

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 07-786V

Filed: May 27, 2011

PETER RAMSEY,	)	
	)	TO BE PUBLISHED
Petitioner,	)	
	)	Entitlement;
v.	)	Hepatitis A; Hepatitis B; Tetanus;
	)	Cause in fact;
SECRETARY OF	)	amnesia; short-term memory loss;
HEALTH AND HUMAN SERVICES,	)	Limbic encephalitis; ADEM
	)	
Respondent.	)	
	)	

Ronald C. Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA, for Petitioner.

Ryan D. Pyles, United States Department of Justice, Washington, D.C. for Respondent.

### **DECISION ON ENTITLEMENT**<sup>1</sup>

**LORD**, Special Master.

#### **I. Introduction and Overview**

On November 8, 2007, Petitioner filed this case under the National Childhood Vaccine Injury Act ("Vaccine Act" or "Act").<sup>2</sup> On July 24, 2006, Petitioner received the Hepatitis A (Hep A), Hepatitis B (Hep B), and Tetanus-diphtheria ("Td") vaccines.<sup>3</sup> Petitioner has alleged that his vaccinations caused him to suffer from limbic encephalitis, or a limbic encephalitis-like condition, which manifested primarily as mild amnesia. Petitioner's theory of causation was that the vaccines initiated an autoimmune response that led to his limbic encephalitis. Petitioner claimed that his theory was supported by the diagnoses of his treating doctors.

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<sup>1</sup> The undersigned intends to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire ruling will be available to the public. Id.

<sup>2</sup> The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 et seq. (2006). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Vaccine Act.

<sup>3</sup> Petitioner received the Hep A & B immunizations in the Twinrix combination vaccine.

Respondent contested vaccine causation. Because the medical records did not document any objective evidence of an inflammatory process or insult to the central nervous system, Respondent challenged whether a theory of vaccine-caused encephalitis was applicable to Petitioner. She argued that Petitioner's clinical condition and laboratory test results were inconsistent with organic brain dysfunction, and therefore Petitioner could not have suffered from encephalitis. Respondent further challenged the assessment made by a treating psychologist that Petitioner had an amnesic disorder.

This case is complicated by numerous inconsistencies in the medical records and the physicians' opinions. In the weeks following vaccination, the symptoms subjectively reported by Petitioner often were not corroborated by the objective findings made on examination. In the year following vaccination, Petitioner saw more than 10 medical professionals and underwent extensive testing. Although some doctors speculated as to the cause of his condition, none of the doctors reached a definitive diagnosis. Thus the medical records alone do not show preponderant evidence that Petitioner suffered from limbic encephalitis or a vaccine-caused injury.

Adding further complexity, Petitioner's expert, Thomas Morgan, M.D., offered three different versions of his theory of post-vaccinal autoimmune disorder. Dr. Morgan appeared to assume that the vaccination caused Petitioner's condition, and then reason backward from there. As a result, not only did Dr. Morgan's causation theory change as facts were brought to his attention, but the facts on which Dr. Morgan relied shifted over the course of the proceedings as well. The shifting of his rationale undercut the persuasiveness of Dr. Morgan's opinion overall.

The parties agreed, however, that it would take at least seven days for a vaccination to cause an autoimmune response. Due to inconsistencies, the record in this case does not clearly establish when the first symptoms of Petitioner's condition occurred. In the days following vaccination, Petitioner went to the doctor several times, but the symptoms recorded at those visits vary. It seems that, within 48 hours of vaccination, Petitioner began to experience some neurological symptoms, such as headache and vertigo, which can be signs of encephalitis. Over the course of a week, his symptoms evolved to include short-term memory problems. Petitioner has claimed that the first symptom of his injury was his short-term memory problem that occurred roughly seven days after vaccination, and not his initial neurological symptoms. Based on the medical records, Petitioner's treating doctors did not distinguish between the symptoms, and no other persuasive evidence sets forth a reason to distinguish between Petitioner's initial neurological symptoms and his memory problems.

I find that Petitioner has not established that he suffered from an organic brain injury following his vaccinations. Treating doctor opinion is not dispositive because, although some treating medical professionals indicated that Petitioner might have suffered from a vaccine-caused encephalopathy, others opined that Petitioner suffered no organic brain injury at all. I considered the record as whole in determining whether Petitioner suffered from the injury he alleged. The laboratory tests and the symptoms as recorded in the medical records did not document any of the cardinal symptoms of limbic encephalitis, and many of the symptoms were inconsistent with an encephalitic process.

As noted by Respondent's expert, Petitioner's behavior was not consistent with a person suffering from an autoimmune-caused brain injury, and the objective findings in the medical records do not support the presence of a post-vaccinal encephalitic process. Dr. Morgan's

opinion was inconsistent and unsupported by the medical records. Moreover, the onset of Petitioner's neurological symptoms occurred too soon for an autoimmune mediated reaction to vaccination.

Accordingly, I find that Petitioner has not satisfied his burden of making a prima facie case of vaccine causation and his petition must be denied. See Althen v. Sec'y of Dep't of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005); Broekelschen v. Sec'y of Dep't of Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010).

## **II. BACKGROUND**

### **A. Petitioner's Medical History and Clinical Course**

Petitioner was born in 1968. He had a pre-vaccination history of head trauma, a compression fracture of his spine, vertigo, and headaches. Pet'r Ex. 15 at 5; see also Pet'r Ex. 6 at 13, 20, 26. According to Petitioner, after injuries in 1997 and 1999, he had some trouble with headaches, but he never had migraines. Pet'r Ex. 15 at 3. In November 2004, Petitioner had an MRI to evaluate his ongoing problem with "severe headaches following head trauma." Pet'r Ex. 8 at 23; see also Pet'r Ex. 15 at 3. His history also included strabismus with diplopia when fatigued and morbid obesity. Pet'r Ex. 11 at 54-55; see Pet'r Ex. 9 at 15 (noting history of strabismus); Pet'r Ex. 15 at 11 (eye surgery at age 14 to correct strabismus).<sup>4</sup> Aside from these ailments, he had no major health problems.

On July 24, 2006, Petitioner received the Hep A, Hep B, and Td vaccinations. Petitioner alleged that these vaccines caused an autoimmune response that led him to develop limbic encephalitis. Limbic encephalitis is the inflammation of the limbic portions of the brain.<sup>5</sup> Limbic encephalitis typically presents with subacute development of memory impairment, confusion, and alteration of consciousness, often accompanied by seizures and temporal lobe signal change on MRI. Jonathan M. Schott, Limbic Encephalitis: A Clinician's Guide, *Practical Neurology* 2006;6;143-53 (Pet'r Ex. 33-E). The "classic syndrome of limbic encephalitis includes the rapid development of irritability, depression, sleep disturbances, seizures, hallucinations, and short-term memory loss." Erden Tüzün & Josep Dalmau, Limbic Encephalitis and Variants: Classification, Diagnosis, and Treatment, *The Neurologist* 13(5);261-71, at 262 (Sept. 2007) (Pet'r Ex. 33-A). "The subacute development, in days or weeks, of short-term memory deficits is considered the hallmark of the disorder . . . ." Id. Diagnosis often is made based on the clinical picture combined with the demonstration of MRI and EEG abnormalities in the temporal lobes, and frequent presence of inflammatory changes in the cerebrospinal fluid ("CSF"). Id.

Shortly after the vaccination, Petitioner recalled experiencing flu-like symptoms. Aff. of Peter Ramsey, at ¶3 (Feb. 20, 2008) (Pet'r Ex. 18). Petitioner claimed that these flu-like symptoms were transient and not related to his autoimmune disorder. Over the course of a few days, the symptoms evolved to include vertigo, photophobia, and memory and attention

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<sup>4</sup> Strabismus is a deviation in the alignment of the eye that a person cannot overcome. Dorland's Illustrated Medical Dictionary (31st ed. 2007) at 1803. It is sometimes referred to as lazy eye. Diplopia is the perception of two images of the same object, sometimes referred to as double vision. Id. at 532.

<sup>5</sup> The Encephalitis Society, Limbic Encephalitis Fact Sheet ([www.encephalitis.info/info/theillness/typesencephalitis/limpic.aspx](http://www.encephalitis.info/info/theillness/typesencephalitis/limpic.aspx)) (Pet'r Ex. 33-B).

problems. Petitioner has claimed that the first symptoms of his vaccine injury were his later-occurring problems with memory and concentration. Pet'r Post-Hr'g Br. at 30. It is not entirely clear when each of Petitioner's neurological symptoms started because the medical records created in the weeks following Petitioner's vaccination contain conflicting information. Additionally, it is unclear when Petitioner's memory problems started because his subjective complaints (e.g., problems with recent memory) did not match the objective findings (e.g., "alert and oriented," normal memory and thought process) on examination. Petitioner's clinical course, the relevant medical records, and the opinions of his treating physicians are discussed below.

## 1. Petitioner's Clinical Course

Petitioner was vaccinated on July 24, 2006. According to his affidavit, on July 25, 2008, Petitioner woke up with a headache, nausea, and fever. Ramsey Aff. at ¶3.

On July 26, 2006, Petitioner felt "really bad," with a fever, nausea, and dizziness. Pet'r Ex. 6 at 4. Petitioner saw April Leuzinger, a physician's assistant, at a walk-in clinic. Pet'r Ex. 7 at 10, 21. He reported that he felt feverish and sweaty within two hours of vaccination. Id. at 10. Petitioner complained that, starting the day after his shot, he experienced fatigue, headaches, sensations of flashing lights when he closed his eyes, and vertigo. Id.<sup>6</sup> Petitioner was described as feeling "out of sorts." Id. at 15. He was positive for the Dix-Hallpike Maneuver. Id. at 10.<sup>7</sup> "Recent and remote memory [was] intact." Id. He was assessed with "fatigue, shot reaction." Id. Petitioner reported that the immunizations were required by his employer because he worked with "instruments in an environmental exposure." Id.

On July 28, 2006, Petitioner was seen by Ms. Leuzinger again. Id. at 3; Pet'r Ex. 9 at 145.<sup>8</sup> He reported that he felt the same as on July 26, 2006, and his symptoms were unchanged. Pet'r Ex. 9 at 145. Ms. Leuzinger described him as "alert and oriented" and able to "answer and ask questions appropriately." Id.

Petitioner returned to Ms. Leuzinger for follow-up on July 31, 2006. Pet'r Ex. 7 at 8. Petitioner reported that his symptoms had somewhat improved and his vertigo had subsided, but he still experienced headaches, photophobia, and fatigue. Id. Ms. Leuzinger noted that "at the last visit CBC [Complete Blood Count], CMP [comprehensive metabolic profile], urine, [and] sed rate were drawn, all of which were unremarkable." Id.<sup>9</sup>

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<sup>6</sup> The record stated that Petitioner received his immunizations on "Sunday" with the listed symptoms starting on "Monday". Sunday was July 23, 2006, however, not July 24, 2006, the documented date of vaccination.

<sup>7</sup> A positive Dix-Hallpike test indicates a person suffers from benign positional vertigo, which is caused by a disturbance in the inner ear. National Library of Medicine, Benign Positional Vertigo, Medline Plus (last updated: Aug. 3, 2010), <http://www.nlm.nih.gov/medlineplus/ency/article/001420.htm>; see Tr. at 149-51.

<sup>8</sup> The medical records list the provider as "A.L." which, presumably, is Ms. Leuzinger.

<sup>9</sup> Complete Blood Count measures the number of red cells, number of white cells, amount of hemoglobin, and the fraction of the blood that is composed of red cells. National Library of Medicine, CBC, Medline Plus (last updated: Mar. 4, 2010), <http://www.nlm.nih.gov/medlineplus/ency/article/003642.htm>. CMP is a group of chemical tests performed on the blood serum, and it measures chemicals that reflect liver and kidney function. National

Ms. Leuzinger's July 31, 2006, records contain the first documentation of memory problems. Petitioner reported difficulty with concentration. Pet'r Ex. 7 at 8. Ms. Leuzinger noted that Petitioner "does still report a cloudiness of memory and short-term memory." Id. She also observed that Petitioner was alert and oriented, and his "recent and remote memory [were] intact; however, answers are slowed." Id. Her assessment was fatigue, headache, and "potential shot reaction." Id. She referred Petitioner for an MRI. Id.

On August 2, 2006, a low-field MRI without contrast of Petitioner's brain revealed, "[t]wo small punctate areas of increased signal are present within the left frontal lobe area white matter tracts, of uncertain etiology or significance. These would be considered long-standing and not an acute process." Id. at 9.<sup>10</sup>

That same day, Petitioner also saw his general care physician, Stanley Smith, M.D. According to the history taken by Dr. Smith, Petitioner started getting a fever, chills, and sweats within two hours of vaccination. Pet'r Ex. 9 at 82. Within 24 hours, he had a headache, had the sensation of flashing lights when he closed his eyes, and had vertigo with movement. Id. "Within 48 hours bright lights began to bother him and his memory became impaired especially his recent memory." Id. His wife reported that Petitioner's memory had seemed to improve over the past couple of days. Id.

Dr. Smith found it striking that Petitioner was oriented to time and place, but he had a difficult time articulating a history and "kind of stare[d] off with a vacant gaze." Id. Dr. Smith referred Petitioner to the Emergency Room (ER) to have a lumbar puncture to rule out encephalitis. Id. He also requested an oligoclonal antibody test for multiple sclerosis. Id.

At the ER, on August 2, 2006, the treating physician described Petitioner as "alert and oriented," and Petitioner responded appropriately to questions with normal thought. Pet'r Ex. 9 at 159. Petitioner's neck was supple with no meningismus (stiffness of the neck). Id. "CBC, basic metabolic profile, urine and urine drug screen [were] without significant abnormalities." Id. at 159-60. The lumbar puncture taken showed Petitioner's cerebrospinal fluid (CSF) had 1 white cell, 18 red cells, and a slightly elevated protein level (72). Id. at 160. The diagnoses were vertigo due to a possible viral syndrome, morbid obesity, and borderline hypotension. Id. He was referred for follow-up with neurologist Kenneth Pervier, M.D.

On August 4, 2006, Petitioner saw Dr. Pervier. Dr. Pervier observed that Petitioner was oriented to person, place, date, and time, and that his "memory seemed fairly good while he was here." Pet'r Ex. 9 at 257. Dr. Pervier reviewed the MRI and found nothing to indicate vasculitis or a diffuse white matter process. Id. at 256. He noted that Petitioner's white and red blood cell counts were "slightly elevated." Id. On physical examination, Dr. Pervier described Petitioner as morbidly obese. Id. at 257.

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Library of Medicine, Comprehensive Metabolic Panel, Medline Plus (last updated: Aug. 27, 2010), <http://www.nlm.nih.gov/medlineplus/ency/article/003468.htm>. "Sed Rate" is the erythrocyte sedimentation rate or ESR. National Library of Medicine, ESR, Medline Plus (last updated: May 7, 2009), <http://www.nlm.nih.gov/medlineplus/ency/article/003638.htm>. "It is a test that indirectly measures how much inflammation is in the body. However, it rarely leads directly to a specific diagnosis." Id.

<sup>10</sup> The areas were "approximately 1 mm in size." Pet'r Ex. 7 at 9. All of Petitioner's MRIs were low-field.

Dr. Pervier's impression was that Petitioner "may have some mild degree of meningismus and possibly even some temporary changes to his memory based on his reported reaction to the inoculations." Pet'r Ex. 9 at 258. Dr. Pervier's plan was to have a follow-up MRI in a week to look for any signs of increased intracranial pressure or inflammatory changes. Id. He referred Petitioner to a speech therapist. Id. He also ordered a full battery of autoimmune and vasculitic studies, including a paraneoplastic antibody panel. Id.

Petitioner filed a workers' compensation claim in August 2006. Pet'r Ex. 1 at 15, 24-25. He described his injury as "fever, dizziness, short term memory loss, chronic headaches – now long term is being affected." Id. at 24.

On August 14, 2006, Petitioner had a follow-up visit with Dr. Smith. Dr. Smith noted that Dr. Pervier ordered a very extensive blood panel seeking evidence of autoimmune disease and paraneoplastic antibodies, but nothing returned positive. Pet'r Ex. 9 at 293. Petitioner's only abnormality was a slightly elevated C-reactive protein (CRP). Id.<sup>11</sup> MRIs taken that day of Petitioner's brain and cervical spine were normal. Id.; Pet'r Ex. 1 at 91-92.

