

CANADA / JUDGMENT

Gutfriend v. Case

2022 BCSC 2055

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Supreme Court of British Columbia

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2022 BCSC 2055 Gutfriend v. Case

IN THE SUPREME COURT OF BRITISH COLUMBIA

Citation:

Gutfriend v. Case,

2022 BCSC 2055

Date: 20221125

Docket: M1955412

Registry: Prince George

Between:

Ruth Catherine Gutfriend

Plaintiff

And

David Case and Gemma Gillis

Defendants

Corrected Judgment: The text of the judgment was corrected throughout the judgment on December 1, 2022

Before: The Honourable Justice Thomas

Reasons for Judgment

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Place and Date of Trial:

Prince George, B.C.

September 13-16, 20-23 and

September 29, 2022

Place and Date of Judgment:

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Table of Contents

Issue. 3

Facts. 3

Legal Test. 3

Step One. 4

Step Two. 4

Application of Findings to Step One. 5

Logically relevant 5

Necessary. 6

No Exclusionary Rule. 6

Properly Qualified Expert 6

Novel or Contested Science. 7

The Law.. 7

Evidentiary Issues. 8

Jacobs Articles. 8

European Guidelines. 9

Raji Review.. 9

Wintermark Committee. 11

Amen Study. 11

ACR Guidelines. 14

CANM Guidelines. 15

Use in Hospitals. 19

Conclusions on Step One. 19

Conclusions on Amen Study. 20

Disposition.. 20

Issue

- [1] This is a voir dire to determine the admissibility of the interpretation of single-photon emission computed tomograph ("SPECT") scans as an adjunct or primary diagnostic tool to diagnosis traumatic brain injury ("TBI").

Facts

- [2] The plaintiff will rely upon an expert report from Dr. Mansouori, whom opines that the plaintiff suffers from a post-concussion syndrome and posttraumatic stress disorder ("PTSD").
- [3] The defendant will rely upon an expert report from Dr. Okorie whom opines that the plaintiff suffers from posttraumatic stress disorder, major depressive disorder, and anxious distress.
- [4] Dr. Cohen performed a SPECT scan on the plaintiff and provides the following interpretation:

impression: cerebral perfusion study consistent with known previous head injury, involving the temporoparietal cortex bilaterally and the parietal-occipital cortex over the convexity, as well as the left infero frontal cortex. Increased perfusion to the deep structures is associated with posttraumatic stress disorder.

- [5] This interpretation was provided to Dr. Mansouori, who opines:

The SPECT scan results confirm the clinical findings of concussion and post-concussion syndrome.

Legal Test

- [6] The parties are in agreement that the use of SPECT scans to diagnose or assist in the diagnosis of a TBI should be characterized as novel science for purposes of assessing admissibility.

- [7] The legal framework for assessing the admissibility of expert evidence is set out in *White Burgess Langille Inman v. Abbott and Haliburton Co.*, [2015] 2 S.C.R. 182. Though expert evidence is presumptively inadmissible, it is admissible when the following steps are satisfied:

Step One

- [8] The evidence must meet all of the threshold preconditions of admissibility:
- a) The evidence must be logically relevant;
 - b) The evidence must be necessary to assist the trier of fact;
 - c) There must be no exclusionary rule prohibiting the reception of the evidence;
 - d) The expert must be properly qualified, which includes as a precondition the requirement that the expert be willing and able to fulfil the duty to the court to provide evidence that is impartial, independent, and unbiased; and
 - e) For opinions based on novel or contested science or science used for a novel purpose, the underlying science must be judged legally reliable for that purpose.

Step Two

- a) The trial judge determines at the gatekeeper stage whether the benefits of admitting the evidence outweigh its potential risk, considering such factors as the degree of: relevance, necessity, reliability and absence of bias;
- b) Put another way, relevance, reliability and necessity are measured against the counterweights of consumption of time, prejudice and confusion;
- c) To be permitted to testify the expert must also attest to their impartiality, independence and absence of bias. Once that has been deposed by the expert the burden shifts to the party opposing the admission of the evidence to show that there is a realistic concern that the expert is unable or unwilling to comply with that duty. If successful, the burden shifts back to the party calling the evidence, who must establish, on a balance of probabilities, this aspect of the admissibility threshold.

Application of Findings to Step One

Logically relevant

- [9] Relevance at this threshold stage refers to whether the evidence has a tendency to make the existence or nonexistence of a fact in issue more or less likely than it would be without the evidence.

