AFFIDAVIT OF ERIN DAVID BIGLER, Ph.D.

STATE OF UTAH)
) ss:
COUNTY OF Utah)

ERIN DAVID BIGLER, Ph.D., being first duly sworn, deposes and states:

1. I am a neuropsychologist with additional training and experience in neuroimaging. I am presently a Professor of Neuroscience and Psychology and Director of the Magnetic Resonance Imaging Research Facility at Brigham Young University. I am also an Adjunct Professor of Psychiatry at the University of Utah and a member of the Utah Brain Institute.

3. Relevant to the issue of brain-imaging and Traumatic Brain Injury (TBI), I have authored the following books: *Neuroimaging I Basic Science* (1996) and *Neuroimaging II. Clinical Applications (1996), Traumatic Brain Injury: Mechanisms of damage, Assessment, Intervention & Outcome* (1990), *Neuropsychological Function and Brain Imaging* (1989).

4. More recently, I have authored chapters in the following books related to brain-imaging and Traumatic Brain Injury: *Understanding Mild Traumatic Brain Injury: Neuropathology and Neuroimaging* (2012), *Structural Imaging*, (2011), *Textbook of Traumatic Brain Injury (2011), Neuroimaging (2009), Neuroimaging and its Role in Developing Interventions* (2007).

5. My *Curriculum Vitae* is attached and identifies additional book chapters and journal articles relevant to the issues of brain imaging and traumatic brain injury of which I am an author.

6. I have reviewed the Motion to exclude the Diffusion Tensor Imaging Sequences of Mr. Ebel's MRI-DTI in this matter and submit this written response.

7. Diffusion tensor imaging (DTI) is a well-established neuroimaging procedure that has been applied to essentially ALL areas of neurological disorders. The United States National Library of Medicine, sponsored by the National Institutes of Health (NIH), lists over 7,500 articles on DTI. Specific to traumatic brain injury (TBI), there are over 750 articles that have applied DTI methods in the evaluation of the effects of TBI and over 100 studies that have specifically addressed DTI in cases of mild traumatic brain injury (mTBI).

8. As an example of recent DTI publications in the peer reviewed literature, a meta-analysis was performed by Aoki et al.[Diffusion tensor imaging studies of mild traumatic brain injury: a meta-analysis. J Neurol Neurosurg Psychiatry. 2012 Sep; 83(9); 870-6] involving cases that used DTI to specifically assess white matter findings in mTBI, demonstrating that DTI findings were consistently present in mTBI which, in turn, lead them to comment on the clinical utility using DTI in mTBI. Hellyer et al. (Individual prediction of white matter injury following traumatic

STATE OF MINNESOTA DISTRICT COURT

COUNTY OF WASHINGTON TENTH JUDICIAL DISTRICT
Personal Injury-Premises

Chelsea Nordstrom,

Plaintiff,

vs.

Fleet and Farm of Menomonie, Inc.,
A Wisconsin corporation d/b/a
Mills Fleet Farm,

Defendant.

Court File No.: 82-CV-11-5842
Judge Richard C. Ilkka

AFFIDAVIT OF JOSEPH C. WU, M.D.

STATE OF CALIFORNIA)
) ss.
COUNTY OF ORANGE)

Joseph C. Wu, M.D., being first duly sworn on oath, states as follows:

1. I am a medical doctor, and I am licensed to practice in the State of California. My practice is located at Irvine Hall of the University of California, Irvine, Brain Imaging Center, Irvine, California 92697. I have been a medical doctor for twenty-one years. I am the Clinical Director of the University of California, Irvine, Brain Imaging Center. I am also an Associate Professor of Psychiatry in the College of Medicine for the University of California, Irvine. I am board-certified in the field of Psychiatry. I have been awarded an Honorary Fellowship in the American Psychiatric Association, which is an honor bestowed upon a select few members who have made significant contributions to the field of psychiatry. I am also a member of the Society for Neuroscience, Biological Psychiatry Society, and Society of Nuclear Medicine.

2. I have published over sixty peer-reviewed articles on the application of brain imaging scans to the study of brain disorders, including articles on dementia, traumatic brain injury, Parkinson's disease, cocaine addiction, schizophrenia, depression, stuttering, bulimia, and solvent exposure. I have been a peer reviewer of brain imaging scan articles for some of the top journals in the field, including Nature magazine (which is regarded as one of the most preeminent scientific journals), Biological Psychiatry, and Psychiatry Research. A chapter that I wrote on "Neuroimaging in Clinical Practice" was published in the top textbook of psychiatry (Kaplan & Sadock's Comprehensive Textbook of Psychiatry, Seventh Edition, Lippincott, Williams & Wilkins, 2000, pp. 373-385). This textbook is regarded as the definitive reference for psychiatrists. This chapter includes a section on the use of brain imaging scans to study traumatic brain injury.

3. I was asked to present a workshop on "A Clinician's Guide to Functional Brain Imaging" at the 1999 American Psychiatric Association's annual meeting in Washington, D.C. I was asked to present a seminar on "Neuroscience and the Law: Brain Imaging" to the 2007 Appellate Judicial Attorneys Institute for the State of California. I was invited to give a lecture at the American Association of Justice 2008 meeting on Traumatic Brain Injury Cases—Neurodiagnostic Imaging. I was invited to give a lecture on "Brain Imaging in Court" at the XXXIst International Congress on Law and Mental Health in 2009, held at the New York University Law School. My work on brain imaging has been presented in Scientific American magazine (October 1999 issue, News and Analysis section), the New York Times on August 13, 1996 (page C8),

in the Los Angeles Times (Orange County Edition, March 5, 1995, page A1), and in Science magazine (July 30, 1993, p. 557).

4. I have also received awards from the National Alliance for Research in Schizophrenia and Depression (NARSAD) for the use of brain imaging scans. I have also been a co-investigator on brain imaging studies from pharmaceutical firms (e.g., Sandoz) to apply brain imaging studies quantitatively toward research into new medications. I have presented on statistical brain imaging scan studies on traumatic brain injury in front of scientific peers at the Society of Neuroscience meeting in Los Angeles in November, 1998. I was also awarded $1,396,428 from the National Institute of Health for a project that utilized brain imaging scans to study depression. This award was rigorously peer reviewed by other brain imaging experts who reviewed my methodology, including the statistical section, and felt that it was meritorious and worthy of federal funding.

5. I have served as a National Institute of Health grant reviewer for the Mental Health Centers for Intervention and Applied Research (CIDAR program) in October 2006 and October 2007. My role was to review PET and DTI and other neurodiagnostic imaging protocols in order to help determine which grants received federal funding. I have also served the Congressionally Directed Medical Research Program (CDMRP) as a grant reviewer for diagnosis and treatment of traumatic brain injuries (TBI) secondary to improvised explosive devices (IEDs) for military personnel serving in Iraq and Afghanistan in December 2008 and June 2009. Traumatic brain injury has been considered the signature injury of the Iraq and Afghanistan campaigns.

I was asked to review neurodiagnostic imaging (PET, MRI) techniques for TBI and methodology for federal funding for the CDMRP program.

6. Attached to this Affidavit as Exhibit 1 is a true and correct copy of my Curriculum Vitae, which I personally prepared, and which provides a true and detailed summary of my education and professional experience. I have used diffusion tensor imaging (DTI) clinically in the assessment of patients with traumatic brain injury and found it to be clinically useful.

7. Diffusion tensor imaging MRI scans are testable and have been subjected to peer review. There have been at least 80 articles in Medline on the use of diffusion tensor imaging and brain injury. These peer-reviewed articles describe the use of DTI scans to test hypotheses regarding brain function and activity in a wide spectrum of conditions, including traumatic brain injury. (See bibliography attached as Exhibit 2.)

8. DTI scans are not specifically diagnostic in and of themselves in isolation but are instead corroborative of brain injuries. The distinction can be highlighted by a metaphor. If a patient has a presentation consistent with pneumonia, a physician can check his temperature. If the patient is febrile, then this information can help corroborate pneumonia. However, fever by itself is not diagnostic of pneumonia. The ability to measure the patient's temperature provides invaluable corroborative clinical information, even if it is not specifically diagnostic.

9. There are many approaches toward validation. The gold standard for validation is peer-reviewed publication, since each manuscript that is independently published has to have been scientifically judged on the validity and reliability of the

methods by neutral scientific referees and not by opposing expert witnesses with an axe to grind.

10. Data collected from studies reveal DTI scans corroborated impaired brain function detected by neuropsychological testing such as memory tests, even when CT and MRI scans show no abnormalities. For example, Miles et al. 2008 noted a significant correlation between neuropsychological deficits and fractional anisotropy in mild traumatic brain injury.

11. In addition, studies also show that DTI scans can detect abnormalities in brain function in mild traumatic brain injured patients years after the date of injury. For example, see Inglese, M. et al. (2005), "Diffuse axonal injury in mild traumatic brain injury: a diffusion tensor imaging study," 103 *J. of Neurosurgery* 298-303 (Aug. 2005), a true and correct copy of which is attached as Exhibit 3. The authors found DTI abnormalities in patients with minor traumatic brain injuries a mean of 5.7 years after the injury, with significantly decreased fractional anisotropy in the patient's corpus callosum, internal capsule, and centrum semiovale.

12. The general acceptance, validity, and admissibility of DTI scans are also addressed in the following: Abraham, A., "Admissibility of Diffusion Tensor Imaging," a true and correct copy of which is attached as Exhibit 4; Affidavit of Randall R. Benson, M.D. (Feb. 1, 2010), a true and correct copy of which is attached as Exhibit 5; Affidavit of F. Reed Murtagh, M.D. (April 22, 2010), a true and correct copy of which is attached as Exhibit 6; and Affidavit of Michael L. Lipton, M.D, Ph.D. (April 29, 2010), a true and correct copy of which is attached as Exhibit 7.

13. Dr. Randall Benson of Detroit Medical Center and Wayne State University uses DTI clinically and notes that this technique "has become generally accepted by the medical community and is now clinically reimbursable by most insurance companies." (See Exhibit 5 at ¶ 1.) Dr. Benson describes a method for DTI fractional anisotropy (FA) assessment in which he looks for large clusters of low FA values. This is an accepted clinical method which I also utilize. Dr. F. Reed Murtagh of the University of South Florida College of Medicine stated in his Affidavit that "DTI studies are not experimental and may be used to diagnose brain injury in individual subjects." (See Exhibit 6 at ¶ 12.) Dr. Michael Lipton, Associate Director of the Gruss Magnetic Resonance Center at the Albert Einstein College of Medicine and Medical Director of clinical MRI services at Montefiore Medical Center, notes in his Affidavit: "In the clinical setting, DTI can be, and is, used to diagnose individual patients." (See Exhibit 7 at ¶ 15.) Dr. Lipton goes on to describe the methodology of assessment using voxel-wise analysis with a cluster threshold of a minimum number of voxels. This is the same fundamental methodology that both Dr. Benson and I utilize. Dr. Benson, Dr. Murtagh, and Dr. Lipton all accept the use of voxel-wise analysis of FA with a minimum cluster size to assess whether there are abnormalities.

14. A true and correct copy of the written testimony of Dr. Randall Benson in the Hearing before the House Judiciary Committee on January 4, 2010 is attached as Exhibit 8. Dr. Benson's written testimony discusses the effective use of DTI to "visualize" diffuse axonal injury from traumatic brain injuries sustained by football players.

15. A true and correct copy of a peer-reviewed study which I co-authored entitled “High-sensitivity and High-specificity of Traumatic Brain Injury diagnostic method using Magnetic Resonance Imaging Diffusion Tensor Imaging” is attached as Exhibit 9.