On August 21 and 31, 2006, Petitioner was evaluated by Anne Ver Hoef, a speech pathologist. Ms. Ver Hoef is not a medical doctor. Based on these visits, Ms. Ver Hoef, in an evaluation report dated September 11, 2006, documented "rather significant deficits in recent memory and new learning, and mild-moderate deficits in language/information processing, verbal reasoning, clarity/organization or language expression, and higher-level concentration tasks." Pet'r Ex. 16 at 6. However, Petitioner was "highly cooperative during the evaluation," and with the help of his wife, provided the pathologist with information about his history and injury. Pet'r Ex. 16 at 2-3. Petitioner continued to see Ms. Ver Hoef for several months. Pet'r Ex. 16 at 23.

On September 6, 2006, Petitioner saw Paul Craig, Ph.D., a neuropsychologist. Dr. Craig's notes reflected the history given by Petitioner and his wife. Pet'r Ex. 9 at 232. Dr. Craig administered over a dozen memory and other mental screening tests. Id. at 236. For most tests, Dr. Craig interpreted the results as showing that Petitioner's mental abilities were average. See id. at 237-40. However, Dr. Craig felt that memory functioning was significantly below what would be expected in light of Petitioner's intellect. Id. at 239. Dr. Craig's report stated that Petitioner "appear[ed] to be moderately depressed and anxious." Id. at 240.

Dr. Craig's diagnostic impression was that Petitioner "unequivocally evidences a mild to moderate amnesic disorder, with onset reportedly occurring at about the time of his vaccinations. . . . Irrespective of the causation issues, there is little or no question that his subjective complaints emerged shortly after his 07/24/06 [vaccinations]." Id. at 240-41. Dr. Craig also observed Petitioner's symptoms were consistent with depression. Id.

In October 2006, Dr. Smith theorized about the nature of Petitioner's injury. On October 4, 2006, Dr. Smith noted that he thought Petitioner was not suffering from an ongoing process, and therefore, another spinal tap to check for encephalitis was not necessary. Pet'r Ex. 10 at

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<sup>11</sup> The C-reactive protein (CRP) test is "a general test to check for inflammation in the body." National Library of Medicine, C-reactive Protein, Medline Plus (last updated: Feb. 22, 2009), <http://www.nlm.nih.gov/medlineplus/ency/article/003356.htm>. The test is not specific, which means it can reveal the presence of inflammation in the body, but it cannot pinpoint the exact location. Id.

165. “I suspect that the anxiety and depression, and financial problems from him not working probably are a bigger driving force for his slow recovery.” Id. According to a handwritten note, dated October 9, 2006, Dr. Smith stated that Petitioner had an adverse reaction to an immunization that caused some neurocognitive dysfunction plus severe depression. Id. Dr. Smith opined that “he suffered a mild encephalitis post vaccination based on examination [and] elevated spinal fluid protein.” Id. On October 12, 2006, Dr. Smith noted that Petitioner may have had “a vaccine-related cerebral nerve system reaction which was probably a low-grade encephalitis culminating in short time memory loss, inability to remain focused . . . , [and] a great deal of anxiety and depression.” Id. at 17.

Petitioner saw psychiatrist Ramzi Nassar, M.D., on November 1, 2006. Dr. Nassar did not formally test Petitioner’s mental status because the recent neuropsychological testing “confirm[ed] that the patient has had unequivocal evidence of a mild-to-moderate amnesic disorder.” Pet’r Ex. 10 at 97-98. Dr. Nassar assessed Petitioner’s mental status finding “no formal thought disorder,” but noting that Petitioner “subjectively state[d] he ha[d] some memory problems.” Id. at 98. Dr. Nassar assessed a mood disorder secondary to general medical condition due to Petitioner’s cognitive decline and chronic pain. Id. He noted that the cognitive decline started around July 24, 2006, and “[t]emporally, this was related to a time when he had hepatitis A, B, and tetanus/diphtheria immunizations.” Id.

Petitioner saw immunologist Jeffrey Demain, M.D., on November 6, 2006. Petitioner demonstrated some sensitivity to gelatin and ammonium persulfate, which are present in the Td vaccine. Pet’r Ex. 10 at 84.<sup>12</sup> Dr. Demain’s testing showed that Petitioner had an elevated CRP. Id. Dr. Demain recommended Petitioner not receive further Twinrix or Td vaccinations until the etiology of Petitioner’s symptoms was clarified. Id. Petitioner reported that he “continue[d] to have memory loss and . . . w[ould] walk into a room and forget why he was going there.” Id. at 82. Dr. Demain’s impression was:

I am uncertain whether the reactivity of his patch test represents a causal link between his systemic symptoms and receiving the vaccine. There have been several [hundred] case reports raising the concern of a possible link between Hepatitis-B immunization and new cases/relapses of multiple sclerosis. . . . Review of these cases suggested the most likely explanation is a coincidental association since the epidemiologic studies did not support causal relationship. His symptoms of headache, dizziness, memory loss, malaise, myalgias and arthralgias are more consistent with some type of systemic inflammatory process. This is further supported by his persistently elevated C-reactive protein. . . . I am uncertain whether [his CSF] was further assessed for evidence of demyelination.

Id. at 84.

On November 15, 2006, Petitioner had a psychotic episode and was hospitalized in the mental health unit of the Providence Alaska Medical Center for a few days. Pet’r Ex. 9 at 13-14. According to Petitioner’s expert, this episode was caused by a reaction to his psychiatric medications. Tr. at 126-27; see Pet’r Ex. 9 at 12, 21 (noting possible reaction to his psychiatric medications).

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<sup>12</sup> Petitioner did not assert a theory of causation based on an allergic reaction to the vaccine components. Dr. Morgan did not appear to rely on the effect of any allergic reaction. Tr. at 124-25.

While hospitalized, on November 18, 2006, Petitioner had a normal neurological exam with Dr. Pervier. Pet'r Ex. 9 at 18-19. Dr. Pervier observed that "Routine memory seemed to be intact though he may be a little bit off with short term." Id. at 19. Dr. Pervier stated that Petitioner "still has headaches, the exact cause of these has never been really found. The workup to date[,] which has included scans, taps, and a tremendous amount of lab [sic], . . . have found essentially nothing." Id. at 18. He recommended a repeat MRI "to look for any evidence of change, demyelinating type process, and of focal encephalitis or any meningeal enhancement anywhere on the scan from the shoulder up." Id. He recommended looking for MS-type changes and running a full demyelinating type panel. Id. An EEG performed on November 20, 2006, was normal. Pet'r Ex. 1 at 239.

On November 20, 2006, Petitioner was discharged from the mental health unit. The discharge diagnoses were: mood disorder secondary to a medical condition, brief psychotic disorder, and amnestic disorder NOS (not otherwise specified). Pet'r Ex. 9 at 20. On November 21, 2006, a follow-up MRI of the brain was normal. Pet'r Ex. 8 at 1.

Over the next few years, Petitioner continued to receive treatment for headaches, memory and attention problems, and other issues.

## **2. Treating Physicians' Opinions**

Following Petitioner's November 2006, hospitalization, his condition remained relatively stable. He continued to receive medical attention, and his physicians reached differing conclusions regarding his condition. Most doctors who treated Petitioner near the time of his vaccinations did not conclude that Petitioner suffered from a vaccine injury or encephalitis. Some later treating doctors, however, endorsed a vaccine-caused encephalopathy diagnosis based on Petitioner's residual symptoms and their impression that Petitioner had received a prior diagnosis. Almost all of his treating doctors felt that Petitioner's condition had a psychiatric component. The most pertinent opinions are summarized below.

### **a. Dr. Pervier**

Dr. Pervier, Petitioner's treating neurologist, was in the best position to make a diagnosis of Petitioner's condition. As detailed above, Dr. Pervier ordered many diagnostic tests, referred Petitioner to other specialists, and reviewed all of the results. Dr. Pervier documented little objective evidence of CNS inflammation; most of Dr. Pervier's statements regarding Petitioner's symptoms were based on Petitioner's subjective reports or indicated a cautious assessment. See Pet'r Ex. 9 at 258 ("may have some mild degree of meningismus and possibly even some temporary changes to his memory based on his reported reaction to the inoculations"); Pet'r Ex. 9 at 19 ("memory seemed to be intact though he may be a little bit off with short term").

On November 18, 2006, Dr. Pervier stated that Petitioner's neurological exam was normal. Id. at 18-19. Dr. Pervier opined that the extensive workup to date "ha[s] found essentially nothing." Id. at 18. Dr. Pervier noted that Petitioner's memory problem "seems to relate as outlined in Dr. Craig's excellent review possibly to the immunization reaction that he had a month ago. We have no evidence at this time though for any ongoing active disease process causing anything to worsen." Id. at 19. It does not appear that Petitioner saw Dr. Pervier again. Dr. Pervier's conclusion appeared to be that, based on the medical record at that point, it was not possible to determine what was wrong with Petitioner. Dr. Pervier did not

diagnose Petitioner with limbic encephalitis, nor did he conclude that Petitioner's condition was caused by a vaccine.<sup>13</sup>

**b. First Workers' Compensation Evaluations**

On November 30, 2006, Petitioner underwent three Independent Medical Evaluations (IMEs) in connection with his workers' compensation claim. Petitioner was evaluated by three doctors: neurologist Stephen Zinsmeister, M.D., toxicologist Brent Burton, M.D., and psychiatrist Eugene Klecan, M.D. All three doctors reviewed the relevant medical history and examined Petitioner. The conclusions of the doctors, however, differed significantly.

Petitioner told Dr. Zinsmeister, the neurologist, that he developed a headache and vertigo the day after he received his vaccinations. Pet'r Ex. 15 at 3. He described his symptoms as frequent headaches and some short-term memory difficulties. Id. at 5. After reviewing the medical records and examining Petitioner, Dr. Zinsmeister concluded that Petitioner had suffered from a post-vaccination encephalopathy with resultant memory loss, headaches, depression, and vertigo. Id. at 6. He concurred with Dr. Craig's diagnosis of a mild to moderate amnesic disorder. Id. at 8.

Toxicologist Brent Burton, M.D., after reviewing the medical record and interviewing Petitioner, determined that "There are no physical impairments documented in the medical record, and none are present on physical examination performed at this time or at any other office visit." Pet'r Ex. 15 at 21. He further stated that Petitioner "express[ed] a variety of somatic complaints that do not correspond with objective findings. Mr. Ramsey most likely is expressing his symptoms on the basis of underlying psychological dysfunction." Id. at 22. His opinion was that "Mr. Ramsey most certainly did not develop any significant adverse effect from the vaccination." Id.

Eugene Klecan, M.D., a psychiatrist, determined that Petitioner suffered primarily from a psychiatric disturbance, and that Petitioner's memory function was entirely normal. Pet'r Ex. 15 at 49. Dr. Klecan's report contained a detailed and thorough analysis of his interview with Petitioner and of Petitioner's medical records.

During the interview, Petitioner reported that during a normal day he would read news and play games on the computer, and that he enjoyed reading classic novels, watching movies and television, and playing his guitar. Id. at 38, 51. Dr. Klecan administered a Luria-Nebraska Neuropsychological Battery test, which screens for organic brain impairments. Id. at 39. Petitioner did not "miss" any questions and did not show any evidence of organic mental difficulties. Id. at 40.<sup>14</sup>

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<sup>13</sup> On March 13, 2007, Petitioner had an appointment Dr. Leland Jones, a general practitioner. Dr. Jones reviewed the medical records and interpreted Dr. Pervier's opinion the same way: "The patient has seen Dr. Pervier, a neurologist, who apparently is unable to come up with any definitive diagnosis." Pet'r Ex. 26 at 232.

<sup>14</sup> Dr. Klecan stated that a score of 8 or higher on the test is indicative of a problem and indicates further neuropsychological testing should be done. Dr. Klecan's description of Mr. Ramsey's performance on the test:

Mr. Ramsey performed on the neuropsychological screening test with absolute perfection. He did not miss a single item. He did not exhibit a single hint of any organic mental difficulties. This screening test, consistent with my 3+ hour in-person interview

Dr. Klecan's report also documents a thorough review of Petitioner's medical history. Dr. Klecan stated that in every physical examination Petitioner's mental status remained normal, including intact recent and remote memory. Id. at 43-44.

Dr. Klecan was quite troubled by Dr. Craig's assessment of Petitioner. Dr. Klecan observed that Dr. Craig never interviewed Petitioner outside the presence of his wife, "a highly relevant omission in any psychological or psychiatric assessment." Id. at 44. He further observed that Dr. Craig found only one isolated deficit among 30 or so normalities. Id. at 49. Dr. Klecan reviewed the history given to Dr. Craig: Petitioner felt dazed and confused, he worried about finances and his workers' compensation claim so much his stomach hurt, he had headaches, he drove to the interview that day, and he had memory problems. Id. at 45. Dr. Klecan described these facts as inconsistent with being dazed and confused, which has a more technical meaning. Id.<sup>15</sup> He cautioned against relying on verbal reports when operating in a "medicolegal context," id. at 55, and he noted that the history given to Dr. Craig differed from the histories previously given to other doctors, id. at 45.

Dr. Klecan concluded that Petitioner had "no organic mental disorder, no acute brain disorder, no encephalopathy. . . . His history and objective findings are not and have never been medically consistent with toxic encephalopathy." Pet'r Ex. 15 at 49. He further explained that "the examinee's psychiatric symptomatology are not rationally explainable by any supposed reaction to an immunization, but are a fairly classic reaction to an insoluble relationship ambivalence. The timing and onset of his symptoms and the attribution of same to some medical event or other is not unusual particularly in somatization or histrionic or hypochondriacal crises." Id. at 49.

On January 11, 2007, Dr. Zinsmeister completed a supplemental medical report for Petitioner's workers' compensation claim. Pet'r Ex. 10 at 11-13. Based on his review of Drs. Burton's and Klecan's reports, he concluded that any organic, vaccine-caused disorder had resolved, and that the continuing problems with headaches, depression, and anxiety could not be vaccine-related. Id. at 11. He maintained, however, that the initial reaction was a vaccine reaction. Id. at 11-12. Dr. Zinsmeister observed that Petitioner's workup has "essentially been

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revealed that his short-term memory is perfectly normal as is his immediate recall, his concentration, his ability to think and do arithmetic and so forth. The perfect score of 0 on this test is considerably better than the majority of normal folks this examiner has assessed over the years. Psychiatric problems he does have, but his problems are not organic. They are in the realm of relationships, problems in living, anxiety, and certainly of ambivalence.

Pet'r Ex. 15 at 40.

<sup>15</sup> Dr. Klecan's report went on to say:

The intensity of his supposed worrying such as his wife described would require much concentration of mental awareness and mental energy, as well as an intact memory, and would in no way be consistent with someone who was 'dazed and confused.' . . . This history as recorded by the psychologist was but further evidence among many pieces of evidence grossly inconsistent with any true organic mental impairment, but very consistent with a psychoemotional, psychosocial subjectivity.

Pet'r Ex. 15 at 45.

negative,” but noted that the mildly elevated spinal fluid protein must be considered abnormal, and this “could correlate with a mild encephalopathy resulting from his immunizations.” Id.

On February 8, 2007, Dr. Zinsmeister submitted another supplemental report for Petitioner’s workers’ compensation claim. Dr. Zinsmeister stated that his only recommendation for treatment of the July 24, 2006, injury was several weeks of speech therapy. Pet’r Ex. 1 at 66. He opined that no permanent partial impairment resulted from the vaccinations. Id. at 67. He opined that “His speech impediment has improved, and should continue to improve. On my examination I did not find objective evidence of any other neurologic impairment, including memory problems. The continuing problem with headaches, depression, and anxiety cannot be related on a more probable than not basis to the [vaccinations] of July 24, 2006.” Id.

All three doctors agreed that, as of November 30, 2006, Petitioner was not suffering from an organic brain injury, such as encephalitis. While Dr. Zinsmeister thought Petitioner had suffered a vaccine reaction, he opined that the reaction had subsided. Both Drs. Burton and Klecan opined that Petitioner’s problem was psychiatric and not related to the vaccinations.

