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Welcome,

To facilitate your review of the services provided by CereScan Corporation, I thought a brief history of the standards utilized in challenging CereScan's services procedures might be of some assistance. As you are likely aware, the Supreme Court case of *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993) defines the factors which Courts are to consider when reviewing the admissibility of expert testimony, although these factors are by no means a "definitive checklist or test"; see *Kumbo* below. These factors are: (1) whether the theory or technique can be tested or has been tested; (2) whether it has been subject to peer review and publication; (3) whether there is a known or potential error rate and/or standards controlling the technique's operation; and (4) does the theory or technique enjoy general acceptance within the relevant scientific community. In fact, the Federal Rules of Evidence have significantly incorporated the essence of the *Daubert* decision by stating, in Rule 702, that (A) witness qualified as an expert...may testify...in the form of an opinion or otherwise if (1) the testimony is based upon sufficient facts or data; (2) the testimony is the product of reliable principles and methods; and (3) the witness has applied the principles and methods reliably to the facts of the case. Obviously, the *Daubert/Kumbo* decisions grasp the concept of flexibility to provide plaintiff's sufficient room to develop and protect their experts and cases.

As technology and scientific knowledge have evolved at an ever increasing pace, courts throughout the country have struggled with the formidable task of separating scientific fact from fiction. In the case of *Frye v. United States*, 293 F. 1013 (1923), the court said "*Just when a scientific principle or discover crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone, the evidential force of the principal must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principal 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.***"

With brain imaging, the initial battle concerning the admissibility of images occurred with PET scans. PET scans are administered in a manner very similar to SPECT scans. Utilizing the *Frye Rule*, courts traditionally allowed opinion testimony where the evidence was outside the realm of common knowledge and the evidence was based on the testimony of a witness qualified as and expert by virtue of training, knowledge, skill or experience in the pertinent subject area. The first significant change in the manner in which at least the federal courts viewed expert testimony occurred in 1993 when the U.S. Supreme Court released an opinion in *Daubert* in which the Court ruled that Rule 702 of

the Federal Rules of Evidence superseded Frye as the appropriate standard for determining admissibility of expert testimony. That Rule says “...*If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.*” Thus, a two part test was established: (1) Does the expert’s opinion relate to a matter of scientific, technical or specialized knowledge and (2) Will the expert’s testimony be helpful to the trier of fact in determining a fact at issue in the case? Factors identified by the Court determine whether such evidence is admissible include whether the evidence is based on a testable theory or technique; whether the theory or technique has been subjected to peer review and publication; the known or potential error rate of the theory or technique; and general acceptance of the theory or technique within the scientific community. It is important to note that nothing in the text of the Rule establishes “general acceptance” as an absolute prerequisite to admissibility, and the Court supported that determination. The drafting history makes no mention of *Frye*, and rigid “general acceptance” requirement would be at odds with the “liberal thrust” of the Federal Rules and their general approach of relaxing the traditional barriers to opinion testimony. Colorado essentially follows the Daubert rule.

More recent US Supreme Court decisions (*Kumho Tire v. Carmichael*, 119 S.Ct. 1167 (1999)) announced what appears to be a rather sweeping dismissal of Daubert, saying that Daubert’s four factors were meant to be helpful, not definitive, and they should only be considered in those cases where the trial court determines that they are reasonable measures of the reliability of expert testimony. *Kumho Tire* gave the trial court great discretion. Other factors courts now consider include the expert’s professional background; independent research conducted by the expert; the use of established techniques; and explanatory testimony (i.e. visual aids).

