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STATEMENT OF IDENTITY AND INTEREST

This case is before the Court on a Petition for Review to resolve a conflict between the Second and Fifth District Courts regarding the admissibility of expert testimony under Frye. The Florida Defense Lawyers' Association ("FDLA") is a statewide organization of defense attorneys with over 1,000 members. The potential admissibility of unreliable evidence is of great significance to the members of FDLA and at issue in many cases handled by FDLA members. FDLA has therefore requested leave to appear as Amicus Curiae in support of the position of Respondents.

This Court has not yet ruled on FDLA's Motion for Leave to Appear as Amicus. FDLA files this proposed brief in order to comply with the timing requirements of Rule 9.370(c).

SUMMARY OF ARGUMENT

The Fifth District properly concluded that the theory that fibromyalgia can be traumatically induced has not reach a level of general acceptance sufficient to meet the Frye reliability requirements. General acceptance and reliability by definition must first be established within the relevant scientific community. The scientific community does not generally accept the premise that fibromyalgia is traumatically induced - to the contrary, the scientific community continues to debate the issue and expressly recognizes that the current research is insufficient.

Furthermore, the only research supporting the theory is questionable in its methods and does not meet Florida's strict legal standards for admissibility. This and other courts have already rejected self-reporting "syndrome" evidence as insufficiently reliable under Frye. The same analysis applies here.

Florida courts have an obligation to keep unreliable expert testimony from a trial, because juries will give great weight to an expert's opinion. The causation theory has simply not been proven reliable enough for a jury to hear. The Fifth District properly fulfilled its gatekeeping function in finding that the Plaintiffs failed to meet their burden of proving reliability and general acceptance under Frye.

ARGUMENT

I. **THE FIFTH DISTRICT PROPERLY EXCLUDED EXPERT TESTIMONY UNDER THE FRYE STANDARD BY ADHERING TO THE TWO PURPOSES OF FRYE.**

A. **FLORIDA APPLIES A STRICT FRYE RELIABILITY STANDARD.**

Frye v. United States, 293 F. 1013 (D.C.Cir.1923), mandates that expert testimony deduced from a scientific principle or discovery is only admissible if the principle or discovery is "sufficiently established to have gained general acceptance in the particular field in which it belongs." 293 F. at 1014.

While the U.S. Supreme Court has adopted a broader standard for admissibility of scientific evidence, see Daubert v. Merrill Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), Florida has declined to apply the more lenient test announced in Daubert. The strict Frye test and its "higher standard of reliability" still control the admissibility of scientific evidence in Florida. See Brim v. State, 695 So.2d 268, 271-72 (Fla.1997); Hadden v. State, 690 So.2d 573, 577 (Fla.1997); Flanagan v. State, 625 So.2d 827, 829 n.2 (Fla.1993); Stokes v. State, 548 So.2d 188, 193 (Fla.1989).

In Stokes v. State, 548 So.2d 188, 193 (Fla.1989), this Court explained the policy underlying the Frye test:

The underlying theory for this rule is that a courtroom is not a laboratory, and as such it is not the place to conduct scientific experiments. 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 193-94.

Likewise, in Hadden v. State, 690 So.2d 573, 578 (Fla.1997), this Court observed that "[n]ovel 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." This Court further cautioned:

[W]e firmly hold 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. Reliability is fundamental to issues involved in the admissibility of evidence. . . . 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.

690 So.2d at 578.

The burden is on the proponent of the 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. Ramirez v. State, 651 So.2d 1164, 1168 (Fla.1995).

B. Florida Courts Admit Only Reliable Evidence

The evidence rejected by this court in Hadden was based on alleged scientific support similar to that offered in this case. In Hadden, this court refused to admit testimony on child sexual abuse accomodation syndrome when such testimony was based on

studies simply linking sexual abuse with certain symptoms. Id. This court held that both profile and syndrome evidence "have not reached the level of general acceptance in the relevant scientific community." Id. at 578-79. This Court held that the proffered syndrome analysis was not a "generally accepted method." The Fifth District reached the same conclusion in Marsh, below, in finding that the alleged causal relationship between trauma and FMS similarly lacked general acceptance.

The standard of reliability in Florida courts is no less than the standard of reliability within the scientific community. "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." Sybers v. State, 841 So. 2d 532, 541-42 (Fla. 1st DCA 2003) (rejecting scientific evidence purporting to establish causation).

