr. Berges, the attending neurologist, testified that he would not have given the tPA even if he knew the onset was within 3 hours because of the drug's contraindication for prior subdural

hematomas. Because Mr. Cox would have never been a candidate for tPA, it could not have been negligent for the hospital to report the time of stroke onset unknown. Additionally, all of the clinical studies for tPA show it would not have given Mr. Cox a 51% improvement over what his recovery would be without tPA. It is essential to note Petitioners' own causation expert agreed that the NINDS Study was authoritative. Her conclusion that Mr. Cox would have better results than the general patient population had no foundation in her clinical experience or background and was merely *ipse dixit*.

There were six additional reversible errors committed at the trial, which Respondents raised in the Second District. These issues do not fall within the Court's jurisdiction as there is no express and direct conflict. Therefore, Respondent asks that any consideration of these additional issues be remanded to the Second District for review, only if necessary, in the event the Petition is granted.

As a second reversible error, the trial court erred in by failing to give a jury instruction on causation according to *Gooding v. University Hospital Building, Inc.* 445 So. 2d 1015 (Fla. 1984). The requirement in *Gooding* that the alleged negligent act be a 51% or greater cause of Mr. Cox's damages distinguished this standard from the mere "loss of a chance" to avoid stroke injuries. The failure to give the special jury instruction left the jury with an improper standard by which to

weigh the evidence. This would necessarily cause a reversible error in the inaccuracies of the guidelines given the jury on causation.

As a third reversible error, the trial court permitted a nurse from Tampa General, to testify that tPA is given at this separate hospital even if the patient had a prior subdural hematoma. This was error because: 1) she testified outside her area of expertise, contrary to well-established Florida law; 2) she is neither a neurologist, internal medicine specialist, emergency room physician, or even a doctor. Yet, this nurse was permitted to testify regarding her perceptions of the tPA administration by doctors at another hospital. Her testimony was incompetent, irrelevant and speculative, and therefore should have been excluded. Also, to the extent she testified about actions taken by other doctors at another hospital, she was impermissibly bolstering her testimony with the opinions of out-of-court experts, without an opportunity for St. Joseph's to cross-examine the physicians who actually administered the tPA at Tampa General.

A fourth reversible error was committed by the admission of testimony that St. Joseph's had failed to acquire "informed consent" from Mrs. Cox, by explaining to her the risks of tPA therapy and having her make the decision of whether to take those risks. The case as pled against St. Joseph's did not contain any allegations about the hospital's failure to obtain "informed consent" from Mrs. Cox, nor could it have pursuant to Florida law; obtaining "informed consent" is not a legal duty of

a hospital in any event. This was not only an abuse of discretion in the admission of an entirely new theory of causation to be brought up at trial, but was outside the legal duties charged to a hospital, and was wildly speculative as well.

Additionally, Dr. Eddy Berges, was compelled by the trial court to render an expert opinion even though Florida law holds this is reversible error for a number of reasons, including the fact that the treating physician may not have access to all of the pertinent facts in order to render an expert opinion, and should not be compelled to render an opinion if he feels he may not be in the capacity to adequately do so. In this case, Dr. Berges testified that he was not aware of the history of Mr. Cox's prior subdural hematoma.

The trial court failed to setoff the medical expenses incurred by the Ministry of Health in Ontario for the bills they incurred in light of the fact that it was not seeking any recovery from the Respondents. Finally, the verdict was against the manifest weight of the evidence, and the combination of errors at trial constitutes a separate basis for reversal and remand.

ARGUMENT

POINT I: WHEN CONFLICT IS PRESENTED ON THE ADMISSIBILITY OF A MEDICAL EXPERT OPINION WHEN PETITIONERS' EXPERT ACCEPTED THE NINDS STUDY AS AUTHORITATIVE AND HER CONCLUSION THAT MR. COX WOULD MORE LIKELY THAN NOT HAVE DONE BETTER THAN THE GENERAL PATIENT POPULATION WAS WITHOUT ANY FOUNDATION AND *IPSE DIXIT*

The Petition should be denied because: a) Petitioner's expert on causation did not have a "sufficient basis", and lacked foundation, to render the opinion predicated on either the generally accepted knowledge of the medical community, her own experience or training, as required by section 90.705, Florida Statutes; b) the other jurisdictions which have reviewed the causal link of the failure to administer tPA to a patient have held a plaintiff cannot show that such failure "more likely than not" led to the plaintiff's injuries; c) Petitioners' expert's opinion relied upon an impermissible stacking of inferences, d) there is no similarity to cases where the expert opinion is challenged because of the failure to rely on an epidemiological study, or where there was an intrusion into the province of the finder of fact; and e) amendment to section 90.705 did not negate the requirement of a "sufficient basis" for an expert opinion; it merely changed the procedure for admission of the basis.

A) PETITIONER'S EXPERT'S OPINION HAD AN "INSUFFICIENT BASIS" AS DEFINED BY SECTION 90.705, FLORIDA STATUTES

Petitioner contends there is a conflict presented by the Opinion because the Second District held the testimony of Dr. Futrell and Dr. Berges was insufficient to present a *prima facie* case in order to defeat Respondent's motion for directed verdict. For the reasons expressed herein, the Opinion is entirely consistent with the holdings of this Court and all other jurisdictions which have considered the

same issue regarding tPA therapy for stroke victims. Petitioners argue that a *prima facie* case is shown when an expert testifies to a conclusion without any foundation, i.e. the expert's saying it makes it so. Neither Florida's Evidence Code, Florida's common law, nor common logic support such a holding. If such were the case, there would never be a basis for a directed verdict if an expert were willing to testify as to any conclusion without regard as to whether the expert is extrapolating from existing data, or is rendering an opinion on a guess, unsupported by any clinical research or result.

The Opinion does not stand for the proposition that if there is a study of any sort which contradicts the conclusion of the expert then a directed verdict must be granted. Instead, the Second District concludes that when an expert recognizes a study as authoritative, such as the NINDS study here, and renders an opinion that runs entirely contrary to that study, without any verifiable, independent scientific basis, that opinion must be considered incompetent, without foundation, and insufficient evidence to go to a jury, or to defeat a directed verdict motion.

It is essential to note that the record in this case establishes Dr. Futrell's reliance upon the NINDS study as the only authoritative study. Even though that study unquestionably holds that 11% of patients receiving tPA will benefit from the therapy, and a total of 31% overall will have favorable results (which includes a 20% patient poll receiving placebo), Dr. Futrell opines she has the exclusive

talent of determining the 100% patient population who will fall into the 11% (or 31%) which will have a favorable outcome. This is the sole basis for her ultimate conclusion that Mr. Cox "more likely than not" would have had a favorable outcome had he received tPA.

