**IN THE SUPREME COURT**
**STATE OF FLORIDA**

JILL MARSH,

**CASE NO. SC06-118**

Petitioner,

vs.

ROBERT EARL VALYOU, JR. and DEBORAH A. VALYOU, THOMAS JONATHAN BURKE and DONNA E. BURKE, and PV HOLDING CORP. d/b/a AVIS RENT-A-CAR,

Respondents.
_____/

ON DISCRETIONARY REVIEW FROM THE
FIFTH DISTRICT COURT OF APPEAL
FIFTH DCA CASE NO. 5D03-188
CIRCUIT COURT CASE NO. CIO-99-6377

# ANSWER BRIEF OF RESPONDENTS THOMAS J. BURKE AND DONNA E. BURKE


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## PRELIMINARY STATEMENT

The parties will be referenced by proper name or by their position below. Amicus curiae, Academy of Florida Trial Lawyers, will be referenced as AFTL.

References to the record on appeal will be made by volume and page number, as (R2.___). References to the supplemental record on appeal will be made by volume and page number, as (SR1._____). References to the record in the Fifth District Court of Appeal will be made as (5D.___).

Reference to plaintiff=s Initial Brief will be made as (1B_____). Reference to AFTL=s Amicus Brief will be made as (AB.___)

## STATEMENT OF THE CASE

Plaintiff appealed from a final judgment entered in favor of Defendants after the trial court granted Defendants= motions in limine to determine admissibility of expert testimony. (R8.2548) The orders in limine precluded Plaintiff from introducing evidence or expert testimony of a causal link between Plaintiff=s alleged trauma and fibromyalgia syndrome (FMS).[1] (R4.742-47) Because Plaintiff=s counsel argued that Plaintiff=s symptoms Adon=t make sense apart from the context of the actual condition themselves, which give rise to the symptoms@ (SR13.4558), the trial judge entertained motions for summary judgment by the Defendants (SR13.4560-62) and entered the final summary judgment. (R8.2548-50)

Plaintiff appealed the judgment to the Fifth District Court of Appeal. After relinquishing jurisdiction to the trial court to conduct a further evidentiary hearing, the Fifth District affirmed the exclusion of expert opinion testimony on the issue of causation. (5D.82-108) The court certified conflict with *State Farm Mutual Automobile Insurance Co. v. Johnson*, 880 So. 2d 721 (Fla. 2d DCA 2004). (5D.108) Plaintiff timely filed a petition invoking this Court=s discretionary jurisdiction.

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[1]Plaintiff was also precluded from introducing evidence or expert testimony of a causal link between alleged trauma and myofascial pain syndrome. (R6.1384-88) Plaintiff has apparently abandoned that issue in this Court.

## STATEMENT OF THE FACTS

Plaintiff alleged in her Complaint that she had sustained injuries and damages as a result of four separate motor vehicle accidents. (R1.1-7) Discovery revealed that Plaintiff would offer expert testimony that one or more of the accidents caused Plaintiff to suffer from FMS. (R.563) Prior to trial Avis filed a motion to determine admissibility of expert testimony. (R3.562-67) Avis requested the court to determine whether the underlying concept that FMS could be directly and proximately caused by trauma had gained general acceptance within the field in which it belongs so as to render causation opinions admissible under *Frye v. United States*, 293 Fed. 1013 (D.C. Cir. 1923). (R3.563) The other Defendants joined in this motion. (R4.742)

Defendants= motion noted that in 1994 a committee of FMS experts convened in Vancouver, British Columbia to address issues relating to FMS. (R3.565) As a result of that conference, a special report entitled *The Fibromyalgia Syndrome: A Consensus Report on Fibromyalgia and Disability* was published in The Journal of Rheumatology in 1996. (R3.565) This report (R3.565-66) and others (R3.515-61) all showed that the question of whether trauma could cause FMS was hotly contested within the medical community.

While there was at that time no reported Florida case in which the theory of post-traumatic FMS had been *Frye*-tested, two federal cases held that expert opinion testimony concerning traumatic causation of FMS was inadmissible. (R3.566) In *Black v. Food Lion, Inc.*, 171 F.3d 308 (5th Cir. 1999), the Fifth Circuit held that an expert=s testimony

that a customer=s fall had caused hormonal damage leading to FMS was not sufficiently reliable. (R3.566) In *Allison v. McGhan Medical Corp.*, 184 F.3d 1300 (11th Cir. 1999), the Eleventh Circuit affirmed the exclusion of expert testimony regarding alleged causation of FMS from silicone breast implants. (R3.566) Copies of relevant case law were filed with the court. (R3.448-514)

Although Defendants requested the trial court to *Frye*-test the underlying theory that FMS could be caused by trauma (R3.566), Plaintiff argued that the motion challenged Plaintiff=s experts= conclusions. (R3.576) Plaintiff agreed that *Frye* applied to the underlying principles on which an expert=s opinion is based (R3.575) but asserted her experts= opinions were not subject to *Frye* because they were based on examination of the patient, clinical history, objective findings such as MRI results and palpable muscle spasms, and the symptomatology and diagnosis of FMS. (R3.573) Plaintiff did not argue that this was an Aimpact@ case to which *Frye* did not apply. (R3.568-76)

Plaintiff asserted that the case law relied upon by Avis was distinguishable and that there were generally accepted medical criteria for diagnosing FMS. (R3.620-25) With respect to causation, Plaintiff quoted from a passage in the Consensus Report in which it was stated that Athe cause(s) of FM are incompletely understood.@ (R3.626) Plaintiff cited an Israeli study which concluded there is a 13 times greater risk of developing FMS following a neck injury than following a broken leg, but Plaintiff conceded the Israeli study only followed people for up to one year following trauma. (R3.627) Plaintiff also relied upon testimony of defense expert, John Russell Rice, M.D., arguing that Dr. Rice

admitted he has treated a patient whose FMS was believed to have been caused by trauma. (R3.627)

Judge Sprinkel reviewed a paper to be presented by Plaintiff=s expert Dr. Romano on November 14, 2001. (R4.9, 11) The court found nothing new that Dr. Romano was considering. (R4.773) The paper only presented Dr. Romano=s point of view on other treatises and other studies concerning the causal connection between trauma and FMS. (R4.773)

Defendants argued that the 1996 Consensus Report was the determinant on the causation issue. (R4.809) Nothing had changed since that time. A 1997 study by Buskila stated there was insufficient evidence that trauma could cause FMS. (R4.809-10) In 2000 Dr. Buskila published a paper in *Current Rheumatology Reports* in which he concluded that data were insufficient to establish causal relationships between trauma and FMS and that further research needed to be done. (R4.811-12) Even a 1997 study by Plaintiff=s expert Dr. Romano stated that the scientific understanding of FMS was still very limited. (R4.812)

The Pennsylvania case of *Riccio v. S & T Contractors* had considered almost everything that was before the trial court in the instant case in concluding that the *Frye* standard had not been met. (R4.814-15) Dr. Rice=s materials relied upon by Plaintiff were of no value because they were anecdotal and dealt with only one patient. (R4.816) The bottom line was that the issue of traumatic causation of FMS was highly contentious

within the relevant scientific community of rheumatology and therefore inadmissible under *Frye*. (R4.817)

In its written order, the court recognized that the Florida Supreme Court has adopted the *Frye* test, under which expert testimony is inadmissible unless it is based on a principle or theory which is sufficiently established to have gained general acceptance in the particular field in which it belongs. (R4.743) Under this test, the trial court must determine whether the proponent of the evidence has met the burden of proving Athe general acceptance of both the underlying scientific principle and the testing procedures used to apply that principle to the facts at hand@ before the evidence may be admitted. (R4.743) This Court had defined Ageneral acceptance@ to mean Aacceptance by a clear majority of the members of the relevant scientific community, with consideration by the trial court of both the quality and quantity of those opinions.@ (R4.743) General acceptance under *Frye* must be established by a preponderance of the evidence, considering expert testimony, scientific and legal writings, and judicial opinions. (R4.743-44)

The trial court=s order reviewed the expert testimony, scientific and legal writings, and judicial opinions submitted by the parties. (R4.744-47) In granting Defendants= motion in limine, the court ruled that Plaintiff would not be permitted to introduce evidence or expert testimony of a causal link between her alleged trauma and FMS. (R4.747) Plaintiff moved for rehearing or clarification of the ruling but did not assert that

this was an Aimpact@ case to which Frye did not apply. (R4.736-38) The court denied Plaintiff=s motion for rehearing or clarification. (R4.740)