As discussed infra, there is no general acceptance of the theory that fibromyalgia can be caused by a car accident or similar traumatic injury. Researchers are presently urging the scientific community to further test this hypothesis. Until reliable and replicable tests confirm such causation, the theory that vehicular trauma causes fibromyalgia syndrome is merely hypothetical and not admissible under Frye.

C. Florida courts must minimize the risk of juror overemphasis of expert testimony.

"The jury will naturally assume that the scientific principles underlying the expert's conclusion are valid. Accordingly, this type of testimony must meet the Frye test, designed to ensure that the jury will not be misled by experimental scientific methods which may ultimately prove to be unsound."

Hadden v. State, 690 So. 2d 573,578 (1997)(quoting Flanagan v. State, 625 So. 2d 827, 828 (Fla. 1993) and analogizing syndrome evidence to profile evidence). The court in Hadden distinguished evidence based on scientific testimony from evidence based on "pure opinion." Id. at 580. Fibromyalgia syndrome falls under the rubric of "syndrome evidence," which "is not made admissible by combining such evidence with pure opinion testimony because such a combination is *not pure opinion evidence based solely on the expert's clinical experience.*" Id. (emphasis added). When an expert is placed on the witness stand, "the expert's pure opinion testimony comes cloaked with the expert's credibility." Id. If unreliable scientific evidence were admitted under the guise of expert opinion testimony, a jury would likely overvalue such testimony.

D. Both the Causation Principle And the Methodology Used to Support it Must Qualify as Reliable Under The Frye Test.

As explained in detail in the briefs filed by Defendants/Respondents, numerous courts, both in Florida and around the country, have held that causation questions are

subject to the Frye and similar reliability requirements. Likewise, several courts and other authorities have specifically concluded that the contention that fibromyalgia can be traumatically induced does not pass the Frye test.

Despite these authorities, or perhaps because of them, Plaintiffs and their Amicus attempt to reframe the "general acceptance" issue as applying only to the differential diagnosis model. See e.g. Marsh v. Valyou, Brief of Amicus Curiae, Academy of Florida Trial Lawyers (brief filed in the Florida Supreme Court) at 2 ("AFTL"). However, the burden is on the proponent of the 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. Ramirez v. State, 651 So.2d 1164, 1168 (Fla. 1995). Here, neither element is met.

AFTL's amicus brief erroneously implies that the Frye standard does not serve a gatekeeping function. AFTL at 15. In fact, gatekeeping is the very purpose of the Frye test. See e.g. Hadden v. State, 690 So. 2d 573 (Fla. 1997)(holding that syndrome evidence linking sexual abuse to an array of symptoms was both subject to a Frye test and deemed inadmissible due to lack of general acceptance in the relevant scientific community); Flanagan v. State, 625 So. 2d 827, 828 (holding that "sexual offender profile evidence is not generally accepted in

the scientific community and does not meet the Frye test for admissibility."); Sybers v. State, 841 So. 2d 532, 542 (Fla. 1st DCA 2003)(holding inadmissible the evidence that an unstable compound "could come only from an injection of" a particular chemical because the relationship was not generally accepted within the relevant scientific community). The Fifth District's analysis properly fulfills this gatekeeping function.

II. WITHIN THE MEDICAL FIELD, THERE IS NO GENERAL ACCEPTANCE OF THE THEORY THAT TRAUMA IS ASSOCIATED WITH FIBROMYALGIA SYNDROME.

Prominent scholar and medical doctor Frederick Wolfe¹ wrote in 2000 that the causal link between trauma and fibromyalgia syndrome (FMS) is "certainly not agreed upon by the scientific community." Frederick Wolfe, For Example Is Not Evidence: Fibromyalgia and the Law, 27 The Journal of Rheumatology 1115 (2000). Since then, numerous articles and studies have revealed that medical experts have not yet reached agreement about the cause (etiology) of FMS. See e.g. Moshe Tishler, Ofer Levy, Ilya Maslakov, Shumel Bar-Chaim, and Mirit Amit-Vazina, Neck Injury and Fibromyalgia - Are They Really Associated?, 33 The Journal of Rheumatology 1183 (2006)("The etiology and