Fundamental to the Second District's decision was the recognition that Dr. Futrell accepted and relied upon the NINDS study and had no clinical studies of her own which applied to Mr. Cox's physical condition. Although she testified she had administered tPA in other instances which were contraindicated, she admitted that none of those cases involved prior subdural hematomas. The reason this distinction is so important is that tPA, as a clot-busting drug, has been characterized as "dangerous" by all of the medical experts, including Dr. Futrell. The reason it is dangerous is that it can actually cause a brain bleed when there would otherwise not be one, and this can result in death of the patient. Dr. Futrell did not have any other statistics on this. Again, Dr. Futrell did not have any explanation for the factual relationship for use in one contraindication as applied to Mr. Cox's other than her review of Mr. Cox's CT scan. She labeled Mr. Cox as having a "super-normal brain" because it did not show the signs of aging she would expect to see. She expressed no clinical experience with a patient with a "super-normal brain" and gave no definition of what would, or would not be, a "super-normal brain". Beyond this she could not connect the dots of why or how a "super-

normal brain" would jump from 11% to 51% in expectations of relief from tPA. This was another inference made by Dr. Futrell without any support, and another *ipse dixit.*

In order to defeat Respondent's motions for directed verdict, Petitioners were required to offer competent evidence that the failure to administer tPA to Mr. Cox was a 51% or greater cause of Mr. Cox's injuries. *See Gooding v. University Hospital Building, Inc.*, 445 So. 2d 1015, 1018 (Fla. 1984). Petitioner's causation expert, Dr. Futrell, was willing to so state but she had no clinical, empirical data to support such a conclusion.

tPA's manufacturer and the FDA, all warn that tPA is not to be given if the patient has suffered a prior subdural hematoma. There was no dispute in the record that Mr. Cox had a prior subdural hematoma, 2 ½ years before the stroke. Another insurmountable causal break, which was undisputed, was that Dr. Berges would not have administered tPA in any event because of Mr. Cox's prior subdural hematoma. It is a mischaracterization to characterize Dr. Berges' testimony as a recanting of any sort. The letter he signed was never admitted into evidence. Thus, there was no "recanting" since he singularly concluded tPA should be administered to Mr. Cox. Thus, it is not an instance of an expert's opinion being challenged on credibility grounds. Dr Berges did not render an opinion to challenge. The cases cited by Petitioners on this point all involve the admission of

competent testimony, which is matched by other competent testimony to alternate facts. *See Haislet v. Crowley*, 170 So. 2d 88 (Fla. 2d DCA 1964). Therefore, the evidence did not, and could not, show that St. Joseph's more likely than not caused Mr. Cox's stroke injuries. For these reasons, the Second District properly determined the trial court erred in failing to grant a directed verdict and JNOV in favor of St. Joseph's.

Florida law has long held that the mere possibility of causation is insufficient to allow a claimant to recover. *See Gooding*; *Greene v. Flewelling*, 366 So. 2d 777 (Fla. 2d DCA 1979). In the present case, there was no evidence to support the contention that if the hospital nurses had determined the time of onset, and a neurologist for a consult had been contacted, then a reasonable neurologist would have given tPA to Mr. Cox. Petitioners' own expert, Dr. Medoff, admitted that it would *not* be a breach of the standard of care to follow the FDA and drug manufacturer's guidelines. If it is not a breach by a physician to refuse to give tPA to a patient with a contraindication, it is illogical to conclude that it could constitute a breach as well. Dr. Futrell opined that she questioned Mr. Cox's prior history but she did not go so far as to say a physician should disregard charted evidence of subdural hematoma and surmise that those medical records are just wrong. Because of Mr. Cox's prior history of subdural hematoma, it would have been a departure from the relevant medical protocol on tPA administration which

provides that tPA is contraindicated with a prior history of intracranial hemorrhage. Therefore, it would be pure speculation that, had a neurologist been called within 3 hours of the onset of symptoms, the neurologist would have ordered the administration of tPA, since it was contraindicated. *See Jackson County Hospital Corp. v. Aldrich,* 835 So. 2d 318 (Fla. 1st DCA 2002).

Petitioners first contend the Opinion is in conflict with *Wale v. Barnes,* 278 So. 2d 601 (Fla. 1973). The basis for their argument is the contention that once the expert says the "magic words" that a health care provider's actions have "more likely than not caused the plaintiff's injuries" then there is nothing more for the court to consider and the case should always proceed to the jury. *Wale* did not involve a challenge to the expert's foundation for the opinion as is presented here. Instead, the plaintiff's witness testified the defendant doctor used the wrong type of forceps for delivery of an infant with a molded or elongated head. There was no challenge to the *foundation* of the opinion.

For the same reason, the other progeny of *Wale* relied upon by Petitioners do not support the petition and are distinguishable. In *Hughes v. Slomka,* 807 So. 2d 98, 100 (Fla. 2d DCA 2002), the court reviewed the testimony of the plaintiff's expert who opined that if the defendant doctor had checked the pulse in the leg at a critical point in time, the amputation of the leg would have been spared. Again, there was no challenge to the *foundation* of the opinion. Similarly, in *Lawrinson v.*

Bartruff, 600 So. 2d 22 (Fla. 2d DCA 1992) there was *no* challenge to plaintiff's causation expert who testified that the defendant's delay in diagnosis in Merkel cell skin cancer caused him to have more of his face excised.

Mezreh v. Bevis, 593 So. 2d 1214 (Fla. 2d DCA 1992), cited by Petitioners, actually supports Respondent's position. In *Mezreh,* the court affirmed the jury verdict because *competent* expert testimony had been admitted to show the causation required by *Gooding*. *Mezreh* distinguished an earlier opinion, *Noor v. Continental Casualty Co.,* 508 So. 2d 363 (Fla. 2d DCA 1987), where the court affirmed a judgment for the defendants because the plaintiff's expert opinion because it was *too speculative.* Thus, the qualitative standard required by section 90.705(2), Florida Statutes, was well recognized. If the expert opinion does not have a sufficient basis, the opinions and inferences of the expert are inadmissible, and are otherwise insufficient to defeat a directed verdict motion. *Fla. Stat. 90.705(2). See also Zack v. Centro Espanol Hospital, Inc.,* 319 So. 2d 34 (Fla. 2d DCA 1975) (inference that a Foley catheter was removed from the plaintiff's bladder with the cap open was based on the physical evidence of the fistula created after the catheter was removed).