The court subsequently scheduled a case management conference to discuss whether the parties anticipated any additional *Frye* hearings and other issues, including whether Plaintiff wished to exclude expert testimony that trauma can *not* cause FMS and, if so, whether a *Frye* hearing was required on that issue. (R4.754-55) At the case management conference the Court directed the parties to file memoranda addressing the effect of the *Frye* ruling on Plaintiff=s claim for damages due to FMS. (R5.885) Defendants= joint memorandum asserted that the ruling effectively barred Plaintiff=s claim for damages for FMS and entitled Defendants to partial summary judgment on that claim. (R5.885)

Citing *United States Sugar Corp. v. Henson*, 2002 W.L. 1208720 (Fla. June 6, 2002), and *Poulin v. Fleming*, 782 So. 2d 452 (Fla. 5th DCA 2001), Defendants asserted that the *Frye* ruling was correct. (R5.886) The proposed testimony of Plaintiff=s experts was necessarily founded upon a scientific theory that trauma was a potential cause of FMS, but such testimony was inadmissible unless the underlying theory was Agenerally accepted@ within the relevant scientific community. (R5.886) Medical literature showed there was no such general acceptance. (R5.886) The overwhelming consensus among FMS experts was that the evidence and data are insufficient to establish causality. (R5.886)

Plaintiff asserted she had a number of injuries and conditions in addition to FMS, including herniated disk at C-5, C-6, complex soft tissue injuries, multiple sprain/strains to the spine, depression, post-traumatic headaches, severe multi-regional myofascial pain, and chronic fatigue. (R5.892, 911) Plaintiff acknowledged it was her burden as the proponent of the causation evidence to prove the general acceptance of both the underlying scientific principle and the testing procedures used to apply that principle to the facts of the case at hand. (R5.895) Plaintiff asserted that an experts= Apure opinion@ testimony was not subject to a *Frye* analysis and that, even if *Frye* was applicable, her expert=s Apure opinion@ testimony was fully admissible. (R5.896-900)

Plaintiff argued that her experts= opinions were based on examination of the patient, the clinical history, objective findings, and the symptomatology and diagnosis of FMS established by the American College of Rheumatology. (R5.900) Plaintiff claimed her experts= opinions were admissible because they were based on the experts= knowledge and experience combined with clinical and objective findings. (R5.901) Plaintiff did not argue that this was an Aimpact@ case to which *Frye* did not apply. (R5.891-908)

After receiving these memoranda, the court conducted another hearing on the *Frye* issue. (R5.1147-1212) The court adhered to its ruling that there would be no expert testimony as to a causal connection between trauma and FMS. (R5.1149) Experts could testify as to whether particular complaints were caused by the accidents, but Plaintiff would not be permitted to label her condition as FMS caused by the accidents. (R5.1150) Because Plaintiff could not put on testimony of FMS being caused by the accidents,

Defendants would not be permitted to put on evidence of a diagnosis of FMS which they could then argue was not caused by the accidents. (R5.1162)

Avis subsequently filed a second motion to determine admissibility of expert testimony under *Frye*. (R6.1357-66) This motion was based on Plaintiff=s stated intent to present testimony and evidence that she suffered myofascial pain syndrome (MPS) as a direct and proximate result of one or more of the subject accidents. (R6.1359) Avis argued there were no scientific studies which showed that MPS is a separate and distinct condition from FMS, and that question was unsettled in the relevant scientific community. (R6.1360-66) Additionally, there were no scientifically valid studies establishing the criteria for diagnosing that condition. (R6.1360-66)

The court granted Defendants= motion in limine as to MPS. (R6.1387) The order precluded Plaintiff from introducing evidence or expert testimony of a causal link between Plaintiff=s alleged trauma and MPS. (R6.1387) Plaintiff has not taken issue with that ruling in this Court.

After issuing its written order, the court called the parties together to determine Plaintiff=s position as to whether there were injuries for which she had expert testimony on causation resulting from the accidents. (SR13.4558) Plaintiff=s counsel stated there were no other organic injuries that she could argue. (SR13.4558) Counsel took the position that Plaintiff=s symptoms Adon=t make sense@ apart from the context of the conditions of FMS and MPS. (SR13.4558)

Based on counsel=s comments, Defendants moved ore tenus for final summary judgment. (SR13.4560) The parties stipulated to waive compliance with the procedural requirements of Rule 1.510(c) of the Florida Rules of Civil Procedure. (R8.2548) On this basis the court entered the final summary judgment. (R8.2548-50)

Plaintiff appealed the judgment to the Fifth District Court of Appeal. (5D.1-3) After the answer briefs were submitted, the Second District issued its opinion in *State Farm Mutual Automobile Insurance Co. v. Johnson*, 880 So. 2d 721 (Fla. 2d DCA 2004), which held that expert opinion on causation of FMS was not subject to the *Frye* analysis. Plaintiff relied on this opinion in her reply brief. (5D.Supp. H)

After briefing was concluded, the Fifth District relinquished jurisdiction to the Circuit Court for an additional evidentiary hearing limited to consideration of new scientific evidence on FMS. (5D.46) On remand the trial court reviewed the previous materials which had been submitted on the *Frye* issue (SR2, Vol. 6.3242-3671) and also considered new articles submitted by Plaintiff (SR2, Vol. 4.2994-3117) and Defendants (SR2, Vol. 5.3118-3241). The court conducted evidentiary hearings (SR2, Vol. 1.2846-2060; SR2, Vol. 3, 2961-2978) and also considered written memoranda of the parties (SR2, Vol. 1.2656-2681; 2682-2722). After considering all of these materials, the trial court held there was no new scientific evidence to support a conclusion that it was generally accepted in the relevant scientific community that trauma causes FMS. (SR2, Vol. 3.2979-2989; 5D.51-60)

After the case was returned to the Fifth District, both sides submitted supplemental case law authorities. (5D.62-68, 69-81) The court also heard oral argument. On December 23, 2005, the court issued its lengthy opinion. (5D.82-108)

In conducting its de novo review of Judge Sprinkel=s decisions, the Fifth District conducted an exhaustive review of both the scientific writings and judicial opinions. (5D.82-108) The court also reviewed the expert testimony offered by Plaintiff. (5D.90-91, 105-06) The Fifth District agreed that no scientifically recognized connection between trauma and fibromyalgia exists, affirmed the trial court and certified conflict with *Johnson*. (5D.108)

Plaintiff timely filed a petition invoking this Court=s discretionary jurisdiction.

## SUMMARY OF THE ARGUMENT

The trial court appropriately applied the *Frye* test to expert opinions regarding causation of Plaintiff=s FMS. Plaintiff did not present to the trial court any argument that the *Frye* test was inapplicable because this was an Aimpact@ case and thus did properly preserve that issue for appellate review. If the issue had been preserved, the trial court=s ruling was nevertheless correct because there is no general acceptance in the relevant scientific community of the theory that trauma can cause FMS.

Because there is no general acceptance in the relevant scientific community of the theory that trauma can cause FMS, Apure opinion@ testimony on causation of Plaintiff=s alleged injuries is not admissible in this case. Such opinions assume that trauma can cause FMS, but there is no reliable evidence to establish general causation. General causation is a predicate for any opinion on specific causation.

Both the medical literature and judicial opinions support the trial court=s rulings in the instant case. Plaintiff had the option to proceed with evidence that her alleged symptoms were caused by the accidents. However, she elected not to go forward. It was that election that resulted in entry of the final summary judgment for Defendants. The judgment should be affirmed.

## ARGUMENT

### I. THIS COURT SHOULD DECLINE TO EXERCISE ITS DISCRETIONARY JURISDICTION UNDER FLORIDA

**CONSTITUTION ARTICLE V, ' 3(B)(4) BECAUSE THERE IS NO CONFLICT BETWEEN DECISIONS.**

The Fifth District certified conflict between its decision and the Second District=s decision in *Johnson,* a careful reading of the two opinions reveals there is no actual conflict. As discussed hereinafter, the two cases are factually and procedurally distinguishable. Because there is no actual conflict, this Court should decline to exercise is discretionary jurisdiction to review the instant case.