- [10] The SPECT scan required the plaintiff to absorb radioactive tracer material. The tracer material enabled external sensors to image the volume of blood perfusion throughout her brain. The image was then processed and interpreted by a clinician with the assistance of computer modelling.
- [11] In interpreting the SPECT scan relative blood perfusion is used as a proxy for metabolic activity. Hypoperfusion is associated with large variety of psychiatric and organic abnormalities, including TBI, posttraumatic stress disorder, depression and anxiety.
- [12] SPECT is very good at identifying areas of hypoperfusion in the brain. It is therefore very good at identifying people whom have neuropsychological sequela arising from psychiatric and/or organic abnormalities. SPECT has a high sensitivity to these conditions.
- [13] The degree to which SPECT can distinguish between these conditions is referred to as specificity. Low specificity is associated with an inability of a test to distinguish between conditions.
- [14] SPECT can be useful in diagnosing conditions that have been identified as having distinct perfusion patterns. Examples of these conditions in the brain include brain death, epilepsy, stroke and rapidly accelerating dementia. SPECT has a high sensitivity and specificity for these conditions.
- [15] If SPECT scans could identify a distinct hypoperfusion pattern for TBI it would be characterized as both sensitive and specific for TBI.
- [16] In the circumstances of this case logical relevance is dependent upon specificity. At a threshold level the SPECT evidence meets the criteria for logical relevance.

Necessary

- [17] Interpreting a SPECT scan lies outside the experience and knowledge of a judge or jury. This meets the criteria for necessity under step one.

No Exclusionary Rule

- [18] There is no exclusionary rule that would prohibit the acceptance of this evidence. However, one of the central issues in this trial will be to determine whether the plaintiff suffers from a TBI or psychiatric issues. Given the central nature of the opinion evidence to an ultimate issue of the case, the evidence should be subject to special scrutiny, as noted by Justice Sopinka in *R. v. Mohan*, [1994] 2 S.C.R. 9 at p. 25 and by Justice Binnie in *R. v. J.-L.J.*, 2000 SCC 51 at para. 37 [J.-L.J.].

Properly Qualified Expert

- [19] It is clear that Dr. Cohen has the proper qualifications to provide an expert opinion on this issue. The defence raises concerns about bias.

[20] Dr. Cohen has provided a statement in his report that his opinion and testimony are in accord with Rule 11-2 of the Supreme Court Civil Rules. In my view, this is sufficient to meet the properly qualified expert requirement at step one. The concerns raised by the defendant with respect to Dr. Cohen's alleged bias should be addressed in step two, which requires, to some degree, a weighing of the evidence.

Novel or Contested Science

The Law

[21] In J.-L.J. the Court dealt with the admissibility of penile plethysmograph evidence. This evidence was generally recognized by the scientific community and is used by psychiatric facilities in Canada to monitor the result of treatment for sexual pathologies and to assess the progress of therapy of known and admitted sexual deviants. In J.-L.J., the defendant called Dr. Beltrami, who attempted to use this therapeutic tool as a forensic tool to determine whether the accused had a profile who matched the standard profile of a person that would commit sexual offences against male children.

[22] In assessing the admissibility of this evidence Binnie J. concluded that evidence based on novel science is subject to special scrutiny. The party tendering the evidence must demonstrate the reliability of the underlying science for the purpose upon which it is submitted.

[23] He noted the factors that inform reliability include, non-exhaustively:

- a) whether the theory or technique can be and has been tested;
- b) whether the theory has been subjected to peer review and publication;
- c) the known or potential rate of error for the existence of standards; and
- d) whether the science and methodology have found general acceptance within the scientific community.

[24] In White Burgess Langille, at para. 54, the Court concluded that after assessing the factors set out by Binnie J., and other relevant factors, the Court "must be satisfied that the potential helpfulness of the evidence is not outweighed by the risk of the dangers materializing that are associated with expert evidence."

Evidentiary Issues

[25] I will consider these factors, keeping in mind the fundamental issue of reliability under the headings of the major evidentiary issues raised in the voir dire.