16. A true and correct copy of a peer-reviewed presentation by me entitled “Mild Traumatic Brain Injury Assessment with Diffusion Tensor Imaging (DTI) and Positron Emission Tomography (PET) scan findings and Neuropsychological Tests of Cognition and Attention” is attached as Exhibit 10.

17. A true and correct copy of a peer-reviewed presentation by me entitled “High-sensitivity and High-specificity of Traumatic Brain Injury diagnostic method using Magnetic Resonance Imaging—Diffusion Tensor Imaging” is attached as Exhibit 11.

18. DTI scans conducted by me for the assessment of brain function met the criteria for admissibility of scientific evidence and reliability and were accepted as evidence in the United States District Court for the Western District of Washington at Tacoma in the case of *Robert Shannon vs. Columbia Basin* (Case No. 3:11-CV-05867-RBL); in the State of Minnesota, Hennepin County, Fourth Judicial District in the case of *Sean Michael Nelson vs. BNSF Railway* (Court File No. 27-CV-12-9171); in the State of Minnesota, Ramsey County, Second Judicial District in the case of *Jean A. Hansen vs. Frank R. Crain* (Court File No.: 62-CV-10-2435); and in the Superior Court of the State of California, Kern County, Department 11, in the case of *Thomas F. Gutcher vs. Toyota Motor Sales, USA, Inc.* (Case No. S-1500-CV-270351-DRL).

19. There are known differences in DTI values based on patient gender, age, and time since injury. Preterm male subjects have lower FA (fractional anisotropy) values in right anterior uncinate fasiculus compared with full term male subjects, whereas female preterm subjects show no difference from full term female subjects in an MRI DTI study published by Constable, et al., "Prematurely Born Children Demonstrate White Matter Microstructural Differences at 12 Years of Age, Relative to Term Control Subjects: An Investigation of Group and Gender Effects," *Pediatrics* 2008:121; 306. A true and correct copy of that article is attached as Exhibit 12. Hsu, et al. (2008) found that full brain FA is negatively correlated with age in a study of 145 adults (aged 30 to 80). Hsu, et al. also found that females overall have lower FA in deep temporal regions on the right side. The area of abnormality that we noted in Ms. Nordstrom were the mid corpus callosum and right superior longitudinal fasiculus. These areas of decreased FA were determined after covarying out age and gender effects to neutralize these factors. Kennedy, et al., in "White matter and neurocognitive changes in adults with chronic traumatic brain injury," *Journal of the International Neuropsychological Society* (2009), 15, 130-136, found that time since injury was correlated negatively with FA in SPF ROI (superior frontal regions of interest). A true and correct copy of that article is attached as Exhibit 13. Time since injury was not associated with change in FA in the centrum semiovale (CS).

20. DTI is **not** used to diagnose the specific **cause** of an alleged brain injury; it is used to diagnose the **existence** of a brain injury. Clinical correlation is necessary to determine the most likely cause of the brain injury.

21. The error rate of DTI can be defined by using a measure such as sensitivity. For tractographic comparison, the sensitivity is approximately 90%. The error rate for DTI with FA z-maps has a sensitivity of approximately 95%. This error rate refers to the ability for blind rater to discriminate an abnormal DTI from a normal DTI.

22. The DTI scan animation comparison video was prepared by my associate, David B. Keator, M.S. Mr. Keator's description of the manner in which this animation was prepared is attached as Exhibit 14. I certify that I furnished the DTI tractography results, the z-map significant statistical results, and the fractional anisotropy (FA) data used by Mr. Keator to generate the DTI scan video. I further certify that the DTI scan video was prepared under my supervision.

23. The normal control used in the comparison video is a 21-year-old female. Her DTI was taken at the University of New Mexico (UNM). It was taken on a 3 Tesla MRI machine. The settings of the DTI machine were 35 directions DTI. The UNM MRI tech is likely the one to have taken the MRI DTI. The normal control was selected for comparison to match Ms. Nordstrom's gender and to be as close as possible to Ms. Nordstrom's age, using the normative database set that I have.

24. Finally, attached hereto as Exhibit 15 is a true and correct copy of my Clinical Correlation Report relating to Chelsea Nordstrom. I hereby adopt and reaffirm the entire contents of that Report as though it were set forth in its entirety within this Affidavit.

FURTHER YOUR AFFIANT SAYETH NOT.

_/s/ Joseph C. Wu_____ _____
Joseph C. Wu, M.D.

Subscribed and sworn to before me
this _6th__ day of November, 2013.

_/s/ Hung M. Dang_____
Notary Public – California
Orange County
Comm. No. 2007728
My Term Expires Feb. 15, 2017

AFFIDAVIT OF ANDREW T. WALKER, M.D.

STATE OF Florida)
) ss:
COUNTY OF Martin)

ANDREW T. WALKER, M.D., being first duly sworn, deposes and states:

1. I am a board-certified neuroradiologist and graduate of Yale University School of Medicine. I completed a Diagnostic Radiology Residency at Harvard Medical School, and thereafter, I completed a neuroradiology fellowship at Yale University School of Medicine. I am also a senior member of the American Society of Neuroradiology (ASNR) and have been in clinical practice for more than 19 years. I have attached hereto a copy of my *Curriculum Vitae*.

2. The use of the MRI sequence Diffusion Tensor Imaging (DTI) is widely and generally accepted in the clinical diagnosis of TBI. It is FDA approved, and is recognized and recommended as a useful MRI technique by the American College of Radiology (ACR), American Society of Functional Neuroradiology (ASFNR), the Defense Centers of Excellence (DCOE), and by the United States Air Force Surgeon General's Center for Excellence in Medical Multimedia (CEMM). DTI is one of the core MRI techniques utilized to evaluate TBI at NICoE, the Department Of Defense's elite brain injury institute at Walter Reed National Medical Center.

3. I have reviewed the motion to exclude DTI evidence in the *Ebel v. Apache*, et. al. matter. The motion omits the literature, and misrepresents the use of DTI in a clinical setting. DTI cannot "manufacture" injury as suggested in the motion. DTI is a well-established reliable tool, and more than meets the five factors of reliable evidence outlined in the motion.

4. The use of DTI in the evaluation of TBI has been tested and validated, peer reviewed, is based upon well-recognized scientific principles, is generally accepted, and has a determinable error rate, all of which are most comprehensively shown in the recent 2013 review article in the *American Journal of NeuroRadiology*, **"A Decade of DTI in Traumatic Brain Injury: 10 Years and 100 Articles Later"** by Hulkower et. al., AJNR, 2013.

5. I have been using the MRI technique, Diffusion Tensor Imaging (DTI) as part of a comprehensive brain MRI examination in my clinical practice for many years. I use the DTI sequence on every brain MRI performed in our Port St. Lucie imaging center, and as such, I have performed over 5,000 brain MRI examinations with DTI over the past approximate 6 years.

6. DTI in its simplest form, tractography, is available at most major hospitals throughout the country. Neurosurgeons rely upon DTI tractography for surgical planning. Quantitative DTI is available from no

less than three additional MRI providers in my immediate geographic practice area in South Florida.

7. DTI is not experimental, novel, or unproven. There have been scores of articles written on DTI in the past 10-15 years. The use of DTI is widely and generally accepted in the clinical diagnosis of TBI in individual patients. In the Hulkower et.al. review, 35 of the 100 DTI papers involved, in some part, the use of DTI to evaluate and diagnose TBI on an individual basis, not simply a group comparison. Their conclusion:

a. "A unifying theme can be deduced from this large body of research: **DTI is an extremely useful and robust tool for the detection of TBI-related brain abnormalities** "; and

b. "We also found an overwhelming **consensus that imaging abnormalities detected with DTI are associated with important clinical outcomes.** This further validates DTI as a meaningful measure of clinically important brain injury" *AJNR*, Jan. 2013, *A Decade of DTI in Traumatic Brain Injury: 10 Years and 100 Articles Later*", Hulkower, et.al.

8. These conclusions from a decade-review of literature are simply reaffirmation of our long-standing recognition of the clinical usefulness of DTI in the evaluation of TBI. Contrary to the motion, standards are in place for the performance and use of DTI clinically. We recommend and abide by the standards put forward by the American Society of Functional Neuroradiology: "ASFNR Guidelines for Clinical Application of Diffusion Tensor Imaging", and the more recent standard put forward by the Defense Centers of Excellence (DCOE).

9. DTI is always and should always be performed as part of a comprehensive Brain MRI examination. When positive, the DTI shows that the white matter tracts are damaged. I recognize that DTI is in a sense non-specific as many diseases that affect the white matter can result in an abnormal DTI, most commonly multiple sclerosis, ischemia and stroke, but even substance abuse or infection in severe cases. Of course, these alternative disease processes must be ruled out/in with clinical correlation. This type of non-specificity is true for most recognized imaging modalities and is not unique to DTI.

10. In addition to clinical correlation, the standard Brain MRI portion of the comprehensive Brain MRI examination allows for the evaluation of the telltale findings of alternative diseases that may affect the white matter. The pattern of an abnormal DTI with the standard Brain MRI showing no evidence of multiple sclerosis, ischemia, stroke, substance abuse or infection is very specific for TBI. Additionally, findings of focal gliosis at the gray matter – white matter junction on the standard Brain MRI make the diagnosis of TBI even more conclusive.

11. Uninformed individuals have attempted to embellish the claim of DTI being non-specific by incorrectly incorporating group comparison research done on a multitude of neuropsychiatric conditions that have shown subtle DTI differences in group comparisons only. This is absolutely incorrect,

and a misuse of the group comparison research. The use of DTI to evaluate TBI is done on an individual basis, and it requires much more damage and abnormality of the white matter to determine a DTI is abnormal on an individual basis.

12. DTI results are not redundant evidence of TBI. The DTI identifies a specific type of TBI, Traumatic Axonal Injury (TAI) also known as Diffuse Axonal Shear Injury (DAI). TBI can occur in multiple ways. The brain can be injured for example by direct head contact, piercing trauma like a bullet, or by violent starts and stops of the body and head, even if the head doesn't actually hit anything. This latter mechanism is called acceleration / deceleration injury and typically damages the white matter resulting in TAI and DAI.

13. The fact that a patient has a TBI with TAI is important clinically, as TAI is considered to be responsible for the majority of TBI-related neurocognitive deficits, and is likely related to poor outcome in mild TBI. Patients with mild TBI that do not have TAI have a better outcome. It is patients with mild TBI that also have TAI that likely constitute the "miserable minority" of mild TBI patients who show persistent cognitive deficits and symptoms. The identification of TAI on DTI is very important in clinically determining this outcome.

14. The pleading submitted references a very low-tier article by a forensic psychiatrist who does not perform DTI, i.e. Dr. Wortzel. The article is incorrect in its premise, is biased in its literature review and literature selection, and is written by an individual who is not a Neurologist, Radiologist, nor Neuroradiologist, and has no expertise in DTI. Dr. Wortzel does not perform clinical quantitative DTI and is thus not a qualified expert to make the comments he does in the article.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Andrew T. Walker MD

ANDREW T. WALKER, M.D.

SUBSCRIBED and SWORN to before me

this 8th day of October, 2013.

Kathryn S Klarmann

NOTARY PUBLIC

NOTARY PUBLIC-STATE OF FLORIDA
Kathryn S. Klarmann
Commission # EE111878
Expires: JULY 17, 2015
BONDED THRU ATLANTIC BONDING CO., INC.

OPINION OF MANLEY W. KILGORE, II, M.D.