## II. STANDARD OF REVIEW.

In the arena of determining the admissibility of novel scientific evidence, it is of paramount importance that the court Anot permit cases to be resolved on the basis of evidence for which a predicate of reliability has not been established. Reliability is fundamental to issues involved in the admissibility of evidence.@ *United States Sugar Corp. v. Henson*, 823 So. 2d 104, 106 (Fla. 2002). Focusing on the prerequisite of scientific dependability, this Court has adhered to the use of the admissibility standard articulated in *Frye v. United States*, 54 App. D.C. 46, 293 F. 1013, 1014 (D.C. Cir. 1923):

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable states is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, *the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.*

*See Castillo v. E.I. Du Pont de Nemours & Co.*, 854 So. 2d 1264, 1268 (Fla. 2003), (emphasis supplied.) This test requires that the scientific principles undergirding the evidence be found by the trial court to be generally accepted by the relevant members of its particular field. *Hadden v. State*, 690 So. 2d 573, 576 (Fla. 1997). AGeneral acceptance@ means acceptance by a clear majority of the members of the relevant scientific community, with consideration by the trial court of both the quality and quantity of those opinions. *Id.* n.2. The proponent of the evidence bears the burden of establishing by a preponderance of the evidence the general acceptance of the underlying scientific principles and methodology. *Castillo*, 854 So. 2d at 1268.

If this Court exercises its discretionary jurisdiction, its review of the *Frye* determination is treated as a matter of law. *Brim v. State*, 695 So. 2d 268, 274 (Fla. 1997). An appellate court should consider the issue of general acceptance at the time of appeal rather than the time of trial. *Henson*, 823 So. 2d at 109. An appellate court may examine expert testimony, scientific and legal writings, and judicial opinions in making its determination. *Id.* The Fifth District did just that in the instant case.

This record shows that the lower courts did not err with respect to any of the *Frye* rulings in the instant case. Judge Sprinkel thoroughly and painstakingly reviewed all of the material submitted to him by both sides in an effort to ensure that expert opinions were scientifically reliable. He not only read the materials but also allowed virtually unlimited hearing time for the parties to argue their positions. The Fifth District similarly

undertook a thoughtful review of all the material submitted by the parties. The courts= decisions were supported by expert testimony, scientific literature, and judicial opinions.

## III. THE TRIAL COURT APPROPRIATELY APPLIED THE *FRYE* TEST TO EXCLUDE EXPERT OPINIONS REGARDING CAUSATION OF PLAINTIFF=S FIBROMYALGIA.

Section 90.702, Florida Statutes, provides as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact in understanding the evidence or in determining a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify about it in the form of an opinion; however, the opinion is admissible only if it can be applied to evidence at trial.

This provision of the Florida Evidence Code clearly requires a scientific basis for an expert medical opinion. When the predicate for an expert opinion on causation is new or novel, it is subject to the *Frye* test in Florida.

The theory that trauma can cause FMS is new or novel. Diagnostic criteria for FMS were only adopted in 1990. Neither Plaintiff nor AFTL dispute that the etiology of FMS is presently unknown to medical science.

Plaintiff argues that Ajust because there is a legitimate controversy within the medical community on a question does not prevent an expert from proffering testimony on that question.@ (IB.23) AFTL argues the Fifth District Atook sides@ in a Alegitimate medical controversy.@ (AB.3) Clearly, if there is a Alegitimate controversy@ over a medical issue, it is axiomatic that there is no Ageneral acceptance@ in the scientific community. The very purpose of the *Frye* test is to address those issues about which

there is a Alegitimate controversy@ in the relevant scientific community. In resolving the *Frye* issue B as in all decision making B the Fifth District was not Ataking sides@ but fulfilling its judicial responsibilities.

Plaintiff baldly asserts that when a medical expert bases his or her opinion on Aclinical experiences, case reports and epidemiological research,@ such evidence is Asufficient under Florida Law for an expert to infer a medical causation.@ (IB.23) Plaintiff failed to support this argument with a single citation to any authority. (IB.23) Plaintiff has never satisfied her burden of establishing by a preponderance of the evidence the general acceptance of the underlying scientific theory that trauma causes FMS.

Plaintiff has not favored this Court with any record reference to her experts= opinions. In the Fifth District Plaintiff relied upon testimony of treating physicians Dr. James Madison (5D.A.4-8) and Dr. Caryn Hasselbring (5D.A.8-10). Neither of these physicians had participated in any research on the issue of causation of FMS.

Dr. Madison is an orthopedic surgeon and not a specialist in rheumatology. (SR1. Vol. 4.3060, 3118) He first saw Plaintiff on August 11, 1995. (SR1. Vol. 4.3060) In 1996 the disorder of fibromyalgia was beginning to appear in the literature. (SR1. Vol. 4.3106) Dr. Madison referred Plaintiff to Dr. Hasselbring, a rheumatologist, in late 1997. (SR1. Vol. 4.3114)

After Plaintiff returned from seeing Dr. Hasselbring, Dr. Madison noted a diagnosis of post-traumatic fibromyalgia. (SR1. Vol. 4, 3119) This was not a scientifically-based diagnosis after evaluation but simply a label placed by Dr. Madison. (SR1. Vol. 4.3121)

Dr. Madison was aware that there were differences of opinion among rheumatologists as to the association between trauma and fibromyalgia, but he was not familiar with the Consensus Report from the Vancouver Conference. (SR1. Vol. 4.3122) He agreed that fibromyalgia could occur spontaneously. (SR1. Vol. 4.3147) He provided no medical basis for a conclusion that the fibromyalgia was traumatically induced. (SR1. Vol. 4, 3145-47)

Dr. Hasselbring diagnosed fibromyalgia syndrome. (SR1. Vol. 11.4103) Dr. Hasselbring did not rule out other conditions because no lab tests were done. (SR1. Vol. 11.4104) Although Dr. Hasselbring opined that Plaintiff=s fibromyalgia began as a result of the multiple automobile accidents (SR1. Vol. 11.4110), this opinion was based on anecdotal case reports that patients developed symptoms after various kinds of physical trauma, illness or emotional stress. (SR1. Vol. 11.4121-22)

Dr. Hasselbring agreed there was controversy in the medical community regarding the causation of fibromyalgia by stress. (SR1. Vol. 11.4124) She agreed that the cause of fibromyalgia was unknown. (SR1. Vol. 11.4125) She was not aware of the Consensus Report. (SR1. Vol. 11.4163) She had not even thought about whether Plaintiff=s fibromyalgia was traumatically caused until she was asked about it by Plaintiff=s attorney before her deposition. (SR1. Vol. 11.4173)

Plaintiff argues the *Frye* test is inapplicable to the causation issue because the testimony of her experts on that issue was Apure opinion.@ The Fifth District found it was Acounterintuitive to permit an expert to ignore scientific literature accepted by the general

scientific community in favor of the expert=s personal experience to reach a conclusion not generally recognized in the scientific community and then allow testimony about that conclusion on the basis that it is >pure opinion.=@ (5D.105) Citing *Castillo*, 854 So. 2d at 1270, and *Henson*, 823 So. 2d at 104, for the proposition that epidemiological studies are not always required to show general acceptance in the scientific community, the Fifth District noted that in this case the experts had agreed that such studies were necessary before a connection could be recognized. (5D.105) Therefore, the trial court correctly decided this issue. (5D.105)

Plaintiff erroneously contends that in *Castillo* this Court held the trial court properly admitted an expert=s Apure opinion testimony@ under a *Frye* analysis. (IB.24-25) *Castillo* was not a Apure opinion@ case. In *Castillo* the defendants asserted that the plaintiffs= expert=s methodology for determining whether and at what level Benlate could cause birth defects in humans was not generally accepted in the scientific community. *Id.* at 1267. This Court framed the issue as being whether the scientific principles upon which the Castillos= experts based their opinions were generally accepted in the scientific community. *Id.* at 1269.

This Court concluded that the methodologies used by the Castillos= experts were generally accepted. Citing *Berry v. CSX Transportation, Inc.*, 709 So. 2d 552, 562 n.9 (Fla. 1st DCA 1998), this Court determined that differential diagnosis is a generally

accepted methodology for addressing *specific* medical causation.[2] *Id.* at 1271. The Castillos= experts= opinions were admissible under *Frye*, not because they involved Apure opinion@ but because the opinions were Abased on relevant scientific methods, processes, and data, and not upon an expert=s mere speculation.@ *Id.*

Apparently concluding that the plaintiff=s doctors offered Apure opinion@ testimony that was not subject to *Frye*, the Second District Court of Appeal in *State Farm Mutual Automobile Insurance Co. v. Johnson*, 880 So. 2d 721 (Fla. 2d DCA 2004), rejected a *Frye* challenge to the admissibility of expert opinion testimony that the plaintiff=s fibromyalgia syndrome was caused by auto accident trauma. The *Johnson* court noted that State Farm did not challenge the principles and methodologies relied upon by

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[2]The *Berry* court recognized the distinction between general and specific causation:

> Epidemiology focuses on the question of general causation, that is, whether a substance is *capable* of causing a particular disease, rather than specific causation, that is, whether the substance *did* cause the disease in a specific individual.