**c. Dr. Smith’s Conclusions**

Dr. Smith was Petitioner’s general doctor, and he treated Petitioner several times around the time of the vaccinations at issue. Dr. Smith reviewed all the test results and consulting physician opinions, including the November 2006 IME reports.

Dr. Smith’s opinion seemed to change over the course of a few days. On October 4, 2006, Dr. Smith “suspected” that Petitioner’s anxiety, depression, and financial problems were causing his slow recovery. Pet’r Ex. 10 at 165. Then, on October 9 and 12, 2006, Dr. Smith endorsed a diagnosis of vaccine-caused encephalitis. Id. at 17, 165.

On January 27, 2007, Dr. Smith reviewed the reports from Drs. Burton, Klecan, and Zinsmeister. Dr. Smith was “particularly struck by the in-depth psychiatric evaluation that Dr. Klecan provided.” Id. at 9. Dr. Smith opined:

I would concur that the duration of this is certainly well beyond the scope of any adverse vaccination reactions that I have seen in the past, and I have never seen people have these psychological impairments arise from such a vaccination, but I still cannot disregard the idea that he received an immunization and then had a period of dysfunction related to the adverse reactions from the vaccine. . . . As to where all this is going to end, I am quite uncertain, and I am sure it will end up in a lengthy court battle, which will be quite expensive.

Id. at 10.

In sum, Dr. Smith seemed vaguely to support vaccine-causation, but his opinion in this respect was based solely on the proximity in time between vaccination and some of Petitioner’s symptoms.

**d. Psychotic Episode Doctors**

Petitioner was treated by a variety of doctors during his November 2006 psychotic episode. The discharge report indicated that his episode may have been caused by taking

three psychotropic drugs simultaneously. Pet'r Ex. 9 at 12, 21; see Tr. at 126-27. The discharge diagnoses were: mood disorder secondary to general medical condition, brief psychotic disorder, and amnestic disorder NOS. Id. at 20. The discharge report indicated that Keith Agustin, D.O., noted a "questionable inflammatory reaction against hepatitis A/B vaccination or tetanus vaccination." Id. at 21. Some notes from his hospital admission purported to opine on the cause of Petitioner's problem. One medical note labeled "medicine," written by an unknown professional on November 18, 2006, stated: "Discussed case c [with] Dr. Pervier. Likely post-vaccine rxn as diagnosis of exclusion." Id. at 27. Another note by "medicine", dated November 19, 2006, stated: "psychosis - ongoing w/u [work-up] to include EEG - post vaccine encephalitis dx [diagnosis] of exclusion, however, seems likely at this time." Id. at 25. It is not clear who authored these notes, and the notes are not supported by any analysis. "Post-vaccine encephalitis" was not included in the discharge diagnosis.

**e. Dr. Craig**

As discussed above, Dr. Craig, a psychologist, diagnosed Petitioner with a mild-to-moderate amnestic disorder in September 2006. While Dr. Craig diagnosed the memory problem, he did not purport to opine on the causation issue; he merely noted the temporal association between Petitioner's subjective complaints and his vaccination. Pet'r Ex. 9 at 240-41 ("Irrespective of the causation issues, there is little or no question that his subjective complaints emerged shortly after his 07/24/06 [vaccinations]").

On June 4, 2007, Dr. Craig reevaluated Petitioner. As compared to September 2006, Petitioner reported that some aspects of his condition seemed better and some seemed worse. Pet'r Ex. 24 at 112. Petitioner reported that he was confused intermittently. Id. Dr. Craig's impression was that Petitioner had developed more serious psychiatric symptoms, thought to be reflective of a major depressive disorder, and the mild-to-moderate amnestic disorder had largely resolved. Id. at 120.

**f. Drs. Jones and Makim**

On March 13, 2007, Petitioner saw a new general practitioner, Leland Jones, M.D. Pet'r Ex. 26 at 232. Dr. Jones reviewed Petitioner's records and stated "The patient has seen Dr. Pervier, a neurologist, who apparently is unable to come up with any definitive diagnosis." Id. Dr. Jones noted that Petitioner had "[b]izarre neurologic symptoms allegedly starting shortly after he had a Twinrix and tetanus shot on July 24, 2006." Id. at 233. Dr. Jones observed that Petitioner had "pretty severe headaches" that were "more or less chronic daily headaches in nature." Id. at 232. Because Petitioner and his wife were unhappy with Dr. Pervier, Dr. Jones referred Petitioner to another neurologist, Jay Makim, M.D. Id. at 233.

On March 14, 2007, Petitioner saw Dr. Makim for headaches, impaired memory, and fatigue. Pet'r Ex. 24 at 140. Petitioner saw Dr. Makim numerous times throughout 2007. After he received Petitioner's prior medical records, Dr. Makim wrote, on April 2, 2007: "CSF-slight high protein 75, but LP [lumbar puncture] was traumatic with high RBC [red blood cell count], no WBC; can occur with many conditions; possible encephalitis, but less likely as no MRI changes, no typical CSF changes, no EEG changes." Pet'r Ex. 26 at 569.

Petitioner saw Dr. Makim again on May 1, 2007. Dr. Makim observed that Petitioner was suffering from depression, and he noted some diplopia. Pet'r Ex. 24 at 137. On May 1, 2007, Petitioner also underwent a sleep study and an EEG. The EEG was slightly abnormal,

but no gross abnormalities were found. Id. at 171, 175. Petitioner's sleep profile was "remarkably normal." Id. at 175. Dr. Makim noted, however, that the EEG suggested a possibility of seizures, and recommended a follow-up EEG. Id. at 135. On August 13, 2007, a follow-up EEG was normal. Id. at 196.

Petitioner saw Dr. Makim in June and July 2007, and Dr. Makim noted that Petitioner was experiencing headaches, depression, and psychological issues. Pet'r Ex. 24 at 135-36. On December 6, 2007, Dr. Makim observed that Petitioner reported suffering from worsening headaches, continued memory difficulty, and depression issues. Id. at 134. Dr. Makim listed a number of conditions under his "Assessment/Diagnosis/Discussion," including: "Headache, intractable, atypical migraine;" "hx [history] of prior vaccine induced probable encephalitis;" depression; and "memory impairment – cause unknown, but has multiple financial and job related issues." Id. While he noted, in December 2007, a history of "probable encephalitis," at none of the visits did he diagnose Petitioner with encephalitis.

**g. Second Workers' Compensation Evaluations**

In October 2007, Petitioner underwent two more workers' compensation IMEs. Walter Ling, M.D., thought that Petitioner had a "probable post-immunization residual encephalopathy with unstable mood, residual loss of memory, difficulty with concentration, mild emotion incontinence and subtle features of a residual amnesic syndrome." Pet'r Ex. 22 at 10. Dr. Ling reached his conclusion based on Petitioner's headaches (several types of headache), Petitioner's wife's reports of memory problems, and "residual emotional incontinence." Id. On examination, however, Dr. Ling stated that Petitioner's intellectual function, attention span, recent memory, and remote memory were normal. Id. at 9.

James Dahlgren, M.D., thought Petitioner had suffered from chronic mercury poisoning and mercury toxicity. Pet'r Ex. 21 at 26-28. He opined that Petitioner was an "egg shell plaintiff who was then vaccinated." Id. at 27. He concluded that Petitioner was totally disabled from work. Id. His diagnosis was "mercury toxicity with an altered immune system leading to toxic encephalopathy as a post vaccination complication." Id. at 28.<sup>16</sup>

**h. Dr. Ellenson**

On May 5, 2008, Petitioner was evaluated by Dr. Franklin Ellenson, a neurologist. Pet'r Ex. 31 at 83. Dr. Ellenson reviewed the medical records and noted that Petitioner had been diagnosed with vaccine related encephalitis. Id. Dr. Ellenson diagnosed Petitioner with chronic daily headaches, medication overuse headaches, and post vaccination encephalopathy. Id. at 85. Petitioner continued to see Dr. Ellenson throughout 2008 and 2009. On September 19, 2009, Dr. Ellenson described Petitioner's condition as suffering from "chronic headaches as well as psychiatric illness likely secondary to encephalitis due to vaccination." Pet'r Ex. 40 at 15.

**i. David Mulholland**

On September 9, 2008, Petitioner's chiropractor, David Mulholland, opined that, "based on the information provided to me both by the patient and by examination," Petitioner suffered

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<sup>16</sup> Although Dr. Dahlgren authored an expert report for this case, he did not set forth a theory based on mercury toxicity.

not from a psychiatric disorder but actually an “encephalopathy or an intracranial injury” with associated psychiatric symptoms. Pet’r Ex. 36 at 50.<sup>17</sup>

## **B. Limbic Encephalitis and ADEM**

### **1. Limbic Encephalitis**

Limbic encephalitis is not a specific disease but rather an anatomical diagnosis that identifies the brain structures that are inflamed; all cases do not share the same cause. Pet’r Ex. 33-B.<sup>18</sup> “The term limbic system is a simplification, particularly as the various parts differ widely in respect to their connections with the [other parts of the brain], their transmitters, and their effects when damaged.” Allan H. Ropper & Martin A. Samuels, Adams and Victor’s Principles of Neurology at 496 (9th ed. 2009) (Ropper & Samuels).<sup>19</sup> The limbic system is a “useful concept,” however, because lesions to the limbic system “most consistently and specifically alter emotionality.” Id. The brain’s limbic system consists of a variety of structures, many of which are involved in memory, higher emotions such as love and sadness, and much of the behavior related to sex, food, the perception of pleasure, and competition with others. Pet’r Ex. 33-B; see Ropper & Samuels at 493-96.

The brain is a complicated organ, and many higher-order brain functions are not anchored to a specific region but depend on the interaction of several different regions. Ropper & Samuels at 430. For example, attention and analytic thinking cannot be localized to any one brain component. Id. Some basic neurological functions, however, are anchored to specific brain regions, and a lesion or damage to that region can cause loss of a particular ability. Id.; see also id. at 417. For example, a specific brain region controls motor activities and another region controls visual perception; damage to those regions can cause a loss of the controlled ability. Id. at 430.

“The occurrence of abnormal emotional reactions in the course of disease is associated with lesions that preferentially involve certain parts of the nervous system.” Ropper & Samuels at 493. These parts are termed the limbic system. Id. While lesions to the limbic system can

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<sup>17</sup> Limbic encephalitis is a neurological condition, and only certain specialists are qualified to opine about it. See Tr. at 123 (Dr. Morgan testified that he would not rely on opinion of occupational medicine physician in this case because the physician was not a neurologist). A chiropractor is not qualified to opine on the difference between a neurological injury and a psychiatric condition. Smith v. Sec’y of Dep’t of Health & Human Servs., No. 08-874V, 2009 WL 4020253, \*3 (Fed. Cl. Spec. Mstr. Oct. 30, 2009) (noting chiropractor would be unqualified to opine on causation because he was not a medical doctor); see Domeny v. Sec’y of Dep’t of Health & Human Servs., No. 94-1086V, 1999 WL 199059, \*14-\*15 (Fed. Cl. Spec. Mstr. Mar. 15, 1999), aff’d 232 F.3d 912 (Fed. Cir. 2000) (per curiam) (finding dentist not qualified to opine on neuropathy); see also Pafford v. Sec’y of Dep’t of Health & Human Servs., 451 F.3d 1352, 1359 (Fed. Cir. 2006) (affirming the special master’s rejection of expert’s testimony because he lacked proper qualifications in the specialty areas in which he testified).

<sup>18</sup> Limbic encephalitis often causes inflammation in other areas of the brain in conjunction with parts of the limbic system. Tüzün & Dalmau, supra Pet’r Ex. 33-A, at 262.

<sup>19</sup> One theoretical way of classifying the various components and structures of the brain is to break them into three categories: the brain stem, the limbic brain, and the neocortex. Pet’r Ex. 33-B. The brain stem is the most primitive and supports many basic and involuntary functions such as breathing. Id. The neocortex is the rational brain and provides logic and thought. Id.; see also Tr. at 13.

affect memory, “[n]ormal memory function, as emphasized, involves many parts of the brain.” Id. at 423.

Limbic encephalitis once was considered to be rare and cancer-related, but it is “now known to be a relatively frequent autoimmune disorder, often unrelated to cancer, and with clinical and immunologic variants that respond to treatment.” Tüzün & Dalmau, supra Pet’r Ex. 33-A, at 262. A clinical picture of limbic encephalitis can be caused by a viral encephalitis or by an autoimmune encephalitis (including paraneoplastic encephalitis and encephalitis associated with voltage-gated potassium channels (“VGKC”)). Id. at 263-65.

The typical symptomatology and presentation of limbic encephalitis varies slightly depending on the causal agent, but many cases share classic symptoms. See id. at 262-67; see also Schott, supra Pet’r Ex. 33-E. Limbic encephalitis typically presents with subacute development of memory impairment, confusion, and alteration of consciousness, often accompanied by seizures and temporal lobe signal change on MRI. Schott, supra Pet’r Ex. 33-E. According to Tüzün and Dalmau, the “classic syndrome of limbic encephalitis includes the rapid development of irritability, depression, sleep disturbances, seizures, hallucinations, and short-term memory loss.” Tüzün & Dalmau, supra Pet’r Ex. 33-A, at 262.

Diagnosis often is based on the clinical picture combined with the demonstration of MRI and EEG abnormalities in the temporal lobes, and frequently, of inflammatory changes in the CSF. Id. “The subacute development, in days or weeks, of short-term memory deficits is considered the hallmark of the disorder, but this deficit is surprisingly overlooked in some patients, either because the patient seems to be extremely confused or because it is overshadowed by other symptoms.” Id. at 262. Although limbic encephalitis can present in a variety of ways, “the EEG is almost always abnormal, revealing foci of epileptic activity in [one] or both temporal lobes or focal or generalized slow activity.” Id. Although short-term memory loss is a feature of limbic encephalitis, the overall clinical picture is more complicated. Id.; see also Tr. at 184, 192-94.

Some of the symptoms of limbic encephalitis are described with medical terms that also have a meaning in common, non-medical usage, of particular relevance here, “confusion” and “short-term memory.”<sup>20</sup>

According to the Ropper & Samuels textbook:

Confusion is a general term denoting the patient’s incapacity to think with customary speed, clarity, and coherence. Its most conspicuous attributes are impaired attention and power of concentration, disorientation . . . , an inability to properly register immediate events and to recall them later, a diminution of all mental activity, including the normally constant inner ideation[,] and sometimes, by the appearance of bewilderment.

Ropper & Samuels at 398. Dorland’s Medical Dictionary defines “confusion” as “disturbed orientation in regard to time, place, or person, sometimes accompanied by disordered consciousness.” Dorland’s at 410.

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<sup>20</sup> Dr. Morgan stated that “there’s a very strict definition for confusion.” Tr. at 94.

Typically, memory loss results in two types of memory deficits: memory recall (retrograde amnesia) and memory formation (anterograde amnesia). Ropper & Samuels at 419, 658; see id. at 399. The two features may vary in severity. Id. at 419. A person suffering primarily from short-term memory loss, or anterograde amnesia, cannot form new memories (the person will retain the ability to recall existing memories). Id. at 401. Short-term memory loss can be caused by an organic injury to the brain. Id. at 421-22. A short-term memory impairment is a more complex and serious problem than being forgetful or easily distractible -- it is a formal problem with laying down new memories and will render a person unable to process and store new information. See Tr. at 186-94; see also Ropper & Samuels at 423.

## **2. ADEM**

Depending on the cause of inflammation, “a syndrome that may start as limbic encephalitis, often evolves to encephalomyelitis with dorsal root ganglionitis.” Tüzün & Dalmau, supra Pet’r Ex. 33-A, at 262.

Acute Disseminated Encephalomyelitis (“ADEM”) is a demyelinating disorder, often of autoimmune origin. ADEM is an “acute or subacute disease characterized by the occurrence of multifocal neurological deficits.” Andreas Rogalweski et al., Improvement of Advanced Postvaccinal Demyelinating Encephalitis Due to Plasmapheresis, Neuropsychiatric Disease and Treatment 2007:3(6) 987-91 (Pet’r Ex. 33-C). Common symptoms include low-grade fever, confusion, seizures, coma, and ataxia. Ropper & Samuels, at 717.<sup>21</sup> The CSF shows slight inflammation and elevation of protein, and there are “usually characteristic confluent bilateral lesions in the white matter in imaging studies.” Id.; see Tr. at 174. The lesions should be of similar age, and there can be a “delay of several days between the clinical manifestations and the first appearance of changes in the MRI.” Id. “Whether a single lesion on MRI can be considered compatible with ADEM is unclear.” Ropper & Samuels at 897. Some cases are less severe, resulting in a “transient encephalitic illness with headaches, confusion, and slight signs of meningeal irritation.” Id.