Petitioners assert a conflict with the holding in *Atkins v. Humes,* 110 So. 2d 663 (Fla. 1959). Aside from the fact that *Atkins* well pre-dates the pre-suit requirements of Chapter 766, Florida Statutes, *Atkins* addressed the issue of

whether, under certain circumstances, expert testimony regarding causation is required in a medical negligence case. The Court cited to instances where the malpractice seemed obvious, i.e. failing to sterilize surgical instruments before surgery. Id. at 666. *Atkins* does not present a conflict in any way with the Opinion. There is absolutely no dispute that this case requires a medical expert to opine as to causation. *See Sims v. Helms*, 345 So. 2d 721, 723 (Fla. 1977). Petitioners lose sight of the role of the trial court in implementing the Florida Evidence Code, however. If there was to be no judicial scrutiny of the competency of the evidence submitted, the Evidence Code would be largely superfluous, and a vast number of cases would then fall into conflict. The remaining cases cited by Petitioners on this point do not stand for the proposition that the expert decides for himself what is sufficient. *See Quinn v. Millard,* 358 So. 2d 1378 (Fla. 3d DCA 1978) (expert's credentials challenged); *Centex-Rooney Construction Co. v. Martin County*, 706 So. 2d 20 (Fla. 4th DCA 1998 (expert's opinion basis unrebutted by defendant); *Lopez v. State,* 478 So. 2d 1110 (Fla. 3d DCA 1985)(alcohol absorption rate for the defendant was the same as the general population; he was not "super-normal); *Gershank v. Dept. of Prof. Reg.*, 458 So. 2d 302 (Fla. 3d DCA 1984)(opinion has no facts about the basis of the opinion); *H.K. Corp v. Estate of Miller,* 405 So. 2d 218 (Fla. 3d DCA 1981)(same).

Florida law supports reversal for lack of causation when there is no showing the Defendant's acts "more likely than not" caused the injuries. In *Jackson County v. Aldrich,* 835 So. 2d 318 (Fla. 1st DCA 2002), the plaintiff failed to establish the requisite proximate cause in a wrongful death action against the hospital. The estate did not establish that the patient with severe burns more likely than not would have survived if the hospital had arranged for the patient's transfer to a burn center. The plaintiff's theory of causation, and expert witness testimony, claimed the patient had a 90% chance of survival at any major burn institute, but the patient died before reaching such a center. *Id* at 327-9. There was no evidence that the patient could have gotten to such a burn center in time. Also, the expert witnesses could not definitely state whether the patient suffered from a fatal hemolysis or a nonfatal rhabdomyololysis as a result of the burns themselves. *Id.*

Similarly, in *McKeithan v. HCA Health Services of Florida, Inc.*, 879 So. 2d 47 (Fla. 4th DCA 2004), the directed verdict was affirmed for medical center because the plaintiff had presented no competent evidence as to causation. The Plaintiff alleged that the nurses should have accessed a chain of command, but did not show that such conduct would likely have led to a different outcome for the patient. *Id* at 48. Applying these holdings to the present facts, the result must be the same: St. Joseph's motion for directed verdict should have been granted.

Separately, the directed verdict should have been granted because there was no competent evidence on causation since it was not established that the tPA, if given, would have "more likely than not" caused a different outcome for Mr. Cox. Florida law provides the "more likely than not" standard is satisfied if a plaintiff presents evidence that establishes that the injured party had a fifty-one percent or better, chance that the injury would not have occurred but for the actions or lack thereof of the health care provider. *Gooding*, at 1020, *Jackson County*, at 328. In the present case, even if the hospital's nurse had known what the time of onset was, and had called a consulting neurologist *and* that neurologist administered tPA despite the protocol, there was still no evidence that the tPA would "more likely than not" have favorably effected the injuries that Mr. Cox sustained as a result of the stroke.

This case does not present an instance where the appellate court is disapproving an *unchallenged* opinion as presented in *Golden Hills Turf & Country Club, Inc.*, 273 So. 2d 375 (Fla. 1973). The challenge to the expert opinion here is that the sufficient basis predicated on competent evidence was entirely absent.

B) OTHER JURISDICTIONS HAVE DECIDED tPA CASES IN ACCORD WITH THE SECOND DISTRICT'S OPINION AND FOUND THERE IS AN INSUFFICIENT BASIS TO FIND ADMINISTRATION OF THIS DRUG WILL ACHIEVE FAVORABLE RESULTS "MORE LIKELY THAN NOT"

Other jurisdictions have ruled that the failure to give tPA cannot be the basis for a medical negligence claim. In Texas, the 5th Circuit affirmed summary judgment in favor of the hospital because the plaintiff failed to make the showing that the failure to administer tPA was "more likely than not" the cause of the plaintiff's injuries. *Young v. Memorial Hermann Hospital System*, 573 F. 3d 233 (5th Cir. 2009). There are many similar facts underlying the decision in *Young* when compared to the present case. As in the present case, the plaintiff's experts recognized the NINDS study as an authoritative scientific study. *See Young v. Memorial Hermann Hospital System,* 2006 WL1984613, p.3. One of the plaintiff's experts testified that he believed the plaintiff more likely than not would have had a very favorable outcome with tPA. *Id.* at 5. However, the expert did not take into account the percentage of patients the plaintiff's age who had favorable outcomes with placebo, and therefore, he overstated the likely results using the NINDS study. The district court found it was of no moment whether the court chose to strike the testimony or if it merely ignored it as incompetent, and in either event there was no causation evidence to go to a jury. *Id.* at 4.

The scientific literature is uniform in the conclusion that patients who receive tPA for stroke treatment have an 11-13% chance of benefiting from the treatment, well short of the 51% required to show "more likely than not." It is curious that Dr. Futrell opines that she can determine who will fall within the small

class of patients who will benefit and yet cannot explain how she does it. Dr. Futrell's opinion is based upon unspecified, untested and unreviewed anecdotal evidence from her own experience, none of which included the use of tPA in a contraindication of prior subdural hematoma. Her surmising that Mr. Cox would have achieved better results than the general population has no "sufficient basis" required to support an expert opinion.

Ipse dixit conclusions by an expert, contrary to reported scientific studies and the expert's own admissions, are dangerous and offer no competent evidence of causation and serve only to mislead a fact finder.

The Supreme Court of Michigan affirmed summary disposition in favor of the hospital and physicians for failure to administer tPA in *Ensink v. Mecosta County General Hospital*, 262 Mich. App. 518, 687 N.W.2d 143 (2004). The Michigan court specifically recognized the need for subtracting from the percentage of patients that had favorable results the twenty percent of patients who recovered in placebo, without any tPA administration. 262 Mich. App. at 539, 687 N.W.2d at 155-56. *See also Flanagan v. Catskill Regional Med. Center, Inc.* ,884 N.Y.S.2d 131, 65 A.D. 3d 563 (N.Y. App. Div. 2009) (summary judgment affirmed in favor of hospital on claim of failure to administer tPA because plaintiff's expert's opinions were too speculative).