709 So. 2d at 554 (emphasis supplied).

Johnson=s experts. *Id.* at 723. Instead, State Farm challenged the opinions reached by the experts. *Id.*

As this Court emphasized in *Henson*, a *Frye* inquiry Amust focus only on the general acceptance of the *scientific principles and methodologies* upon which the expert relies in rendering his or her opinion. . . . The opinion of the testifying expert need not be generally accepted as well.@ 823 So. 2d at 110. Because the issue in *Johnson* was whether the experts= *opinions* met the *Frye* standard and not whether the *underlying scientific principle* that trauma causes FMS was generally accepted in the relevant scientific community, the reasoning in *Johnson* is not applicable to the instant case.

As Plaintiff notes in her Initial Brief, the Second District in *Johnson* interpreted this Court=s decision in *Henson* as holding that the *Frye* standard only applies when an expert opinion is based upon new or novel scientific *techniques*. (IB.26) That construction of *Henson* was incorrect. This Court stated in *Henson* that the *Frye* standard requires that Athe thing from which the [expert=s] deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.@ 823 So. 2d at 106, citing *Frye*, 293 F. at 1014. The purpose of the *Frye* test is to ensure reliability of decisions and results by focusing on the prerequisite of scientific dependability. 823 So. 2d at 106, 107. To achieve that purpose, this Court concluded in *Henson* that

> [U]nder *Frye* and its Florida progeny, when the expert=s opinion is based upon *generally accepted scientific principles and methodology*, it is not necessary that the expert=s deductions based thereon and opinion also be generally accepted as well.

*Id.* at 109-10 (emphasis supplied).

Defendants in the instant case have always directed their *Frye* challenge to whether the underlying ***scientific principle*** that trauma may cause FMS is generally accepted in the relevant scientific community. Plaintiff concedes in her Initial Brief that Aunder *Frye*, it is not the expert=s opinion that must be generally accepted, it is the underlying principle B >the thing from which the deduction is made.=@ (IB.27) By Plaintiff=s own admission, the lack of general acceptance in the scientific community of the theory that trauma can cause FMS renders inadmissible Plaintiff=s expert testimony seeking to show that her FMS was caused by accident trauma.

To the extent that *Johnson* may be read as holding that a mere showing of an Aassociation between trauma and FMS@ satisfies *Frye* so as to permit testimony of a ***causal relationship*** between trauma and FMS, such reasoning is contrary to Florida law. A mere association is not the same as scientific causation.

The First District discussed the distinction between Aassociation@ and Acausation@ in *Berry v. CSX Transportation, Inc.*, 709 So. 2d 552, 558 (Fla. 1st DCA 1998):

> AAssociation is not causation.@ . . . Association is a term used to describe the relationship between exposure to a chemical agent and disease that occurs more frequently together than one would expect by chance. . . . Establishing an association does not necessarily mean that there is a causal effect between the exposure and the disease. . . . Causation, by comparison, constitutes an association between two events in which one event is a *necessary link* in a chain of events that results in the effect.

(Emphasis supplied, citations omitted.)

The First District noted that, if an epidemiological study finds an association between a particular exposure and a disease, scientists can analyze the study to consider whether the reported association reflects a cause-and-effect relationship or is a spurious finding. 709 So. 2d at 558. In so doing, researchers look for alternative explanations for the association such as bias or confounding factors. *Id.* Information bias may occur where an interviewer whose Aawareness of the identity of cases and controls . . . may influence the structure of the questions and the interviewer=s manner, which in turn may influence the response. *Id.*

Even when there is a statistical association and no bias, the association may be the result of a confounding factor. *Id.* For example, a study finding that individuals with grey hair have a higher rate of death than those with another hair color does not establish that there is a causal association between grey hair and death but might be explained by the confounding factor of advanced age. *Id.* Additionally, a temporal association alone is not sufficient to establish causation. *Id.* at 559 n.6.

The plaintiff in *Berry* claimed that long term exposure to excessive levels of organic solvents caused toxic encephalopathy. *Id.* at 554. The First District recognized that both general and specific causation must be established for evidence of causation to be admissible. The court concluded that the epidemiological science and methodology on

general causation[3] was established, reliable, and well-founded. *Id.* at 568. For that reason the court disagreed with the trial court=s rejection of the plaintiff=s expert=s testimony on specific causation[4]. *Id.* at 571. The expert used differential diagnosis to eliminate possible causes of the plaintiff=s symptoms other than exposure to the chemicals at issue. *Id.*

Consistent with the reasoning in *Berry*, the medical literature on FMS expressly recognizes that a mere finding of an association between trauma and FMS is insufficient to show a causal relationship. For example, although the 1997 Buskila study found an increased incidence of FMS in Israeli patients who suffered injuries to the neck and lower extremities, the study concluded that "**[**t]he present data in the literature are insufficient to indicate whether causal relationships exist between trauma and [FMS]." In the 2002 study by A. W. Al-Allaf, et al., the authors acknowledged that their study ***did not*** provide a basis for finding that reliable evidence exists linking trauma to FMS. Rather, they pointed out that A[f]urther *prospective* studies are needed to confirm this association and to determine whether trauma has a causal role...in the development of [FMS].@

As the court observed in *Riccio v. S & T Contractors*, 2001 W. L. 1334202 (Pa. Com. Pl. June 22, 2001), an inference of causation based on a mere association is Aan

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[3]See n.3, *supra*.

[4]See n.3, *supra*.

example of the classical logical fallacy of concluding causation from chronology alone known generally as *non causa pro causa* and more particularly as *post hoc ergo propter hoc*.@ The *Riccio* court agreed with the observation in *Black v. Food Lion, Inc.*, 171 F. 3d 308, 312 (5th Cir. 1999), that this fallacy Ais as unacceptable in science as in law.@ *Riccio*, at *8.

Plaintiff acknowledges at multiple points in her Brief that under *Frye* it is the underlying principle B Athe thing from which the deduction is made@ B that must be generally accepted. (IB.27, 28) This was precisely the basis of the Fifth District=s opinion. The Fifth District concluded that an expert=s opinion that the plaintiff=s FMS was caused by trauma Arequires . . . an underlying scientific assumption B that trauma can cause FMS B which is not involved in pure opinion cases.@ (5D.104) Consistent with this Court=s prior decisions, the Fifth District determined that Athe underlying scientific principle (sometimes referred to as the issue of >general causation=) would appear to be subject to the tests established in *Frye* and/or *Daubert*.@ (5D.104-05)

The concepts of general and specific causation were discussed in *In Re Breast Implant Litigation*, 11 F. Supp. 2d 1217 (D. Colo. 1998):[5]

> General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual=s injury.

[5]This discussion is particularly pertinent to AFTL=s argument at AB.4-7.

> In order to establish their claims, Plaintiffs Amust show both general and specific causation B that is, that breast implants are capable of causing@ the conditions complained of, and that Abreast implants were the cause-in-fact@ of the specific conditions.

*Id.* at 1224. Applying these principles in *Breast Implant Litigation*, the court determined that the plaintiffs= causation evidence was not scientifically reliable. No plaintiffs= expert witness report stated an opinion on general causation, and the physician witnesses offered only specific causation opinions. *Id.* at 1228. The reports submitted by the plaintiffs= experts failed to present a single peer-reviewed, controlled epidemiologic study that supported their causation theories. *Id.* The substantial body of epidemiological evidence did not demonstrate that silicone breast implants more likely than not caused any known disease. *Id.*

The court rejected the plaintiffs= argument that their treating physicians should be able to offer causation opinions based on the process of differential diagnosis. *Id.* at 1229. Such testimony was not scientifically reliable because it confused the two distinct burdens of establishing both general and specific causation. *Id.*

> [D]ifferential diagnosis is a patient-specific process of elimination that medical practitioners use to identify the Amost likely@ cause of a set of signs and symptoms from a list of possible causes. However, differential diagnosis does not by itself prove the cause, even for the particular patient. Nor can the technique speak to the issue of general causation. Indeed, differential diagnosis assumes that general causation has been proven for the list of possible causes it eliminates.
>
> The process of differential diagnosis is undoubtedly important to the question of Aspecific causation.@ If other possible

> causes of an injury cannot be ruled out, or at least the probability of their contribution to causation minimized, then the Amore likely than not@ threshold for proving causation may not be met. But, it is also important to recognize that a fundamental assumption underlying this method is that the final, suspected Acause@ remaining after this process of elimination must actually be capable of causing the injury. That is, the expert must Arule in@ the suspected cause as well as Arule out@ other possible causes. And, of course, *expert opinion on this issue of Ageneral causation@ must be derived from a scientifically valid methodology*.