There have been reports of cases of post-vaccinal ADEM, including one that initially presented as limbic encephalitis. Rogalewski et al., supra Pet’r Ex. 33-C. In that case, the patient presented with “fever, visual hallucination, tonic-clonic seizures and progressive amnesic impairment three weeks after active vaccination with recombinant hepatitis A- and hepatitis B-virus, diphtheria, tetanus, and poliovirus antigen.” Id. at 987. The initial, tentative diagnosis was limbic encephalitis. Id. Ten weeks later, the patient presented with central facial paresis, tongue deviation, dysarthria, and severe dysphagia. Id. An MRI showed multiple white matter lesions. Id. at 987-88. The patient was diagnosed with post-vaccinal ADEM. Id. at 988.

## **C. Petitioner’s Experts’ Opinions**

### **1. Dr. Morgan**

Dr. Morgan is a practicing neurologist and teaches clinical neurology at Brown University School of Medicine. Tr. at 7. He also practices disability medicine, on which he spends about 50% of his time. Tr. at 61. Dr. Morgan’s primary area of specialization is the neurology of

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<sup>21</sup> Ataxia is a failure of muscle coordination. Dorland’s at 172.

injury. Tr. at 8. He sees many post-traumatic disorders, brain injuries, work injuries, and sports injuries that involve the nervous system and the neuromuscular system. Id.

**a. Expert Report**

In his expert report, Dr. Morgan opined that Petitioner developed “an acute to subacute limbic encephalitis within a few days to weeks of his hepatitis A, hepatitis B, and tetanus vaccin[at]ions.” Pet’r Ex. 33 at 5. Petitioner’s memory and other psychiatric symptoms were anatomically specific, localizing Petitioner’s injury to the limbic system. Id. at 6.

Dr. Morgan opined that Petitioner met the diagnostic criteria for limbic encephalitis. Pet’r Ex. 33 at 6. The neurological symptoms were meningismus, recent memory loss, and elevated CSF protein and subsequently an elevated CRP. Id. at 5. “The classic presentation of Mr. Ramsey would make autoimmune limbic encephalitis the most likely diagnosis based on the clinical neurologic method.” Id. at 7. Multiple diagnostic tests excluded other causes of limbic encephalitis, such as cancer. Id. at 6. Dr. Morgan asserted that Dr. Smith and Dr. Pervier clinically diagnosed Petitioner with limbic encephalitis, and the diagnosis was supported by Drs. Craig, Zinsmeister, Ling, and Dahlgren. Id. at 5-6.

According to Dr. Morgan, it is well known that limbic encephalitis can be caused by an autoimmune reaction. Pet’r Ex. 33 at 6. He opined that Petitioner’s post-vaccinal limbic encephalitis likely was caused by “molecular mimicry between vaccine proteins and the neuronal or myelin cells in the hippocampus, similar to other autoimmune encephalitides (i.e., ADEM).” Id.

**b. Testimony at Hearing**

At hearing, Dr. Morgan fleshed out many of the details of his theory. Dr. Morgan testified that when neurologically evaluating a patient, the neurologist’s proper first step is to isolate or localize the problem areas of the brain. Tr. at 14-15, 24. He opined that Petitioner’s symptomatology -- problems with recent but not remote memory -- localized his problem to the limbic area of the brain. Tr. at 15-17.

“The subacute development in days or weeks of short term memory deficits is considered the hallmark of [limbic encephalitis].” Tr. at 55 (quoting Tüzün & Dalmau, supra Pet’r Ex. 32-A, at 262). Dr. Morgan observed that the Tüzün & Dalmau article lists symptoms that would be seen in classic paraneoplastic limbic encephalitis, but the criteria may exclude less typical cases that, in practice, are not uncommon. Tr. at 102-03. Contrary to his opinion in his expert report, Dr. Morgan testified that Petitioner had an atypical as opposed to a classic case of limbic encephalitis, and this made it difficult for the treating physicians to diagnose the problem. Tr. at 84-85.

Dr. Morgan also testified that Petitioner likely suffered from a localized form of ADEM, which presented as limbic encephalitis. Tr. at 116-17. Dr. Morgan compared limbic encephalitis to ADEM. Tr. at 45-48. Dr. Morgan stated that both disorders can have an autoimmune basis, that ADEM can have a limbic preference and present as limbic encephalitis, and that ADEM does not always result in myelitis. Tr. at 46-47. Dr. Morgan also discussed the Rogalewski et al. case report of an individual with post-vaccinal ADEM that initially presented as limbic encephalitis, and he claimed it supported his conclusion. Tr. at 56-57; see Pet’r Ex. 33-C.

Dr. Morgan explained that the following facts were important in reaching his conclusion that Petitioner's clinical condition was consistent with vaccine-induced limbic encephalitis:

- Petitioner had a local, generalized reaction immediately following his vaccination. Tr. at 22. According to Dr. Morgan, however, the early symptoms, which included headache and photophobia, were part of a different process than the process that led to limbic encephalitis. Tr. at 65-68.

- Seven days after vaccination, Petitioner started having memory problems. Tr. at 22-23. Doctors noted memory deficits, a blank stare, seeming to be "out of it." These symptoms permitted an anatomic diagnosis and implicated the limbic system. Tr. at 23-24. Dr. Morgan seemed to opine that, because this was the first symptom implicating the limbic system, it was the first symptom of limbic encephalitis. Tr. at 64-68. Additionally, after observing that Dr. Smith noted some nystagmus, Dr. Morgan stated that nystagmus was a neurological symptom. Tr. at 23, 26, 28.<sup>22</sup>

- When Dr. Pervier evaluated Petitioner, he noted that something was wrong, "but he couldn't pinpoint it. . . . [T]here was nothing really strikingly objective." Tr. at 18. The spinal fluid showed increased protein, and Dr. Pervier noted some meningismus, or stiffness of the neck. Tr. at 29-30. It appeared Dr. Pervier was concerned about a reaction involving the limbic lobe, because he ordered antibody tests and referred Petitioner to have a speech examination and psychological workup. Tr. at 18-19, 31-33.

- Both the speech pathologist and the psychologist found a striking recent memory loss. Tr. at 19. Dr. Morgan asserted that Drs. Smith and Pervier then arrived at a working diagnosis of limbic encephalitis. Tr. at 19.

- Over the next few months, Petitioner continued to report problems with recent memory. Tr. at 40-43, 119-22. This implicated ongoing problems with the limbic system, and Petitioner's treating physicians continued to note the diagnosis of limbic encephalitis. Tr. at 59-60.

Based on the foregoing facts, and on anatomic localization, the timing of onset, the exclusion of other causes in a differential diagnosis, and consistency with molecular mimicry, Dr. Morgan concluded Petitioner suffered a vaccine injury.

Dr. Morgan conceded that some facts were not fully supportive of his conclusion of vaccine-caused limbic encephalitis. He recognized that the low-field, open MRIs were normal. He opined that the normal MRIs did not rule out encephalitis, because to see the type of encephalitis that Petitioner had, a high-field MRI probably would be necessary. Tr. at 35-36. On cross-examination, Dr. Morgan conceded that a low-field MRI commonly can detect small punctate lesions. Tr. at 78. However, he testified that to see the specific areas at issue, the MRIs done were inadequate. Id.

He conceded that Petitioner did not have an elevated white blood cell count, as is often but not always found with inflammation. Tr. at 95-96. He also conceded that no antibody tests were positive. Tr. at 131-32. He explained that at the time, limbic encephalitis, although commonly associated with cancer, was not yet widely associated with a non-cancer

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<sup>22</sup> Nystagmus is involuntary shaking of the eye. Dorland's at 1327.

autoimmune response. Tr. at 19, 131-32. He conceded that no testing confirmed the presence of an immune-mediated disorder, but opined that the clinical picture supported such a disorder. Tr. at 131-32.

He conceded that he was unaware of any association between limbic encephalitis and infection with bacterial tetanus or the wild hepatitis A and B viruses. Tr. at 86.

Dr. Morgan conceded that Dr. Pervier's August 4, 2006, examination did not show evidence of memory problems. Tr. at 119-20. He conceded that depression can cause short-term memory loss, but opined that Petitioner's deficit in recent memory was beyond what is caused by depression. Tr. at 111-12. He agreed, however, that the record did not contain much evidence of a progressive amnesic impairment. Tr. at 122. He conceded that Petitioner was never confused when he visited a doctor. Tr. at 94.

Dr. Morgan testified that Petitioner's psychotic episode was not related to limbic encephalitis, and was more likely caused by simultaneously taking three psychiatric medications. Tr. at 126-27.

## **2. Dr. Dahlgren**

Petitioner also filed an expert report by James Dahlgren, M.D. Pet'r Ex. 29. Dr. Dahlgren had previously evaluated Petitioner and submitted a report on his behalf in connection with Petitioner's workers' compensation claim. Dr. Dahlgren authored a new report for this case. Dr. Dahlgren did not testify at hearing for Petitioner, nor has he submitted any additional reports.

Petitioner does not appear to rely heavily on Dr. Dahlgren's report.<sup>23</sup> In his pre-hearing brief, Petitioner cited Dr. Dahlgren's report for the proposition that Petitioner had vaccine-caused autoimmune limbic encephalitis. Pet'r Pre-Hr'g Br. at 15-16. Petitioner did not mention Dr. Dahlgren's report or medical literature at hearing or in his post-hearing brief.

Dr. Dahlgren's report primarily was a summary of Petitioner's medical history and an overview of many of the 53 medical articles listed as references to the report.

Dr. Dahlgren commented on a number of issues in his report. Dr. Dahlgren asserted that Petitioner "most likely has a genetic predisposition to an autoimmune disorder that was triggered by his vaccination." Pet'r Ex. 29 at 13. He opined that molecular mimicry is a mechanism of Hep B vaccine-induced autoimmunity. Id. at 15. Dr. Dahlgren then explained that Petitioner's "symptoms are consistent with an encephalitis/encephalopathy and demyelination. This is supported by the clinical symptoms, the persistently elevated CRP, and the elevated protein in the CSF. While demyelination was suspected, he had two MRIs, and neither showed demyelination. Given the entire clinical picture however, demyelination cannot be ruled out." Id. at 15-16.

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<sup>23</sup> Because Petitioner has not significantly relied on Dr. Dahlgren's opinion, and instead relied on Dr. Morgan's opinion, I place more weight on Dr. Morgan's opinion.

Dr. Morgan did not place much weight on Dr. Dahlgren's opinion either. "I didn't really rely on it that much. He's not really a neurologist. He's an occupational medicine physician. So, I know it was a pretty extensive report, but I don't think he filed [sic] a neurologic method." Tr. at 123.

Dr. Dahlgren opined that aluminum, which is commonly used as an adjuvant in vaccines, has been shown to cause allergic reactions, and it may induce autoimmune diseases. Id. at 19. He further opined that “Mercury has been implicated as a cause of autoimmune reactions for decades.” Id. at 21.<sup>24</sup>

Dr. Dahlgren concluded that Petitioner’s vaccinations “induced an autoimmune response as a result of an allergic reaction to the attack to his nervous system and the presence of serum antigens which continued to target his immune system resulting in a persistent dysfunctional state.” Id. at 24-25.

#### **D. Respondent’s Expert Opinion**

Respondent offered the opinion of Thomas Leist, M.D., a neurologist. Dr. Leist is the chief of clinical neuro-immunology and director of the Multiple Sclerosis Center at Thomas Jefferson University. Tr. at 144. His patient care is largely restricted to neurological manifestations of autoimmune disorders. Tr. at 145. Dr. Leist stated that, not counting his MS patients, he sees about five or six cases of encephalitis each year, and he sees limbic encephalitis about once per year. Id.

##### **1. Expert Reports**

Dr. Leist opined that Petitioner did not suffer from an organic brain injury. In his expert reports, Dr. Leist opined that none of the medical tests supported the presence of an inflammatory process in the CNS or a diagnosis of an encephalitis. Resp’t Ex. A at 10-11. It was his opinion that Petitioner suffered no injury from his vaccinations. Id. at 12. Dr. Leist also opined that Petitioner reported he started experiencing neurologic symptoms within 24 hours of vaccination. Id. at 11. This put the onset of his condition too soon for an autoimmune mediated reaction. Id.

Dr. Leist also opined that the results of Dr. Craig’s September 6, 2006, examination of Petitioner were not consistent with a severe inflammatory process in the CNS affecting cognitive function. Id. at 10. Petitioner’s behavior at the time -- independently using a computer, driving, fully taking care of daily living activities -- was not consistent with diffuse, severe injury to the CNS leading to a cognitive decline. Id. at 11.

In a supplemental report, Dr. Leist challenged Dr. Morgan’s assertion that Petitioner suffered from limbic encephalitis. Using the description of limbic encephalitis in an article cited by Dr. Morgan, Dr. Leist evaluated Petitioner’s clinical picture. Resp’t Ex. B at 2; see Tüzün & Dalmau, supra Pet’r Ex. 33-A. Dr. Leist conceded that Petitioner’s CSF protein, specifically albumin (a type of protein found in the CSF), and red cell count were slightly elevated on August 2, 2006. Resp’t Ex. B at 2. Dr. Leist asserted the CSF sample was not consistent with inflammation because it did not show an elevated white blood cell count. Id. As for the blood work, he explained that an elevated CRP with a normal ESR is not supportive of a systemic inflammatory condition. Id. He noted that Dr. Pervier documented a normal mental status on

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<sup>24</sup> Dr. Dahlgren’s expert report did not discuss mercury poisoning. In Dr. Dahlgren’s October 2007 IME, however, he opined that Petitioner suffered from mercury poisoning, and not autoimmune encephalitis. See Pet’r Ex. 21 at 26-28.

August 2, 2006, and that taken together, these findings did not support the presence of an inflammatory process of the central nervous system (“CNS”) (including encephalitis). Id.

“Lack of inflammatory changes in the cerebrospinal fluid, absence of changes on MRI, lack of objective findings during examination, and a normal electroencephalogram in November 2006 are not supportive of the process outlined in Dr. Morgan’s report.” Id. at 3. He opined that the low-field MRIs were able to detect punctate lesions, and therefore the techniques applied to the MRI studies were capable of discerning abnormal signals in the brain tissue. Id.

## **2. Testimony at Hearing**

At hearing, Dr. Leist testified that Petitioner did not suffer an adverse reaction to his July 24, 2006 vaccinations. Dr. Leist was influenced by the lack of confirmatory test results in the record and the lack of documentation of any overt symptoms of encephalitis or any other neurological injury. Tr. at 147-48. Petitioner did not present with the cardinal features of limbic encephalitis and no testing revealed any evidence of limbic encephalitis. Tr. at 151. Dr. Leist’s opinion was that the clinical manifestations with which Petitioner presented were insufficient to diagnose limbic encephalitis. Tr. at 148, 151.

In a case like Petitioner’s, Dr. Leist stated that he would look for the presence of an inflammatory process, as Petitioner’s physicians did. Tr. at 154. Dr. Leist opined that none of the “paraclinical” exams -- MRI, EEG, and spinal fluid examination -- showed evidence of encephalitis. Tr. at 148. Dr. Leist agreed that a higher resolution MRI would be more informative, but because the lower field MRI showed some small abnormalities, he opined that the resolution was sufficient to see deformities of similar size. Tr. at 176-78. Dr. Leist stated that in order for a patient to have a significant clinical abnormality, as Petitioner alleged he had, that patient would have to have a “larger” area of damage. Tr. at 178-79. By “larger,” Dr. Leist meant “An area that is a few cc’s, a few millimeters large, not punctate.” Tr. at 179. He stated that, in the majority of patients that he sees with limbic encephalitis, he would see abnormalities on an open MRI. Tr. at 179-80.