I, Manley W. Kilgore, II, M.D. render the following opinion:

1. I served as Chief of the Department of Neurology at the Baptist Medical Center for 25 years.

2. The Baptist Healthcare System is the largest in Northeast Florida.

3. I am thoroughly familiar with the use of PET and DTI and both tests are accepted as diagnostic tools in clinical practice.

4. I review the literature routinely and am not aware of any state in which the use of these imaging tests is not accepted in clinical practice.

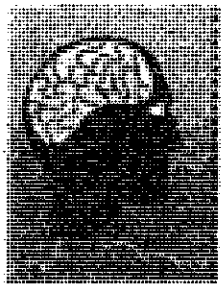
5. As a result of my background, I consistently update information concerning valid, recognized diagnostic tools in brain injury and DTI has been a valid diagnostic tool for clinical purposes for many years.

6. I am personally aware that there are several private practices utilizing DTI on a clinical basis to diagnose brain injury and the same is true in Tampa, Orlando and Jacksonville has at least two private practices utilizing DTI.

7. DTI is a valid clinical diagnostic tool for brain injury including hypoxic brain injury.

Date: 3/14/2013

MANLEY W. KILGORE, II, M.D.



Center for Neurorehabilitation Services

March 15, 2013

Re: Barbara Rotunda

I am the Medical Director of Center for Neurorehabilitation Services, P.C., and specialize in the evaluation, diagnosis and treatment of acquired brain injury. Attached is a copy of my Curriculum Vitae. In addition to the specifics set forth in my CV, I have been appointed by both the National Institute of Health and the Centers for Disease Control to evaluate the scientific validity of studies researching the brain and brain injury.

As a treating physician and as a researcher, I am required to have current knowledge of the diagnostic tools being used in clinical practice to evaluate, diagnose and treat brain injury. Causation is always part of this process.

I know that Diffusion Tensor Imaging (DTI) and Positron Emission Tomography (PET) are currently being used for clinical practice in hospitals and private practice settings throughout the United States. DTI is a valid clinical diagnostic tool for brain injury, including hypoxic brain injury and I use the findings from MRI/DTI imaging studies in my clinical practice.

I am also familiar with the scientific standards used by Dr. Joseph Wu in the interpretation of PET and DTI. Dr. Wu's scientific standards and criteria are valid and equal to those used and accepted both in the scientific research community and the clinical practice of treating brain injury.

Within medical certainty, the findings and diagnosis of Barbara Rotunda's brain injury, as demonstrated by imaging interpreted by Dr. Joseph Wu, is accurate. It is my medical opinion, based on the history, evaluation, testing, examination, and neurorehabilitation treatment as well as the imaging studies, that Barbara Rotunda suffered an insult to the brain due to improper administration of sedation on 14 September 2006 and that hypoxic event resulted in permanent brain injury. My opinion is within reasonable medical certainty.

Gregory J. O'Shanick, M.D.

10710 Midlothian Turnpike • Suite 125 • Richmond, VA 23235 • (804) 897-1688 • Fax (804) 897-5283

THE ACADEMIC NEUROLOGY NETWORK, INC.
11850 W. State Road 84, Suite A-7
Davie, Florida 33325
Nicholas D.A. Suite, M.D.

OPINION OF NICHOLAS D. A. SUITE, M.D.

I, Nicholas D. A. Suite, M.D., render the following opinion:

1. I have been a Board Certified neurologist in clinical practice for the last 19 years.

2. I am thoroughly familiar with the use of DTI and DTI is accepted as a diagnostic tool in clinical practice.

3. I review the literature routinely and am not aware of any state in which the use of this imaging test is not accepted in clinical practice.

4. As a result of my background, I consistently update information concerning valid, recognized diagnostic tools in brain injury and DTI has been a valid diagnostic tool for clinical purposes for many years.

5. I am personally aware that DTI is used to aid in clinical diagnosis in several different locations in the State of Florida.

6. DTI is both a valid and valuable clinical diagnostic tool to assist in making the diagnosis of mild, moderate and severe traumatic brain injury.

October 31, 2013
DATE

NICHOLAS D.A. SUITE, M.D.

Tel (954)626-0617 Email: academicneurologynetwork@gmail.com Fax (954) 626-0619

Weiss & Newberry Medical Associates
1051 Port Malabar Blvd. NE, Ste 6
Palm Bay, FL 32905
321-727-9063

OPINION OF GARY M. WEISS, M.D.

I, Gary M. Weiss, M.D., render the following opinion:

1. I have been a practicing neurologist with Gary M. Weiss M.D., P.A. since October of 1985.

2. I am thoroughly familiar with the use of DTI and DTI is accepted as a diagnostic tool in clinical practice.

3. I review the literature routinely and am not aware of any state in which the use of this imaging test is not accepted in clinical practice.

4. As a result of my background, I consistently update information concerning valid, recognized diagnostic tools in brain injury and DTI has been a valid diagnostic tool for clinical purposes for many years.

5. I am personally aware that DTI is used to aid in clinical diagnosis in several different locations in the State of Florida.

6. DTI is a valid clinical diagnostic tool for mild, moderate and severe traumatic brain injury.

Date: 11-1-13

GARY M. WEISS, M.D.

AFFIDAVIT OF WILLIAM W. ORRISON, JR., M.D.

STATE OF NEVADA)
) ss:
COUNTY OF CLARK)

WILLIAM W. ORRISON, JR, M.D., being first duly sworn, deposes and states:

1. I am a treating medical doctor for Mr. James Ebel and am Board Certified in Radiology with additional qualifications in Neurology and Neuroradiology. I completed Residency training in Neurology at the University of Wisconsin in 1979. Thereafter, I completed Residency training in Radiology at the University of Wisconsin in 1981. I completed an advanced fellowship in Neuroradiology in 1982.

2. I served as an Associate Professor of Radiology and Neurology at the University of New Mexico School of Medicine, and was the Fellowship Program Director in Neuroradiology from 1985-1997. Thereafter, I was both Professor of Radiology and Chairman of Radiology at the University of Utah School of Medicine from 1996-2001. I am currently a Professor of Medical Education at the University of Nevada School of Medicine, and am in clinical practice specializing in neuroradiology.

3. I have authored 5 books in Neuroimaging published in 3 languages, and 145 peer reviewed journal articles related to my profession. I have also authored 24 book chapters, 170 abstracts, and have attached hereto a copy of my *Curriculum Vitae* which provides additional detail as to my training in the area of brain-imaging including MRI-DTI. As summarized below, DTI is a reliable and robust imaging modality that is widely accepted and used for the evaluation of traumatic brain injury.

4. Mr. Ebel was referred as a patient to my clinical practice by his treating neurologist for neuroimaging within 30-days of a reported roll-over motor vehicle accident. He was seen at my office on May 11, 2010. He was again referred for comparison imaging on November 7, 2012 as post-concussive symptoms persisted. The statements made herein are of my own personal knowledge and I am prepared to testify thereto.

5. I have reviewed the Defendant's "MOTION TO EXCLUDE ALLEGED "EVIDENCE" OF MILD BRAIN INJURY MANUFACTURED BY PLAINTIFFS' USE OF DIFFUSE TENSOR IMAGING ("DTI")."

6. This declaration will address the clinical use of DTI and specifically address Defendant's comments in the motion. I am intimately familiar with the clinical use of DTI as it relates to Traumatic Brain Injury (TBI), as well as the DTI analysis performed by Dr. Benson. Dr. Benson has several peer-reviewed publications regarding DTI and TBI, and his methodology and findings have been tested, peer reviewed, and follow DTI techniques generally accepted in our discipline.

7. According to the Defendant's MOTION – "Plaintiff's treating neuroradiologist (Orrison) determined that changes in white matter as revealed in DTI findings "were consistent with Plaintiff's age".

This statement is misleading. First, it only references the first of two scans. Second, I addressed with DTI only one area of fiber tracks. My first DTI analysis was not as thorough and comprehensive as that of Dr. Benson, but it was by no means inconsistent with his findings. The tracks were found to be abnormal by me and do not contradict Dr. Benson's report which I have reviewed. Dr. Benson provides a much more detailed analysis of the DTI for the entire brain. My DTI evaluation was limited to one area. It is misleading to suggest that I, as Plaintiff's treating neuroradiologist, found that all changes in white matter as revealed in DTI findings "were consistent with Plaintiff's age" – as the defendants have presented this information since I made no comment regarding the white matter DTI other than to look at a single area.

Further, the motion omits my second reading when the patient persisted with post-concussive symptoms. In my November 11, 2012 imaging I specifically noted that Mr. Ebel had findings of "shearing (diffuse axonal) injury related to the clinical history of head trauma." The motion reads as if it is my opinion that Mr. Ebel did not have imaging evidence of traumatic brain injury, and is different than Dr. Benson. Mr. Ebel did in fact have imaging consistent with TBI, and the location of his injury (grey-white junction) is typical of what we see in traumatic brain injury. Dr. Benson's more extensive DTI analysis does not "manufacture" inconsistent findings, but rather, supports and is consistent with my findings.

8. According to the Defendant's motion: "Use of DTI images is "the means" in question and Plaintiff's retained expert admits that DTI findings alone cannot establish the fact of a brain injury."

This statement inaccurately suggests that MRI imaging alone determines etiology of abnormality while the DTI sequence does not. I am unaware of any MRI technology, DTI or otherwise, that can by itself unequivocally determine etiology.

For example, an abnormal lung mass revealed on conventional MRI imaging of the chest can represent a benign mass, sarcoidosis, a cancerous tumor, tuberculosis, or other differential diagnosis. We do not ignore the imaging because it cannot "by itself" tell us the exact etiology. The findings on most MRI studies virtually always lead to a differential diagnosis with rare exceptions. The critical point is if the findings on an MRI-DTI are consistent with brain injury. We can than proceed to clinically rule out alternative diseases such as multiple sclerosis, stroke, substance abuse or infection. If the findings on MRI-DTI are consistent with brain injury the degree to which such injury has affected the patient as well as the time sequence of events is a clinical rather than solely neuroradiological determination. However, we do not ignore the neuroradiological evidence as clinicians, as such imaging evidence can help the understanding of an injury and assist in predicting clinical outcome.

Imaging can provide valuable insight to rule-out alternative disease processes. For example, Mr. Ebel's MRI findings did not progress or worsen in the 2 ½ years between the scans I performed in May 2010 and November 2012. There are alternative disease processes (e.g.

micro-vascular disease) that would be expected to progressively worsen with time. Further, there are locations in the brain which are well-known and described in the literature to be more specific to trauma, i.e. injury at the grey-white junction which was in fact clearly identified in Mr. Ebel. We do not clinically "ignore" these findings.

9. According to the Defendant's "MOTION" – "Experimental DTI findings to suggest a mTBI exists are not probative because they cannot be traced back to any particular cause."

As discussed in more detail below, DTI is not experimental. In a recent review of 100 separate articles on DTI over the past decade, it was reported by the *American Journal of Neuroradiology* that: "**the consensus is that DTI effectively differentiates patients with TBI and controls, regardless of the severity and timeframe following injury.**" This article, entitled "**A Decade of DTI in Traumatic Brain Injury, 10 Years and 100 Articles Later** illustrates that DTI is not an experimental tool. As noted above, the findings on MRI studies virtually always lead to a differential diagnosis with rare exceptions. The critical point is that the findings on Mr. Ebel's MRI were consistent with brain injury. In Mr. Ebel's case, he did in fact have findings in locations that are typically associated with trauma. To ignore the neuroradiological evidence would result in also ignoring the studies addressing recovery-outcome. This would be clinically inappropriate.