PET scans are now typically allowed as probative for the diagnosis of brain injury. *Hose v. Chicago Northwestern Transportation Co.* 70 F.3d 968 (1995); *Penney v. Prazair*, 116 F.3d 330 (1997); *People v. Weinstien*, 156 Misc. 2d 34.; *U.S. v. Mezvinsky*, 206 F. Supp 2d 661 (2002); *U.S. v. Gigante*, 982 F.Supp. 194 (1998); *Jackson v. Calderon, Warden of “California State Prison at San Quentin*, 1997 WL 855516 (D.D.Cal.); *Barnes v. Secretary, Department of Health and Human Services*, 1997 WL 620115; *Timothy McCollum and Lee Ann McCollum as Parents and Natural Guardians of Grant F. McCollum*, 1998 WL 338237. Similarly, many courts are now allowing the results of SPECT scans. Among them include *Rhilinger v. Jancsics*, 1998 WL 1182058 (Mass.Super. 1998) “...Evidence of SPECT imaging is admissible where it was one of a constellation of diagnostic tools in support of a diagnosis.” In this case the court included a thorough discussion of SPECT scans, and noted that the medical community had used SPECT technology for at least 15 years prior. The court concluded that there was no dispute that SPECT scans show abnormalities in brain function nor was there a dispute that SPECT scans cannot conclusively establish the existence or non-existence of Toxic Solvent Encephalopathy in a patient. In *Guilbeau v. W.W. Henry Co.*, 85 F.3d 1149 (1996), a chronic toxic encephalopathy case resulting from a short-term exposure to chemicals contained in a carpet adhesive, Judge Reynado Garzo expressed his belief that

the plaintiff carried his burden in proving causation through the use of SPECT scan evidence despite a rigorous cross-examination regarding the lack of foundation for whether SPECT was reliable. In *Baxter v. Ohio Department of Transportation*, 2002 WL 318505 (Ohio.App. 2002), the “...Court determined that the testimony and opinions by expert witness who testified that SPECT scan provided objective evidence of accident victim’s diminished brain activity should not have been disregarded because it confirmed the expert’s opinion that the victim suffered from significant memory and attention deficits and depression, and that those problems stemmed from the accident.” In *Smith v. Mullin*, 379 F.3d 919 (2004), the “...Court actually found that defendant was prejudiced by his counsel’s failure to present evidence of his mental retardation and brain damage as a defense to the murders and the court noted in the opinion that evidence of his brain damage was shown in SPECT scans.” Further, *In re Air Crash at Little Rock Arkansas*, 291 F.3d 503 (2002), the Court indicated that expert testimony would have been admitted if “...the expert cited to “a positron emission tomography (PET) scan or a single positron emission computed tomography (SPECT) scan.” And in *Fini v. General Motors Corp.* 2003 WL 1861025, the court concluded that the use of SPECT may have important implications for classification and management of patients with mild head trauma, and concluded that the evidence demonstrated that SPECT scans were generally accepted within the scientific community as having an ability to show abnormalities in brain functioning .

There are some states, however, where the Frye “general acceptance” standard still applies. In these states, SPECT has run into some opposition. In California (*The People v. Paul Seong Chul Yum*), while SPECT was endorsed as a diagnostic tool in the diagnosis of stroke, epilepsy or seizure and dementia, it was questioned as a diagnostic tool for brain trauma and psychiatric disorders, and was not allowed by the court. Also, in a FELA action alleging multiple chemical sensitivity syndrome, a trial court excluded an expert’s testimony which relied heavily on SPECT images (*Summers v. Missouri Pacific Railroad System*, 897 F. Supp. 533 (1995)

In Colorado, the Colorado Rules of Evidence provide the modern guidelines for the admissibility of expert testimony; *People v. Shreck*, 22 P.3d 68 (2001). Under the Colorado Rules of Evidence (CRE 402), all relevant evidence is admissible, except as provided by constitution, rule, or statute, and irrelevant evidence is not admissible. Evidence is relevant if it has any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence. CRE 401 and 402 reflect liberal admission of evidence, while CRE 702 and 403 temper that broad admissibility by giving courts discretion to exclude expert testimony if it is unreliable, irrelevant or if “its probative value is substantially outweighed by the danger of unfair prejudice.” Under *Shreck*, the Supreme Court held that scientific evidence is admissible if the testimony is reliable and relevant.