Dr. Leist recognized that Petitioner’s tests showed protein (albumin) in his spinal fluid, but he testified that if brain tissue were being destroyed, the spinal fluid protein would have shown an increase in myelin basic protein as well. Tr. at 167-68. Brain tissue destruction would increase myelin basic protein and other CSF proteins and albumin might be increased along with those proteins. Tr. at 167-68. He stated the CSF red cell count was only slightly elevated, not enough to indicate a problem. Tr. at 155. Dr. Leist also explained that, in a patient with limbic encephalitis, he would expect to see more spinal fluid evidence of an inflammatory process than just elevated protein. Tr. at 155-56.

Dr. Leist proposed some alternative explanations for the CSF abnormality. He opined that the slightly elevated protein and red cell count could be caused by contamination of the spinal fluid sample from a slightly hemorrhagic spinal tap. Resp’t Ex. B at 2.<sup>25</sup> It could also have resulted from Petitioner’s past spinal injury if the injury reduced the circulation of spinal fluid. Tr. at 153-54. He also felt that the spinal fluid findings were more consistent with a

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<sup>25</sup> Based on notations in the medical records, Dr. Makim, one of the treating neurologists, also felt the spinal tap was traumatic. On April 2, 2007, Dr. Makim wrote: “CSF-slight high protein 75, but LP was traumatic with high RBC, no WBC; can occur with many conditions; possible encephalitis, but less likely as no MRI changes, no typical CSF changes, no EEG changes.” Pet’r Ex. 26 at 569.

metabolic syndrome in the context of obesity rather than an ongoing intracranial inflammatory process. Tr. at 170-71.

Dr. Leist conceded that Petitioner's CRP levels were abnormal, but he explained why the laboratory tests as a whole were inconsistent with an ongoing inflammatory process. Tr. at 153-54. He would expect an elevated ESR if an inflammatory condition were present, and Petitioner's ESR of two was very low (normal is around 20). Tr. at 170. He opined that an inflammatory process initiates, peaks, and then dies down, so a consistent and stable CRP would not indicate an inflammatory process. Tr. at 245. He also opined that an intracranial process will not elevate the CRP. Tr. at 244-45.

Dr. Morgan had opined that meningismus would be a sign of encephalitis. Dr. Leist, however, did not see evidence of meningismus in Petitioner's medical records. His opinion was that Dr. Pervier did not find that Petitioner had meningismus, but instead noted that he "may have mild meningismus." Tr. at 169; see Pet'r Ex. 9 at 258. He interpreted Dr. Pervier's cautious statements as documenting Petitioner's subjective complaints. Tr. at 169. He also explained that meningismus would indicate inflammation of the spinal fluid, and if Petitioner's spinal fluid were inflamed, evidence of the inflammation would have been found in the CSF. Tr. at 156.

Dr. Leist felt that the nystagmus observed in the weeks after vaccination was not a neurological sign in Petitioner's case. Tr. at 163-64. First, the nystagmus was "unsustained nystagmus," which does not normally indicate a central process. Id. Second, Petitioner had a history of eye muscle problems, including strabismus, which can influence the presentation of unsustained nystagmus. Id.

Dr. Leist questioned Dr. Morgan's assumption that short-term memory problems indicated an organic injury to the limbic system. Dr. Leist stated that while limbic encephalitis typically causes short-term memory problems, short-term memory problems alone do not indicate limbic encephalitis because such memory problems can be caused by many disorders. Tr. at 182-86. Additionally, while limbic encephalitis patients have short-term memory problems, they have other problems that often overshadow memory deficits. Tr. at 184. Limbic encephalitis causes a mental problem that is more complex than being forgetful or, for example, not remembering where one put one's keys; it prevents a person from absorbing and analyzing new information, and it causes a person to be care dependent. Tr. at 191-94.

Dr. Leist's opinion was that Petitioner's behavior was not consistent with limbic encephalitis. He went over some of the evidence of Petitioner's mental condition. Dr. Leist explained that while Dr. Craig's report stated that Petitioner unequivocally had a mild-to-moderate amnesic disorder, it went on to say that Petitioner could store and retrieve new information. Tr. at 215-16. The ability to lay down and retrieve new information is inconsistent with limbic encephalitis and an organic amnesic disorder. Tr. at 171-72.<sup>26</sup> He opined that persons with limbic encephalitis would not be driving because they would be unable to analyze

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<sup>26</sup> Dr. Leist also opined on the deficiencies noted by the speech pathologist, Ms. Ver Hoef. Ms. Ver Hoef found deficits in recent memory, new learning, language information processing, and verbal reasoning, and she found that Petitioner had mild deficits in clarity of organization of language and expression and in higher concentration tasks. Tr. at 213. This broader dysfunction indicated problems outside of the limbic system, and Dr. Leist testified it was inconsistent with a focal disorder of the limbic system, as occurs with limbic encephalitis. Tr. at 213-14.

and respond to changes in road conditions, *i.e.*, cars braking or turning onto the road in front of them, traffic lights, street signs, etc. Tr. at 189-94. Dr. Leist stated that gazing off, as observed by Dr. Smith, would be consistent with depression, and is not specific to limbic encephalitis. Tr. at 164-65.

## **E. Court Exhibits**

On December 22, 2010, I filed two exhibits into the record and gave the parties notice of my intent to take judicial notice of a standard neurology textbook. Order, Dec. 22, 2010. The parties were provided one month to file any comments on those sources.

The textbook was Adams and Victor's Principles of Neurology (9th ed. 2009), by Allan H. Ropper & Martin A. Samuels. Neither party objected to my use of the textbook.

The two articles I filed discussed an autoimmune disorder in which the immune system makes antibodies to Voltage Gated Potassium Channels (VGKC). VGKC antibodies attack receptors in the brain, which results in limbic encephalitis. The two articles are: M.J. Thieben *et al.*, Potentially Reversible Autoimmune Limbic Encephalitis with Neuronal Potassium Channel Antibody, 62 *Neurology* 1177-82 (2004) (cited at Ropper & Samuels at 1433) (Ct Ex. 1); and Angela Vincent *et al.*, Potassium Channel Antibody-Associated Encephalopathy: a Potentially Immunotherapy-Responsive Form of Limbic Encephalitis, 127 *Brain* 701-12 (2004) (cited at Ropper & Samuels at 666) (Ct. Ex. 2).

The Thieben article reported the results of a retrospective study of seven patients with encephalitis associated with autoantibodies to VGKCs. Thieben *et al.*, *supra*, at 1177. The article stated that patients with VGKC antibodies responded rapidly to steroid treatment. *Id.* at 1180. "The clinical and radiologic findings at initial evaluation [of the patients in the study] were indistinguishable from those of paraneoplastic limbic encephalitis." *Id.* at 1181. The authors suggested that autoimmune limbic encephalitis was a form of neuronal autoimmunity within a pathogenic spectrum of disorders. *Id.*

The Vincent article discussed a retrospective study of ten patients who presented with clinical features of a subacute amnesic encephalopathy. Vincent *et al.*, *supra*, at 701-02. The article reviewed the symptoms of the patients and the patients' treatments and responses. *Id.* "Clinically, these cases do not differ substantially from other forms of amnesic encephalopathies, such as the paraneoplastic form of limbic encephalitis." *Id.* at 711.

### **1. Petitioner's Comments**

On January 24, 2011, Petitioner filed a supplemental expert report from Dr. Morgan. Dr. Morgan opined that the textbook and two articles "support[ed] [his] opinion that Mr. Ramsey sustained a post vaccinal autoimmune non-paraneoplastic limbic encephalopathy (encephalitis) as a result of his [vaccinations] on 07/24/06." Pet'r Ex. 41.

In the supplemental report, Dr. Morgan asserted that the mechanism of injury was a "delayed inflammatory immune mediated reaction with antibodies to the abundant neuronal voltage gated potassium channels in the limbic structures." Pet'r Ex. 41 at 3. Dr. Morgan stated: "Mr. Ramsey's clinical timeline revealed findings of short term memory loss, vertigo, depression and acute psychosis. These findings are consistent with the confusional agitated

state, memory defect and hallucinations that evolve subacutely over days to weeks that are characteristic manifestations of a limbic encephalopathy (encephalitis).” Id. at 2.

Dr. Morgan explained how the Court’s exhibits supported his opinion. He asserted that, according to Ropper & Samuels (p. 21), a high field coronal MRI with fluid-attenuated inversion recovery imaging is required to detect autoimmune brain lesions in the limbic lobe. Pet’r Ex. 41 at 3.

He reviewed the two articles and opined that the patients reported in the articles presented with symptoms similar to Petitioner’s. For example, in Thieben, one patient had normal spinal fluid cell count; two others had mildly elevated CSF protein. Pet’r Ex. 41 at 3. In Vincent, one patient had a raised CRP. Pet’r Ex. 41 at 3-4. Dr. Morgan noted that patients reported in both articles had abnormal neuropsychological testing with characteristics of recent memory loss as well as other findings. Id. He claimed that these articles supported his conclusion that Petitioner’s symptoms were consistent with limbic encephalitis and that Petitioner suffered from an autoimmune-mediated, post-vaccinal encephalopathy. Id. at 4.

“In conclusion, it is my opinion that these references and the Principles of Neurology provide support that Mr. Ramsey’s clinical diagnosis was a post vaccinal immune mediated limbic encephalopathy (encephalitis).” Id.

## **2. Respondent’s Comments**

Initially, Respondent filed a short responsive brief, which argued that the articles did not support a theory of vaccine-caused ADEM and the cases reported were inconsistent with Petitioner’s condition. After Petitioner filed the supplemental report from Dr. Morgan, Respondent requested leave to file a supplemental expert report. Respondent claimed Dr. Morgan set forth a new theory of causation based on VGKCs instead of ADEM. Petitioner objected, claiming Dr. Morgan’s theory encompassed any autoimmune disorder that resulted in inflammation and demyelination. I granted Respondent’s motion. Respondent then filed, on March 16, 2011, a supplemental report from Dr. Leist.

Dr. Leist reviewed the court’s exhibits, and explained why they did not apply to Petitioner. Together, the two articles presented details about 17 different patients. Dr. Leist observed that “Seventeen of 17 patients in the two studies had abnormal [EEGs] and 15 of the 17 patients reported had seizures.” Resp’t Ex. D. He observed that two patients in the Vincent article had severe mental problems: “Case 1 had ‘a 5-year retrograde amnesia, and confabulation.’ In Case 4 the ‘Mini-Mental State Examination score was 16/30 and there was profound memory impairment.’ Both patients had seizures.” Resp’t Ex. D at 3. He compared these cases to Petitioner, who had normal EEGs and no seizures, and whose mental status was normal on July 26 and August 4. Id. at 2.

Dr. Leist concluded that “Neither seizures, nor EEG abnormalities, nor typical MRI findings, nor a low serum sodium level, nor an elevated CSF white cell count, nor an objective record of impairments of daily functioning have been documented in Mr. Ramsey’s case.” Resp’t Ex. D at 3. “It remains my opinion that Mr. Ramsey did not sustain any injury as a consequence of his [vaccinations].” Id.

## **F. Arguments**

## 1. Petitioner's Arguments

In a post-hearing brief, filed on June 25, 2010, Petitioner summarized the medical records, focusing on statements by physicians that Petitioner suffered from an encephalopathy and associated Petitioner's condition with vaccination.

Petitioner argued that Dr. Morgan's theory of an immune-mediated disorder, occurring through molecular mimicry, was biologically plausible. Pet'r Post-Hr'g Br. at 18. According to Petitioner, the Tüzün article supported Dr. Morgan's opinion by demonstrating that limbic encephalitis is more common than previously thought, and that it can be immune-mediated. Id. at 20. He argued that his condition was consistent with limbic encephalitis because memory problems are the hallmark of limbic encephalitis and Petitioner had an elevated CSF protein. Id. at 19-20. He noted that behavioral issues, psychosis, and hallucinations also may occur. Id. at 20.

He further argued that Dr. Morgan's theory was that molecular mimicry caused a localized form of ADEM. Id. at 18. ADEM can present as limbic encephalitis, and this was supported by the Rogalewski et al. article (Pet'r Ex. 33-C). Pet'r Post-Hr'g Br. at 18-19, 21.

He argued that he had shown a logical sequence of cause and effect. He summarized Dr. Morgan's testimony as relying on the clinical facts, the opinions of several treating physicians, the timing of the symptoms after the vaccines, the absence of another cause, the plausible mechanism of molecular mimicry, and the occurrence of the predicted prognosis. Id. at 21. He claimed that Petitioner's treating physicians believed that his vaccinations caused his brain injury. Id. at 23-24.

He argued that seven to eight days was an appropriate interval for onset of a vaccine-induced autoimmune disorder. Id. at 30. He argued that the onset of Petitioner's memory problems was consistent with that timing. Id.

He argued that Dr. Leist's testimony was biased and unreliable. He also asserted that Dr. Leist's testimony that Petitioner "did not have limbic encephalitis because he drove a car is meant to mislead the . . . special master." Id. at 34.

## 2. Respondent's Arguments

In a post-hearing brief, filed on July 26, 2010, Respondent argued that Petitioner was not entitled to compensation. Respondent claimed that Petitioner had not established that a vaccination could cause limbic encephalitis. Further, Respondent claimed that Petitioner had not established that he had either limbic encephalitis or ADEM. Resp't Post-Hr'g Br. at 10.

Respondent asserted that Petitioner presented no evidence showing any connection between Twinrix or tetanus vaccines and limbic encephalitis. She argued that molecular mimicry-induced demyelination via ADEM does not explain how a vaccination could cause limbic encephalitis. Id. at 13. She asserted that Dr. Morgan's theory was unreliable because the limbic system is gray matter and does not have white matter, which contains myelin. Id. at 13-14. Further, she argued that Petitioner presented no case reports associating vaccination with limbic encephalitis. Id. at 14-15.

Respondent argued that, without a medical theory, Petitioner could not prove cause and effect. Id. at 15. Respondent asserted that Petitioner did not present with the cardinal features of limbic encephalitis, and Petitioner's clinical picture was inconsistent with limbic encephalitis. Id. at 10-11. No objective tests, such as the MRIs and EEGs, showed evidence of limbic encephalitis or an inflammatory condition. Id. at 11. Additionally, Petitioner's ability to function was inconsistent with suffering short-term memory loss. Id. at 12.

Respondent argued that the statements of some of Petitioner's treating physicians were insufficient to prove a logical sequence of cause and effect. Id. at 15-16. Respondent argued that a greater number of treating physicians made findings inconsistent with limbic encephalitis. See id. at 16-19. It was significant that none of Petitioner's treating physicians documented any neurological problems. Id. at 17. Many stated that psychological problems were the more likely cause of Petitioner's difficulties. Id. at 17-18.

Respondent conceded that many of Petitioner's physicians noted some temporal association or noted an impression of a possible reaction to vaccination. Id. at 16-19. Respondent noted that Dr. Smith endorsed a vaccine caused encephalopathy but argued that none of Petitioner's medical records supported that conclusion. Id. at 16-17. Respondent also conceded that Dr. Ling assessed Petitioner as having an encephalopathy. Id. at 18. Respondent argued that Dr. Ling did not base his opinion on Petitioner's entire medical history, and that language in Dr. Ling's opinion indicated that Dr. Ling was engaging in speculation. Id. Respondent claimed many of the other physicians who stated that Petitioner had an encephalopathy did not reach independent conclusions. Id. at 19.

Finally, Respondent argued that Petitioner had not established that his condition started in a medically appropriate timeframe. Respondent claimed that, according to Dr. Morgan, an appropriate timeframe would be seven days to several weeks. Id. at 20. Petitioner reported neurological symptoms within 48 hours of vaccination. Id. Respondent claimed there was no basis for concluding that Petitioner's reaction did not start until seven days after vaccination. Id. at 20-21.

### **III. DISCUSSION**

#### **A. Overview**

This discussion begins with a review of the legal standards for establishing a case of vaccine causation. In particular, it notes the recent decision in Broekelschen v. Secretary of Department of Health & Human Services, 618 F.3d 1339 (Fed. Cir. 2010), affirming that a special master may deny compensation if the petitioner does not establish that he actually suffers from the condition allegedly caused by vaccination. Next, I discuss the opinions of the two experts who appeared at hearing, and why I find Dr. Leist's opinion to be more persuasive than Dr. Morgan's. I discuss this preliminarily because the experts' testimony influenced my assessment of the medical records, which I discuss thereafter. I conclude that Petitioner has not established that he had limbic encephalitis or a similar disorder based on the test results reported in his medical records, his documented physical and mental symptoms, and the opinions of treating professionals. Lastly, I find that Petitioner has not presented preponderant evidence to satisfy any of the Althen prongs.