*Id.* at 1229-30 (emphasis supplied). The court concluded that differential diagnosis may be utilized by a clinician to determine what recognized disease or symptom the patient has, but it is incapable of determining whether exposure to a substance caused disease in the legal sense. *Id.* at 1230.

The court rejected the plaintiffs= reliance on their experts= individual clinical experience as proof of general causation. *Id.* Characterizing such experience as the equivalent of a series of case reports or observations about a particular patient, the court noted that such reports Auniversally are regarded as an insufficient scientific basis for a conclusion regarding causation because case reports lack controls.@ *Id.*

> Such case reports are not reliable scientific evidence of causation, because they simply describe reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation. Even if some credibility were given to the study, it does not have the degree of clarity required for a validation of its results or its methodology which is sufficient for objective and independent peer review.

*Id.* at 1231. While case reports can be used to generate hypotheses about causation, scientifically valid cause and effect determinations depend on controlled clinical trials and epidemiological studies. *Id.* at 1230.

The plaintiffs in *Breast Implant Litigation* relied on various studies and articles. *Id.* at 1231. The court concluded these materials as a whole did not reasonably support the causation conclusions of plaintiffs= experts. *Id.* Many of the articles were inconclusive, merely recommending that further studies be done. *Id.* Others indicated there was no increased risk associated with silicone breast implants and a particular condition. *Id.* at 1231-32 (citing specific studies and results).

Finally, the court rejected the argument that causation may be inferred based upon the temporal sequence of implantation and the onset of illness. *Id.* at 1232. The court noted that a temporal relationship by itself provides no evidence of causation because it is not derived from the scientific method. *Id.* At best evidence of temporality addressed the issue of specific causation and thus was inadmissible where there was no admissible evidence of general causation. *Id.*

The foregoing analysis is equally applicable to the instant case. Because it is not generally accepted that trauma is a potential cause of FMS, any reliance upon Adifferential diagnosis@ or Apure opinion@ is invalid. This Court has repeatedly reaffirmed that both the Aunderlying scientific principles@ *and* the Amethodology@ used by the expert in forming his or her opinions must be Agenerally accepted in the relevant scientific community@ to satisfy *Frye*. *E.g.*, *Castillo,* 854 So. 2d at 1268; *Henson,* 823 So. 2d at 106.

In *Henson* the underlying principle that Aorganophosphates are neurotoxic@ was generally accepted in the scientific community. 823 So. 2d at 109. In *Castillo* it was generally accepted that benomyl is a teratogen in rats and that a compound causing an effect in one mammalian species will cause it in another species. 854 So. 2d at 1270, 1273. Thus, general causation was established in both cases, and the issue in both cases was whether experts= methodology for establishing specific causation was generally accepted. This Court explicitly found in both cases that the testimony in question was founded upon generally accepted underlying causal principles. Because the underlying causal theories and methodologies were generally accepted, the experts= use of differential diagnosis to deduct the specific cause of the plaintiffs= injuries was acceptable methodology.

In the instant case there is no reliable evidence of Ageneral causation@ derived from scientifically valid methodology. The opinions of Plaintiff=s experts based on differential diagnosis do not relate to general causation. The literature does not reasonably support the general causation theories underlying the opinions of Plaintiffs= experts.

The cases upon which Plaintiff relies do not undermine the requirement for scientifically reliable proof of general causation before an expert may offer an opinion regarding specific causation. In *Rickgauer v. Sarkar*, 804 So. 2d 502, 503 (Fla. 5th DCA 2001), the Fifth District affirmed the trial court=s exclusion of an expert=s opinion that the court characterized as Apure opinion@ not subject to the *Frye* test. However, the court noted that the purpose of the *Frye* test is to guarantee the reliability of new or novel

scientific evidence through its general acceptance by the relevant scientific community. *Id.* Nothing in *Rickgauer* suggested that the *Frye* test would not apply under circumstances as in the instant case where there is no general acceptance in the relevant scientific community of the general causation theory upon which an expert=s opinion is based. Such an opinion would lack scientific reliability and could not assist the trier of fact in understanding the evidence or in determining any fact in issue. *See* ' 90.702, Fla. Stat.

In *Holy Cross Hospital, Inc. v. Marrone*, 816 So. 2d 1113, 1117 (Fla. 4th DCA 2001), the court noted that the mere contention that an expert=s testimony was Apure opinion@ is not sufficient to characterize it as such. The court must examine the expert=s entire testimony in order to determine whether it actually is Apure opinion.@ *Id.* Upon reviewing the record in *Marrone*, the court concluded the expert=s opinion was at least in part derived from conclusions drawn from staging studies done by others. *Id.* To the extent the expert attempted to use staging studies in a new and novel manner, his testimony was not Apure opinion@ and his methodology needed to be *Frye*-tested. *Id.* at 1119.

This Court undertook a similar analysis in *Hadden v. State*, 690 So. 2d 573 (Fla. 1997). This Court held that upon proper objection prior to introduction of a psychologist=s expert testimony offered to prove the alleged victim of sexual abuse exhibits symptoms consistent with one who has been sexually abused, the trial court must determine whether the testimony is admissible under *Frye*. *Id.* at 575. In such testimony

the expert testifies on the basis of studies that children who have been sexually abused develop certain symptoms. *Id.* The expert then links the type of syndrome symptoms to the child victim in the case. *Id.*

The district court had determined that the testimony in *Hadden* was couched in terms of the expert=s training and experience and was thus opinion testimony not covered by *Frye*. *Id.* at 576. This Court concluded that the syndrome testimony went beyond pure opinion and needed to be examined in light of the record, scientific literature and judicial decisions. *Id.* at 576-77. Because such evidence had not to date been found to be generally accepted in the relevant scientific community, expert testimony offered to prove the alleged victim of sexual abuse exhibits symptoms consistent with one who has been sexually abused should not be admitted. *Id. at 577.*

The Court noted that the underlying theory for the *Frye* rule is that a courtroom is not a laboratory, and as such is not the place to conduct scientific experiments. *Id.* If the scientific community considers a procedure or process unreliable for its own purposes, then the procedure must be considered less reliable for courtroom use. *Id.* at 577-78. This Court held firmly to the principle that it is the function of the court to not permit cases to be resolved on the basis of evidence for which a predicate of reliability has not been established. *Id.* at 578.

> Novel scientific evidence must 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.

*Id.* (emphasis supplied). The *Hadden* Court concluded that while the debate continued among experts regarding whether the syndrome was an adequate therapeutic tool for determining the presence of abuse, there was no consensus among experts that it is useful as substantive evidence of guilt. *Id.* at 579.

Examining Plaintiff=s experts= entire testimony in the instant case reveals that they did not render Apure opinions.@ Opinions that Plaintiff=s FMS was caused by trauma necessarily assumed that trauma *could* cause FMS. Because the literature shows there is no consensus among experts that trauma can cause FMS, the predicate of reliability cannot be established and the opinions are not admissible under *Frye/Hadden*.

Plaintiff acknowledges that under *Frye* it is not the expert=s opinion that must be generally accepted but the underlying principle **B** Athe thing from which the deduction is made.@ (IB.27) This concession defeats her argument that her experts= opinions are admissible. There is no general acceptance in the relevant scientific community of the theory that trauma can cause FMS. Because there is no generally accepted scientific foundation for expert opinions that Plaintiff=s FMS was caused by trauma, those opinions are not admissible.

Remarkably, Plaintiff contends that Defendants Ado not challenge the Plaintiff=s experts= basis for their opinions.@ (IB.28) Nothing could be further from the truth. Defendants have *always* challenged the basis for Plaintiff=s experts= opinions. Defendants=

*Frye* motion requested the court to determine whether the underlying concept that FMS could be caused by trauma was sufficiently established to have gained general acceptance with the field in which it belongs so as to be admissible under *Frye*. (R.563)

Plaintiff argues that Defendants Acan[not] . . . seriously contest the fact that the insult from trauma or injury can lead to FM because their own expert admitted that trauma can >indirectly cause FMS.=@ (IB.29) Plaintiff then cited to excerpts from the deposition of Dr. John Rice. At SR6.3413-14 (Depo. pp.129-30) Dr. Rice testified that he Athinks@ trauma can cause a permanent injury that causes pain and either emotional or physical dysfunction to the point that disturbs sleep that can then indirectly result in symptoms of increasing fatigue, sleep disturbance and pain that could be called FMS. At SR6.3417-18 (Depo. pp.133-34) Dr. Rice testified there had been situations in which he thought an injury led to symptoms of FMS. At SR6.3445-46 (Depo. pp.161-62) he testified that in 1987 he published a chapter in a book entitled *The Complicated Medical Patient* in which he wrote that traumatic injury was a Apossibility@ of something that could cause secondary FMS. (SR6.3446)

This testimony of Dr. Rice is not relevant to the *Frye* issue. His statements are hypotheses or theories raising the possibility of causation. Dr. Rice does not contend that these theories are generally accepted in the relevant scientific community.