¹ Wolfe was "one of the first to coin the term 'fibromyalgia.'" CUTTING EDGE REPORTS, http://www.rheuma21st.com/archives/cutting_edge_fibro_wolfe.html. See also Frederick Wolfe, The Clinical Syndrome of Fibrositis, 81 THE AMERICAN JOURNAL OF MEDICINE 7 (1986)(reviewing then-termed "fibrositis" as a clinical syndrome).

pathophysiology of [FMS] remain unclear[.]"); A.W. Al-Allaf, K.L. Dunbar, N.S. Hallum, B. Nosratzadeh, K.D. Templeton, and T. Pullar, A Case-Control Study Examining the Role of Physical Trauma in the Onset of Fibromyalgia Syndrome, 41 *Rheumatology* 450 (2002)("The aetiology of primary FMS remains unclear."); see also Neil D. Kodosi, Confronting Experts Whose Opinions are Neither Supported nor Directly Contradicted by Scientific Literature, 80-JUN Fla. B. J. 80 (2006)(stating that the Fifth District in Marsh properly relied on "the overwhelming wealth of literature, stating that the causes of fibromyalgia were unknown[.]").

Nor is trauma the only alleged cause of fibromyalgia. Researchers have extensively studied potential causes such as disturbances in non-REM sleep, hormonal factors, infectious factors, and stressful conditions. Al-Allaf, supra at 450. An early study hypothesized that genetics was "probably" a factor in developing FMS. George W. Waylonis, Patrick G. Ronan, and Chrisanne Gordon, A Profile of Fibromyalgia in Occupational Environments, 73 *American Journal of Physical Medicine & Rehabilitation* 112, 114 (1994). Another study noted that "adverse psychosocial factors, aspects of health beliefs and behavior, and a history of reporting somatic symptoms" have been predictive factors in the onset of chronic pain. Elaine F. Harkness, Gary J. Macfarlane, Elizabeth Nahit, Alan J. Silman,

and John McBeth, Mechanical Injury and Psychosocial Factors in the Work Place Predict the Onset of Widespread Body Pain: A Two-Year Prospective Study Among Cohorts of Newly Employed Workers, 50 Arthritis and Rheumatism 1655 (2004)(examining the effect of work-related risk factors as predictors of new-onset widespread pain among newly employed workers).

Medical authors warn that prematurely accepting an association between trauma and fibromyalgia syndrome could do more harm than good, to both individual patients and society. J.B. Winfield, Fibromyalgia: What's Next? 10 Arthritis Care Research 219 (1997) and F. Wolfe, T. Aarflot, D. Bruusgaard, K.G. Henriksson, G. Littlejohn, H. Moldofsky, et al. Fibromyalgia and Disability: Report of the Moss International Working Group on Medico-Legal Aspects of Chronic Widespread Musculoskeletal Pain Complaints and Fibromyalgia, Scandinavian Journal of Rheumatology 112 (1995).

In short, the scientific community is still debating both the premise of whether fibromyalgia can be traumatically caused, and what method of testing can reliably be used to determine causation. There is no general acceptance.

- A. The results of the "Buskila study" are limited to an unreplicated correlation, not an established causal relationship.

The AFTL amicus brief attempts to build a "general acceptance" theory of the causal relationship between trauma and

FMS. AFTL at 9. The authors rely on the assumption that "epidemiological studies are...generally accepted as a basis for inferring medical causation." Id. AFTL uses this premise to conclude that the Buskila study effectively proves a causal link between trauma and FMS. Id. (referring to Dan Buskila, Lily Neumann, Genady Vaisberg, Daphna Alkalay, and Frederick Wolfe, Increased Rates of Fibromyalgia Following Cervical Spine Injury: A Controlled Study of 161 Cases of Traumatic Injury, 40 Arthritis & Rheumatism 446 (1997)). This theory of causation is wholly unsupported. The authors themselves concede that the significance of the Buskila study is limited to a correlation between FMS and soft tissue trauma to the neck. Buskila, supra, at 451. The Buskila "Discussion" section indicates that the authors themselves view their study as only the first among many attempts to discover an alleged causal relationship. Id. at 450-51.