- [26] There have been thousands of articles published on SPECT. However, the key issue is the use of SPECT on TBI; specifically as a diagnostic tool. The voir dire focused on four articles: two authored by Jacobs (1994 and 1996; the "Jacobs Articles"), one authored by Raji (2014; the "Raji Review") and one authored by Amen (2015; the "Amen Study"). The articles were marked for identification.
- [27] SPECT imaging has also been the subject of several guidelines, including the European Association of Nuclear Medicine Neuro-imaging Committee's guidelines (2009; the "European Guidelines"), the American College of Radiology's Wintermark Committee (2015; the "Wintermark Committee"), the American College of Radiology generally (2016 and 2020; the "ACR Guidelines"), and the Canadian Association of Nuclear Medicine's guidelines (2021; the "CANM Guidelines").
- [28] The findings I have made with respect to the articles were derived from my assimilation of the expert evidence contained in reports and oral testimony. The same is true for the guidelines, but I have also relied upon the specific wording contained in the guidelines which were entered as numbered exhibits.

Jacobs Articles

- [29] The first significant articles were published by Jacobs in 1994 and 1996. These articles referred to a prospective study that dealt with a small sample of people whom had already been diagnosed with TBI. The studies found a positive relationship between SPECT scans and chronicity of symptoms in the sample population. The Jacobs Articles indicated SPECT scans may have a prognostic value with respect to TBI. The articles did not investigate a diagnostic use for SPECT.
- [30] The results have not been replicated.

European Guidelines

- [31] The European Guidelines which set out the recommended usage of SPECT were published in a mainstream peer-reviewed medical journal in 2009. The guidelines note under the header "Indications for SPECT":

A.4 Evaluation of traumatic brain injury. SPECT has shown perfusion abnormalities in traumatic brain injury despite normal morphology, and results are considered to have a prognostic value for persistence of neuropsychological sequela.

- [32] Dr. Cohen testified there is a clear distinction in medicine between "diagnosis", which is an attempt to identify a disease, and "prognosis", which is the likely course of a disease in the future. In my view, these words are not interchangeable and do not mean the same thing.

- [33] I conclude the European Guidelines do not endorse a diagnostic use for SPECT with respect to TBI. They state that SPECT has a prognostic value for persistence of neuropsychological sequela in patients already diagnosed with TBI. The recommendations are consistent with the findings arising from the Jacobs Articles, including the use and context of the word "prognostic".

Raji Review

- [34] The Raji Review was a systematic review of all of the literature dealing with the use of SPECT in TBI up until 2013. Dr. Raji was the lead author of the review, but both Drs. Tarzwell and Cohen, both of whom testified on behalf of the plaintiff, assisted with the review.
- [35] A systemic review of literature is helpful in defining areas of consensus within the scientific community and identifying gaps in knowledge that can be addressed with original work. The review was published in the journal PLOS ONE. I will discuss this journal later in my reasons.
- [36] Dr. Cohen testified that the Raji Review demonstrated that SPECT was much more sensitive to TBI than magnetic resonance imaging (MRI), such that a negative SPECT finding was associated with no sequela and no ongoing injury. However, no studies demonstrated a pathognomonic indicator of TBI utilizing SPECT; while some showed "somewhat associative patterns" between SPECT and TBI, none were "for sure" definitive. I accept his evidence on this issue and interpret this to mean the Raji Review confirmed SPECT has high sensitivity for TBI but low specificity.
- [37] This means that SPECT can detect hypoperfusion that is associated with neuropsychological sequela associated with TBI, but it cannot determine whether the hypoperfusion (and by proxy neuropsychological sequela) are due to numerous other conditions, such as depression, posttraumatic stress disorder, anxiety, and/or lack of sleep.
- [38] I also find that the Raji Review found empirical support for the proposition that SPECT findings may have a prognostic value for persistence of neuropsychological sequela. The primary support for this lies in the Jacobs Articles, which the Raji Review found were the highest quality studies identified in the review and received the greatest emphasis. This was confirmed by all of the experts whom testified.
- [39] In my view, the Raji Review demonstrates that the state of knowledge on the use of SPECT for identifying TBIs has not changed significantly following the unreplicated Jacobs Articles. This finding is not only based on the testimony provided by Drs. Cohen, Cheung, Siu and Worsley with respect to the Raji Review and Jacobs Articles, but also with respect to my findings on the Wintermark Committee and the AEC and CANM Guidelines summarized later in these reasons.
- [40] Dr. Cohen testified that a prospective researcher made a formal proposal to replicate the Jacobs Articles, but that funding could not be obtained for the attempt to replicate it.