The Supreme Court of Oregon rejected the plaintiff's attempt to recover from the hospital and treating physicians for the decedent's death from a stroke which she alleged was due to the failure to give tPA. *Joshi v. Providence Health System of Oregon Corp.*, 342 Or. 152, 149 P. 3d 1164 (2006). Recognizing that tPA would have afforded, at most, a 30 percent chance of improvement in outcome, the court affirmed the directed verdict in favor of the defendants because the plaintiff was unable to prove "more likely than not" the plaintiff would have had a more favorable outcome with tPA. *Id. at 1166.* The plaintiff's argument in *Joshi* was the same as the argument here, i.e. that the plaintiff should be allowed to proceed to a jury based on a "loss of chance of survival" and not the "more likely than not" standard present in Florida. *Id.* In this regard, Florida stands with the vast majority of jurisdictions which have rejected the "lost chance" theories of recovery. *See, e.g., Kilpatrick v. Bryant,* 868 S.W.2d 594, 603 (Tenn. 1993); *Fennell v. So. Maryland Hosp. Center, Inc.,* 320 Md. 776, 580 A. 2d 206 (1990); *Duarte v. Zachariah,* 22 Cal.App. 4th 1652, 28 Cal. Rptr. 2d 88 (1994). In those jurisdictions where "lost chance" may serve as the standard, the courts are empowered to reduce the damages when it appears the jury is assessing all of the plaintiff's damages. *See Hargroder v. Unkel,* 888 So. 2d 953 (La. 2004).

If the Court were to grant the petition, finding that despite the generally accepted information on tPA, an expert may at one time find the NINDS study

authoritative and reliable yet simultaneously eschew the findings, without logical or mathematical extrapolation. In this regard, the Court will be set on a course where the other jurisdictions who have decided this issue will not follow.

C) PETITIONERS' CAUSATION OPINION IMPERMISSIBLY STACKS INFERENCES

Petitioners cannot prove causation because they rely on circumstantial evidence and the improper stacking of inferences to prove that Mr. Cox more likely than not would have benefited from tPA. As the Court explained in *Nielsen v. City of Sarasota*, 117 So. 2d 731, 733 (Fla. 1960), quoted in *Stanley v. Marceaux*, 991 So. 2d 938, 940 (Fla. 4th DCA 2008):

> [I]n a civil case, a fact may be established by circumstantial evidence as effectively and as conclusively as it may be proved by direct positive evidence. The limitation on the rule simply is that if a party to a civil action depends upon the inferences to be drawn from circumstantial evidence as proof of one fact, it cannot construct a further inference upon the initial inference in order to establish a further fact unless it can be found that the original, basic inference was established to the exclusion of all other reasonable inferences.

The *Stanley* court went on to say, "the rule that an inference may not be stacked on another inference is designed to protect litigants from verdicts based upon conjecture and speculation." *Id*. (citing *Voelker v. Combined Ins. Co. of Am.*, 73 So. 2d 403, 407 (Fla. 1954)).

Dr. Futrell's opinion is flawed because it cannot be shown that her original basic inference was established to the exclusion of all other reasonable inferences. *See Food Fair Stores, Inc. v. Trusell*, 131 So.2d 730 (Fla. 1961). In fact, there are

several flaws in Dr. Futrell's opinion that render it improper, and show that the jury's verdict could have only been grounded in conjecture and speculation. She testified:

> "My conclusions were that Mr. Cox arrived at the emergency room in the appropriate time window to receive tPA, that he was an appropriate candidate for tPA, and that all of the indications we have from his clinical status in the emergency room and the CT in the emergency room suggest that he probably would have had a very good outcome had he received the medication." (T. 1052 – 1053)

Dr. Futrell's opinion on causation is grounded in the assumption that tPA would have worked on Mr. Cox had it been administered to him. (T. 1078). However, this inference cannot be established to the exclusion of all other reasonable inferences. The NINDS study on administering tPA to stroke victims, showed only an 11% increase in recovery (20% of patients recovery when not provided any medication, and 31% of patients recovery with tPA). Dr. Futrell recognized this study and its findings as authoritative. (T. 1097 – 1098; 1100 – 9) Petitioners have produced no competent evidence showing a more favorable outcome, and certainly no statistics reflecting that administering tPA has a greater than 50% success rate. Petitioners try to counter this defect in their theory by arguing that it is more likely than not that Mr. Cox would have been one of the 31% that would have benefited from tPA. (T. 1077 – 1078). This theory is flawed because it assumes that doctors can predetermine who would benefit from tPA. If this were true, then tPA would only be given to patients that would benefit, and

would never be given to patients that would not recover. Using Petitioner's premise, the success rate for tPA should be 100%. It is not, and this argument fails.

Dr. Futrell's opinion is also flawed because it assumes that Mr. Cox was an appropriate candidate for tPA based upon the stacking of inferences, which cannot be proved to the exclusion of others: 1) Dr. Futrell assumes that Mr. Cox had no subdural hematoma, and that he was a great candidate for tPA, even though the charted medical records report a prior hematoma, and Dr. Futrell has not seen the necessary CT scan to refute this; (T. 1053; 1060-2) Though the medical records indicate that Mr. Cox previously had a subdural hematoma, Dr. Futrell assumes that Mr. Cox's brain is "super normal" because it appeared better than expected for his age, according to the CT. (T. 1064). In addition, this does not explain why this increases his chance of benefiting from tPA.; 3) Dr. Futrell assumes that Mr. Cox did not have a prior stroke because she did not see it in the CT she reviewed, but even she stated that *this is not conclusive* that a prior stroke did not occur. (T. 1065) Dr. Futrell assumes that even if the medical records show a previous subdural hematoma, so long as it did not occur within the past 3 months, tPA can still be administered safely. This assumption is based on the FDA warning/manufacturer's insert which identifies "severe head trauma" as a contraindication, and provides that so long as there was no severe head trauma

within the last 3 months, then tPA is safe. Dr. Futrell assumes that this 3 month period applies to *all* contraindications, even though the warning/insert does not state this. (T. 1083 – 1084). The FDA approved these guidelines as written, and if the expiration of three months negated other contraindications, the warning would have so stated. (T. 1128). The opinion necessarily assumes the study forgot to include this or it was so unimportant that affirmatively chose to leave it out; 4) Dr. Futrell assumes that it is safe to give tPA to a patient with contraindications so long as the indications and contraindications balance out in favor of administering tPA. This balancing is not included in the warning/insert. (T. 1084– 1087). Further, she gives no objective standard for the "balancing."; 5) Dr. Futrell assumes that "active bleeding" is the only "absolute" contraindication for which the above-mentioned balancing does not occur. There is no "absolute" language on the package/insert, and nothing to differentiate active bleeding from any other contraindication. (T. 1084-7); 6). Dr. Futrell assumes that because she has given tPA to stroke victims with contraindications other than a subdural hematoma, it would have worked on Mr. Cox if he had a subdural hematoma.(T. 1067). She gives no medical, chemical or practical reason why this is so and she admitted she has never administered tPA to someone with a prior subdural hematoma. (T. 1120 – 22).

