COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS. SUPERIOR COURT DEPT.
C.A. NO. 08-2380

XXX,
Plaintiff

v.

GIGS, LLC, and
WENDELL LEE ZORMAN,
Defendants

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO PRECLUDE EVIDENCE RELATING TO DIFFUSION TENSOR IMAGING ("DTI") PURSUANT TO *DAUBERT* AND *LANIGAN* STANDARDS

I. INTRODUCTION:

Now comes the Plaintiff in the above-referenced matter, who hereby requests that this Honorable Court deny Defendants' Motion to Preclude Any Reference to DTI Testing. In support of his opposition, Plaintiff states as follows:

1. **DTI is an FDA-approved, peer reviewed, commercially-marketed, and widely available MRI method which has been in clinical use for many years. During this time, DTI has been used to detect and diagnose white matter (axonal) damage -- the injury claimed by the Plaintiff;**

2. **DTI has been admitted into evidence by three courts, while being challenged on *Daubert* or *Frye* bases. One court has credited DTI findings in a bench trial; and**

3. **The defense expert[1] has written in peer-reviewed journals that DTI can diagnose white matter (axonal) injury.**

[1] The Defendants' Motion cites various articles and makes the point that their expert, Dr. Bammer, has published many articles regarding the use of DTI. It is interesting that none of the articles attached to the defendant's motion are authored by Dr. Bammer.

II. BRIEF STATEMENT OF THE CASE:

On March 21, 2006, XXX's van was rear-ended by a tractor-trailer weighing approximately 100,000 pounds and travelling approximately 25-30 mph. This impact caused a chain-reaction, five-car pile-up. XXX had an amnesic gap and complained of head pain within minutes of the crash. For hours, XXX was acting dazed and confused, had problems remembering the accident and would repeat himself. He initially went to the emergency room at Beth Israel Hospital with his wife, but was acting irrational and would not wait for medical attention. He left the hospital and went to see his primary care physician in Chelsea.

By that night, XXX was dizzy and had worsening headaches. He developed problems concentrating and other signs of post-concussive syndrome shortly after the crash. Both his primary care physician and his treating physiatrist at the Spaulding Rehabilitation Traumatic Brain Injury Clinic have diagnosed XXX with post-concussive syndrome, otherwise called Mild Traumatic Brain Injury ("mTBI").

III. DR. BENSON'S OPINIONS:

Dr. Benson first examined XXX on January 6, 2010, before the DTI testing was performed upon XXX. Dr. Benson did not review any medical records prior to this examination. This is Dr. Benson's practice, as he believes it eliminates any bias resulting from other treating doctor's opinions.[2] Dr. Benson performed a clinical interview along with a full neurobehavioral examination. At that time, he wrote an office note stating (under the section labeled "Assessment"): "my assessment is that he likely did sustain a traumatic brain injury."[3] Again, Dr. Benson notes that he had not reviewed medical records or imaging results prior to providing this assessment.

Dr. Benson then obtained the preliminary results of the imaging. He issued a report that stated: "Low FA in these white matter regions is consistent with traumatic axonal injury

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[2] *See* Affidavit of Randall Benson, M.D. attached as Exhibit 1 at p. 6, paragraph 28.
[3] Dr. Benson's initial note is attached as Exhibit 2.

suggestive by the patient's history of being rear-ended by a large truck and postconcussive syndrome."[4]

Later, Dr. Benson performed a further analysis of the DTI results, along with a further review of the other MR sequences. Dr. Benson wrote 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. Pallor of corticospinal tract bilaterally may represent Wallerian degeneration of these fibers...
>
> 1. A few scattered subcortical gray-white junction foci suggesting traumatic injury.
> 2. Pallor in central white matter involving corticospinal tracts suggesting Wallerian degeneration.
> 3. Many scattered bilateral areas of reduced FA suggesting axonal injury from trauma.
> 4. Above *findings suggest the possibility of traumatic axonal injury secondary to stretch or shear injury caused by accelerative forces such as may have been experienced by the patient in the car accident described. .*"[5]

Thus, the DTI findings are supported and validated by the MR findings, a point ignored by the defense. Defendants' motion states "Detectable abnormalities (on DTI) are usually associated with evidence in conventional MRI." While this argument is not true, XXX did show an abnormality on a Flair MRI sequence at the junction of the grey/white matter, a classic location of axonal shearing.[6]

After reviewing the medical records, obtaining the full results of imaging and conducting a phone interview with Mrs. XXX, Dr. Benson prepared a full report. In his report, he writes as follows:

> "In summary, it is my opinion based on the above cited evidence that XXX suffered:
> 1. A concussion
> 2. Post-concussive symptoms
> 3. A whiplash injury to his cervical spine

[4] The initial DTI report is attached as Exhibit 3.
[5] The final DTI report is attached as Exhibit 4.
[6] *See* Exhibit 1, at p. 5, paragraph 23.

4. Permanent neurological impairment compromising his ability to perform his job, compromising his quality of life due to somatic and cognitive symptoms causally related to the motor vehicle crash which occurred 3/21/06."[7]

IV. THE ROLE OF DTI IN DR. BENSON'S OPINIONS:

DTI alone cannot diagnose brain injury. Like other radiological tests, DTI can locate abnormalities that can suggest or be consistent with a particular etiology, but in and of itself, are not diagnostic. By locating white matter (axonal) damage in the brain consistent with mTBI, DTI findings provide a tool upon which a clinician may support a diagnosis of mTBI. As Dr. Benson writes:

> "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, XXX'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 XXX, I did, along with other doctors who examined him."[8]

DTI provides a basis for the physician to conclude that XXX's symptoms have an organic basis. *See* Rhilinger v Jancsics, et al, 1998 WL 1182058 (Mass.Super.)[9]

The organicity of XXX's complaints is a key issue in this matter. The defense has taken the position that the changes in XXX are accounted for by one of two choices: either he is a frank malingerer, or; he has had an emotional overreaction to the crash. Either way, the defense claims that the crash of March 21, 2006 caused no lasting organic injury to XXX's brain. But

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[7] *See* Exhibit 4.

[8] *See* Exhibit 1, at p. 7.