10. According to the Defendant's "MOTION: in New Mexico, five factors must be considered in determining whether scientific evidence is reliable:

> (1) whether a theory or technique has been tested; (2) peer review of the theory or technique; (3) the known potential rate of error in using a particular scientific technique "and the existence and maintenance of standards controlling the technique's operation;" and (4) whether the theory or technique has been generally accepted in the particular scientific field; and (5) "whether the scientific technique is based upon well-recognized scientific principles and whether it is capable of supporting opinions based upon reasonable probability rather than conjecture.
>
> I will address each of these below:

11. **The DTI-sequence of MRI has been extensively tested**; Diffusion tensor imaging (DTI) has been developed and refined for almost two decades. Testing of the DTI sequence is revealed by a PubMed literature search for diffusion tensor imaging, diffusion tensor tractography, diffusion tensor MR tractography, and MRI fiber tracking conducted on Mar 21, 2007 which yielded 1,490 references dating from 1994 to 2007. In the following two years, the number of DTI applications and utilizations for different conditions continued to rapidly climb. An identical PubMed search conducted on July 20, 2009 yielded 2,960 references. The literature created during the intervening two years from 2007 to 2009 nearly doubled (n=2,960) the amount of articles that were produced in the preceding 13 years (n=1,490). This literature illustrates extensive testing of DTI.

12. **DTI has been extensively peer reviewed;**

Rather than refer the Court to each of the hundreds of different articles supporting the use of DTI for evaluation of TBI, I would note that the *The American Journal of NeuroRadiology* recently published an article entitled: "A Decade of DTI in Traumatic Brain Injury, 10 Years and 100 Articles Later" in January, 2013. The authors noted that "**the consensus is that DTI effectively differentiates patients with TBI and controls, regardless of the severity and timeframe following injury.**" Further, the paper reaffirmed what we already knew before this publication, i.e. "**DTI is an extremely useful and robust tool for the detection of traumatic brain injury related brain abnormalities.**" A PubMed literature search for diffusion tensor imaging as a search term conducted on Oct 4, 2013 yielded 7,506 references (5 fold growth from 2007; 2.5 fold growth from 2009). Most of the articles listed in PubMed that utilize DTI technology are focused on the brain. Recently, the use of DTI has expanded to numerous other organ systems. However, most of the 7,506 articles are based on DTI analyses of the central nervous system.

13. **The known potential rate of error and existence and maintenance of standards controlling DTI**

The same article noted above established and reviewed these elements which is why we consider DTI "an extremely useful and robust tool for the detection of traumatic brain injury related abnormalities." The potential error rate for DTI in accurately identifying fiber track damage is well-known and described in the literature. It is recognized as a "robust tool for the detection of traumatic brain injury related brain abnormalities." *Id.* There are published guidelines for operation and interpretation of DTI (see attached "ASFNR Guidelines for Clinical Application of Diffusion Tensor Imaging.") and the literature has extensively detailed the existence and maintenance of the techniques controlling DTI. There are numerous peer-reviewed and case-control studies in the medical literature allowing for individual evaluations of brain injured patients using DTI. The comparison of cases (patients with a history of traumatic brain injury) and controls (no history of traumatic brain injury) utilizing DTI is an accepted methodology and standard technique utilized in order to demonstrate the clinical utility of DTI in adding incremental diagnostic information to structural MRI, multimodal MR studies, other imaging modalities and the clinical condition. (Arfanakis, Cordes et al. 2002; Ptak, Sheridan et al. 2003; Huisman, Schwamm et al. 2004; Gupta, Saksena et al. 2005; Inglese, Makani et al. 2005; Ewing-Cobbs, Hasan et al. 2006; Nakayama, Okumura et al. 2006; Voss, Uluc et al. 2006; Wilde, Bigler et al. 2006; Wilde, Chu et al. 2006; Bazarian, Zhong et al. 2007; Benson, Meda et al. 2007; Han, Kim et al. 2007; Kraus, Susmaras et al. 2007; Newcombe, Williams et al. 2007; Wozniak, Krach et al. 2007; Xu, Rasmussen et al. 2007; Yuan, Holland et al. 2007; Bendlin, Ries et al. 2008; Ewing-Cobbs, Prasad et al. 2008; Hanten, Wilde et al. 2008; Lipton, Gellella et al. 2008; Miles, Grossman et al. 2008; Newcombe, Williams et al. 2008; Niogi, Mukherjee et al. 2008; Niogi, Mukherjee et al. 2008; Rutgers, Fillard et al. 2008; Rutgers, Toulgoat et al. 2008; Wang, Bakhadirov et al. 2008; Wei, Tharmakulasingam et al. 2008; Wilde, McCauley et al. 2008 ; Kumar, Gupta et al. 2009; Lipton, Gulko et al. 2009; Lo, Shifteh et al. 2009; Tollard, Galanaud et al. 2009).

As just a sampling, the following articles pertain to the use of DTI in traumatic brain injury case-control studies:

1) As early as May of 2002, DTI was reported in the medical literature to show abnormalities in patients who suffered from mild brain trauma as compared to normal control subjects. "This study included five patients with mild traumatic brain injury (three men and two women) and 10 volunteers with no known neurologic disorders (five men and five women)." This study reported abnormalities in the patients with mild brain injury that were not found in the control subjects or the uninvolved sides of the injured patient's brains: "Patients displayed significant reduction of diffusion anisotropy in several regions compared with the homologous ones in the contralateral hemisphere. Such differences were not observed in the control subjects. Significant reduction of diffusion anisotropy was also detected when diffusion tensor results from the patients were compared with those of the controls. Please note that this **paper was submitted for publication in June of 2001 and accepted for publication in Oct. of 2001** "Received June 5, 2001; accepted after revision October 22, 2001.". Since it takes a considerable amount of time to prepare a publication for submission, this work was performed approximately 13 years ago. (Arfanakis, Cordes et al. 2002).

2) Another May 2002 report of similar findings of DTI abnormalities in head trauma that included patients with mild injury was presented to the American Society of Neuroradiology in May 2002."Presented at the 40th Annual Meeting of the American Society of Neuroradiology, May 2002, Vancouver, British Columbia, Canada." This peer reviewed publication evaluated brain injured patients and controls. The most severely injured subjects requiring neurosurgical intervention were excluded. "In addition, patients who had required emergency neurosurgical or surgical interventions or had experienced cardiovascular arrest ($n = 7$) were excluded." The patient population included patients with very mild head injury (modified Rankin Score = 0).." Their work was reported more than 10 years ago. The authors also state that CT and conventional MR imaging are not sufficient to evaluate brain trauma. "CT and conventional MR imaging underestimate injury and correlate poorly with outcome. New MR imaging techniques, including diffusion tensor imaging (DTI), can provide information about brain ultrastructure by quantifying isotropic and anisotropic water diffusion." In addition these authors conclude that DTI findings correlate well with both the acute and chronic clinical findings of brain trauma. "DTI reveals changes in the white matter that are correlated with both acute GCS and Rankin scores at discharge may be a valuable biomarker for the severity of tissue injury and a predictor for outcome." This article also serves as an example of how far the medical literature falls behind the actual practice of medicine. This article was first presented to the neuroradiology community in May of 2002, received for publication in Feb. of 2003, accepted for publication in Aug. of 2003 and finally published in March of 2004. "Received February 14, 2003; accepted after revision August 21, 2003." However, this information was available to Neuroradiolgists during the same month in May of 2002 from two separate sources (Huisman, Schwamm et al. 2004).

3) In 2005, DTI was reported in a case control study that compared 46 mild brain injured patients to 29 normal control subjects. "Forty-six patients with mild TBI and 29 healthy volunteers underwent a magnetic resonance (MR) imaging protocol including: dual-spin echo, fluid-attenuated inversion recovery, T2-weighted gradient echo, and diffusion tensor imaging sequences. In 20 of the patients, MR imaging was performed at a mean of 4.05 days after injury. In the remaining 26, MR imaging was performed at a mean of 5.7 years after injury." The

authors of this study conclude: "Because diffusion tensor imaging changes are present at both early and late time points following injury, they may represent an early indicator and a prognostic measure of subsequent brain damage (Inglese, Makani et al. 2005).".
4) In 2006 a study of 23 patients with mild TBI who had no abnormalities on routine MR imaging was compared to healthy controls. "Non-missile traumatic brain injury (nmTBI) without macroscopically detectable lesions often results in cognitive impairments that negatively affect daily life. AIM: To identify abnormal white matter projections in patients with nmTBI with cognitive impairments using diffusion tensor magnetic resonance imaging (DTI). METHODS: DTI scans of healthy controls were compared with those of 23 patients with nmTBI who manifested cognitive impairments but no obvious neuroradiological lesions." These authors conclude in 2006 that: "Disruption of the corpus callosum and fornix in patients with nmTBI without macroscopically detectable lesions is shown. DTI is sensitive enough to detect abnormal neural fibres related to cognitive dysfunction after nmTBI (Nakayama, Okumura et al. 2006)."
5) In 2007, another study compared DTI in mild traumatic brain injured patients to normal control subjects. These authors found not only that there were abnormalities on DTI in the patients that were not seen in the normal controls but that these abnormalities also correlated with the clinical abnormalities in these patients. "Collectively, DTI detected significantly lower trace and elevated FA values in mild TBI subjects compared to controls. These abnormalities correlated to poor clinical outcome (Bazarian, Zhong et al. 2007)."
6) Yet another 2007 study compared mild brain injured patients to control subjects: "six mild TBI (GCS 13-15), and 14 healthy age-matched controls." This study found that the severity of the abnormalities on DTI correlated with the clinical findings in the injured patients. "FA is globally decreased in WM, including mild TBI, possibly reflecting widespread involvement. FA changes appear to be correlated with injury severity suggesting a role in early diagnosis and prognosis of TBI (Benson, Meda et al. 2007)."
7) In another 2007 article that included mild traumatic brain injured patients compared to controls the authors stated: "Traumatic brain injury (TBI) is a serious public health problem. Even injuries classified as mild, the most common, can result in persistent neurobehavioural impairment. Diffuse axonal injury is a common finding after TBI, and is presumed to contribute to outcomes, but may not always be apparent using standard neuroimaging. Diffusion tensor imaging (DTI) is a more recent method of assessing axonal integrity in vivo." The authors compared 20 mild and 17 moderate to severe brain injured patients to 18 controls. "Twenty mild, 17 moderate to severe TBI and 18 controls underwent DTI and neuropsychological testing." Decreased FA values were found in both the moderate to severe and the mild patients compared to the control subjects, and as would be expected the DTI results were worse in the more severely injured patients. "Decreased fractional anisotropy was found in all 13 regions of interest for the moderate to severe TBI group, but only in the cortico-spinal tract, sagittal stratum and superior longitudinal fasciculus for the mild TBI group. The authors conclude that the more severe the DTI abnormalities the more severe the clinical symptoms, and that this relationship holds even when the DTI is performed years after the injury. "The present data emphasize that white matter changes exist on a spectrum, including mild TBI. An index of global white matter neuropathology (White Matter Load) was related to cognitive function, such that greater white matter pathology predicted greater cognitive deficits. Mechanistically, mild TBI white matter changes may be primarily due to axonal damage as opposed to myelin damage. The more severe injuries impact both. DTI provides an objective means for determining the relationship of cognitive deficits to TBI, even in cases where the injury was sustained years prior to the