To determine reliability, courts consider whether the scientific principles underlying the testimony are reasonably reliable, and whether the expert is qualified to opine on such matters (*People v. Martinez*, 74 P.3d 316 (2003)). The Colorado Supreme Court, in *People v. Ramirez*, Case No. 06SC71, on March 26, 2007, opined that the only

speculative testimony that would be unreliable and therefore inadmissible under CRE 702 is such opinion testimony that has no analytically sound basis. The Court stated that “admissible expert testimony must be grounded in the methods and procedures of science rather than subjective belief or unsupported speculation.” However, the Court stated that the proponent need not prove that the expert is indisputably correct or that the expert’s theory is generally accepted in the scientific community. Instead, the proponent must show only that the method employed by the expert in reaching the conclusion is scientifically sound and that the opinion is based on facts which satisfy Rule 702 reliability requirements.

When determining relevance, the Court in the *Ramirez* case stated that the court must determine whether the proffered evidence is useful to the fact finder, or if it has any tendency to make the existence of a fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence. Such factors as elements of the particular claim, the nature and extent of other evidence in the case, the expertise of the proposed expert witness, the sufficiency and extent of the foundational evidence upon which the expert witness’ ultimate opinion is to be based, and the scope and content of the opinion itself are relevant to such a determination. In the *Ramirez* case, even the statement of “*mere possibilities*” was considered by the court as *relevant* to the fact finder in deciding the outcome. And the mere fact that the expert in the *Ramirez* case used the term “suspicious” in her findings was not so speculative as to make such testimony unreliable.

In Colorado, Senior Judge Zita L. Weinshienk of the US District Court for the District of Colorado allowed Brain Matters Imaging Centers (predecessor to CereScan) testimony in the case of *Searcy v. Hamburger* (2005). In a non-Brain Matters Imaging Centers/CeresScan case dealing with SPECT, Judge Chris Melonakis, of the Adams County District Court, in the case of *Campbell v. T.R. Transportation*, also accepted expert testimony concerning SPECT. More recently, Chief Justice Charles M. Barton of the Chaffee County District Court, in allowing the testimony of Dr. Theodore Henderson as an expert and the admissibility of evidence concerning SPECT scans in the case of *Vittoria Ernst v. Kayleen Fraley* (May, 2007), Case Number 05CV207), found (i) that “Evidence of a SPECT scan ...is admissible;” (ii) “(Evidence of a SPECT scan) is also relevant as scientific evidence;” (iii) “The theory and technique (SPECT) can and has been tested and has been subjected to peer review and publication;” (iv) The scientific technique’s know or potential rate of error is acceptable; (v) “The existence and ,and maintenance of standards controlling the technique’s (SPECT)operation is well documented;” (vi) “The technique (SPECT) has been generally accepted;” (vii) “The relationship of the proffered technique (SPECT) to more established modes of scientific analysis is established;” (viii) “The existence of specialized literature dealing with the technique (SPECT) is demonstrated;” (ix) “The non-judicial uses to which the technique (SPECT) are put...demonstrate that this technology and analysis are used in the course of non-forensic medical treatment;“ (x) the evidence has been offered and accepted in previous cases to support or dispute the merits of a particular scientific procedure; and (xi) “the probative value of the proposed scientific evidence is not substantially outweighed by the danger of unfair prejudice, confusion of issues, or misleading the jury,

and will not result in undue delay, waste of time or needless presentation of cumulative evidence.