It has *never* been Defendants= position, as contended by Plaintiff at page 29 of her Initial Brief, that the *Frye* test applies to her experts= opinions. It has *always* been Defendants= position that the opinions are inadmissible because the underlying concept

that FMS could be directly and proximately caused by trauma has not been sufficiently established to have gained general acceptance within the relevant scientific community. That was the trial court=s well-reasoned conclusion, affirmed by the Fifth District. That conclusion should be affirmed by this Court.

## IV. THE FIFTH DISTRICT DID NOT APPLY A *DAUBERT* ANALYSIS IN THE INSTANT CASE BUT APPROPRIATELY CONSIDERED *DAUBERT* CASES IN RESOLVING THE ISSUE AT HAND.

Plaintiff and AFTL assert that the Fifth District was mistaken in noting that the admissibility test employed by federal courts is more liberal than the *Frye* test. Plaintiff=s argument ignores that the Supreme Court itself characterized the analysis it adopted in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), as a Aflexible@ one. 509 U.S. at 594. The Court variously described the *Frye* test as Arigid,@ *id.* at 588; Aaustere,@ *id.* at 589; and Auncompromising,@ *id.* at 596. Furthermore, the *Daubert* Court made it clear that the focus of the evidentiary inquiry for admissibility of expert opinions Amust be solely on principles and methodology, *not* on the conclusions that they generate.@ *Id.* at 595 (emphasis supplied).

> Its overarching subject is the scientific validity B and thus the evidentiary relevance and reliability B of the principles that underlie a proposed submission.

*Id.* at 594-95.

The *Daubert* Court set forth a two-pronged analysis for federal courts to employ when determining admissibility of expert testimony. *Id.* at 592. Trial judges must 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. *Id.* As to the first

prong, the issue is whether the reasoning or methodology underlying the testimony is scientifically valid. *Id.* at 592-93.

Although this Court in *Castillo* characterized the first prong of this analysis as the *Frye* test, 854 So. 2d at 1276, the *Daubert* opinion makes it clear that Awidespread acceptance can be an important factor,@ but it is not required in making a reliability assessment of scientific evidence. *Id.* at 594. Other factors include whether the theory or technique can be and has been tested and whether the theory or technique has been subjected to peer review and publication. *Id.* at 593. In the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error and the existence and maintenance of standards controlling the technique=s operation. *Id.* at 594.

Nothing in *Daubert* suggests that an expert=s opinion, as opposed to the principles and methodology on which it is based, is subject to admissibility analysis. To the contrary, the Court explicitly stated that the focus must be Asolely on principles and methodology, not on the conclusions that they generate.@ The plain language of the opinion refutes Plaintiff=s assertion that the *Daubert* standard is more rigorous than the *Frye* test.

Most of the cases[6] relied upon by the Fifth District as Aconvincing and the weight of authority compelling,@ were decided under a more liberal standard than the *Frye* test which is applicable in Florida. The courts employing a *Daubert* analysis were free to determine that expert opinions on causation of FMS were admissible, whether or not it is

[6]Specifically, the cases cited on page 33 of Plaintiff=s Initial Brief.

generally accepted in the scientific community that trauma can cause FMS. Using that analysis, the overwhelming majority of courts considering the issue have determined that the scientific validity of the underlying causation principle had not been sufficiently established for purposes of evidentiary reliability.

In *Black v. Food Lion, Inc.*, 171 F.3d 308 (5th Cir. 1999), the Fifth Circuit concluded that a single physician=s opinion that the plaintiff=s fall led to FMS was inadmissible. 171 F.3d at 313. The theory had not been verified by testing and thus had not been peer-reviewed. *Id.* Citing the Consensus Report, the court noted that, if medical science did not know the cause of FMS, then one doctor=s Atheory@ of causation was isolated and unsubstantiated. *Id.* It also followed from the scientific literature that the doctor=s theory had failed to gain acceptance within the medical profession. *Id.* Experts in the field concluded that the ultimate cause of FMS could not be known, and mere conjecture did not satisfy the standard for general acceptance. *Id.* Because the doctor=s testimony was unsupported by a specific methodology that could be relied upon and was contradicted by the general level of current medical knowledge, the trial court abused its discretion by admitting that testimony. *Id.*

The Fifth Circuit revisited the issue in *Vargas v. Lee*, 317 F.3d 498 (5th Cir. 2003). The question in that case was whether scientific understanding of FMS had progressed sufficiently since *Black* to permit admission of expert testimony on causation. *Id.* at 501. The court ruled that additional studies which had not been produced in *Black* only bolstered the conclusion that expert testimony on the causation issue was not sufficiently reliable to be admitted into evidence. *Id.* at 502.

In *Riccio v. S & T Contractors*, 56 Pa. D. & C. 4th 86, 2001 Pa. D. & C. LEXIS 207 (C.P. 2001), the court applied a *Frye* analysis in determining that evidence of a causal relationship between trauma and the plaintiff=s FMS was inadmissible. *Id.* at 89. The court analyzed much of the literature submitted by the parties and AFTL in the instant case. The court noted the following from the 1996 Consensus Report:

> While the association between work disability or compensation and FM is well established, data regarding causality are largely absent. . . .
>
> Overall, then, data from the literature are insufficient to indicate whether causal relationships exist between trauma and FM. The absence of evidence, however, does not mean that causality does not exist, rather that appropriate studies have not been performed.

58 Pa. D. & C. 4th at 96, citing Consensus Report at 534-35 (A.1-2). The Aconsensus statement@ was that the cause(s) of FMS are incompletely understood. 58 Pa. D. & C. 4th at 97, citing Consensus Report at 536 (A.3).

A 2000 report prepared by the Consensus Report=s lead researcher, Dr. Frederick Wolfe, noted that physicians have only an incomplete understanding of the mechanisms by which FMS develops. Dr. Wolfe observed that epidemiological studies that might be able to unravel causal issues in FMS that follows upon trauma or other events had not been performed. 58 Pa. D. & C. 4th at 98.

The article entitled *FMS Consensus Report: Additional Comments* proposed an alternative model of causality which considered consistency of association, dose-response relationship, and biologic plausibility. *Id.* at 101-02. However, the authors of *Additional Comments* did not assert either that the alternative causal model was generally accepted in

the relevant scientific community or that this community, when utilizing the alternative model, had arrived at a consensus as to the causal role played by trauma in the onset or course of FMS. *Id.* at 102. Therefore, the *Additional Comments* did not support admissibility of causation evidence.

The 1997 "Israeli study" by Buskila concluded that FMS was 13 times more frequent following neck injury than following lower extremity injury. *Id.* However, the authors opined that, "despite extensive research, the etiology and pathophysiology of FMS were still unclear . . . . Evidence that trauma can cause FMS comes from a few case series or case reports and is insufficient to establish causal relationships." 58 Pa. D. & C. 4th at 97.

An article entitled *Chronic Pain Solutions* authored by Mark J. Pellegrino, M.D. (one of Plaintiff's experts in the instant case) described his review of records of FMS patients and cataloged them according to the patients' report of onset of symptoms. *Id.* at 107. Because a catalog of patient self-reports was not an epidemiological study, the court determined the article was insufficient to demonstrate anything more than temporal coincidence. *Id.* at 107-08.

After discussing other materials, the *Riccio* court concluded that none of the authorities had the effect of establishing a consensus in the relevant scientific community as to the cause of FMS or the particular causal role of trauma in the onset or development of FMS. *Id.* at 111. Furthermore, courts in other jurisdictions had concluded there was no reliable evidence to support the admissibility of evidence of a causal connection between trauma and FMS. *Id.* at 111-12. Finally, the court noted the fundamental distinction between a physician's ability to render a medical diagnosis based

on clinical experience and the ability to render an opinion on causation of a plaintiff=s injuries. *Id.* at 115-16. The ability to diagnose medical conditions was not remotely the same as the ability to deduce, delineate, and describe in a scientifically reliable manner the causes of those medical conditions. *Id.* at 116.