[9] Holding that a SPECT Scan is scientifically reliable and testimony as to its use in coming to the diagnosis of the plaintiff would be helpful to a fact finder. The Court noted that the "plaintiff's experts do not opine that the SPECT scan does, in fact, establish the diagnosis," but rather, that the plaintiff's expert merely asserted that "it is one of a constellation of diagnostic tools which they used and considered with their conclusion that [plaintiff] suffers from [the subject injury]" *Id.* at 5. The Rhilinger decision is attached as Exhibit 5.

the findings from the QEEG test, the MRI (Flair sequence) and the DTI test contradict the defense. In fact, the DTI shows axonal[10] damage in the general areas where XXX's electrical activity is abnormal; the DTI test serves to demonstrate the QEEG's reliability and vice versa. The Flair sequence of the MRI further serves to corroborate the findings.

V. DIFFUSION TENSOR IMAGING, HOW IS IT DONE:

DTI is a sequence of an MR examination that examines the microstructure of the white matter (axons) of the brain.[11] As a large majority of mild traumatic brain injury is not detectable on CT Scan or standard MR scans, a major drive behind the development of DTI software was to detect white matter abnormalities.[12]

DTI works by measuring the distribution of water through portions of the brain.[13] DTI is based upon the known physics of the flow of water.[14] On a purely smooth surface, water will flow equally in all directions in a manner called an isotropic distribution. If, however, there are barriers to flow (such as found in the white matter of the brain), water will move unequally in all directions, called anisotropic distribution.[15]

Water distribution in healthy, intact white matter tends to be anistropic.[16] But as white matter is damaged, the outer membranes are broken down causing the water to diffuse in a more isotropic distribution.[17]

DTI divides the brain into thousands of voxels. Voxels are like pixels of a digital camera, except they are three dimensional. DTI measures the distribution of water through each voxel in the brain and provides a score between 0 and 1.[18] In the medical literature, that score is referred

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[10] Axons are, in essence, the wiring for all brain cells. Damage to the axons can leads to abnormal electrical activity.
[11] *See* Exhibit 1, at p. 3, paragraph 6.
[12] *Id.* at p. 3, paragraph 7.
[13] *Id.* at p. 3, paragraph 8.
[14] *Id.*
[15] *Id.*
[16] *See* Exhibit 1, at p. 3, paragraph 11.
[17] *Id.*
[18] *Id.* at p. 3, paragraph 10.

to as FA (fractional anisotropy). A lower score means that the distribution of water is more isotropic (equal in all directions), with a score of 0 representing pure isotropic distribution. A higher score means the distribution is more anisotropic, with a score of 1 being close to a straight line. It is well known that axonal injury will result in decreased FA scores.[19] Dr. Benson has an average FA score from his normative database for each voxel that was compared to XXX's. Dr. Benson also corrected for XXX's age and the fact that the DTI was performed on a 3T scanner.[20]

The DTI software then counts the FA score on a voxel-by-voxel basis and compares it to normal population. In XXX's case, the computer highlighted FA scores that were 3 standard deviations below the average FA score.[21] The odds of having an FA score 3 standard deviations below normal are 1 out of 660.[22] The computer performed 134,733 voxel analyses. So, statistically speaking there should only be 202 voxels that were 3 standard deviations below normal if XXX had normal white matter.[23] XXX had 681 such voxels, more than three times the number that would be expected by chance.[24]

In addition to searching for voxels that are extremely abnormal, the DTI software looked to see if the voxels were clustered in greater amounts than the normal.[25] The odds of having such an abnormal cluster of voxels are 1 in 4,166.[26] XXX had five such clusters. The odds of that happening without white matter injury are essentially impossible.[27]

Beyond the statistical impossibility, Dr. Benson further verified his findings. He confirmed these findings using a Tract Based Spatial Statistic ("TBSS"). This method is used throughout the world to reduce error caused by misaligning XXX's brain from the normative database.[28] The TBSS confirmed XXX's preliminary findings.[29]

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[19] *Id.* at p. 3, paragraph 11.
[20] *Id.* at p. 4, paragraph 17.
[21] *See* Exhibit 1, at p. 4, paragraph 18.
[22] *Id.*
[23] *Id.* at p. 4, paragraph 19.
[24] *Id.*
[25] *Id.* at p. 4, paragraph 20.
[26] *See* Exhibit 1, at pp. 4-5, paragraph 20.
[27] *Id.* at p. 5, paragraph 21.
[28] *Id.* at p. 5, paragraph 22.
[29] *Id.*

VI. ARGUMENT

DTI IS ACCEPTED WITHIN THE SCIENTIFIC COMMUNITY IN ASSISTING WITH THE DIAGNOSIS OF MILD TRAUMATIC BRAIN INJURY. DTI's RELIABILITY HAS BEEN DEMONSTRATED BY THE PEER-REVIEWED LITERATURE AND NUMEROUS COURTS HAVE ADMITTED IT AND ACCEPTED ITS FINDINGS.

A. LEGAL STANDARD

"The role of expert testimony is to assist jurors in interpreting evidence that lies outside their common experience." Commonwealth v. Shanley, 455 Mass. 752, 761 (2010). "Expert testimony is sufficiently reliable [for this purpose] if the underlying theory or methodology is *either* (1) generally accepted in the relevant scientific community, *or* (2) satisfies the alternative requirements adopted in Lanigan. *Id.* at 761-762 (emphasis added). *See* Commonwealth v. Lanigan, 419 Mass. 15, 26 (1994) ("proponent of scientific opinion evidence may demonstrate the reliability or validity of the underlying scientific theory or process by some other means, that is, without establishing general acceptance"); Commonwealth v Sands, 424 Mass. 184, 185-186 (1997) ("party seeking to introduce scientific evidence may lay a foundation either by showing that the underlying scientific theory is generally accepted within the relevant scientific community, or by showing that the theory is reliable or valid through other means") *See Also* Federico v. Ford Motor Co., 67 Mass. App. Ct. 454 (2006); Com. v. Zimmerman, 70 Mass. App. Ct. 357 (2007); Smith v. Bell Atlantic, 63 Mass. App. Ct. 702 (2005).

Among the factors for a court to consider regarding admissibility under the new more flexible Daubert/Lanigan test are whether the theory or methodology: (1) has been or can be tested; (2) has been subject to peer review and publication; (3) has an unacceptably high known or potential rate of error; (4) has been developed outside of litigation; and (5) has been generally accepted in the relevant scientific community. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593-595 (1993); Commonwealth v. Lanigan, 419 Mass. 15 (1994); Commonwealth v. Powell, 450 Mass. 229 (2007).