In all of these Daubert-related challenges, the focus is typically on old reports concerning the applicability of SPECT scans to *mild* TBI cases. You will find frequent reference to the report of the Technology Assessment Subcommittee of the American Academy of Neurology (TTASAAN) published in 1996, describing SPECT as “investigational” in evaluating mild TBI. It is well known that the leading radiopharmaceutical for brain SPECT research--HMPAO—was not stabilized for clinical application until 1993. Although the TTASAAN report was published in January, 1996, it was approved for publication in early October, 1994. As such, only a very limited number (6) of clinical brain SPECT studies using HMPAO was available to TTASAAN during the 1996 report’s research and writing process. In addition, the Society of Nuclear Medicine Brain Imaging Council (SNMBIC) in its 1998 report establishing procedural guidelines for SPECT noted that “multiple-detector or other dedicated SPECT cameras generally produce results superior to single detector general purpose units.” In fact, both the TTASAAN report and the SNMBIC report endorse the use of SPECT in moderate to severe TBI. The SNMBIC report states that “...the use of SPECT... in the management of patients with moderate-to-severe trauma is now well recognized.” Similarly, the TTASAAN report was conservative in its assessment of SPECT only as to diagnosis of mild TBI. It is also significant to note that the majority of studies reviewed in both the 1996 TTASAAN report and the 1998 SNMBIC report were severely limited not only by the limited number of cases, but also by the use of single-head cameras.

Since those reports, the field has obviously progressed. Since, 1996, there have been over 150 additional peer-reviewed scientific studies concerning SPECT in mild-to-moderate TBI using HMPAO and more advanced multiple-detector (head) cameras. Even the TTASAAN related mild TBI concern has now been addressed in scientific literature (Jacobs reports), which in fact concluded that the ability of SPECT to predict outcomes in mild TBI is unmatched by other modalities.

In recognition of these significant advancements, the European Association of Nuclear Medicine, citing both the TTASAAN and SNMBIC reports, considers the evaluation of TBI as a “common indication” for the utilization of brain SPECT imaging. Also, the American College of Radiology and the Society of Nuclear Medicine both agree that SPECT is an accepted diagnostic test for the evaluation of TBI. Most third party insurance payors, including Medicare, now reimburse for the utilization of SPECT in TBI cases. In fact, Medicare, by accepting SPECT for coverage, has classified SPECT as a “...safe and effective; not experimental or investigational; appropriate; accepted standard of medical practice.” The National Transportation Safety Board has also accepted SPECT as a legitimate diagnostic tool, particularly for neurological applications (*Hinson v. Hoover*, NTSB Order No. EA-4094).

Some of the materials we can make available to referring counsel include:

- Motion in Limine regarding the testimony of a Brain Matters Imaging Centers' physician and Plaintiff's Response in the case of *Peters v. Udy* (Larimer County District Court);
- Motion in Limine regarding the testimony of a Brain Matters Imaging Centers physician, and Plaintiff's Response and Defendant's supplemental motion in support of Motion in Limine in the case of *Meyer v. Maupin*, (Weld County District Court);
- Motion to Exclude the Testimony of Theodore Henderson, M.D. Regarding SPECT scans in the case of *Vittoria Ernst v. Kayleen Fraley* in the Chaffee County District Court, Colorado;
- Plaintiff's Response in the *Vittoria Ernst* case;
- Talking point summary memo addressing many points previously encountered in deposition testimony.
- A sampling of research excerpts supporting SPECT.

In addressing the many issues with SPECT as it relates to admissibility, we at CereScan focus on the following to assist you in your efforts to survive *Daubert* challenges:

1. We attempt to clearly identify SPECT methodology and support that positions as generally accepted in our field;
2. We present testimony to establish the repeatability and our ability to recognize and distinguish failure from success;
3. We continue our efforts to publish CereScan sponsored materials in peer reviewed and other journals;
4. We continuously research and collect peer-reviewed articles and books supporting SPECT in its many applications;
5. We continue to test SPECT methodologies to ensure reliability;
6. We can confirm that our methodology as used in preparation for legal testimony is the same as we use in non-litigation settings.
7. We can testify concerning known or potential rates of error in SPECT methodology.

I hope this information is enlightening and helpful. If you have not already been provided with our extensive list of medical references supporting the use of SPECT for TBI evaluation and diagnosis, they are available on our website. I am

Yours aye,

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