- [41] The issue to be decided by the court in this case is whether the plaintiff's neuropsychological sequela is due to a TBI or depression and/or anxiety, or some combination thereof.
- [42] Dr. Tarzwell testified that the Raji Review supports the proposition that SPECT should be part of the clinical evaluation in the diagnosis and management of TBI. Dr. Tarzwell's view was objected to by Drs. Cheung, Siu and Worsley. I will comment on Dr. Tarzwell's opinions later in these reasons, but I do not accept his evidence as to the state of scientific empirical knowledge as of 2015.

Wintermark Committee

- [43] In February 2015, the American College of Radiology's Wintermark Committee produced evidence and recommendations for advanced neuro and neurovascular imaging techniques for TBI. Dr. Tarzwell described these recommendations as the product of a "blue ribbon" committee that was designed "to set the standard for the next decade or so." In my view, at the time it was published, this represented an authoritative review and summary of the scientific empirical evidence pertaining to the use of SPECT in TBI. This view was supported by all of the experts whom testified.
- [44] The Wintermark Committee referred to the Raji Review and noted that while the research to date showed promising results in group comparison analysis, there was insufficient evidence supporting use of SPECT for routine use for either diagnosis and/or prognosis at the individual patient level. The principal author of the Raji Review, Dr. Raji, was a member of the Wintermark Committee. I infer Dr. Raji had direct input into the Wintermark Committee recommendations with respect to the use of SPECT for TBI.
- [45] The Wintermark Committee acknowledges that imaging is a rapidly evolving field and a number of recommendations will be updated to reflect advances in medical knowledge.
- [46] I am satisfied that the Wintermark Committee recommendations contain an accurate summary of the consensus of the state of empirical knowledge for the use of SPECT as it related to TBI as of February 2015.

Amen Study

- [47] Dr. Amen and Dr. Raji were the lead authors of the Amen Study. Dr. Tarzwell assisted with this study, as he did with the Raji Review. The Amen Study noted that TBI and PTSD often present with overlapping symptoms which provide challenges in diagnosis and treatment. The purpose was to see if SPECT could be used in a "novel" way to assist in the diagnostic separation of the two disorders.

- [48] The Amen Study consisted of two groups. The first group contained 400 patients whom were compared to a control group of 100 "unicorns", described as people who had a perfectly clean psychological and neurological profile. The SPECT scans were able to distinguish TBI from the control group and distinguish TBI from PTSD with over 80% specificity and 100% sensitivity.
- [49] The second group contained larger numbers of patients whom were tested against a control group more representative of real-world conditions. The SPECT scans were able to distinguish TBI from the control group with a 54% specificity and distinguish TBI from PTSD with a 60% specificity. The sensitivity was 70% and 80%, respectively.
- [50] The Amen Study concluded that TBI was associated with widespread hypoperfusion while PTSD is associated with regional hyperperfusion. Replication of this work would provide a basis for identification of biomarkers distinguishing TBI from PTSD.
- [51] The article was published in PLOS ONE, a journal which charges authors a fee to have their articles published. The extent that the article received peer review from reviewers with specialized knowledge was unclear. I share Dr. Worsley's concern that charging authors a fee for publication creates an incentive to publish articles without rigorous review. I find the PLOS ONE journal is not a leading medical journal and is not generally referred to or consulted by relevant specialists.
- [52] Notwithstanding that finding, the interpretation and impact of this study was a matter of dispute amongst the experts.
- [53] Dr. Tarzwell stated that the results of the Amen Study clearly contradict the limitations of SPECT for diagnostic purposes as stated by the Wintermark Committee. Given the high specificity associated with the findings, the Amen Study demonstrates that SPECT "is a diagnostic test of TBI." In his report, Dr. Tarzwell asserts that if the Wintermark Committee had completed their report six months later, their conclusions would have been dramatically different.
- [54] When asked how the Wintermark Committee could have been unaware of the Amen Study when Dr. Raji, one of the principal authors of the Amen Study, was on the committee, Dr. Tarzwell stated that Dr. Raji was "shy of controversy" and was content to let "data speak for itself." I find the Wintermark Committee was aware of the Amen Study when they drafted their recommendations due to Dr. Raji's presence on the committee.
- [55] Dr. Tarzwell stated in his testimony at the voir dire that the Amen Study provided "ground-breaking" results with respect to the ability of SPECT to diagnose TBI. When asked why this testimony differed from the written conclusions contained in the Amen Study, which itself noted that "replication in smaller cohorts would provide a basis for identifying biomarkers to distinguish TBI from PTSD", Dr. Tarzwell testified that "one always pulls punches" in academic articles. Dr. Tarzwell did agree that this was the conclusion of the Amen Study and that he was a co-author of the conclusion as recorded in the article.