#### **B. Petitioner's Burden of Proof**

The Vaccine Act created the National Vaccine Injury Compensation Program (“Vaccine Program”) under which compensation may be paid for vaccine-related injury or death. 42 U.S.C. § 10(a); Walther v. Sec’y of Dep’t of Health & Human Servs., 485 F.3d 1146, 1149 (Fed. Cir. 2007). To receive compensation, a petitioner must prove that either: (1) he suffered a “Table Injury” -- that is, an injury falling within the Vaccine Injury Table -- corresponding to one of his vaccinations, or (2) he suffered an “off-Table” injury that was actually caused by or “caused-in-fact” by a vaccine. See §§ 13(a)(1)(A), 11(c)(1); Shalala v. Whitecotton, 514 U.S. 268, 270 (1995). In this case, Petitioner alleged that he suffered an off-Table injury.

To prove an off-Table claim, a petitioner must show, by a preponderance of the evidence, “that the vaccine was ‘not only a but-for cause of the injury but also a substantial factor in bringing about the injury.’” Moberly v. Sec’y of Dep’t of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting Shyface v. Sec’y of Dep’t of Health & Human Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)). A petitioner may satisfy this standard by providing evidence, in the form of medical records or reliable medical opinion, to establish “(1) a medical theory causally connecting the vaccination to the injury, (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury, and (3) a proximate temporal relationship between the vaccination and the injury.” Althen, 418 F.3d at 1278. The Althen “prongs must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” Pafford v. Sec’y of Dep’t of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006); see Walther, 485 F.3d at 1150 (noting adoption of actual causation standard of the Restatement (Second) of Torts). Evidence used to satisfy one prong of Althen can overlap to satisfy another prong. Cappizzano v. Sec’y of Dep’t of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

The preponderance of evidence standard under the Vaccine Act requires proof that a vaccine more likely than not caused the vaccinee’s injury. Althen, 418 F.3d at 1279. Proof of actual causation must be supported by a sound and reliable “medical or scientific explanation that pertains specifically to the petitioner’s case, although the explanation need only be ‘legally probable, not medically or scientifically certain.’” Moberly, 592 F.3d at 1322 (quoting Knudsen v. Sec’y of Dep’t of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)); see also Grant v. Sec’y of Dep’t of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (medical theory must support actual cause). Mere temporal association is not sufficient to prove causation in fact; a petitioner must present a medical theory that is supported either by medical records or by the opinion of a competent physician. Grant, 956 F.2d at 1148.

A petitioner may use circumstantial evidence to prove her case, and “close calls” regarding causation must be resolved in favor of the petitioner. Althen, 418 F.3d at 1280. Causation can be supported by a treating physician’s opinion that a vaccination was causally linked to the vaccinee’s injury if the special master finds the opinion to be both reliable and persuasive. Moberly, 592 F.3d at 1324-25. Where treating physicians note a temporal, but not a causal, relationship, a special master may place less weight on their opinions. Cedillo v. Sec’y of Dep’t of Health & Human Servs., 617 F.3d 1328, 1348 (Fed. Cir. 2010). Where treating doctors are not consistent in their diagnoses and do not provide reasoning for their statements, a special master may place less weight on treating physician opinion as a whole. Broekelschen, 618 F.3d at 1347.

A special master’s function is “to determine ‘based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that

the vaccine caused the [person's] injury.” Andreu v. Sec’y of Dep’t of Health & Human Servs., 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting Knudsen, 35 F.3d at 549). Causation is determined on a case-by-case basis, with “no hard and fast per se scientific or medical rules.” Knudsen, 35 F.3d at 548. A special master can find that a petitioner has established causation in fact based on the medical records alone. Althen, 418 F.3d at 1279 (quoting § 13(a)(1)) (a petitioner “must prove causation in fact by a ‘preponderance of the evidence,’ substantiated by medical records or medical opinion” (emphasis in original)).

When the parties dispute the nature of the vaccinee’s injury, the special master may determine the nature of the injury before considering causation. In Broekelschen, the Federal Circuit held that identification of the petitioner’s injury is a prerequisite to the Althen analysis. Broekelschen, 618 F.3d at 1346. The petitioner’s symptoms in that case were consistent with two different conditions (a vascular condition and an inflammatory condition), which differed significantly in their pathology. Id. The petitioner presented evidence on causation concerning one condition, but because the conditions’ etiologies were different, that evidence did not support causation concerning the other condition. The Federal Circuit noted that a petitioner is not required to establish an exact diagnosis, but upheld the special master’s decision first to determine from which injury the petitioner suffered, and then to determine whether the petitioner had established causation. Id. at 1346. The majority upheld the special master’s determination to deny compensation because the petitioner did not have the injury allegedly caused by the vaccine, warning that it would be improper to “forc[e] [such a] case to align with our Althen precedent.” Id. at 1349.

Once the petitioner has met the initial burden of proof, “the burden shifts to the government to prove ‘[by] a preponderance of the evidence that the petitioner’s injury is due to a factor unrelated to the . . . vaccine.’” de Bazan v. Sec’y of Dep’t of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008) (citations omitted). If the petitioner fails to establish a prima facie case of causation, however, the burden does not shift. Doe 11 v. Sec’y of Dep’t of Health & Human Servs., 601 F.3d 1349, 1357-58 (Fed. Cir. 2010).

### **C. The Experts’ Opinions**

#### **1. Dr. Morgan**

Before addressing my specific findings, I note that I find Dr. Leist’s opinion to be more persuasive than Dr. Morgan’s. Dr. Morgan shifted the basis for his opinion in his expert reports and filings. In addition, he ignored facts inconsistent with his opinion, and he interpreted ambiguous facts only in a light favorable to his opinion, casting doubt on his objectivity. As inconsistent information and new information was brought to his attention, Dr. Morgan’s opinion evolved to fit the evidence, without any convincing explanation for the changes in his opinion.

To start, Dr. Morgan did not consider Petitioner’s prior injuries in reaching his opinion. See Mr. Ramsey’s Clinical Timeline (Pet’r Trial Ex. 4) (a timeline of events that started on July 24, 2006). Petitioner’s records showed a history of headaches and possible spinal injury. Pet’r Ex. 6 at 13, 20; Pet’r Ex. 11 at 54-55. Dr. Morgan opined that none of the medical records that preceded Petitioner’s vaccination had anything to do with Petitioner’s post-vaccination condition. Tr. at 109-10. Therefore, he did not consider Petitioner’s history of headaches as possibly related to Petitioner’s symptoms, which included a chronic headache. Similarly, he did not consider Petitioner’s pre-vaccination spinal cord injury in evaluating the results of laboratory

tests, nor Petitioner's pre-vaccination strabismus and diplopia in evaluating the initial symptoms of Petitioner's alleged vaccine injury, which included slight CSF abnormalities and nystagmus.

Dr. Morgan's characterization of Petitioner's condition changed repeatedly. In his expert report, Dr. Morgan stated: "The classic presentation of Mr. Ramsey would make autoimmune limbic encephalitis the most likely diagnosis based on the clinical neurologic method." Pet'r Ex. 33 at 7 (emphasis added). Then, under cross-examination at hearing, when he was asked why Petitioner's EEG was never abnormal, Dr. Morgan explained that Petitioner actually had an atypical presentation of limbic encephalitis. Tr. at 84-85. "Was this a classic form of limbic? No. That's why -- that's why people struggle with this disorder. This -- I agree, in the classic form, you might see more than we see in this patient. But if I waited for classic forms of everything, I probably wouldn't make a lot of diagnoses." Tr. at 84-85.

Dr. Morgan's opinion on the mechanism of injury evolved as well. In his report, he opined that Petitioner suffered from limbic encephalitis. Pet'r Ex. 33 at 6. He opined that the mechanism for a post-vaccinal autoimmune limbic encephalitis would likely be molecular mimicry, similar to other autoimmune encephalitides such as ADEM. Id. Thus, his opinion was that the process was similar to but distinct from ADEM. At hearing, Dr. Morgan opined that Petitioner actually suffered from a focal form of ADEM presenting as limbic encephalitis. Tr. at 86-87. Dr. Morgan opined that ADEM was the causal mechanism, but then he also opined that Petitioner did not have encephalomyelitis. Tr. at 46-47.<sup>27</sup>

In support of his ADEM theory, he discussed a case report of post-vaccinal ADEM that initially presented as limbic encephalitis. Tr. at 56-58; see Rogalewski et al., supra Pet'r Ex. 33-C. That patient presented with fever, visual hallucinations, tonic clonic seizures, and progressive amnesic impairments. Tr. at 118. Dr. Morgan opined that Petitioner suffered from the same condition, but when questioned, he conceded that Petitioner did not have a fever, visual hallucinations, or tonic clonic seizures at the time of onset. Tr. at 118-19. While Dr. Morgan claimed that Petitioner had a progressive amnesic impairment, he conceded that little evidence in the record supported that conclusion. Tr. at 119-22.

In his supplemental report, Dr. Morgan's theory of causation evolved again. Dr. Morgan stated that the mechanism of injury was a "delayed inflammatory immune mediated reaction with antibodies to the abundant neuronal voltage gated potassium channels in the limbic structures." Pet'r Ex. 41 at 3. The report did not mention ADEM.

Dr. Morgan's interpretation at hearing of the symptoms of limbic encephalitis was at odds with the medical literature he referenced. See Pet'r Ex. 33. The articles he cited mentioned many symptoms, including confusion, vertigo, seizures, and hallucinations. See Tüzün & Dalumau, supra Pet'r Ex. 33-A, at 262; Schott, supra Pet'r Ex. 33-E, at 143-46. At hearing, however, Dr. Morgan stated that "The signs of limbic encephalitis [are] recent memory, recent memory, recent memory." Tr. at 53. He explained that it is recent memory loss that makes a condition limbic encephalitis, not fatigue and not headache. Tr. at 66. By stressing memory loss, Dr. Morgan was able to assert that Petitioner's other symptoms -- which occurred within the first week after his vaccinations -- were not part of his vaccine "reaction." See Tr. at

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<sup>27</sup> To circumvent the objection that Petitioner did not show any evidence of myelitis, Dr. Morgan opined that encephalomyelitis is both encephalitis and myelitis, but both components need not be present -- one could just have the encephalitis component, as Petitioner did, and still be consistent with encephalomyelitis. Tr. at 47, 88.

66-67, 118. Dr. Morgan's characterization of the symptoms of limbic encephalitis seemed idiosyncratic and lacked support in the medical literature. As a result, it appeared that he was distorting the medical facts in order to make it appear more likely that Petitioner had suffered a vaccine injury; this approach produced the opposite effect from that intended.

In his supplemental report, Dr. Morgan reviewed Petitioner's symptoms: "[His] clinical timeline revealed findings of short term memory loss, vertigo, depression and acute psychosis. These findings are consistent with the confusional agitated state, memory defect[,] and hallucinations that evolve subacutely over days to weeks that are characteristic manifestations of a limbic encephalopathy." Pet'r Ex. 41 at 2. The review of the symptoms in the supplemental report seemed to contradict Dr. Morgan's earlier opinions. The report listed vertigo as a symptom, but Dr. Morgan had opined previously that vertigo was not a symptom of Petitioner's condition. Tr. at 65-67; see Pet'r Ex. 7 at 10 (on July 26, 2006, Petitioner complained that he started experiencing vertigo the day after his shot). Dr. Morgan had testified that he agreed with the treating psychiatrist that Petitioner's psychotic episode was due to his medications and not an encephalitic condition. Tr. at 126-27. Dr. Morgan had conceded that Petitioner was never confused. Tr. at 93-94. He also had conceded that Petitioner did not have visual hallucinations. Tr. at 119.

Considered as a whole, Dr. Morgan's opinion was unpersuasive. His opinion continually changed without explanation as new information was brought to his attention. He contradicted himself in his various reports. In his final supplemental report, he appeared to concede inadvertently that Petitioner's symptoms appeared too soon for an autoimmune-mediated disorder to have taken place. See Pet'r Ex. 41 at 1 (vertigo was a symptom of his injury). Most importantly, his treatment of the facts and medical literature called his objectivity into question, undermining his reliability.

## **2. Dr. Leist**

Dr. Leist, on the other hand, maintained the same opinion throughout the proceeding. He addressed information inconsistent with his opinion and explained why he did not find that information persuasive. Based on the record as a whole, Dr. Leist's opinion is more reliable.

Dr. Leist supported his opinion that Petitioner did not have limbic encephalitis with objective factors in the medical record. Based on the medical literature filed by Petitioner, Dr. Leist showed that Petitioner did not meet the diagnostic criteria for limbic encephalitis. See, e.g., Resp't Ex. B at 2.

None of the imaging tests showed evidence of brain lesions or brain dysfunction. Dr. Leist opined that if a patient had gray matter injury as part of a new disease process, there would be evidence of the damage. Tr. at 258. He would have expected to see the damage on either an MRI or EEG, and he would have expected to see that the damage was affecting the patient's ability to function in activities of daily living. Tr. at 256-58. He opined that any brain lesion that caused a clinically significant memory problem would have been visible on a low-field MRI. Tr. at 178-79.

Dr. Leist addressed the protein in Petitioner's spinal fluid. He conceded the presence of protein in the form of albumin (a type of protein), but opined that destruction of cerebral tissue would result in an increase in myelin basic protein, not in albumin. Tr. at 167-68. He proposed some alternative explanations for the increased protein. He also conceded that Petitioner's

blood CRP levels were abnormal, but he explained why the laboratory tests as a whole were inconsistent with an ongoing inflammatory process. He opined that an inflammatory process initiates, peaks, and then dies down, so a consistent and stable CRP, even if elevated, would not indicate an inflammatory process. Tr. at 245.

Dr. Leist stated that, following vaccination, doctors did not document any abnormalities in Petitioner's mental status. See Tr. 210-18. He explained that Petitioner's behavior, as documented in the medical records, was inconsistent with organic brain dysfunction. See Tr. at 256-57. He evaluated Dr. Craig's opinion and Ms. Ver Hoef's opinions, and he explained why their conclusions were not supported by the findings documented in their records.

While limbic encephalitis will cause impairment of short-term memory, many other disorders will cause problems with short-term memory. Tr. at 182-84. Dr. Leist explained that it was improper to assume that Petitioner had limbic encephalitis based on his subjective complaints of memory problems. Id.

Dr. Leist evaluated all of the evidence in Petitioner's medical record. He explained why he found some evidence less significant. His opinions were consistent with the medical literature on limbic encephalitis. He also related his opinion to his own experience treating patients with that disorder.

**D. Petitioner Has Not Satisfied His Burden of Proof.**

**1. Petitioner Has Not Established that He Had Limbic Encephalitis.**

The evidence presented by Petitioner is insufficient to show that he suffered from an organic brain disorder. In the year following vaccination, Petitioner was evaluated by more than 10 doctors. These doctors reached different conclusions and recorded significant variations in Petitioner's symptoms. Taken together, their opinions do not establish that Petitioner suffered from limbic encephalitis. Based on the objective findings documented in the medical records, I find that Petitioner has not shown he had encephalitis or encephalopathy.<sup>28</sup>

The core elements of limbic encephalitis are short-term memory loss, confusion, and often, seizures. Tüzün & Dalmau, supra Pet'r Ex. 33-A, at 262. MRIs often show evidence of injury, and an EEG is almost always abnormal. Id. The CSF frequently shows the presence of inflammatory changes. Id.

A comparison of the symptoms of limbic encephalitis to Petitioner's condition as documented in the medical records shows that Petitioner's clinical picture was inconsistent with a diagnosis of limbic encephalitis. Neither the MRIs nor the EEGs confirmed the presence of an organic brain injury. Petitioner's laboratory work showed a few abnormalities, but the abnormalities were not consistent with an inflammatory condition. Petitioner's behavior and mental status were inconsistent with that of a person suffering from clinical limbic encephalitis. Thus, the record contains little objective evidence that Petitioner suffered from limbic encephalitis and much to indicate that he did not.

**a. Imaging Tests**

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<sup>28</sup> The persuasiveness of treating doctor testimony will be addressed in the next section.