A review of the caselaw after Daubert shows that the rejection of expert testimony is the exception rather than the rule. Fed. R. Evid. 702 advisory committee's note. *See Also* In re: Gadolinium-Based Contrast Agents Products Liability Litigation, 2010 WL 1924476 (N.D. Ohio 2010) (stating rejection of expert testimony is exception rather than rule). The Second Circuit has noted that "Daubert reinforces the idea that there should be a presumption of admissibility of evidence," and the Circuit has interpreted Daubert as having "advanced a bias in favor of admitting evidence short of that solidly and indisputably proven to be reliable." Borawisk v. Shay, 68 F.3d 597, 610 (2d Cir. 1996). A trial court's role as gatekeeper is not meant to replace the adversary system. U.S. v. 14.38 Acres of Land Situated in Leflore County, Mississippi, 80 F.3d 1074, 1078 (5th Cir. 1996). Challenges to the methodology used by an expert witness are usually adequately addressed by cross-examination. U.S. v. Diaz, 300 F.3d 66, 76-77 (1st Cir. 2002). "If nothing else, Frye and Daubert stand for the proposition that only in the most extreme and thereby prejudicial circumstances should the trier of fact be prevented from hearing and weighing opinion of the expert." Stanley Tulchin Assoc. v. Grossman, 2002 NY Slip Op 50428U. The Supreme Court was careful to stress in Daubert that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." 509 U.S. at 595.

B. DTI IS GENERALLY ACCEPTED IN THE RELEVANT SCIENTIFIC COMMUNITY.

Massachusetts law directs a court to look first to the "general acceptance" requirement and, if that is satisfied, to find the proffered evidence admissible. Lanigan, 419 Mass at 26 ("[G]eneral acceptance . . . will continue to be the significant, and often the only, issue.") "Lanigan's progeny make clear that general acceptance in the relevant community . . . continues to be sufficient to establish the requisite reliability for admission in Massachusetts courts regardless of other Daubert factors." Powell, 450 Mass. at 238 *quoting* Commonwealth v. Patterson, 445 Mass. 626 at 640-641. **"General acceptance does not necessarily mean that a majority of the scientists involved subscribe to the conclusion. Rather, it means that those espousing the theory or opinion have followed generally accepted scientific principles and methodology in evaluating clinical data to reach their conclusions."** Zito v. Zabarsky, 28 A.D.3d 42 (2006) *quoting* Beck v. Warner-Lambert Co. (2002 NY Slip Op 40431[u], *6-7). Therefore, the relevant community is comprised of "those espousing the theory" and the test is whether that community has "followed generally accepted scientific principles." *Id.*

DTI is FDA-approved, reimbursable by insurance companies, and used clinically throughout the country and the world.[30] As Dr. Benson writes:

> "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.
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> 25. DTI is used clinically at the Detroit Medical Center and as a diagnostic tool. In fact, the entire sequence given to XXX, 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."[31]

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[30] *See* the Affidavit of F. Reed Murtagh, M.D., attached as Exhibit 6; Dr. Murtagh's curriculum vitae is attached as Exhibit 7; *see also,* Videotaped Trial Testimony of Michael Lipton, M.D. in the case of Yang-Weissman v. South Carolina Prestress Corporation, United States District Court, District of South Carolina, Civil Action No. 4:07-CV-3643 attached as Exhibit 8, at pp. 28, 53, 55-56; Affidavit of Dr. Lipton in the Yang case attached as Exhibit 9; Dr. Lipton's curriculum vitae is attached as Exhibit 10. The defense in Yang attempted to exclude DTI evidence, but the Court did not rule as the case settled for $3,000,000 while the Motions were pending.

[31] *See* Exhibit 1 at p. 5.

In written testimony before the United States Congress House Judiciary Committee on January 4, 2010, Dr. Benson wrote as follows:

> "DTI is able to 'visualize' diffuse axonal injury from TBI. In some cases location of lesions appear to correlate with specific symptoms but generally the severity of DAI as indicated by DTI is strongly predictive of general neurocognitive disability."[32]

Dr. Benson's opinion is hardly alone. Dr. Lipton[33] testified in April, 2010, as follows:

"Q. Is DTI in clinical use?
A. Yes, it is.
Q. Is it experimental?
A. No.
Q. All right. Is it used—
A. People are certainly investigating it and trying to make improvements. But it's, you know, an FDA-approved technique that's in clinical use...
Q. Can diffusion-tensor imaging be used to diagnose a particular patient
A. Yes, it can...
Q. Is DTI in use in other medical centers other than Einstein and Montefiore?
A. Yes, it is.
Q. And is it in use throughout the United States?
A. I believe it's in use throughout the world...
Q. Dr. Lipton, is there literature endorsing the assessment of individual subjects using DTI?
A. Yes there is.
Q Can DTI be used to detect abnormalities due to traumatic brain injury?
A. There are.
Q. Are there studies of individuals or groups?
A. Both
Q. Are there papers which support the use of DTI to diagnose traumatic brain injury in individual subjects?
A. Yes, there are"[34]

Dr. Lipton created a list of articles that support the use of DTI in traumatic brain injury by its ability to diagnose axonal damage consistent with TBI.[35]

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[32] Dr. Benson's testimony to Congress is attached as Exhibit 11 at p. 15.
[33] Dr. Lipton is a neuroradiologist at the Albert Einstein College of Medicine and the Director of Research and Development as well as the Medical Director at the Montefiore Medical Center. He has over ten years experience working with DTI and eight years specifically using DTI to diagnose brain injury. *See,* Lipton Affidavit attached as Exhibit 9.
[34] *See,* Exhibit 8, Lipton testimony at pp. 28, 53-58, 96.
[35] *See,* Lipton testimony at pp. 58-59. The list is attached as Exhibit 12.

Dr. Benson and Dr. Lipton's views are echoed by Dr. Murtagh. Dr. Murtagh is Board Certified in Radiology with an added Qualification in Neuroradiology.[36] Dr. Murtagh submitted an affidavit that states as follows:

> "6. DTI improves the diagnosis and management of patients suffering from traumatic brain injury...
>
> 7. ...I have been actively involved in MR imaging since 1984 and in Diffusion Tensor Imaging since 2004.
>
> 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...
>
> 12. DTI studies are not experimental and may be used to diagnose brain injury in individual subjects."[37]

As shown above, DTI is generally accepted in the scientific community for assistance in the diagnosis of traumatic brain injury.