It is apparent that a jury could not reach a conclusion imposing liability on St. Joseph's without indulging in the prohibited stacking of one inference upon another

inference in a situation where, admittedly, the initial inference was not justified to the exclusion of all other reasonable inferences. *Food Fair Stores, Inc. v. Trusell*, 131 So. 2d at 733. *See also Johnson Constr. Management, Inc. v. Lopez*, 902 So. 2d 206, 208-9 (Fla. 3d DCA 1005) (directed verdict is proper when no evidence or reasonable inferences establish causation).

Dr. Futrell's opinion was premised on speculation and conjecture in that it belied warnings for the drug and the only patient study available, universally recognized as authoritative. As Dr. Berges testified a prior subdural hematoma was a totally "new ballgame". To carry Petitioners' theory of causation to its conclusion, if the physician in charge of Mr. Cox's care had ordered tPA "off label", even with Mr. Cox's history of prior subdural hematoma, Respondents would still be liable for damages because they acted against the warnings given by the U. S. Government and the manufacturer, who are charged with conducting the research to determine the safe boundaries for a drug's use. In this reverse situation, St. Joseph's would face liability for failing to comply with the unambiguous guidelines for the tPA, according to Petitioners' own expert witness Dr. Medoff.

Mere speculation and conjecture, unsupported by the evidence, cannot be the legal basis for causation in a professional negligence case. *See Proto v. Graham*, 788 So. 2d 393, 396 (Fla. 5th DCA 2001)(reversed denial of motion for DV on legal malpractice case, citing *Gooding*). In this case, Dr. Futrell's testimony

was based solely on speculation and conjecture because she ignored the warnings for the drug's use, and has no scientific or empirical basis for doing so. It is insufficient to deny a motion for directed verdict through the use of expert testimony rendered which has no foundation other than to say the expert has taken such action in the past. Florida courts have consistently held, the fact that an expert witness states that his testimony is generally accepted does not necessarily make it so. *See Brim v. State*, 779 So. 2d 427, 434 (Fla. 2d DCA 2000) (trial court should determine whether there is a quantitative and qualitative acceptance of the science); *Holy Cross Hosp., Inc. v. Marrone*, 816 So. 2d 1113, 1119 (Fla. 4th DCA 2001); *Greyhound Lines, Inc. v. Mayo*, 207 So. 2d 1, 5 (Fla. 1968); *Crawford v. Shivashankar*, 474 So. 2d 873 (Fla. 1st DCA 1985).

A similar challenge to legal causation was presented in *Posner v. Walker*, 930 So. 2d 659 (Fla. 3d DCA 2006). The plaintiff's decedent had a long history with pain management and eventually became addicted to pain medicine and overdosed. The 3d DCA reviewed the jury's verdict in favor of the plaintiffs and determined the verdict was against the manifest weight of the evidence. *Id.* The evidence showed the decedent had not taken any of the medication prescribed by the defendant doctor and had been administered drugs by another doctor, who was implicated. The plaintiffs called an expert to testify that the defendant doctor failed to have an "exit strategy" for the medications, erroneously continued to

prescribe drugs, failed to refer the patient to a pain clinic, did not order urinalysis, and failed to elicit family support or contact pharmacies. The 3d DCA reversed because none of these charges were factually sustained as being a cause of death.

Important to the analysis of causation in *Posner* was the 3d DCA's recitation of the Court's standard for expert opinions in medical negligence cases. *Id.* at 665. This standard provides: "[t]he opinion of an expert is not sufficient to eliminate the necessity of proving the foundation facts necessary to support the opinion." *Id.* at 665. Applying this recognized standard to the present case, Dr. Futrell could not base her opinion on "foundation facts" because she supposed that the health care providers would and should totally disregard the warnings of the FDA and the drug manufacturer in the administration of tPA. The foundation facts in this case also failed to establish that the administration of the tPA would have "more likely than not" affected or improved Mr. Cox's injuries in any way. *See also Paddock v. Chacko*, 522 So. 2d 410, 417 (Fla. 5th DCA 1988)(no causation from the psychiatrist's failure to have face-to-face meeting with patient who became suicidal because it was mere speculation what measures should have been taken which had not already been recommended by defendant).

The 4th DCA has also affirmed a directed verdict in favor of the defendant obstetrician who was accused of failing to perform a risk evaluation before labor and ordered a physician to manage care of the plaintiff through her delivery. *Ewing*

v. Sellinger, 758 So. 2d 1196 (Fla. 4th DCA 2000). According to the plaintiff's theory of negligence, the on-call physician would have ordered a C-section, which would have avoided the injuries sustained. *Id. at 1198.* However, the 4th DCA held the record showed the on-call doctor which was on staff at the time testified that he would not have ordered a C-section because labor was progressing adequately, according to the fetal heart monitor strips. *Id.* Therefore, there was no causal link to the alleged failure to require the on-call physician since he would not have taken any additional action in any event. *Id*.

The most compelling part of the analysis of legal causation in this case is the fact that Petitioners' own expert testified that treating doctors who elect to follow the manufacturer's guidelines for tPA, which disallows the use of tPA with a history of prior subdural hematoma, would be within the standard of care. Taken this as true, it is a true Hobson's choice to find legal causation to support negligence against St. Joseph's because tPA was not administered to Mr. Cox. If it would have been within the applicable standard of care to not give the tPA, neither Respondent can be legally liable for following the applicable standard of care.

For the same reasons, the trial court should have granted St. Joseph's motions because the verdict was against the manifest weight of the evidence. *See Brown v. Estate of A.P. Stuckey,* 749 So. 2d 490, 495 (Fla. 1999).

D) THERE IS NO SIMILARITY TO THE USE OF EPIDEMIOLOGICAL STUDIES AS A SWORD OR A

SHIELD AS WAS CONSIDERED IN *MARSH V. VALYOU,* AND NO IMPINGEMENT ON THE JURY'S FUNCTION

This case does not present the concerns the Court expressed in excessive reliance on epidemiological studies. *See Marsh v. Valyou,* 977 So. 2d 543 (Fla. 2007); *Castillo v. E.I. DuPont De Nemours & Co., Inc.,* 854 So. 2d 1264 (Fla. 2003); *U.S. Sugar Corp. v. Henson,* 823 So. 2d 104 (Fla. 2002). To begin with, whether or not the *Frye* standard applies here does not affect the outcome. Petitioners would argue that Dr. Futrell's testimony is "pure opinion" and therefore can be based on here experience and training. *Marsh, at 548.* However, the point is Dr. Futrell has neither experience or training to establish a competent basis for her opinions.