The results of the Buskila study are far from "generally accepted," contrary to the AFTL's assertions. See e.g. AFTL Amicus Brief at 9. The Buskila study has not only been criticized by authors of subsequent studies (see Al-Allaf, discussed infra) but has been refuted by contrary results (see Tishler, discussed infra). Three years after the study, the co-author of the study, Frederick Wolfe, cautioned readers that the

scientific community has not agreed upon the theory that trauma cases FMS. Wolfe, supra (II), For Example is Not Evidence.

The causal link between trauma and fibromyalgia syndrome is thus neither conclusive nor generally accepted. The Fifth District correctly noted that "the relevant authorities have held that anecdotal evidence or clinical experience is insufficient to establish a (general) causal connection between trauma and fibromyalgia without further testing." Marsh v. Valyou, 917 So. 2d 313, 327 (Fla. 5th DCA 2005). The aforementioned studies in fact urged further testing.

B. Subsequent authors criticize the Buskila study.

Five years after the Buskila study, the scientific community concluded that there was still no solid evidence of a link between physical trauma and fibromyalgia. See e.g. Al-Allaf, supra at 451 ("Although an association between fibromyalgia and physical trauma has been suspected, there is limited evidence either to support or to refute this."). The Al-Allaf authors urged, "[f]urther prospective studies are needed to confirm this association and to determine whether trauma has a causal role[.]" Id. at 453. Al-Allaf also criticized the Buskila study on the grounds that there was "inherent bias in ascertaining the diagnosis of [fibromyalgia syndrome] in individuals with neck injuries[.]" Id. at 452.

The alleged causal link found in the 1997 Buskila study is therefore of minimal significance.

Amicus curiae AFTL tries to minimize what they dub "cautious rhetoric often used by scientific researchers." AFTL at 17. However, cautionary language should be dismissed as mere "rhetoric" *only* when the theory has otherwise been sufficiently tested. Otherwise, cautionary language, such as that contained in the Al-Allaf study (supra), serves the important purpose of guiding future researchers. The Marsh court correctly relied on the insufficiency of present data and necessity of future studies to verify the results of Buskila et al. See e.g. Marsh, 917 So. 2d at 316-17.

C. Prospective studies are more reliable than retrospective studies to establish causation.

In Brim v. State, 695 So. 2d 268, 272 (Fla. 1997), this Court noted that the *quality* of evidence is at least as important as the quantity of evidence supporting a scientific theory. While many authors have speculated about a link between trauma and fibromyalgia, few reliable studies have attempted to establish such causation. Of these studies, only two were prospective, which is widely considered to be more reliable than the more common, less expensive retrospective studies.

A prospective (cohort) study compares two groups over time, measuring the incidence rate of a disorder in the group exposed

to a variable compared with the group not exposed. 3 Expert Witness Checklists § 14:70 (3d ed.). The two groups should be as similar possible. Young K. Lee, Beyond Gatekeeping: Class Certification, Judicial Oversight, and the Promotion of Scientific Research in "Immature" Pharmaceutical Torts, 105 Colum. L. Rev. 1905, 1919 (2005). More expensive and complex than retrospective studies, prospective studies give scientists greater control over possible confounding variables. Id. Prospective studies also allow scientists to compare exposed individuals to their "pre-exposure" selves. Id. On the other hand, retrospective studies use data such as self-reports to "compare an affected group with an unaffected control group to discern a common factor" in attempt to explain the illness or disorder. 3 Expert Witness Checklists § 14:70 (3d ed.).

Of the two types of epidemiologic studies, prospective studies are more reliable. Lee, supra, at 1920. Retrospective research techniques such as interviewing subjects and reviewing records are "usually less accurate than prospective studies." Michael D. Green, Causation in Pharmaceutical Cases, SL038 ALI-ABA 139, 212 (2005). See also LeRoy L. Kondo, The Tangled Web: Complexities, Fallacies, and Misconceptions Regarding the Decision to Release Treated Sexual Offenders from Civil Commitment to Society, 23 N. ILL. U. L. REV. 195, 211 ("[P]rospective studies are acknowledged as more powerful

statistical tools because researchers have greater control over the experimental design of prospective studies[.]"). Current researchers in the field believe that the link between trauma and FMS "must be based on solid epidemiologic and *controlled prospective studies*." Moshe Tishler, Ofer Levy, Ilya Maslakov, Shumel Bar-Chaim, and Mirit Amit-Vazina, Neck Injury and Fibromyalgia - Are They Really Associated?, 33 *The Journal of Rheumatology* 1183, 1184 (2006)(emphasis added).