- [56] Dr. Cohen testified the Amen Study was designed to test whether SPECT could be used to discriminate between PTSD and TBI. It was not designed to examine whether SPECT can diagnose TBI. He further noted SPECT cannot diagnose TBI, nor can its findings serve as a biomarker for TBI. In re-examination, he clarified that, in his opinion, SPECT could have a "diagnostic impact" for diagnosing TBI, but it is not a "stand alone diagnostic test".
- [57] Dr. Siu testified the Amen Study was not designed to diagnose TBI but was designed to see if SPECT imaging could distinguish between patients who had been diagnosed with TBI from those diagnosed with PTSD. This represented a major limitation on the conclusions that one can be drawn from the study, such that the study's conclusions could not be applied to a clinical setting.
- [58] Dr. Cheung and Dr. Worsley echoed Dr. Siu's concerns. They testified the study was created to answer a binary question and was not designed to evaluate SPECT's ability to diagnose TBI. Therefore, the specificity rates associated with the study cannot be applied to a real-world situation involving assessment or diagnosis of TBI. They also raised concerns about the validity of the study and the sample groups utilized in the study.
- [59] I will set out my findings with respect to the Amen Study later in these reasons.

ACR Guidelines

- [60] The American College of Radiology has published appropriate use criteria in 2016 and 2020 in mainstream peer-reviewed medical journals. The ACR Guidelines note:

Despite the promise of perfusion imaging (whether employing SPECT or CT/MRI based techniques) for the detection of functional injury that may be occult on structural imaging, there is insufficient evidence to support the routine clinical use of SPECT at the individual patient level.

- [61] The reference for this recommendation is the Wintermark Committee recommendations. Drs. Worsley, Siu and Cheung are of the view that the ACR Guidelines are the leading reference for nuclear medicine and for radiology. Drs. Cohen and Tarzwell are of the view that the nuclear medicine community is the group that is best suited to determine appropriate guidelines and that the ACR appears to have overlooked the Amen Study and simply relied upon the Wintermark Committee.
- [62] In my view, the relevant community cannot be narrowly defined to one speciality or sub-speciality. Assessing and diagnosing TBI is a cross-disciplinary activity. The relevant scientific community is made up of health care practitioners with appropriate training and expertise. I would note that Dr. Amen, a psychiatrist, was acknowledged as being one of the most experienced interpreters of SPECT scan within the TBI context.

[63] In 2021, the ACR, the American College of Nuclear Medicine, the Society of Nuclear Medicine, the American College of Radiology, and Society of Pediatric Radiology published guidelines regarding the use of SPECT. It is a consensus guideline between the leading North American nuclear medicine organizations. The guidelines provide no discussion on the use of SPECT imaging with respect to diagnosing TBI or as an adjunct to assist in diagnosing TBI.

CANM Guidelines

[64] Dr. Cohen led a group of people whom drafted guidelines for the Canadian Association of Nuclear Medicine. Dr. Tarzwell was a member of the drafting group. The association is a small group of perhaps 300 specialists and is not known for publishing guidelines. The CANM Guidelines were accepted by the executive of the association in 2021.

[65] Dr. Cohen testified one reason the guidelines were produced was that the European Guidelines had not been updated since the Amen Study.

[66] The stated focus of the CANM Guidelines in the abstract was:

to assist Canadian nuclear medicine specialists in conducting standard examinations for brain perfusion SPECT imaging which will increase the diagnostic impact of this technique in clinical practice.

[67] The majority of the CANM Guidelines dealt with the techniques and protocols to follow when conducting SPECT exams to ensure the procedures are conducted in a standardized manner. This is critical to ensure consistent reliable results due to the sensitivity and inherent frailties of the SPECT procedure.

[68] The CANM Guidelines also provide a number of common indications for SPECT scans. This guideline states the following with respect to the use of SPECT for TBI:

SPECT has shown perfusion abnormalities and TBI despite normal morphology and results are considered to have a prognostic value for persistence of neuropsychological sequela.