evaluation (Kraus, Susmaras et al. 2007)."
8) A 2008 study used DTI to evaluate patients with mild traumatic brain injury comparing 17 patients with 10 healthy controls. "We retrospectively analyzed diffusion tensor MRI (DTI) of 17 patients (nine women, eight men; age range 26-70 years) who had cognitive impairment due to mild TBI that occurred 8 months to 3 years prior to imaging." Comparison was made to 10 healthy controls. Abnormal decreased FA values were seen in the corpus callosum of these patients. "Areas of significantly decreased FA ($p < 0.005$) were found in the subject group in corpus callosum, subcortical white matter, and internal capsules bilaterally." The authors also state: "Similar, though less extensive, findings were demonstrated in each individual patient." The authors conclude: "Evaluation of single subjects also reveals foci of low FA, suggesting that DTI may ultimately be useful for clinical evaluation of individual patients
(Lipton, Gellella et al. 2008)."
9) Another study published in 2008 compared 17 mild traumatic brain injured patients to 29 control subjects. "Seventeen patients with MTBI and 29 sex- and age-matched healthy controls were studied" This study also found a decrease in FA values in head injured patients as compared to controls. "Compared to controls, average MD was significantly higher ($p = 0.02$) and average FA significantly lower ($p = 0.0001$) in MTBI patients. These authors conclude: "DTI may provide short-term non-invasive predictive markers of cognitive functioning in patients with MTBI (Miles, Grossman et al. 2008)."
10) An additional study in 2008 compared 34 patients with mild brain injury to 26 control subjects. "Thirty-four adult patients with mild TBI with persistent symptoms were assessed for DAI by quantifying traumatic microhemorrhages detected on a conventional set of T2*-weighted gradient-echo images and by DTI measures of fractional anisotropy (FA) within a set of a priori regions of interest. FA values 2.5 SDs below the region average, based on a group of 26 healthy control adults, were coded as exhibiting DAI." These authors found DTI damage in multiple brain regions. "DTI measures revealed several predominant regions of damage including the anterior corona radiata (41% of the patients), uncinate fasciculus (29%), genu of the corpus callosum (21%), inferior longitudinal fasciculus (21%), and cingulum bundle (18%)." The authors conclude: "Microstructural white matter lesions detected by DTI correlate with persistent cognitive deficits in mild TBI, even in populations in which conventional measures do not. DTI measures may thus contribute additional diagnostic information related to DAI
(Niogi, Mukherjee et al. 2008)."
11) A 2009 study of 20 mild traumatic brain injured patients compared to 20 control subjects showed decreased FA values that correlated to decreased executive function. "Diffusion-tensor imaging and standardized neuropsychologic assessments were performed in 20 patients with mTBI within 2 weeks of injury and 20 matched control subjects." This study showed that lower frontal FA values were found in patients with decreased executive function. "Multiple clusters of lower frontal white matter FA, including the dorsolateral prefrontal cortex (DLPFC), were present in patients ($P < .005$), with several clusters also demonstrating higher MD ($P < .005$). Patients performed worse on tests of executive function. Lower DLPFC FA was significantly correlated with worse executive function performance in patients ($P < .05$)." The authors concluded: "Impaired executive function following mTBI is associated with axonal injury involving the DLPFC." (Lipton, Gulko et al. 2009).
12) In 2012 diffusion tensor imaging was used to confirm mild traumatic brain injury in a 68-year-old previously healthy woman who was involved in a motor vehicle accident. After the accident, she experienced symptoms indicative of mild traumatic brain injury and a diagnosis of

post-concussion syndrome was suggested. Diffusion tensor imaging revealed decreased fractional anisotropy in the region immediately adjacent to both lateral ventricles, which was used to confirm the diagnosis. There was a significant relationship between the clinical assessment and imaging results. The authors conclude: "This would not have been possible using traditional imaging techniques and highlights the benefits of using diffusion tensor imaging in the sub-acute assessment of minor traumatic brain injury." (Krishna, Giordano, et al. 2012).
13) A 2013 paper evaluated diffusion tensor imaging (DTI) and multiple measures of cognitive functioning in 12 individuals with a history of traumatic brain injury (TBI) and 12 control participants. The study used neuropsychological tests and detailed analysis of DTI. The TBI group demonstrated DTI values suggesting decreased white matter integrity and correlated with severity of brain injury. Both groups showed correlations between DTI parameters and cognitive measures, with more significant correlations observed for the TBI group. White matter changes in the CC were evident chronically and were related to severity of injury. The authors conclude: "Diffusion tensor imaging parameters suggesting disruptions in white matter in the CC may be implicated in impaired performance, both in terms of cognitive tasks and reaction time, after TBI." (Arenth, Russell, et al 2013).

14. **Whether the theory or technique has been generally accepted in the particular scientific field;**

The acceptance of the MRI-DTI sequence is reflected by peer-reviewed medical literature, by the publication of guidelines for operation and interpretation as well as years of daily use of the imaging method in the care of patients. In the case of diffusion tensor imaging there are published guidelines for operation and interpretation (see attached "ASFNR Guidelines for Clinical Application of Diffusion Tensor Imaging."). As is evident from the peer-reviewed published literature on utilization of DTI in patients suffering from mild head trauma, DTI is an important imaging method in the evaluation of patients. It is used by numerous radiology departments as shown in the above publications. I have personally been using DTI on a daily clinical basis for over 5 years and have performed more than 10,000 DTI examinations. I rely on the literature to form the basis of my use of DTI and DTI is not experimental in view of daily clinical use and more than 7,000 peer-reviewed publications on the topic dating to 1994.

15. According to Defendant's "MOTION, DTI is a relatively new type of MRI that measures the movement of water along a magnetic field. There is no known potential rate of error in using DTI to diagnose mTBI in a single-subject, Id., and there are no standards controlling the technique's operation."

This is simply not correct. I have addressed above how well-established the use of DTI is in the clinical evaluation of TBI in single subjects. There are published guidelines for operation and interpretation of DTI (see attached "ASFNR Guidelines for Clinical Application of Diffusion Tensor Imaging.") In addition to the 12 other case controlled studies included above, case 12 (Krishna, Giordano, et al) is another example of the reliable use of DTI to make a diagnosis of traumatic brain injury in a "single-subject" involved in an isolated event of trauma.

16. According to the Defendant's "MOTION, "While DTI research shows differences between brains that have suffered mTBI from normal brains, the "readiness for single-subject use" of DTI in diagnosing mTBI in a clinical setting "has yet to be demonstrated".

This is incorrect. DTI has been extensively reported in the peer-reviewed medical literature to make a diagnosis of traumatic brain injury in a "single-subject" who was involved in isolated trauma. (Krishna, Giordano, et al). Further, Gold, MM, Lipton, ML. Neurological Picture: Diffusion Tractography of axonal degeneration following shear injury, *J. Neurol Neurosurg*, 2008; 79:1374-75 report the use of DTI in individual TBI cases. I will not reiterate the extensive literature on this subject.

17. According to the Defendant's "MOTION, DTI Findings Are Non-Specific, i.e., One Cannot Determine the Etiology of White Matter Changes."

This is a misleading statement as it again inaccurately suggests that reliable imaging "by itself" and without clinical correlation should have the ability to exclusively and unequivocally determine etiology. As with my lung-mass analogy above, no MRI imaging "by itself" gives unequivocal etiology. However, we do not ignore the neuroradiological data because it does not "by itself" unequivocally provide the etiology.

18. Defendant's "MOTION" cites a forensic psychiatrist's article (Wortzel) in support. To my knowledge Dr. Wortzel is neither a neurologist nor neuroradiologist. The article was not published in any neuroimaging, neurology, or Brain-Trauma/Brain Rehabilitation Journal. The article has a vey low peer reviewed Impact Factor of 0.93, which means it comes from a minimally influential journal. To understand, at most Universities, if you consistently publish in journals with low impact factors (<1.0) you would not be able to obtain tenure. The literature cited herein is far more authoritative and comprehensive than the article by Dr. Wortzel.

The references I have relied upon include the following:

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FURTHER YOUR AFFIANT SAYETH NAUGHT.

WILLIAM W. ORRISON, JR, M.D.

SUBSCRIBED and SWORN to before me
this 10th day of October, 2013.

ABDI HERSI

NOTARY PUBLIC

H. ABDI
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 09-02-2015
Certificate No: 11-5561-1

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS. SUPERIOR COURT DEPT.

C.A. NO. 08-2380

RICHARD ZAWASKI,
Plaintiff

v.

GIGS, LLC, and
WENDELL LEE ZORMAN,
Defendants

AFFIDAVIT OF RANDALL BENSON, M.D.

I, Randall Benson, hereby depose and state under oath as follows:

I. My credentials:

1. That I am currently employed by the Detroit Medical Center and Wayne State University as a neurologist. I attended Hahnemann University in Philadelphia and did a residency at Boston University in neurology. I completed a fellowship in behavioral neurology and cognitive neuroimaging at Massachusetts General Hospital. This fellowship included clinical training in cognitive disorders as well as research and development of clinical neuroscience applications of functional MRI . This technique has become generally accepted by the medical community and is now clinically reimbursable by most insurance companies. I am also board certified in neurology and psychiatry. My curriculum vitae is attached to this Affidavit as Exhibit A. I have published extensively on brain injury and Diffusion Tensor Imaging (DTI) in peer-reviewed journals as shown in Exhibit A.

2. As part of my work, my group at Wayne State has been using advanced MRI imaging to study brain injuries in former National Football League football players. This work was funded by the NFL to study 120 former players. I was recently asked to testify before the United States House Judiciary Committee (January 4, 2010) at a field hearing on the subject of brain injuries in football players. I suggested that advanced imaging methods (including DTI) would improve the diagnosis and management of concussions in sports. I showed the committee and attendees imaging data from sports and non-sports related brain injuries. Additionally, I am an investigator on a 15-year, continuously funded National Institute on Disability and Rehabilitation Research (NIDRR) grant (project entitled, "Utility of MRI Techniques in Prediction of TBI Outcome"). The current grant award includes both DTI and SWI imaging

components and was subjected to peer-review by NIDRR which is a division of the U.S. Department of Education.

3. I have been actively involved in MR imaging since 1992 and in Diffusion Tensor Imaging (DTI) since 2004.

4. I have unique qualifications as an expert on this case. I am a fellowship-trained behavioral neurologist who has evaluated and treated hundreds of patients with head trauma and have been engaged in brain imaging research using advanced MRI methods for 18 years. My focus has been TBI imaging for the past 5 years at the MR Research Center at Detroit Medical Center together with an MR scientist, E. Mark Haacke, Ph.D. I published a seminal paper delineating the alterations in DTI parameters in TBI and the correlation of DTI (FA) with injury severity including mild TBI. Along with the members of my research group, I have presented or published extensively on the use of DTI for TBI emphasizing proper methodology and precautions to avoid misinterpretation. On June 2-3, 2010, in recognition of the already demonstrated importance of diffusion tensor imaging to diagnose TBI, the U.S. Army Telemedicine and Advanced Technology Research Command (TATRC) sponsored the "Diffusion MRI TBI Roadmap Development Workshop", wherein it was acknowledged that, "*DTI has detected abnormalities associated with brain trauma at several single centers*" and "*the workshop seeks to identify and remove barriers to rapid translation of advanced diffusion MRI technology for TBI...in order to expedite getting the benefits of diffusion MRI to reach those who need it most, especially injured soldiers and veterans*". As one of 50 or so "experts from academia, industry, government agencies and several European nations", I presented in a session entitled, "Experience in Neuroimaging Translation to Clinical Use". My talk entitled, "Global and Voxel-based approaches to DTI in TBI" included a comprehensive approach to imaging mild TBI which was the culmination of over six years of peer-reviewed published research on DTI and TBI. I used both group and single cases to demonstrate the clinical validity and reliability of DTI in TBI. In addition to demonstrating the excellent correlation between DTI and injury severity, I showed the repeatability of DTI for a single mTBI case scanned in two different cities, and for a different mTBI case scanned twice 6 weeks between scanning sessions. I also used a third mTBI case to demonstrate the excellent correspondence between hemorrhage location (using susceptibility imaging) and abnormally low FA on DTI in these cases. Other speakers presented data showing the correlations of DTI with neurocognitive outcome and experience using DTI on Iraq war veterans. A major focus of the meeting was the need to standardize DTI methods across imaging sites in order to make it widely available as a diagnostic modality at clinical sites for civilian and military TBI.