The problem with Al-Allaf's and other retrospective studies is that the results depend heavily on patient recall. Yoram Shir, John X. Pereira, Mary-Ann Fitzcharles, Whiplash and Fibromyalgia: An Ever-Widening Gap, 33 *The Journal of Rheumatology* 1045, 1046 (2006). The authors of the Al-Allaf study conceded that "[o]ur own results are, of course, retrospective and may be influenced by recall bias." Al-Allaf, supra, at 453. The Buskila study was a prospective study, and prior to 2006, it was "the only prospective study of a causative link between trauma and [FMS]." Tishler, supra, at 1183.

D. The results of the 2006 Tishler study refute the results of the 1997 Buskila study.

The most recent relevant study focused on the alleged link between trauma (specifically, whiplash injury) and fibromyalgia syndrome. Tishler, supra ("Tishler study"). The driving force behind the Tishler study was "[t]he absence of similar studies

[to Buskila's] and the increasing medico-legal issues and ramifications" of the alleged association between FMS and trauma. Id. The Tishler study criticized the Buskila study, noting that "[w]e believe our study is more accurate and its methodology makes our results more solid." Id. at 1185. A major distinction in the data set was that the patients in the Buskila study were attending an occupational injury clinic, whereas the patients in the Tishler study had been diagnosed with whiplash injury after a car accident. Id. The Tishler study "followed [the participants] prospectively starting immediately after discharge from the emergency room." Id. The authors noted that this distinction likely yielded less bias because the patients in the Buskila study "were not representative of the whole injured group." Id.

Using a less-biased data set than the Buskila study, the Tishler study failed to replicate the results of the similarly prospective Buskila study. Id. at 1185. In the "Discussion" section, the authors concluded that "[t]he issue of trauma and FM remains controversial," Id. at 1184, and "well-controlled multinational studies with large cohorts of patients are needed to resolve this complex issue." Id. at 1185. The Tishler study reveals that the debate is far from over. Thus, a causal link between trauma and FMS has yet to be established, much less "generally accepted" by the medical community.

E. Establishing a causal relationship requires replication of results.

Replication of results is an important factor in assessing the validity of a study, especially a study in which the participants self-report symptoms. Sarah H. Ramsey, Robert F. Kelly, Social Science Knowledge in Family Law Cases: Judicial Gate-Keeping in the Daubert Era, 59 U. MIAMI L. REV. 1, 75 (2004)("Within the scientific community, one of the necessary conditions for widespread acceptance of a finding is that it has been replicated."). Replication means that similar results can be produced using the same or similar circumstances in subsequent studies. Id. at 74. "As a general rule, peer reviewers and the scientific community give greater credence to research findings that have been replicated than to those that are reported for the first time." Id. See also Krista L. Duncan, "Lies, Damned Lies, and Statistics"? Psychological Syndrome Evidence in the Courtroom after Daubert, 71 Ind. L. J. 753 (1996)(noting that replication is a "core element...of 'good science.'")

F. Peer acceptance of the recent Tishler study.

In the same journal issue as the Tishler study, an editorial affirmed the conclusions of the study and said "[t]he debate is...not completely settled for an association of a triggering event and the onset of [fibromyalgia syndrome]."

Yoram Shir, John X. Pereira, Mary-Ann Fitzcharles, Whiplash and Fibromyalgia: An Ever-Widening Gap, 33 The Journal of Rheumatology 1045, 1046 (2006). The Tishler study and its affirmation in the Shir editorial are the most recent developments in the controversy of whether trauma causes fibromyalgia. These recent developments highlight the lack of any "general acceptance" of an association, much less a causal connection, between fibromyalgia and trauma.

III. COMPENSATION AND PERCEPTION OF RISK SIGNIFICANTLY INFLUENCE THE DEVELOPMENT OF FIBROMYALGIA.

Studies show that factors related to litigation have a proportional relationship with the development of fibromyalgia. Florida courts should take these variables into account because the public perception of compensation and risk could quickly result in the courts being flooded with post-vehicular trauma cases.