As the Court aptly held in *Hadden v. State*, 690 So. 2d 573, 578 (Fla. 1997),

> "Novel scientific evidence must also be shown to be reliable on some basis other than simply that it is the opinion of the witness who seeks to offer the opinion. In sum, we will not permit factual issues to be resolved on the basis of opinions which have yet to achieve general acceptance in the relevant scientific community; to do otherwise would permit resolutions based upon evidence which has not been demonstrated to be sufficiently reliable and would thereby cast doubt on the reliability of the factual resolutions."

The Court's decisions in this area have expressed concern that limitations on an expert's extrapolations from generally accepted theories of causation could be too restrictive. However, the Court has never receded from requiring any such extrapolations to stem from either the generally accepted data or the expert's own

experience and training. This is indeed the rub here. Dr. Futrell did not, and could not, rely upon her own experience in treating stroke patients with prior subdural hematomas, so she has to *assume* she would have the same result as with other contraindications yet she has no experience, no training.

Dr. Futrell states that Mr. Cox would have had a favorable result because Mr. Cox has a super-normal brain, and ergo super-normal will more likely than not have favorable results- again, no experience and no training. Although Dr. Futrell clearly recognizes the NINDS study as authoritative, she discards the findings entirely as to the patient population results in the study, and not by a small margin, but by four hundred percent, because she claims to have anecdotally had a better clinical experience than the study. She gives no explanation of how the study can be authoritative on one hand and so utterly wrong on another. As this Court has consistently held, the departure from the findings generally accepted in the medical community is allowable but not so completely unfettered as to require no basis from *experience* or *training*.

E) THE AMENDMENT TO SECTION 90.705 IN 1979 DID NOT NEGATE THE REQUIREMENT FOR A SUFFICIENT BASIS FOR THE EXPERT OPINION

Petitioners argue that the change to section 90.705, Florida Statutes, negates the need for a showing a basis for the opinion since expert opinions may now be introduced without *prior disclosure* of the underlying data or facts. *See*

Petitioner's Brief at 30-32. However, the Court has held the rule precluding expert testimony based on insufficient data, although procedurally modified, remains substantively the same. *Husky Industries, Inc. v. Black,* 434 So. 2d 988, 993 (Fla. 1983).

Petitioners' reliance on *Jackson v. State,* 648 So. 2d 85 (Fla. 1994) is misplaced. They contend the holding in *Jackson* establishes a substantive change to section 90.705 when instead, the Court merely ruled that it was not an abuse of discretion for the trial court to refuse to admit the videotape of a hypnosis session with the criminal defendant because the State would not have an opportunity to cross-examine. Instead, the trial court allowed the expert to describe the procedure in court, which afforded the State the opportunity to cross-examine. This was not an instance where the expert gave an opinion without a foundation. As the Court noted, the expert followed the procedure previously accepted by the Court for hypnosis testimony in *Bundy II. Bundy v. State,* 471 So. 2d 9 (Fla. 1985), *cert. denied,* 479 U.S. 894, 107 S.Ct. 295, 93 L.Ed.2d 269 (1986). Thus, *Jackson* supports Respondents' arguments because it reflects one of the many instances where the Court has established foundation thresholds for experts. Applying Petitioners' arguments to *Jackson*, there would have been no need to devise an acceptable procedure to govern exams under hypnosis; if an expert reaches a conclusion he need not declare the basis for the opinion. However, as section

90.705 also provides "… the court in its discretion may require such disclosure [of the facts and data upon which the opinion is based]" If as Petitioners suggest, the opinion is direct evidence regardless of whether there is a sufficient basis or not, there would be no reason for the court to require any such disclosure. In fact, it would be an improper intrusion into the fact finding process for the trial court to do so. Yet, no explanation is given for the inclusion of this language in section 90.705. The statute is to be construed according to its plain meaning. *See Vocelle v. Knight Bros. Paper Co.,* 118 So. 2d 664 (Fla. 1st DCA 1960). This is yet another indication of why Petitioners argument is invalid.

POINT II: THE TRIAL COURT ERRED IN FAILING TO GIVE THE PROPER JURY INSTRUCTION ON CAUSATION ACCORDING TO GOODING V. UNIVERSITY HOSPITAL BUILDING, 445 So. 2d 1015 (FLA. 1984)

The remaining points were raised on appeal below and not reached by the Second District. Because they do not fall within the Court's jurisdiction, if the petition is granted, these issues should be remanded to the Second District.

Instead of a jury instruction tailored to the standard of causation in *Gooding,* the trial court gave the standard jury instruction on causation. When requesting the special instruction St. Joseph's demonstrated: 1) the requested instruction accurately stated the applicable law; 2) the testimony and other evidence supported the giving of the instruction, and 3) the instruction was necessary to resolve the issues to be decided by the jury. *See Force v. Ford Motor Co.* 879 So. 2d 103 (Fla.

5th DCA 2004). Thus, the failure to give the requested jury instruction constituted reversible error. *Craig v. School Bd. of Broward County*, 679 So. 2d 1219, 1221 (Fla. 4th DCA 1996) ; *Wallace v. Fisher*, 567 So. 2d 505 (Fla. 5th DCA 1990). Although the requested jury instruction was not part of the Standard Jury Instructions, Florida law provides that it is still error to *fail* to give it since it adequately instructs the jury in the circumstances in the case. *See Lynch v. McGovern*, 270 So. 2d 770, 771 (Fla. 4th DCA 1972). *Banks v. Hospital Corp. of America*, 566 So. 2d 544, 545 (Fla. 4th DCA 1990). Without the special jury instruction, the jury was left to assume that the level of causation was the mere loss of a "chance" of recovery which is precisely what the Court disallowed in *Gooding*. *See Wallace v. Fisher*, 567 So. 2d 505 (Fla. 5th DCA 1990). The jury instruction actually given left the jury to believe that causation was based on whether Mr. Cox had merely a reduced chance of a better outcome, which is substantially less than the showing required by *Gooding.* For these additional reasons, the Court should reverse and remand for a new trial, and order that the special *Gooding* jury instruction be given.