C. DTI IS DEMONSTRABLY RELIABLE UNDER A DAUBERT/LANIGAN ANALYSIS.

When the court does *not* find general acceptance then it should look to the other factors to determine if reliability can be established. *See* Lanigan, 419 Mass. at 26; Daubert, 509 U.S. 593-585; Patterson, 445 Mass. 640-641. "Where general acceptance is not established by the party offering the expert testimony, a full Daubert analysis provides an alternate method of establishing reliability." Zito, 28 A.D.3d 42. The Third Circuit has held, under Daubert, that "the judge should only exclude the evidence if the flaw is large enough that the expert lacks 'good grounds' for his or her conclusions." In re: Paoli R.R. Yard PCB Litig., 35 F.3d 717, 746 (3d Circ. 1994); *see* Daubert, 509 U.S. at 590.

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[36] *See* Exhibit 6 Murtagh Affidavit, at paragraph 1.
[37] *Id.* at pp. 6, 7, 10 and 12.

DTI is demonstrably reliable through the other factors set forth in Daubert/Lanigan because it (1) has been tested; (2) has been peer-reviewed; (3) has a low error rate; and (4) has been developed independent of litigation. Therefore, evidence of DTI is admissible even if this Court does not find acceptance in the relevant scientific community of DTI.

1. DTI HAS BEEN TESTED IN PEER-REVIEWED ARTICLES:

DTI has been tested through multiple peer-reviewed studies. As of early 2010, there are 3,472 papers on DTI that have been published in peer-review journals.[38] 83 of the papers are on DTI and TBI and 35 of those papers employed a control group for statistical analysis.[39] Dr. Benson's methodology has been subject to the peer-review process through medical groups and the federal government.[40] Plaintiff attaches an Annotated Appendix of Peer Review Articles that demonstrate DTI's reliability in diagnosing axonal damage. The following are quotes from the medical literature demonstrating DTI's effectiveness in detecting white matter damage associated with TBI:

1. Benson, Randall – *Global White Matter Analysis of Diffusion Tensor Images is Predictive of Injury Severity in Traumatic Brain Injury* – **Journal of Neurotrauma** Volume 24, Number3, 2007 –
   "FA changes appear to be correlated with injury severity suggesting a role in early diagnosis and prognosis of TBI..."
   "The present study demonstrates the ability of a white matter FA histogram-based method of analyzing MRI diffusion tensor images to discriminate between persons with traumatic brain injury and healthy volunteers and to predict short term clinical outcome from TBI".[41]

2. Kumar, Raj – *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* – **J Head Trauma Rehabil** Vol. 25, No 1, pp. 31-42
   "...(DTI) has been shown to be a valuable technique for in vivo quantification of white matter microstructural alterations following TBI."
   "However, changes in DTI indices were observed, confirming that DTI appears to be a more sensitive measure than volume of injury in these patients."
   "In conclusion, our study suggests that FA and RD indices are surrogate markers of microstructural alterations in patients with TBI over time and correlate significantly with

[38] *See* Exhibit 1 at paragraph 38.
[39] *Id.*
[40] *Id.* at paragraph 2.
[41] *See* Annotated Appendix, Article 3, at pp. 446, 453.

some NPT scores. The recovery in these indices in some regions of that CC[42] is associated with recovery in neurocognitive deficits, suggesting that these indices may be used as an objective marker for the residual injury in these patients."[43]

3. Chappell, Michael – *Multivariate analysis of diffusion tensor imaging data improves the detection of microstructural damage in young professional boxers* – **Magnetic Resonance Imaging** (2008) –
"DTI is a valuable tool to identify microscopic changes in brain tissue resulting from damage or disease…"
"This scatter plot shows the expected pattern that with mild head injury MD increases and FA decreases."[44]

4. Mayer, A.R, Ph.D. – *A prospective diffusion tensor imaging study in mild traumatic brain injury* – **Neurology** 2010;74: 643-650
"Current results also suggest that DTI results are more accurate in objectively classifying mTBI patients from carefully matched HC[45]"."[46]

5. Bigler, Eric, Ph.D. – *Diffusion tensor imaging: A Biomarker for Mild Traumatic Brain Injury?* – **Neurology** 2010;74:626-627 –
"DTI is particularly sensitive in assessing white matter (WM) microstructure, even in parenchyma deemed normal. The sensitivity of DTI for WM injury makes it especially important in understanding mTBI…"[47]

6. Lipton, Michael, M.D., Ph.D. – *Diffusion-Tensor Imaging Implicates Prefrontal Axonal Injury in Executive Function Impairment Following Very Mild Traumatic Brain Injury* – **Radiology**: Volume 252:Number 3-September 2009 –
"Detection of ultrastructural damage by using DT imaging is a major advance in diagnostic imaging. Several studies have supported the capability of FA to help identify white matter abnormalities in patients with traumatic brain injury including mTBI. As confirmed by our findings, abnormal FA is detected even in the absence of other imaging abnormalities."
"In conclusion, we found that lower DLPFC[48] white matter FA in acute mTBI helps predict impairment executive function in these patients."[49]

7. Lipton, Michael – *Multifocal White Matter Ultrastructural Abnormalities in mild Traumatic Brain Injury with Cognitive Disability: A Voxel-Wise Analysis of Diffusion Tensor Imaging* – **Journal of Neurotrauma** 25:1335-1342 (November, 2008)
"Diffuse tensor MRI (DTI) shows lower fractional anisotropy (FA) in TBI patients that may correlate with disability."

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[42] CC stands for Corpus Collosum.
[43] *See* Annotated Appendix, Article 11, at pp. 32, 40, 41.
[44] *See* Annotated Appendix, Article 6, at pp. 1, 5.
[45] HC stands for Healthy Controls.
[46] *See* Annotated Appendix, Article 15, at p. 648.
[47] *See* Annotated Appendix, Article 5, at p. 626.
[48] DLFPC stands for dorsolateral prefrontal cortex.
[49] *See,* Annotated Appendix, Article 13, at pp. 820, 823.