A. Money plays a factor in self-reporting of fibromyalgia syndrome.

Reports of chronic pain syndromes such as fibromyalgia fluctuate depending on a likelihood of compensation. Several studies in the late 1990s showed a relationship between post-traumatic development of chronic pain and liberal compensation systems. R. Bellamy, Compensation Neurosis: Financial Reward for Illness as Nocebo, 336 Clin. Orthop. 94 (1997); J. Rainville, J.B. Sobel, C. Hartigan, and A. Wright, The Effect of

Compensation Involvement on the Reporting of Pain and Disability by Patients Referred for Rehabilitation of Chronic Low Back Pain, 22 Spine 2016 (1997); M.H. Miller and D.J. Topliss, Chronic Upper Limb Pain Syndrome (Repetitive Strain Injury) in the Australian Workforce: A systematic Cross Sectional Rheumatological Study of 229 Patients, 15 J. Rheumatol. 1705 (1998). The Buskila study noted that "a diagnosis of FMS may initiate compensation claims. In settings where compensation is widely available, illnesses similar to FMS have been shown to increase[.]" Buskila at 451.

B. Perception of risk and other psychological factors play a role in the incidence rate of fibromyalgia syndrome.

A 1999 article by Ferrari and Russell indicated that perception of a risk of chronic illness, or "increased perceived threat," resulted in a higher risk of chronic symptom development. R. Ferrari, A. S. Russell, Epidemiology of Whiplash: An International Dilemma, 58 Ann. Rheum. Dis. 1 (1999). The authors surveyed cross-cultural reporting of chronic symptoms. Id. The authors attribute the significant differences among FMS rates in various countries to "social structural determinants" and "a host of psychological factors." Id. The Ferrari study cites "a route to compensation" as a possible explanation for a higher incidence of whiplash reporting in Australia. Id. Even the authors of the Buskila

study noted a potential social impact on the reported severity of FMS. Buskila at 451.

The correlation between compensation and fibromyalgia is but one reason that this Court should adhere to the strict Frye test. This Court should continue to require general acceptance of the science behind the theory before allowing the theory to be presented in Florida's courts.

CONCLUSION

The Fifth District correctly applied the Frye standard to exclude expert testimony, in which the expert opined that trauma causes fibromyalgia syndrome ("FMS"). Admissibility of expert testimony under Frye is a narrow, rather than a liberal, standard. As applied by Florida courts, the two purposes of Frye are to restrict expert testimony to reliable evidence and to prevent a juror from overvaluing expert testimony. Because the alleged causal relationship between trauma and FMS is still hypothetical and largely untested, such evidence does not meet the strict "generally accepted" standard under Frye. The twin purposes of Frye would thus be thwarted if the court allows a doctor to testify that trauma causes FMS.

Respectfully submitted,

Tracy Raffles Gunn
FOWLER WHITE BOGGS BANKER P.A.
P.O. Box 1438
Tampa, FL 33601
Telephone No.: (813) 228-7411
Telecopy: (813) 229-8313
Attorneys for Amicus Curiae, Florida
Defense Lawyers Association

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and accurate copy of the above and foregoing has been furnished by U.S. Mail to:

John T. Stemberger, Esquire Law Office of John Stemberger 4853 S. Orange Avenue, Ste. C Orlando, FL 32806 Counsel for Petitioner	Joseph C. Brock, Esquire 545 Delaney Avenue, Suite 7 Orlando, FL 32801 Counsel for Respondents, Valyou
Elizabeth C. Wheeler, Esquire Elizabeth C. Wheeler P.A. 220 North Palmetto Avenue Orlando, FL 32801 Counsel for Respondents, Burke	E. Peyton Hodges, Esquire Cameron, Hodges, Colmean, LaPointe & Wright, P.A. 14 W. Church Street, Ste. 301 Orlando, FL 32801 Counsel for Respondent, PV Holding Corp.

on September 19, 2006.

Attorney

CERTIFICATE OF COMPLIANCE

I HERBY CERTIFY that this brief complies with the font requirements of Florida Rule of Appellate Procedure 9.210(a)(2).

Tracy Raffles Gunn
FOWLER WHITE BOGGS BANKER P.A.
P.O. Box 1438
Tampa, FL 33601
Telephone No.: (813) 228-7411
Fax No.: (813) 229-8313
Attorneys for Amicus Curiae, Florida
Defense Lawyers Association

#2249744v1