POINT III: THE TRIAL COURT ERRED IN DENYING ST. JOSEPH'S OBJECTION TO THE INTRODUCTION OF THE OPINION OF NURSE CHAMBERS REGARDING HER KNOWLEDGE OF TPA ADMINISTRATION AT TAMPA GENERAL BECAUSE APPELLANTS COULD NOT CROSS-EXAMINE THE PHYSICIANS ORDERING THE THERAPY, THE TESTIMONY WAS INCOMPETENT BECAUSE NURSE CHAMBERS TESTIFIED OUTSIDE HER AREA OF EXPERTISE, THE EVIDENCE WAS IRRELEVANT, AND ANY PROBATIVE VALUE WAS

OUTWEIGHED BY THE POTENTIAL TO MISLEAD AND CONFUSE THE JURY

It is axiomatic that in medical malpractice cases, the standard of care is determined by a consideration of expert testimony. *See Sweet v. Sheehan,* 932 So. 2d 365 (Fla. 2d DCA 2006). Over the hospital's objection, Nurse Chambers was permitted to testify regarding the administration of tPA therapy at Tampa General to patients with prior subdural hematomas or intracranial hemorrhage. This testimony constituted reversible error for a number of reasons. First, it allowed Nurse Chambers to improperly bolster her opinions on the medical care given by the doctors, by criticizing the care Mr. Cox received at St. Joseph's without the hospital's ability to cross-examine the physicians who may have ordered the tPA at Tampa General regarding all of the considerations that went into their decisions to order tPA, even if the patient had prior history of intracranial hemorrhage. The net effect was to allow a nurse expert to testify as to the opinions and decisions of physicians in another setting without any ability to counter the circumstances upon which such decisions were made. Indeed, Nurse Chambers could not state the bases for any of the decisions made by physicians at Tampa General, and even if she could have explained those circumstances, she would not have had the medical expertise to properly and adequately explain the reasons for the other medical therapies. *See Linn v. Fossum,* 946 So. 2d 1032 (Fla. 2007). The jury had no way of distinguishing the lack of capacity for Nurse Chambers to speak on behalf of

other physicians or the hospitals. The jury had only the admitted evidence to weigh.

St. Joseph's had no way of challenging her testimony since Nurse Chambers could not name a single patient who received tPA under the stated circumstances at Tampa General. This constitutes reversible error because there can be no way to establish to what extent Nurse Chambers was seriously in error in her memory of what happened at Tampa General. There is a possibility that no such order for tPA was ever placed, or that there was not a confirmed diagnosis of a prior cranial hematoma in the Tampa General patients. The hospital had no opportunity to cross-examine those instances at Tampa General in which a physician allegedly made such a call for the TPA therapy or if they had other reasons to explain giving such therapy. Most importantly, no evidence was introduced about the results achieved in any of these other patients.

Additionally, Nurse Chambers testimony was only a conduit for the introduction of evidence which would have otherwise been inadmissible. This has uniformly been disallowed pursuant to Florida law. *See also Schwartz v. State*, 695 So. 2d 452 (Fla. 4th DCA 1997). According to established Florida law, admission of this type of evidence completely undermines the Evidence Code because "the evidence is presented to the jury without affording the opposing party

an opportunity to cross-examine and impeach the source of the hearsay." *Linn*, 946 at 1038 (citing *Gerber v Iyengar*, 725 So. 2d 1181, 1185 (Fla. 3d DCA 1998).

The Court addressed this issue in *Linn* in late 2006, resolving a conflict between the 1st and 4th Districts. The question certified to the Court was whether an expert can testify on direct examination that the expert relied on consultations with colleagues or other experts in forming his or her opinion. *Id.* at 1033. The Court determined that such testimony was not permissible because it impermissibly permits the testifying experts to bolster their opinions and creates the danger that the testifying experts will serve as conduits for the opinions of others who are not subject to cross-examination. 946 So. 2d 1032. The Court deemed this to be a "curbside consult" which did not permit the opposing party to challenge the bases for those third party "experts." *Id* at 1040. The testimony offered in *Linn* should have been excluded, according to the supreme court, because the other experts did not have "first-hand knowledge of the case" and it is therefore "a conduit for inadmissible hearsay." *Id.* at 1037-8.

Also, any probative value of the testimony was far outweighed by the potential that the jury was misled or confused by the presentation of this evidence. This is another basis for the proper exclusion of such testimony, according to the supreme court. *Linn*, at 1040-1. Nurse Chambers could not identify any of the patients involved in the administration of tPA therapy with prior intracranial

hemorrhages she said had occurred at Tampa General. There was no way for the jury to properly assess the circumstances of any such treatment, and whether, given those other circumstances, those treating physicians would have elected to give Mr. Cox TPA therapy knowing his prior intracranial bleeding history.

The danger is too great that an inference will be created for the jury to assume that the "experts agreed", with the testifying witness, which is tantamount to improper bolstering of the witness' testimony. *Linn* at 1040-1. All of this is contrary to the purpose of section 766.102(5), Florida Statutes, which imposes additional requirements to ensure a testifying expert has the necessary expertise. *Id.*

Finally, and most importantly, Nurse Chambers was not competent to give the testimony regarding the efficacy of giving tPA therapy in any event. Florida law specifically requires that an expert witness has the necessary expertise to testify in a medical malpractice case. *Fla. Stat.§766.102(5).* It is also fundamental to Florida's medical malpractice statute that a medical expert must meet the definition of a "similar health care provider." *Fla. Stat. §766.102(2)(a)(b) and (c); See Juarbe v. Gomez*, 762 So. 2d 534 (Fla. 4th DCA 2000) (plaintiff's expert did not meet the definition of "similar health care provider" under section 766.102(2)(a), (b) or (c) because the specialty involved was cytopathology, and the expert was apparently not a cytopathologist). When the trial court permitted this testimony

over St. Joseph's objection, it committed reversible error because it is fundamental that a nursing expert is incompetent to provide medical opinions regarding the decision-making and actions taken by physicians at other hospitals. The testimony of Nurse Chambers could not be considered harmless error in light of the fact that the use of tPA therapy for a patient with a history of subdural hematoma was so focal to the issue of causation as against Respondents.

Petitioners maximized the import of this testimony by highlighting Nurse Chambers testimony during closing argument (T. 2005). Respondents' trial counsel told the jury that if Mr. Cox had been delivered to Tampa General, a charge nurse would have told them tPA had been given under similar circumstances a handful of times (T.2005).

For these reasons, 1) hearsay; 2) lack of competence; 3) improper bolstering; and 4) relevance outweighed by prejudice, the Court should reverse because the jury improperly considered this Nurse's testimony regarding tPA administration.