"DTI was used to identify white matter abnormalities in patients with persistent cognitive impairment following mTBI"
"...showing a pattern of abnormalities in mTBI that is similar to DAI. Even more recently, Niogi et al reported voxel-wise analysis of DTI in mTBI and showed correlation of white matter abnormalities with a single reaction time measure."
"We have shown that DTI can identify abnormalities in patients cognitively impaired following mTBI."[50]

8. Kraus, Marilyn F. – *White matter integrity and cognition in chronic traumatic brain injury: a diffusion tensor imaging study* – **Brain** (2007) pp. 1-12 .
"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."
"DTI allows for the specific examination of the integrity of white matter tracts, tracts which are especially vulnerable to the mechanical trauma of TBI."
"Because DTI is more sensitive to changes in the microstructure of white matter, it shows considerable promise in the assessment of TBI."
"The data presented here demonstrate that DTI allows for a more sensitive delineation of severity and mechanism of white matter pathology, and may help to explain apparent discrepancies between clinically diagnoses injury severity and cognitive outcomes across the spectrum of TBI."[51]

9. Lo, Calvin – *Diffusion Tensor Imaging Abnormalities in Patients with Mild Traumatic Brain Injury and Neurocognitive Impairment* – **Comput Assist Tomogr**, Volume 33, Number 2, March/April 2009
"Our results demonstrate a significant decrease in FA within the genu of the corpus callosum in patients with persistent cognitive impairment after mild TBI".
"Our study shows that DTI can be used to detect differences between patients with cognitive impairment after mild TBI and controls."[52]

10. Wu, Trevor – *Evaluating the Relationship between Memory Functioning and Cingulum Bundles in Acute Mild Traumatic Brain Injury using Diffusion Tensor Imaging* – **Journal of Neurotrauma** 27:303-307 (February 2010) –
"...and decreased FA and increased ADC in chronic TBI have been attributed to white matter injury and degeneration."[53]

11. Wilde, E. A. – *Diffusion tensor imaging of acute mild traumatic brain injury in adolescents* – **Neurology** 70 March 18, 2008 –
"Diffusion tensor imaging (DTI) is an imaging technique acquired on a standard MTI scanner that has been shown to be far more sensitive to white matter injury than conventional MRI."
"Validity of DTI in adult TBI has been supported by a positive correlation of FA in the internal capsule and splenium with the Glashow Coma Scale (GCS) score..."

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[50] *See,* Annotated Appendix, Article 12, at pp. 1336, 1338, 1340, 1341.
[51] *See,* Annotated Appendix, Article 10, at pp. 1, 3, 11.
[52] *See,* Annotated Appendix, Article 14, at pp. 295-96.
[53] *See,* Annotated Appendix, Article 22, at p. 303.

"...the DTI indices were sensitive to pathologic processes of MTBI that contributed to the postconcussion symptom severity of our patients."[54]

12. Bigler, E.D. – *Voxel-Based Analysis of Diffusion Tensor Imaging in Mild Traumatic Brain Injury in Adolescents* – **AJNR Am J Neuroradiol** 31, Feb 2010
"Whole brain WM DTI measures can detect abnormalities in acute mTBI associated with PCS symptoms in adolescents."
"The present study revealed significant alteration in DTI metrics in a group of patients with mTBI in several brain regions, and these changes were highly correlated with PSC severity and emotional distress."
"Voxel based DTI analysis is a capable of identifying potentially diffuse axonal injury vulnerable regions invisible to CT and conventional MR imaging, which may assist in classification, early diagnosis, and treatment."[55]

13. Yuan, W – *Diffusion Tensor MR Imaging Reveals Persistent White Matter Alteration after Traumatic Brain Injury Experienced during Early Childhood* – **AJNR Am J Neuroradiol** 28:1919-25 Nov-Dec 2007 –
"DTI is an advanced MR imaging technique that can detect in vivo anisotropic diffusion properties in WM."
"...that DTI is a feasible, sensitive, and noninvasive means of examining WM changes in young children with moderate, as well as severe, injuries."[56]

14. Rutgers, D.R. – *White Matter Abnormalities in Mild Traumatic Brain Injury: A Diffusion Tensor Imaging Study* – **AJNR Am J Neuroradiol** 2008
"DTI quantifies white matter architecture through an extensive description of water diffusion and allows for the reconstruction of white matter fibers in 3D through fiber tracking Algorithms."
"...patients with mild TBI had multiple white matter regions with reduced FA, predominately involving cerebral lobar white matter, cingulum, and corpus callosum."
"...that subacute or early chronic DTI changes are an indicator of long-term DTI abnormalities in mild TBI."
"The present study shows that patients with mild TBI have multiple white matter regions with abnormality reduced FA, predominately in cerebral lobar white matter, cingulum, and corpus callosum."[57]

1a. DTI HAS BEEN APPROVED BY THE FDA

DTI software was submitted in 2001 to the FDA for Section 510(k) premarket notification and was granted permission to be marketed with the following language under Indications for Use: "Diffusion tensor imaging produces magnetic resonance (MR) images

[54] *See,* Annotated Appendix, Article 21, at pp. 949, 952.
[55] *See,* Annotated Appendix, Article 4, at pp. 340, 346.
[56] *See,* Annotated Appendix, Article 23, at pp. 1919, 1924.
[57] *See,* Annotated Appendix Article 18, at pp. 1, 4, 5.

whose contrast is dependent on the local diffusion coefficient of water. **Diffusion tensor imaging can be used to image the directional dependence of the diffusion coefficient in tissue such as white matter.**"[58] The FDA tested the software for "safety and effectiveness" before granting permission for it to be marketed, specifically the:

> "effectiveness of a device is . . . [determined] on the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, **from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have**." 21 U.S.C. 360c.(3)(A) (emphasis added).

The DTI software was being manufactured by GE Medical Systems and the application states that the "Diffusion Tensor Imaging Option was evaluated to the IEC 601-2-33 International medical equipment safety standard for Magnetic Resonance Systems. **Evaluation testing confirmed accuracy statements** in the User manual."[59] In 2003, the FDA granted permission for a device to be marketed that stated DTI "differentiates tissues with restricted diffusion from tissues with normal diffusion" and whose indications for use concluded that **"[t]hese images when interpreted by a trained physician, yield information that may assist in diagnosis."**[60]

1b. The Literature cited by the defense supports the use of DTI to diagnose axonal damage

The following are quotes from the literature cited by the defense that support the use of DTI:

Defense Exhibit 11: S.N. Niogi – *Extent of Microstructural White Matter Injury in Post concussive Syndrome Correlates with Impaired Cognitive Reaction Time: A 3T Diffusion Tensor Imaging Study of Mild Traumatic Brain Injury* – **AJNR Am J Neuroradiol** 29:967-73 May 2008

> "Conclusion: 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."