The trial court in the instant case also relied on *Jones v. Conrad*, 2001 Ohio App. LEXIS 3897 (Ct. App. 2001). In that case the trial court noted that an expert witness= knowledge could not be based on subjective belief or unsupported speculation. *Id.* at *11. Instead, Athe knowledge must apply to a >body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds.=@ *Id.* Although the physician in *Jones* was qualified to testify as an expert and to discuss the diagnosis of FMS, there was no reliable scientific or other basis for his opinion on causation in light of the Consensus Report. *Id.* at *8, *13.

Other cases have held inadmissible experts= opinions relating FMS to trauma. *E.g.*, *Gross v. King David Bistro, Inc.*, 83 F. Supp. 2d 597 (D. Md. 2000) (holding that a temporal connection, differential diagnosis, and an expert=s medical experience and training were not sufficient bases to admit opinions on causation of FMS where medical studies showed that the pathogenesis of FMS remains in doubt); *Hultberg v. WalMart Stores, Inc.*, 1999 U.S. Dist. LEXIS 6057 (E.D. La. 1999) (following *Black* where there was no evidence indicating that studies had subsequently been conducted to support causality of FMS by trauma); *Schofield v. Laboscam, Inc.*, 2002 Me. Super. LEXIS 123 (2002) (adhering to the conclusion that evidence regarding traumatic causation of FMS was unreliable and must be excluded).

The Fifth District correctly noted at the time of its decision that *Johnson* was the only reported decision in the United States allowing evidence linking FMS to trauma under *Frye*. Plaintiff asserts there are Aa number of cases in other jurisdictions where a *Frye* test was applied to examine the admissibility of post-traumatic FMS testimony.@ She failed to cite a single case which has held such causation evidence admissible under *Frye*.[7] (IB.34 n.11)

The case of *Grant v. Boccia*, 132 Wn. App. 1016, 2006 Wash. App. LEXIS 894, 2006 WL 775162 (Wash. App. Div. 3),[8] was decided after the Fifth District issued its opinion in *Marsh*. The *Grant court* actually relied on *Marsh* in concluding that expert testimony causally linking trauma and FMS was inadmissible under *Frye*. In conducting its de novo review, the *Grant* court rejected the same arguments put forth by Plaintiff in the instant case. The court noted that its conclusion was consistent with decisions by many other courts that had excluded such evidence both under *Frye* and Athe less

[7]Plaintiff first cited *McCabe v. Big Lots Stores, Inc*., 2003 WL 23979225 (E.D. Wash.). This document is not a court decision but a plaintiff=s response to a motion in limine. The case of *Byrum v. Superior Court of Los Angeles County*, 2002 Cal. App. Unpub. LEXIS 3809 (Cal. Ct. App. 2d Dist. 2002), also cited by Plaintiff, has not been certified for publication or ordered published for purposes of Rule 977, California Rules of Court. Rule 977(a) prohibits courts and parties from citing or relying on opinions not certified for publication or ordered published. Because the case may not be relied upon in the very state in which it was decided, it should not be considered by this Court. Furthermore, the rule in California is apparently that expert medical opinion is *never* subject to a *Frye* analysis. 2002 Cal. App. Unpub. LEXIS 3809 at *5. That is not the rule in Florida.

[8]The Washington court granted a motion to publish the opinion on June 6, 2006.

stringent test enunciated in *Daubert*.@ *Id.* As support the *Grant* court cited *Marsh* as well as *Riccio, Black,* and *Vargas. Id*. at *12-14.

The *Grant* court also cited *Wynacht v. Beckman Instruments, Inc.*, 113 F. Supp. 2d 1205 (E.D.Tenn. 2000), and *Maras v. Avis Rent A Car System, Inc.*, 393 F. Supp. 2d 801 (D. Minn. 2005). In *Wynacht* the court noted a fundamental distinction between a treating physician=s ability to render a medical diagnosis based on clinical experience and the ability to render an opinion on causation of the plaintiff=s injuries: the ability to diagnose medical conditions Ais not remotely the same, however, as the ability to deduce, delineate, and describe, in a scientifically reliable manner, the causes of those medical conditions.@ 2006 Wash. App. LEXIS 547 *15.

The *Maras* court followed *Black* and *Vargas* in excluding evidence that trauma caused or aggravated the plaintiff=s FMS. The court noted that the Al-Allaf study (SR2.3223-26) relied upon by AFTL acknowledged that Athe aetiology [or cause] of primary [FMS] remains unclear@ and that Athe role of physical trauma in precipitating FMS is uncertain. . . .@ *Id.* at 807. The study also concluded that further studies were needed to determine whether trauma has a causal role or if there are more important factors in the development of FMS. *Id.* at 807-08. The study conceded that its Aresults are, of course, retrospective and may be influenced by recall bias.@ *Id.* at 808. The *Maras* court also considered other studies which concluded that it remains an open question as to whether trauma causes FMS and that further studies are needed.[9] *Id.* at 808.

[9]One of these studies, AFMS Following Trauma: Psychology or Biology?@ is included in the record at SR2.3236-41.

The *Maras* court found unpersuasive the case of *Reichert v. Phipps*, 84 P.3d 353, 364 (Wyo. 2004). In that case decided under *Daubert*, the court held that expert testimony on causation should have been submitted to the jury. Noting that Asome medical experts believe that physical trauma can cause FM,@ the court implicitly rejected the *Frye* requirement that the underlying scientific principle must be generally accepted in the relevant scientific community in order for expert opinion to be admissible. *Reichert* is clearly a minority opinion among courts following the *Daubert* standard and is not applicable to the *Frye* issue in the instant case.

Although Plaintiff acknowledges that *Frye* requires the basis of an expert=s opinions to be generally accepted as a predicate to admissibility, she argues that the Fifth District erred in excluding her expert=s opinions because they were based on an underlying scientific assumption **B** that trauma can cause FMS. (IB.34-36) Plaintiff contends that this analysis by the Fifth District was essentially a rejection of the opinions themselves. (IB.34-36) To the contrary, the Fifth District=s analysis was nothing more than a recognition of the principle enunciated by this Court almost 50 years ago in *Arkin Construction Co. v. Simpkins*, 99 So. 2d 557 (Fla. 1957):

> It is elementary that the conclusion or opinion of an expert witness based on facts or inferences not supported by the evidence in a cause has no evidential value. It is equally well settled that *the basis for a conclusion cannot be deduced or inferred from the conclusion itself.* The opinion of the expert cannot constitute proof of the existence of the facts necessary to the support of the opinion.

*Id.* at 561 (emphasis supplied).

The Fifth District essentially followed the rationale of *Arkin* in its *Marsh* opinion. (5D.105) The court concluded that an expert=s Apure opinion@ could not establish the basis for the opinion. Noting that the relevant authorities have to date held that anecdotal evidence or clinical experience is insufficient to establish a (general) causal connection between trauma and FMS without further testing, the Fifth District concluded that the experts have agreed that the studies are necessary before a connection can be recognized. (5D.105)

Clearly, an opinion that a particular person=s FMS was caused by trauma must be founded upon an underlying assumption that trauma can cause FMS. When that underlying assumption **B** the scientific principle **B** has not been generally accepted in the relevant scientific community, the opinion has no evidential value. Such an opinion lacks the predicate of reliability which this Court has consistently required as fundamental to issues involved in the admissibility of evidence. *See, e.g., Henson*, 823 So. 2d at 106.

## V. PLAINTIFF WAIVED HER ARGUMENT THAT THIS IS AN AIMPACT@ CASE BY FAILING TO RAISE THE ISSUE PRIOR TO APPEAL. IF THE ISSUE WAS NOT WAIVED, IT IS NOT APPLICABLE TO THE INSTANT CASE.

Plaintiff=s argument that the *Frye* test is not applicable because this is an Aimpact@ case was *never made to the trial court*. Because Plaintiff did not assert this ground for admissibility in the trial court, the issue was not properly preserved for appellate review. *See Rezzarday v. West Florida Hospital*, 462 So. 2d 470 (Fla. 1st DA 1984). If the issue had been preserved, it does not warrant reversal of the judgment in the instant case.