II. What is DTI;

5. A traditional MRI shows the structure of the brain. The majority of people who have sustained mild traumatic brain injury ("mTBI") have normal MRI findings, even when they have significant impairment. An overwhelming majority of people with mTBI have normal CT

scans even with significant impairments. In fact, I have personally been involved with patients in coma who have normal CT Scans.

6. DTI examines the microstructure of the white matter of the brain, allowing for the detection of microscopic pathology or abnormality of the white matter. DTI is an FDA approved, peer reviewed and approved, commercially marketed, and widely available MRI method which has been in clinical use for many years.

7. DTI is a more sensitive technology that can reveal abnormalities that are not visible on standard MRIs. In fact, a major drive in the research and development of DTI is its ability to detect that which is largely invisible to MRI and CT.

8. DTI measures the direction of movement or flow (known as diffusion) of water molecules through tissue. DTI is based upon the basic physics of the flow of water. With *no barriers* to flow, water will move in an isotropic distribution, which means it will move equally in all directions. If there *are barriers* to flow, it will move anisotropically or unequally in all directions.

9. DTI has the ability to measure the distribution of water throughout the brain by specifically measuring the flow of water in the many voxels of the brain. Voxels are like the pixels in a digital camera. Unlike an image from a digital camera, however, each of the MRI pixels has three dimensions, the left-right and up-down dimensions of the slice as well as the thickness of the slice. When multiple slices are stacked atop one another, the result is the full volumetric representation of the brain.

10. DTI measures the distribution of water in each voxel with the degree of anisotropy (non-sphericity) expressed as a fraction of the total diffusion, i.e., fractional anisotropy (FA), which can range between zero (completely isotropic diffusion) and one (completely anisotropic diffusion).

11. White matter of the brain is comprised of axons which are long processes extending from the nerve cells which constitute the gray matter. Axons are organized into thick, tubular tracts which extend from one brain region to another similar to electrical cables. Water diffusion is much greater along the long axon than across it and therefore has a relatively anisotropic distribution (higher FA). Closed head injury (or non-penetrating TBI), induced by sudden acceleration or deceleration of the head, results in widely scattered damage to white matter fibers known as "diffuse axonal injury". This damage includes segmental breakdown in the outer membrane of the axon increasing diffusion in the short axis dimension leading to more isotropic distribution (decreased FA).

12. Since milder traumatic injuries, which are not visualized on standard clinical MRI scans, cause a relatively modest reduction in FA which cannot be seen by visual inspection, quantitative analysis of images is performed, whereby a TBI patient's FA images are statistically analyzed using a set of non-TBI controls' brain images as the reference standard. This method is performed in an automated fashion on the white matter *globally* and *voxel by voxel* after coregistration of brain images or tracts into standard space. Comparing TBI images against a set of non-TBI brain images has been demonstrated by my group to be a sensitive, reliable, and objective means of distinguishing normal from TBI.

III. The control group:

13. The control group, against which Mr. Zawaski's images were compared, statistically fits within the generally accepted definition of "control group" in empirical science. I have presented this methodology at The American Academy of Neurology and The International Society of Magnetic Resonance in Medicine annual meetings. This is the control group I use clinically at the Detroit Medical Center when performing DTI on mTBI patients and other TBI patients.

14. The control group of 19 that I used met the following inclusion criteria: 1) no history of TBI; 2) no history of neurologic or psychiatric disorder

15. In addition, quantitative results with this control group of 19 have been demonstrated by my lab previously to be indistinguishable from a group of 50 healthy volunteers containing a wide age range but are achievable at a fraction of the time.

IV. How Mr. Zawaski's DTI was calculated:

16. For the voxel based analysis, to ensure excellent registration between Mr. Zawaski's images and the controls, an automated multistep process was performed which included both linear and nonlinear matching to template with white matter weighting, elimination of non white matter voxels in any subject and use of an FA minimum to minimize areas of major fiber incoherences.

17. The age effect on FA is well known in the peer-reviewed literature and easily controlled for. Likewise, the difference between a 1.5T and 3T MRI is easily accounted for, as I have personally conducted studies wherein multiple people were scanned using both a 1.5T scanner and then a 3T scanner, and their FA scores have been compared. From these studies published in peer reviewed literature, the difference in the strength of the scanner signal is easily accounted for by a mathematical formula.

18. For Mr. Zawaski's quantitative analysis, only voxels with FA values reduced by more than 3 standard deviations from the mean were counted as abnormal. Three standard deviations covers 99.7% of the distribution pattern. That means that the odds of randomly falling three standard deviations below the mean by pure chance is 0.15 out of a hundred and the odds of finding a voxel three standard deviations above the mean is also .15 out of 100 (or 1 out of 660).

19. Since the computer performed 134,733 voxel analyses, statistically speaking, there should be by chance 202 voxels (.0015%) that are at least 3 standard deviations below the mean. Mr. Zawaski's image results revealed a total of 681 voxels which were at least 3 standard deviations below the mean or more than 3 times what would be expected by chance.

20. To minimize the false positive rate (number of voxels incorrectly called abnormal) a size criterion had to be met for clusters with voxels of reduced FA. Specifically, cluster size had to be at least 1 standard deviation greater than the mean cluster size for the controls (upper 16%). The probability of having large clusters (contiguous voxels) of reduced

FA is determined analytically on the control group in order to further ensure that the patient in question is similar or significantly different from the control group. Since the odds of having a cluster of this size was 1 out of 6, the odds of having voxels of sufficiently reduced FA included in clusters which are 1 standard deviation larger than the mean was 1 in 4,166. Mr. Zawaski had five such clusters which met both voxel-wise and cluster-wise thresholds.

21. Statistically speaking, the clusters of abnormal voxels found in areas of Mr. Zawaski's brain were there by chance are next to impossible. DTI determined that Mr. Zawaski has abnormally reduced FA in several white matter tracts including corticospinal, coronal radiata, internal capsule, deep temporal white matter and corpus callosum.

22. I then confirmed these findings using Tract Based Spatial Statistics, a second method of quantification of the DTI imaging results which is less prone to false positive error caused by mis-registration between subjects' brain images. The second method, tract based spatial statistics, is used world-wide to reduce the error caused by misalignment of brain images. The results of these two different methods using different statistics and different alignment methods were concordant in revealing abnormalities in the same locations—locations which are typical of traumatic axonal injury.

23. Further validating the DTI results are findings on the Flair Sequence MR exam. I found as follows:

"A few very small high signal foci located at gray-white junction bilaterally on FLAIR. Likely represent trauma rather than ischemia given size and location."

Injury at the junction of gray-white matter is classic in traumatic axonal injury.

24. It is generally accepted in the scientific community throughout the peer reviewed literature that DTI is a reliable and accurate tool to detect microscopic damage done to the white matter of the brain. There have been numerous validation studies in the peer reviewed literature, including studies that Dr. Bammer's testimony himself cites, that validate the use of DTI to detect axonal injury.

25. DTI is used clinically at the Detroit Medical Center and as a diagnostic tool. In fact, the entire sequence given to Mr. Zawaski , including DTI, was the standard trauma protocol at the Detroit Medical Center. I understand that DTI is used clinically in other parts of the country and is reimbursable by health insurance companies.

V. The Role of DTI in diagnosing mTBI:

26. The defense is correct that DTI cannot tell the reason why there is damage to the white matter or when it occurred; DTI is not alone in this "deficiency". There are very few tests that are highly specific. However, using that logic, CT, MRIs, X-ray, ultrasound, radionucleotide scanning and other clinical radiologic tests are not reliable because they are not specific; hematomas shown on CT or MRI could have been caused by TBI, stroke, or an aneurysm. A blood test showing an elevated CPK MB fraction could be caused by a heart attack or an electric shock through the heart.

27. Significant brain injury from trauma does not require loss of consciousness or even clinical symptoms at the time of injury and is therefore difficult to diagnose accurately on clinical grounds alone. Standard clinical imaging is usually negative, since the pathology is *microscopic damage to axons*, i.e., "diffuse axonal injury", which is undetectable by standard structural imaging and clinical EEG. Only the more severe cases or those complicated by hemorrhage reveal changes on standard clinical imaging. The clinical consequences of this type of injury, particularly milder cases, which affects the connections *between* nerve cells rather than the nerve cell bodies themselves, are usually cognitive and psychiatric and frequently misattributed to: 1) side effects of medications; 2) post-traumatic stress disorder, and; 3) malingering. The importance of "mild" TBI has certainly been brought to the public's attention recently through two wars where TBI was the signature wound and through sports-related TBI in former and current NFL football players who manifest cognitive and neuropsychiatric symptoms or overt dementia. Very recently, autopsy results on a 26 year old active NFL player, with no history of concussion in college or the NFL, revealed evidence of *moderate chronic* traumatic brain injury, giving credence to the notion that sub-concussive blows to the head *do* cause significant brain injury, even when there are no obvious clinical symptoms.

28. As is my customary practice, I met with Rich Zawaski before reviewing any medical records. I do this to avoid any bias towards previous diagnoses made by other clinicians. I interviewed the patient at length and performed a neurobehavioral examination. I utilized the results of medically accepted neurological and mental status examination techniques to formulate my clinical assessment. With respect to my overall opinions I relied on my education, experience and training and generally accepted scientific methodologies. I then wrote an office note as is my customary practice wherein I felt that he likely sustained a traumatic brain injury.

29. I then had the initial results of the trauma imaging protocol administered to Mr. Zawaski. I found, "Low FA in these white matter regions is consistent with traumatic axonal injury suggested by the patient's history of being rear-ended by a large truck and postconcussive syndrome."

30. I also found "A few areas of decreased signal on FLAIR in bilateral superior frontal gyral white matter suggesting chronic microvascular change or less likely trauma."

31. I performed the second analysis using TBSS that confirmed my earlier findings. On a closer review of the FLAIR, I determined that the abnormality was more likely due to trauma rather than ischemia, given its size and the location at the junction of the gray-white junction. This region is more susceptible to trauma.

32. I also interviewed Mrs. Zawaski on February 21, 2010. Mrs. Zawasksi provided further history and evidence of traumatic brain injury. By this time, I had fully reviewed the medical records which provided documentation of classic postconcussive syndrome and provided me multiple sources to document a change in Mr. Zawaski's functioning, post-crash.

33. My clinical examination of Rich, together with his history and presentation, validated the detection of diffuse axonal injury with DTI. In addition, the QEEG results validated the results of the DTI.

34. While DTI itself cannot diagnose the cause of the white matter damage, Mr. Zawaski's history and medical records provide a solid basis to conclude the damage shown on DTI and FLAIR was caused by the events of March 21, 2006.

35. The role of DTI and the purpose for which I (or anyone else) used it is a tool to help assist in the diagnosis of traumatic brain injury. It is for this reason that I use the term "suggests" in the DTI report. DTI did not diagnose mTBI in Rich Zawaski, I did, along with other doctors who examined him.