None of Petitioner's imaging tests was consistent with encephalitis. None of Petitioner's EEGs showed any abnormalities.<sup>29</sup> As explained by Tüzün & Dalmau, "[r]egardless of the type of presentation, the EEG is almost always abnormal." Tüzün & Dalmau, supra Pet'r Ex. 33-A, at 262.

Petitioner underwent multiple MRIs and all were normal.<sup>30</sup> The MRIs did not show signs of an encephalopathy or demyelination. Dr. Morgan claimed the seemingly normal MRIs were too weak to rule out encephalopathy. Dr. Leist agreed that a higher resolution MRI would have been more informative. He explained, however, that because the MRIs were able to show punctate abnormalities, they would have shown any lesion that could cause a clinically significant manifestation of injury. Tr. at 176-79. He stated that, in the majority of patients that he sees with limbic encephalitis, he would see abnormalities on an open MRI. Tr. at 179-80.

By itself, the absence of MRI evidence of limbic encephalitis would be insufficient to rule it out. Petitioner also had normal EEGs, however, which is inconsistent with a finding of limbic encephalitis. The absence of any imaging evidence weakens Petitioner's claim that he suffered from limbic encephalitis.

#### **b. Laboratory Tests**

Petitioner's laboratory tests also do not support a diagnosis of limbic encephalitis. I will evaluate each type of test in turn.

**CSF.** Based on a spinal tap taken on August 2, 2006, Petitioner had a slightly elevated level of protein in the spinal fluid, Pet'r Ex. 9 at 160, which consisted of an elevated level of albumin, id. at 151. His CSF was otherwise normal. Id. at 160. The parties dispute whether these findings show evidence of inflammation.

According to Dr. Morgan, inflammation often results in white cells in the CSF, but it also could result in protein elevation. Tr. at 95-96. Dr. Morgan asserted that a post-vaccine focal encephalopathy might not result in the spinal fluid cells indicating inflammation. Tr. at 51-53. One might see cells in the CSF post vaccine, but not necessarily -- "you don't always see . . . all the ducks lined up." Tr. at 52. He explained that in post-infectious and post-vaccinal conditions, the reaction is delayed, and the direct inflammation can come and go before the condition starts. Tr. at 95-98. Dr. Morgan opined that an elevated protein could mean that the spinal fluid irritant is still present, and a lack of white cells could indicate a post-vaccinal or post-infectious condition. Tr. at 97.

Dr. Leist asserted that if a person had an inflammatory condition of the CNS, the spinal fluid would show direct evidence of a "fulminate or ongoing inflammatory process." Tr. at 155-56. Additionally, if meningismus were a symptom of that process, as Petitioner claimed, an

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<sup>29</sup> Pet'r Ex. 1 at 239 (11/20/2006); Pet'r Ex. 24 at 171 (5/1/2007); Pet'r Ex. 24 at 196 (8/13/2007).

<sup>30</sup> MRIs were taken on August 2, 2006 (Pet'r Ex. 7 at 9), August 14, 2006 (Pet'r Ex. 9 at 293), and November 21, 2006 (Pet'r Ex. 1 at 254).

irritant or inflammatory cells would be present. Tr. at 155-56.<sup>31</sup> A slightly elevated protein with a normal white cell count is not indicative of an inflammatory process. Resp't Ex. B at 2.

Dr. Leist also testified that if brain tissue were being destroyed, the spinal fluid protein would show an increase in myelin basic protein but not necessarily in albumin. Tr. at 167-68. His opinion was that the spinal fluid findings were not consistent with an ongoing intracranial inflammatory process. Tr. at 170-71.<sup>32</sup> Dr. Leist gave other possible explanations for the abnormal results. Tr. at 219-20.

I find that the spinal fluid findings are inconsistent with limbic encephalitis. I am persuaded by Dr. Leist's testimony that, while the CSF findings are not totally inconsistent with recent inflammation, they are not supportive of an ongoing, progressive inflammatory disorder of the CNS. If Petitioner's disorder had progressed, as he alleged, see Tr. at 119-21, Petitioner's CSF on August 2, 2006, most likely would have shown evidence of ongoing inflammation.

**Blood Tests.** In repeated blood tests, Petitioner had a consistently elevated CRP. Pet'r Ex. 9 at 60. The other results, including his ESR, were normal. See Pet'r Ex. 9 at 293; Pet'r Ex. 12 at 16.

Dr. Morgan opined that an elevated CRP was a sign of inflammation. Tr. at 135-36. When asked on cross-examination, Dr. Morgan stated that a normal ESR and elevated CRP could be consistent with infection, systemic conditions, rheumatoid arthritis, and atherosclerosis. Tr. at 135-36.

Dr. Leist opined that a consistently elevated CRP with a normal ESR is not indicative of a systemic inflammatory condition. Resp't Ex. B at 2; Tr. at 171. Dr. Leist noted that Petitioner's CRP was consistently elevated over time and that Petitioner's ESR was very low. Tr. at 170. Taking those two facts together, Dr. Leist opined they were more indicative of a metabolic syndrome than an inflammatory process. Tr. at 170-71.

Based on all the evidence of record, including the experts' opinions, I find that Petitioner's blood work is not supportive of an ongoing inflammatory condition.

**Antibody Tests.** The antibody laboratory tests did not show any antibodies known to cause limbic encephalitis. On August 7, 2006, antibody panels for paraneoplastic, Pet'r Ex. 9 at 259, ANNA-1 (Hu), and ANNA-2 (Ri), were negative, id. at 260.

Despite an extensive workup, none of the results supported a diagnosis of limbic encephalitis. Dr. Smith described the blood tests as "a very extensive blood panel looking up for autoimmune disease and paraneoplastic antibodies, and thus far nothing has returned positive." Id. at 293. As Dr. Pervier summarized on November 18, 2006, "The workup to date which has included scans, taps, and a tremendous amount of lab, . . . have found essentially nothing." Id. at 18.

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<sup>31</sup> Dr. Leist asserted that, at the time of the spinal tap, Petitioner had no nuchal (neck) rigidity, indicating no inflammation of the spinal fluid. Resp't Ex. B at 2; Tr. at 156.

<sup>32</sup> Although elevated spinal fluid protein could be a sign of inflammation, it is a non-specific finding that also could be a sign of many other problems. See Pet'r Ex. 10 at 170 (Dr. Smith noted elevated CSF protein could have many different causes); Tr. at 153-56.

Many other antibodies are known to cause autoimmune encephalitis. Additional tests were not conducted because, as Dr. Morgan explained, the medical community did not begin to recognize, until after 2006, the prevalence of non-paraneoplastic limbic encephalitis. Tr. at 137. While the absence of confirmation by antibody tests does not rule out limbic encephalitis, it does not provide any support for the condition.

I find the lab results do not support Petitioner's claim that he suffered from limbic encephalitis.

**c. Physical Symptoms**

Petitioner's physical symptoms were somewhat consistent with limbic encephalitis, but Petitioner disclaimed many of them because they occurred too soon to be consistent with an autoimmune-mediated vaccine reaction. Additionally, pervasive inconsistencies throughout the medical record make it difficult to place much weight on these symptoms.

On July 26, 2006, two days post-vaccination, Petitioner reported vertigo. Pet'r Ex. 7 at 10. On July 31, 2006, Petitioner reported that his vertigo had subsided. Id. at 8. Petitioner has maintained that this vertigo was not a symptom of his alleged vaccine injury, and that memory loss, first noted on July 31, 2006, was the first symptom.

On July 31, 2006, Petitioner first reported photophobia. Id. On August 2, 2006, however, he reported that his photophobia began within 48 hours of vaccination. Pet'r Ex. 9 at 82. On July 26, 2006, two days after his vaccination, he had denied photophobia. Pet'r Ex. 7 at 10.

In his expert report, Dr. Morgan claimed Petitioner's meningismus was a symptom of encephalitis. Pet'r Ex. 33 at 5. Dr. Pervier's August 4, 2006, assessment was that "patient may have some mild degree of meningismus." Pet'r Ex. 9 at 258. On August 2, 2006, Dr. Smith did not observe any neck abnormalities, however. Pet'r Ex. 8 at 82. On July 31, 2006, Petitioner's neck was "supple." Pet'r Ex. 7 at 8. On August 14, 2006, Dr. Pervier did not record whether Petitioner's neck was normal or abnormal. Pet'r Ex. 9 at 293. On cross-examination, Dr. Morgan conceded that other exams showed no "nuchal rigidity," which is a test for meningismus. Tr. at 76.

Dr. Morgan also asserted that nystagmus was a neurological sign of Petitioner's injury. Tr. at 23, 26. Dr. Leist conceded that Petitioner showed nystagmus, but emphasized that it was described as "unsustained nystagmus." Tr. at 164. Dr. Leist explained that unsustained nystagmus is not indicative of a central process, and its presence can be related to eye muscle problems such as strabismus. Tr. at 163-64. Dr. Morgan did not explain how Petitioner's history of strabismus and diplopia could have contributed or not to his nystagmus because Dr. Morgan did not consider Petitioner's prior history. See Tr. at 109-10.

I find no persuasive evidence confirming Petitioner's allegation that he suffered from the physical symptoms of limbic encephalitis.

**d. Mental Status**

As documented in the medical records, Petitioner's mental status and behavior following vaccination were inconsistent with clinically significant encephalitis.

Between July 24 and September 6, 2006, no treating medical providers documented any objective impairment in Petitioner's mental status. It was not until Dr. Craig assessed Petitioner with a mild-to-moderate amnesic disorder on September 6, 2006, that a medical professional documented Petitioner's subjective complaint of memory loss. Subsequently, no other treater formally documented any memory impairment. No treating physician independently concluded that Petitioner suffered from an amnesic disorder.

Dr. Nassar, a psychiatrist, noted that Petitioner subjectively stated that he had some memory problems and Dr. Craig's testing confirmed an amnesic disorder, but upon evaluation, Dr. Nassar found no formal thought disorder. Pet Ex. 10 at 97-98.<sup>33</sup>

On November 18, 2006, Dr. Pervier noted that Dr. Craig found that Petitioner had a mild to moderate amnesic disorder, but on physical examination, Dr. Pervier found "routine memory seemed to be intact though he may be a little bit off with short term. For more details, of course, see Dr. Craig's note." Pet'r Ex. 9 at 18-19.

As pointed out by Dr. Klecan, Dr. Craig's testing revealed dysfunction in only 1 out of 30 areas. On November 30, 2006, all three independent medical evaluators for workers' compensation concluded that Petitioner, at that time, was not suffering from a memory impairment. Pet'r Ex. 1 at 67 (Dr. Zinsmeister, no objective evidence of neurological impairment); Pet'r Ex. 15 at 21 (Dr. Burton); Pet'r Ex. 15 at 49.

As noted by Dr. Leist, and by doctors who evaluated Petitioner for workers' compensation, Petitioner's behavior was inconsistent with that of a person experiencing an organic brain injury. An individual with limbic encephalitis needs help with the activities of daily living. Tr. at 194. Tüzün & Dalmau state that "[m]ost patients seem to be quietly confused, repeating over and over the same questions." Tüzün & Dalmau, supra Pet'r Ex. 33-A, at 262. Petitioner was driving, reading, watching movies, surfing the Internet, and playing games. Pet'r Ex. 15 at 38, 51. He claimed to forget why he walked into rooms and to spend a lot of time in parking lots trying to remember where to go next. Pet'r Ex. 10 at 82. This is not indicative of a short-term memory impairment due to limbic encephalitis. See Tüzün & Dalmau, supra Pet'r Ex. 33-A, at 262.

In sum, the medical record contains little to support Petitioner's assertion that he suffered from limbic encephalitis. Most of his symptoms and test results are inconsistent with encephalitis and provide no support for his allegations.

## **2. Treating Doctors' Opinions**

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<sup>33</sup> As a psychiatrist with an M.D., Dr. Nassar's opinion regarding Petitioner's medical condition is more persuasive than that of Dr. Craig, a psychologist with a Ph.D. See Dwyer v. Sec'y of Dep't of Health & Human Servs., No. 03-1202V, 2010 WL 892250, \*64 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (giving greater weight to M.D. epidemiologists' opinions on medical issues than to Ph.D. epidemiologist's opinion); Id. at \*77 (Ph.D. toxicologist not qualified to opine on medical matter); see also Pafford, 452 F.3d at 1359 (affirming the special master's rejection of expert's testimony because he lacked proper qualifications in the specialty areas in which he testified).

The opinion of treating physicians can be quite probative on the question of causation. Andreu, 569 F.3d at 1375-76. A special master is not required to give a treating physician's opinion significant weight, however, where a temporal, but not a causal, relationship is noted. Cedillo, 617 F.3d at 1348; see also Moberly, 592 F.3d at 1323 (A physician's recognition of a temporal association between vaccination and injury is not, without more, supportive of causation). Where treating doctors are not consistent in their diagnoses and do not provide reasoning for their statements, a special master may place less weight on treating physician opinion as a whole. Broekelschen, 618 F.3d at 1347.

In Andreu v. Secretary of Department of Health & Human Services, the Federal Circuit found that treating physician testimony was sufficient to establish a logical sequence of cause and effect. A physician in that case testified "unequivocally" that he believed the vaccination caused the injury alleged (seizure disorder), and he explained the rationale for his conclusion. He explained that he could identify the cause of seizures in 70 to 75% of patients, but he was unable to find a cause for the vaccinee's seizures. He further explained that the timing was consistent with a vaccine-caused seizure, which led him to conclude that the vaccine caused the seizure. Andreu, 569 F.3d at 1376. His testimony was supported by the testimony of another treating physician. The second treating physician explained that some evidence supported finding that the vaccine caused the seizure, but he was reluctant to attribute causation to the vaccine.

The facts in Moberly v. Secretary of Department of Health & Human Services were very similar to Andreu. In Moberly, however, the Federal Circuit found the treating physicians' opinions were insufficient to establish causation. The Federal Circuit upheld the lower courts' findings that none of the vaccinee's treating physicians offered a reliable statement that the vaccine caused the injury. The Moberly court noted the similarities to Andreu, and stated "In Andreu, however, there was direct testimony from Andreu's treating physicians stating 'unequivocally' that the [vaccination] caused his seizures. . . . In this case, by contrast, there was no treating physician evidence that supported the claim of causation." 592 F.3d at 1324-25. The Circuit stated, "Instead, the notations in [the vaccinee's] medical records regarding the temporal proximity of the [vaccination] to the seizures were all speculative." Moberly, 592 F.3d at 1323.

In Broekelschen, the medical records contained conflicting diagnoses. The Federal Circuit upheld the special master's finding that "certain evidence, such as the medical records and doctors' notes, were not as persuasive as other evidence because the treating doctors were 'not consistent in their diagnoses.'" Broekelschen, 618 F.3d at 1347 (quoting the special master's decision, 2009 WL 440624, at \*43). The Federal Circuit also upheld the special master's finding that a detailed discharge summary by one doctor was more persuasive than notes by other doctors that did "not provide any reasoning for their statements." Broekelschen, 618 F.3d at 1347 (quoting SM's decision).

In this case, Petitioner was seen by a number of physicians. None of the physicians endorsed a diagnosis of vaccine-induced limbic encephalitis or ADEM. Considered as a whole, the doctors' conclusions do not support a finding that Petitioner had limbic encephalitis or a vaccine-caused brain injury.

Dr. Pervier, Petitioner's treating neurologist, was in the best position to make a diagnosis of Petitioner's condition. Dr. Pervier's conclusion appeared to be that it was not possible to

determine what was wrong with Petitioner. Pet'r Ex. 9 at 18 (in November 2006, Dr. Pervier opined that the extensive workup to date "ha[s] found essentially nothing").

Dr. Craig, a psychologist, diagnosed Petitioner with a mild-to-moderate amnesic disorder, but he did not opine on vaccine causation. Pet'r Ex. 9 at 240-41 ("Irrespective of the causation issues, there is little or no question that his subjective complaints emerged shortly after his 07/24/06 [vaccinations]"). Dr. Craig's report and opinion do not support a finding of limbic encephalitis or a vaccine-caused injury.

Dr. Nassar, a psychiatrist, did not document a formal thought disorder, but noted that Petitioner "subjectively state[d] he ha[d] some memory problems." Pet'r Ex. 10 at 98. He also noted a temporal association, but he stated no opinion on causation. Id.