Plaintiff relies on *Florida Power & Light Co. v. Tursi*, 729 So. 2d 995 (Fla. 4th DCA 1999), for the proposition that this is an Aimpact@ case to which the *Frye* standard

does not apply. However, *Tursi* involved an admittedly Aharmful toxin@ (PCB=s) which impacted the plaintiff=s right eye. *Id.* at 996. Four years later he developed a cataract in his right eye. *Id.*

The *Tursi* court held that pure opinion testimony was admissible to establish that the PCB=s caused the cataract. *Id.* Tthe causation issue was not whether PCB=s can cause cataracts but whether this type of trauma could have ultimately resulted in a cataract. *Id.* Because the case involved one incident of trauma, an immediate injury, and a more serious injury developing four years later at the site of the trauma, the court concluded the causation opinion was no more novel that an orthopedist testifying that a neck injury, which did not manifest itself with symptoms until four years after a collision, was caused by the accident. *Id.* at 997.

*Tursi* does not support Plaintiff=s argument that pure opinion testimony was admissible in the instant case even if it was an Aimpact@ case. In *Tursi* the underlying scientific principle B that trauma could cause cataracts B was not a new or novel theory. *Id.* at 997. Furthermore, under the circumstances of that case, the treating ophthalmologist was able to rule out other causes of the cataract. *Id.* at 996.

The Fifth District correctly determined that *Tursi* does not apply to the instant case. In the instant case both the medical literature and judicial opinions show that the theory that trauma can cause FMS has not been scientifically proven and is not generally accepted in the relevant scientific community. In the instant case the *Frye* test was properly applied to ensure the jury would not be misled by expert testimony based on causation theory that may ultimately prove to be unsound.

## VI. THE FIFTH DISTRICT DID NOT ERR IN ITS *FRYE* ANALYSIS.

The Fifth District did not impose a Anew level of exacting knowledge and understanding of both the biological and physiological processes including the precise pathogenesis of a medical condition@ (IB.39) by following this Court=s oft-stated requirements for admissibility of novel expert opinion testimony. Plaintiff and AFTL seemingly advocate abandonment of any gate-keeping function of the courts when it comes to expert opinion testimony. However, this Court has recognized the danger of misleading or confusing the jury with expert testimony based on a new or untried scientific theory. *Ramirez v. State*, 810 So. 2d 836 (Fla. 2001). AScientific@ reliability must be established as a predicate to Alegal@ reliability. *Id.* at 842.

The Fifth District did not hold that expert opinion evidence causally linking trauma and FMS would never be admissible. The court concluded only that there is presently no general acceptance in the scientific community of the theory that trauma can cause FMS. In reaching this decision the Fifth District and the trial judge followed the mandate of this Court that new or novel scientific evidence must be treated as a matter of admissibility for the judge rather than a matter of weight for the jury. *Brim v. State*, 695 So. 2d 268, 272 (Fla. 1997). To hold admissible an expert=s Apure opinion@ that a plaintiff=s FMS was caused by trauma would abdicate the court=s responsibility to ensure reliability of decisions and results by focusing on the prerequisite of scientific dependability. *See Henson*, 823 So. 2d at 106, 107.

In *Brim* this Court recognized that two conflicting principles or theories cannot simultaneously satisfy the *Frye* test. 695 So. 2d at 272. Either one principle or theory satisfies *Frye* and the other does not, or both principles or theories fail to satisfy *Frye*. Applying this logic to the instant case, it is clear that the general causation issue was one

for the courts to decide as the theories that trauma does or does not cause FMS are mutually inconsistent. Unless and until there is general acceptance in the medical community of one or the other of those theories, expert opinions as to causation of FMS are scientifically unreliable and thus legally unreliable.[10]

## VII. EVEN IF THE METHODOLOGIES USED BY PLAINTIFF=S EXPERTS WERE GENERALLY ACCEPTED BY THE SCIENTIFIC COMMUNITY TO ESTABLISH SPECIFIC CAUSATION, THE OPINIONS WOULD BE INADMISSIBLE BECAUSE THE UNDERLYING PRINCIPLE OF GENERAL CAUSATION HAS NOT BEEN GENERALLY ACCEPTED.

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[10]The two out-of-state cases cited by Plaintiff are inapposite. Both were worker=s compensation cases in which the admissibility of expert opinion on causation was not challenged, and the only issue was whether the lower tribunal=s findings were supported by the evidence. In *Rawls v. Coleman-Frizzell, Inc.*, 653 N.W.2d 247 (S.D. 2002), the court upheld denial of benefits based on a determination that the claimant failed to prove that a work-related accident was a contributing factor to her FMS. In so holding the court noted that the claimant must do more than prove that an injury sustained at her workplace preceded her medical problems when medical testimony established that the etiology of FMS is unknown. *Id.* at 252, 254. In *Waldorf Corp. v. Industrial Commission*, 303 Ill. App. 3d 477, 708 N.E.2d 476 (1st Dist. 1999), the court upheld an award of worker=s compensation benefits based solely on the timing of onset of symptoms shortly after a work-related injury.

Remarkably, after briefing these issues in the trial court, the Fifth District, and again in the trial court for the evidentiary hearing, Plaintiff still misunderstands the difference between general and specific causation. Plaintiff=s argument in this section fails to recognize that an opinion on specific causation necessarily must be founded on a generally accepted underlying scientific principle of general causation. It is the underlying principle that has always been in question in the instant case.

Plaintiff=s experts did not base their causation opinions on Agenerally accepted basic underlying principles,@ as suggested at page 42 of her Initial Brief. Indeed, Plaintiff failed to describe the Agenerally accepted basic underlying principles@ on which her experts purportedly relied. Her reference to the Single Photon Emission Computed Tomography (SPECT) scan as an example of a new and novel test or technique that would be subject to a *Frye* hearing is inapplicable because, as Plaintiff states, the scan would only show that a person was suffering from FMS. The issue in this case is not whether Plaintiff has FMS but whether it was caused by trauma.

Plaintiff=s discussion of three AConsensus Reports@ likewise misses the point. None of these reports provides even a theory as to how trauma might result in FMS. Each of the reports was actually a review of existing data and not a scientific study attempting to correlate a cause-and-effect relationship between trauma and FMS. The Fifth District noted that each of these reports concluded the data are insufficient to indicate whether a causal relationship exists between trauma and FMS. (5D.85-87)

A prospective observational study has now been conducted and the results published in the June 2006 issue of The Journal of Rheumatology.[11] The Tishler study involved 153 patients who served as the study group. *Id.* at 1183. All patients in the study group were diagnosed with whiplash injuries following car accidents and were recruited from the Emergency Room at Asaf-Harofe Medical Center. *Id.* The control group consisted of 58 patients hospitalized in the orthopedic, surgery, and neurosurgery wards of the hospital because of severe trauma following a car accident. *Id.* The two groups were followed for several months (the control group for over a year), and only one patient in the study group but no patient in the control group developed symptoms and signs that fulfilled the 1990 American College of Rheumatology criteria for FM. *Id.* at 1184.

The authors noted that the only prospective study that found a causative link between trauma and FMS was by Buskila, et al.[12] The Tishler study could not confirm these earlier findings. Tishler at 1185. The Tishler study did not support earlier observations about a link between neck trauma and FMS. *Id.*

The Tishler study is the most recent report on the controversial subject of trauma and FM. The study supports the analysis of the Fifth District in the instant case. There

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[11]Tishler M., Levy O., Maslakov I., Bar-Chaim S., and Amit-Vazina M., *Neck Injury and FMS B Are They Really Associated?*, THE JOURNAL OF RHEUMATOLOGY 2006, Vol. 33, No. 6, pp.1183-85.

[12]Buskila D., Neumann L., Vaisberg G., Alkalay D., Wolfe F., *Increased rates of FMS following cervical spine injury. A controlled study of 161 cases of traumatic*

is still no general acceptance of the traumatic causation theory. Moreover, the Tishler study confirms that the theory of traumatic causation is scientifically unreliable.

Plaintiff and AFTL agree there is Alegitimate controversy@ as to whether or not trauma can cause FM. Because there is Alegitimate controversy,@ there is no general acceptance of the underlying scientific principle. The Fifth District correctly held that Plaintiff=s expert opinions on causation were not admissible because the basis for those opinions lacked scientific reliability.

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*injury*, ARTHRITIS RHEUM 1997; 40:446-52.

## CONCLUSION

There is no general acceptance within the relevant scientific community of the theory that trauma can cause FMS. The trial court and the Fifth District correctly concluded that the opinions of Plaintiff=s experts on these issues were inadmissible, and those rulings should be affirmed. Nothing in the trial court=s orders precluded Plaintiff from presenting causation testimony as to her alleged injuries and symptoms without the label of FMS. Plaintiff waived the right to trial on these issues, and the final summary judgment in favor of Defendants should be affirmed.


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## CERTIFICATE OF TYPE SIZE AND STYLE

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