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[58] *See* Kroger, 510(k) Application and response letter from the FDA, attached as exhibit 13, (emphasis added).
[59] *Id.* (emphasis added).
[60] See Philips Medical Systems North American Company, 510(k) Application and response letter from the FDA, attached as exhibit 14, (emphasis added).

"Fractional anisotropy (FA), a normalized measure of anisotropy, has been shown to be sensitive to microstructural changes in white matter integrity. Such measurements quantify the extent of damage following TBI and are more sensitive than conventional MR imaging to axonal injury in a mouse model of TBI."

"The purpose of this study was to determine the predominant areas of damage in mild TBI and whether the spatial extent of white matter injury on DTI can be used as an effective biomarker for global cognitive outcome."

"DTI results were significantly correlated with cognitive reaction time..."

"...it is generally accepted that loss of the microstructural integrity of white matter reduces FA values."

"We find that the extent of microstructural white matter injury on DTI in patients with mild TBI with post concussive syndrome is associated with poorer reaction time in a simple cognitive task..."

"DTI may serve as a microstructural imaging biomarker for long-term neurocognitive impairments in TBI."[61]

Defense Exhibit 12: Belanger, Heather, Ph.D. – *Recent Neuroimaging Techniques in Mild Traumatic Brain Injury* – **J Neuropsychiatry Clin Neurosci** 19:1, Winter 2007 –

"...DTI has demonstrated sensitivity to mild TBI at least up to 1 month post injury."[62]

Defense Exhibit 15: Stein, Murray, M.D., M.P.H – *Exploring the Convergence of Posttraumatic Stress Disorder and Mild Traumatic Brain Injury* – **Am J. Psychiatry** 166:7, July 2009 –

"...this literature does suggest that brain regions vulnerable to the impact and inertial biomechanical forces associated with TBI show higher rates of both structural and functional abnormalities."

"One of the most promising tools in this regard is diffusion tensor imaging. This technique permits the tracing of fiber tracts and the quantification of disturbance in their anisotropy, thereby providing a putative biomarker of white matter tract damage."[63]

Defense Exhibit 16: Niogi, Sumit, N. – *Structural Dissociation of attention control and memory in adults with and without mild traumatic brain injury* – **Brain** (2008) 131, 3209-3221

"...direct evidence that tract-specific variation in microstructural white matter integrity among normal controls and among mild TBI patients can account for much of the variation in performance in specific cognitive domains. More generally such findings suggest that diffusion anisotropy measurement can be used as a quantitative biomarker for neurocognitive function and dysfunction."

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[61] *See,* Defense Exhibit 11, at pp. 967 - 972.
[62] *See,* Defense Exhibit 12, at p. 7.
[63] *See,* Defense Exhibit 15, at p. 773.

"...DTI studies have shown that performance in specific cognitive functions is associated with white matter organization and integrity..."
"The major finding in this 3T DTI study was that microstructural white matter integrity of bilateral UR is associated with memory performance while integrity of the left ACR is associated with attentional control."
"...DTI can be used as a microstructural imaging biomarker for cognitive function and dysfunction."
"Recent investigations have shown, however, that DTI is more sensitive to axonal injury that conventional MR imaging techniques in TBI patients (Arfanakis et al., 2002; Husiman et al., 2004; Ingles et al. 2005; Newcombe et al 2007) and in a mouse model of TBI (Mac Donald et al. 2007)."
"...DTI can be used to differentiate long-term impairments in separable cognitive domains, further validating DTI as a potential biomarker for cognitive dysfunction in TBI."
"Numerous studies have established FA as a marker for white matter integrity in TBI, demyelinating diseases, and as a correlate of cognitive function in normal populations (Tuch et al. 2005; Mabbott et al, 2006." "...scanned within a large range of time post injury (1-53 months). However, correlations did not change significantly after controlling for time elapsed post-injury. Thus it is likely that those with chronic symptoms have stable lesions that did not resolve."
"This study provides evidence that DTI may serve as a microstructural imaging biomarker for cognitive dysfunctions and variations within normal cognitive functions."[64]

Defense Exhibit 17: Li, Xue-Yuan – *Diffuse axonal injury: novel insights into detection and treatment* – **J Clin Neurosci** (2009) doi: 10.1016/j.jocn 2008.08.005 –

"This suggests that DTI is highly sensitive to axonal injury, and in addition may have a high negative predictive value. The sensitivity of DTI in this context has been corroborated in another study, which noted that the axial diffusivity derived from DTI accurately matched the pattern of axonal damage."
"...which suggests that DTI may be a sensitive tool in detecting DAI in the super accurate phase."[65]

Defense Exhibit 18: Inglese, Matilde, M.D., Ph.D. – *Diffuse axonal injury in mild traumatic brain injury: a diffusion tensor imaging study* – **J Neurosurg** 103:298-303, 2005

"Furthermore it has been shown to be a sensitive and early indicator of TBI. Arfanakis, et, al."
"Diffusion tensor imaging is able to probe structural properties of tissue such as size, shape, integrity, and orientation of water filled space that are inaccessible to other MR imaging modalities."[66]

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[64] *See,* Defense Exhibit 16, at pp. 3209, 3217-3220.
[65] *See,* Defense Exhibit 17, at. p. 615.
[66] *See,* Defense Exhibit 18, at pp. 299, 301.

2. DTI HAS BEEN PEER REVIEWED:

"Submission to the scrutiny of the scientific community is a component of 'good science', in part because it increases the likelihood that substantive flaws in methodology will be detected." Daubert, 509 U.S. at 593. DTI has been subjected to peer review by the National Institute on Disability and Rehabilitation Research (NIDRR), which is a division of the U.S. Department of Education.[67] There are approximately 3,472 papers on DTI published in peer reviewed journals, the first one published in 1994, and of which over 83 concern traumatic brain injuries.[68] As shown above, DTI has extensive support in the peer reviewed literature. Plaintiff also refers the Court to pages 8-11 of Dr. Benson's affidavit[69] for further support for the use of DTI to diagnose mTBI.

3. DTI HAS A LOW ERROR RATE:

In assessing the reliability of a particular scientific technique, consideration should generally be given to the known or potential rate of error and the existence and maintenance of standards controlling the technique's operation. Daubert, 509 U.S. at 594.