Dr. Smith was Petitioner's general doctor. Dr. Smith reviewed all the test results and consulting physician opinions. Dr. Smith appeared to endorse a theory of vaccine-causation, but he also recognized the uncertainty in the record. "I would concur that the duration of this is certainly well beyond the scope of any adverse vaccination reactions that I have seen in the past, . . . but I still cannot disregard the idea that he received an immunization and then had a period of dysfunction related to the adverse reactions from the vaccine." Id. at 10. Again, temporal association is the main factor Dr. Smith identified as indicating causation.

Dr. Demain, an immunologist, opined that he was "uncertain whether the reactivity of his patch test represents a causal link between his systemic symptoms and receiving the vaccine." Pet'r Ex. 10 at 84. He also recommended that Petitioner avoid the Hep A, Hep B, and Tetanus vaccines until the etiology of Petitioner's condition was better understood. This is indicative of suspected causation, but stops far short of an opinion that the vaccine caused Petitioner's symptoms. Weighed against other medical opinion and the facts in the record as a whole, it is not persuasive evidence of vaccine causation.

Petitioner was treated by a variety of doctors during his November 2006 psychotic episode. While two notes suggested a post-vaccine encephalopathy, the author of these statements is not known, and they were not supported by analysis. Nor were the assertions included in the discharge report. See Pet'r Ex. 9 at 20-22 (the report stated one doctor noted a questionable inflammatory reaction to vaccination). Consequently, while the statements support vaccine causation, they are of only limited probative value. Additionally, while the discharge report mentioned a diagnosis of an amnesic disorder, it did not diagnose any kind of encephalitis.

Petitioner had three workers' compensation evaluations on November 30, 2006. Drs. Burton and Klecan felt Petitioner was not suffering from organic brain dysfunction, and that his condition was psychiatric. Dr. Zinsmeister thought Petitioner may have suffered from a residual injury, but he later explained that he observed no organic problem when he evaluated Petitioner on November 30, 2006. While I do not place as much weight on the IME doctors' conclusions as I do on those of the treating doctors, the IME doctors' observations confirm that Petitioner was not suffering from an ongoing process or an organic brain injury in November 2006. Cf. Andreu, 569 F.3d at 1383 (noting that medical records are considered trustworthy because "[w]ith proper treatment hanging in the balance, accuracy has an extra premium") (quoting Cucuras v. Sec'y of Dep't of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993)).

Dr. Makim was uncertain what caused Petitioner's condition. Initially, he thought encephalitis was unlikely given the absence of positive EEG and MRI results, and given the lack of an active inflammatory process. Pet'r Ex. 26 at 569. In December 2007, he listed "hx [history] of prior vaccine induced probable encephalitis;" depression; and "memory impairment – cause unknown, but has multiple financial and job related issues." Pet'r Ex. 24 at 134. This was the first time Dr. Makim mentioned vaccine-induced encephalitis, and he did so in the context of a historical statement, not as a diagnosis. He also listed a variety of possible pathologies, such as depression, for Petitioner's condition. Further, he did not associate Petitioner's memory impairment with an encephalopathy.

In October 2007, Petitioner had two more workers' compensation evaluations. Dr. Ling concluded that Petitioner had a residual encephalopathy. Pet'r Ex. 22 at 10. Dr. Dahlgren concluded that Petitioner suffered from mercury poisoning. Pet'r Ex. 21 at 26-28.

Dr. Ellenson, a neurologist, stated in 2008 that Petitioner had a post-vaccination encephalopathy. Pet'r Ex. 28 at 41. Dr. Ellenson appears to have based his note solely on his retrospective reading of the medical records, which contained poorly supported statements regarding vaccine causation. See Pet'r Ex. 31 at 83. Dr. Ellenson's characterization of Petitioner's injury therefore is less persuasive than the opinions of Dr. Pervier and Dr. Makim, both of whom treated Petitioner closer in time to his alleged injury.

In sum, treating physician opinion is at best inconclusive. Dr. Pervier's opinion did not support a finding of limbic encephalitis or a vaccine-caused injury. Dr. Makim, Petitioner's next neurologist, did not diagnose Petitioner with limbic encephalitis. Dr. Smith suspected a vaccine injury due to the temporal relationship, but his cautious assessment does not outweigh the assessments of Petitioner's treating neurologists. While the later treating doctors and IMEs characterized Petitioner as having a history of encephalitis or post-vaccinal encephalopathy, their interpretations of the medical records are less persuasive than the opinions of the contemporaneous treating physicians.

#### **E. Petitioner Has Not Established Actual Causation.**

Petitioner's allegation was that his vaccinations caused an autoimmune reaction, which lead to limbic encephalitis or ADEM, which caused his amnesia and headaches. Petitioner's theory of causation was premised on the assertion that Petitioner suffered from limbic encephalitis or ADEM. Because Petitioner has not established that he suffered from limbic encephalitis, ADEM, or another type of autoimmune-mediated encephalitis, his evidence is insufficient to show that his vaccinations were a but-for cause of his injuries. While Althen is less useful as an analytic tool in cases like this, Broekelschen, 618 F.3d at 1349, because Petitioner has asserted that the evidence satisfies the Althen prongs, I evaluate each prong of the Althen test below.

##### **1. Althen Prong 1**

Under Althen prong 1, a petitioner must set forth a biologically plausible theory explaining how the vaccine received by the petitioner could cause the injury complained of. See, e.g., Andreu, 569 F.3d at 1375. Evidence should be viewed by the preponderance of the evidence standard and "not through the lens of the laboratorian." Id. at 1380. Although the theory of causation need not be corroborated by medical literature or epidemiological evidence,

the theory must be sound, reliable, and reputable -- in other words, the theory need not be scientifically certain, but it must have a scientific basis. See id. at 1379-80.

I find that Petitioner has not established a medically plausible theory linking his vaccinations to his alleged persistent, mild amnesic disorder and headaches. Petitioner has presented no evidence showing that the Hep A, Hep B, or Td vaccinations can cause chronic headaches and mild amnesia in the absence of encephalitis. Petitioner's evidence focused on limbic encephalitis and ADEM, but Petitioner has not established that he suffered from either of those conditions. Thus, Petitioner has not established a biologically plausible theory of causation that applies to his case. See Broekelschen, 618 F.3d at 1346.

As discussed above, Petitioner has not established that he suffered from encephalitis, ADEM, or any other injury that could have been caused by vaccination. Based on the medical literature and the experts' opinions, it seems plausible that the Hep A and Hep B vaccines could cause an autoimmune-mediated disorder or encephalitis. Although no evidence directly shows that a vaccination could lead to limbic encephalitis, the evidence is at least supportive of a theory that post-vaccinal processes could lead to autoimmune encephalitis in some cases. I need not decide in this case whether vaccination can cause autoimmune encephalitis because the pertinent inquiry is whether this person's vaccination can cause this person's injury, and not whether the vaccination can cause the injury in the abstract. Broekelschen, 618 F.3d at 1346 (holding that each prong of the Althen test is decided relative to the injury).

Were Petitioner able to show that he suffered from an autoimmune disorder or a type of encephalitis, I would have to look more closely at prong 1 to determine if it were satisfied. On this record, however, Petitioner has not satisfied prong 1 of Althen, because there is no preponderant evidence of a plausible biological theory of vaccine causation that applies to his case. See Moberly, 592 F.3d at 1322; Broekelschen, 618 F.3d at 1345-46 ("causation is relative to the injury," and the theory must pertain specifically to the petitioner's case).

## **2. Althen Prong 2**

The second prong of Althen requires a petitioner to prove "a logical sequence of cause and effect show[ing] that the vaccination was the reason for the injury." Andreu, 569 F.3d at 1374 (quoting Althen). The sequence of cause and effect must be "logical" and legally probable, not medically or scientifically certain." Knudsen, 35 F.3d at 548-49. Under prong 2, petitioners are not required to show "epidemiologic studies, rechallenge, the presence of pathologic markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect . . ." Capizzano, 440 F.3d at 1325. Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second Althen factor. Capizzano, 440 F.3d at 1325-26; Andreu, 569 F.3d at 1375-77 (treating physician testimony).

I find that Petitioner has not established a logical sequence of cause and effect connecting his vaccination to his injury. Petitioner's argument was that his vaccinations caused an autoimmune response, which resulted in encephalitis or ADEM, which caused Petitioner to suffer from short-term memory deficits and headaches. Petitioner claimed that his treating physicians' diagnoses were sufficient to satisfy this prong, but as discussed above, his treating physicians' opinions overall were inconclusive. Most of the physicians treating Petitioner around the time of his alleged injury, including Dr. Pervier, did not diagnose him with a vaccine-caused injury or limbic encephalitis.

Petitioner also relied on the opinion of Dr. Morgan to satisfy this prong. Dr. Morgan presented three theories of causation: autoimmune mediated limbic encephalitis, ADEM presenting as limbic encephalitis, and limbic encephalitis cause by VGKC antibodies. Petitioner's clinical course was not consistent with any of those theories.

As discussed, Petitioner has not established that he suffered from limbic encephalitis, whether caused by a general autoimmune process or by an autoimmune reaction to VGKC antibodies. Petitioner's clinical course and progression were not consistent with a post-vaccinal autoimmune reaction. As Dr. Leist explained, he would have expected a process that initiated, worsened, and then resolved. Petitioner's reported symptoms fluctuated in the weeks following vaccination. The laboratory studies did not document any signs of limbic encephalitis, an autoimmune reaction, or an active inflammatory process.

The record contains no evidence that Petitioner suffered from ADEM. Petitioner exhibited no symptoms of ADEM, which include confusion, seizures, and ataxia. Ropper & Samuels at 717. Dr. Morgan compared Petitioner to the Rogalewski *et al.* case report, but Petitioner did not have hallucinations, seizures, or any other symptom of ADEM. Further, the characteristic feature of ADEM is an imaging study showing the presence of confluent bilateral lesions on the white matter of the brain. Ropper & Samuels at 717; Tr. at 174. Petitioner's MRIs showed no abnormalities. His MRI, like his laboratory tests, showed no signs of demyelination.

Finally, Petitioner's mental status as documented in the medical records was inconsistent with that of a person suffering from an organic brain impairment, whether it was limbic encephalitis or ADEM presenting as limbic encephalitis. The record shows he was able to lay down new memories, enjoy activities that required handling new information, and fully manage his activities of daily living. *See* Tr. at 256-57.

In sum, Petitioner has not established a logical sequence of cause and effect connecting his vaccinations to his alleged injury.

### **3. Althen Prong 3**

To show causation, a petitioner must establish that the injury occurred within a time frame that is consistent with the theory of causation set forth. *Pafford*, 451 F.3d at 1358. A temporal relationship between receipt of a vaccine and alleged onset of symptoms, without more, is insufficient to establish a causal relationship in a cause-in-fact case. *Grant*, 956 F.2d at 1148. What constitutes an appropriate temporal association is a question of fact and will vary with the particular theory of causation advanced. *Id.*; *de Bazan*, 539 F.3d at 1352.

In this case, both experts at hearing agreed that seven days after vaccination would be the earliest medically appropriate time of onset. Tr. at 49, 161-62. Based on contemporaneous medical records, I find that Petitioner has not established that his neurological symptoms started at a medically appropriate time.

Petitioner argued that his condition did not start until his memory problems were first reported, which was on July 31, 2006, approximately seven days post-vaccination. In his expert report, Dr. Morgan opined that the neurological symptoms became "prominent" approximately 10 to 14 days following vaccination. Pet'r Ex. 33 at 5. At hearing, he testified that short-term

memory problems started on July 31, which is “about seven, eight days” post vaccine. Tr. at 49. Later he testified that Petitioner’s memory impairment started on August 2, 2006, when he saw Dr. Smith, and then was verified by Dr. Pervier on August 4, which was about 9 days post-vaccine. Tr. at 119.

In explaining why the timing of onset was appropriate, Dr. Morgan reviewed the chronology of the symptoms. He testified that Petitioner had a localized reaction, which developed into some headaches and dizziness. Tr. at 22. Then around July 31, Petitioner reported trouble with memory and concentration. Tr. at 22. His symptoms progressed and a few days later Dr. Smith noted memory deficits and bizarre behavior. Tr. at 23-24. He noted Petitioner had problems with balance and some nystagmus, which are neurological signs. Tr. at 25-27. Dr. Morgan testified that “what sticks out is this memory, this blank stare type information, some meningismus, and is now starting to localize this into the limbic area of the brain.” Tr. at 23.

At hearing, Dr. Morgan asserted that memory loss was the first symptom of Petitioner’s limbic encephalitis. Tr. at 65. He conceded that fatigue, headache, and photophobia also can be symptoms of limbic encephalitis. Tr. at 65-66. He asserted that Petitioner’s early reported symptoms were part of a different process than the limbic encephalitis. Tr. at 67. “The thing that makes limbic encephalitis is memory. It’s not fatigue. And it’s not headache.” Tr. at 66; see also Tr. at 53 (“The signs of limbic encephalitis [are] recent memory, recent memory, recent memory”).

In reaching his opinion, Dr. Morgan interpreted the medical records somewhat strangely. See Tr. at 70-72. Dr. Smith’s notes documented that Petitioner reported that “within 48 hours, bright lights began to bother him and his memory became impaired, especially his recent memory.” Pet’r Ex. 9 at 82. Dr. Morgan claimed that, as he read it, “within 48 hours” meant “within the past 48 hours.” Tr. at 71-72. Eventually, he conceded that the sentence as written appeared to state that memory problems began within 48 hours of vaccination. Tr. at 71-72.

While at hearing Dr. Morgan stressed that memory impairment was the first symptom of limbic encephalitis, in his supplemental report, Dr. Morgan opined that vertigo was a symptom too. Pet’r Ex. 41. Petitioner started experiencing vertigo, however, within 48 hours of vaccination. Overall, I find Dr. Morgan’s opinion on onset to be unpersuasive, and his interpretation of the evidence is troublesome.

In contrast to Dr. Morgan’s opinion, neither Dr. Leist nor Petitioner’s treating physicians differentiated among the neurological symptoms. Dr. Leist saw no reason to differentiate the neurological symptoms of headache, flashing lights, and vertigo from memory problems. Tr. at 159-61. No treating doctors differentiated between Petitioner’s initial reported symptoms of headache, flashing lights, and vertigo and his symptoms after he reported memory loss on July 31, 2006. The medical records show that treating doctors regarded all the symptoms as part of the same process.

Dr. Pervier described the history of Petitioner’s condition as starting within two hours of vaccination, when Petitioner started experiencing generalized malaise, fevers, chills, diaphoresis, and positional lightheadedness (vertigo). Pet’r Ex. 10 at 142.

Dr. Demain described Petitioner's symptoms as "headache, dizziness, memory loss, malaise, myalgias, and arthralgias." Id. at 84. Petitioner reported that he still was having some photophobia. Id. at 82.

Dr. Craig's history noted that Petitioner experienced a fever within 20 minutes of vaccination, and "[t]he following morning, he continued to feel feverish, dazed, and confused. He was also experiencing vertigo, and has felt sluggish thereafter." Pet'r Ex. 9 at 232-33.

Dr. Zinsmeister: "The abrupt onset of headache and vertigo could be caused by immunization reaction." Pet'r Ex. 10 at 12. "He did have acute onset of symptoms which have been described to be caused by immunizations, including encephalopathy, vertigo, headaches, and local reaction including swelling and malaise." Id.

Petitioner has not established that his initial symptoms of vertigo, headache, and malaise were part of a different process than his memory problems. Accordingly, I find that the first symptoms of Petitioner's condition occurred too soon after vaccination for an autoimmune reaction to have occurred.

#### **IV. CONCLUSION**

Petitioner did not satisfy the legal requirements for proving that his vaccinations were a legal cause of his injury. Therefore, I find that Petitioner has not established entitlement to compensation under the Vaccine Act, and his petition must be **DISMISSED**. In the absence of a timely motion for review filed pursuant to Vaccine Rule 23, the Clerk is directed to enter judgment according to this decision.<sup>34</sup>

**IT IS SO ORDERED.**

s/ Dee Lord  
Dee Lord  
Special Master

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<sup>34</sup> Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by each party filing a notice renouncing the right to seek review by a United States Court of Federal Claims judge.