VI. Problems with Dr. Bammer's purported testimony:

36. Dr. Bammer's purported testimony states that "the scientific community uses DTI as an investigative tool... to understand the pathophysiology of certain diseases." Certainly, in order for DTI to be useful for understanding the pathophysiology of **any** disease, it must be believed that DTI has the requisite sensitivity and specificity to do so. He is wrong when he states that "detectable abnormalities [in DTI] are usually associated with other abnormalities in conventional MRI." This is circular logic. **DTI's utility is in its sensitivity to microstructural alterations not evident on clinical imaging.**

37. Dr. Bammer's purported testimony states "If an abnormality was seen four years after the subject accident, abnormalities should have been seen in plaintiff's CT Scan taken within three days after the accident." This is not medically supported. CT Scan cannot detect axonal shearing and is only useful in brain imaging to detect blood on the brain. In my clinical practice, I have seen patients in coma who have normal CT Scans. CT Scans cannot and do not show axonal shearing.

38. Dr. Bammer also states that Mr. Zawaski's DTI results could be explained by working with a jackhammer. I am not aware of any studies that indicate that use of a jackhammer causes axonal damage. I am not aware that Mr. Zawaski was involved in any other incident that accounts for the damage to his white matter.

VII. DTI in the medical literature:

39. The first DTI paper was published in 1994.

40. As of early, 2010, there are currently 3,472 papers on DTI which have been published in peer review journals to date, of which 83 concern *both* DTI and TBI. A control group was used for statistical analysis of results for 35 of the 83 papers.

41. A number of studies to date, many of which the defense cites, have shown DTI measures correlate with severity of TBI, with specific neuropsychological impairment and with long-term outcome. Equivocal or negative results have largely been obtained only in the early acute setting because of the early cytotoxic edema seen in the first few days.

42. In their Motion, the defense's references to the literature do not include more recent references which reflect progress in the field. The following quotes reflect the increasing confidence that DTI can be used as a surrogate for white matter injury, that the degree of DTI abnormality reflects neurocognitive impairment and that DTI reflects histopathological changes:

"*This study supports the view that DTI is a valuable tool for assessing the integrity of white matter structures and for selectively predicting functional motor deficits in TBI patients*"

1. Hum Brain Mapp. 2010 Jul;31(7):992-1002.

Brain-behavior relationships in young traumatic brain injury patients: DTI metrics are highly correlated with postural control.

Caeyenberghs K, Leemans A, Geurts M, Taymans T, Linden CV, Smits-Engelsman BC, Sunaert S, Swinnen SP, J Head Trauma Rehabil. 2010 Jul-Aug;25(4):241-55.

"*researchers have shown that frontal and temporal association white matter pathways are most frequently damaged in mTBI and that the microstructural integrity of these tracts correlates with behavioral and cognitive measures.*"

Diffusion tensor imaging of mild traumatic brain injury.
Niogi SN, Mukherjee P. Neuropsychologia. 2010 Apr;48(5):1472-82. Epub 2010 Feb 1.

"*based on the combined application of DTI and behavioral measures, was the most effective in distinguishing between TBI patients and controls.* "

Brain-behavior relationships in young traumatic brain injury patients: fractional anisotropy measures are highly correlated with dynamic visuomotor tracking performance.

Caeyenberghs K, Leemans A, Geurts M, Taymans T, Vander Linden C, Smits-Engelsman BC, Sunaert S, Swinnen SP. Neurology. 2010 Feb 23;74(8):643-50. Epub 2010 Jan 20.

"*Diffusion tensor imaging measurement may have utility for objectively classifying mTBI, and may serve as a potential biomarker of recovery.*"

A prospective diffusion tensor imaging study in mild traumatic brain injury.

Mayer AR, Ling J, Mannell MV, Gasparovic C, Phillips JP, Doezema D, Reichard R, Yeo RA. Comment in: Neurology. 2010 Feb 23;74(8):626-7.

The Mind Research Network, Pete & Nancy Domenici Hall, 1101 Yale Blvd. NE, Albuquerque, NM 87106, USA. amayer@mrn.org

"Whole-brain WM DTI measures can detect abnormalities in acute mTBI associated with PCS symptoms in adolescents."

AJNR Am J Neuroradiol. 2010 Feb;31(2):340-6. Epub 2009 Dec 3.

Voxel-based analysis of diffusion tensor imaging in mild traumatic brain injury in adolescents.

Chu Z, Wilde EA, Hunter JV, McCauley SR, Bigler ED, Troyanskaya M, Yallampalli R, J Head Trauma Rehabil. 2010 Jan-Feb;25(1):31-42.

"FA and RD indices appear to be surrogate markers of microstructural alterations in patients over time and correlate significantly with some of the NPT scores. The recovery in these indices associated with recovery in neurocognitive deficits suggests that these indices may be used as an objective marker for residual injury in these patients."

Serial changes in diffusion tensor imaging metrics of corpus callosum in moderate traumatic brain injury patients and their correlation with neuropsychometric tests: a 2-year follow-up study.

Kumar R, Saksena S, Husain M, Srivastava A, Rathore RK, Agarwal S, Gupta RK. J Neurotrauma. 2009 Nov;26(11):1879-90.

Department of Neurosurgery, Chhatrapati Shahuji Maharaj Medical University, Lucknow, India.

"These results indicate that DTI is a useful technique not only for detecting DAI lesions but also for examining cognitive disorders in DAI patients."

Clinical utility of diffusion tensor imaging for evaluating patients with diffuse axonal injury and cognitive disorders in the chronic stage.

Sugiyama K, Kondo T, Oouchida Y, Suzukamo Y, Higano S, Endo M, Watanabe H, Shindo K, Izumi S. Radiology. 2009 Sep;252(3):816-24. Epub 2009 Jun 30.

"Lower DLPFC FA was significantly correlated with worse executive function performance in patients (P < .05)."

Diffusion-tensor imaging implicates prefrontal axonal injury in executive function impairment following very mild traumatic brain injury.

Lipton ML, Gulko E, Zimmerman ME, Friedman BW, Kim M, Gellella E, Gold T, Shifteh K, Ardekani BA, Branch CA. J Comput Assist Tomogr. 2009 Mar-Apr;33(2):293-7.

"These results demonstrate low FA and high ADC in the genu of the corpus callosum of mild TBI patients with persistent cognitive impairment"

Diffusion tensor imaging abnormalities in patients with mild traumatic brain injury and neurocognitive impairment.

Lo C, Shifteh K, Gold T, Bello JA, Lipton ML. Cancer Res. 2009 Feb 1;69(3):1190-8. Epub 2009 Jan 20.

"DTI indices reflected the histopathologic changes of WM damage and our results support the use of DTI as a biomarker."

Longitudinal diffusion tensor magnetic resonance imaging study of radiation-induced white matter damage in a rat model. Brain. 2008 Dec;131(Pt 12):3209-21. Epub 2008 Oct 24.

Wang S, Wu EX, Qiu D, Leung LH, Lau HF, Khong PL.

"More generally, such findings suggest that diffusion anisotropy measurement can be used as a quantitative biomarker for neurocognitive function and dysfunction."

Structural dissociation of attentional control and memory in adults with and without mild traumatic brain injury.

Niogi SN, Mukherjee P, Ghajar J, Johnson CE, Kolster R, Lee H, Suh M, Zimmerman RD, Manley GT, McCandliss BD.

SIGNED UNDER THE PAINS AND PENALTIES OF PERJURY THIS DAY OF JULY, 2010

RANDALL BENSON, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

HUANNI YANG-WEISSMAN, Plaintiff, v. SOUTH CAROLINA PRESTRESS CORPORATION, Defendant.	Civil Action No: 4:07-cv-03643-RBH

AFFIDAVIT OF MICHAEL L. LIPTON, M.D., PH.D.

PERSONALLY APPEARED before me, Michael L. Lipton, M.D., Ph.D., who, after being duly sworn, does state as follows:

1. I am above the age of majority, competent to testify to the matters herein, and make this declaration upon my own personal knowledge and belief.

2. I am a neuroradiologist and am board certified by the American Board of Radiology in diagnostic radiology. I also have a Certificate of Added Qualification and a current Maintenance of Certification, both in the field of neuroradiology.

3. I am the Associate Director of the Gruss Magnetic Resonance Research Center at the Albert Einstein College of Medicine and serve as its Director of Research for the Department of Radiology. I am an associate professor of radiology, psychiatry, behavioral sciences and neuroscience. I am also the Medical Director for the clinical MRI services at Montefiore Medical Center.

4. I am an attending physician at Montefiore Medical Center, Jacobi Medical Center, and North Central Bronx Hospital.

5. Due to my education, training, experience, research and publications in the field of neuroradiology, I am familiar with and knowledgeable concerning the standards and practices of neuroradiologists, including the conduct, review, and interpretation of neuroimaging studies acquired by means of magnetic resonance imaging ("MRI"). My curriculum vitae is attached to this affidavit as Exhibit A.

6. Heidi Yang-Weissman, the Plaintiff in this lawsuit, was referred to me by her treating physician, Morton Finkel, M.D. On July 15, 2009, a non-contrast MRI of Mrs. Yang-Weissman's brain was performed including diffusion tensor imaging ("DTI") on a Philips 3.0 Tesla MRI scanner.

7. While the traditional MRI shows the structure of the brain, DTI is more sensitive and can reveal abnormalities that are not visible on standard MRIs.

8. DTI is in widespread clinical use and is also extensively used in brain research.

9. I have over ten years' experience working with DTI technology and over eight years' experience using DTI technology in conjunction with the diagnosis of brain injury.

10. DTI is capable of reliably and accurately indicating the presence of brain injury. This fact is widely documented in the peer-reviewed medical literature and published studies.

11. Thousands of papers endorsing the use of DTI have been published in peer reviewed journals, many of which have specifically concerned DTI and traumatic brain injury. Numerous peer-reviewed studies have established that abnormal anisotropy as measured by DTI demonstrates evidence of traumatic brain injury pathology not detectable using other imaging methods.

12. DTI measures the direction of movement or flow (known as diffusion) of water molecules through tissue.

13. Unlike other imaging technologies, DTI permits examination of the microscopic structure of the white matter of the brain, allowing for the detection of microscopic pathology or abnormality of the white matter.

14. In the white matter of a normal/healthy brain, the direction of water diffusion is very uniform. Injury disrupts the normal structure of white matter leading to less uniform direction of diffusion.

15. In the clinical setting, DTI can be, and is, used to diagnose individual patients.

16. Regions of abnormally nonuniform diffusion (called low anisotropy) due to brain injury may be visible on visual inspection of the fractional anisotropy images (known as "FA images"). However, visual assessment of such images has limited sensitivity and may miss significant abnormalities.

17. It is for this reason that quantitative measurement of the images is necessary to ensure sensitivity, reliability and objectivity. This can be accomplished by performing a voxel-wise analysis.

18. A voxel-wise analysis consists of examining each voxel in the patient's DTI images and determining whether that voxel is significantly different from the same location in a group of normal or "control" individuals.

19. The control subjects used to determine the "normal range" should be selected through an extensive testing and screening process to eliminate any unsuitable candidates. This screening process eliminates any control subjects with evidence of medical illness, substance abuse, medication usage, psychiatric disease, and neurological disease. The control subjects used in any diagnostic analysis, including the analysis of Mrs. Yang-Weissman, are carefully selected

to match the patient's age and gender. The control subjects are also imaged using the exact same equipment and imaging parameters as the patients.

20. The resulting range of measurements obtained from the DTI studies performed on the control subjects are used to define the normal distribution, for each voxel. The normal distribution will have a mean or an average and abnormalities in a patient's DTI measurements are detected according to how far they deviate from that mean. This comparison is thus done on a voxel-by-voxel basis.

21. Typically, any measurement of a patient that is two standard deviations or more from the mean is considered significantly abnormal. In such a situation, where a patient's measurement is two standard deviations or more away from the mean of the normal distribution, there is only a 5% chance that the finding of abnormality is a false positive, or, due to inherent variability rather than actual abnormality. Notably, this 5% criterion is the standard for determination of clinically significant findings in medical research.