[69] The CANM Guidelines then provide a summary of the Raji Review and the Amen Study. With respect to the Raji Review, the summary focused on the Jacobs Articles and concludes that there was:

a correlation between abnormal SPECT findings and neuropsychological deficits. This suggests that abnormalities found with brain SPECT can correlate with and therefore be predictive of functional outcomes.

[70] I note the use of the word "prognosis" and the Raji Review are essentially the same as my findings with respect to the Jacobs Articles and the Raji Review.

[71] With respect to the Amen Study, the CANM Guidelines noted:

A retrospective study of over 20,000 subjects showed that SPECT can distinguish traumatic brain injury from posttraumatic stress disorder with 80 to 100% sensitivity and an average of 70% specificity. Replication of this study in a smaller sample of 196 military veterans with traumatic brain injury, posttraumatic stress disorder or both showed accuracy of between 83% and 94% in distinguishing between these conditions.

- [72] This is similar to the published conclusions of the Amen Study which indicate the significance of the study is the finding that SPECT was able to distinguish TBI from PTSD. There is no mention of a "ground-breaking" discovery of an ability to diagnose TBI using SPECT.
- [73] The CANM Guidelines were not published in a leading peer-reviewed medical journal, nor have they been subjected to peer review. Dr. Cohen testified that he would "love" to get them published in such a journal and perhaps get them on PubMed, but has been unable to do so.
- [74] I was troubled that there was no conflict of interest disclosure requirements associated with the CANM Guidelines. Dr. Cohen has provided at least 200 medical-legal reports for Dr. Mehdiratta using SPECT for identifying TBI over the last three years, a period which spans the creation and publication of the guidelines. Dr. Cohen has also invested close to \$3,000,000 in SPECT technology at his hospital. In my view, these are interests that should have been noted in a disclosure statement.
- [75] The CANM Guidelines were included in the Canadian Medical Association ("CMA") database in 2021. Dr. Cohen testified that a general practitioner whom was a member of the CANM executive arranged for the guidelines to be published on the CMA registry.
- [76] The CMA publishes "thousands of guidelines" that are endorsed by Canadian medical associations. While they try to ensure that the guidelines they publish are evidence-based, they do not peer review guidelines included in their registry and they do not have nuclear medicine specialists on their staff. I find the CMA keeps a depository of guidelines published by recognized Canadian medical associations.
- [77] Dr. Tarzwell noted the following in his report, which was consistent with his testimony:

In my opinion, and the opinions of the Canadian Association of Nuclear Medicine and the Canadian Medical Association, brain perfusion SPECT is a medically recognized brain diagnostic technology, able to affirmatively diagnose mild traumatic brain injury in the setting of negative CT or MRI.

- [78] Dr. Tarzwell's interpretation of the guidelines is inconsistent with the clear wording of the text of the CANM Guidelines and Dr. Cohen's evidence. I find his interpretation of the guidelines and attribution of his opinion to the CMA to be consistent with the tenor of his evidence as a whole, which overstated and exaggerated the conclusions flowing from the research he was associated with.

- [79] This is particularly problematic within the context of developing areas of science where the trier is more reliant upon the accuracy and impartiality of experts than in more conventional areas. I found Dr. Tarzwell's evidence to be unreliable and place no weight on it when it was not corroborated by other sources.
- [80] Dr. Cohen provided a more nuanced interpretation of the guidelines. He testified the CANM Guidelines were intended to reflect his opinion that SPECT scans may be used to assist in the diagnosis of TBI. The imaging has not revealed a biomarker for TBI and can only be used as a tool to assist in the diagnostic process. The basis for this guideline was to reflect the developments in scientific knowledge arising from the Amen Study.
- [81] Drs. Cheung, Siu and Worsley testified the guidelines do not say SPECT can be used to diagnose TBI, only that studies suggest SPECT has a prognostic value for the persistence of neuropsychological sequela. They say the Raji Review and Amen Study do not provide an empirical basis for using SPECT to diagnose or assist in the diagnosis of TBI at a clinical or individual level. In their view, the appropriate guidelines are the ones published by the ACR.
- [82] Despite the fact that Dr. Cohen -- and, to a lesser extent, Dr. Tarzwell -- were involved in drafting the guidelines, I agree with the interpretation of the CANM Guidelines put forth by Drs. Cheung, Siu and Worsley. The guidelines do not say SPECT can be used to diagnose TBI. The abstract says that the aim is to "assist Canadian nuclear medicine specialists in conducting standard examinations" for SPECT "which will increase the diagnostic impact" of the technique. The use of the word "diagnostic impact" is within the context of the critical need for specialized and consistent procedures to obtain valid SPECT scans.
- [83] It is important to note that SPECT is utilized to diagnose a number of disorders. Noting that SPECT can be utilized in the diagnosis of epilepsy and brain death, for example, does not mean it can be utilized to diagnose a different disorder such as TBI.
- [84] The use of SPECT with respect to TBI is set out in the common indications section of the guideline. It clearly states SPECT can have a prognostic value for persistence of neuropsychological sequela. There is no mention of using SPECT for the purpose of diagnosing TBI. Given the evolution of scientific literature surrounding the use of SPECT in assessing TBI, I find the genesis for the use of "prognosis" comes from the Jacobs Articles and is distinct from "diagnosis".