The defense has not cited one article that indicates that DTI is prone to false positives. To the contrary, the defense cites to literature illustrating DTI's promise as a biomarker for TBI.

As described in Dr. Benson's affidavit, the odds of XXX's findings occurring as a result of chance are statistically impossible.[70] There is little doubt that DTI demonstrates that XXX has damage to his white matter that are typical for traumatic axonal injury. The findings are confirmed by XXX's symptoms, the findings on MR Flair and the QEEG.

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[67] *See,* Exhibit 1 at p. 1, paragraph 23.
[68] *Id.* at p. 7, paragraph 40.
[69] Exhibit 1.
[70] *See,* Exhibit 1 at pp.4- 5, paragraph 20.

4. DTI WAS NOT DEVELOPED FOR LITIGATION

One such factor applicable here is whether experts are "proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1317 (9th Cir. 1995). In the present matter, Dr. Benson did not develop his opinions regarding DTI for the purpose of testifying. Rather, Dr. Benson has submitted peer reviewed articles and testimony to the United States Congress that support the use of DTI for the diagnosis of mTBI. He employs DTI in his work for the NFL and recently spoke at a conference of experts on DTI to bring the benefits of DTI to our soldiers and veterans. Dr. Benson's anticipated trial testimony concerning DTI and its validity and reliability have all grown naturally and directly out of research and other activities conducted completely independent of this lawsuit.

4a. Dr. Bammer, the defense expert, has given opinions in this case that contradict his non-litigation opinions.

Dr. Bammer has admitted in a supplemental report that the testimony he proposes to give this Court contradicts his prior writings:

> "Without confirmatory studies many other authors have pick(ed) up on the cliché that DTI is a sensitive biomarker for subtle brain damage/abnormality without truly confirming these findings. That way, the assumption that DTI is a sensitive technique to measure microstructural damages has been propagated along many times over several publications. **Ironically, this author has used these phrases, too.** In retrospect, these statements should not have been made without clear proof."[71]

The following are quotes from Dr. Bammer's writings that contradict his opinions in this case:

1. Bammer, R – *New methods in Diffusion Weighted and Diffusion Tensor Imaging – Magn Reson Imaging* - **Clin N Am** 2009 May; 17(2):175-204.

> "Considerable strides have been made by countless individual researchers in diffusion weighted imaging (DWI) to push DWI from an experimental tool – limited to a few institutions with specialized instrumentation – to a powerful tool used routinely for

[71] *See* Dr. Bammer's Supplement, attached as Exhibit 15 at p. 6.

diagnostic imaging...Advancements in DWI, such as q-space imaging but most importantly diffusion tensor imaging (DTI), have demonstrated great utility in furthering the diagnostic potential of MRI to reveal tissue features otherwise occult to conventional MRI."[72]

2. Bammer, R. – *Changes in parahippocampal white matter integrity in amnesic mild cognitive impairment: A diffusion tensor imaging study* – **Behav Neurol** 2009; 21(1):51. doi.10.3233/BEN-2009-0235

"Diffusion tensor imaging (DTI) makes it possible to examine the microstructural integrity of white matter in vivo and is especially indicative for diseases causing neuronal or axonal damage."[73]

3. Bammer, R. – *Diffusion MR Imaging in Multiple Sclerosis: Technical Aspects and Challenges* – **AJNR Am J Neuroradiol** 28:411-20 March 2007 –

"Over the past 15 years, diffusion weighted (DW) MR imaging has increasingly been applied to the brain and is now available for the clinical investigation of numerous conditions, including multiple sclerosis . . . DT MR imaging appears to offer improved pathologic specificity over conventional MR imaging for assessing the degree of damage in individual MS lesions, and its quantitative nature allows an assessment of the more widespread tissue damage occurring outside such lesions."[74]

4. Bammer, R – *Cognitive Processing Speed and the Structure of White Matter Pathways: Convergent Evidence from Normal Variation and Lesion Studies* – **Neuroimage** 2008 August 15;42(2): 1032-1044. Doi:101016/j.neuroimage.2008.03.057 –

"In order to investigate the relationship between cognitive speed of processing and white matter organization, we first examined the relation between performance on the Digit-Symbol test and diffusion tensor imaging (DTI) of white matter, a technique which makes possible in vivo exploration of microstructural features of white matter with quantitative methods (Basser and Pierpaoli, 1996; Beaulieu, 2002; Le Bihan and van Zijl, 2002). The most commonly used DTI derived measure of white matter microstructure is fractional anisotrophy (FA), a scalar quantity derived from diffusion tensors that reflects the degree to which diffusion of water molecules is constrained in space due to local tissue properties including density, directional coherence, diameter, and myelination level of white matter fibers (Basser and Pierpaoli, 1996), the same properties that influence neural signal transmission. The sensitivity of FA to local organization of fibers has been utilized to demonstrate correlations between psychological variables an subtle variations in regional properties of white matter structures that are not accessible through other imaging modalities (Deutsch et al., 2005; Klingberg et al, 2000; Madden et al., 2004; Moseley et al., 2002; Schulte et al., 2005; Tuch et al., 2005)"[75]

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[72] Attached as Exhibit 16 at p. 1.
[73] Attached as Exhibit 17 at p. 2.
[74] Attached as Exhibit 18 at p. 411.
[75] Attached as Exhibit 19 at p. 3.

"Neurological patients with lesions in left parietal white matter, encompassing the region found in the DTI investigation, and neighboring cortical regions BA 39 and 40 were found to have reduced processing speed compared to patients who did not have lesions in these areas."[76]

D. DTI HAS BEEN ADMITTED BY COURTS UNDER BOTH *FRYE* AND *DAUBERT* STANDARDS[77]

In Rye v. Kia Motors America, Inc., a defendant filed a Motion in Limine to exclude Dr. Benson's testimony involving DTI.[78] Like the instant case, the defendant argued that "Dr. Benson's use of a statistical comparison to conclude that the plaintiff has suffered a closed head injury is not a generally accepted methodology."[79] Like the instant case, the defense argued that the literature supporting DTI compared TBI patients to normal and that simple correlations between diffusivity in the brain for those who suffer TBI are not sufficient to support using DTI to assist in diagnosing brain damage.[80] After reviewing briefs from both sides, the Court denied the defendant's motion and allowed Dr. Benson to testify.[81] The court indicated that it had heard oral arguments and considered itself "fully advised" on the issue.[82]

In Lamasa v. Bachman, the Supreme Court, Appellate Division, First Department, New York, considered whether a trial court properly admitted evidence of mild traumatic brain injury that had been obtained through DTI.[83] The court held that DTI evidence was properly admitted because it could not be characterized as novel science and that the defendant's concerns went to the weight of the evidence, not its admissibility.[84] The court reasoned that "plaintiffs' experts,

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[76] *Id.* at p. 7.