22. In performing the voxel-wise analysis on Mrs. Yang-Weissman's DTI study, only those measurements that fell at least five standard deviations from the mean of the normal distribution were considered to be abnormal.

23. The result of this analysis is a determination of all the voxels that vary significantly from the mean and therefore are presumptively abnormal. However, I take the analysis a step further and do not conclude that all of those single-voxel abnormalities indicate true abnormal findings. Rather, to reach the conclusion that an abnormality is present in Mrs. Yang-Weissman's brain, I required that a minimum of 100 single-voxel abnormalities be adjacent or touching before concluding that an abnormality was present.

24. Because false positive results, by definition, are random errors, it is not statistically plausible to find multiple false positive results clustering in the same brain region in the same individual; random errors will occur as isolated voxels, or clusters of few voxels, and will be randomly distributed across the brain.

25. Based on his affidavit dated March 16, 2010, it appears as if Dr. Maldjian, the Defendant's expert, assumes that I employed a simple voxel-wise t-test, comparing Mrs. Yang-Weissman's fractional anisotropy images to a group of normal controls.

26. Such an approach, particularly if standard statistical thresholds were used, could yield spurious results in addition to any real findings that might be present, due to inherent variability in the measurement as opposed to true differences between the patient and the normal group.

27. I did not employ a simple voxel-wise t-test. I performed a standardized z-score analysis, where Mrs. Yang-Weissman's DTI measurements were compared to the measurements of a comparable control group and the standardized z-score was computed for each voxel, describing the patient's fractional anisotropy relative to that of the normal population. I then utilized a very strict criterion for abnormality (see above) and only accepted large clusters of abnormal voxels as true abnormalities (see above).

28. In examining the MRI studies for Mrs. Yang-Weissman and in reporting my findings and conclusions regarding those studies, I relied on my training, experience, and education as a board certified neuroradiologist.

29. The statements and opinions expressed in this affidavit are based upon my training, experience, and education and are rendered to a reasonable degree of medical and scientific certainty.

FURTHER AFFIANT SAYETH NOT.

Michael L. Lipton, M.D., Ph.D.

Subscribed and sworn to before me

This 29th day of April, 2010.

Notary Public for the State of New York
My Commission Expires: 6.19.2010

JACQUELINE REID
Notary Public, State of New York
Qualified in Bronx County
No. 01RE6147919
My Commission Expires 06-19-2010

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

HUANNI YANG-WEISSMAN,	)	**C.A. NO. 4:07-CV-3643**
	)	
PLAINTIFF,	)	
	)	
v.	)	
	)	
SOUTH CAROLNA PRESTRESS CORPORATION,	)	
	)	
	)	
DEFENDANT.	)	

AFFIDAVIT OF F. REED MURTAGH, M.D.

STATE OF FLORIDA)
)
COUNTY OF HILLSBOROUGH)

F. Reed Murtagh, M.D. being duly sworn, deposes and states as follows:

I am over twenty-one years of age and am otherwise competent to make this affidavit.

1. That I am currently employed by Imaging Consultants of Florida at 3301 USF Alumni Drive, Tampa, Florida 33612. I attended the College of William and Mary and obtained a B.A. degree in 1966 and the Temple University School of Medicine where I obtained an M.D. degree in 1971. I did a Surgery Internship at the University of North Carolina and Residency in Diagnostic Radiology at the University of Miami, Jackson Memorial Medical Center. I also did a fellowship in Neuroradiology at the University of Miami and I am certified by the American Board of Radiology in which I have an added Qualification in Neuroradiology. My Curriculum Vitae is attached hereto as Exhibit A. I am a member of the American College of Radiology as well as the American Society of Pediatric Neuroradiologists, American Society of Functional

Neuroradiology, American Society of Spine Radiology and Association of University Radiologists.

2. I served as the Director of the Division of Neuroradiology at the University of South Florida College of Medicine in Tampa Florida and was a Professor of Radiology at the University of South Florida College of Medicine Department of Radiology.

3. I am currently a member of the Diagnostic Imaging Department of the Moffitt Cancer Center and Research Institute and Professor, Department of Oncological Sciences at the University of South Florida College of Medicine at the Moffitt Cancer Center.

4. I am a Journal Reviewer for the American Journal of Neuroradiology, the Journal of Magnetic Resonance Imaging and Neuroradiology. I have published numerous papers a list of which is included in my Curriculum Vitae.

5. I have had significant training in the diagnosis of cognitive disorders as well as research and development in applications of MRI. I am very familiar with Diffusion Tensor Imaging and the fact that is well reviewed and peer-reviewed journals. The technique is generally accepted by the medical community and is clinically reimbursable by most insurance companies.

6. DTI improves the diagnosis and management of patients suffering from traumatic brain injury. I have been actively involved in MR Imaging since 1984.

7. I have been actively involved in MR imaging since 1984 and in Diffusion Tensor Imaging since 2004. The first DTI paper was published in 1994. There are currently 3,472 papers on DTI which have been published in peer-review journals to date of which 83 are on DTI and TBI. A control group was used for statistical analysis of results for 35 of the 83 papers.

8. I have reviewed the DTI studies dated 7/15/2009 performed on Heidi Yang-Weissman by Michael Lipton, M.D. of Albert Einstein Medical Center and Montefiore Hospital in New York. Dr. Lipton is a well respected neuroradiologist who is published in this field.

9. The DTI studies performed by Dr. Lipton are state of the art and done properly in every way.

10. DTI technology is currently being used to diagnose brain injury in individual patients using the methodology employed by Dr. Lipton. This methodology is set forth as the subject of peer-reviewed literature of which I am aware.

11. I agree with Dr. Lipton that the MRI/DTI studies performed by him on Heidi Yang-Weissman dated 7/15/2009 may reflect Diffuse Axonal Injury and that this clinical diagnosis can be assisted by the DTI imaging, technique and methodologies employed by Dr. Lipton.

12. DTI studies are not experimental and may be used to diagnose brain injury in individual subjects.

FURTHER AFFIANT SAYETH NOT.

F. Reed Murtagh, M.D.

Subscribed and sworn to before me
This 22nd day of April, 2010.

Patricia F. McGuigan
Notary Public for

PATRICIA F. MCGUIGAN
MY COMMISSION # DD 607708
EXPIRES: January 20, 2011
Bonded Thru Budget Notary Services

My Commission Expires:

STARK & STARK
Princeton Pike Corporate Center
993 Lenox Drive, Building
P.O. Box 5315
Princeton, NJ 08543-5315
(609) 896-9060
Attorneys for Plaintiffs

PRISCILLA MARTIN and LAWRENCE MARTIN, Plaintiffs, NIKE, INC., NEFTALKI RAMIREZ, JOHN DOES (fictitious disignations) and ABC CORPORATIONS (fictitious designations), Defendant.	SUPERIOR COURT OF NEW JERSEY OCEAN COUNTY - LAW DIVISION Docket No. OCN-L-3392-09 CIVIL ACTION **CERTIFICATION FOR ERIN BIGLER, PH.D.**

ERIN BIGLER, Ph.D., upon his oath certifies and says:

1. I am a psychologist licensed to practice psychology in the State of Utah.

2. A copy of my curriculum vitae is attached and incorporated herein.

3. I have been supplied with a copy of defendant Nike's Notice of Motion with accompanying brief and attachments with regard to its motion to bar the introduction of Diffusion Tensor Imaging results performed by Randall Benson, M.D.

4. It is my opinion that Diffusion Tensor Imaging is a scientifically valid assessment tool to assist in the diagnosis of mild traumatic brain injury.

5. DTI is being used clinically and as a diagnostic tool.

6. While DTI cannot diagnose the cause of the white matter damage, it is an acceptable assessment tool to use in conjunction with history, review of medical records, and/or clinical examination to make a diagnosis of traumatic brain injury.

I hereby certify that the aforementioned statements made by me are true to the best of my knowledge. I am aware that if any of the statements made by me are willfully false I am subject to punishment.

ERIN BIGLER, PH.D.

Dated:

brain injury. Ann Neurol. 2012 Nov 29. doi: 10.1002/ana.23824. [Epub ahead of print]) showed that DTI provided "diagnostic information about clinically significant traumatic axonal injury" in their TBI study.

9. Probably the best indicator of the importance of DTI in evaluating TBI is the fact that the NIH and the Department of Defense (DoD) sponsor the use of DTI. Specifically, DTI is an approved neuroimaging technique in the evaluation of TBI, including mTBI as sponsored by the Defense and Veterans Brain Injury Center (DVBIC). In fact, the DVBIC webpage (www.dvbic.org) outlines the use of DTI in the evaluation of mTBI. Essentially all major neuroimaging studies that investigate TBI of all severity levels utilize DTI in their assessment of brain injury.

10. This motion to exclude is, of course, a legal document and not a scientific treatise on the subject. It "cherry picks" items that I have used to give the impression that DTI is not being used clinically, which of course it is, and that its utility is only experimental, which of course it is not. Physicians may order that a DTI sequence be obtained on any patient where they may feel that the information to be clinically useful. As a clear indication of the widespread use of DTI, ALL MRI platforms regardless of vendor now have DTI sequences that can be run and ordered by any physician. Obviously, I would not be writing about a technique that I did not believe is scientifically sound and advancing the field.

11. From my perspective, the clinician needs to use all relevant information in assessing a patient with a history of traumatic injury and DTI provides additional relevant information. No one in Mr. Ebel's case is relying solely on the DTI findings as an independent and definitive diagnostic procedure. Furthermore, there is no debate about whether Mr. Ebel has white matter hyperintensities on the fluid attenuated inversion recovery (FLAIR) imaging sequences. DTI provides another MRI method to assess white matter integrity. The utilization of DTI is similar to the clinical use of imaging in other settings.

12. There are numerous DTI examples in the literature of how a clinical problem, like assessing a patient with a documented brain tumor who has minimal clinical and neuropsychological deficits, where the DTI provides additional useful clinical information. The DTI information can be integrated by those who evaluate the patient and utilize the neuroimaging findings as part of the assessment (see Bozzali et al. white matter integrity assessed by diffusion tensor tractography in a patient with a larger tumor mass but minimal clinical and neuropsychological deficits. *Functional Neurology*, 2012, Oct-Dec; 27(4); 239-246). This case study by Bozzali et al. demonstrates the added value of performing DTI wherein the clinician integrates the information with all aspects of the case. This is the well-established technique of "clinical correlation" that has been part of medicine and psychology since their inception as clinical disciplines. DTI in this case study by Bozzali et al. does not "diagnose" the tumor, but provides important clinical information about the white matter effects of the tumor that the clinician uses in integrating all findings relevant to the patient in question. Clinicians use tools such as DTI to integrate with other information in the evaluation of a patient, their history, symptoms and complaints.

13. In summary, DTI is in widespread use, including clinical use across the world. It provides unique information about white matter integrity across a broad spectrum of neurological and neuropsychiatric disorders that offers information that cannot be otherwise obtained. It is not being used as a "stand-alone" procedure in Mr. Ebel's case and the clinical correlation of DTI, as was done in Mr. Ebel's case, is similar to the clinical correlation of imaging findings in multiple other areas of medicine and psychology. DTI is a well-established reliable, tested, and peer reviewed method of assessing brain integrity.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

ERIN D. BIGLER, Ph.D.

SUBSCRIBED and SWORN to before me this 10th day of October, 2013.

NOTARY PUBLIC

SUSAN WHEATLEY
NOTARY PUBLIC - STATE OF UTAH
COMMISSION# 661451
COMM. EXP. 01-27-2017