POINT IV: THE TRIAL COURT ERRED IN ADMITTING EVIDENCE THAT APPELLANT HAD NOT ADVISED MRS. COX OF THE RISKS OF TPA THERAPY AS THE MEDICAL NEGLIGENCE ALLEGED WAS NEVER A LACK OF "INFORMED CONSENT"

During Respondents' case they offered testimony that Mrs. Cox should have been given information about tPA to attempt to show that had she been informed about tPA she would have given consent to the therapy. (T. 1454-8) This theory was never pled or prosecuted before the time of trial. Petitioners' first attempt to

introduce this testimony was during the direct examination of Dr. Futrell. The trial court sustained the objection to the irrelevant and speculative testimony. The trial court initially granted the objection since an "informed consent" theory had never been pled. However, the trial court ultimately allowed Respondents to introduce Mrs. Cox's testimony that had she been given the statistical risks of the therapy, she would have authorized tPA on the day of the incident (T. 1455-8). This constituted a radical change in the theory of Respondents' case which severely prejudiced St. Joseph's which was given no opportunity to present the defense that "informed consent" is not a proper basis of liability in Florida.

Florida law confines liability for the failure to obtain informed consent to medical practitioners. *See Cedars Medical Center v. Ravelo*, 738 So. 2d 362 (Fla. 3d DCA 1999) (citing Fla. Stat. §766.103). As the Third District noted in *Cedars*, the reason for this legislative restriction is that only a treating physician has the training, experience, skill and background regarding the patient's condition to obtain an "informed" decision on the performance of a medical procedure. For this additional reason, this testimony constituted harmful, reversible error as to St. Joseph's.

In addition, the trial court abused its discretion in permitting an entirely new theory on liability during trial. *See Drackett Products Co. v. Blue*, 152 So. 2d 463 (Fla. 1963). In *Drackett*, the mother of the injured child was permitted to testify at

trial that if she knew before the accident that the defendant's product, Drano, would explode if water were introduced to the can, she would have never kept it on the shelf. The warning on the Drano can advised to keep water out of the can but did not state it was potentially explosive).

Because "informed consent" is not a proper basis for a claim against the hospital, a new trial should be granted.

POINT V: THE TRIAL COURT ERRED IN ORDERING DR. BERGES, A TREATING PHYSICIAN, REQUIRING THAT HE RENDER AN EXPERT OPINION

Dr. Berges was deposed in the case and advised that he would not render any expert opinions concerning issues in the case. Plaintiff's filed a motion to require Dr. Berges to render expert opinions, which the trial court granted. The testimony of the second deposition of Dr. Berges was read in part in Plaintiffs' case in chief (T.1558-1611). Dr. Berges acknowledged that he did not have access to a full set of the records pertaining to Mr. Cox, and was unaware that he had experienced a prior subdural hematoma. Notwithstanding this, his opinion regarding the use of tPA was read into evidence by the Plaintiffs. In this way, Dr. Berges was forced to render an expert opinion in the case, contrary to Florida law.

A treating professional cannot be forced to render standard of care opinions regarding other treating health care providers in the case. *See Meltzer v. Coralluzzo,* 499 So. 2d 69 (Fla. 1986); *See also Young v. Metropolitan Dade*

County, 201 So. 2d 594, 596 (Fla. 3d DCA) *cert. denied*, 207 So. 2d 690 (Fla. 1967). This is especially true where, as here, the doctor has no knowledge of the facts, and has not agreed to testify as an expert. The fact that a medical expert refuses to render an expert opinion may well reflect that witness' lack of comfort with the level of background knowledge or his own level of expertise for the questions being asked.

The trial court committed reversible error in compelling Dr. Berges to testify. Because he was not a retained expert, his testimony may have carried greater weight with the jury. The deliberations of the jury were necessarily tainted by the receipt of expert testimony that should have been excluded for the established rationales given by Florida courts on this issue. *See Kridos v. Vinskus*, 483 So. 2d 727 (Fla. 4th DCA 1985).

POINT VI: THE TRIAL COURT ERRED IN ADMITTING EVIDENCE OF MEDICAL EXPENSES PAID BY THE ONTARIO MINISTRY OF HEALTH WITH NO EVIDENCE RESPONDENTS WOULD EVER HAVE BEEN LIABLE FOR THE DEBT, AND THE BILLS WERE NEVER PRODUCED AND THE EVIDENCE WAS THEREFORE INCOMPETENT

The trial court permitted Respondents/Plaintiffs to present evidence of medical expenses paid by the Ontario Ministry of Health without any evidence that they would have ever been liable for the debt overly Respondents' timely objection. The Ontario Ministry of Health is a public agency of Ontario where the Coxes resided. The evidence showed that total of $100,487.73 Canadian was for medical

care which was free to the Respondents, and they were never responsible for the payment of those medical expenditures. According to the uncontroverted testimony of the Ministry's official, the Ministry had no right to recover the value of these expenditures from Respondents. Therefore, these expenses were improperly submitted to the jury. *See Cooperative Leasing, Inc. v. Johnson*, 872 So. 2d 956 (Fla. 2d DCA 2004). This error was further compounded by the fact that the trial court allowed the introduction of these expenses without requiring the production of the actual medical bills which did not establish that the treatments were reasonable and necessary or related to the damages claimed by the Respondents.

Further, the insurance payment summaries created by the Ministry, Green Shield and World Access were documents of payments made by collateral source providers. Therefore, the Plaintiffs should not have been allowed to introduce these collateral source documents into evidence. *See Gromley v. GTE Products Corp.*, 587 So. 2d 455 (Fla. 1991) (as a rule of evidence, the collateral source rule prohibits, upon proper objection, the introduction of any evidence relating to past payments made from collateral sources). This constitutes a separate reason for reversal and a new trial.

Finally, Respondents introduction of this evidence violated section 90.956, Florida Statutes, because the trial court admitted as summaries of other evidence the insurance payment schedules even though Plaintiffs had not afforded Appellants an opportunity to review the underlying documentation which was the subject of the summary and determine if the summaries were accurate and related to the damages claimed in this case. *See Tallahassee Housing Authority v. Florida Unemployment Appeals Comm.*, 483 So. 2d 413, 415 (Fla. 1986).

CONCLUSION

Respondent respectfully requests the Court adopt the holding of the Second District in all respects, or in the alternative, decline jurisdiction in this case because no express and direct conflict is presented. Even if the Court were to decide the Second District's opinion is not in accord with Florida law for some reason, Respondent requests the Court remand the case to the Second District for the purpose of reviewing the remaining issues on appeal which have been raised by Respondent relating to the trial.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U.S. Mail this ____3rd__ day of March, 2010 to and Joel D. Eaton, Esq., Podhurst Orseck, P.A., 25 W. Flagler Street, Suite 800, Miami, FL 33130;

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CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY that the Answer Brief on the Merits of Appellant, ST. JOSEPH'S HOSPITAL, complies with the requirements of Rule 9.210, Fla. R. App. P., and is printed in Times New Roman 14-point font.

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