Use in Hospitals

- [85] There was unsatisfactory evidence about the clinical use of SPECT in hospitals. The difficulty is that brain perfusion SPECT accounts for only a fraction of SPECT scans that are performed, and the use of SPECT for TBI only a fraction of the brain perfusion scans. In addition, many of the traumatic brain studies are for research or medical-legal purposes. Therefore, it is difficult to determine clinical usage unless one is active in the facility.

[86] Drs. Siu and Worsley testified that, to their knowledge, SPECT is only used for TBI at Lions Gate Hospital. Dr. Cheung testified that the Sunnybrook hospital does not use SPECT for TBI in a clinical setting.

[87] Dr. Cohen testified that SPECT is not widely used for psychiatric usage and for TBI outside of his hospital. However, it would be more widely used if he could convince people to use it.

Conclusions on Step One

[88] I have made the following findings:

1. A consensus of the state of empirical knowledge with respect to the use of SPECT and TBI as of 2015 is set out in the Wintermark Blue Ribbon Committee. This does not support the use of SPECT for individual clinical diagnostic purposes; and
2. None of the subsequent relevant published guidelines on the use of SPECT endorse the use of SPECT for individual clinical diagnostic purposes.

[89] However, this does not resolve the issue. In my view and given these findings, the critical issue is to determine how reliable is the use of SPECT as a tool to assist in the diagnosis of TBI.

[90] In my view, Dr. Cohen's position that it is appropriate to use SPECT for this purpose is based on the Jacobs Articles, the Raji Review and the Amen Study.

[91] The Jacobs Articles concludes that SPECT may have a prognostic value for persistence of neuropsychological sequela. In my view, this does not support the use of SPECT for diagnostic purposes.

[92] The Raji Review demonstrated that the state of knowledge on the use of SPECT for TBI had not changed significantly following the Jacobs Articles, which have not been replicated. In my view, this does not support the utilization of SPECT for diagnostic purposes.

Conclusions on Amen Study

[93] The Amen Study used SPECT to distinguish TBI from post-traumatic stress disorder. The most comparable specificity rating to the general population was 54%, which is slightly better than a coin toss.

[94] The defendant has raised a number of methodological and sampling issues with respect to the study. However, it is not necessary to delve into those concerns.

- [95] My assessment of the evidence has led me to conclude that the specificity demonstrated in the Amen Study is not translatable for diagnostic purposes in an individual clinical setting because of the bivariate nature of the study. The study simply was not designed to assess the diagnostic capabilities of SPECT for TBI; it was designed to distinguish TBI from PTSD. As such, it is not appropriate to use the results of the Amen Study for diagnostic purposes as proposed by Dr. Cohen.
- [96] This is consistent with the Wintermark Committee recommendations and with all of the relevant guidelines, including the CANM Guidelines which were primarily authored by Dr. Cohen.

Disposition

- [97] SPECT remains a very sensitive test for TBI. Unfortunately, the specificity is not sufficient to provide legally reliable information for diagnostic purposes in a setting where the issue is to distinguish brain injury from other psychiatric disorders and/or conditions.
- [98] Given my findings, I am of the view that it is unnecessary to proceed to Stage Two.
- [99] I order:
- a) Dr. Cohen's report dated January 17, 2022 is not admissible; and
 - b) Any reference to the brain perfusion SPECT; or Dr. Cohen's findings or opinions; are not admissible and are to be redacted from otherwise admissible documents.
- [100] If the parties need to resolve the issue of costs, or feel it would be useful to schedule a further management conference before the resumption of the trial, they are directed to submit a request to appear before me through the registry.

"Thomas J."

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