[77] The defense does not point to, nor is the Plaintiff aware of, any case that excludes DTI under either a *Frye* or *Daubert* analysis.

[78] Case No. 07-701204-NP, (Mich. Feb. 16, 2010) (order denying defendant's motion in limine to preclude testimony of Dr. Randall Benson), attached as Exhibit 20.

[79] *See,* Brief of defendant, Rye v. Kia Motors America, Inc., Case No. 07-701204-NP (Mich. Feb. 16, 2010), attached as Exhibit 21 at p. 6.

[80] *Id.*

[81] Exhibit 20; *See also,* Exhibit 21; Brief of plaintiff, Rye v. Kia Motors America, Inc., Case No 07-701204-NP (Mich. Feb. 16, 2010), attached as Exhibit 22.

[82] *See,* Exhibit 20.

[83] 56 A.D.3d 340 (N.Y. App. Div. 2008), attached as Exhibit 23. The plaintiff alleged he suffered a mild traumatic brain injury after being rear-ended by a truck while parked at a red light. *Id.*

[84] *Id. See Also,* Brief and Appendix for Plaintiffs-Respondents at 44-46, Lamasa v. Bachman, 2008 WL 5949015 (N.Y.A.D. 1 Dept.) (Appellate Brief) (No. 2008-0468), attached as Exhibit 24. The Plaintiff's expert testified that DTI is a reliable method for determining the presence of brain injury in the brain's white matter, that DTI has been

relying on objective medical tests, testified to brain damage and other injuries that they attributed to trauma, and the **conflicting medical evidence and opinions of defendant's experts concerning the permanence and significance of plaintiff's injuries simply raised issues of fact for the jury.**"[85] In denying defendant's motion for relief, the lower court explained that:

> DTI is an imaging technique used to study the random motion of hydrogen atoms within water molecules in biological tissue (e.g., brain white matter) and spatially map this diffusion of water molecules, *in vivo.* DTI provides anatomical information about tissue structure and composition. Changes in these tissue properties can often be correlated with processes that occur, among other causes, as a result of disease and trauma.[86]

The lower court further held that, as to the issues of causation and the precise physical injuries the plaintiff suffered as a result of the collision, "the parties had numerous expert witnesses testifying and in considering the conflicting testimony of the parties' respective expert witnesses, the jury was not required to accept one expert's testimony over that of another, but was entitled to accept or reject either expert's position in whole or in part."[87] On appeal, the New York Supreme Court, Appellate Division, upheld the trial court's admission of the challenged expert testimony.[88]

In Booth v. Kit, the U.S. District Court for the District of New Mexico denied the defendant's motion to strike, limit, or exclude, expert testimony that, in part, relied on DTI testing.[89] The court held that the expert's testimony was admissible under Rule 702 because the reasoning and methodology underlying the testimony was scientifically valid and therefore sufficiently reliable.[90] The court indicated that Dr. Orrison's reasoning and methodology had been sufficiently tested, peer reviewed, lacked a high error rate, and was generally accepted in

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cleared by the FDA, that DTI can reveal abnormalities that aren't visible on standard MRIs, and that "[a]mong the benefits of use and study of diffusion tensor imaging, at this point it is fair to say that it is an accepted fact, or given, that DTI indexes brain injury." *Id.*

[85] Exhibit 23 (emphasis added).

[86] Lamasa v. Bachman, 2005 WL 1364515 (N.Y.Sup.), attached as Exhibit 25, at *2, FN3.

[87] *Id.* at *6 (citations omitted).

[88] Exhibit 23.

[89] Civ. No. 06-1219 JP/KBM, 2009 U.S. Dist. Lexis 125754, at *12, (D. N.M. March 23, 2009), attached as Exhibit 26. The expert in that case, Dr. William W. Orrison, Jr., MD reviewed the plaintiff's medical history and performed a PET scan, an MRI scan, and a DTI study. *Id.* at *9.

[90] *Id.* at *7-12.

the scientific community.[91] The court made clear that "any perceived weakness in Dr. Orrison's conclusions **may be attacked on cross examination or by contradictory opinions by one or more other qualified experts.**"[92]

In LeBoeuf v. B & K Contractors, Inc., a trial court judge properly allowed experts from both sides to testify regarding plaintiff's brain damage and the various tests performed on him (including DTI) in a bench trial restricted to damages.[93] The trial court judge found that the plaintiff did have a brain injury and awarded him damages.[94] In affirming the plaintiff's award, the appeals court noted that the "expert medical testimony regarding the nature and degree of injuries [the plaintiff] sustained was conflicting" and that the trial court judge found "that the evidence established [the plaintiff] sustained a mild brain injury."[95] The appeals court decline[d] to disturb the trial court's award of general damages.[96]

VII. CONCLUSION

This Court should deny the Defendants' Motion to Exclude Evidence Related to DTI. DTI is generally accepted in the relevant scientific community, as amply illustrated by the voluminous peer reviewed literature (including that of the Defendants' expert), for diagnosing white matter damage. DTI is demonstrably reliable, as the methodology described by Dr. Benson is not only peer reviewed but also inherently reliable based upon statistics; the odds of Dr. Benson's findings being random/false positive are essentially impossible. When courts have considered the general acceptance and/or reliability of DTI they have unanimously found the evidence admissible. The defense has not been able to identify one single case where DTI

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[91] *Id.*
[92] *Id.* at *12 (emphasis added).
[93] 2008 1351 (La.App. 4 Cir. May 27, 2009) at *15, *41-42; 10 So. 3d 897; 2009 La. App. Unpub. Lexis 324, attached as Exhibit 27.
[94] *Id.* *49-52.
[95] *Id.* at *49-50.
[96] *Id.* at *50.

evidence was excluded under any test of admissibility. For the above stated reasons, this Court should find DTI evidence reliable and deny the defendant's motion.

Respectfully submitted,
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